AQUA

ZUKUNFT DURCH QUALITÄT

German Hospital Quality Report 2013

Commissioned by:

Gemeinsamer
Bundesausschuss

Table of Contents

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Committed to quality

Dr. Regina Klakow-Franck

Esteemed Readers,

As an impartial member and chairwoman of the Subcommittee for Quality Assurance on the Federal Joint Committee (G-BA), I am delighted to be able to give readers an insight into selected areas from the current German Hospital Quality Report as well as briefly describe the further developments they can look forward to. External hospital quality assurance is the flagship of the G-BA's quality assurance (QA) measures. In 2013, 1,557 hospitals transmitted 3,153,099 QA records. A total of 434 quality indicators were collected on the 30 clinical areas; 403 of these indicators allowed trending conclusions to be made. 40 of them, or 9.9 %, showed improvements, whereas the results on 17 quality indicators (4.2 %) worsened. In the overwhelming majority of indicators (n = 346 or 85.9 %) there were no changes over the previous year. Rather, the quality level remained stable across the board.

Understandably, the clinical areas and indicators with hitherto unexhausted potential for quality improvement are especially interesting. For example, three indicators collected for the clinical area *Total knee replacement – Primary implantation* exhibited a significantly negative trend compared to the last data collection year. It was particularly the growing number of patients who sadly are unable to walk after the procedure that drove the responsible Federal Experts' Working Group to warrant an "extended need for action" in this area. To improve how the clinical experience is presented, the G-BA resolved to adopt the recommendations by the Federal Experts' Working Group for a follow-up procedure in the area *Total knee replacement – Primary implantation*. Starting with data collection year 2015, follow-up data will be routinely collected for the clinical area *Total knee replacement – Primary implantation*. The transparency of treatment quality in neonatology has also risen constantly. The website *www.perinatalzentren.org* went online at the end of February 2014. On this site, hospitals licensed to care for preterm infants and neonates with very low birth weights can publish their treatment results data voluntarily. In the next step, all hospitals caring for "preemies" and neonates are required to publish their data and results on this site. A chapter entitled "Presenting the quality of care in preterm infants transparently online" in the present German Hospital Quality Report provides comprehensive explanations on this subject. I would especially like to direct the reader's attention to the special chapter on nosocomial infections. In a comparison between 2013 and 2012, it is noteworthy that the rate of nosocomial pneumonia following orthopedic surgery is tending to increase, but is due largely to a different age and risk distribution of patients. Essentially, what is apparent is that the risk of postoperative infection depends on the type and extent of surgery as well as on age.

Not least due to the demographic trends that throw ever-greater challenges at medical care, great things are expected from quality assurance. The coalition agreement between the CDU/CSU and the SPD put quality assurance high up on the healthcare policy agenda. As meanwhile enacted in the German Act to Improve the Financial Structure and the Quality of the Statutory Health Insurance Scheme (GKV-FQWG), it is imperative that greater transparency on the quality of care be created. There are concrete plans to raise the comprehensibility of hospital quality reports and generate internet-accessible comparison lists on inpatient quality of care in selected clinical areas, in other words, to develop our own hospital evaluation portal under commission by the G-BA. The use of routine data, in the narrower sense referring to the claims data filed with the health insurance companies pursuant to section 284 of the German Social Code, Book Five (SGB V), should moreover not only create greater transparency on the quality of care in hospitals, but on outpatient care as well. Patient surveys are intended to be developed as a third data basis to flank the QA documentation by healthcare providers and claims data. The G-BA and the AQUA Institute have in part shifted this new horizon of expectations closer, for example, by consistently driving forward the risk adjustment of indicators on outcome quality – indispensable for the purposes of public reporting. In 2006, only 30 indicators were risk-adjusted, whereas 2013 can boast as many as 167. The use of health insurance claims data has likewise been launched. For example, when developing data-driven inpatient follow-up or cross-sectoral QA procedures, the AQUA Institute now regularly tests which quality indicators can be mapped based on claims data. The joint data collection office for the health insurance companies required to collect claims data is in preparation and should go into operation in early 2015. Patient surveys in connection with the cross-sectoral QA procedures on percutaneous coronary interventions and arthroscopic interventions on the knee joint are already in the development phase.

At this point, the staff at the AQUA Institute, and Professor Joachim Szecsenyi by name, are warmly thanked for the work they have done on behalf of the G-BA. Deep appreciation is furthermore deserved by all those participating in the creation of the Federal Analyses and of this Hospital Quality Report: The members of the Federal Experts' Working Groups for their critical evaluation of the results and expedient proposals for further developments in the clinical areas and indicators and those medical and nursing professionals at the hospitals who provided the basis for quality comparisons through their documentation of the clinical experience. The commitment at the healthcare frontline is more important than any quality legislation.

Dr. Regina Klakow-Franck
Impartial member of the Federal Joint Committee,
Chairwoman of the Subcommittee for Quality Assurance of the G-BA

Introduction

Information from the AQUA Institute

In pursuit of further development

Professor Joachim Szecsenyi, M.D.

Esteemed Readers,

You are holding in your hand the fifth German Hospital Quality Report prepared by the AQUA Institute. If one compares the first report from 2009 with the current version, the difference in the number of pages already shows that quality assurance has not stood still in the past years. Whereas the 2009 report had only 160 pages, the current one has nearly 260 pages. Traditionally, the results from the individual clinical areas form its core. Those years have seen the number of background texts, which have been included in the report due to further developments or as completely new topics, increase and their content grow.

The "Summary" chapter lists the major developments and results in the clinical areas that are supplemented by topically related aspects. This type of summary appeared for the first time in the German Hospital Quality Report 2012 and, on repeated request, was re-included in the report with updated numbers, data and facts. There you will find a fast, sound overview of the contents. The clinical area *Nursing: Prevention of pressure ulcers*, for example, is mentioned. It has been possible to markedly reduce the documentation load at the hospitals in this area by applying the data already used in the hospital information system. This yielded a substantial reduction in manual documentation, while recording data on a much greater number of patients. The website *www.perinatalzentren.org* which went online at the end of February 2014, is also talked about briefly. On this website, expecting parents and referring physicians can find the right hospital according to various criteria whenever a baby is predicted to be born prematurely with a weight below under 1,500 g. The website illustrates how information on quality assurance can be used as a genuine decision-making aid.

The chapter "From the hospital onto the Web" is also devoted to the topic of "Orientation for patients and physicians" and describes the path quality documents take from the hospital to the web-based hospital guides and includes a non-exhaustive list of internet addresses. Transparency is one of the central issues in quality assurance. For years, the ability to create more clarity has been the topic of much discussion in the healthcare system. On the one hand, more information is publically available today than ever before; on the other hand, the complaint is that it is not always understandable for patients. The demand for the simplest and most unequivocal statements has become louder; however, there are various obstacles standing in the way. To create fair comparisons between various hospitals, for example, the differences between them must be addressed. Summary mention here is made of the catchphrase "risk adjustment" (for more details, refer to the chapter "Status and perspectives of quality assurance"). This corrective tool is used in quality comparisons to account for the respective factors affecting the different patient groups (e.g., disease severity, concomitant findings, age, etc.). A specialized hospital treating primarily difficult cases will likely have higher complication rates than a normal hospital that treats lower-risk patients. Although the specialized hospital will certainly be the better choice because of its above-

average experience and competence, it would presumably score worse without risk adjustment. Another key point is that the search for a hospital is not only dictated by quality results alone, but depends on the patients themselves as well. Not every intervention is always worth traveling a long-distance to a specialized hospital. Rather, visiting a hospital in the patient's own region can be fully sufficient, especially when an intervention is involved that requires no special knowledge above and beyond the conventional level. Harmonizing all these and other aspects in a fair and easy-to-understand comparative system is a real challenge.

Important partial objectives have been achieved with regard to the envisioned implementation of cross-sectoral quality assurance. In addition to documentation by healthcare providers, the use of routine data and the inclusion of patient surveys are important pillars of quality assurance for the future. For these, promising concepts have been developed and some of which were already tested. Today we are standing at the threshold of cross-sectoral analysis; this momentum should be utilized to cast the knowledge gained over the past years in a suitable mold and turn it into reality.

Changes in the healthcare system are made by taking many tiny steps to reach the goal. The journey there cannot be traveled alone. We would therefore like to express our special thanks to the Federal Joint Committee, the quality managers at the hospitals, the staff at the State Administrative Offices and the representatives on the state committees, the Federal Experts' Working Groups, the medical societies and patient representatives as well as the self-governing bodies. Moreover, we would also like to thank our co-operation partners at the universities of Nijmegen (NL) and Heidelberg. My special gratitude is extended to the AQUA staff who tackled their tasks with great energy, a high degree of stamina and excellent specialized knowledge about quality assurance.

Göttingen, August 2014

Prof. Dr. Joachim Szecsenyi
Managing Director, AQUA Institute

Summary

Dr. Petra Kaufmann-Kolle

For many years now, certain medical and nursing services in Germany have been subject to the statutory requirement for data-driven quality assurance. The present German Hospital Quality Report 2013 has compiled the current results of such external hospital quality assurance (esQS). Moreover, the present report also contains background information, quality targets, comparisons with the previous years, results of the Structured Dialogue, evaluations and recommendations from experts. It also includes explanations about the prerequisites for further developments and/or about the status quo in and perspectives on quality assurance.

Since 2009, the AQUA Institute has supported the Federal Joint Committee (G-BA) in implementing external quality assurance pursuant to section 137a of the German Social Code, Book Five (SGB V). Its scope of responsibility not only covers the monitoring, care and further development of external hospital QA, but also extends to the development and incremental establishment of cross-sectoral quality assurance in particular. Among others, the aim is to coordinate the quality requirements of the inpatient and outpatient sectors in sensible alignment with each other in order to guarantee a high quality of care in the interests of patients and healthcare providers and/or to achieve its continual improvement in a dialogue with all stakeholders. Accordingly, the respective sections of the German Hospital Quality Report point out developments and upcoming innovations associated with the cross-sectoral approach (see chapter "Status and perspectives of quality assurance").

Within the scope of external hospital quality assurance on (data) collection year 2013, over 3.2 million records from 1,557 hospitals nationwide were analyzed (see chapter "Data basis") for the 30 clinical areas defined by the G-BA; in the previous year, it was nearly 4.2 million records. These numbers alone illuminate an important change that has significantly lowered the documentation cost for healthcare providers: Beyond the use of health insurance claims data, the AQUA Institute has consid-erably improved the cost-benefit ratio of external hospital QA for the existing clinical area *Nursing: Prevention of pressure ulcers* by using routine data from the hospital information system. Whereas previously approximately 1.2 million cases had to be documented "by hand" irrespective of the presence of a pressure ulcer, starting in data collection year 2013, this was only required for (approx. 300,000) cases with a pressure ulcer present. Although fewer cases need to be documented, data on a substantially larger number of patients (16.5 million) are collected because now the entire (data) collection year is considered and patients ≥ 20 years of age are included. Formerly, only a quarterly random sample of over 74-year-olds was involved. To obtain the risk adjustment basic data mandatory for this clinical area, the AQUA Institute has specified an automated risk statistic that the hospitals are required to deliver once a year. In the year of its launch, around 94 % of the hospitals had already complied with this requirement. In the other areas subject to mandatory documentation, case completeness in relation to the delivered records ranged from 99.0 to 103.8 % across the individual clinical areas – once again showing slight improvement over the previous year.

The achievement of quality targets is measured by a total of 434 indicators in 30 clinical areas. Of these, 167 indicators (78 of which are regression-based) are risk-adjusted, i.e., they account for the different factors influencing patient-related risks, e.g., age or previous diseases. In addition to high data validity and reliability, this is particularly important for ensuring a fair comparison of results. On the federal level, 40 out of a total of 434 indicators showed significant improvement, 17 significantly worsened and 346 indicators remained unchanged in terms of the federal results – all compared to the previous year. In 31 indicators, no statement can be made regarding any change over the previous year (e.g., in the case of newly introduced or changed indicators).

Table 1: Indicators with a special need for action (C indicators) in data collection years 2012 and 2013

Clinical area	C indicator*	2012	2013
Community-acquired pneumonia	Determination of respiratory rate on admission (QI-ID 50722)		■
Pacemaker – Revision/system replacement/removal	Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention (QI-ID 51988)		■
Implantable cardioverter defibrillators – Implantation	Guideline-compliant indication (QI-ID 50004)		■
Implantable cardioverter defibrillators – Revision/system replacement/removal	Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention (QI-ID 52001)		■
Aortic valve surgery, isolated	Indication for catheter-supported aortic valve replacement based on logistic euroSCORE I (QI-ID 51088)	■	
Breast surgery	Lymph node removal with DCIS and breast-conserving therapy (QI-ID 50719)		■
Obstetrics	Presence of a pediatrician at premature births (QI-ID 318)		■

*   QI-ID = Identification number of the quality indicators

Summary

The tasks assigned to the total of 14 Federal Experts' Working Groups supported by the AQUA Institute within the scope of external hospital quality assurance include the analysis of the need for action with regard to the quality of medical and nursing care pursuant to the objectives of quality assurance, the evaluation of the data analysis results as well as the derivation of the necessary measures. Based on results of data collection year 2013, the Federal Experts' Working Groups determined that the majority of quality targets have been achieved and one can speak of a good quality of care in German hospitals overall. Nevertheless, the number of so-called C indicators – requiring a special need for action – has increased over the previous year (2012: 1 C indicator; 2013: 6 C indicators). At first glance, this appears to suggest a worsening of quality. Indeed, an assessment of the need for action on the federal level illustrates which measures the Federal Experts' Working Group deems necessary beyond the measures of the Structured Dialogue: The Experts' Working Groups saw a standard need for action in the case of 224 indicators (need for action A, A indicator), where the computational discrepancies needed to be clarified directly with the healthcare providers in the Structured Dialogue. It was the Federal Experts' Working Groups' opinion that the computational discrepancies in 26 indicators should additionally be made an issue, e.g., at medical conferences as well; here, an extended need for action was seen (need for action B, B indicator). In relation to certain aspects of care, the Federal Experts' Working Groups see a special need for action (need for action C, C indicator) in 6 indicators in total. In addition to the measures described above, it has also been deemed important to develop and update guidelines and/or to implement existing ones more intensively or to examine whether the results are attributable to wrong incentives in the remuneration system (Table 1).

Since 2005, the hospitals have been legally bound by section 137 SGB V to regularly publish the results of QA based on the specifications of the G-BA. The G-BA followed the recommendations of the AQUA Institute on public reporting of quality indicators at hospital level and set down the indicators subject to mandatory reporting for data collection year 2013 (see chapter "Public reporting at hospital level"). They are labeled (🛈) accordingly in the tables below. Moreover, the indicator "Indication for catheter-supported aortic valve replacement based on logistic euroSCORE I" (QI-ID 51914) also became subject to mandatory reporting in accordance with the G-BA's plenary decision dated June 19, 2014. This was the case, although contrary to the usual methodology, no testing and assessment with respect to its suitability for public reporting had been undertaken by the AQUA Institute in advance: In light of the dramatic increase in catheter-supported aortic valve interventions (i.e., replacement of the aortic heart valve guided by a heart catheter) registered over the past 6 years and the fact that the number of catheter-supported interventions on the aortic valve exceeded conventional ones (i.e., replacement of the aortic heart valve by open surgery), for the first time in data collection year 2013, the Federal Experts' Working Group for Coronary Surgery deemed it particularly important to publish the result on indication on the hospital level in the first year after the indicator is introduced. Whereas the results of a mere 29 quality indicators were published up to the year 2011, their numbers have significantly risen after testing by the AQUA Institute (2011: 182 indicators; 2012: 289 indicators; 2013: 295 indicators). That signifies a marked elevation in transparency of quality in the healthcare system.

The adequate care of preterm infants with very low birth weights has long been the focus of quality assurance. Here, the central question is who can provide the most optimal care for these children. The AQUA Institute was commissioned by the G-BA in March 2011 to describe the reportable results relating to the quality of care at perinatal centers in layman terms and make them available on a publicly accessible website. On February 28, 2014, the website *www.perinatalzentren.org* went online and the response was very positive. The participation of hospitals in centralized publication of results is presently voluntary: For example, outcome data on 90 of the approx. 200 perinatal centers are currently published on the portal. The primary aim of the website is to help heighten transparency on and comparability of the quality of care. By making the presentation of the results more geared towards laymen, one further step has been taken towards more quality transparency (see chapter "Presenting the quality of care in preterm infants transparently online").

The Structured Dialogue is conducted in the event of computational discrepancies, i.e., when the results lie outside a set reference range (see chapter "Structured Dialogue"). With application of new evaluation categories in 2013, the proportion of qualitatively discrepant results (based on data collection year 2012) after conclusion of the Structured Dialogue nearly doubled across all clinical areas. This increase is most likely attributable to the fact that the new evaluation system no longer contains the key code 2 ("The result is classified as qualitatively non-discrepant after conclusion of the Structured Dialogue. The results will be subject to special monitoring in the follow-up.") In the past, this evaluation key was frequently used for cases that could not be allocated with unequivocal certainty. The revised evaluation categories no longer allow borderline cases of this type. The statements must now be evaluated more concretely after review.

A data validation is conducted annually: Based on data collection year 2012, improvements in documentation quality were determined by both the Basic Statistical Testing with the Structured Dialogue and by the sampling procedure with data synchronization (usually 5 % of the healthcare providers in three clinical areas). Particularly regarding case completeness, the trend is gratifying. Whereas the number of computational discrepancies in the discrepancy criteria on plausibility and record completeness declined marginally, the documentation rates of the individual hospitals have improved markedly over the previous years. Nevertheless, the sampling procedure revealed that the data validity of the observed hospitals varied strongly in the examined clinical areas. Nevertheless, data validity has improved in clinical areas where a sampling procedure had already been performed for the second time (*Liver transplantation*; *Aortic valve surgery, isolated*). In the wake of implementing the individual elements of data validation, several starting points showed on the part of all stakeholders where improvements are indicated. Besides the individual improvement measures initiated directly at the affected hospitals, methodological changes have also been implemented, such as revision of the filling-out instructions, evaluation and modification of discrepancy criteria, etc. This ought to uncover potential documentation errors even more effectively. Moreover, recommendations to the State Administrative Offices for Quality Assurance (LQS) were drafted that aim to harmonize the evaluation of results and simplify the collection and analysis of the documentation errors occurring.

Summary

The entire quality assurance is subjected to constant monitoring and updating – in particular with the aim of properly mapping the quality of care, enabling a fair comparison of hospitals and lowering documentation costs. As part of system maintenance (see chapter "Maintenance of current clinical areas"), constant work is being done on updating and further improving the implementation of the quality assurance procedures.

Like last year, the present German Hospital Quality Report contains a chapter on the important topic of nosocomial infections (see chapter "Results of external hospital quality assurance on nosocomial infections"). This gives a summarizing presentation of relevant results from various clinical areas of external hospital quality assurance: In the investigated clinical areas, the wound infection rates have largely remained consistently unchanged over the past years. These results are, for the most part, also consistent with the data on hospital infection rates obtained under other national and international surveillance systems.

Infections resulting from therapeutic and nursing interventions at medical treatment and nursing centers (i.e., nosocomial) pose a problem in medical care that ought to be taken seriously. Against this background, the AQUA Institute has been commissioned by the G-BA to develop, in close consultation with the scientific professional associations, two cross-sectoral procedures for statutory quality assurance on the topics "Prevention of nosocomial infections: Postoperative wound infections" and "Prevention of nosocomial infections: Vessel catheter-associated infections". Both procedures are currently being subjected to a feasibility study.

Particulars from the individual clinical areas

In the three cardiac surgery clinical areas (*Aortic valve surgery, isolated*; *Coronary surgery, isolated*; *Combined coronary and aortic valve surgery*), where heart valves are replaced and/or surgery is performed on coronary blood vessels, the quality of care on the federal level continued to be high in the previous years as well. Although examination of the results on the hospital level does reveal some inhomogeneity, the Federal Experts' Working Group sees no special need for action – i.e., clarification of the computational discrepancies within the scope of the Structured Dialogue is viewed as sufficient.

Leading medical professional associations in Europe and the USA have issued the consensus-based recommendation that catheter-supported aortic valve implantation (i.e., replacement of the aortic heart valve using a heart catheter) should only be performed on otherwise inoperable or multimorbid patients who are at high risk if they undergo surgery. The high-paced rise in the number of catheter-supported aortic valve implantations in recent years has caused them to overtake conventional (open-surgical) interventions for the first time. Problematical is the fact that certain catheter-supported aortic valve implantations are being performed in some hospitals that are not equipped with their own heart surgery department despite the comparatively higher complication risk as compared to conventional interventions. Indeed, this affected close to 400 patients at 17 hospitals in data collection year 2013.

In the clinical areas of Coronary surgery, isolated and Aortic

valve surgery, the development of follow-up indicators based on health insurance claims data has currently been commissioned for longitudinal analysis beyond the hospital stay. Since the intention in these clinical areas is to implement diagnosis-related quality assurance more intensely, it will be possible to arrive at more detailed conclusions about the quality of care moving forward. This same would also be desirable for the combined cardiac surgery interventions.

The clinical areas of transplantation medicine and living donations (*Liver transplantation*, *Kidney transplantation*, *Heart transplantation*, *Lung and heart-lung transplantation*, *Pancreas and pancreas-kidney transplantation*, *Living liver donation*, *Living kidney donation*) can be attested to have an overall good quality of care, and one which is very good with a view to the small group of living donors (living liver donors and living kidney donors). With the exception of lung and heart-lung transplantations, the number of transplantations has indeed dropped markedly.

In the clinical areas of transplantation medicine, the case completeness of QA documentation on each intervention itself is nearly 100 %. What has been problematic in the past years is the follow-up on affected patients beyond their hospital stay. The worst-case analysis applied for the first time last year, where patients with no data available on survival status were counted as "deceased", appears to have produced the intended effect: The documentation quality has markedly improved in all clinical areas of transplantation medicine.

In heart transplantations, a worsening in the 1-year survival rate was registered. The reasons will be elucidated in the Structured Dialogue. Here, it would be helpful – as in the other clinical areas of transplantation medicine – to merge the pseudonymized donor and recipient data and that way, through deeper analysis, further develop the allocation rules on a continuous and long-term basis. One responsible working group of the G-BA has issued recommendations for further developments in transplantation medicine. As a consequence of this, the AQUA Institute will make a further development for the 2016 data specification within the scope of system maintenance. This will be aimed at enabling follow-up analyses for the future on the health insurance claims data from all transplantation areas except for kidney transplantations (see the following section) and isolated pancreas transplants.

It is gratifying that the G-BA has commissioned the development of a cross-sectoral QA procedure on replacement therapy for end-stage kidney failure. The future aim of this procedure is to analyze dialysis and kidney transplantations jointly with the help of health insurance claims data.

As was the case last year, the quality of care in the clinical areas of orthopedic/trauma surgery was on a good level overall. There are positive trends in outcome quality and the repeat improvements in the indicators on properly diagnosed indications in the primary implantations of artificial hip and knee joints should be highlighted. That said, one critical note must be made that last year the death of 300 patients was directly connected to the primary implantation of a hip replacement. The causality is less attributable to the interventions themselves, but rather to the severe multi-morbidities of the patients who are often of highly advanced age. Insofar, an appeal should be made to the

Summary

decision-makers to engender a special sensitivity in relation to this medical indication.

Besides the merging of the endoprosthetic clinical areas resolved by the G-BA starting in data collection year 2015, it is desirable to extend the databases, i.e., to introduce public reporting as well as the use of health insurance claims data to achieve better assessment of long-term outcome quality. This is the only way that the quality of care can also be reviewed after hospital discharge.

There are a total of 6 clinical areas that measure the quality of care in implanted pacemakers and/or cardioverter defibrillators (*Pacemaker implantation*, *Pacemaker – Replacement of generator/battery*, *Pacemaker–Revision/system replacement/ removal* and 3 analogous clinical areas for *Implantable cardioverter defibrillators*). The Federal Experts' Working Group continues to rate the quality of care in pacemaker implantation as high at the federal level. However, one should not overlook the fact that revision interventions due to procedure-related sequelae are required after the implantation of pacemakers and cardioverter defibrillators with an all too common frequency. Moreover, some of the treatment outcomes at the hospitals show substantial variance. In implantable cardioverter defibrillators, the Federal Experts' Working Group sees a special need for action in relation to the medical indication (Table 1). Although the proportion of guideline-compliant indications has improved compared to the previous year, there is still a special need for action resulting from the numerous computational discrepancies, which will be the subject of the Structured Dialogue with the affected hospitals. In the opinion of the Federal Experts' Working Group, it is necessary to update and more precisely define the relevant guidelines regarding the medical indication. In revision interventions, the Federal Experts' Working Group sees a special need for action in both pacemakers and cardioverter defibrillators with regard to procedure-associated problems as an indication for re-hospitalization: Repeat inpatient interventions are required at too high a frequency. On top of that, the complication rates are currently being underestimated: Firstly, data on perioperative complications have only been collected thus far when they occurred up to the end of the respective hospital stay. Secondly, postoperative complications leading to re-hospitalization could previously not be accounted for whenever various hospitals were involved in the course of treatment. Hence, the cross-institutional and thus complete collection of peri- and postoperative complications will not be possible until the introduction of a follow-up analysis. This is planned (in the inpatient sector) for the 3 clinical areas on pacemaker care starting 2015 and is currently undergoing development for cardioverter defibrillator care. In the future, this follow-up will permit a cross- institutional evaluation of the medium- and long-term sequelae of inpatient pacemaker care. The Federal Experts' Working Group also sees the need for improvement with respect to the implementation of intraoperative thresholds and amplitude measurements during pacemaker or defibrillator interventions: Without these measurements, the functionality of an implantable rhythm device cannot be validated as safe or reliable. Unfortunately, all too often the aforementioned measurements are refrained from.

The clinical area *Coronary angiography and percutaneous coronary intervention (PCI)*, which focuses on the examination and treatment of coronary blood vessels guided by a heart catheter, registers a fundamentally stable and good quality of care across all indicators. Striking is the fact that the radiation exposure of patients (dose area product) during heart catheterization procedures has been showing a continuous decline for several years now. The Federal Experts' Working Group for Cardiology supports the further developments on the indicators for medical indication within the existing external hospital quality assurance procedure as defined by the planned cross-sectoral procedure and envisaged for next year. Currently, it must still be assumed that under-documentation of complications (abbreviated MACCE) continues to exist in external hospital quality assurance. This cannot be overcome until claims data are included.

For this reason among others, the AQUA Institute was commissioned by the G-BA in 2013 to undertake preparatory services for the use of health insurance claims data. Moreover, data on outpatient PCIs should also be collected. The commissioned work comprised two successive subprojects. First, a general specification was developed for the use of health insurance claims data in order to test and coordinate the technical specifications and fundamentals for later implementation of routine operations by the G-BA and to support establishment of the structures necessary for this. The second step was to develop a topic-specific data specification for collecting claims data in the QA procedure *Percutaneous coronary intervention (PCI) and coronary angiography*. In this context, the indicators originally agreed for QA documentation at the healthcare providers were empirically reviewed as to whether and to what extent the information needed for their computation could also be collected via health insurance claims data. One aim is to examine the follow-up of patients beyond their outpatient and/or inpatient treatment – called follow-up – particularly by analyzing the health insurance claims data. Additionally, the AQUA Institute was also commissioned to develop instruments for mapping the patient's perspective (patient survey) for the planned quality assurance procedure *Percutaneous coronary intervention (PCI) and coronary angiography*.

An invasive procedure called *carotid artery revascularization* can be performed to eliminate narrowing of the carotid artery, ensure adequate blood flow (revascularization) and thereby prevent an impending stroke. It can be performed as open surgery or with catheter support. In the clinical area *Carotid artery revascularization*, marked changes over the previous year have been observed in the number of both catheter-supported and open-surgical revascularizations. The decline in the latter can in part be attributed to the fact that the procedure is documented as "open-surgical" whenever it is switched from a catheter-supported to an open-surgical revascularization. On the basis of the decline in numbers from (data collection year) 2012 to 2013, the Federal Experts' Working Group indeed has considerable doubts as to whether all catheter-supported carotid artery revascularizations are performed under inpatient conditions. In view of the large numbers of specialist groups undertaking catheter interventions, it must be assumed that a considerable part of the clinical process in the contracted physician sector is not being mapped in the existing clinical area because the data are only being collected on inpatient interventions. The Federal Experts' Working Group therefore recommends further development of the existing clinical area in order to use health insurance claims data to include all patients with carotid artery

Summary

revascularizations in quality assurance in the future, irrespective of the place where treatment is rendered. Using health insurance claims data would also additionally facilitate a longitudinal observation that would allow collection of the complications like stroke or death that sometimes do not occur until after the hospital stay.

The fact that it is currently not possible to map the postoperative complications that do not emerge until after discharge from the hospital also applies to other clinical areas such as *Cholecystectomy* (removal of the gallbladder). Particularly given the steadily shorter lengths of hospital stay, this fact is problematic and, consequently, does not allow a comprehensive estimation of the quality of care by the Federal Experts' Working Group until after follow-up indicators have been introduced. Such indicators had already been designed as part of the further development of the clinical area, but are currently not yet being applied due to a lack of legal foundation. The Federal Experts' Working Group recommends that these indicators not yet in use be implemented as promptly as possible. Nevertheless, the Federal Experts' Working Group rates the quality of care within the scope of hospital stays as good overall.

Although the clinical area *Community-acquired pneumonia* (pneumonia acquired outside of a hospital) shows a good quality of care in general, a special need for action was seen in the indicator "Determination of respiratory rate on admission" (QI-ID 50722) (Table 1): Despite improvements in the last years, the result at the federal level is not within the reference range. The many qualitative discrepancies discussed in the Structured Dialogue on data collection year 2012 made it clear that the determination of respiratory rate still does not represent a broadly comprehensive standard, but indeed an important and easy-to-use instrument for estimating the severity of acute, cardiac, respiratory or metabolic diseases that is recommended in both German and international guidelines.

On the federal level, the quality of care in the clinical area *Breast surgery* (operations performed on the mammary gland) is good overall. Nevertheless, the Federal Experts' Working Group sees a special need for action in "Lymph node removal with DCIS and breast conserving therapy" (QI-ID 50719) (Table 1). Against the background of these guideline recommendations, the nationwide overall rate indicates that a substantial proportion of patients accounted for are overtreated. Therefore, in the estimation of the Federal Experts' Working Group, there is not only a need to make the healthcare situation a topic of discussion within the Structured Dialogue with the affected hospitals, but to address it at medical conferences as well. With regard to comprehensive mapping of the quality of care, efforts should be made to survey those treated.

The clinical area *Gynecological surgery* focuses on interventions on ovaries and fallopian tubes. For the first time, removal of the uterus (hysterectomy) has no longer been recorded, which is why the number of transmitted records has dropped by approx. 100,000. But, due to the frequency of the latter intervention and the necessity of a strict indication, it is essential in the Federal Experts' Working Group's view to develop new indicators for hysterectomy as soon as possible. Moreover, the Federal Experts' Working Group discussed including urogynecological procedures like incontinence surgery and treatments for blad-

der and uterine prolapses in quality assurance in the future as well. The cross-sectoral care of patients with ovarian, cervical and endometrial cancers is a topic relevant to any quality assurance relating to gynecological surgery.
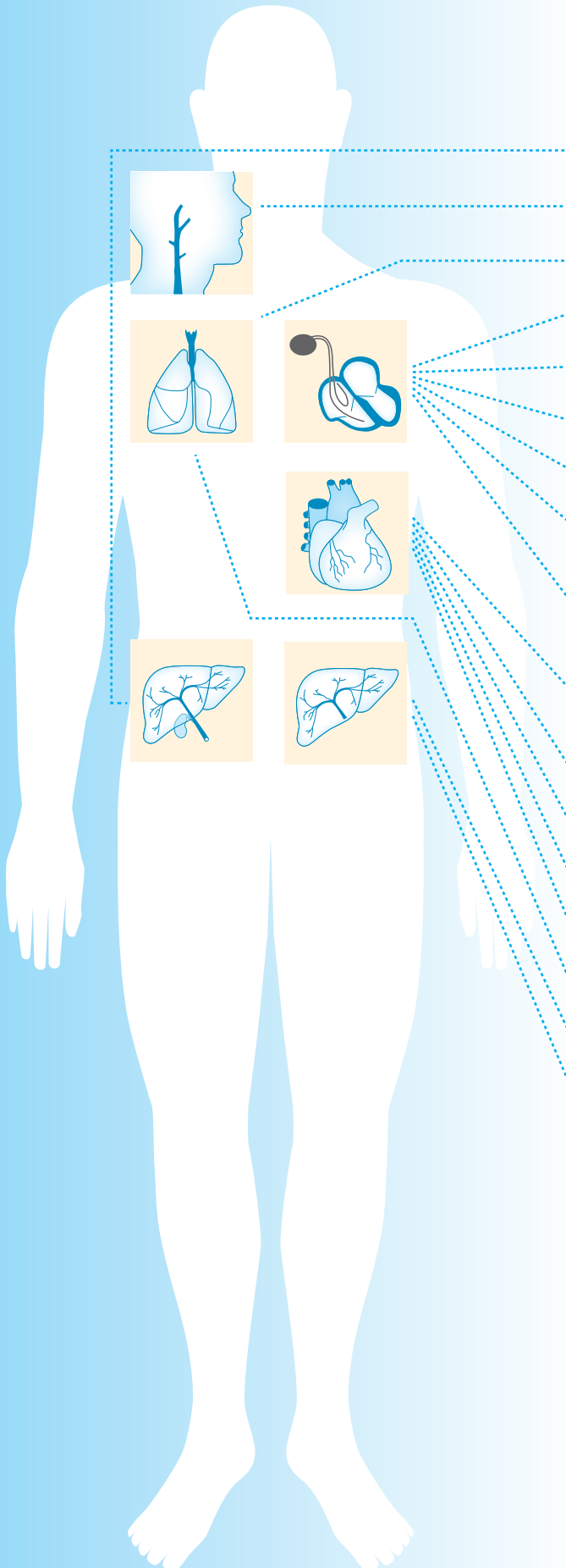
In the clinical areas *Obstetrics* and *Neonatology* (care of preterm infants), the healthcare situation at the federal level in relation to (data) collection year 2013 is viewed as good to very good overall. Nevertheless, the Federal Experts' Working Group sees a special need for action in part because there is a very large range across the hospital-based results on several indicators: Preterm infants should be treated by specialized physicians, given that the presence of a pediatrician, beside the overall organizational structure, decisively impacts treatment outcome. Unfortunately, virtually one in three hospitals was computationally discrepant on the affected indicator. To draw attention to structural problems and where necessary to create the framework for further legal regulations, the indicator "Presence of a pediatrician at premature births" (QI-ID 318) is classified as having a special need for action (Table 1).

As mentioned at the beginning in connection with the clinical area *Nursing: Prevention of pressure ulcers*, routine data were used for the first time within the scope of quality assurance. This lowered the documentation cost for healthcare providers substantially. On the other hand, the target population of patients included in quality assurance is substantially larger than before. Neither a final interpretation of the results nor a direct comparison with those of the previous year is possible in light of the comprehensive changes involved with considering a substantially larger target population, the use of routine data and the newly introduced risk statistic.

The present results illustrate how the previous measures of external hospital quality assurance have not only made a major contribution to continuation of, but also to an improvement in the quality of care at hospitals. Beyond this, however, further steps are indispensible and should be coordinated with all players involved in statutory quality assurance. Examples are transparency in public reporting or, wherever possible, the introduction and further developments of risk-adjusted quality indicators.

Analysis 2013

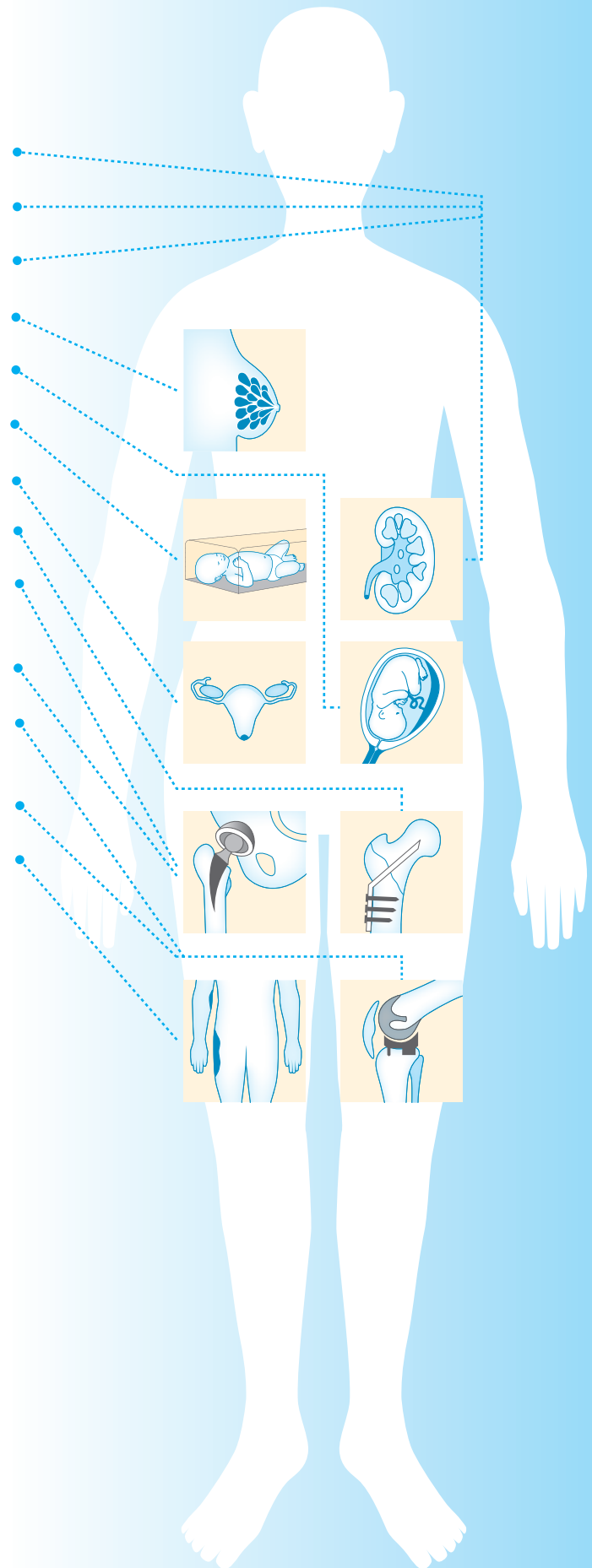## Overview of existing QA procedures (clinical areas)

Analysis 2013

Overview of existing QA procedures (clinical areas)

Cholecystectomy

Lisa Manderscheid, Priv.-Doz. Dr. Sven Meyer, Dr. Thomas König, Federal Experts' Working Group for Abdominal Surgery

Introduction
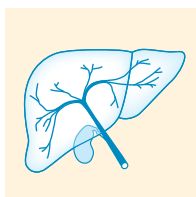
Gallstone disease is the most common illness of the gallbladder and the bile ducts. Between around 15 to 20 % of the population have gallstones; two-thirds of the sufferers are women. Most patients with gallstones remain asymptomatic (have no symptoms) and therefore do not require treatment. However, treatment is indicated whenever the gallstones are located in the bile ducts because the associated obstruction of the bile flow can cause jaundice and the danger of bile duct inflammation – even without symptoms.

Characteristic signs of painful gallstones (symptomatic cholelithiasis) include severe colic attacks in the mid- or right epigastric region that can also radiate to the back or right shoulder. Occasionally, this is associated with nausea and vomiting. Gallstones are primarily diagnosed by ultrasound examination.

Painful gallstones are typically treated by surgical removal of the gallbladder (cholecystectomy). Approximately 175,000 such interventions are performed in Germany every year; approximately 90 % of all cholecystectomies are performed by laparoscopy, i.e., the gallbladder is removed by means of what is called keyhole surgery. There are more recent methods by which surgical access is accomplished through natural orifices, for example, the vagina. The risk thereof cannot yet be estimated conclusively. In rare cases, the removal of the gallbladder during abdominal surgery performed for other reasons may be reasonable and necessary (incidental cholecystectomy).

During the surgical treatment of cholelithiasis, isolated cases of severe complications can occur, such as injuries to the biliary tract or blood vessels. The frequency of such events is monitored and analyzed as part of external hospital quality assurance. Due to the relevance of these severe complications, the results of the indicators "Closure or transection of the main bile duct" (QI-ID 220) and "Ratio of the observed to the expected rate (O / E) of closures or transections of the main bile duct" (QI-ID 50786) are presented comprehensively in the following.

Services subject to mandatory documentation

Cholecystectomies with and without bile duct revision performed to diagnose acute pancreatitis, a non-malignant disease of the gallbladder or biliary tract. Interventions performed for malignant de novo neoplasms in the gastric organs are excluded, as are cholecystectomies performed during an intervention for other reasons (simultaneous cholecystectomy).

Changes in comparison to the previous year

The risk adjustment models were adapted for the indicators "Ratio of the observed to the expected rate (O / E) of closures or transections of the main bile duct" (QI-ID 50786), "Ratio of the observed to the expected rate (O / E) of reinterventions due to complications" (QI-ID 50791), "Ratio of the observed to the expected rate (O / E) of deaths" (QI-ID 51391) and "In-hospital mortality for low mortality risk" (QI-ID 50824). The risk factor "Open-surgical interventions" was omitted.

Results

In the clinical area *Cholecystectomy*, the Federal Experts' Working Group classifies the quality of care during the hospital stay as good. Postoperative complications not occurring until after discharge from the hospital can currently not be mapped. Particularly given the steadily shorter lengths of hospital stay, this fact is confounding and, consequently, will not allow the Federal Experts' Working Group to judge the quality of care comprehensively until after follow-up indicators are introduced. Such indicators were previously developed as part of the further development of the procedure, but are currently not yet applied due to a lack of legal basis. The Federal Experts' Working Group recommends the seamless implementation of this further development.

In the Structured Dialogue for data collection year 2012, a total of 840 computational discrepancies were evaluated. In 271 cases, the respective hospitals were notified of computational discrepancies, with a statement being requested for 567 discrepancies. Thereupon, 516 computational discrepancies were assessed as "qualitatively non-discrepant". By contrast, 3.3 % (n = 28) of the computational discrepancies were determined to be deficiencies in process-related or structural quality, particularly with regard to the handling of injuries to the main bile duct, mortality in low-risk surgeries and documentation. More extensive measures were performed on 23 computational discrepancies. This included 4 "colleague-to-colleague" talks and a total of 19 target agreements on organizational aspects and surgical techniques.

Looking forward

Since no valid guideline currently exists on the diagnosis and treatment of cholelithiasis, the indication indicator had already been suspended for data collection year 2012. Nevertheless, the Federal Experts' Working Group continues to classify this indicator as exceedingly relevant. At present, all remaining quality indicators exclusively map outcome quality. The Federal Experts' Working Group therefore recommends that the professional associations urgently enact an evidence-based guideline that adequately maps the optimal standard of surgical and interventional care.

The Federal Experts' Working Group anticipates that the quality of care can be more extensively evaluated beyond discharge once the existing clinical area is seamlessly converted to the QA procedure described according to the report on further development, including the introduction of follow-up indicators using health insurance claims data.

Cholecystectomy

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	172,138	173,488	173,029	100.3 %
Hospitals	1,098	1,084	1,080	100.4 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	173,375	100 %
< 20 years	2,454	1.4 %
20 – 29 years	11,922	6.9 %
30 – 39 years	18,408	10.6 %
40 – 49 years	28,359	16.4 %
50 – 59 years	33,701	19.4 %
60 – 69 years	30,523	17.6 %
70 – 79 years	33,152	19.1 %
≥ 80 years	14,856	8.6 %
Sex		
Male	63,341	36.5 %
Female	110,034	63.5 %
ASA classification		
ASA 1: A normal healthy patient	36,306	20.9 %
ASA 2: A patient with mild systemic disease	94,477	54.5 %
ASA 3: A patient with severe systemic disease	39,156	22.6 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	3,232	1.9 %
ASA 5: A moribund patient who is not expected to survive without the operation	204	0.1 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/12n1/

Cholecystectomy

Case-based aggregate results (patients)

| | | | 2012 | 2013 | | | |
| | | | | Cases (patients) | | | |
QI-ID	Name of the quality indicator		Result	Result	Numerator (O | E) *	Denominator	Trend
	Intervention-specific complications						
220	Occlusion or transection of the main bile duct	⚠	0.12 %	0.12 %		213	→
50786	Ratio of the observed to the expected rate (O / E) of closures or transections of the main bile duct	⚠	1.00	1.00	213 0.12 %	214 0.12 %	173,375	→
613	Complications requiring treatment after laparoscopically initiated surgery		2.4 %	2.4 %		3,886	163,936	→
	General postoperative complications						
224	General postoperative complications		2.9 %	2.8 %		4,839	173,375	→
225	General postoperative complications after laparoscopically initiated surgery		2.1 %	2.1 %		3,394	163,936	→
226	General postoperative complications after open surgery		15.1 %	15.4 %		1,407	9,151	→
	Reintervention due to complications						
51169	Reintervention due to complications	⚠	2.4 %	2.4 %		4,176	173,375	→
50791	Ratio of the observed to the expected rate (O / E) of reinterventions due to complications	⚠	1.00	1.02	4,176 2.41 %	4,111 2.37 %	173,375	→
227	Reintervention due to complications after laparoscopically initiated surgery	⚠	1.2 %	1.2 %		1,168	98,267	→
	In-hospital mortality						
51392	In-hospital mortality	⚠	0.9 %	0.9 %		1,557	173,375	→
51391	Ratio of the observed to the expected rate (O / E) of deaths	⚠	1.00	0.96	1,557 0.90 %	1,614 0.93 %	173,375	→
50824	In-hospital mortality for low mortality risk	⚠	0.12 %	0.12 %		205	173,375	→

* for regression-based quality indicators

Cholecystectomy

Hospital-based aggregate results for utilization in quality assurance

| | | | 2013 | | | |
| | | | **Hospitals** | | **Evaluation** | |
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
	Intervention-specific complications					
220	Occlusion or transection of the main bile duct	Sentinel event	1,082	184	X	A
50786	Ratio of the observed to the expected rate (O / E) of closures or transections of the main bile duct	n.d.*	1,082	–	X	X
613	Complications requiring treatment after laparoscopically initiated surgery	≤ 5.6 % (TO; 95th percentile)	1,080	56	2	A
	General postoperative complications					
224	General postoperative complications	≤ 7.0 % (TO; 95th percentile)	1,082	58	2	A
225	General postoperative complications after laparoscopically initiated surgery	≤ 5.6 % (TO; 95th percentile)	1,080	50	2	A
226	General postoperative complications after open surgery	≤ 35.5 % (TO; 95th percentile)	958	100	2	A
	Reintervention due to complications					
51169	Reintervention due to complications	n.d.*	1,082	–	X	X
50791	Ratio of the observed to the expected rate (O / E) of reinterventions due to complications	≤ 2.33 (TO; 95th percentile)	1,082	55	2	A
227	Reintervention due to complications after laparoscopically initiated surgery	n.d.*	1,067	–	X	X
	In-hospital mortality					
51392	In-hospital mortality	n.d.*	1,082	–	X	X
51391	Ratio of the observed to the expected rate (O / E) of deaths	≤ 3.52 (TO; 95th percentile)	1,082	51	2	A
50824	In-hospital mortality for low mortality risk	Sentinel event	1,082	169	X	A

TO = Tolerance range; * not defined

Indicator group (vertical labels along left side)

Cholecystectomy

QI-ID 220: Occlusion or transection of the main bile duct

Description	
Numerator	Patients with closure or transection of the main bile duct
Denominator	All patients
Reference range	Sentinel event
Risk adjustment	No further risk adjustment
QI-ID	220
Comparability with the previous year's results	Comparable

Case-based results (patients)					
	2009	**2010**	**2011**	**2012**	**2013**
Aggregate result	235	177	180	212	213
Confidence interval	–	–	–	–	–
Total number of cases	171,966	171,519	173,296	172,072	173,375

Aggregate result of all patients
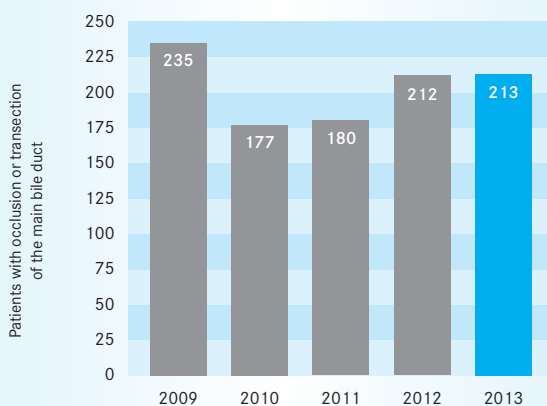
Hospital-based results	
Target population of all hospitals	1,082
Number of hospitals with 0 cases	2

1,025 Hospitals with ≥ 20 cases

Number of computationally discrepant hospitals	184 of 1,025

57 Hospitals with 1 to 19 cases

Number of computationally discrepant hospitals	0 of 57
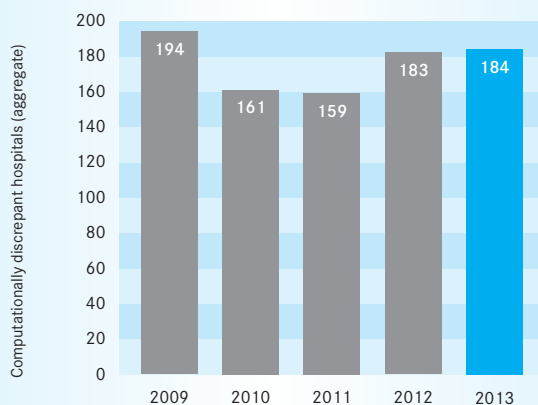
Quality target

Intervention-specific complications requiring treatment, partially dependent on the surgical technique, should occur rarely.

Background

The indicator describes the number of patients who incurred a closure or transection of the main bile duct.

Injuries to the main bile duct including its anatomically related structures in the hepatoduodenal ligament are associated with high morbidity and/ or mortality. Whereas in the early 1990s the rate of biliary tract injuries during laparoscopic cholecystectomy was higher than with open surgery, these differences have meanwhile been reversed, with laparoscopic cholecystectomy representing the method of choice almost everywhere.

Evaluating the results

Compared to the previous year (212 cases), the results for the indicator have remained nearly the same. The range increased for hospitals with at least 20 cases (0 to 5.0 %) compared to the previous year (2012: 0.0 to 3.2 %). This year, none of the hospitals with fewer than 20 cases registered any patient with closure or transection of the main bile duct.

In the Structured Dialogue on data collection year 2012, 17 notices were sent and 166 statements requested. Ultimately, 147 hospitals were classified as "qualitatively non-discrepant" and 12 hospitals as "qualitatively discrepant". The number of qualitatively discrepant hospitals has thus increased over the previous year (n = 7), however, there is no evidence that the quality of care has worsened at the federal level.

At 7 hospitals, an evaluation was not possible due to improper documentation. At present, the Federal Experts' Working Group classifies this quality indicator with regard to the need for action as Category A. Since it is a sentinel event indicator, all cases should be followed up with statements in the Structured Dialogue, which is not the case at the moment. Higher rates than those currently documented are anticipated because injuries of the main bile duct can also manifest after hospital discharge.

Cholecystectomy

QI-ID 50786: Ratio of the observed to the expected rate (O/E) of occlusions or transections of the main bile duct

Quality target

Intervention-specific complications requiring treatment, partially dependent on the surgical technique, should occur rarely.

Background

The indicator describes the ratio of the observed to the expected risk-adjusted rate for the occurrence of closure or transection of the main bile duct.

One meta-analysis has reported the rate of intervention-specific complications in laparoscopic cholecystectomy to be 1.35 %. However, it must be borne in mind that comparison is only possible to a limited extent due to varying definitions of the complications and the different documentation periods.

Since data collection year 2011, a risk adjustment has been performed on the outcome indicator "Closure or transection of the main bile duct" (QI-ID 220). The risk factors selected are collected in the QA documentation and point to relevant impacts on the closure or transection of the main bile duct occurring in the statistical estimation model.

Evaluating the results

The O / E of 1.0 shows that the 2013 result for this quality indicator did not change over the previous year. For both observed (O) and expected cases (E) a minimal increase has been registered that is attributable to the target population. The range (0 to 43.98) for hospitals with at least 20 cases is substantial. At hospitals with fewer than 20 cases no patients incurred an occlusion or a transection of the main bile duct.

No reference range has been defined for the present risk-adjusted indicator. This is due to the fact that the hospitals with computational discrepancies had already been evaluated within the scope of the Structured Dialogue on the indicator "Occlusion or transection of the main bile duct" (QI-ID 220), i.e., a sentinel event indicator.

Description

Numerator	Patients with occlusion or transection of the main bile duct
Denominator	All patients
O (observed)	Observed rate of occlusions or transections of the main bile duct
E (expected)	Expected rate of occlusions or transections of the main bile duct, risk-adjusted using the logistic cholecystectomy score for QI-ID 50786
Reference range	Not defined
Risk adjustment	Logistic regression
QI-ID	50786
Comparability with the previous year's results	Limited comparability

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	1.61	1.00	1.00	1.00
Confidence interval	–	1.38 – 1.86	0.86 – 1.16	0.87 – 1.14	0.87 – 1.14
Total number of cases	–	171,519	173,296	172,072	173,375
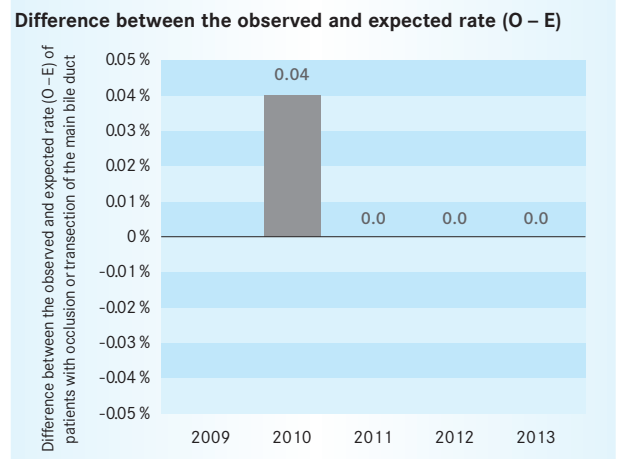
Difference between the observed and expected rate (O – E)

Hospital-based results

Target population of all hospitals	1,082
Number of hospitals with 0 cases	2

1,025 Hospitals with ≥ 20 cases
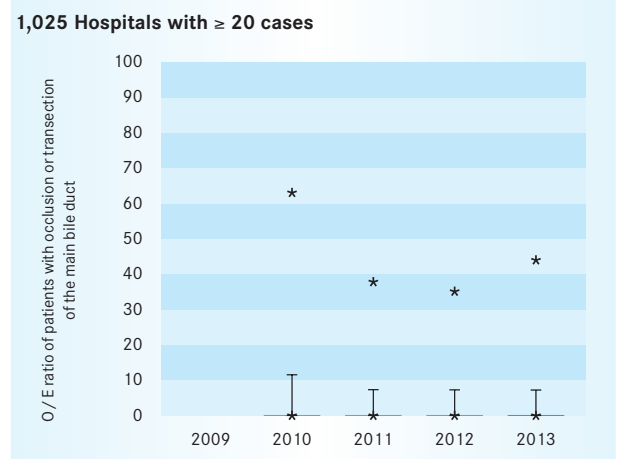
Median	0.00	Number of computationally discrepant hospitals	–
Range	0.00 – 43.98		

57 Hospitals with 1 to 19 cases

Median	0.0	Number of computationally discrepant hospitals	–
Range	0.00 – 0.00		

Carotid artery revascularization

Priv.-Doz. Dr. Sven Meyer, Lisa Manderscheid, Teresa Thomas, Federal Experts' Working Group for Vascular Surgery

Introduction
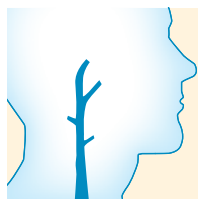
The two carotid arteries (arteriae carotis) supply the brain with oxygen and vital nutrients via the blood and are therefore considered central blood vessels. A narrowing (stenosis) or an occlusion of the carotid artery with restricted blood flow to the brain (ischemia) or plaques dislodged from the calcified vessel wall (embolization) can often lead to a stroke. The main cause of narrowing of the arteries is arterial calcification (arteriosclerosis).

The treatment method depends on the degree of narrowing of the neck arteries. The degree of stenosis, i.e., the degree of narrowing, is recorded internationally according to the NASCET method. NASCET (*North American Symptomatic Carotid Endarterectomy Trial*) is the name of a randomized study that determined degree of stenosis by angiography (visualization of blood vessels using imaging procedures). Nowadays the degree of stenosis is usually determined by ultrasound (duplex sonography) and the results reported in NASCET values. In asymptomatic patients with only slight narrowing, medication-based treatment may be sufficient. However, for higher degrees of narrowing and for symptomatic cases, an invasive intervention can be required. The decision about the type of therapy should be made in consultation with all medical specialties involved in treatment.

This invasive intervention is known as carotid artery revascularization. Applying this procedure eliminates the narrowing of the carotid artery (carotid stenosis) and prevents an impending stroke. Carotid artery revascularization may be unilateral or - in rare cases - bilateral, as required. Two different methods are employed for carotid artery revascularization. Thromboendarterectomy removes the deposits from the blood vessel in open surgery in order to reconstruct the diseased artery. This type of intervention is also known as carotid artery reconstruction. Alternatively, the vessel can be dilated using a balloon catheter (catheter-supported) and treated by implanting a wire mesh tube (stent).

At the time of the introduction of the quality assurance procedure, healthcare deficiencies were suspected, especially regarding the indication and the execution of the intervention. Consequently, the documentation for quality assurance is focused on the key parameters of the correct indication for the treatment of carotid artery stenosis – with or without symptoms (symptomatic/asymptomatic) – as well as strokes and deaths with a time-dependent relation (periprocedurally) to the carotid artery revascularization. Possible complications are by definition always attributed to the first intervention, since in the case of a bilateral intervention the allocation of a subsequent complication to one or other side is possible only to a limited extent.

Services subject to mandatory documentation

Open surgical or endovascular procedures performed on the extracranial part of the internal carotid artery, the external carotid artery and the common carotid artery, excluding transpositions of the carotid arteries; exceptions to this include polytrauma and aortic dissection as well as extracorporeal membrane oxygenation (ECMO) and pre-ECMO therapy.

Changes in comparison to the previous year

As a result of the restructuring of the documentation forms for data collection year 2013, it is now possible to record subsequent interventions in a differentiated manner so that an overall assessment is made of strokes and deaths over the whole hospital stay in relation to the first treated side.

- Interventions in which a carotid artery stent is inserted to create access during an intracranial procedure are excluded from the indicator calculation for catheter-supported carotid artery revascularizations.
- Catheter-supported interventions in which a switch is made to open surgery are included in the universe of indicators for catheter-supported interventions since 2013.
- For catheter-supported and open surgical carotid artery revascularizations, the previously separately assessed indicators for moderate and high-grade symptomatic carotid artery stenoses have been combined, as recent study results no longer suggest any differentiation for an indication in symptomatic stenoses of more than 50 %.
- In addition, two new risk-adjusted indicators have been developed for the rate-based, non-risk-adjusted indicators of the previous year for periprocedural (i.e., in a time-dependent relation to the surgery) or severe strokes and death in catheter-supported carotid artery revascularizations.

Since, in addition, various reference ranges have been defined, a comparable indicator set is now available for both catheter-supported and open surgical carotid artery revascularization. This also includes the triggering of the Structured Dialogue.

Results

The overall results for the data from 2013 continue to show a good quality of care for carotid artery revascularization. This includes asymptomatic and symptomatic carotid artery stenoses for both the indication as well as the periprocedural development of complications.

In the second year since the inclusion of carotid artery revascularization, the number of recorded cases in the clinical area has decreased. In 2012, a total of 33,473 records were available for analysis, whereas in 2013 the number of open surgical and catheter-supported carotid artery revascularizations combined was 32,604. The case completeness of the clinical area as a whole, with 99.4 %, continues to be high. 98.9 % of 609 hospitals that performed the services concerned provided records for 2013. The number of minimal data sets decreased from 153 in 2012 to 118 in 2013.

As a result of the restructuring of the documentation forms for data collection year 2013, it is possible to record subsequent interventions in a differentiated manner so that an overall assessment is made of strokes and deaths over the whole hospital stay in relation to the first treated side. A further carotid artery revascularization during the same hospital stay was performed in a total of 267 patients (0.8 % of all carotid artery interventions), 179 of which underwent the procedure following open surgical intervention and 88 following catheter-supported carotid artery revascularization as the first intervention. A further revascularization was performed on the same vessel in 198 cases (0.6 %) and on the contralateral carotid artery in

Carotid artery revascularization

69 cases (0.2 %). The follow-up intervention was performed by open surgery in 168 cases (0.5 %) and catheter-supported in 99 cases (0.3 %).

With the exception of the indicators for the indication regarding asymptomatic carotid artery stenoses, the Federal Experts' Working Group does not see a special need for action for individual quality indicators. The computationally discrepant hospitals were examined within the Structured Dialogue. In catheter-supported carotid artery revascularizations, the reference ranges for the indicators for the indication and for the risk-adjusted outcome indicators on stroke and death are used for the first time to trigger the Structured Dialogue for the data collection year 2013.

A total of 125 computational discrepancies were examined within the Structured Dialogue for the data collection year 2012. Notices were sent out in 43 cases and statements were requested in 82 cases. In 6 meetings, a total of 7 target agreements – among others on diagnostic aspects, indication, specialist care and matters relating to surgical technique – were concluded. No on-site inspections took place in the Structured Dialogue for the data collection year 2012. Following the conclusion of the Structured Dialogue, 10 cases were classified as "qualitatively discrepant" after examination, but without any further information in this respect from the State Administrative Offices for Quality Assurance (LQS). In 5 cases, this was due to improper documentation. 68 cases were assessed as "qualitatively non-discrepant".

After adaptation of the data field on the technique of thromboendarterectomy in 2011, the Federal Experts' Working Group noted in the Federal Analyses for the data collection years 2011 and 2012 that, contrary to the guideline recommendations, direct suturing of the vessel instead of patch insertion had been used in a relatively high proportion of patients to close the arteriotomy. An inquiry was therefore made to the State Administrative Offices for Quality Assurance about the relevant data field in the Structured Dialogue for the data collection year 2012. In particular, as part of a survey of all hospitals in which more than 5 cases of this technique were documented, the Federal Experts' Working Group requested a review as to whether this technique had been correctly documented and, where applicable, why this technique was used. Feedback from the State Administrative Offices from the Structured Dialogue showed that 47 % of hospitals had mentioned improper documentation as a reason and 16 % incorrect coding. 65 % of hospitals reported that direct suturing was performed in justified individual cases to prevent an aneurysm as a result of suturing a patch in the case of vascular ectasia, while 14 % of hospitals explained that direct suturing was no longer used following the publication of the S3 guideline on carotid artery revascularization. Multiple responses were possible. Since, in addition, the number of documented cases of direct suturing declined following the publication of the S3 guideline on carotid artery revascularization, the Federal Experts' Working Group sees no further need for action and will monitor future development.

Looking forward

The Federal Experts' Working Group attentively monitors the numerical changes in catheter-supported and open surgical carotid artery revascularizations in this clinical area in comparison with the previous year. In total, the number of revascularized patients fell by 976 patients from 2012 to 2013: In open surgical revascularizations, the number of patients dropped by 617 (2012: 26,958; 2013: 26,341) and in catheter-supported procedures by 359 patients (2012: 6,176; 2013: 5,817). As a result of the possibility of the additional recording of multiple interventions since 2013 and including the change from catheter-supported to open surgical revascularization, the number of catheter-supported revascularizations dropped (2012: 6,176; 2013: 5,903). In addition to carotid artery revascularizations, a total of 344 dilatations or stent implantations were performed on the internal carotid artery to create an access for a primary intracranial procedure in data collection year 2013, but these were not included in the calculation of the indicators.

The largest decline was observed in patients with carotid artery interventions under special conditions, in particular emergency interventions, interventions due to an acute progressive stroke or when the internal carotid artery lesions exhibited a particular morphology and anatomy. This decline applies equally to open surgical and catheter-supported revascularizations. In the opinion of the Federal Experts' Working Group, it also reflects an increasing tendency to a conservative and usually purely medication-based treatment in verified carotid artery stenoses despite an unequivocal guideline recommendation for primary or secondary prevention. The Federal Experts' Working Group therefore recommends that, in addition to maintaining the clinical area of Carotid artery revascularization, the G-BA should commission a nationwide cross-sectoral quality assurance procedure for stroke management, including patients with transient ischemic attacks.

On the basis of the decline in numbers from data collection year 2012 to 2013, the Federal Experts' Working Group furthermore has considerable doubts as to whether all catheter-supported carotid artery revascularizations are actually performed under in-patient conditions. In view of the large numbers of medical specialists undertaking catheter interventions, it can be assumed that there is a relevant amount of interventions in the accredited physician sector that is not reflected in this clinical area because of the previous focus on the in-patient sector. The Federal Experts' Working Group therefore recommends that the prevailing clinical area be developed into a cross-sectoral procedure using health insurance claims data. On the one hand, this could include all patients with carotid artery revascularizations irrespective of treatment location and, on the other, could enable a follow-up beyond the patient's hospital stay in order to be able to fully record complications, such as strokes and death, that sometimes do not occur until after hospital stay has ended.

The Federal Experts' Working Group adopts a critical approach to the existing results on periprocedural strokes and deaths in simultaneous open surgical carotid artery revascularization in conjunction with aortocoronary bypass surgery in the case of asymptomatic stenosis of the internal carotid artery. In the data collection year 2013, a total of 494 open surgical revascularizations (1.9 %) were performed simultaneously with aortocoronary

Carotid artery revascularization

bypass surgery. In 2012, this procedure was performed in 478 interventions (1.8 %). In 2013, 440 of these simultaneous interventions that occurred in the same session were performed in patients without symptomatic carotid artery stenosis. Serious complications developed in a total of 39 of these patients: 19 patients (4.3 %) suffered a stroke; 23 patients (5.2 %) died, 3 of them following a stroke (Fig. 1). Accordingly, the proportion of patients who suffered a stroke or died periprocedurally was 8.9 % for asymptomatic patients with simultaneous aortocoronary bypass surgery (36 of 440 patients), while the rate-based, non-risk-adjusted result for an isolated open surgical carotid artery revascularization in all patients (QI-ID 51175) was 2.4 %. As simultaneous interventions were not recorded for the indicators for periprocedural strokes and death after open surgical carotid artery revascularization in asymptomatic carotid artery stenosis with (QI-ID 606; 2013 result: 2.2 %) and without (QI-ID 605; 2013 result: 1.3 %) contralateral carotid artery stenosis, the Federal Experts' Working Group recommends that a new indicator with a reference range be introduced for simultaneous procedures, effective for data collection year 2014.

Figure 1: Stroke and death after simultaneous open surgical carotid
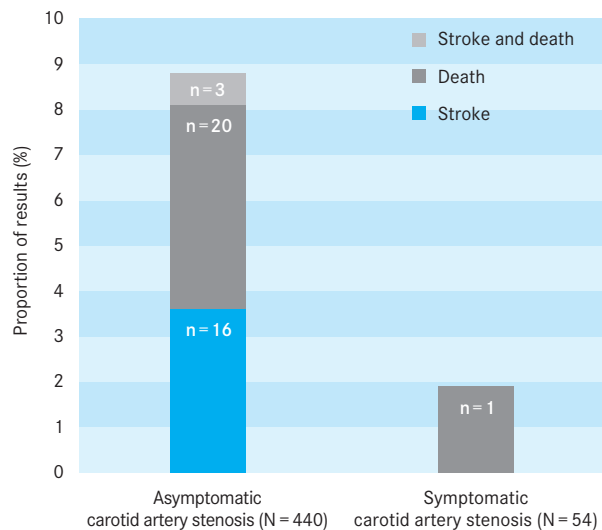
artery revascularization and aortocoronary bypass surgery

Finally, the Federal Experts' Working Group welcomes the inclusion of the clinical area Carotid artery revascularization in the data validation for data collection year 2013 to check the quality of the documentation and to establish new discrepancy criteria that account for further developments in the clinical area.

Carotid artery revascularization

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	33,473	32,604	32,813	99.4 %
Hospitals	599	602	609	98.9 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	32,486	100 %
< 50 years	571	1.8 %
50 – 59 years	3,970	12.2 %
60 – 69 years	8,692	26.8 %
70 – 79 years	14,148	43.6 %
80 – 89 years	4,952	15.2 %
≥ 90 years	153	0.5 %
Sex		
Male	22,274	68.6 %
Female	10,212	31.4 %
Nature of intervention*		
Open surgery	26,507	80.9 %
Catheter-supported revascularization	5,883	18.0 %
Switch from catheter-supported revascularization to open surgery	20	< 0.1 %
Catheter-supported revascularization as access to intracranial procedure	344	1.1 %
ASA classification*		
ASA 1: A normal healthy patient	1,386	4.2 %
ASA 2: A patient with mild systemic disease	9,725	29.7 %
ASA 3: A patient with severe systemic disease	20,530	62.7 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	1,086	3.3 %
ASA 5: A moribund patient who is not expected to survive without the operation	27	0.1 %
Treated patients by indication group		
Patients with open surgical revascularization (in indication groups)		
Asymptomatic carotid artery lesion	14,473	55.0 %
Symptomatic carotid artery lesion – elective	9,139	34.8 %
Carotid artery surgery under special conditions	1,982	7.5 %
Simultaneous procedures	699	2.7 %
Patients with catheter-supported revascularization (in indication groups)		
Asymptomatic carotid artery lesion	3,071	53.2 %
Symptomatic carotid artery lesion – elective	1,539	26.6 %
Carotid artery surgery under special conditions	756	13.1 %
Simultaneous procedures	409	7.1 %

* The numbers differ between the tables because the target populations are different:
top – procedures (several procedures possible per patient), bottom – patients.

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German): *www.sqg.de/themen/10n2/*

Carotid artery revascularization

Case-based aggregate results (patients)

QI-ID	Name of the quality indicator		2012 Result	2013 Result	2013 Cases (patients) Numerator (O | E) *		Denominator	Trend
603	Indication in asymptomatic carotid artery stenosis – open surgery	⚠	97.2 %	97.2 %		14,074	14,473	→
604	Indication in symptomatic carotid artery stenosis – open surgery	⚠	98.3 %	98.8 %		9,033	9,139	→
605	Periprocedural strokes or death in asymptomatic carotid artery stenosis without contralateral carotid artery stenosis – open surgery		1.2 %	1.3 %		155	12,096	→
606	Periprocedural strokes or death in asymptomatic carotid artery stenosis and contralateral carotid artery stenosis – open surgery		2.3 %	2.2 %		43	1,978	→
51859	Periprocedural strokes or death in symptomatic carotid artery stenosis – open surgery		2.6 %	2.7 %		245	9,033	→
	Periprocedural strokes or death – open surgery							
51175	Periprocedural strokes or death – open surgery	⚠	2.3 %	2.4 %		629	26,339	→
11704	Ratio of the observed to expected rate (O / E) of periprocedural strokes or deaths – open surgery	⚠	1.00	1.02	629 2.39 %	619 2.35 %	26,339	→
	Severe strokes or death – open surgery							
51176	Severe strokes or death – open surgery	⚠	1.3 %	1.4 %		361	26,339	→
11724	Ratio of the observed to expected rate (O / E) of severe strokes or deaths – open surgery	⚠	1.00	1.04	361 1.37 %	349 1.32 %	26,339	→
51437	Indication in asymptomatic carotid artery stenosis – catheter-supported	⚠	95.2 %	95.6 %		2,937	3,071	→
51443	Indication in symptomatic carotid artery stenosis – catheter-supported	⚠	97.7 %	97.8 %		1,505	1,539	→
51445	Periprocedural strokes or death in asymptomatic carotid artery stenosis without contralateral carotid artery stenosis – catheter-supported	⚠	1.7 %	1.7 %		42	2,452	→
51448	Periprocedural strokes or death in asymptomatic carotid artery stenosis and contralateral carotid artery stenosis – catheter-supported		1.4 %	1.9 %		9	485	→
51860	Periprocedural strokes or death in symptomatic carotid artery stenosis – catheter-supported		3.9 %	4.2 %		63	1,505	→
	Periprocedural strokes or death – catheter-supported							
51457	Periprocedural strokes or death – catheter-supported		4.3 %	3.6 %		211	5,805	→
51873	Ratio of the observed to expected rate (O / E) of periprocedural strokes or deaths – catheter-supported		1.00	0.96	211 3.63 %	219 3.78 %	5,805	→
	Severe strokes or death – catheter-supported							
51478	Severe strokes or death – catheter-supported		2.8 %	2.2 %		130	5,805	→
51865	Ratio of the observed to expected rate (O / E) of severe strokes or deaths – catheter-supported		1.00	1.01	130 2.24 %	128 2.21 %	5,805	→

Indicator group labels appear alongside the groups for QI-IDs 51175/11704, 51176/11724, 51457/51873, and 51478/51865.

* for regression-based quality indicators

Carotid artery revascularization

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
603	Indication in asymptomatic carotid artery stenosis – open surgery	≥ 90.0 % (TA)	519	33	1	A
604	Indication in symptomatic carotid artery stenosis – open surgery	≥ 90.0 % (TA)	513	8	1	A
605	Periprocedural strokes or death in asymptomatic carotid artery stenosis without contralateral carotid artery stenosis – open surgery	n.d.*	515	–	X	X
606	Periprocedural strokes or death in asymptomatic carotid artery stenosis and contralateral carotid artery stenosis – open surgery	n.d.*	422	–	X	X
51859	Periprocedural strokes or death in symptomatic carotid artery stenosis – open surgery	n.d.*	513	–	X	X
Indicator group	Periprocedural strokes or death – open surgery					
51175	Periprocedural strokes or death – open surgery	n.d.*	548	–	X	X
11704	Ratio of the observed to expected rate (O / E) of peri-procedural strokes or deaths – open surgery	≤ 3.23 (TO; 95th percentile)	548	44	2	A
Indicator group	Severe strokes or death – open surgery					
51176	Severe strokes or death – open surgery	n.d.*	548	–	X	X
11724	Ratio of the observed to expected rate (O / E) of severe strokes or deaths – open surgery	≤ 4.01 (TO; 95th percentile)	548	31	2	A
51437	Indication in asymptomatic carotid artery stenosis – catheter-supported	≥ 90.0 % (TA)	317	51	1	B
51443	Indication in symptomatic carotid artery stenosis – catheter-supported	≥ 90.0 % (TA)	260	15	1	A
51445	Periprocedural strokes or death in asymptomatic carotid artery stenosis without contralateral carotid artery stenosis – catheter-supported	n.d.*	300	–	X	X
51448	Periprocedural strokes or death in asymptomatic carotid artery stenosis and contralateral carotid artery stenosis – catheter-supported	n.d.*	193	–	X	X
51860	Periprocedural strokes or death in symptomatic carotid artery stenosis – catheter-supported	n.d.*	259	–	X	X
Indicator group	Periprocedural strokes or death – catheter-supported					
51457	Periprocedural strokes or death – catheter-supported	n.d.*	355	–	X	X
51873	Ratio of the observed to expected rate (O / E) of peri-procedural strokes or deaths – catheter-supported	≤ 2.36 (TO; 95th percentile)	355	42	2	A
Indicator group	Severe strokes or death – catheter-supported					
51478	Severe strokes or death – catheter-supported	n.d.*	355	–	X	X
51865	Ratio of the observed to expected rate (O / E) of severe strokes or deaths – catheter-supported	≤ 4.35 (TO; 95th percentile)	355	25	2	A

TO = Tolerance range; TA = Target range; * not defined

Community-acquired pneumonia

Dr. Klaus Richter, Leif Warming, Dr. Thomas König, Federal Experts' Working Group for Pneumonia

Introduction
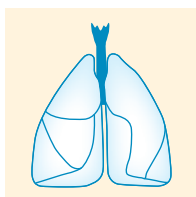
Pneumonia can be classified according to the nature of the causative pathogen and to whether the patient acquired the disease outside of the hospital (community-acquired) or during a hospital stay (nosocomial). Community-acquired pneumonia is the most common cause of death due to infection in Germany. An increased mortality rate can be caused by inadequate treatment of pneumonia.

To measure the quality of care and, if necessary, initiate steps to improve it, pneumonia was included in the services subject to mandatory documentation within the external quality assurance of inpatients since 2005. Approximately 230,000 patients with community-acquired pneumonia (CAP) are treated annually as inpatients in Germany. More than 10 % of these patients die during their hospital stay. The quality indicators in this area provide insights into the quality of care and aim at optimizing it.

Services subject to mandatory documentation

Patients who are at least 18 years old with pneumonia acquired outside of the hospital and treated in the hospital.

Changes in comparison to the previous year

Because of the positive results from previous years, the reference ranges of both indicators for early mobilization (QI-ID 2012 and QI-ID 2013) were changed for data collection year 2013 from "tolerance ranges" (10th percentile) to "target ranges". For the indicator "Early mobilization within 24 hours after admission for risk class 1 (CRB-65-SCORE = 0)"[1], a target range of ≥ 95 % was set; for the indicator "Early mobilization within 24 hours after admission for risk class 2 (CRB-65-SCORE = 1 or 2)" a target range of ≥ 90 % was set.

In addition, the indicator "No review of the diagnostic or therapeutic process for risk class 3 (CRB-65-SCORE = 3 or 4)" (QI-ID 2019) was changed to a sentinel event indicator so that now each case results in a discrepancy. The reason behind this is that there were only 32 hospitals with a total of 36 cases in 2012 that were "computationally discrepant" regarding this indicator and that the Federal Experts' Working Group considers the review of the diagnostic or therapeutic process to be urgently necessary particularly for severely ill patients (risk class 3).

Results

A total of 6 process indicators have significantly improved in comparison to the previous year and 4 remain unchanged. The rate of the indicator "Fulfillment of clinical stability criteria until discharge" (QI-ID 2036) in 2013 has slightly, but significantly decreased by 0.4 percentage points to 97.6 %. The result at the federal level is thus still clearly within the reference range. The results of the 2 process indicators "Complete determination of clinical stability criteria until discharge" (QI-ID 2028) and "Determination of respiratory rate on admission" (QI-ID 50722) have further improved but are still outside the reference range.

For mortality indicators, 4 of the 5 indicators have further im-

proved remarkably, although the results need to be examined critically. For risk class 1, there has been no tendency to a change in the value for in-hospital mortality.

In the clinical area of *Community-acquired pneumonia*, palliative care patients should be excluded from the calculation of the indicators, as the objective of treatment in palliative care patients is fundamentally different from that in other patients treated in this clinical area. These patients, however, continue to be included in the calculation of the indicator group "First blood gas analysis or pulse oximetry" and the indicator "Determination of respiratory rate on admission" (QI-ID 50722), as these measurements should be performed routinely on admission, regardless of the patient's status of health and prognosis.

The death of palliative care patients is not included in the calculation of indicators for mortality. A specific documentation field can be used to exclude these patients if certain requirements are met. These requirements were loosened in the data collection year 2012. As a result, there was a marked increase in the proportion of dying patients classified in this way: whereas in 2011 the figure was still 24 %, in 2013 there was an increase up to 47 % in 2013.

The Federal Experts' Working Group assumed last year that the field for documenting treatment limitation ("Documentation treatment limitation") used to limit the target population was most likely biased by unsystematic over- or underdocumentation. Analyses of the data from 2013 by the AQUA Institute and feedback from the Federal States confirmed this assumption that the field was difficult to understand and therefore incorrect coding was common. The outcome indicators in particular are affected by this fact in the form of unrealistically low mortality rates. The Federal Experts' Working Group will take this factor into account in future analysis. Because of the need for further methodological development, the Federal Experts' Working Group defined a need for action of X for the mortality indicators.

In the data collection year 2011 there were a total of 3,563 computational discrepancies, whereas in 2012 a total of 3,302 computational discrepancies were observed for the clinical area *Community-acquired pneumonia*. In conclusion, 17.6 % of the computational discrepancies were rated as "qualitatively discrepant" in the Structured Dialogue – although for almost half of the computational discrepancies only notices were sent out, so that a classification as "qualitatively discrepant" was not actually possible here. In 14.1 % of the computational discrepancies, the classification was "Evaluation not possible due to improper documentation".

Many discrepancies were observed in particular regarding the indicators "Complete determination of stability criteria until discharge" (QI-ID 2028) and "Determination of respiratory rate on admission" (QI-ID 50722). Depending on the indicator, these included documentation errors, intrahospital transfers to departments in which measurements were not performed routinely, frequent changes of shifts in the medical department, high staff turnover or delay in the diagnosis of community-acquired pneumonia until after admission. However, it is precisely the latter that is viewed in a particularly critical light by the Federal Experts' Working Group as a reason for the non-determination

Community-acquired pneumonia

of respiratory rate on admission. In respect to the quality assurance measures that were introduced, some Federal States reported having drawn hospitals' attention to the importance of the documentation particularly for risk adjustment and training as a component of target agreements. In one Federal State, the admission process of many hospitals was restructured and special documentation forms were developed.

Looking forward

The Federal Experts' Working Group recommends the following for the suspected over-documentation of the field "Documentation treatment limitation":

- The field "Documentation treatment limitation" will in the future no longer result in the exclusion of patients from the indicators for mortality. Risk-adjusted indicators will be used for the comparison of in-hospital mortality.
- The Federal Experts' Working Group will propose a procedure for dealing with process indicators by the autumn session 2014.
- The Federal Experts' Working Group recommends that health insurance claims data should be used as soon as possible to obtain valid mortality rates beyond the hospital stay (e.g. 30-day mortality).

As far as the indicator "Determination of respiratory rate on admission" (QI-ID 50722) is concerned, the results of the Structured Dialogue make it clear that the indicator is generally accepted. Necessary changes have been instigated but also need to be further intensified in the future. For this reason, the indicator mentioned is again classified as C. In addition, in order to inform as many physicians as possible about the importance of determining the respiratory rate, an article has been submitted to the journal *Deutsches Ärzteblatt* and has been accepted for publication.

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[1] The risk-adjustment of certain indicators was performed using the CRB-65-Score, which includes criteria such as pneumonia-induced disorientation, spontaneous respiratory rate ≥ 30/min, blood pressure ≤ 60 mmHg diastolic or < 90 mmHg systolic and age ≥ 65 years. Each criterion is assigned one risk point.

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	243,566	260,661	258,949	100.7 %
Hospitals	1,271	1,257	1,266	99.3 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	259,737	100 %
18 – 19 years	686	0.3 %
20 – 29 years	4,222	1.6 %
30 – 39 years	6,412	2.5 %
40 – 49 years	11,465	4.4 %
50 – 59 years	21,262	8.2 %
60 – 69 years	33,010	12.7 %
70 – 79 years	74,592	28.7 %
80 – 89 years	82,554	31.8 %
≥ 90 years	25,534	9.8 %
Sex		
Male	145,371	56.0 %
Female	114,366	44.0 %
CRB-65-Score		
0	43,630	16.8 %
1	138,733	53.4 %
2	60,399	23.3 %
3	11,299	4.4 %
4	5,676	2.2 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/PNEU/

Community-acquired pneumonia

Case-based aggregate results (patients)

			2012	2013			
				Cases (patients)			
QI-ID	Name of the quality indicator		Result	Result	Numerator (O | E) *	Denominator	Trend
	First blood gas analysis or pulse oximetry						
2005	First blood gas analysis or pulse oximetry within 8 hours after admission	⚠	96.8 %	97.2 %	252,566	259,737	↗
2006	First blood gas analysis or pulse oximetry within 8 hours after admission (not admitted from another hospital)	⚠	96.9 %	97.4 %	242,827	249,433	↗
2007	First blood gas analysis or pulse oximetry within 8 hours after admission (admitted from another hospital)	⚠	93.6 %	94.5 %	9,739	10,304	→
2009	Antimicrobial therapy within 8 hours after hospitalization (not from another hospital)	⚠	94.3 %	94.6 %	210,044	222,050	↗
	Early mobilization within 24 hours after admission						
2012	Early mobilization within 24 hours after admission for risk class 1 (CRB-65-SCORE = 0)	⚠	95.6 %	95.9 %	34,176	35,620	→
2013	Early mobilization within 24 hours after admission for risk class 2 (CRB-65-SCORE = 1 or 2)	⚠	91.2 %	90.9 %	115,627	127,158	→
2015	Clinical monitoring of CRP or PCT within the first 5 days after admission	⚠	97.9 %	98.2 %	206,305	210,170	↗
	Verification of the diagnostic or therapeutic process						
2018	Review of the diagnostic or therapeutic process for risk class 2 (CRB-65-SCORE = 1 or 2)	⚠	96.7 %	97.5 %	19,436	19,928	↗
2019	No review of the diagnostic or therapeutic process for risk class 3 (CRB-65-SCORE = 3 or 4)	⚠	1.97 %	2.02 %	35	1,730	→
2028	Completely measured clinical stability criteria at discharge	⚠	91.9 %	92.9 %	154,443	166,311	↗
2036	Fulfilled clinical stability criteria at discharge	⚠	98.0 %	97.6 %	150,797	154,443	↘
	In-hospital mortality						
11878	In-hospital mortality	⚠	8.7 %	7.9 %	18,155	230,951	↗
50778	Ratio of the observed to the expected rate (O / E) of deaths	⚠	1.00	0.93	18,155 7.86 % | 19,482 8.44 %	230,951	↗
11879	In-hospital mortality for risk class 1 (CRB-65-SCORE = 0)	⚠	1.8 %	1.7 %	692	41,740	→
11880	In-hospital mortality for risk class 2 (CRB-65-SCORE = 1 or 2)	⚠	9.2 %	8.2 %	14,562	176,806	↗
11881	In-hospital mortality for risk class 3 (CRB-65-SCORE = 3 or 4)	⚠	25.3 %	23.4 %	2,901	12,405	↗
50722	Determination of respiratory rate on admission	⚠	91.2 %	93.4 %	238,499	255,233	↗

*   for regression-based quality indicators

Community-acquired pneumonia

Hospital-based aggregate results for utilization in quality assurance

				2013			
				Hospitals		Evaluation	
	QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
Indicator group		First blood gas analysis or pulse oximetry					
	2005	First blood gas analysis or pulse oximetry within 8 hours after admission	≥ 95.0 % (TA)	1,254	215	2	A
	2006	First blood gas analysis or pulse oximetry within 8 hours after admission (not admitted from another hospital)	n.d.*	1,242	–	X	X
	2007	First blood gas analysis or pulse oximetry within 8 hours after admission (admitted from another hospital)	n.d.*	1,087	–	X	X
	2009	Antimicrobial therapy within 8 hours after hospitalization (not from another hospital)	≥ 90.0 % (TA)	1,235	207	2	A
Indicator group		Early mobilization within 24 hours after admission					
	2012	Early mobilization within 24 hours after admission for risk class 1 (CRB-65-SCORE = 0)	≥ 95.0 % (TA)	1,166	315	2	A
	2013	Early mobilization within 24 hours after admission for risk class 2 (CRB-65-SCORE = 1 or 2)	≥ 90.0 % (TA)	1,225	434	2	A
	2015	Clinical monitoring of CRP or PCT within the first 5 days after admission	≥ 95.0 % (TA)	1,235	100	1	A
Indicator group		Verification of the diagnostic or therapeutic process					
	2018	Review of the diagnostic or therapeutic process for risk class 2 (CRB-65-SCORE = 1 or 2)	≥ 95.0 % (TA)	1,147	163	1	A
	2019	No review of the diagnostic or therapeutic process for risk class 3 (CRB-65-SCORE = 3 or 4)	Sentinel event	691	30	X	A
	2028	Completely measured clinical stability criteria at discharge	≥ 95.0 % (TA)	1,228	398	3	B
	2036	Fulfilled clinical stability criteria at discharge	≥ 95.0 % (TA)	1,206	164	2	A
Indicator group		In-hospital mortality					
	11878	In-hospital mortality	≤ 13.8 % (TO; 90th percentile)	1,248	115	2	X
	50778	Ratio of the observed to the expected rate (O / E) of deaths	n.d.*	1,248	–	X	X
	11879	In-hospital mortality for risk class 1 (CRB-65-SCORE = 0)	≤ 4.4 % (TO; 90th percentile)	1,179	112	2	X
	11880	In-hospital mortality for risk class 2 (CRB-65-SCORE = 1 or 2)	≤ 14.4 % (TO; 90th percentile)	1,235	118	2	X
	11881	In-hospital mortality for risk class 3 (CRB-65-SCORE = 3 or 4)	≤ 40.7 % (TO; 90th percentile)	1,091	161	2	X
	50722	Determination of respiratory rate on admission	≥ 98.0 % (TA)	1,254	608	3	C

TO = Tolerance range; TA = Target range; * not defined

Community-acquired pneumonia

QI-ID 50722: Determination of respiratory rate on admission

Description	
Numerator	Patients with respiratory rate measured on admission
Denominator	All patients not mechanically ventilated on admission
Reference range	≥ 98.0 % (target range)
Risk adjustment	No further risk adjustment
QI-ID	50722
Comparability with the previous year's results	Comparable

Case-based results (patients)					
	2009	**2010**	**2011**	**2012**	**2013**
Aggregate result	–	–	87.7 %	91.2 %	93.4 %
Confidence interval	–	–	87.5–87.8 %	91.1–91.3 %	93.3–93.5 %
Total number of cases	–	–	230,687	238,525	255,233

Aggregate result of all patients
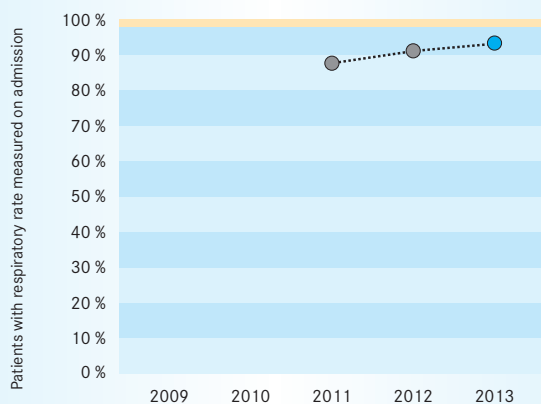
Hospital-based results	
Target population of all hospitals	1,254
Number of hospitals with 0 cases	3

1,131 Hospitals with ≥ 20 cases
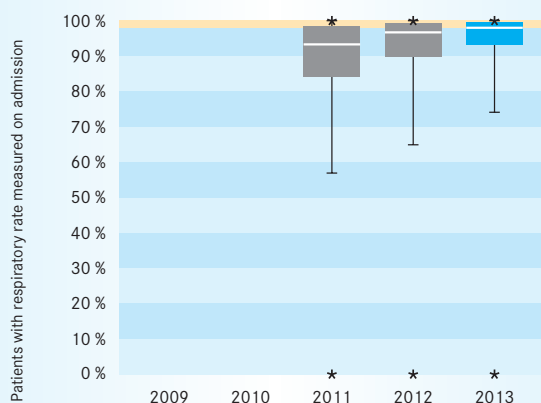
Median	98.0 %	Number of computationally discrepant hospitals	548 of 1,131
Range	0.0–100.0 %		

123 Hospitals with 1 to 19 cases

Median	100.0 %	Number of computationally discrepant hospitals	60 of 123
Range	0.0–100.0 %		

Quality target

Respiratory rate determined as often as possible on admission.

Background

Community-acquired pneumonia is associated with high morbidity and mortality. It is the most common cause of death due to infection in Germany. While the mortality rate varies with age and the presence of other risk factors, approximately 13 – 14 % of treated inpatients die. Insufficient treatment can be associated with an up to 11-fold increase in mortality. Additionally, many patients also suffer from severe underlying diseases. Some studies suggest that mortality can be reduced by introducing appropriate measures.

The determination of the respiratory rate is an important and simple measure to estimate the severity of acute, cardiac, respiratory or metabolic diseases. Since a close relation between respiratory rate and mortality is demonstrated, the determination of respiratory rate upon patient's admission should be recommended in both German and international guidelines.

The respiratory rate determination on admission is an important clinical parameter and part of the CRB-65-Score. By recording it on admission, a statement can be made about the severity of the pneumonia and the prognostic course of treatment. Therefore, the score can be used for the risk adjustment of the mortality indicators in community-acquired pneumonia.

Evaluating the results

In the Structured Dialogue 2013, measures were taken for 61 % (n = 774) of the hospitals on the basis of the results of data collection year 2012. For the first time since the introduction of the quality indicator in 2011, all the Federal States were asked for statements in the Structured Dialogue. In conclusion, 19 % (n = 241) of the hospitals were rated as "qualitatively discrepant" regarding this indicator. In 9.4 % (n = 119) of the hospitals, a rating was not possible because of improper documentation. Ten "colleague-to-colleague" talks were held and 80 target agreements were concluded. No on-site inspections were carried out.

Compared to the previous year, the indicator "Respiratory rate measured on admission" has witnessed further improvements in the data collection year 2013 in relation to the federal result (plus 2.2 percentage points as compared to the data collection year 2012). However, the indicator clearly continues to miss the reference range – in data collection year 2013 almost half of all hospitals (n = 608) are "computationally discrepant". The Federal Experts' Working Group therefore again classifies the need for action as C.

Pacemaker — Implantation

Dr. Karl Tasche, Prof. Dr. Jürgen Pauletzki, Florian Rüppel, Federal Experts' Working Group for Pacemakers and Implantable Cardioverter Defibrillators

Introduction
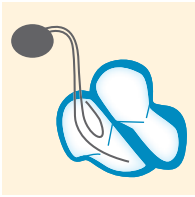
After meticulous diagnostics and exclusion of reversible causes, cardiac arrhythmias manifesting as too slow a heartbeat, called bradycardia, can necessitate the implantation of a pacemaker. These kinds of electrical "pacing systems" are implanted in order to reduce the patients' disease-specific symptoms, which can extend to fainting spells and loss of consciousness. In certain forms of bradycardia, a pacemaker can extend the patient's life expectancy ("prognostic indication").

A further area of application for pacemakers is advanced pump failure of the heart (heart failure), in which the two main chambers and/or a number of wall segments of the left chamber no longer work in synchrony. This can be seen on the electrocardiogram (ECG) by a left bundle branch block. This form of heart failure can be treated by electrical stimulation (cardiac resynchronization therapy).

The decision for a pacemaker treatment (indication) should be rendered in compliance with the guidelines.

The quality of pacemaker therapy is assessed based on data from three clinical areas (*Pacemaker – Implantation; Pacemaker – Replacement of generator/battery; Pacemaker – Revision/system replacement/removal*). Since 2000, the data collected for the purpose of quality assurance are additionally used to fill a pacemaker register that provides annual information about the healthcare situation in this sector in Germany (*www.pacemaker-register.de*).

External quality assurance for pacemaker therapy currently only records the inpatient sector. Starting in 2015, the introduction of a hospital follow-up is planned so that complications not occurring until after the patient leaves the hospital are also collected.

Services subject to mandatory documentation

Isolated pacemaker primary implantations as well as system changes from implantable cardioverter defibrillator to pacemaker.

Changes in comparison to the previous year

Instead of the two previous quality indicators for the duration of intervention in one-chamber systems (VVI) and dual-chamber systems (DDD), the new indicator "Duration of intervention" (QI-ID 52128) was introduced for the two systems combined. The results on this indicator are detailed below. Otherwise, no major changes over the previous year were made to the quality indicators or data basis in this clinical area.

Until 2015, the quality indicators "Guideline-compliant indication for bradycardia" (QI-ID 690) and "Guideline-compliant system selection for bradycardia" (QI-ID 2196) cannot be updated based on the new European guidelines governing pacemaker and cardiac resynchronization therapy that were issued mid 2013 for conventional pacemakers. This is because adjustments need to be made to the data specification (data col-

lection). For particulars, see chapter "Maintenance of current clinical areas (system maintenance)". The new guidelines only marginally affect the evaluation of guideline-compliance with indication and system selection for bradycardia. For that reason, the Federal Experts' Working Group deems the previously valid algorithms as justifiable and advisable for the two aforementioned indicators until further notice.

Results

In data collection year 2013, no significant changes in the overall rate were found in any of the quality indicators compared to the previous year. On the federal level, the quality of care in pacemaker implantation thus remained consistently high. Notwithstanding, some of the treatment outcomes at the hospitals showed substantial upward and downward variance. The deviations from the respective reference range are considered as computational discrepancies and will be cleared by the responsible bodies within the Structured Dialogue.

In data collection year 2013, there was a particularly high frequency of computational discrepancies in the indicators on perioperative complications (QI-ID 1103, QI-ID 209, QI-ID 581) as well as in the new indicator "Duration of intervention" (QI-ID 52128). Peri- and postoperative complications – as a sequela or outcome of interventions – are one of the problem fields associated with treatments using implantable rhythm devices. The duration of intervention is an "indirect" indicator of process quality (workflows in the operating room) and structural quality (experience of the surgeons). A high proportion of interventions lasting longer than the system-specific threshold value may point to deficits in structural and process quality and be associated with an elevated complication risk.

The Structured Dialogue on the results of data collection year 2012 led to a follow-up on 849 computational discrepancies at 494 hospitals. In 447 cases, statements were requested and in 24 cases, "colleague-to-colleague" talks were held with representatives of the hospitals. In 32 cases, target agreements were made with respect to concrete improvement measures. After conclusion of the Structured Dialogue, 68 hospitals continued to be ranked as "qualitatively discrepant" (due to a total of 91 qualitative discrepancies).

Looking forward

The small caseloads per hospital beg the question as to whether quality indices should be introduced to improve the discriminatory power of the indicators (for particulars, see chapter "Risk adjustment and caseload-prevalence problem"). At present, a certain proportion of pacemaker treatments in Germany are carried out by smaller hospitals. Not rarely, their total number of interventions is less than 20 a year. In this respect, even a few isolated complications can lead to a hospital being rated as "computationally discrepant". Results that are less dependent on isolated complications can be generated by indexing. The indicators for the group "Perioperative complications" already currently possess comparably good discriminatory power: The Structured Dialogue has confirmed qualitative discrepancies for a relatively high proportion of computational discrepancies. But indexing can achieve yet further improvements in the discrimi-

Pacemaker — Implantation

natory power for this indicator group as well.

The example of the indicator group "Perioperative complications" can be used to describe yet another developmental perspective of the clinical area *Pacemaker – Implantation*. The current quality indicators of the aforementioned group only capture complications occurring up to the end of the patient's hospital stay. Therefore, it can be assumed that the actual complication rates are underestimated. However, complete capture of peri- and postoperative complication data will be possible with the introduction of the follow-up analysis planned starting 2015. This follow-up will permit the evaluation of medium- and long-term sequelae of pacemaker implantations. Particularly interesting is the full scope of the post-pacemaker implantation complications requiring revision interventions. At present, revision interventions in the respective clinical area are captured (*Pacemaker – Revision/system replacement/removal*). However, without the planned follow-up, the revision interventions could previously not be assigned to their corresponding implantations.

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	76,282	75,661	75,694	100.0 %
Hospitals	988	977	979	99.8 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	75,575	100 %
< 50 years	1,741	2.3 %
50 – 59 years	3,005	4.0 %
60 – 69 years	8,936	11.8 %
70 – 79 years	31,166	41.2 %
80 – 89 years	27,103	35.9 %
≥ 90 years	3,624	4.8 %
Sex		
Male	41,323	54.7 %
Female	34,252	45.3 %
ASA classification		
ASA 1: A normal healthy patient	5,919	7.8 %
ASA 2: A patient with mild systemic disease	32,818	43.4 %
ASA 3: A patient with severe systemic disease	34,103	45.1 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	2,619	3.5 %
ASA 5: A moribund patient who is not expected to survive without the operation	116	0.2 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/09n1/

Pacemaker — Implantation

Case-based aggregate results (patients)

QI-ID	Name of the quality indicator		2012 Result	2013 Result	Cases (patients) Numerator (O | E) *	Denominator	Trend
690	Guideline-compliant indication for bradycardia	⚠	96.6 %	96.6 %	71,221	73,708	→
2196	Guideline-compliant system selection for bradycardia	⚠	97.4 %	97.5 %	71,155	72,946	→
52128	Duration of intervention		84.6 %	85.1 %	64,228	75,446	→
	Fluoroscopy time						
10223	Fluoroscopy time up to 9 minutes when a single-chamber system (VVI) is implanted	⚠	94.8 %	95.0 %	14,509	15,267	→
10249	Fluoroscopy time up to 18 minutes when a dual-chamber system (DDD) is implanted	⚠	98.1 %	98.2 %	55,072	56,079	→
	Intracardiac signal amplitudes						
582	Atrial leads with amplitude ≥ 1,5 mV	⚠	92.2 %	92.3 %	52,775	57,152	→
583	Ventricular leads with amplitude ≥ 4 mV	⚠	98.9 %	98.8 %	73,917	74,807	→
	Perioperative complications						
1103	Surgical complications	⚠	1.0 %	0.9 %	684	75,575	→
209	Atrial lead dislodgement	⚠	0.9 %	0.9 %	558	59,010	→
581	Ventricular lead dislodgement	⚠	0.8 %	0.7 %	562	75,374	→
	In-hospital mortality						
1100	In-hospital mortality	⚠	1.3 %	1.4 %	1,067	75,575	→
51191	Ratio of the observed to the expected rate (O / E) of deaths	⚠	1.00	1.06	1,067 / 1.41 % ∣ 1,003 / 1.33 %	75,575	→

* for regression-based quality indicators

Pacemaker — Implantation

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
690	Guideline-compliant indication for bradycardia	≥ 90.0 % (TA)	973	53	1	A
2196	Guideline-compliant system selection for bradycardia	≥ 90.0 % (TA)	973	57	1	A
52128	Duration of intervention	≥ 60.0 % (TO)	973	117	3	A
	Fluoroscopy time					
10223	Fluoroscopy time up to 9 minutes when a single-chamber system (VVI) is implanted	≥ 75.0 % (TO)	946	34	2	A
10249	Fluoroscopy time up to 18 minutes when a dual-chamber system (DDD) is implanted	≥ 80.0 % (TO)	953	9	2	A
	Intracardiac signal amplitudes					
582	Atrial leads with amplitude ≥ 1,5 mV	≥ 80.0 % (TA)	955	40	1	A
583	Ventricular leads with amplitude ≥ 4 mV	≥ 90.0 % (TA)	971	9	1	A
	Perioperative complications					
1103	Surgical complications	≤ 2.0 % (TO)	973	162	2	A
209	Atrial lead dislodgement	≤ 3.0 % (TO)	956	129	2	A
581	Ventricular lead dislodgement	≤ 3.0 % (TO)	973	94	2	A
	In-hospital mortality					
1100	In-hospital mortality	n.d.*	973	–	X	X
51191	Ratio of the observed to the expected rate (O / E) of deaths	≤ 4.03 (TO; 95th percentile)	973	61	2	A

TO = Tolerance range; TA = Target range; * not defined

Pacemaker – Implantation

QI-ID 52128: Duration of intervention

Quality target

Shortest possible duration of intervention.

Background

Since data collection year 2013, the duration of intervention for VVI one-chamber systems and DDD dual-chamber systems have been combined into one indicator. The new indicator offers the advantage that it is not susceptible to the problem of small caseloads, while – at the same time – enabling the inclusion of AAI, VDD and CRT systems, for which no review of the duration of intervention had been possible. The duration of intervention is an important indicator of structural and process quality:

- From 1997 to 2008, the median duration of intervention in pacemaker implantations has dropped by 25 % (from 60 to 45 minutes).
- In implantations with subsequent lead complications, the duration of intervention is markedly longer than in complication-free interventions.
- The duration of intervention decreases with increasing experience of the surgeon.

The quality indicator "Duration of intervention" verifies whether the pre-defined time targets are maintained during pacemaker implantation. In accordance with the complexity of the pacemaker systems, these times are staggered as follows:

One-chamber systems (50 minutes) < Dual-chamber systems (80 minutes) < CRT systems (180 minutes)

It is self-evident that the appropriate surgery time is dictated by each individual case. The primary objective of every intervention is to have optimally positioned leads that ensure the functionality of the pacemaker. Under certain circumstances, therefore, the search for an optimal lead position also means that longer intervention times have to be accepted. Moreover, longer intervention times are to be expected in multimorbid patients.

Thus, the indicator "Duration of intervention" allows a tolerance up to a certain proportion of implantations when the recommended time targets are exceeded. According to the reference range definition, a hospital does not become computationally discrepant until less than 60 % of the interventions performed stay within the time targets. Hence, isolated upper time excursions do not lead to the Structured Dialogue.

Evaluating the results

The results of data collection year 2013 show that the time targets in at least 40 % of the implantations could not be maintained in 117 (12 %) out of 973 hospitals.

Using the earlier indicators for duration of intervention (QI-ID 10148, QI-ID 10178), 26 hospitals out of the total of 118 hospitals that were computationally discrepant regarding the duration of intervention in data collection year 2012 were finally rated as "qualitatively discrepant". These results suggest evidence of potential deficiencies in care that need to be investigated.

Description

Numerator	Patients with a duration of intervention up to 50 minutes for single-chamber systems (VVI, AAI), up to 80 minutes for dual-chamber systems (VDD, DDD), up to 180 minutes for CRT systems
Denominator	All patients with implanted single-chamber system (VVI, AAI), dual-chamber system (VDD, DDD), or CRT system
Reference range	≥ 60.0 % (tolerance range)
Risk adjustment	Stratification
QI-ID	52128
Comparability with the previous year's results	The present indicator was newly introduced in 2013 and retrospectively calculated for data collection year 2012.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	84.6 %	85.1 %
Confidence interval	–	–	–	84.3 – 84.9 %	84.9 – 85.4 %
Total number of cases	–	–	–	76,039	75,446

Aggregate result of all patients
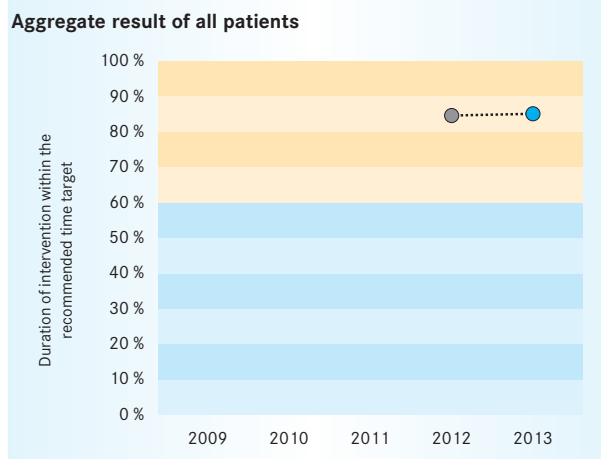
Hospital-based results

Target population of all hospitals	973
Number of hospitals with 0 cases	4

803 Hospitals with ≥ 20 cases
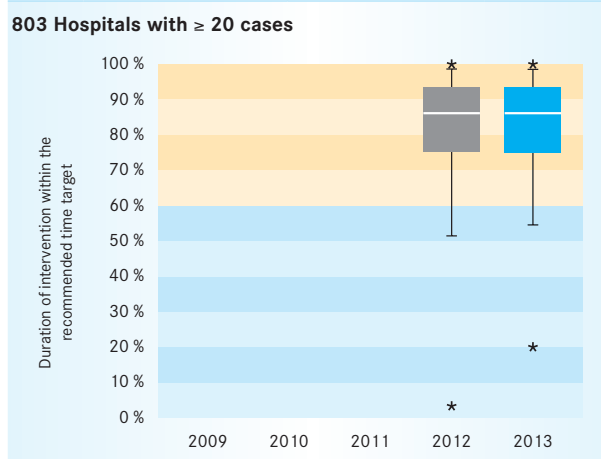
Median	86.1 %	Number of computationally discrepant hospitals	68 of 803
Range	20.0 – 100.0 %		

170 Hospitals with 1 to 19 cases

Median	76.9 %	Number of computationally discrepant hospitals	49 of 170
Range	0.0 – 100.0 %		

Pacemaker — Replacement of generator/battery

Dr. Karl Tasche, Prof. Dr. Jürgen Pauletzki, Florian Rüppel, Federal Experts' Working Group for Pacemakers and Implantable Cardioverter Defibrillators

Introduction
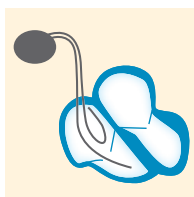
A pacemaker consists of a generator that houses the electronic circuits and the battery as well as one or more leads. The latter serve as "antennas" for the heart's own signals and transmit the pacemaker's stimulation pulse. Several years after implantation of a pacemaker, when the battery becomes depleted, the generator/battery will be replaced (removal of the old and implantation of a new generator/battery).

The aim of pacemaker therapy is to reduce the patients' bradycardia while avoiding impairment of their quality of life. The number of follow-up procedures after first-time implantation of a pacemaker should therefore be kept as low as possible. Follow-up interventions are required in the event of:

- Complications, e.g., lead dislodgement, defective generators/batteries, or infections of the pacemaker system.

- Depleted generator(s)/battery(ies) of the pacemaker. Pacemaker batteries cannot be replaced separately, i.e., replacement of the complete generator/battery is always required. The generator/battery should be replaced as rarely as possible to avoid any unnecessary burden to the patients – accordingly, the aim should be for long generator/battery lifetimes.

The clinical area *Pacemaker – Replacement of generator/battery* tests the isolated replacements of pacemaker generators/batteries that are usually required in the case of a depleted battery; corrections to pacemaker pouches and leads are excluded from the evaluation. These are captured in the clinical area *Pacemaker – Revision/system replacement/removal*.

The quality indicators in the present clinical area measure the lifetime of the generator/battery until its replacement, the duration of the intervention, perioperative complications, the implementation of necessary measurements (pacing threshold and amplitude measurements) as well as the mortality in the hospital.

The generator/battery replacement itself is a rather simple surgical procedure; nevertheless, pouch hematomas and wound infections can occur as complications. According to the available state of evidence, the risk of a wound infection increases with the number of replacement surgeries.

Services subject to mandatory documentation

Isolated replacement of pacemaker generator/battery.

Changes in comparison to the previous year

The reference range for the intervention time (QI-ID 210) was adjusted in alignment with the results of more recent studies – the time target for the duration of intervention to replace the generator/battery of cardioverter defibrillators is now 45 minutes. The reference range of this indicator was extended from ≥ 80 % to ≥ 60 %. This was done to prevent hospitals becoming computationally discrepant due to a low proportion of clinical cases in which a longer duration of intervention cannot be avoided.

Results

Positive developments have been registered for the measurement of intraoperative pacing thresholds and amplitudes in atrial and ventricular leads. Both the computational discrepancies and the qualitative discrepancies (verified after the Structured Dialogue), however, show that further improvements are required in this area nevertheless. The disturbance-free sensing of the heart's own electrical activity and the reliable transmission of electrical stimulation pulses to the heart are elementary prerequisites for the functionality of the pacemaker. Therefore, intraoperative pacing threshold and amplitude measurements are indispensable during interventions on the pacemaker system.

As was also the case with implantable cardioverter defibrillators, it has been shown that the few deaths during generator/battery replacements were not procedure-related. Nevertheless, the Structured Dialogue on the 2012 results revealed that the pacemaker system failed due to an extremely depleted battery in several of the patients who died. In these cases, the generators/batteries were apparently not replaced until very late – this led to an exacerbation of the clinical picture, which may have been a causal factor in the death of these patients.

The Structured Dialogue on the results of data collection year 2012 led to a follow-up on 814 computational discrepancies at 421 hospitals. Statements were requested in 364 cases. In 12 cases, "colleague-to-colleague" talks were held with representatives of the hospitals. In 26 cases, target agreements were made with respect to concrete improvement measures. After conclusion of the Structured Dialogue, 99 cases (49 hospitals) continued to be ranked as "qualitatively discrepant".

The Structured Dialogue on data collection year 2012 focused on intraoperative pacing threshold and amplitude measurements and documentation of the lifetimes of the replaced pacemaker generators/batteries. It is desirable to correct the documentation deficits relating to lifetimes: this is because several indicators of this clinical area cannot be calculated otherwise; consequently, the target agreements concluded with 11 hospitals to this effect are welcome.

Looking forward

Among the pivotal quality indicators for this clinical area are those that measure the lifetime of the generator/battery. Among others, the lifetimes are influenced by the following factors:

- Generator/battery properties such as energy use and battery capacity
- Quality of the programming
- Pacing threshold and stimulation needs of the patient

A major influence on the lifetime of a pacemaker generator/battery is also the quality of the follow-ups after implantation of the device. These follow-up examinations are frequently performed in the outpatient setting which is why they remain outside the purview of current (hospital) quality assurance. This circumstance points to the necessity to further develop the quality assurance of pacemaker therapy into a cross-sectoral procedure.

Pacemaker — Replacement of generator/battery

Moreover, the quality indicators for generator/battery lifetime in this clinical area only allow the actual lifetimes to be estimated approximately because only a cross-section of generator/battery replacements is evaluated on an empirical basis. By contrast, a longitudinal design would allow documentation of the long-term course of treatment starting with primary implantation of the pacemaker including follow-up examinations, generator/battery replacements, revision interventions, system replacements and removals as long as a link via pseudonymized patient-identifying data is possible. With such longitudinal data, much more valid indicators can be developed. The Federal Experts' Working Group therefore welcomes the planned introduction of a hospital follow-up procedure, which will be introduced starting in 2015.

Preliminary to the introduction of a hospital follow-up procedure, the current aim of further development will be to simplify the indicator set. The following approaches are suggested for this purpose:

- Combine the previous 4 quality indicators on the lifetimes of pacemaker generators/batteries into indices.
- Create indices for the quality indicators on pacing threshold and amplitude measurements as well.

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	17,238	17,756	17,486	101.5 %
Hospitals	929	920	917	100.3 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	17,740	100 %
< 50 years	509	2.9 %
50 – 59 years	497	2.8 %
60 – 69 years	1,522	8.6 %
70 – 79 years	5,722	32.3 %
80 – 89 years	7,548	42.5 %
≥ 90 years	1,942	10.9 %
Sex		
Male	9,271	52.3 %
Female	8,469	47.7 %
ASA classification		
ASA 1: A normal healthy patient	1,565	8.8 %
ASA 2: A patient with mild systemic disease	8,688	49.0 %
ASA 3: A patient with severe systemic disease	7,159	40.4 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	319	1.8 %
ASA 5: A moribund patient who is not expected to survive without the operation	9	0.1 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German): *www.sqg.de/themen/09n2/*

Pacemaker — Replacement of generator/battery

Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator	2012 Result	2013 Result	Cases (patients) Numerator	Cases (patients) Denominator	Trend
Indicator group		Lifetime of the old pacemaker generator/battery					
	1092	Lifetime of the old pacemaker generator/battery < 4 years in a single-chamber system (AAI, VVI)	0.48 %	0.80 %	33	4,102	→
	480	Lifetime of the old pacemaker generator/battery > 6 years in a single-chamber system (AAI, VVI)	92.4 %	92.7 %	3,803	4,102	→
	1093	Lifetime of the old pacemaker generator/battery < 4 years in a dual-chamber system (VDD, DDD)	0.82 %	0.66 %	83	12,506	→
	481	Lifetime of the old pacemaker generator/battery > 6 years in a dual-chamber system (VDD, DDD)	87.0 %	88.2 %	11,027	12,506	→
	11484	Documentation of the lifetime of the pacemaker generator/battery	95.4 %	95.7 %	16,969	17,740	→
	210	Duration of intervention up to 45 minutes	93.2 %	93.2 %	16,533	17,740	→
Indicator group		Intraoperative pacing threshold measurement					
	482	Intraoperative pacing threshold measurement of the atrial leads ⚠	94.7 %	95.6 %	10,521	11,006	↗
	483	Intraoperative pacing threshold measurement of ventricular leads ⚠	96.8 %	97.4 %	17,384	17,843	↗
Indicator group		Intraoperative amplitude measurement					
	1099	Intraoperative amplitude measurement of atrial leads ⚠	96.2 %	97.2 %	11,554	11,892	↗
	484	Intraoperative amplitude measurement of ventricular leads ⚠	96.8 %	97.0 %	14,021	14,460	→
	1096	Surgical complications	0.3 %	0.2 %	31	17,740	→
	51398	In-hospital mortality	0.19 %	0.20 %	35	17,740	→

Pacemaker — Replacement of generator/battery

## Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
	Lifetime of the old pacemaker generator/battery					
1092	Lifetime of the old pacemaker generator/battery < 4 years in a single-chamber system (AAI, VVI)	Sentinel event	781	31	X	X
480	Lifetime of the old pacemaker generator/battery > 6 years in a single-chamber system (AAI, VVI)	≥ 75.0 % (TO)	781	63	2	A
1093	Lifetime of the old pacemaker generator/battery < 4 years in a dual-chamber system (VDD, DDD)	Sentinel event	883	72	X	X
481	Lifetime of the old pacemaker generator/battery > 6 years in a dual-chamber system (VDD, DDD)	≥ 50.0 % (TO)	883	20	2	A
11484	Documentation of the lifetime of the pacemaker generator/battery	≥ 90.0 % (TA)	920	128	2	A
210	Duration of intervention up to 45 minutes	≥ 60.0 % (TO)	920	24	2	A
	Intraoperative pacing threshold measurement					
482	Intraoperative pacing threshold measurement of the atrial leads	≥ 84.2 % (TO; 5th percentile)	877	88	2	A
483	Intraoperative pacing threshold measurement of ventricular leads	≥ 88.4 % (TO; 5th percentile)	918	60	2	A
	Intraoperative amplitude measurement					
1099	Intraoperative amplitude measurement of atrial leads	≥ 87.2 % (TO; 5th percentile)	884	65	2	A
484	Intraoperative amplitude measurement of ventricular leads	≥ 87.9 % (TO; 5th percentile)	910	63	2	A
1096	Surgical complications	≤ 1.0 % (TO)	920	25	1	A
51398	In-hospital mortality	Sentinel event	920	34	X	X

TO = Tolerance range; TA = Target range

Pacemaker — Revision/system replacement/removal

Dr. Karl Tasche, Prof. Dr. Jürgen Pauletzki, Florian Rüppel, Federal Experts' Working Group for Pacemakers and Implantable Cardioverter Defibrillators

Introduction
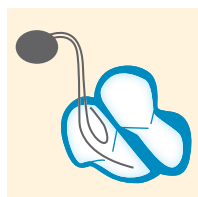
The quality of care in the primary implantation of a pacemaker as well as in the isolated replacement of a pacemaker generator/battery is collected in separate clinical areas. The present clinical area covers the quality assurance for repeat interventions (revisions) on pacemakers, their removal (explantation) or system replacements.

Revision interventions are subdivided according to indication for follow-up intervention:

- Hardware problem: Follow-up intervention due to a technical problem with the pacemaker generator/battery (malfunction or too short lifetime) or the leads (late occurrence of lead fractures or insulation defects)
- Procedure-associated problem: Complication with the generator/battery pouch or leads occurring shortly after a preceding pacemaker intervention
- Infection: Early system or lead infection

The quality indicators in this clinical area cover the indications for follow-up interventions, the measurement of pacing thresholds and/or signal amplitudes of the leads as well as perioperative complications and hospital mortality.

In order to achieve a rough approximation of the actual complication rate and since follow-up of all primary pacemaker implantations will not be possible until 2015, the number of implantations and replacements of generator/battery (surgery volumes) at the care-providing hospital will be considered the target population for the indicators on revision interventions. With the introduction of a hospital follow-up starting in 2015, the presently used quality indicators on complications as indication for intervention will be converted to longitudinally-based indicators.

Services subject to mandatory documentation

Pacemaker revisions (including generator/battery and lead replacements) and pacemaker removals and system changes between pacemaker systems.

Changes in comparison to the previous year

With data collection year 2013, the indicators on the indication for revision have been re-structured to obtain an indicator set without content overlap. As part of this process, the indicators on pouch problems (QI-ID 693) and lead problems (QI-ID 694) used up to 2012 have been combined into a new quality indicator "Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention" (QI-ID 52001). Moreover, the introduction of the quality indicator "Hardware problem (generator/battery or lead) as indication for follow-up intervention" (QI-ID 51987) allows generator/battery- and lead-related hardware problems with pacemakers to be integrated in quality assurance for the first time. The quality indicators on procedure-associated problems (QI-ID 51988) and on infections (QI-ID 51994) only consider complications occurring within the first year after implantation of the generator/battery and/

or lead because complications occurring later can no longer be regarded as procedure-related with sufficient certainty.

Results

The Federal Experts' Working Group sees a special need for action with regard to procedure-associated problems: Repeat inpatient interventions are required at too high a frequency. At 162 hospitals (18.3 % of all hospitals) computational discrepancies, i.e., results outside of the reference range (more than 6.0 %), were determined for this indicator. In the federal average, a revision had to be performed due to a procedure-associated problem within one year after 3.3 % of all pacemaker interventions, although this rate is systematically underestimated due to the still lacking follow-up. The indicator "Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention" (QI-ID 51988) is detailed in the following.

The Structured Dialogue on the results from data collection year 2012 for all indicators of the clinical area led to a follow-up on 748 computational discrepancies at 470 hospitals. Statements were requested on 405 discrepancies. In 12 cases, "colleague-to-colleague" talks were held with representatives of the hospitals. In 27 cases, target agreements were made with respect to concrete improvement measures. After conclusion of the Structured Dialogue, 81 cases (64 hospitals) were evaluated as "qualitatively discrepant". A high proportion of the qualitative discrepancies concerned revision interventions that had to be performed due to lead problems. These revision interventions should be rated as evidence of deficiencies in previous pacemaker interventions. Within the Structured Dialogue, it became apparent that several hospitals with a low surgery frequency lacked sufficient experience in pacemaker implantation. One State Administrative Office for Quality Assurance (LQS) held clinical talks with hospitals with high implantation volumes but low complication rates. In the talks, the good results of these hospitals were confirmed. The distinguishing characteristic of the responsible surgeons was their great commitment to scrupulously selecting the leads to be used and comprehensive, detailed knowledge of the technical features of pacemaker leads.

Looking forward

The aim of further developments in the present clinical area is to improve the discriminatory power of the indicators on pacing threshold and amplitude measurements and perioperative complications. Low caseloads per hospital are characteristic for these indicators. This contributes to an unfavorable ratio of computational discrepancies to qualitative discrepancies verified in the Structured Dialogue. The formation of quality indices might be considered a future solution to the problem.

The indicators for signal amplitude should be tested to see whether either the performance of amplitude measurements should be evaluated or the achievement of acceptable values for the signal amplitude – or both criteria, as previously.

The indicators for revision interventions constitute another area to work on. The content hereof was defined in a more precise way for data collection year 2013. The more precise definition was also introduced in parallel for the clinical area *Implantable*

Pacemaker — Revision/system replacement/removal

cardioverter defibrillators – Revision/system replacement/removal. The next step in development is to introduce a follow-up on pacemaker interventions, which will be carried out routinely starting in 2015.

Normally, fixed reference ranges that can be justified based on the scientific literature and the data basis previously collected within the scope of external hospital quality assurance are to be preferred over percentile-based reference ranges. In the case of the latter, a certain proportion of hospitals will always become computationally discrepant (usually the 5th or 95th percentile), irrespective of the level of the results. Therefore, the Federal Experts' Working Group will review the introduction of fixed versus percentile-based reference ranges. In the present clinical area, this applies to the indicators on hardware problems as indication for follow-up intervention (QI-ID 51987) and on risk-adjusted mortality (QI-ID 51404).

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	13,508	13,591	13,690	99.3 %
Hospitals	907	885	884	100.1 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	13,525	100 %
< 50 years	620	4.6 %
50 – 59 years	655	4.8 %
60 – 69 years	1,639	12.1 %
70 – 79 years	5,446	40.3 %
80 – 89 years	4,526	33.5 %
≥ 90 years	639	4.7 %
Sex		
Male	7,391	54.6 %
Female	6,134	45.4 %
ASA classification		
ASA 1: A normal healthy patient	983	7.3 %
ASA 2: A patient with mild systemic disease	5,344	39.5 %
ASA 3: A patient with severe systemic disease	6,684	49.4 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	477	3.5 %
ASA 5: A moribund patient who is not expected to survive without the operation	37	0.3 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German): *www.sqg.de/themen/09n3/*

Pacemaker — Revision/system replacement/removal

Case-based aggregate results (patients)

| | | 2012 | 2013 | | | |
| | | | Cases (patients) | | | |
QI-ID	Name of the quality indicator	Result	Result	Numerator (O | E) *	Denominator	Trend
51987	Hardware problem (generator/battery or lead) as indication for follow-up intervention	0.4 %	0.4 %	418	93,315	→
51988	Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention	3.3 %	3.3 %	3,114	93,315	→
51994	Infection or generator/battery perforation as indication for follow-up intervention	0.3 %	0.2 %	229	93,315	→
	Intraoperative pacing threshold measurement of revised leads					
494	Intraoperative pacing threshold measurement of atrial leads	98.5 %	98.5 %	2,398	2,434	→
495	Intraoperative pacing threshold measurement of ventricular leads	99.2 %	99.3 %	5,388	5,427	→
	Intraoperative amplitude measurement in revised leads					
496	Intraoperative amplitude measurement of atrial leads	98.8 %	98.8 %	2,517	2,548	→
497	Intraoperative amplitude measurement of ventricular leads	99.1 %	98.8 %	4,985	5,043	→
	Intracardiac signal amplitudes of revised leads					
584	Revised atrial leads with intracardiac signal amplitude ≥ 1.5 mV	92.7 %	92.3 %	2,384	2,584	→
585	Revised ventricular leads with intracardiac signal amplitude ≥ 4 mV	98.7 %	98.8 %	5,003	5,062	→
	Perioperative complications					
1089	Surgical complications	1.2 %	0.9 %	128	13,525	→
10638	Dislodgement of revised atrial lead for indicated lead problems in the atrium	1.0 %	0.9 %	24	2,720	→
10639	Dislodgement of revised ventricular lead for indicated lead problems in the ventricle	0.6 %	0.7 %	36	5,518	→
	In-hospital mortality					
51399	In-hospital mortality	1.3 %	1.2 %	161	13,525	→
51404	Ratio of the observed to the expected rate (O / E) of deaths	1.00	0.94	161 1.19 %	172 1.27 %	13,525	→

Indicator group labels appear along the left margin for the grouped indicators.

*   for regression-based quality indicators

Pacemaker — Revision/system replacement/removal

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		Evaluation	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
51987	Hardware problem (generator/battery or lead) as indication for follow-up intervention	≤ 2.2 % (TO; 95th percentile)	883	39	2	A
51988	Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention	≤ 6.0 % (TO)	883	162	2	C
51994	Infection or generator/battery perforation as indication for follow-up intervention	≤ 1.0 % (TO)	883	54	2	A
	Intraoperative pacing threshold measurement of revised leads					
494	Intraoperative pacing threshold measurement of atrial leads	≥ 95.0 % (TA)	638	24	1	A
495	Intraoperative pacing threshold measurement of ventricular leads	≥ 95.0 % (TA)	789	16	1	A
	Intraoperative amplitude measurement in revised leads					
496	Intraoperative amplitude measurement of atrial leads	≥ 95.0 % (TA)	646	20	1	A
497	Intraoperative amplitude measurement of ventricular leads	≥ 95.0 % (TA)	781	28	1	A
	Intracardiac signal amplitudes of revised leads					
584	Revised atrial leads with intracardiac signal amplitude ≥ 1.5 mV	≥ 80.0 % (TA)	652	87	1	A
585	Revised ventricular leads with intracardiac signal amplitude ≥ 4 mV	≥ 90.0 % (TA)	786	18	1	A
	Perioperative complications					
1089	Surgical complications	≤ 2.0 % (TO)	884	78	2	A
10638	Dislodgement of revised atrial lead for indicated lead problems in the atrium	≤ 3.0 % (TO)	659	21	1	A
10639	Dislodgement of revised ventricular lead for indicated lead problems in the ventricle	≤ 3.0 % (TO)	794	27	1	A
	In-hospital mortality					
51399	In-hospital mortality	n.d.*	884	–	X	X
51404	Ratio of the observed to the expected rate (O / E) of deaths	≤ 4.74 (TO; 95th percentile)	884	37	2	A

TO = Tolerance range; TA = Target range; * not defined

Pacemaker — Revision/system replacement/removal

QI-ID 51988: Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention

Description	
Numerator	Patients suffering from a lead or pouch problem after previous pacemaker surgery performed at the same hospital. The following complications are considered: Pouch problems: Twitching of the pectoral muscle, pouch hematoma or other pouch problem whenever the generator/battery was implanted in that data collection year or in the previous year. Lead problems: Dislodgement, lead fracture, insulation defects, connector defect, diaphragmatic stimulation, myopotential inhibition/oversensing, sensing failure/undersensing, stimulation loss/increase in pacing threshold, perforation or other lead problem. The aforementioned problems will only be considered if the implantation of the affected lead took place less than one year prior thereto.
Denominator	All patients with pacemaker implantation (09/1) or replacement of generator/battery (09/2)
Reference range	≤ 6.0 % (tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	51988
Comparability with the previous year's results	The indicator was newly introduced in 2013 and retrospectively calculated for data collection year 2012.

Case-based results (patients)					
	2009	2010	2011	2012	2013
Aggregate result	–	–	–	3.3 %	3.3 %
Confidence interval	–	–	–	3.2 – 3.4 %	3.2 – 3.5 %
Total number of cases	–	–	–	93,462	93,315

Aggregate result of all patients
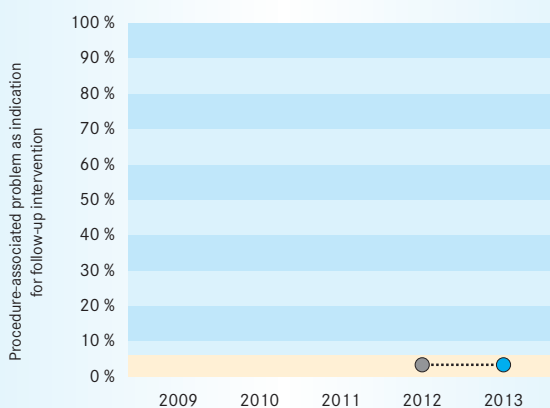
Hospital-based results	
Target population of all hospitals	883
Number of hospitals with 0 cases	2

826 Hospitals with ≥ 20 cases
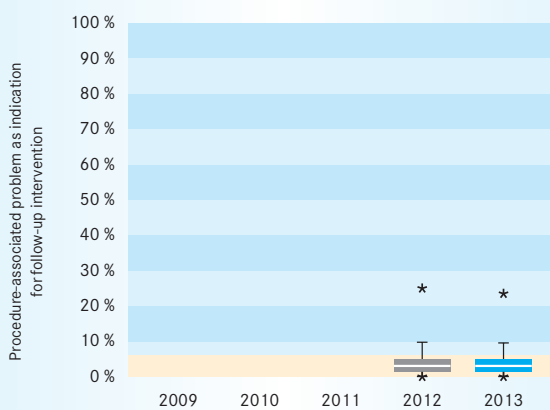
Median	3.1 %	Number of computationally discrepant hospitals	137 of 826
Range	0.0 – 23.5 %		

57 Hospitals with 1 to 19 cases

Median	0.0 %	Number of computationally discrepant hospitals	25 of 57
Range	0.0 – 37.5 %		

Quality target

The lowest possible frequency of procedure-associated problems in relation to the hospital's own implantation volume.

Background

The quality indicator counts all re-hospitalizations due to procedure-associated problems. It was calculated for the first time in data collection year 2013 and combines the two indicators "Pouch problem as indication for intervention" (QI-ID 693) and "Lead problem as indication for intervention within one year" (QI-ID 694) that were valid up to 2012. As has been implemented for lead problems since data collection year 2011, the new quality indicator exclusively considers complications occurring within less than one year of lead and/or generator/battery implantation. The fixed reference range of the old indicator on lead problems of ≤ 6.0 % has been kept.

Like the clinical area *Implantable cardioverter defibrillators – Revision/system replacement/removal*, follow-up interventions are included on all patients who had undergone a preceding intervention at the same hospital. Revision interventions that belong to clinical courses where two or more hospitals are involved are thus not accounted for by external hospital quality assurance. The target population for this indicator can, at present, only be estimated based on the surgery volume of the same hospital in the same year.

Evaluating the results

The result for this quality indicator was 3.3 % at the federal level. 162 hospitals (18.3 %) were computationally discrepant, i.e., they showed results of over 6.0 % and were thus above the reference range. These results should be regarded as potential deficiencies in pacemaker therapy; this particularly applies when revisions of prior interventions at other hospitals are also considered (which is possible on the federal level) – the aggregate result is then 4.0 %.

In this situation, the Federal Experts' Working Group sees a special need for action: In addition to the usual work-up of the computational discrepancies within the Structured Dialogue, more extensive measures are required. One measure might include, for example, an exchange of information between responsible professional associations to elucidate how this healthcare situation can be improved or whether it might be appropriate or necessary to change or amend guidelines. It should be pointed out, however, that postoperative complications, especially lead problems, after pacemaker interventions are an internationally well-known problem as well. The relative frequency of these complications in Germany is on a level with the results of comparable industrialized nations. Notwithstanding the above, all options should be exploited to improve the healthcare situation for pacemaker patients.

The introduction of a hospital follow-up on pacemaker therapy starting in data collection year 2015 also marks the introduction of a longitudinal analysis for the indicator on procedure-associated problems. This permits all revision interventions on the hospital level to be accounted for in the calculations, even when the index and follow-up interventions were performed at different hospitals.

Implantable cardioverter defibrillators — Implantation

Dr. Karl Tasche, Prof. Dr. Jürgen Pauletzki, Florian Rüppel, Federal Experts' Working Group for Pacemakers and Implantable Cardioverter Defibrillators

Introduction
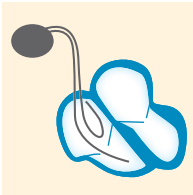
Sudden cardiac death is one of the most common causes of death in Western industrial nations. In most cases, it is the result of diseases of the coronary arteries (coronary heart disease, CHD) or of the heart muscle (cardiomyopathy). These can cause life-threatening cardiac arrhythmias. Pacemakers are implanted if the heart beat is too slow as a result of disorders of stimulus formation or conduction. High-frequency and life-threatening rhythm disorders of the heart chambers (ventricular tachycardia, ventricular flutter, ventricular fibrillation), however, cannot be treated with a pacemaker. In such cases, an implantable cardioverter defibrillator (ICD) is used, i.e., one which also offers all the functions of a pacemaker.

The implantation of an ICD is indicated if a high risk of dangerous arrhythmias is determined based on special cardiological examinations (primary prevention). If the patient has a history of life-threatening cardiac arrhythmias and there is no treatable (reversible) underlying cause for them, the ICD is implanted for secondary prevention. The device can eliminate these life-threatening rhythm disorders by delivering a shock or rapid impulses (antitachycardia stimulation) and thus prevent sudden cardiac death.

A further area of application for ICD therapy is advanced pump failure of the heart (heart failure), in which the two main chambers and/or a number of wall segments of the left chamber no longer work in synchrony. This can be seen on the electrocardiogram (ECG) by a left bundle branch block. This form of heart failure can be treated by electrical stimulation (cardiac resynchronization therapy, CRT). Affected patients are also at increased risk of sudden cardiac death. That is why combination devices are mostly implanted. These treat the heart's insufficiency with resynchronization therapy and thereby prevent sudden cardiac death from life-threatening arrhythmias of the heart chambers (CRT-D devices) in combination.

Quality aspects of ICD treatment measured by means of quality indicators are:

- Guideline-compliant indication for ICD therapy
- Guideline-compliant selection of a suitable system
- Shortest possible duration of intervention and a short fluoroscopy time during implantation
- The lowest possible peri-interventional complication rate
- Amplitude measurements in atrial and ventricular leads
- Low mortality (in the hospital)

An ICD is generally implanted under the skin, mostly under the chest muscle below the left clavicle. Similar to pacemakers, ICD implantation is nowadays a routine intervention associated with a low complication rate.

As with pacemaker therapy, the quality of care is assessed in 3 clinical areas which cover the spectrum of inpatient ICD treatment:

- Implantable cardioverter defibrillators – Implantation (ICD primary implantation and system conversion from pacemaker to ICD)
- Implantable cardioverter defibrillators – Replacement of generator/battery
- Implantable cardioverter defibrillators – Revision/system replacement/removal (follow-up intervention in patients already implanted with an ICD)

As with pacemakers, the data collected for the purpose of quality assurance are additionally used to fill a cardioverter defibrillator register that provides annual information about the healthcare situation in this sector in Germany (since 2010; *www.pacemaker-register.de*).

Services subject to mandatory documentation

Isolated ICD primary implantations as well as system conversion from pacemaker to an implantable cardioverter defibrillator.

Changes in comparison to the previous year

The Structured Dialogue for data collection year 2012 focused on the indicators "Guideline-compliant indication" (QI-ID 50004) and "Guideline-compliant system selection" (QI-ID 50005). These indicators were revised and optimized for data collection year 2013. The indicator for system selection had already been adapted to the new European guidelines on pacemaker and cardiac resynchronization therapy.

Starting with data collection year 2013, the duration of intervention is no longer evaluated in 3 separate indicators for single- or dual-chamber systems and CRT systems, but in one mutual indicator with a set reference range of ≥ 60.0 %. The threshold levels were adapted to the various cardioverter defibrillator types.

Results

Positive trends were registered for the indicators "Guideline-compliant indication" (QI-ID 50004), "Guideline-compliant system selection" (QI-ID 50005) and "Duration of intervention" (QI-ID 52129). At the same time, these indicators also cover the key problem fields. The ranges of the hospital results for the three indicators are substantial; there were a high number of computational discrepancies in data collection year 2013. The Federal Experts' Working Group sees a special need for action for the indicator "Guideline-compliant indication" (QI-ID 50004). This indicator and the indicator "Guideline-compliant system selection" (QI-ID 50005) are detailed in the following.

The duration of intervention can provide evidence about process quality (regarding workflows in the operating room) and structural quality (experience of the surgeons). A high proportion of interventions lasting longer than the system-specific threshold value may point to deficits in structural and process quality and be associated with an elevated complication risk. The result of the new indicator (QI-ID 52129) on the federal level has improved – compared to the retrospectively calculated result for 2012. Nevertheless, the results for data collection year

Implantable cardioverter defibrillators — Implantation

2013 were outside of the tolerance range in at least one in every 10 hospitals: In aggregate, 64 hospitals (9.5 %) were computationally discrepant.

The Structured Dialogue on data collection year 2012 yielded the following results for the present clinical area: With a total of 770 computational discrepancies at 417 hospitals, statements were requested in 422 cases. In 8 cases, "colleague-to-colleague" talks were held with representatives of the hospitals. In 20 cases, target agreements were concluded with respect to concrete improvement measures. After conclusion of the Structured Dialogue, 37 results (29 hospitals) were classified as "qualitatively discrepant".

In the present clinical area, a data validation was performed for data collection year 2012. As the results of the sampling procedure with data synchronization showed, the documentation quality was mostly rated as "good" to "excellent". The data validity was classified as "requires improvement" for only 27.3 % of the verified fields. High data quality is paramount for calculating valid quality indicators. Therefore, 4 continued discrepancy criteria of Basic Statistical Testing will be applied (i.e., these criteria will be evaluated annually from now on).

Looking forward

Considering the results of the Structured Dialogue on data collection year 2013, the Federal Experts' Working Group will examine the extent to which the indicator on the guideline-compliant indication (QI-ID 50004) needs to be adapted further. Otherwise, methodological further developments will focus on the revision of quality indices for the following areas:

- Fluoroscopy time (starting in data collection year 2015, the radiation burden will be documented via the dose area product)
- Amplitude measurements in atrial and ventricular leads
- Perioperative complications

What has still not been resolved is the issue of risk adjustment for perioperative complications. Here, the low caseloads per hospital and low prevalence rates for the corresponding event are typical of the individual indicators – factors which compound an adequate risk adjustment. In this respect, it might also be helpful to create an index of indicators.

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	29,612	29,514	29,534	99.9 %
Hospitals	654	673	673	100.0 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	29,458	100 %
< 50 years	2,578	8.8 %
50 – 59 years	4,946	16.8 %
60 – 69 years	7,210	24.5 %
70 – 79 years	11,692	39.7 %
80 – 89 years	3,001	10.2 %
≥ 90 years	31	0.1 %
Sex		
Male	23,130	78.5 %
Female	6,328	21.5 %
ASA classification		
ASA 1: A normal healthy patient	471	1.6 %
ASA 2: A patient with mild systemic disease	7,583	25.7 %
ASA 3: A patient with severe systemic disease	20,057	68.1 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	1,332	4.5 %
ASA 5: A moribund patient who is not expected to survive without the operation	15	0.1 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/09n4/

Implantable cardioverter defibrillators — Implantation

Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator		2012 Result	2013 Result	2013 Cases (patients) Numerator (O | E)*	Denominator	Trend
	50004	Guideline-compliant indication	⚠	92.8 %	93.6 %	27,586	29,458	↗
	50005	Guideline-compliant system selection	⚠	93.2 %	94.8 %	27,736	29,269	↗
	52129	Duration of intervention		84.6 %	86.1 %	25,193	29,269	↗
Indicator group		Fluoroscopy time						
	50010	Fluoroscopy time up to 9 minutes when a single-chamber system (VVI) is implanted	⚠	94.3 %	94.7 %	11,038	11,658	→
	50011	Fluoroscopy time up to 18 minutes for a dual-chamber system (VDD, DDD) implantation	⚠	93.8 %	94.5 %	7,139	7,556	→
	50012	Fluoroscopy time up to 18 minutes for a CRT-system implantation	⚠	97.3 %	97.6 %	9,418	9,650	→
Indicator group		Intraoperative amplitude measurement						
	50015	Intraoperative amplitude measurement of atrial leads	⚠	99.6 %	99.7 %	16,256	16,300	→
	50016	Intraoperative amplitude measurement of ventricular leads	⚠	99.7 %	99.6 %	28,741	28,857	→
Indicator group		Perioperative complications						
	50017	Surgical complications	⚠	1.1 %	1.1 %	317	29,458	→
	50018	Lead dislodgement or dysfunction of the atrial lead	⚠	0.5 %	0.5 %	78	16,842	→
	50019	Lead dislodgement or dysfunction of a ventricular lead	⚠	0.5 %	0.7 %	207	29,241	→
Indicator group		In-hospital mortality						
	50020	In-hospital mortality	⚠	0.5 %	0.6 %	184	29,458	→
	51186	Ratio of the observed to the expected rate (O / E) of deaths	⚠	1.00	1.22	181 0.62 %	148 0.51 %	29,051 →

* for regression-based quality indicators

Implantable cardioverter defibrillators — Implantation

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		Evaluation	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
50004	Guideline-compliant indication	≥ 90.0 % (TA)	672	133	1	C
50005	Guideline-compliant system selection	≥ 90.0 % (TA)	672	98	1	A
52129	Duration of intervention	≥ 60.0 % (TO)	672	64	2	A
	Fluoroscopy time					
50010	Fluoroscopy time up to 9 minutes when a single-chamber system (VVI) is implanted	≥ 75.0 % (TO)	639	14	2	B
50011	Fluoroscopy time up to 18 minutes for a dual-chamber system (VDD, DDD) implantation	≥ 80.0 % (TO)	603	47	2	B
50012	Fluoroscopy time up to 18 minutes for a CRT-system implantation	≥ 90.0 % (TO)	484	36	2	B
	Intraoperative amplitude measurement					
50015	Intraoperative amplitude measurement of atrial leads	≥ 95.0 % (TA)	617	7	1	A
50016	Intraoperative amplitude measurement of ventricular leads	≥ 95.0 % (TA)	672	11	1	A
	Perioperative complications					
50017	Surgical complications	≤ 4.5 % (TO; 95th percentile)	672	34	2	A
50018	Lead dislodgement or dysfunction of the atrial lead	≤ 2.7 % (TO; 95th percentile)	617	32	2	A
50019	Lead dislodgement or dysfunction of a ventricular lead	≤ 3.4 % (TO; 95th percentile)	672	34	2	A
	In-hospital mortality					
50020	In-hospital mortality	n.d.*	672	–	X	X
51186	Ratio of the observed to the expected rate (O / E) of deaths	≤ 6.26 (TO; 95th percentile)	671	33	2	A

TO = Tolerance range; TA = Target range; * not defined

Implantable cardioverter defibrillators — Implantation

QI-ID 50004: Guideline-compliant indication

Quality target

As often as possible guideline-compliant indication for implantation of a cardioverter defibrillator.

Background

The indications for implantable cardioverter defibrillators (ICD) to protect against sudden cardiac death are basically classified into two different types of prevention: When an ICD is implanted after a so-called index event, e.g., tachycardia-induced cardiovascular arrest or weaker symptoms like syncope or angina pectoris, this is referred to as secondary prevention. By contrast, the implantation of an ICD in patients at a high risk for sudden cardiac death without a prior index event occurring is called primary prevention. The implantation of a pacemaker is classified as guideline-compliant when one of the indications mentioned in the following exists:

- Secondary prevention: In ventricular fibrillation or persistent ventricular tachycardia with clinical symptoms, after syncope with reduced pumping capacity of the heart or congenital heart disease, in persistent ventricular tachycardia without clinical symptoms
- Primary prevention: Myocardial infarction not more than 28 days and/ or 40 days in the past, in dilated cardiomyopathy, heart failure, Brugada's syndrome, short QT syndrome or long QT syndrome, hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy

Evaluating the results

The proportion of guideline-compliant indications has clearly improved (2011: 90.6 %; 2013: 93.6 %). The Federal Experts' Working Group nevertheless sees a special need for action with regard to guideline-compliant indications. On the one hand, this is based on the numerous computational discrepancies. On the other, updating and a more precise definition of the guidelines is also mandated, particularly in the area of rendering the indication for primary prevention – where the existing ambiguities should be eliminated. To achieve an improvement in healthcare overall, the Federal Experts' Working Group considers a double-track approach necessary: The Structured Dialogue should be implemented on a consistent basis at all hospitals which were computationally discrepant in data collection year 2013. Moreover, the affected medical societies should work towards updating and/or re-drafting the corresponding European guidelines.

Description

Numerator	Patients with guideline-compliant system selection for ICD implantation
Denominator	All patients
Reference range	≥ 90.0 % (target range)
Risk adjustment	No further risk adjustment
QI-ID	50004
Comparability with the previous year's results	Comparable to a limited extent

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	88.4 %	90.6 %	92.8 %	93.6 %
Confidence interval	–	88.0–88.8 %	90.2–90.9 %	92.5–93.1 %	93.4–93.9 %
Total number of cases	–	25,582	28,452	29,574	29,458

Aggregate result of all patients
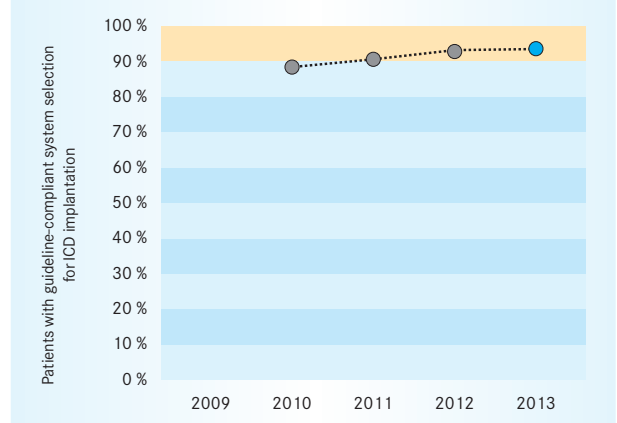
Hospital-based results

Target population of all hospitals	672
Number of hospitals with 0 cases	1

422 Hospitals with ≥ 20 cases
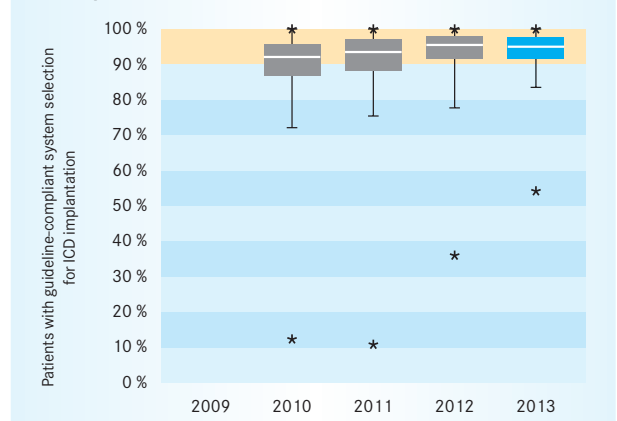
Median	95.0 %	Number of computationally discrepant hospitals	73 of 422
Range	54.2 – 100.0 %		

250 Hospitals with 1 to 19 cases

Median	100.0 %	Number of computationally discrepant hospitals	60 of 250
Range	0.0 – 100.0 %		

Implantable cardioverter defibrillators – Implantation

## QI-ID 50005: Guideline-compliant system selection

Description

Numerator	Patients with guideline-compliant system selection for ICD implantation
Denominator	All patients with implanted single-chamber system (VVI), dual-chamber system (VDD, DDD) or CRT system
Reference range	≥ 90.0 % (target range)
Risk adjustment	No further risk adjustment
QI-ID	50005
Comparability with the previous year's results	Comparable to a limited extent

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	84.5 %	87.3 %	93.2 %	94.8 %
Confidence interval	–	84.1–85.0 %	86.9–87.7 %	92.9–93.5 %	94.5–95.0 %
Total number of cases	–	25,469	28,313	29,424	29,269
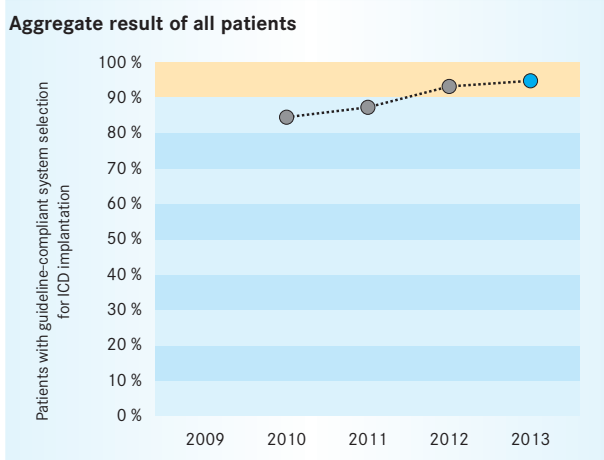
Aggregate result of all patients

Hospital-based results

Target population of all hospitals	672
Number of hospitals with 0 cases	1

422 Hospitals with ≥ 20 cases
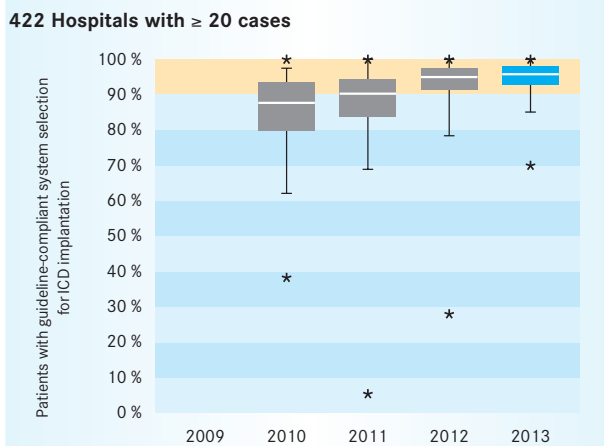
Median	95.8 %	Number of computationally discrepant hospitals	53 of 422
Range	70.0 – 100.0 %		

250 Hospitals with 1 to 19 cases

Median	100.0 %	Number of computationally discrepant hospitals	45 of 250
Range	0.0 – 100.0 %		

Quality target

As often as possible guideline-compliant system selection.

Background

In contrast to pacemaker therapy, neither the German guideline on the implantation of cardioverter defibrillators nor the European-American guideline on the care of patients with ventricular arrhythmias and on the prevention of sudden cardiac deaths give clear recommendations on system selection for implantation of an ICD. This fact motivated the Federal Experts' Working Group to base an algorithm on the German guidelines governing pacemaker therapy as well as on the current European guidelines governing pacemaker and cardiac resynchronization therapy. This algorithm maps out the guideline-compliant system selection for implantation of cardioverter defibrillators. For data collection year 2013, the algorithm has been simplified – the differentiation between DDD systems with and without AV management has been omitted. With regard to the indication for a CRT system, the current European guidelines governing pacemaker and cardiac resynchronization therapy have been implemented on a consistent basis.

Before a cardioverter defibrillator is implanted, a differentiation must be made between systems, depending on the indication. The algorithm for making a guideline-compliant system selection uses 15 data fields from QA documentation. In simple terms, the algorithm of the indicator contains a characteristic data pattern for every implantable ICD system. These data describe a constellation of findings that must be present for a certain cardioverter defibrillator system to count as a "guideline-compliant selection". If the algorithm does not find a pattern that fits the implanted ICD system of a patient, the corresponding ICD implantation is rated "not guideline-compliant".

Evaluating the results

The proportion of decisions for guideline-compliant system selections has clearly increased and is presently at 94.8 %. Compared to the previous year, the number of computationally discrepant hospitals has dropped substantially.

The Structured Dialogue on the 2012 results led to the analysis of the results of 241 hospitals, from 183 of whom statements were requested. In 3 meetings, a total of 8 target agreements were concluded. After conclusion of the Structured Dialogue, 18 hospitals were evaluated as "qualitatively discrepant"; 57 hospitals were not evaluable due to improper documentation.

Implantable cardioverter defibrillators — Replacement of generator/battery

Dr. Karl Tasche, Prof. Dr. Jürgen Pauletzki, Florian Rüppel, Federal Experts' Working Group for Pacemakers and Implantable Cardioverter Defibrillators

Introduction
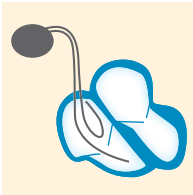
An implantable cardioverter defibrillator (ICD) is used for the treatment of rapid, life-threatening arrhythmias of the heart chambers (ventricular tachycardia, ventricular flutter, ventricular fibrillation). This device can eliminate life-threatening cardiac arrhythmias by delivering a shock or rapid impulses (antitachycardia stimulation) and thus prevent sudden cardiac death. ICD has all functions of a pacemaker.

Similar to a pacemaker, an ICD consists of a generator that houses the electronic circuits (microcomputer) and the battery. The generator is connected to the heart by electrodes. The ICD is generally implanted under the skin or under the chest muscle below the left clavicle.

Replacement of the generator/battery is needed after depletion following a lifetime of several years. The leads can usually be left in the heart while the generator/battery is being replaced. The quality of the intervention for isolated replacement of the ICD generator/battery is recorded in the quality indicator in the clinical area *Implantable cardioverter defibrillator – Replacement of generator/battery*. In addition to the lifetime of the replaced generator/battery these indicators also measure the intervention time, the pacing threshold measurement or signal amplitude measurement of the leads as well as perioperative complications and mortality.

The documentation of ICD treatment (replacement of generator/battery) in conjunction with external quality assurance became mandatory on January 1, 2010. Due to the increasing number of implantations and costly treatments, quality assurance allows an evaluation of the quality of care in Germany.

Services subject to mandatory documentation

Isolated generator/battery replacement of implantable cardioverter defibrillators.

Changes in comparison to the previous year

The reference range for the intervention time (QI-ID 50025) was changed according to the results of most current studies – the time target for replacing the generator/battery of cardioverter defibrillators is currently 60 minutes. Additionally, the reference range of ≥ 80 % was lowered to ≥ 60 %. This was done to prevent hospitals being classified as computationally discrepant due to low proportion of clinical cases in which a longer duration of intervention cannot be avoided.

For the indicator "Intraoperative amplitude measurements of pace-sense leads (first or second ventricular lead)" (QI-ID 52003), the target population was limited to the right ventricular leads – amplitude measurements are not required for left ventricular leads.

Results

The results of data collection year 2013 show an overall good quality of care The improvement in generator/battery lives is positive: There were fewer VVI[1] generators/batteries registered that did not achieve a minimum lifetime of 3 years. Again, there were essentially no procedure-related deaths that occurred during revisions of the generators/batteries of cardioverter defibrillators in data collection year 2013. However, the Structured Dialogue revealed that in the data collection year 2012 the delayed replacement of generator/battery for several patients resulted in failure of the ICD system due to an extremely depleted battery, which in turn resulted in worsening of the patient's clinical status. This may have been the cause for the death of the patients.

Qualitatively discrepant results were observed in data collection year 2013, particularly in the quality indicators for intraoperative pacing thresholds and amplitude measurements. The capability of the system to stimulate the heart as needed is measured based on the pacing thresholds. Optimal (or at least acceptable) signal amplitudes provide proof that an ICD system is reliably recording the heart's activity. Without these measurements, the functionality of the ICD system cannot be guaranteed. The indicators verify whether these two measurements were performed. As the current results on pacing thresholds and amplitude measurements show, the quality of care cannot be judged solely on the basis of averaged results. The results of the indicators on the federal level are approximately 100 %, i.e., nationwide, there was a failure to perform pacing threshold and amplitude measurements in only 0.9 % to 1.2 % of generator/battery replacements. On the hospital level, however, different results were observed. The range extends across many hospitals with good or very good results to hospitals which clearly missed the mark in terms of the reference range (pacing threshold and amplitude measurements in at least 95 % of clinical cases).

The discussion of the Structured Dialogue on the results of data collection year 2012 led to a follow up on a total of 313 computational discrepancies at 198 hospitals. Statements were requested in 187 cases. In 1 case, a "colleague-to-colleague" talk was held with the hospital. In 4 cases, target agreements were made with respect to concrete improvement measures. In conclusion, the Structured Dialogue classified 36 cases (18 hospitals) as "qualitatively discrepant".

Looking forward

The aim of further development in the present clinical area is to simplify the indicator set. The following approaches are suggested for this purpose:

- It should be examined whether the 3 indicators on the minimum lifetime of the generators/batteries of the different cardioverter defibrillators should be summarized into one quality index in the future. Moreover, it is planned to define a reference range based on the data basis that meanwhile has become sufficient.

- It has also been considered for the future to merge the quality indicators on pacing thresholds (QI-ID 50026, QI-ID 50027) and amplitude measurements (QI-ID 50028, QI-ID 52003) into one index.

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[1] Common type of single-chamber ICD system

Implantable cardioverter defibrillators —
Replacement of generator/battery

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	7,066	8,436	8,412	100.3 %
Hospitals	570	596	600	99.3 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	8,419	100 %
< 50 years	557	6.6 %
50 – 59 years	1,102	13.1 %
60 – 69 years	2,016	23.9 %
70 – 79 years	3,347	39.8 %
80 – 89 years	1,364	16.2 %
≥ 90 years	33	0.4 %
Sex		
Male	6,498	77.2 %
Female	1,921	22.8 %
ASA classification		
ASA 1: A normal healthy patient	383	4.5 %
ASA 2: A patient with mild systemic disease	2,690	32.0 %
ASA 3: A patient with severe systemic disease	5,109	60.7 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	231	2.7 %
ASA 5: A moribund patient who is not expected to survive without the operation	6	0.1 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/09n5/

Implantable cardioverter defibrillators — Replacement of generator/battery

Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator		2012 Result	2013 Result	2013 Cases (patients) Numerator	2013 Cases (patients) Denominator	Trend
Indicator group		Lifetime of the old cardioverter defibrillator generator/battery						
	50021	Lifetime of the old cardioverter defibrillator generator/battery with single-chamber system (VVI) under 3 years		1.8 %	0.8 %	24	2,910	↗
	50022	Lifetime of the old cardioverter defibrillator generator/battery with dual-chamber system (VDD, DDD) under 3 years		1.4 %	0.9 %	19	2,208	→
	50023	Lifetime of the old cardioverter defibrillator generator/battery with CRT system under 3 years		2.7 %	1.8 %	54	2,982	→
	50025	Duration of intervention up to 60 minutes	⚠	90.8 %	91.4 %	7,693	8,419	→
Indicator group		Intraoperative pacing threshold measurement						
	50026	Intraoperative pacing threshold measurement of the atrial lead	⚠	98.4 %	99.0 %	4,248	4,291	→
	50027	Intraoperative pacing threshold measurement of ventricular leads	⚠	98.5 %	98.8 %	11,445	11,589	→
Indicator group		Intraoperative amplitude measurement						
	50028	Intraoperative amplitude measurement of atrial lead	⚠	98.6 %	99.0 %	4,823	4,871	→
	52003	Intraoperative amplitude measurement of pace-sense lead (first or second ventricular lead)		99.0 %	99.1 %	7,706	7,778	→
	50030	Surgical complications	⚠	0.45 %	0.43 %	36	8,419	→
	50031	In-hospital mortality	⚠	0.23 %	0.18 %	15	8,419	→

Implantable cardioverter defibrillators — Replacement of generator/battery

## Hospital-based aggregate results for utilization in quality assurance

	QI-ID	Name of the quality indicator	Reference range	2013 Hospitals		Evaluation	
				Total	Discrepant (computationally)	Category	Need for action
Indicator group		Lifetime of the old cardioverter defibrillator generator/battery					
	50021	Lifetime of the old cardioverter defibrillator generator/battery with single-chamber system (VVI) under 3 years	n.d.*	485	–	X	X
	50022	Lifetime of the old cardioverter defibrillator generator/battery with dual-chamber system (VDD, DDD) under 3 years	n.d.*	466	–	X	X
	50023	Lifetime of the old cardioverter defibrillator generator/battery with CRT system under 3 years	n.d.*	448	–	X	X
	50025	Duration of intervention up to 60 minutes	≥ 60.0 % (TO)	596	32	2	A
Indicator group		Intraoperative pacing threshold measurement					
	50026	Intraoperative pacing threshold measurement of the atrial lead	≥ 95.0 % (TA)	525	20	1	A
	50027	Intraoperative pacing threshold measurement of ventricular leads	≥ 95.0 % (TA)	594	35	1	A
Indicator group		Intraoperative amplitude measurement					
	50028	Intraoperative amplitude measurement of atrial lead	≥ 95.0 % (TA)	534	23	1	A
	52003	Intraoperative amplitude measurement of pace-sense lead (first or second ventricular lead)	≥ 95.0 % (TA)	589	23	1	A
	50030	Surgical complications	Sentinel event	596	31	X	X
	50031	In-hospital mortality	Sentinel event	596	15	X	X

TO = Tolerance range; TA = Target range; * not defined

Implantable cardioverter defibrillators — Revision/system replacement/removal

Dr. Karl Tasche, Prof. Dr. Jürgen Pauletzki, Florian Rüppel, Federal Experts' Working Group for Pacemakers and Implantable Cardioverter Defibrillators

Introduction
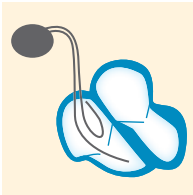
An implantable cardioverter defibrillator (ICD) is used for the treatment of high-frequency, life-threatening arrhythmias of the heart chambers (ventricular tachycardia, ventricular flutter, ventricular fibrillation). Similar to a pacemaker, an ICD consists of a generator that houses the electronic circuits (microcomputer) and the battery. The generator is connected to the heart by leads. Primary implantation of an ICD and the isolated replacement of the ICD generator/battery are both documented in their own clinical areas. The present clinical area *Implantable cardioverter defibrillators – Revision/system replacement/removal* measures quality assurance for repeat interventions (revision) on ICDs, their removal (explantation) or system replacements.

Revision interventions are subdivided according to indication for follow-up intervention:

- Hardware problem: This indication for follow-up intervention involves a technical problem with the ICD generator/battery (malfunction or too short lifetime) or the leads (late occurrence of lead fractures or insulation defects)
- Procedure-associated problem: Complication with the generator/battery pouch or leads occurring shortly after a preceding ICD intervention
- Infection: Early system or lead infection

The quality indicators in this clinical area cover the indications for follow-up interventions, the measurement of pacing thresholds and/or signal amplitudes of the leads as well as perioperative complications and in-hospital mortality.

The documentation of ICD interventions in conjunction with external quality assurance became mandatory on January 1, 2010. Specifically against the backdrop of increasing numbers of implantations and cost-intensive treatments, these procedures are important in order to obtain a representative picture of the quality of care in Germany. The indication for a revision or a system replacement also allows conclusions to be drawn about the medical quality of previous interventions, including product defects.

Services subject to mandatory documentation

Revisions of implantable cardioverter defibrillator (including generator/battery and lead replacements), cardioverter defibrillator removals and system changes between ICD systems.

Changes in comparison to the previous year

The indicators for rendering the indication for revision have been restructured to avoid overlap in content. This restructuring involved adding lead fractures and insulation defects occurring later than one year after lead implantation to the indicator on generator/battery problems (QI-ID 50033) used up to 2012 and transferring it into the new quality indicator "Hardware problem (generator/battery or lead) as indication for follow-up intervention" (QI-ID 52000). Furthermore, the indicators on pouch problems (QI-ID 50032) and lead problems (QI-ID 50034) valid up to 2012 have been combined into one new quality indicator, which covers procedure-associated problems (QI-ID 52001).

Moreover, starting 2013, complications will not be considered in the quality indicators on procedure-associated problems (QI-ID 52001) and infections (QI-ID 52002) unless implantation of the generator/battery took place more than a year prior thereto. This is because the complications arising could no longer be regarded as procedure-related with sufficient certainty.

Results

With regard to procedure-associated problems (QI-ID 52001) as indications for repeat hospital interventions, the Federal Experts' Working Group sees a special need for action:

- On the federal average, a revision due to a procedure-associated problem had to be performed within one year after 5.2 % of all ICD interventions. This figure underestimates the actual proportion of revisions (6.6 %) because it only accounts for follow-up interventions at the same hospital. The actual hospital-specific revision rates for procedure-associated problems cannot be determined until after a follow-up that also analyzes the clinical courses involving several hospitals.
- Computational discrepancies, i.e., results above the reference ranges, were determined for 188 hospitals (34.1 % of the hospitals).

The Structured Dialogue on the results of data collection year 2012 for the clinical area led to an analysis of a total of 263 computational discrepancies at 163 hospitals. In 161 cases, statements were requested, in 3 cases, "colleague-to-colleague" talks were held with representatives of the hospitals. In 1 case, target agreements were concluded with respect to concrete improvement measures. After conclusion of the Structured Dialogue, 4 hospitals continued to be evaluated as "qualitatively discrepant" (on 7 indicators).

Looking forward

The aim of further development of this clinical area is to improve the discriminatory power of the indicators on pacing threshold and amplitude measurements and perioperative complications. Low caseloads per hospital with prevalence rates close to 0 % or 100 % – depending on the indicator target – are characteristic for these indicators; these characteristics contribute to an unfavorable ratio of computational discrepancies to qualitative discrepancies confirmed in the Structured Dialogue. Therefore, the intention is to combine indicators into quality indices.

Another area to work on is the indications for revision interventions. The content hereof was defined in a more precise way for data collection year 2013. The more precise definition was also introduced in parallel for the clinical area *Pacemaker – Revision/system replacement/removal*. The next development step, commissioned by the G-BA in June 2014, was the introduction of cross-institutional follow-up on cardioverter defibrillator revisions.

Fundamentally, fixed reference ranges that can be justified based on the scientific literature and the data basis collected within the scope of external hospital quality assurance, are to be preferred over percentile-based reference ranges. For the

Implantable cardioverter defibrillators — Revision/ system replacement/removal

latter, a certain proportion of the hospitals will become computationally discrepant at any rate (at least 5 %), irrespective of the level of the results. This does not constitute an optimal approach when even those hospitals with the "poorest" results still at least provide satisfactory medical care and/or those hospitals with the "best" results do not. The approach is equally suboptimal when the results of markedly more than 5 % of the hospitals suggest potential deficiencies in care. Therefore, the Federal Experts' Working Group will review the introduction of fixed instead of percentile-based reference ranges. This applies to the indicators on hardware problems as indication for follow-up intervention (QI-ID 52000) and on risk-adjusted mortality (QI-ID 51196).

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	8,826	9,217	9,183	100.4 %
Hospitals	536	558	565	98.8 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	9,160	100 %
< 50 years	799	8.7 %
50 – 59 years	1,512	16.5 %
60 – 69 years	2,319	25.3 %
70 – 79 years	3,545	38.7 %
80 – 89 years	977	10.7 %
≥ 90 years	8	0.1 %
Sex		
Male	7,199	78.6 %
Female	1,961	21.4 %
ASA classification		
ASA 1: A normal healthy patient	262	2.9 %
ASA 2: A patient with mild systemic disease	2,065	22.5 %
ASA 3: A patient with severe systemic disease	6,299	68.8 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	507	5.5 %
ASA 5: A moribund patient who is not expected to survive without the operation	27	0.3 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German): *www.sqg.de/themen/09n6/*

Implantable cardioverter defibrillators — Revision/ system replacement/removal

Case-based aggregate results (patients)

| | | | 2012 | 2013 | | | |
| | | | | Cases (patients) | | | |
QI-ID	Name of the quality indicator		Result	Result	Numerator (O | E)*	Denominator	Trend
52000	Hardware problem (generator/battery or lead) as indication for follow-up intervention		n.c.**	4.3 %		2,045	47,037	n.a.***
52001	Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention		n.c.**	5.2 %		1,956	37,877	n.a.***
52002	Infection as indication for follow-up intervention		n.c.**	1.1 %		400	37,877	n.a.***
	Intraoperative pacing threshold measurement in revised leads						
50037	Intraoperative pacing threshold measurement of atrial leads		98.9 %	99.2 %		2,078	2,095	→
50038	Intraoperative pacing threshold measurement of ventricular leads		98.9 %	99.0 %		6,605	6,673	→
	Intraoperative amplitude measurement in revised leads						
50039	Intraoperative amplitude measurement of atrial leads		99.2 %	99.4 %		2,282	2,295	→
50040	Intraoperative amplitude measurement of ventricular leads		99.1 %	99.0 %		3,600	3,637	→
	Perioperative complications						
50041	Surgical complications		1.5 %	1.3 %		119	9,160	→
50042	Lead dislodgement or dysfunction of the atrial lead		0.5 %	0.8 %		18	2,354	→
50043	Lead dislodgement or dysfunction of a ventricular lead		0.4 %	0.7 %		45	6,214	→
	In-hospital mortality						
50044	In-hospital mortality		1.4 %	1.6 %		146	9,160	→
51196	Ratio of the observed to the expected rate (O / E) of deaths		1.00	1.12	146 / 1.59 %	130 / 1.42 %	9,160	→

Indicator group (×4, left margin labels)

* for regression-based quality indicators; ** not calculated; *** not applicable

Implantable cardioverter defibrillators — Revision/ system replacement/removal

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		Evaluation	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
52000	Hardware problem (generator/battery or lead) as indication for follow-up intervention	≤ 9.2 % (TO; 95th percentile)	558	28	2	A
52001	Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention	≤ 6.0 % (TO)	552	188	2	C
52002	Infection as indication for follow-up intervention	≤ 4.3 % (TO; 95th percentile)	552	30	2	A
	Intraoperative pacing threshold measurement in revised leads					
50037	Intraoperative pacing threshold measurement of atrial leads	≥ 95.0 % (TA)	394	14	1	A
50038	Intraoperative pacing threshold measurement of ventricular leads	≥ 95.0 % (TA)	510	20	1	A
	Intraoperative amplitude measurement in revised leads					
50039	Intraoperative amplitude measurement of atrial leads	≥ 95.0 % (TA)	407	12	1	A
50040	Intraoperative amplitude measurement of ventricular leads	≥ 95.0 % (TA)	481	15	1	A
	Perioperative complications					
50041	Surgical complications	≤ 5.2 % (TO; 95th percentile)	558	28	1	A
50042	Lead dislodgement or dysfunction of the atrial lead	≤ 4.2 % (TO; 95th percentile)	407	13	1	A
50043	Lead dislodgement or dysfunction of a ventricular lead	≤ 4.6 % (TO; 95th percentile)	512	21	1	A
	In-hospital mortality					
50044	In-hospital mortality	n.d.*	558	–	X	X
51196	Ratio of the observed to the expected rate (O / E) of deaths	≤ 4.48 (TO; 95th percentile)	558	24	1	A

TO = Tolerance range; TA = Target range; * not defined

Implantable cardioverter defibrillators — Revision/system replacement/removal

QI-ID 52000: Hardware problem (generator/battery or lead) as indication for follow-up intervention

Quality target

The lowest possible frequency of revisions due to cardioverter defibrillator hardware problems in relation to the hospital's own implantation volume.

Background

All re-hospitalizations at a hospital due to hardware problems are captured by the quality indicator. Starting in data collection year 2013, it will be calculated and will additionally consider lead fractures and insulation defects occurring later than one year after lead implantation alongside generator/battery problems. Lead fractures and insulation defects within one year after lead implantation are additionally considered in the indicator "Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention" (QI-ID 52001).

Hardware problems include technical malfunctions of the ICD generator/battery mandating a repeat intervention, and generator/battery lifetimes of less than 3 years. This indicator also covers the generator/battery problems additionally documented in the clinical area *Implantable cardioverter defibrillators – Replacement of generator/battery* and thus, similar to the indicator "Hardware problems (generator and/or lead) as indication for follow-up procedure" (QI-ID 51987) in the clinical area *Pacemaker – Revision/system replacement/removal*, all hardware-related revision interventions where the prior intervention was performed at the *same* hospital. The revision burden is underestimated because revision interventions that belong to the clinical courses where two or more hospitals are involved are presently not yet accounted for by external hospital quality assurance.

Evaluating the results

The federal level result of 4.3 % is consistent with the extent of hardware problems to be expected from implantable cardioverter defibrillators according to empirical studies. However, at 6.4 %, the result turns out to be clearly higher when all revision interventions, i.e., those where the prior intervention was performed at another hospital, are also considered. This bias will be corrected by the planned clinical monitoring (follow-up) on ICD interventions the AQUA Institute was commissioned to develop in June 2014.

In data collection year 2013, 28 hospitals were computationally discrepant; at these hospitals, a revision due to a hardware problem was indicated after 1 in 10 ICD surgeries (or more frequently).

Description	
Numerator	Patients suffering from a hardware problem of the ICD system occurring after previous ICD or pacemaker surgery performed at the same hospital. The following hardware problems are additionally considered: Generator/battery: Indications for replacement that might suggest generator/battery problems (malfunction/recall or other indication) or lifetimes of less than 3 years (documented in clinical areas 09/5 and 09/6). Leads: Lead fractures or insulation defects occurring later than one year after implantation of the affected lead or the time interval to lead implantation not known.
Denominator	All interventions by the respectively reporting hospital(s)
Reference range	≤ 9.2 % (95th percentile, tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	52000
Comparability with the previous year's results	Not calculated in the previous year

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	–	4.3 %
Confidence interval	–	–	–	–	4.2–4.5 %
Total number of cases	–	–	–	–	47,037

Aggregate result of all patients
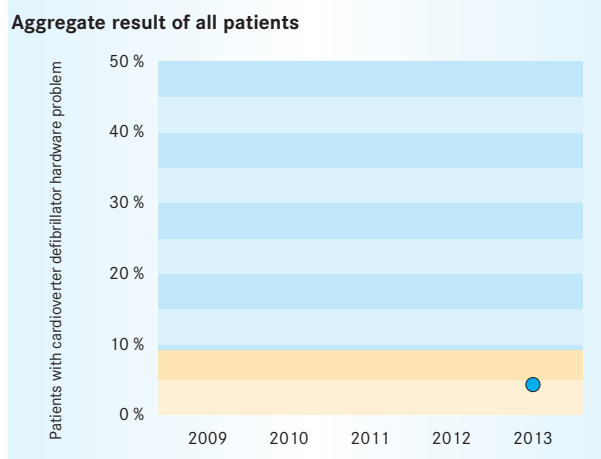
Hospital-based results

Target population of all hospitals	558
Number of hospitals with 0 cases	0

460 Hospitals with ≥ 20 cases
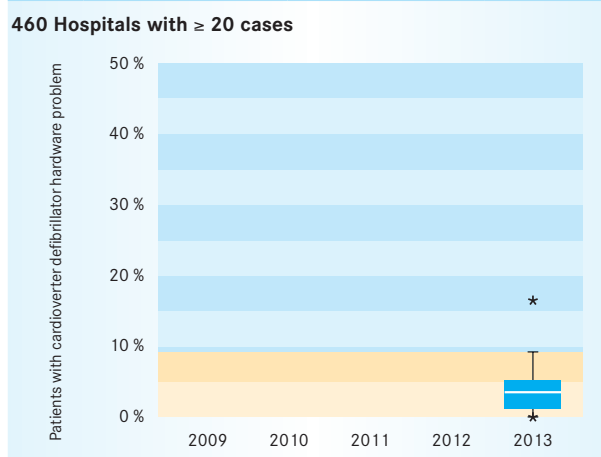
Median	3.4 %	Number of computationally discrepant hospitals	16 of 460
Range	0.0 – 16.5 %		

98 Hospitals with 1 to 19 cases

Median	0.0 %	Number of computationally discrepant hospitals	12 of 98
Range	0.0 – 50.0 %		

Implantable cardioverter defibrillators — Revision/system replacement/removal

QI-ID 52001: Procedure-associated problem (lead or pouch problem) as indication for follow-up intervention

Description

|	
Numerator	Patients suffering from a lead or pouch problem after previous ICD or pacemaker surgery performed at the same hospital. The following complications are considered: Pouch problems: Pouch hematoma or other pouch problem as long as the implantation of the generator/battery took place in the data collection year or in the previous year or the time of generator/battery implantation is not known. Lead problems: Dislodgement, lead fracture/insulation defect, diaphragmatic stimulation, oversensing, undersensing, stimulation loss/increase in pacing threshold, perforation or other lead problem. The aforementioned problems will not be considered unless the implantation of the affected lead took place less than one year prior thereto.
Denominator	All patients with implantation of cardioverter defibrillator (09/4) or replacement of generator/battery (09/5)
Reference range	≤ 6.0 % (tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	52001
Comparability with the previous year's results	Not calculated in the previous year

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	–	5.2 %
Confidence interval	–	–	–	–	4.9 – 5.4 %
Total number of cases	–	–	–	–	37,877

Aggregate result of all patients
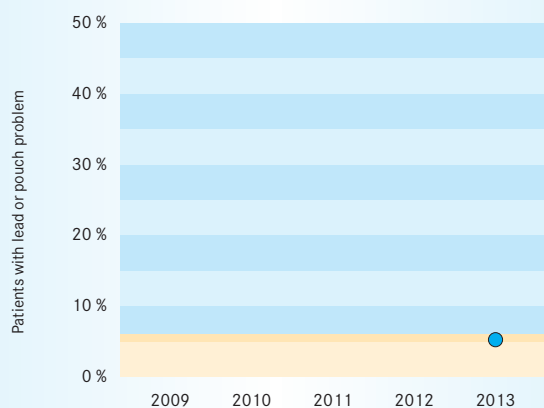
Hospital-based results

Target population of all hospitals	552
Number of hospitals with 0 cases	6

451 Hospitals with ≥ 20 cases
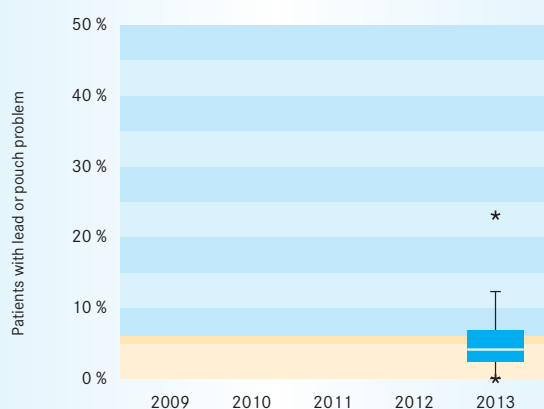
Median	4.1 %	Number of computationally discrepant hospitals	147 of 451
Range	0.0 – 23.1 %		

101 Hospitals with 1 to 19 cases

Median	0.0 %	Number of computationally discrepant hospitals	41 of 101
Range	0.0 – 50.0 %		

Quality target

The lowest possible frequency of procedure-associated problems in relation to the hospital's own implantation volume.

Background

All re-hospitalizations at a hospital due to procedure-associated problems are captured by the quality indicator. It was calculated for the first time in data collection year 2013, and combines the two indicators "Pouch problem as indication for intervention" (QI-ID 50032) and "Lead problem as indication for intervention" (QI-ID 50034) that were valid up to data collection year 2012. In contrast to these two indicators, the new quality indicator exclusively considers complications occurring within less than one year of lead and/or generator/battery implantation. Moreover, a fixed reference range of ≤ 6.0 % was selected instead of a percentile-based reference range.

Evaluating the results

The aggregate result for this quality indicator was 5.2 %. 188 hospitals (34.1 %) were computationally discrepant, i.e., they showed results of over 6.0 % and were thus above the reference range. These results should be regarded as potential deficiencies in implantable cardioverter defibrillator care. Since revision interventions at other hospitals are not additionally accounted for, the federal results suggest that the previously used applied calculation method without cross-institutional follow-up underestimated the frequency of procedure-associated problems by approx. 20 %.

Postoperative complications after cardioverter defibrillator interventions are also an internationally known problem and occur in Germany at a similar frequency as in comparable industrialized nations. Notwithstanding the above, all options should be exploited to improve this situation. Therefore, the Federal Experts' Working Group sees a special need for action here: In addition to the usual work-up of the computational discrepancies in the Structured Dialogue, more extensive measures are required, e.g., an exchange of information between responsible medical societies, or even supplementing existing guidelines, as appropriate.

After excluding pouch and lead problems occurring later than one year after implantation of the cardioverter defibrillator, this new indicator still only considers complications that were most likely caused by a lack of quality in the implantation process. To differentiate early from late complications, data fields are presently required that measure the time elapsing before a removed or revised lead has to be implanted. The introduction of a follow-up would enable an even more valid measurement of this time interval without explicitly documenting it, and – by obviating the aforementioned data fields – could lower documentation costs for the healthcare providers as well.

Coronary angiography and percutaneous coronary intervention (PCI)

Prof. Dr. Jürgen Pauletzki, Dr. Karl Tasche, Florian Rüppel, Federal Experts' Working Group for Cardiology

Introduction
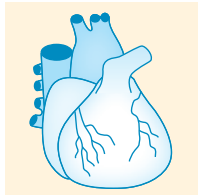
Coronary artery disease (CAD) is defined as a narrowing of the coronary arteries. The extent and localization of the stenoses are visualized by coronary angiography. The outcome of the coronary angiography is critical for deciding whether a balloon dilatation, possibly in conjunction with stenting or heart surgery (called bypass surgery), is necessary to restore blood supply (revascularization).

Percutaneous Coronary Intervention (PCI) includes balloon dilatation and stenting. During a PCI, a catheter with a small balloon attached to its tip is advanced over a guide wire up to the narrowing of the coronary vessel. Filling the balloon dilates (widens) the narrowing (balloon dilatation). To obtain the best long-term result in balloon dilatation while preventing the coronary arteries from narrowing again, a small "wire mesh" (stent) may be implanted if appropriate.

In addition to diagnosis, quality assurance in this area focuses on success and complication rates as well as the radiation burden to the patient. In this regard, the distinction is important as to whether coronary angiography and PCI should be performed separately or within the scope of a combined intervention ("one-stage PCI").

Services subject to mandatory documentation

Coronary angiography and percutaneous coronary intervention (PCI) in patients who are at least 18 years old.

Changes in comparison to the previous year

In the specification for data collection year 2013, the data field on transfer services was rephrased such that the question was changed from whether *no* transfer services where present, to whether *any* transfer services had existed. This reversed the meaning of the key values to be entered. Although all individual healthcare providers had been pre-informed in December 2012, the AQUA Institute and the State Administrative Offices for Quality Assurance (LQS) found a higher rate of documentation errors in this data field in 2013. For this reason, a reference range for the indicators "Rare recommendation for invasive therapy after coronary angiography" (QI-ID 2061) and "Common recommendation for invasive therapy after coronary angiography" (QI-ID 50750) was omitted in 2013 and the G-BA was requested to suspend the reporting requirement for the indicators.

The limitation of the target population to patients with PCI and length of stay of more than one day was suspended for the indicator "Incomplete documentation on diabetes mellitus and kidney failure" (QI-ID 2311). This meant that 494,281 more patients were included in this indicator.

After testing their suitability for public reporting, the G-BA decided that the indicators "Isolated coronary angiography with a contrast media volume > 150 ml" (QI-ID 51405), "Isolated PCI with a contrast media volume > 200 ml" (QI-ID 51406) and "One-stage PCI with a contrast media volume > 250 ml" (QI-ID 51407) also had to be published in the hospitals' quality reports starting in data collection year 2013.

Results

Again in data collection year 2013, the results point to an on average good quality of care in the clinical area *Coronary angiography and percutaneous coronary intervention (PCI)*.

The primary objective of coronary intervention – to improve myocardial circulation – was achieved in nearly 95 % of patients nationwide. This not only applied to the elective dilatation of vessel narrowing (stenoses), but also particularly to the emergency reopening of occluded coronary vessels in patients with acute myocardial infarction. The outcome indicators "Achieving the recanalization target in PCI with the indication 'Acute coronary syndrome with ST elevation up to 24 h'" (QI-ID 2063) and "Achieving the recanalization target in all PCI" (QI-ID 2064) remained stable at a high level.

Compared to the previous year, the risk-adjusted indicators for mortality showed no significant changes, neither after diagnostic ("Ratio of the observed to the expected rate (O / E) of deaths in isolated coronary angiography", QI-ID 50829) nor after therapeutic heart catheterization ("Ratio of the observed to the expected rate (O / E) of deaths in PCI", QI-ID 11863). The mortality rates in elective heart catheterization (coronary angiography or PCI) are low in patients without acute myocardial infarction. Overall mortality is determined by the mortality rate in patients with acute myocardial infarction. Further improvement measures at the hospitals should concentrate on this aspect. The Federal Experts' Working Group therefore continues to recommend a diagnosis-related focus of quality assurance on acute myocardial infarction.

The indicators on radiation protection show continuous improvement. The proportion of heart catheter examinations exceeding the recommended reference dose of the administered irradiation has declined significantly for the third year in a row. There have also been significant improvements in the volume of contrast media administered during heart catheterization.

For data collection year 2012, a total of 1,074 computational discrepancies were found for quality indicators of the clinical area *Coronary angiography and percutaneous coronary intervention (PCI)*. After review in the Structured Dialogue, 85 of them proved to be qualitative discrepancies.

The indicator "Isolated coronary angiography with dose area product > 3,500 cGy*cm²" (QI-ID 12774) was selected for detailed representation because this is where sustainable quality improvements were achieved.

Looking forward

Within the scope of developing the planned cross-sectoral QA procedure *Percutaneous coronary intervention (PCI) and coronary angiography*, the trial run at inpatient and outpatient hospitals was successfully concluded in 2013. On this followed the empirical testing of the included health insurance claims data. The data specification for the existing inpatient clinical area was further developed such that the adaptation to the data fields and the diagnostic indicators for the planned cross-sectoral procedure is ready for data collection year 2014 (e.g., data fields: "Door time", "Balloon time", "Coronary blood flow (TIMI)"; indicator: "Proportion of isolated coronary angiographies without

Coronary angiography and percutaneous coronary intervention (PCI)

pathological findings"). Moreover, the G-BA has commissioned the AQUA Institute to develop a procedure-specific patient survey for the cross-sectoral QA procedure.

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	733,424	729,553	725,967	100.5 %
Hospitals	890	885	912	97.0 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	729,451	100 %
< 30 years	2,275	0.3 %
30 – 39 years	7,893	1.1 %
40 – 49 years	47,083	6.5 %
50 – 59 years	123,266	16.9 %
60 – 69 years	170,798	23.4 %
70 – 79 years	267,744	36.7 %
≥ 80 years	110,392	15.1 %
Sex		
Male	470,956	64.6 %
Female	258,495	35.4 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/21n3/

Explanations to the following tables:

*   for regression-based quality indicators

**   not defined

***   not applicable

T   = tolerance range

[1]   MACCE = Major Adverse Cardiac and Cerebrovascular Events (intra- and post-procedural: stroke, heart attack, death)

[2]   The dose area product (Gy*cm² = 100cGy*cm²) is defined as the product of the irradiated area (in cm²) and the dose effective there (Gy = Gray).

Coronary angiography and percutaneous coronary intervention (PCI)

Case-based aggregate results (patients)

| | | | 2012 | 2013 | | | Trend |
| | | | | | Cases (patients) | | |
QI-ID	Name of the quality indicator		Result	Result	Numerator (O | E)*	Denominator	
399	Signs of ischemia as indication for elective coronary angiography	⚠	92.4 %	92.9 %	383,153	412,517	↗
	Recommended for invasive therapy after coronary angiography						
2061	Rare recommendation for invasive therapy after coronary angiography		39.7 %	40.5 %	180,103	444,295	n.a.***
50750	Common recommendation for invasive therapy after coronary angiography		39.7 %	40.5 %	180,103	444,295	n.a.***
2062	PCI despite lack of clinical and/or non-invasive signs of ischemia	⚠	4.0 %	3.7 %	5,318	144,028	↗
	Achieving the recanalization target in PCI						
2063	Achieving the recanalization target in PCI with the indication "Acute coronary syndrome with ST elevation up to 24 h"	⚠	94.5 %	94.6 %	44,495	47,031	→
2064	Achieving the recanalization target in all PCI	⚠	94.4 %	94.4 %	289,429	306,537	→
	MACCE[1]						
414	MACCE in isolated coronary angiography		1.3 %	1.4 %	6,202	435,907	↘
415	MACCE in PCI		3.3 %	3.5 %	10,288	293,544	↘
2232	MACCE in primary PCI due to an ST elevation infarction		8.8 %	9.3 %	4,749	51,053	→
	In-hospital mortality						
416	In-hospital mortality in isolated coronary angiography	⚠	1.1 %	1.2 %	4,966	411,621	↘
50829	Ratio of the observed to the expected rate (O / E) of deaths in isolated coronary angiography	⚠	1.00	1.05	4,189 1.10 % | 4,006 1.06 %	379,598	→
417	In-hospital mortality in PCI	⚠	2.7 %	2.8 %	8,143	290,087	→
11863	Ratio of the observed to the expected rate (O / E) of deaths in PCI	⚠	1.00	1.04	7,370 2.58 % | 7,095 2.49 %	285,248	→
2311	Incomplete documentation on diabetes mellitus and kidney failure		1.4 %	1.5 %	10,592	729,451	→
	Fluoroscopy time						
419	Median of fluoroscopy time in isolated coronary angiography	⚠	3.0 min	3.0 min		453,737	→
2073	Median of fluoroscopy time in PCI	⚠	9.0 min	9.3 min		306,537	↘
	Dose area product[2]						
12774	Isolated coronary angiography with dose area product > 3,500 cGy*cm²	⚠	26.4 %	23.9 %	108,139	452,436	↗
12775	One-stage PCI with dose area product > 6,000 cGy*cm²	⚠	29.7 %	28.0 %	8,387	29,938	↗
50749	One-stage PCI with dose area product > 8,000 cGy*cm²	⚠	24.4 %	22.0 %	60,558	275,534	↗
12773	Missing documentation of the dose area product		0.4 %	0.3 %	1,992	760,274	↗
	Contrast media volume						
51405	Isolated coronary angiography with a contrast media volume > 150 ml	⚠	8.5 %	8.0 %	36,151	453,737	↗
51406	Isolated PCI with a contrast media volume > 200 ml	⚠	20.5 %	21.2 %	6,379	30,117	→
51407	One-stage PCI with a contrast media volume > 250 ml	⚠	16.2 %	15.7 %	43,405	276,420	↗

For explanations of the table, see previous page.

Coronary angiography and percutaneous coronary intervention (PCI)

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
399	Signs of ischemia as indication for elective coronary angiography	≥ 80.0 % (TO)	822	59	2	A
	Recommended for invasive therapy after coronary angiography					
2061	Rare recommendation for invasive therapy after coronary angiography	n.d.**	833	–	X	X
50750	Common recommendation for invasive therapy after coronary angiography	n.d.**	833	–	X	X
2062	PCI despite lack of clinical and/or non-invasive signs of ischemia	≤ 10.0 % (TO)	647	44	2	A
	Achieving the recanalization target in PCI					
2063	Achieving the recanalization target in PCI with the indication "Acute coronary syndrome with ST elevation up to 24 h"	≥ 85.0 % (TO)	617	21	2	A
2064	Achieving the recanalization target in all PCI	≥ 85.0 % (TO)	730	26	2	A
	MACCE[1]					
414	MACCE in isolated coronary angiography	≤ 3.5 % (TO; 95th percentile)	865	46	2	A
415	MACCE in PCI	≤ 6.8 % (TO; 95th percentile)	730	48	2	A
2232	MACCE in primary PCI due to an ST elevation infarction	≤ 17.1 % (TO; 95th percentile)	620	44	2	A
	In-hospital mortality					
416	In-hospital mortality in isolated coronary angiography	n.d.**	861	–	X	X
50829	Ratio of the observed to the expected rate (O/E) of deaths in isolated coronary angiography	≤ 2.35 (TO; 95th percentile)	858	42	2	A
417	In-hospital mortality in PCI	n.d.**	726	–	X	X
11863	Ratio of the observed to the expected rate (O/E) of deaths in PCI	≤ 2.19 (TO; 95th percentile)	725	39	2	A
2311	Incomplete documentation on diabetes mellitus and kidney failure	n.d.**	875	–	X	X
	Fluoroscopy time					
419	Median of fluoroscopy time in isolated coronary angiography	≤ 5.0 min (TO)	865	36	2	A
2073	Median of fluoroscopy time in PCI	≤ 12.0 min (TO)	730	84	2	A
	Dose area product[2]					
12774	Isolated coronary angiography with dose area product > 3,500 cGy*cm²	≤ 47.2 % (TO; 95th percentile)	860	57	2	A
12775	One-stage PCI with dose area product > 6,000 cGy*cm²	≤ 57.3 % (TO; 95th percentile)	545	34	2	A
50749	One-stage PCI with dose area product > 8,000 cGy*cm²	≤ 46.1 % (TO; 95th percentile)	713	49	2	A
12773	Missing documentation of the dose area product	≤ 0.9 % (TO; 90th percentile)	875	97	2	A
	Contrast media volume					
51405	Isolated coronary angiography with a contrast media volume > 150 ml	≤ 19.7 % (TO; 95th percentile)	865	43	2	A
51406	Isolated PCI with a contrast media volume > 200 ml	≤ 50.7 % (TO; 95th percentile)	547	38	2	A
51407	One-stage PCI with a contrast media volume > 250 ml	≤ 35.7 % (TO; 95th percentile)	719	55	2	A

Indicator group (repeated as row group label on the left margin)

Coronary angiography and percutaneous coronary intervention (PCI)

QI-ID 12774: Isolated coronary angiography with dose area product > 3,500 cGy*cm²

Quality target

As few as possible isolated coronary angiographies with a dose area product > 3,500 cGy*cm².

Background

This indicator is important for patient protection and for occupational safety. Heart catheter examinations always require the application of radiation to verify the position of the catheter and to be able to visualize the coronary vessels filled with contrast media as well as the aorta and the cardiac spaces. In the estimation of the *European Society for Cardiology*, the radiation burden through cardiologic examinations to date already amounts to 40 % of the medical radiation burden (excluding irradiation for cancer) of the overall population. At the same time, the occupational radiation burden to interventional cardiologists is two to three times higher than to their counterparts in diagnostic radiology. To protect patients and examiners, the administered radiation dose should be kept as low as possible.

The radiation burden is measured as dose area product (Gy*cm² = 100 cGy*cm²), defined as the product of the irradiated area (in cm²) and the radiation dose effective there and expressed in "Gray" (Gy). In 2010, the German Federal Office for Radiation Protection set a reference dose of 3,500 cGy*cm² for purely diagnostic heart catheterizations (called isolated coronary angiographies). This indicator measures the proportion of coronary angiographies at a hospital that exceeds this reference dose.

Evaluating the results

Since the introduction of a new, set reference dose for the dose area product and redesign of the indicator into a rate-based indicator, the federal value improved significantly for the third year in a row. The rate of isolated coronary angiographies exceeding the reference dose of 3,500 cGy*cm² was 23.9 % in 2013 (2012: 26.4 %). The median (1,977 vs. 2.105 cGy*cm²) and the mean dose area product (2.707 vs. 2.881 cGy*cm²) declined similarly. Compared to 2010, the rate of coronary angiographies exceeding the reference dose dropped by a quarter. The median and the mean dose area product each dropped by nearly 20 %. Such a sustainable reduction in the radiation burden is evident in both coronary angiographies (QI-ID 12774) as well as in coronary interventions (QI-ID 50749 and QI-ID 12773). However, the fact that there are still hospitals where the majority of isolated coronary angiographies exceeded the reference dose (in isolated cases even up to 76 %) gives grounds for concern – seeing as today's modern heart catheter systems allow examinations to be performed with merely one-tenth of the reference dose. Continuing education for cardiologists on the optimized implementation of heart catheterization may also markedly reduce radiation burden.

The Structured Dialogue on the results of data collection year 2012 led to a follow-up on 53 qualitatively discrepant hospitals, 16 of whom were evaluated as "qualitatively discrepant". 12 hospitals showed evidence for process-related and structural deficiencies, 2 hospitals could not provide satisfactory explanations for their computational discrepancies and another 2 hospitals were "qualitatively discrepant" for other reasons. The largest number of qualitatively discrepant hospitals in the clinical area *Coronary angiography and percutaneous coronary intervention (PCI)* was shown in the indicators on dose area product.

Description

Numerator	Isolated coronary angiography with dose area product > 3.500 cGy*cm²
Denominator	All coronary angiographies with known dose area product
Reference range	≤ 47.2 % (95th percentile, tolerance range)
Risk adjustment	Stratification
QI-ID	12774
Comparability with the previous year's results	Comparable

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	32.2 %	29.9 %	26.4 %	23.9 %
Confidence interval	–	32.1–32.3 %	29.7–30.0 %	26.3–26.5 %	23.8–24.0 %
Total number of cases	–	441,175	447,529	459,887	452,436

Aggregate result of all patients
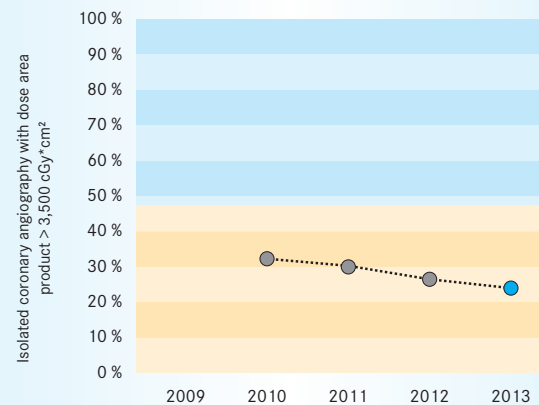
Hospital-based results

Target population of all hospitals	860
Number of hospitals with 0 cases	25

706 Hospitals with ≥ 20 cases
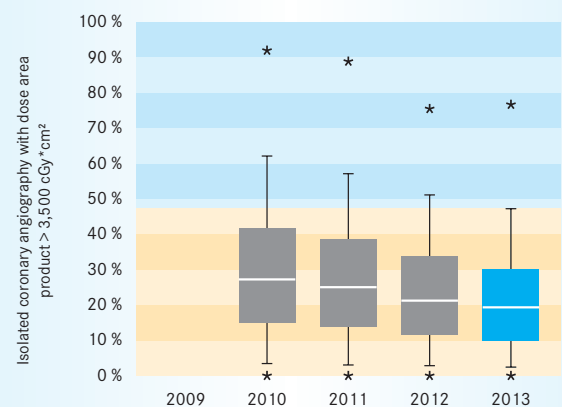
Median	19.3 %	Number of computationally discrepant hospitals	34 of 706
Range	0.0 – 76.7 %		

154 Hospitals with 1 to 19 cases

Median	9.2 %	Number of computationally discrepant hospitals	23 of 154
Range	0.0 – 100.0 %		

Coronary surgery, isolated

Dr. Tonia Kazmaier, Martina Köppen, Federal Experts' Working Group for Coronary Surgery

Introduction

Coronary artery disease (CAD) is defined as a narrowing of the coronary blood vessels. In most cases, hardening of the arteries (arteriosclerosis) is the cause of the disease. In the advanced stage of CAD, there is disproportion between oxygen demand and supply in the myocardium (heart muscles). This clinical picture manifests, for example, as sudden attacks of pain in the chest (angina pectoris).

The clinical consequences of CAD – including heart failure, myocardial infarction and cardiac arrhythmias – rank top in the statistics among the causes of death in Germany. Besides lowering mortality, the main objectives in the treatment of chronic CAD are to enhance the patient's quality of life by decreasing the frequency of angina pectoris, improving the patient's exercise capability, preventing clinical consequences of CAD (particularly myocardial infarction and heart failure).

Bypass surgery is one of the options for treating narrowed coronary vessels. This procedure involves taking a blood vessel (vein or artery) from elsewhere of the body and using it to replace the stenotic or occluded section of the coronary vessel. The clinical area presented here considers patients who have undergone surgery exclusively on their coronary blood vessels, hence the term "isolated coronary surgery".
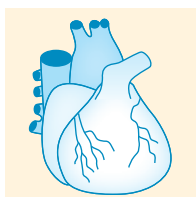
Services subject to mandatory documentation

All coronary surgeries performed on patients older than 18 years are documented. Simultaneous surgeries on the heart, heart valves (with the exception of the aortic valve) and vessels close to the heart as well as simultaneous interventions on the internal carotid artery and heart surgery performed for treating polytrauma are excluded from the mandatory documentation. To ensure comparability of hospital-based results, the analysis of this clinical area only presents isolated surgeries on the coronary arteries.

Changes in comparison to the previous year

None.

Results

All results at the federal level in this clinical area are almost unchanged compared to the previous year. Consideration of the results at the hospital level reveals a certain inhomogeneity. However, the Federal Experts' Working Group's sees no special need for action because the overall spread of the results is not wide enough and the explanation of the computational discrepancies has been evaluated as sufficient in the Structured Dialogue.

Based on the data from 2012, a total of 15 computationally discrepant results (15 hospitals) were identified by the quality indicators and the Structured Dialogue initiated in the clinical area *Coronary surgery, isolated*. After conclusion of the Structured Dialogue, 7 computational discrepancies (7 hospitals) were evaluated as "qualitatively discrepant". Representatives of one hospital were invited to a "colleague-to-colleague" talk. The talk examined the reasons for the computationally discrepant result on the indicator "Ratio of the observed to the expected rate (O / E) of deaths" (QI-ID 11617); target agreements were concluded to improve quality. The representatives of this hospital were instructed to analyze their cases of death, particularly in the low-risk cohort, in all clinical areas with cardiac procedures and surgeries and to report the results to the Federal Experts' Working Group. Moreover, in a target agreement, it was stipulated that interdisciplinary morbidity and mortality conferences should be held at regular intervals, the minutes thereof be taken and a complication management concept be developed.

Looking forward

The aggregate results in this clinical area are stable for the currently evaluable quality indicators and indicate a good quality of care. However, to arrive at more comprehensive conclusions about the quality of care, it is necessary to extend the observation period. The Federal Experts' Working Group therefore welcomes the fact that the Federal Joint Committee has commissioned the institution mandated by section 137a of the German Social Code, Book Five (SGB V), to develop a follow-up method for the clinical area *Coronary surgery, isolated*, i.e., to collect follow-up data after one and after several years using the health insurance claims data. The development of follow-up indicators will add more quality aspects and allow more detailed assessment.

In the past 5 years, the caseload in the clinical area *Coronary surgery, isolated* dropped by nearly 8 %. This caseload trend can neither be explained by current scientific recommendations / guidelines nor by demographic developments. To achieve a more exact interpretation, it would make sense to consider the different therapeutic options in aggregate – commensurate with the clinical picture of coronary artery disease (CAD) – not just the procedure "Coronary surgery, isolated". For that reason, the Federal Experts' Working Group only regards the development of follow-up indicators based on health insurance claims data for the clinical area *Coronary surgery, isolated* as the first step only. The next step should be to apply the health insurance claims data for a comprehensive examination of the two major pillars in the treatment of coronary artery disease – percutaneous coronary intervention (PCI) and isolated coronary surgery.

Coronary surgery, isolated

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	67,600	67,443	67,567	99.8 %
Hospitals	94	97	100	97.0 %
Of which coronary surgery, isolated				
Records	40,532	39,907	n.a.	n.a.

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	39,598	100 %
< 50 years	1,813	4.6 %
50 – 59 years	6,864	17.3 %
60 – 69 years	11,597	29.3 %
70 – 79 years	15,931	40.2 %
80 – 89 years	3,362	8.5 %
≥ 90 years	31	0.1 %
Sex		
Male	31,392	79.3 %
Female	8,206	20.7 %
ASA classification		
ASA 1: A normal healthy patient	1,059	2.7 %
ASA 2: A patient with mild systemic disease	3,842	9.7 %
ASA 3: A patient with severe systemic disease	28,629	72.3 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	5,832	14.7 %
ASA 5: A moribund patient who is not expected to survive without the operation	236	0.6 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):

www.sqg.de/themen/HCH-K/

Coronary surgery, isolated

Case-based aggregate results (patients)

| | | | 2012 | 2013 | | | |
| | | | | **Cases (patients)** | | | |
QI-ID	Name of the quality indicator		Result	Result	Numerator (O | E) *	Denominator	Trend
332	Use of the left internal mammary artery	ⓘ	94.1 %	94.2 %		31,825	33,801	→
	Postoperative mediastinitis						
2256	Postoperative mediastinitis after elective/urgent surgery		0.4 %	0.3 %		116	33,798	→
2257	Postoperative mediastinitis in risk class 0 or 1 (by NNIS)[1]		0.4 %	0.3 %		97	31,301	→
2259	Neurological complications in elective/urgent surgery		0.8 %	0.9 %		280	32,189	→
	Mortality						
348	In-hospital mortality	ⓘ	3.1 %	3.0 %		1,187	39,561	→
349	In-hospital mortality after elective/urgent surgery	ⓘ	2.0 %	1.9 %		654	33,822	→
11617	Ratio of the observed to the expected rate (O / E) of deaths	ⓘ	1.00	0.93	1,126 2.90 % | 1,216 3.13 %	38,847	→
353	Status on the 30th postoperative day	ⓘ	79.2 %	79.2 %		31,347	39,561	→
351	Mortality after 30 days	ⓘ	3.1 %	3.1 %		719	22,899	→

Note: *Indicator group* labels appear in the left margin spanning the mediastinitis/neurological rows and the mortality rows.

* for regression-based quality indicators

[1] NNIS *(National Nosocomial Infections Surveillance)*: This is an additive score used in risk adjustment; one risk point is assigned whenever ASA ≥ 3, surgery time > 75th percentile of the distribution of the surgery type under review and / or the intervention is contaminated or septic.

Coronary surgery, isolated

Hospital-based aggregate results for utilization in quality assurance

	QI-ID	Name of the quality indicator	Reference range	2013 Hospitals Total	2013 Hospitals Discrepant (computationally)	2013 Evaluation Category	2013 Evaluation Need for action
	332	Use of the left internal mammary artery	≥ 90.0 % (TA)	80	4	1	A
Indicator group		Postoperative mediastinitis					
	2256	Postoperative mediastinitis after elective/urgent surgery	n.d.*	80	–	X	X
	2257	Postoperative mediastinitis in risk class 0 or 1 (by NNIS)	≤ 1.3 % (TO; 95th percentile)	80	2	2	A
	2259	Neurological complications in elective/urgent surgery	≤ 2.1 % (TO; 95th percentile)	80	3	2	A
Indicator group		Mortality					
	348	In-hospital mortality	n.d.*	80	–	X	X
	349	In-hospital mortality after elective/urgent surgery	n.d.*	80	–	X	X
	11617	Ratio of the observed to the expected rate (O / E) of deaths	≤ 1.56 (TO; 90th percentile)	80	7	2	A
	353	Status on the 30th postoperative day	n.d.*	80	–	X	X
	351	Mortality after 30 days	n.d.*	44	–	X	X

TO = Tolerance range; TA = Target range; * not defined

Coronary surgery, isolated

QI-ID 353: Status on postoperative day 30

Description	
Numerator	Patients with known status on the 30th postoperative day (follow-up rate)
Denominator	All patients undergoing isolated coronary surgery in their primary surgery
Reference range	Not defined
Risk adjustment	No further risk adjustment
QI-ID	353
Comparability with the previous year's results	Comparable

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	77.1 %	78.5 %	78.3 %	79.2 %	79.2 %
Confidence interval	76.7–77.5 %	78.1–78.9 %	77.9–78.7 %	78.8–79.6 %	78.8–79.6 %
Total number of cases	42,861	41,359	40,311	40,160	39,561

Aggregate result of all patients
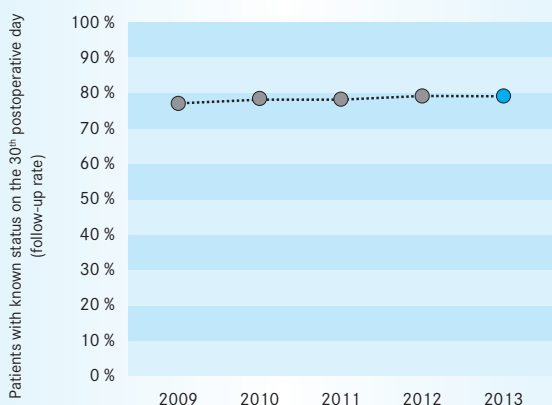
Hospital-based results

Target population of all hospitals	80
Number of hospitals with 0 cases	17

79 Hospitals with ≥ 20 cases
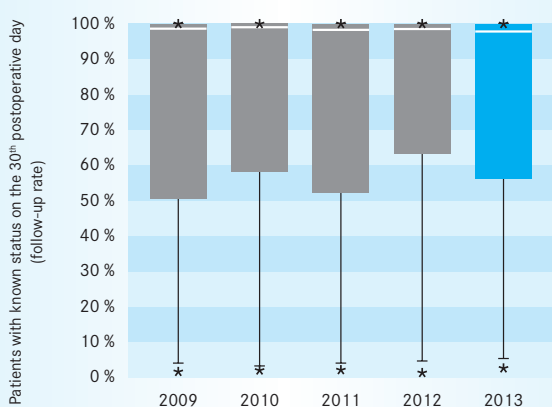
Median	97.8 %	Number of computationally discrepant hospitals	–
Range	2.6 – 100.0 %		

1 Hospital with 1 to 19 cases

Median	0.0 %	Number of computationally discrepant hospitals	–
Range	0.0 – 0.0 %		

Quality target

Most frequent rate of known status on the 30th postoperative day.

Background

The indicator measures the follow-up rate with respect to patients who underwent surgery on their coronary vessels. This provides conclusive evidence about the extent to which the hospital knows the status of each patient 30 days after surgery. The analysis of perioperative mortality is one of the standards for studying postoperative complications. The indicator "In-hospital mortality" (QI-ID 348) captures all patients who died in the hospital during the same stay, without stating the respective time of death.

However, conclusions about the outcome quality of a hospital can only be reached after considering the fact that patients might not have been captured who were transferred earlier to another hospital and died. For that reason, the literature will frequently cite 30-day mortality alongside in-hospital mortality. However, 30-day mortality is not solely influenced by the quality of the care. The outcomes of medical and nursing care also depend on the risk profile of the patients treated in the respective department.

Evaluating the results

In data collection year 2013, the voluntarily documented status on the 30th postoperative day was known in 79.2 % of the cases. Compared to 2009, this rate has only risen marginally (77.1 %). The indicator "Mortality after 30 days" (QI-ID 351) is calculated exclusively for hospitals whose rate on the indicator "Status on the 30th postoperative day" (QI-ID 353) is > 97 %. This applies to 44 out of a total of 80 participating hospitals.

The Federal Experts' Working Group points out that an urgent need to follow up on patients beyond their primary hospital stay continues to exist in order to be able to analyze medium and long-term results as well. The Federal Experts' Working Group therefore welcomes the fact that the Federal Joint Committee has commissioned the institution mandated by section 137a SGB V to develop a follow-up method for the clinical area *Coronary surgery, isolated* using health insurance claims data.

Aortic valve surgery, isolated

Dr. Tonia Kazmaier, Martina Köppen, Federal Experts' Working Group for Heart Surgery

Introduction
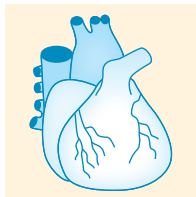
The aortic valve is the "gateway" between the left cardiac ventricle and the aorta. Aortic valve failure is referred to when this valve fails to close properly. A narrowing of this valve is termed aortic valve stenosis.

Both of these functional disorders require the heart to work harder to pump blood and lead to an overburdening of the heart muscle. The symptoms of aortic valve stenosis depend on how severely the blood flow is restricted. Possible signs include exercise-induced shortness of breath, premature fatigue, dizziness and tendency to collapse, irregular cardiac rhythm or heart pain. Low-grade aortic valve stenosis often follows an asymptomatic course. In severe cases, diseases of the aortic valve are treated surgically by implanting an artificial heart valve.

Aortic valve replacement can be performed by "open" surgery where the heart is stopped and a heart-lung machine is employed. Access is gained to the heart through the rib cage (i.e., conventional method).

In patients with high surgical risk, the aortic valve can optionally be implanted by a catheter-supported method. This procedure uses either a "transapical" or "endovascular" (synonym: transvascular) access during surgery.

■ In transapical aortic valve replacement, the apex of the heart is exposed by making a 3- to 5-cm-long incision through the ribs (left rib cage, in the 4th or 5th intercostal space).

■ Endovascular aortic valve replacement only requires a targeted puncture, usually into the inguinal artery.

Both catheter-supported methods are initiated by dilating the segment of the old, constricted aortic valve using a special balloon catheter system. Next, the folded heart valve prosthesis is advanced through a catheter into this position, where the prosthesis is deployed.

The clinical area presented here only considers patients in whom the aortic valve alone was treated.

Because the "conventional" and/or "catheter-supported" procedures are very different and also, in particular, the affected patients differ in terms of risk profile, the two methods are calculated separately:

■ Aortic valve surgery, isolated – conventional
■ Aortic valve surgery, isolated – catheter-supported

Services subject to mandatory documentation

All surgical interventions on the aortic valve in patients aged > 18 years using the heart-lung machine as well as all catheter-supported interventions on the aortic valve (transapical or endovascular) are recorded. Simultaneous surgery on the heart, heart valves (with the exception of the aortic valve) and vessels close to the heart as well as simultaneous interventions on the internal carotid artery and heart surgery performed to treat multiple trauma are excluded from mandatory documentation.

Changes in comparison to the previous year

The risk adjustment model that has been used successfully for years has been further developed ("Aortic valve score 2.0") on the basis of current data (a 50 % random sample of data from 2011 and 2012). The new model no longer includes in the risk assessment those risk factors from the old model that current data showed to no longer significantly impacted mortality. In addition, new risk factors that do significantly impact mortality (e.g., diabetes mellitus) have been added. For particulars, see chapter "Risk adjustment and caseload-prevalence problem".

Based on recognized guidelines, the indicators "Indication for catheter-supported aortic valve replacement based on logistic euroSCORE I" (QI-ID 51914) and "Indication for catheter-supported aortic valve replacement based on logistic aortic valve score 2.0" (QI-ID 51915) have been introduced. These new indicators are a further methodological development of the previous indicators "Indication for catheter-supported aortic valve replacement based on logistic euroSCORE I" (QI-ID 51088) and "Indication for catheter-supported aortic valve replacement based on logistic AKL score" (QI-ID 51434), which they replace. In addition to the medical indication criteria used previously (high risk based on euroSCORE, age > 75 years), other criteria are now considered as well (porcelain aorta, frailty, prognosis-limiting second disease, malignancy, patient's wish).

In order to also be able to record periprocedural complications (chronologically related to the surgery) in this clinical area, the indicators "Intraprocedural complications" (QI-ID 51916) and "Vascular complications" (QI-ID 52007) have been newly developed.

Results

The aggregate results in this clinical area are stable and indicate a good quality of care.

Since 2010, the completeness of the documentation has been studied separately for the endovascular and transapical access. The completeness rates have steadily improved over recent years and are now in an acceptable range for the endovascular access as well, at a total of 97.5 %. To achieve further improvement, the Structured Dialogue is held with all hospitals showing a documentation rate of less than 95 % (n = 9).
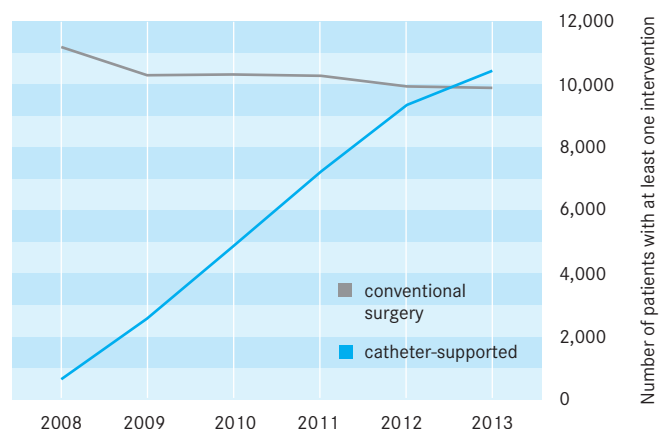

Figure 1: Number of patients with at least 1 aortic valve intervention

Aortic valve surgery, isolated

In the past 6 years, the number of records provided for catheter-supported aortic valve surgery has increased from 637 to 10,602. For the first time in data collection year 2013, more catheter-supported interventions were performed on the aortic valve than conventional (Fig. 1).

In data collection year 2013, an aortic valve was implanted without institutionalized cardiac surgery in 4.6 % of patients at 17 hospitals (Fig. 2) overall. Compared to the previous year, the proportion of patients and the number of hospitals has barely changed (2012: 4.8 %; n = 18). Five hospitals that undertook catheter-supported aortic valve implantations in data collection year 2012 no longer provided this service in 2013. Four hospitals provided this service for the first time in data collection year 2013.
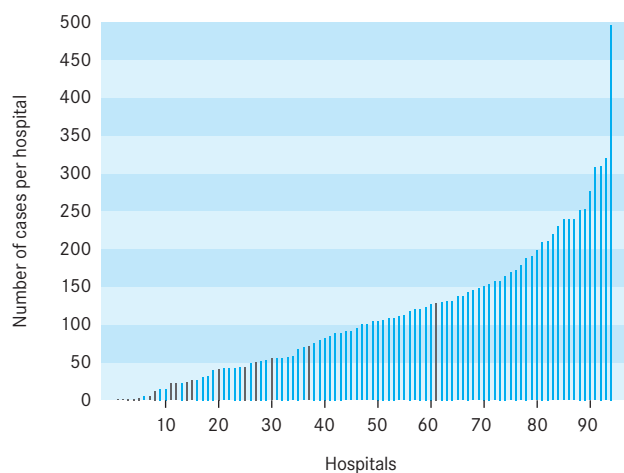

Figure 2: Catheter-supported aortic valve interventions by number of cases per hospital in data collection year 2013: Institutionalized cardiac surgery present (blue), cardiac surgery not present (gray)

Based on the data from 2012, a total of 26 computationally discrepant results (22 hospitals) were identified and the Structured Dialogue initiated in the clinical area *Aortic valve surgery, isolated*. After the completion of the Structured Dialogue, 12 computational discrepancies (11 hospitals) were evaluated as "qualitatively discrepant". Representatives of 2 hospitals were invited to a "colleague-to-colleague" talk. In the discussion with the representatives of one hospital, the reasons for the computationally discrepant result in the indicator "Ratio of the observed to the expected rate (O / E) of deaths" (QI-ID 12092) were examined and a target agreement for quality improvement was concluded with the particular aim of reducing the mortality rate. It was stipulated that regular and minuted interdisciplinary morbidity and mortality conferences should be implemented in addition to a thorough internal analysis of the deaths. Above and beyond this, a concept of complication management was to be developed. Proof of its implementation has meanwhile been provided and the results are checked continuously. The representatives of the other institution were urged to improve the department's documentation and reporting system and to send a documentation workflow to the Federal Experts' Working Group as proof thereof since the main causes of the computational discrepancies here were documentation problems.

For data collection year 2012, a reference range (10th percentile) was defined for the first time for the indicator "Indication for catheter-supported aortic valve replacement based on logistic euroSCORE I" (QI-ID 51088). Thus, in 10 % of hospitals with the lowest rates of fulfillment of the indication criteria, it was possible to analyze the reasons for this within the framework of the Structured Dialogue. To obtain the most targeted information on how the quality requirements of the guidelines were implemented and what further reasons other than age and high risk would be accepted by the hospitals as indication criteria for catheter-supported aortic valve replacement, the Federal Experts' Working Group developed a special questionnaire that was sent out to all hospitals with a computationally discrepant result. The survey revealed that a special team for catheter-supported aortic valve interventions had been set up in all the hospitals mailed. However, the composition of the teams and, in particular, the frequency of discussions (e.g., "daily" versus "once a month") varied greatly. Half the hospitals surveyed reported discussing all patients with aortic valve stenosis within this team with the aim of establishing the medical indication. Only two of these hospitals reported that minutes of these sessions had been taken. Besides age and euroSCORE, guideline-compliant reasons such as porcelain aorta or frailty were frequently mentioned as additional indication criteria. Other reasons such as heart failure, dialysis or dementia were also given as indication criteria.

Looking forward

In recent years, the management of aortic valve stenoses has changed considerably with the introduction of catheter-supported procedures. Quality assurance of aortic valve surgery has made it possible to support innovation and monitor this change. This is of particular importance as German legislation currently allows the virtually uncontrolled introduction of new – and scientifically almost untested – medical devices into hospital care. Within the scope of external quality assurance, it would also be possible in individual cases to undertake effective action with respect to patient safety – e.g., in terms of diagnosis. It has been shown that external quality assurance can be of great benefit, particularly in areas of healthcare that are undergoing change.

The Federal Experts' Working Group takes a critical view on the fact that the invasive care of mitral valve diseases is currently undergoing dramatic changes without being subject to external quality assurance or structured multicenter quality monitoring. In the interests of patient safety, there appears to be an urgent need to reactivate the quality assurance procedure in this area that was abandoned about 10 years ago.

The indicator set for the clinical area *Aortic valve surgery, isolated* has undergone continual development in recent years. For 3 years now, this has also involved recording the aspect of rendering the medical indication. By introducing new data fields, the indicator group "Indication for catheter-supported aortic valve replacement" has been further developed such that the recommendations from international guidelines can now be comprehensively mapped. With the introduction of indicators on periprocedural complications, the quality of the result in terms of adverse events is now extensively recorded.

Aortic valve surgery, isolated

The observation period for recording and assessing the outcome quality is still unsatisfactory at present. The restriction to inpatient stays limits the predictive power of the result indicators. The further development commissioned by the Federal Joint Committee in 2013 will make it possible to determine the optimum observation periods for comparing healthcare providers in terms of outcome quality thanks to the use of health insurance claims data.

Overall, it may be ascertained that the clinical area *Aortic valve surgery, isolated* already possesses good instruments for mapping the quality of care and will experience a marked improvement thanks to the use of health insurance claims data. However, it is not currently possible, even with the claims data, to record the extent to which the primary treatment aims have been achieved. A supplementary patient survey here could contribute to a further substantive analysis of the quality assurance procedure. The extension of the indicator set to include indicators from a patient survey would allow very extensive consideration of the relevant aspects of the quality of care in this clinical area, which in turn would be regarded as nearly optimal within the scope of practical possibilities.

Aortic valve surgery, isolated

Data basis				
	2012	**2013**		
	Reported	Reported	Expected	Case completeness
Records	67,600	67,443	67,567	99.8 %
Hospitals	94	97	100	97.0 %
Of which, aortic valve surgery, isolated – conventional				
Records	10,324	10,117	n.a.	n.a.
Of which clinical area for target caseload: Aortic valve surgery, isolated – catheter-supported endovascular				
Records	6,782	7,682	7,876	97.5 %
Of which clinical area for target caseload: Aortic valve surgery, isolated – catheter-supported transapical				
Records	2,903	2,920	2,921	100.0 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
Isolated aortic valve surgery – conventional
www.sqg.de/themen/HCH-AORT-CHIR/
Isolated aortic valve surgery – catheter-supported
www.sqg.de/themen/HCH-AORT-KATH/

Basic statistics		
Aortic valve surgery, isolated – conventional		
	2013	
	Number	Proportion
Age distribution		
Number of patients	9,883	100 %
< 50 years	606	6.1 %
50 – 59 years	1,265	12.8 %
60 – 69 years	2,285	23.1 %
70 – 79 years	4,552	46.1 %
80 – 89 years	1,164	11.8 %
≥ 90 years	11	0.1 %
Sex		
Male	5,967	60.4 %
Female	3,916	39.6 %
ASA classification		
ASA 1: A normal healthy patient	353	3.6 %
ASA 2: A patient with mild systemic disease	1,163	11.8 %
ASA 3: A patient with severe systemic disease	7,384	74.7 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	948	9.6 %
ASA 5: A moribund patient who is not expected to survive without the operation	35	0.4 %

Basic statistics		
Aortic valve surgery, isolated – catheter-supported		
	2013	
	Number	Proportion
Age distribution		
Number of patients	10,426	100 %
< 50 years	16	0.2 %
50 – 59 years	50	0.5 %
60 – 69 years	356	3.4 %
70 – 79 years	3,386	32.5 %
80 – 89 years	6,036	57.9 %
≥ 90 years	582	5.6 %
Sex		
Male	4,860	46.6 %
Female	5,566	53.4 %
ASA classification		
ASA 1: A normal healthy patient	199	1.9 %
ASA 2: A patient with mild systemic disease	709	6.8 %
ASA 3: A patient with severe systemic disease	7,814	74.9 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	1,662	15.9 %
ASA 5: A moribund patient who is not expected to survive without the operation	42	0.4 %

Aortic valve surgery, isolated

Case-based aggregate results (patients)

| | | | 2012 | 2013 | | | |
| | | | | Cases (patients) | | | |
QI-ID	Name of the quality indicator		Result	Result	Numerator (O | E)*	Denominator	Trend
Aortic valve surgery, isolated – conventional							
	Postoperative mediastinitis						
2263	Postoperative mediastinitis after elective/urgent surgery		0.3 %	0.2 %	19	9,493	→
2280	Postoperative mediastinitis in risk class 0 or 1 (NNIS)[1]		0.2 %	0.2 %	15	7,719	→
2282	Neurological complications of elective/urgent surgery		0.8 %	0.8 %	75	9,116	→
52006	Intraprocedural complications		0.5 %	0.5 %	50	9,853	→
	Mortality						
340	In-hospital mortality	⚠	2.9 %	2.8 %	278	9,853	→
341	In-hospital mortality after elective/urgent surgery	⚠	2.2 %	2.3 %	217	9,501	→
12092	Ratio of the observed to the expected rate (O / E) of deaths	⚠	0.91	0.86	271 / 2.78 % | 314 / 3.22 %	9,758	→
345	Status on the 30th postoperative day	⚠	80.5 %	79.5 %	7,838	9,853	→
343	Mortality after 30 days	⚠	2.8 %	2.8 %	161	5,709	→
Aortic valve surgery, isolated – catheter-supported							
	Indication for catheter-supported aortic valve replacement						
51914	Indication for catheter-supported aortic valve replacement based on logistic euroSCORE I	⚠[2]	n.c.**	74.8 %	7,728	10,335	n.a.***
51915	Indication for catheter-supported aortic valve replacement based on logistic aortic valve score 2.0		n.c.**	60.9 %	6,250	10,268	n.a.***
12001	Neurological complications of elective/urgent surgery		1.3 %	1.6 %	148	9,464	→
51916	Intraprocedural complications		5.1 %	5.5 %	568	10,409	→
52007	Vascular complications		7.3 %	8.5 %	885	10,409	↘
	Mortality						
11994	In-hospital mortality	⚠	5.8 %	5.7 %	595	10,409	→
11995	In-hospital mortality after elective/urgent surgery	⚠	5.6 %	5.4 %	557	10,322	→
12168	Ratio of the observed to the expected rate (O / E) of deaths	⚠	0.94	0.90	586 / 5.71 % | 648 / 6.31 %	10,268	→
11997	Status on the 30th postoperative day	⚠	73.2 %	70.8 %	7,374	10,409	↘
11996	Mortality after 30 days	⚠	6.7 %	6.5 %	262	4,005	→

* for regression-based quality indicators; ** not calculated; *** not applicable

[1] NNIS *(National Nosocomial Infections Surveillance)*: This involves what is called an additive score used in risk adjustment: one risk point is assigned whenever ASA ≥ 3, duration of surgery > 75th percentile of the distribution of the duration of the procedure for the type of surgery under review, and/or the intervention is contaminated or septic.

[2] In accordance with the G-BA's plenary decision dated 19 June 2014, this indicator is subject to mandatory reporting. Contrary to the usual methodology, no testing and assessment were performed with this indicator with respect to its suitability for public reporting.

Aortic valve surgery, isolated

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		Evaluation	
QI–ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
Aortic valve surgery, isolated – conventional						
	Postoperative mediastinitis					
2263	Postoperative mediastinitis after elective/urgent surgery	n.d.*	80	–	X	X
2280	Postoperative mediastinitis in risk class 0 or 1 (NNIS)	≤ 1.2 % (TO; 95th percentile)	80	3	1	A
2282	Neurological complications of elective/urgent surgery	≤ 2.7 % (TO; 95th percentile)	80	3	1	A
52006	Intraprocedural complications	n.d.*	80	–	X	X
	Mortality					
340	In-hospital mortality	n.d.*	80	–	X	X
341	In-hospital mortality after elective/urgent surgery	n.d.*	80	–	X	X
12092	Ratio of the observed to the expected rate (O / E) of deaths	≤ 1.91 (TO; 90th percentile)	80	8	1	A
345	Status on the 30th postoperative day	n.d.*	80	–	X	X
343	Mortality after 30 days	n.d.*	43	–	X	X
Aortic valve surgery, isolated – catheter-supported						
	Indication for catheter-supported aortic valve replacement					
51914	Indication for catheter-supported aortic valve replacement based on logistic euroSCORE I	≥ 52.0 % (TO; 10th percentile)	93	9	2	B
51915	Indication for catheter-supported aortic valve replacement based on logistic aortic valve score 2.0	n.d.*	93	–	X	X
12001	Neurological complications of elective/urgent surgery	≤ 3.5 % (TO; 95th percentile)	92	4	1	A
51916	Intraprocedural complications	n.d.*	93	–	X	X
52007	Vascular complications	n.d.*	93	–	X	X
	Mortality					
11994	In-hospital mortality	n.d.*	93	–	X	X
11995	In-hospital mortality after elective/urgent surgery	n.d.*	93	–	X	X
12168	Ratio of the observed to the expected rate (O / E) of deaths	≤ 1.82 (TO; 95th percentile)	93	6	2	A
11997	Status on the 30th postoperative day	n.d.*	93	–	X	X
11996	Mortality after 30 days	n.d.*	34	–	X	X

TO = Tolerance range; * not defined

Aortic valve surgery, isolated

QI-ID 52006: Intraprocedural complications – conventional

Quality target

Rare occurrence of intraprocedural complications.

Background

Patients with acute and severe aortic valve failure have a poor prognosis in the absence of surgery due to their hemodynamic instability. The operative mortality rate in isolated aortic valve surgery is relatively low at less than 3 %. However, an analysis of secondary endpoints showed that an isolated catheter-supported aortic valve intervention has a higher risk for cerebrovascular events (e.g., stroke) and vascular (vessel-related) complications and a higher incidence of paravalvular leakage (valve ring leak) than isolated conventional aortic valve replacement surgery.

The systematic recording of intraprocedural complications can provide information about the quality of care and expose any areas of deficiency in care, as well as providing an impetus for implementing and controlling quality improvement strategies.

Evaluating the results

This indicator was newly developed for data collection year 2013 and consequently there is as yet no reference range.

In data collection year 2013, an intraprocedural complication was documented in only 50 out of 9,853 cases. This small number indicates that conventional aortic valve surgery is a method with high procedural safety. A definitive assessment, however, is not currently possible. The Federal Experts' Working Group will define a reference range for the data collection year 2014 so that further findings can be collected within the scope of the Structured Dialogue.

Description	
Numerator	Patients in whom at least one severe intraprocedural complication occurred
Denominator	All patients undergoing isolated conventional aortic valve surgery in their primary surgery
Reference range	Not defined
Risk adjustment	No further risk adjustment
QI-ID	52006
Comparability with the previous year's results	The indicator was newly introduced and calculated retrospectively for the previous year.

Case-based results (patients)	2009	2010	2011	2012	2013
Aggregate result	–	–	–	0.5 %	0.5 %
Confidence interval	–	–	–	0.4–0.7 %	0.4–0.7 %
Total number of cases	–	–	–	9,900	9,853

Aggregate result of all patients
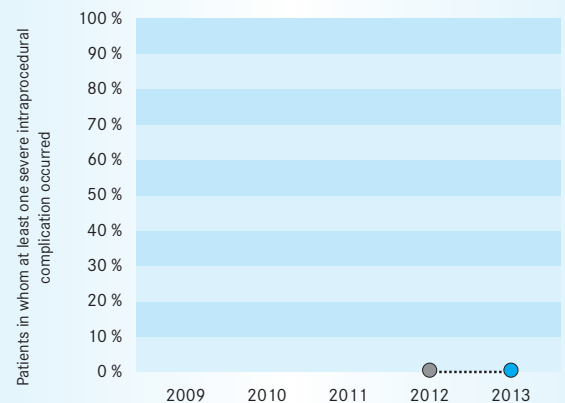
Hospital-based results	
Target population of all hospitals	80
Number of hospitals with 0 cases	17

77 Hospitals with ≥ 20 cases
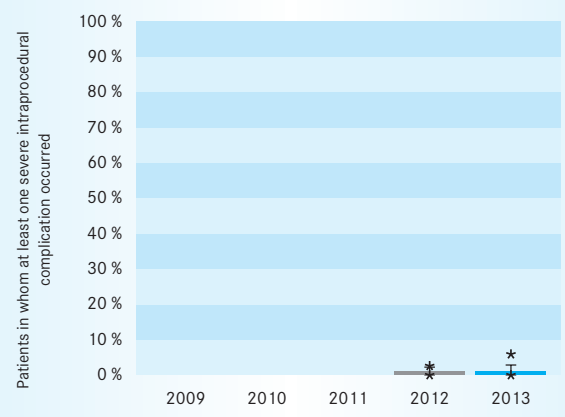
Median	0.0 %	Number of computationally discrepant hospitals	–
Range	0.0 – 5.9 %		

3 Hospitals with 1 to 19 cases

Median	0.0 %	Number of computationally discrepant hospitals	–
Range	0.0 – 0.0 %		

Aortic valve surgery, isolated

QI-ID 51914: Indication for catheter-supported aortic valve replacement based on logistic euroSCORE I

Description

Numerator	Patients > 75 years with a logistic euroSCORE I > 20 % or existing contraindication to open surgery
Denominator	All patients undergoing primary isolated catheter-supported surgery on the aortic valve in their primary surgery and with complete documentation for the logistic euroSCORE I
Reference range	≥ 52.0 % (10th percentile, tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	51914
Comparability with the previous year's results	A retrospective calculation for data collection year 2012 is not possible because the corresponding parameters were not recorded.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	–	74.8 %
Confidence interval	–	–	–	–	73.9–75.6 %
Total number of cases	–	–	–	–	10,335

Aggregate result of all patients
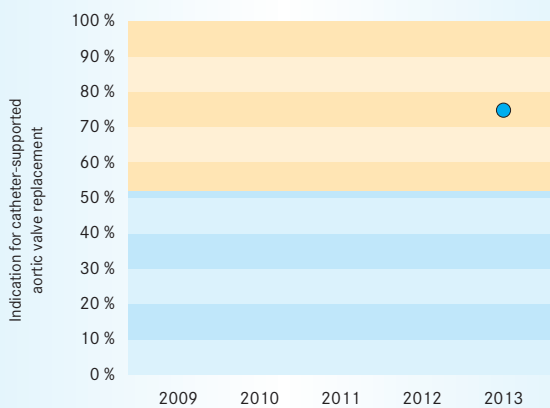
Hospital-based results

Target population of all hospitals	93
Number of hospitals with 0 cases	4

83 Hospitals with ≥ 20 cases
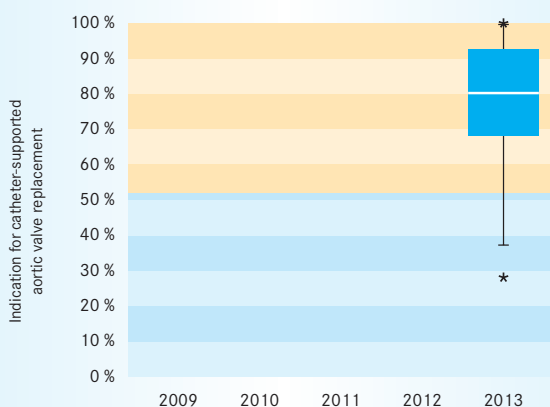
Median	80.2 %	Number of computationally discrepant hospitals	8 of 83
Range	28.1 – 100.0 %		

10 Hospitals with 1 to 19 cases

Median	100.0 %	Number of computationally discrepant hospitals	1 of 10
Range	0.0 – 100.0 %		

Quality target

Indication for catheter-supported aortic valve replacement where possible only in patients > 75 years and have a logistic euroSCORE I > 20 % or where there is an existing contraindication to open surgery.

Background

Scientific interdisciplinary publications and leading medical groups inEurope and the USA have a consented recommendation that transcatheter aortic valve implantation (TAVI) should only be undertaken in inoperable patients or multimorbid patients who are at high operative risk. Recognized reasons for catheter-guided interventions in addition to age and high risk are a prognosis-limiting secondary disease, porcelain aorta, a non-curatively treated malignancy, frailty of the patient, or the patient's express wish. It is undisputed that frail patients have a higher surgery-related mortality than non-frail patients; however, the concept of frailty is variously defined indeed. It should be pointed out, however, that currently available study results on transcatheter aortic valve implantation do not allow sufficient analysis of the benefit-versus-harm potential of the procedure. In particular, due to the lack of long-term results, in addition to the above-mentioned recommendations there continues to be an internationally unrestricted consensus that the method should only be used on inoperable patients or patients at very high operative risk, and subject to strict, interdisciplinary rendering of the medical indication.

The indicator provides important evidence on whether to extend the medical indication for catheter-supported aortic valve replacement, contrary to consensus-based recommendations, despite the lack of documented benefit and long-term results.

Evaluating the results

Based on recognized guidelines, the indicator underwent further methodological development over the previous year. Some criteria for an appropriate medical indication were dropped, while others were included for the first time (see Changes in comparison to the previous year). The result of the indicator has changed markedly from the previous year because the indication criteria were modified (result under old definition: 38.1 %; result under new definition: 74.8 %). Some criteria for establishing an appropriate medical indication were documented particularly often (high risk, age > 75 years, frailty, patient's wish). However, it should be borne in mind that – with the exception of age – the treating physician's subjective interpretation also has an influence on many of these criteria. The very large range of results shows that the recommendations for diagnosis for catheter-supported aortic valve replacement in the individual hospitals continue to be applied very differently. For data collection year 2013, the 10th percentile was defined as the reference range. Therefore, the Structured Dialogue will be held with 9 hospitals whose indicator outcome was less than 52 %. The quality of the medical indication will also be a focus of the Structured Dialogue this year. The results show that patient care in this clinical area must continue to be analyzed scrupulously.

Aortic valve surgery, isolated

QI-ID 51916: Intraprocedural complications – catheter-supported

Quality target

Rare occurrence of intraprocedural complications.

Background

The proportion of patients dying during catheter-supported surgery is relatively small (less than 6 %). However, an analysis of secondary end-points shows that an isolated catheter-supported aortic valve intervention has a higher risk for cerebrovascular events, vascular complications and a higher incidence of paravalvular leakage than isolated conventional aortic valve replacement surgery.

The systematic recording of intraprocedural complications not only provides information about the quality of care and exposes any areas of deficiency in care, but, in particular, can give an impetus for implementing and controlling quality improvement strategies as well.

Evaluating the results

This indicator has been newly developed for data collection year 2013. Therefore, there is no defined reference range yet. Compared with conventional aortic valve replacement surgery, catheter-supported aortic valve implantation is accompanied by special intraprocedural complications associated with the method. The overall rate of intraprocedural complications is 5.5 % and, thus, about 10 times higher than in conventional aortic valve replacement surgery.

There is a strikingly large dispersion of the results between participating hospitals. For data collection year 2014, the Federal Experts' Working Group will define a reference range so that further analyses can be undertaken in the Structured Dialogue.

Description

Numerator	Patients in whom at least one severe intraprocedural complication occurred
Denominator	All patients undergoing isolated catheter-supported aortic valve surgery in their primary surgery
Reference range	Not defined
Risk adjustment	No further risk adjustment
QI-ID	51916
Comparability with the previous year's results	This indicator was newly developed and calculated retrospectively for data collection year 2012.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	5.1 %	5.5 %
Confidence interval	–	–	–	4.7–5.6 %	5.0–5.9 %
Total number of cases	–	–	–	9,332	10,409
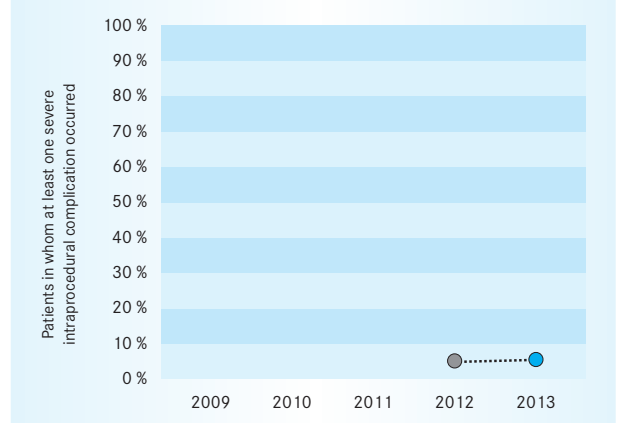
Aggregate result of all patients

Hospital-based results

Target population of all hospitals	93
Number of hospitals with 0 cases	4

84 Hospitals with ≥ 20 cases
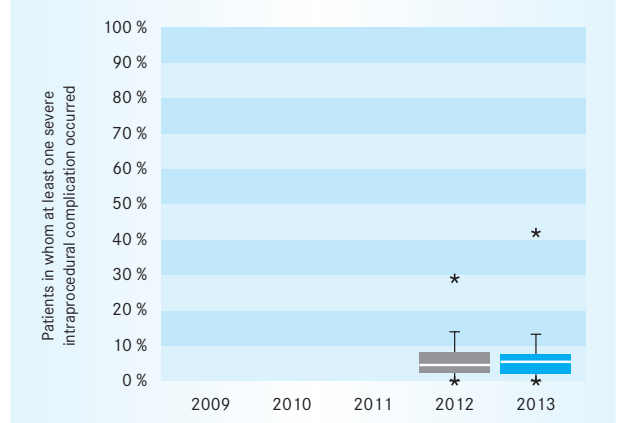
Median	5.4 %	Number of computationally discrepant hospitals	–
Range	0.0–40.6 %		

9 Hospitals with 1 to 19 cases

Median	0.0 %	Number of computationally discrepant hospitals	–
Range	0.0–50.0 %		

Aortic valve surgery, isolated

QI-ID 52007: Vascular complications – catheter-supported

Description

Numerator	Patients in whom at least one vascular complication occurred
Denominator	All patients undergoing isolated catheter-supported aortic valve surgery in their primary surgery
Reference range	Not defined
Risk adjustment	No further risk adjustment
QI-ID	52007
Comparability with the previous year's results	This indicator was newly developed and calculated retrospectively for data collection year 2012.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	7.3 %	8.5 %
Confidence interval	–	–	–	6.8–7.9 %	8.0–9.1 %
Total number of cases	–	–	–	9,332	10,409
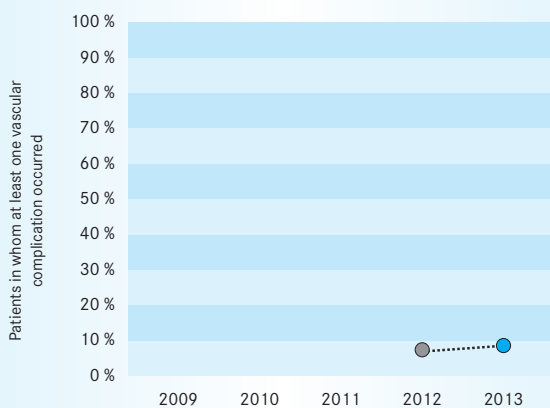
Aggregate result of all patients

Hospital-based results

Target population of all hospitals	93
Number of hospitals with 0 cases	4

84 Hospitals with ≥ 20 cases
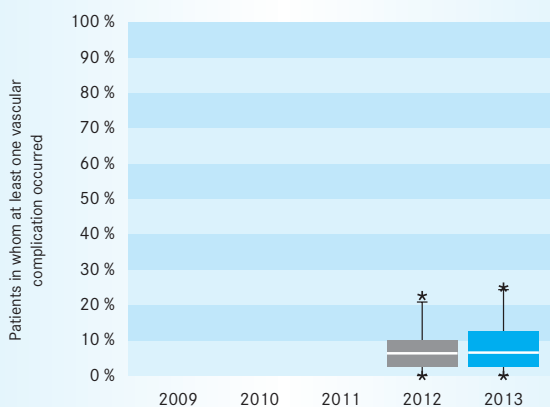
Median	6.5 %	Number of computationally discrepant hospitals	–
Range	0.0 – 25.0 %		

9 Hospitals with 1 to 19 cases

Median	0.0 %	Number of computationally discrepant hospitals	–
Range	0.0 – 8.3 %		

Quality target

Rare occurrence of vascular complications.

Background

Vascular complications such as tears, obstruction or injury to the vessel wall (dissection of the iliofemoral artery) or the aorta necessitating intervention can occur at the endovascular access itself.

The systematic recording of arterial vascular complications can provide information about quality of care and disclose any deficiencies of care.

Evaluating the results

This indicator was newly developed for data collection year 2013, which means that no reference range was defined for the first year of inclusion in routine operations. The result at the federal level is comparable with the data from published studies.

For the next year, the Federal Experts' Working Group will define a reference range so that a Structured Dialogue can be held with computationally discrepant hospitals with reference to this indicator as well.

Aortic valve surgery, isolated

QI-ID 12168: Ratio of the observed to the expected rate (O / E) of deaths – catheter-supported

Quality target

Lowest possible in-hospital mortality.

Background

The study of perioperative mortality (chronologically related to the surgery) is standard practice in the consideration of postoperative complications (those emerging after surgery). All patients who die during the same inpatient stay in hospital are recorded. A fair comparison of the results of different hospitals is only possible if allowance is made for patient-related risks by means of a risk adjustment.

In Europe, the logistic or additive euroSCORE is frequently used for risk adjustment. Since results in the past had shown that the euroSCORE overestimates the risk of cardiac surgery, a new model was developed in 2008 jointly with the Federal Experts' Working Group for risk adjustment of in-hospital mortality in isolated aortic valve surgery – the AKL score. The risk adjustment model used successfully for years has been further developed on the basis of current data (a 50 % random sample of data from 2011 and 2012). In the new model "Aortic valve score 2.0", certain risk factors from the old model that the current data used showed to have no significant effect on mortality are no longer included in the risk assessment (myocardial infarction within the previous 21 days, LVEF between 30 % and 50 %, reoperation on heart/aorta, lung disease: COPD). Instead, new risk factors that significantly impact mortality (e.g., diabetes mellitus) have been added.

Evaluating the results

Based on the results of the indicator group "Mortality" in the clinical area for target caseload *Aortic valve surgery, isolated* – catheter-supported, the Federal Experts' Working Group rates the quality of care overall as good at the federal level. An analysis of the risk classes shows that the observed mortality in the low risk classes is somewhat above the expected mortality. In the high-risk classes, however, substantially fewer patients died than were to be expected from the risk model. This confirms the consensus formulated in guidelines and position papers that catheter-supported methods are particularly beneficial for high-risk patients.

The Federal Experts' Working Group points out that there continues to be an urgent need to prolong the follow-up period in order to be able to analyze medium- and long-term outcomes as well. The Federal Experts' Working Group therefore welcomes the fact that the Federal Joint Committee has commissioned the institution mandated by section 137a SGB V to develop a follow-up procedure for the clinical area *Aortic valve surgery, isolated* using health insurance claims data.

Description

Numerator	Deceased patients
Denominator	All patients undergoing isolated catheter-supported surgery on the aortic valve in their primary surgery and with complete documentation for the logistic aortic valve score 2.0
O (observed)	Observed death rate
E (expected)	Expected death rate, risk-adjusted for logistic aortic valve score 2.0
Reference range	≤ 1.82 % (95th percentile, tolerance range)
Risk adjustment	Logistic regression
QI-ID	12168
Comparability with the previous year's results	Limited comparability

Ergebnis auf Basis der Fälle (Patienten)

	2009	2010	2011	2012	2013
Aggregate result	1.22	1.06	1.06	0.94	0.90
Confidence interval	–	0.95 – 1.18	0.97 – 1.15	0.87 – 1.03	0.84 – 0.98
Total number of cases	2,519	4,711	6,971	9,216	10,268
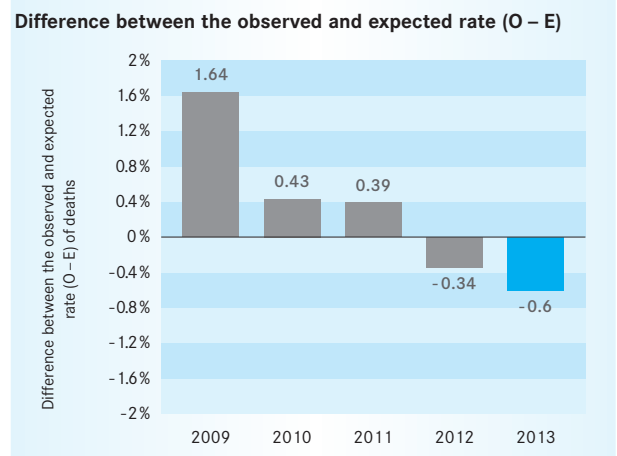
Difference between the observed and expected rate (O – E)

Hospital-based results

Target population of all hospitals	93
Number of hospitals with 0 cases	4

83 Hospitals with ≥ 20 cases
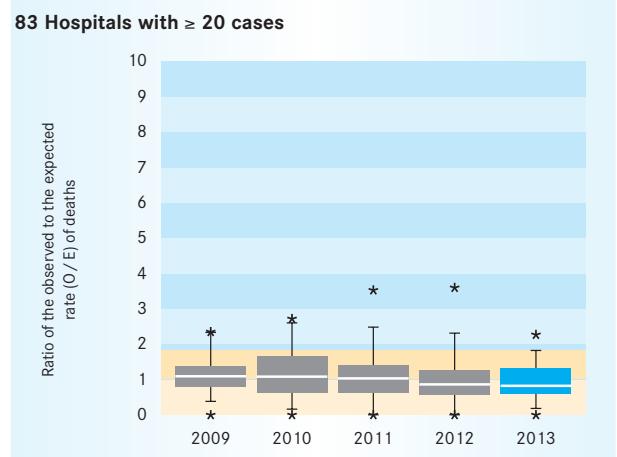
Median	0.82	Number of computationally discrepant hospitals	4 of 83
Range	0.00 – 2.27		

10 Hospitals with 1 to 19 cases

Median	0.00	Number of computationally discrepant hospitals	2 of 10
Range	0.00 – 4.91		

Combined coronary and aortic valve surgery

Dr. Tonia Kazmaier, Martina Köppen, Federal Experts' Working Group for Coronary Surgery

Introduction

Combined coronary and aortic valve surgery is the term used to describe procedures where blood vessels are grafted from another part of the body to bridge stenotic or occluded sections of a coronary artery (called bypasses) and, simultaneously, the aortic valve is replaced by an artificial heart valve.

Patients in this clinical area represent a special heart surgery risk group because frequently concomitant diseases are present in addition to coronary heart disease and aortic valve disease.

Services subject to mandatory documentation

All combined surgeries performed on the coronary arteries and the aortic valve using the heart-lung machine in patients older than 18 years are documented.

The following procedures are excluded from mandatory documentation: simultaneous surgery on the heart, on the heart valves (with the exception of the aortic valve) and on the vessels near the heart as well as simultaneous intervention on the internal carotid artery and heart surgery performed to treat polytrauma.

The analysis of this clinical area only includes combined surgery on the coronary arteries and aortic valve in order to ensure comparability of the hospital-based results.

Changes in comparison to the previous year

None.

Results

The aggregate results in this clinical area are stable for the currently evaluable quality indicators and point to a good quality of care. Given the higher risk profile of the patients treated, the indicator results in this clinical area are, as was to be expected, not as good as in the other clinical areas covering cardiac surgeries. The nationwide variance in results on the hospital level is also relatively large; this makes the Structured Dialogue even more important for differentiating qualitative discrepancies from random events, especially considering the sometimes small caseloads as well.

The indicator results (aggregate case-based results) have not changed significantly over the previous year. For that reason, the following will refrain from a detailed presentation of any particular indicator.

Based on the data from 2012, a total of 17 computationally discrepant results of quality indicators (14 hospitals) was identified in this clinical area and analyzed in the Structured Dialogue. In conclusion, 7 discrepancies (6 hospitals) were evaluated as "qualitatively discrepant". Representatives of one hospital were invited to a "colleague-to-colleague" talk. The representatives of this hospital were instructed to analyze their cases of death, particularly in the low-risk cohort, in all clinical areas with cardiac surgeries and to report the results to the Federal Experts'

Working Group. Moreover, in a target agreement it was stipulated that interdisciplinary morbidity and mortality conferences should be held at regular intervals, the minutes thereof be taken and a complication management concept be developed.

Looking forward

Especially due to demographic changes an increasing number of patients will be receiving combined interventions. However, the number of patients who received one combined surgery on the coronary arteries and the aortic valve within one data collection year has decreased by almost 10 % over the past 5 years. Since it is currently not possible to link the different existing quality assurance procedures, no answer can currently be given as to how many patients suffering from coronary heart disease and a disease of the aortic valve receive a percutaneous coronary intervention in combination with a conventional and/or catheter-supported aortic valve replacement. Consequently, no conclusions on the quality of care or on long-term survival are possible in this regard.

In order to at least achieve a longitudinal evaluation, the Federal Experts' Working Group recommends creating the prerequisites for implementing a longer-term follow-up strategy (collecting follow-up data after one and after several years) that utilizes health insurance claims data (e.g., similar to the already commissioned development of a follow-up strategy for the clinical areas *Aortic valve surgery, isolated* and *Coronary surgery, isolated*).

Combined coronary and aortic valve surgery

Data basis				
	2012	**2013**		
	Reported	Reported	Expected	Case completeness
Records	67,600	67,443	67,567	99.8 %
Hospitals	94	97	100	97.0 %
Of which combined coronary and aortic valve surgery				
Records	7,141	6,901	n.a.	n.a.

Basic statistics		
	2013	
	Number	Proportion
Age distribution		
Number of patients	6,717	100 %
< 50 years	60	0.9 %
50 – 59 years	375	5.6 %
60 – 69 years	1,254	18.7 %
70 – 79 years	3,781	56.3 %
80 – 89 years	1,236	18.4 %
≥ 90 years	11	0.2 %
Sex		
Male	4,854	72.3 %
Female	1,863	27.7 %
ASA classification		
ASA 1: A normal healthy patient	122	1.8 %
ASA 2: A patient with mild systemic disease	593	8.8 %
ASA 3: A patient with severe systemic disease	5,144	76.6 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	828	12.3 %
ASA 5: A moribund patient who is not expected to survive without the operation	30	0.5 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/HCH-M/

Combined coronary and aortic valve surgery

Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator		2012 Result	2013 Result	2013 Cases (patients) Numerator (O | E)*	Denominator	Trend
Indicator group		*Postoperative mediastinitis*						
	2283	Postoperative mediastinitis after elective/urgent surgery		0.6 %	0.3 %	20	6,381	→
	2284	Postoperative mediastinitis in risk class 0 or 1 (NNIS)[1]		0.5 %	0.3 %	14	5,204	→
	2286	Neurological complications of elective/urgent surgery		1.7 %	1.6 %	95	6,054	→
Indicator group		*Mortality*						
	359	In-hospital mortality	⚠	5.3 %	4.6 %	308	6,715	→
	360	In-hospital mortality after elective/urgent surgery	⚠	4.5 %	3.9 %	246	6,386	→
	12193	Ratio of the observed to expected rate (O / E) of deaths	⚠	1.00	0.86	300 4.50 % 349 5.25 %	6,660	→
	11391	Status on the 30th postoperative day	⚠	82.6 %	81.5 %	5,471	6,715	→
	362	Mortality after 30 days	⚠	4.8 %	4.8 %	206	4,326	→

* for regression-based quality indicators

[1] NNIS (*National Nosocomial Infections Surveillance*); this is an additive score used in risk adjustment. One risk point is assigned whenever ASA ≥ 3, surgery time > 75th percentile of the distribution of the surgery times for the surgery type under review and/or the intervention is contaminated or septic.

Combined coronary and aortic valve surgery

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
	Postoperative mediastinitis					
2283	Postoperative mediastinitis after elective/urgent surgery	n.d.*	78	–	X	X
2284	Postoperative mediastinitis in risk class 0 or 1 (NNIS)	≤ 2.2 % (TO; 95th percentile)	78	3	2	A
2286	Neurological complications of elective/urgent surgery	≤ 5.1 % (TO; 95th percentile)	78	3	2	A
	Mortality					
359	In-hospital mortality	n.d.*	78	–	X	X
360	In-hospital mortality after elective/urgent surgery	n.d.*	78	–	X	X
12193	Ratio of the observed to expected rate (O/E) of deaths	≤ 1.61 (TO; 90th percentile)	78	8	2	A
11391	Status on the 30th postoperative day	n.d.*	78	–	X	X
362	Mortality after 30 days	n.d.*	47	–	X	X

TO = Tolerance range; * not defined

Heart transplantation

Dr. Klaus Richter, Martina Köppen, Federal Experts' Working Group for Heart Transplantation

Introduction
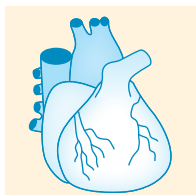
Heart transplantation is a highly sophisticated, yet well-established medical intervention. To be qualified for heart transplantation, the patient must have an advanced stage of an incurable heart disease (refractory end-stage heart failure) with very low survival time without this surgical intervention. In this context, the risk associated with the surgical intervention and the potential long-term complications must be lower than the patient's individual risk of dying from the actual underlying disease. Heart transplantation is only indicated after excluding all other organ-conserving (both medical and surgical) treatment options.

In the early days of heart transplantation, donors were only accepted if they were younger than 40 years and had no history of cardiac diseases. Nowadays, organs are accepted from donors up to 70 years of age. Although a change in the transplantation law in August 2012 obliges recipient hospitals to appoint a transplantation coordinator to support the organ donation process, overall the number of donors has slightly decreased in data collection year 2013. On the one hand, not all potential donors are reported by hospitals and, on the other hand, the refusal rate of organ donation from a deceased relative can, in some cases, is up to 50 %. As a result, the waiting time for heart transplantation has dramatically increased in the past 10 years. Considering the shortage of donor organs, waiting times for transplantation can be bridged by using heart support systems (assist device systems). No conclusions on the situation of patients on the waiting list regarding their quality of life and mortality can be drawn with the current quality assurance procedure.

In the results of follow-up survival rates (longitudinal observation), in addition to the existing indicators showing the 1-, 2- or 3-year survival rates for patients with known survival status, the indicator result will also be recorded as a worst-case analysis. This means that all patients with unknown survival status will be considered as deceased. The indicator therefore measures the actual documented deaths and deaths that cannot be excluded due to improper documentation. In this way, worst-case indicators provide information on the documentation and/or the quality of aftercare in a hospital.

In the results of the previous year, it should be noted that records, which had not been supplied in data collection year 2012, could be submitted subsequently. These records are included in the calculation of the previous year's results presented here. This means that the results may deviate from those of the Federal Analysis 2012.

Services subject to mandatory documentation

All heart transplantations.

Changes in comparison to the previous year

In a joint session with representatives from all Federal Experts' Working Groups for Transplantation Medicine, it was decided to consider only two indicators in the indicator groups for 1-, 2- and 3-year survival rates: survival with known status and

as worst-case analysis. Reference ranges are introduced for each of the worst-case indicators.

Results

Compared to the previous year, slightly more computational discrepancies were observed in the clinical area *Heart transplantation* in the data collection year 2012 and these were discussed in the Structured Dialogue 2013. This may be explained by the introduction of the worst-case indicators. A total of 22 computational discrepancies were investigated in the Structured Dialogue. In conclusion, the Structured Dialogue classified 16 indicator results as "qualitatively non-discrepant" and 6 computational discrepancies confirmed a qualitative deficiency. Representatives of 4 hospitals were invited to a "colleague-to-colleague" talk. The qualitatively discrepant results were due to structural deficiencies and the resulting process deficiencies. Corresponding improvement measures were defined in jointly formulated target agreements, whose timely implementation will be checked over the course of time.

In data validation, a reverification on the basis of selected data fields was undertaken in 4 transplantation centers for data collection year 2012. This involved examining 20 patient records in one hospital. Since a total of only 5 resp. 10 heart transplantations were carried out in data collection year 2012 in the other 3 hospitals, only these cases were included in the reverification. In terms of data validity, the vast majority of data fields were rated as "good" or "excellent". However, 2 data fields had documentation problems and their data validity was rated "requires improvement".

The 1-year survival rate, the most important parameter for the transplantation outcome has deteriorated in the data collection years 2012 and 2013, compared to the respective previous year. The negative trend in the 1-year survival rate reflects the worsening of in-hospital mortality rates in 2011 and 2012. The Federal Experts' Working Group therefore emphasizes the importance of a precise analysis of the causes. The 2- and 3-year survival rates, however, were clearly above the reference range and, thus, continue to be good.

Looking forward

The Structured Dialogue needs to examine the information on the high in-hospital mortality rates reported. The 1-year survival result, which was worse than the previous year, ought to be critically questioned as well.

The inadequate quality of aftercare described in the previous years is no longer the main focus here. Rather, the decrease in organ donations might be the reason behind this, despite changes to the transplantation law. The low number of donors has lead to accepting qualitatively poorer organs and to a marked increase in the implantation of heart support systems.

Confirmed information on the causes and associations between donor criteria and transplantation outcomes can only be obtained by introducing a comprehensive transplantation registry.

Findings from the Structured Dialogue on the last two years

Heart transplantation

have also shown that ensuring the necessary structural and process quality has played a major role in improving the outcomes. Target agreements concluded with the hospitals, in the corresponding "colleague-to-colleague" talks and on-site visits are suitable instruments for achieving quality assurance measures and improvements in the view of the Federal Experts' Working Group.

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	323	273	263	103.8 %
Hospitals	22	23	23	100.0 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	305	100 %
< 1 year	4	1.3 %
1 – 9 years	15	4.9 %
10 – 19 years	23	7.5 %
20 – 29 years	26	8.5 %
30 – 39 years	22	7.2 %
40 – 49 years	54	17.7 %
50 – 59 years	97	31.8 %
60 – 69 years	60	19.7 %
70 – 79 years	4	1.3 %
≥ 80 years	0	0.0 %
Sex		
Male	219	71.8 %
Female	86	28.2 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German): *www.sqg.de/themen/HTX/*

[1] Priv.-Doz. Dr. Ingo Kaczmarek up to March 2014

Heart transplantation

Case-based aggregate results (patients)

QI-ID	Name of the quality indicator		2012 Result	2013 Result	2013 Cases (patients) Numerator	2013 Cases (patients) Denominator	Trend
2157	In-hospital mortality	⚠	18.3 %	19.9 %	55	276	→
	30-day survival						
12539	Unknown survival status 30 days after transplantation	⚠	0.00 %	0.00 %	0	330	→
12542	30-day survival (with known status)	⚠	89.5 %	88.2 %	291	330	→
	1-year survival						
12253	1-year survival (with known status)	⚠	80.3 %	74.2 %	244	329	→
51629	1-year survival (worst-case analysis)	⚠	80.1 %	73.9 %	244	330	→
	2-year survival						
12269	2-year survival (with known status)	⚠	76.6 %	76.8 %	268	349	→
51631	2-year survival (worst-case analysis)	⚠	76.2 %	76.4 %	268	351	→
	3-year survival						
12289	3-year survival (with known status)	⚠	72.6 %	73.9 %	269	364	→
51633	3-year survival (worst-case analysis)	⚠	72.4 %	72.7 %	269	370	→

Heart transplantation

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
2157	In-hospital mortality	≤ 20.0 % (TO)	23	9	1	B
	30-day survival					
12539	Unknown survival status 30 days after transplantation	Sentinel event	22	0	X	X
12542	30-day survival (with known status)	n.d.*	22	–	X	X
	1-year survival					
12253	1-year survival (with known status)	n.d.*	22	–	X	X
51629	1-year survival (worst-case analysis)	≥ 75.0 % (TO)	22	9	3	B
	2-year survival					
12269	2-year survival (with known status)	n.d.*	22	–	X	X
51631	2-year survival (worst-case analysis)	≥ 70.0 % (TO)	22	7	1	A
	3-year survival					
12289	3-year survival (with known status)	n.d.*	24	–	X	X
51633	3-year survival (worst-case analysis)	≥ 65.0 % (TO)	24	8	1	A

TO = Tolerance range; * not defined

*Indicator group* (rotated labels alongside grouped rows)

Heart transplantation

QI-ID 51629: 1-year survival (worst-case analysis)

| Description	
Numerator	Patients for whom information is available that they are alive 1 year after transplantation
Denominator	All patients with heart transplantation in data collection year 2012 without retransplantation in 2013
Reference range	≥ 75.0 % (tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	51629
Comparability with the previous year's results	Comparable

Case-based results (patients)					
	2009	**2010**	**2011**	**2012**	**2013**
Aggregate result	–	–	78.6 %	80.1 %	73.9 %
Confidence interval	–	–	74.2–82.5 %	75.6–83.9 %	68.9–78.4 %
Total number of cases	–	–	370	351	330

Aggregate result of all patients
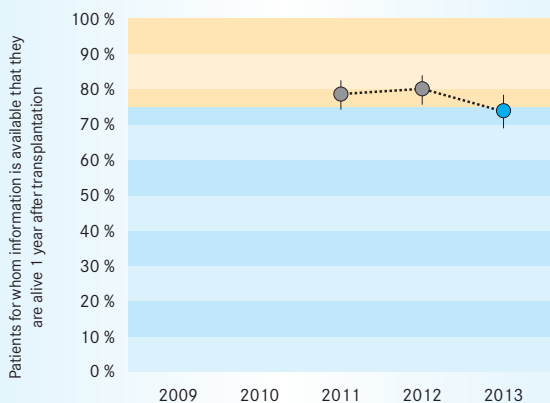
Hospital-based results	
Target population of all hospitals	22
Number of hospitals with 0 cases	1

6 Hospitals with ≥ 20 cases

Median	73.9 %	Number of computationally discrepant hospitals	6 of 6
Range	57.7 – 82.9 %		

16 Hospitals with 1 to 19 cases

Median	75.0 %	Number of computationally discrepant hospitals	3 of 16
Range	0.0 – 100.0 %		
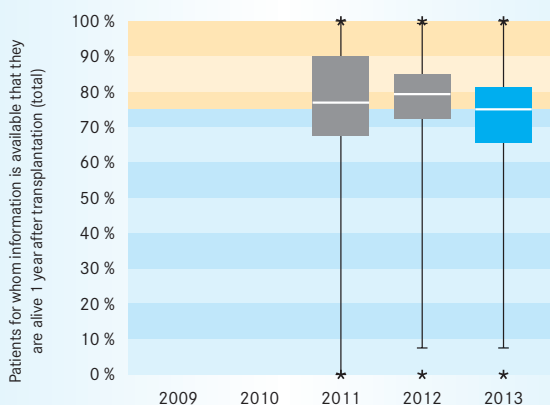
Quality target

The highest possible 1-year survival rate.

Background

Heart transplantation represents a treatment option for selected patients with terminal heart failure. Following transplantation, patients are at risk of acute transplant rejection reactions or the development of a transplantation failure. Furthermore, there are side effects resulting from the immunosuppressive therapy that need to be recognized and treated, such as infections, kidney function disorders, hypertension or metabolic disturbances. Patients therefore require life-long aftercare following organ transplantation.

According to the literature and to an international registry recording a large proportion of the heart transplantations undertaken worldwide, the success of heart transplantation is measured predominantly based on survival rates over time following organ transplantation. Thus, the quality of aftercare has a markedly greater effect on patient survival as the length of time after the transplantation increases.

According to the Federal Experts' Working Group, long-term survival rates, as described in the international literature, are essential indicators for the quality of heart transplantation and the aftercare of patients with heart transplantation.

According to the Federal Experts' Working Group, conclusions can be drawn about the quality of treatment of a transplantation center based on survival rates in the first three years after transplantation.

The indicator includes all patients in the target population who underwent transplantation one year previously, regardless their survival status. Worst-case analysis means that all patients with unknown survival status are considered as deceased. The indicator therefore measures actual deaths and deaths that cannot be excluded due to improper documentation within one year after transplantation. A Structured Dialogue will be conducted on this indicator.

Evaluating the results

Considering the overall good, high documentation rate, the overall result reveals a deteriorating trend compared to the previous year, though no statistically significant difference was observed due to the low number of cases. The overall result is outside the reference range. The 1-year survival rate, the most important parameter for the primary transplantation outcome has deteriorated markedly in the last 2 years. The Federal Experts' Working Group therefore emphasized the importance of a precise analysis of the causes. The following reasons are suspected: increasing donor age (proportion of over 50-year-old patients approx. 23 % in 2012 and 2013 vs. 18 % in 2011) and consequently reduced organ quality, as well as sometimes very long "cold ischemia times" (> 5 h) and the increasing number of patients with mechanical circulatory support.

Lung and heart-lung transplantation

Dr. Klaus Richter, Martina Köppen, Federal Experts' Working Group for Lung and Heart-Lung Transplantation

Introduction
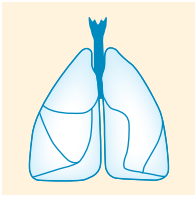
End-stage lung disease is an indication for lung and heart-lung transplantations if the life expectancy of the patient is expected to be very low without this intervention. To be qualified for transplantation, diseases of other vital organs such as the liver and kidneys must be excluded.

Heart-lung transplantation is a major surgical intervention associated with a high risk. Therefore, the decision-making involved with putting a patient on a transplantation waiting list should be done very thoroughly by weighing the risk of transplantation against the prognosis of other treatment options. However, other procedures to replace the lung function that are currently available offer only a short-term solution by bridging the waiting period for an organ. Compared to the heart, the transplantation window in lung transplantation is much narrower.

The allocation of organs for transplantation is based on the medical urgency and anticipated survival after transplantation. The rationale behind the *Lung Allocation Score* (LAS) re-introduced in 2012 is that organs be allocated to recipients who need the transplant most urgently and in whom the lung transplantation is expected to have the best chances for a successful outcome.

In addition to the existing indicators showing 1-, 2- or 3-year survival rates for patients with known survival status, the indicator result will also be presented as a worst-case analysis. This means that all patients who lack a survival status are considered as deceased. In this way, worst-case indicators measure actual deaths and deaths that cannot be excluded due to lack of documentation. Thus, these indicators provide information on the aftercare and quality of documentation in a hospital.

In the results of previous year, it should be noted that records, which had not been supplied in data collection year 2012, can be submitted subsequently. Those records are included in the calculation of the previous year's results presented here. This means that the results may deviate from those of the Federal Analysis 2012.

Services subject to mandatory documentation

All lung and heart-lung transplantations.

Changes in comparison to the previous year

In a joint session with representatives from all Federal Experts' Working Groups for Transplantation Medicine, it was decided to consider two indicators in the indicator groups for 1-, 2- and 3-year survival rates: survival with known status and worst-case analysis. Reference ranges are introduced for each of the worst-case indicators.

Results

The results of the Structured Dialogue based on data from 2012 showed a total of 14 computational discrepancies. After reviewing the statements, representatives of one hospital were invited to a "colleague-to-colleague" talk. There was evidence

of structural and process deficiencies, particularly at the interface between the transplantation and the aftercare entity. Consequently, the final evaluation was "qualitatively discrepant". The improvement measures mutually agreed on in writing with the hospital are currently being implemented. Due to documentation errors, another 3 computationally discrepant indicator results could not be evaluated. In conclusion, the Structured Dialogue rated the other 10 hospital-based results as qualitatively non-discrepant. In one hospital, an on-site inspection concerning the qualitative deficiencies identified in data collection year 2010 was conducted (previously reported on in the German Hospital Quality Report 2012). During the inspection, the previously implemented optimization measures were impressively confirmed. The hospital has complied with the comprehensive specifications of the target agreement and the current results indicate these positive changes.

Compared to the results of the previous year, the case completeness of data collection for 2013 has continued to improve. It is as high as 100 % on 1- and 3-year survival rates.

Both in-hospital and 1-year-mortality rates are – as in the previous year – equally low. Likewise, the 2-year survival rate has improved significantly, reflecting the very good perioperative result of 2011. The 3-year survival rate remains unchanged; although a marked increase in the next two years is expected as well.

Looking forward

The data on in-hospital mortality rate and on 1- and 2-year-survival rate demonstrate that the perioperative and medium-term quality of care in lung and heart-lung transplantations is very good. Only the 3-year-survival rates have not yet reached the required quality level.

Due to good outcomes in post-transplantation 1- and 2-year survival rates in 2011 and 2012, it is expected that the national average of the 3-year survival rate will be within the reference range next year.

In contrast to other transplantation areas, the number of lung and combined heart-lung transplantations (2013: n = 348) continues to show a remarkable increase. This can be explained by a direct association with the structural changes in the allocation system (introduction of LAS).

Lung and heart-lung transplantation

Data basis				
	2012	**2013**		
	Reported	Reported	Expected	Case completeness
Records	349	348	343	101.5 %
Hospitals	15	16	16	100.0 %

Basic statistics		
	2013	
	Number	Proportion
Age distribution		
Number of patients	380	100 %
< 1 year	0	0.0 %
1 – 9 years	[ ]*	[ ]*
10 – 19 years	14	3.7 %
20 – 29 years	35	9.2 %
30 – 39 years	37	9.7 %
40 – 49 years	60	15.8 %
50 – 59 years	152	40.0 %
60 – 69 years	81	21.3 %
70 – 79 years	0	0.0 %
≥ 80 years	0	0.0 %
Sex		
Male	213	56.1 %
Female	167	43.9 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/LUTX/

* Result not shown on data protection grounds

[1] Priv.-Doz. Dr. Ingo Kaczmarek up to March 2014

Lung and heart-lung transplantation

Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator		2012 Result	2013 Result	Cases (patients) Numerator	Denominator	Trend
	2155	In-hospital mortality	⚠	9.9 %	11.2 %	39	348	→
Indicator group		*1-year survival*						
	12397	1-year survival (with known status)	⚠	80.9 %	81.0 %	286	353	→
	51636	1-year survival (worst-case analysis)	⚠	80.9 %	81.0 %	286	353	→
Indicator group		*2-year survival*						
	12413	2-year survival (with known status)	⚠	64.7 %	76.1 %	248	326	↗
	51639	2-year survival (worst-case analysis)	⚠	64.7 %	75.8 %	248	327	↗
Indicator group		*3-year survival*						
	12433	3-year survival (with known status)	⚠	59.6 %	56.3 %	161	286	→
	51641	3-year survival (worst-case analysis)	⚠	59.1 %	56.3 %	161	286	→

Lung and heart-lung transplantation

Hospital-based aggregate results for utilization in quality assurance

	QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
				2013			
				Hospitals		**Evaluation**	
	2155	In-hospital mortality	≤ 20.0 % (TO)	16	5	2	A
Indicator group		1-year survival					
	12397	1-year survival (with known status)	n.d.*	15	–	X	X
	51636	1-year survival (worst-case analysis)	≥ 70.0 % (TO)	15	3	2	A
Indicator group		2-year survival					
	12413	2-year survival (with known status)	n.d.*	15	–	X	X
	51639	2-year survival (worst-case analysis)	≥ 65.0 % (TO)	15	4	2	A
Indicator group		3-year survival					
	12433	3-year survival (with known status)	n.d.*	12	–	X	X
	51641	3-year survival (worst-case analysis)	≥ 60.0 % (TO)	12	7	3	A

TO = Tolerance range; * not defined

Lung and heart-lung transplantation

QI-ID 51641: 3-year survival (worst-case analysis)

Quality target

The highest possible 3-year survival rate.

Background

Combined heart-lung transplantations are very rare, also in a global comparison. Annually, data on around 60 to 80 heart-lung transplantations are submitted to the *Registry of the International Society of Heart and Lung Transplantation* (ISHLT) which collects information on the worldwide thoracic organ transplantation experiences. In 2007, 18 combined heart-lung transplantations were performed in Germany, compared to 264 isolated lung transplantations in the same period.

In a comparative presentation of quality in this indicator, lung and heart-lung transplantations are viewed together since both patient groups show great similarities regarding the intervention. Mortality over time is the most relevant indicator for measuring outcome quality in lung and heart-lung transplantations. It is highest within the first post-transplantation year. The ISHLT Registry has been reporting a continuous decrease in early-stage mortality in post lung transplantation since 1986. For example, the 1-year survival rate was 70.5 % in the observation period from 1988 to 1994 and rose to 81.4 % between 2000 and 2006 (ISHLT 2008). This suggests that transplantation centers have developed successful strategies for reducing potentially fatal complications in the early postoperative phase. The main causes of death reported during the first year after single or double-lung transplants are transplant failure, non-cytomegaly virus-related infections, cardiovascular complications and chronic transplant failure (bronchiolitis obliterans syndrome). Mortality is also influenced by the recipient's underlying disease that is the medical indication for the transplantation and by his clinical condition at the time of the transplantation.

In contrast to the 1-year survival rate, the long-term survival is essentially influenced by the quality of aftercare. Appropriate infrastructure and staffing are needed for regular follow-up examinations and should be guaranteed.

The present indicator "3-year survival (worst-case analysis)" includes all patients in the target population who received their transplant one year prior, regardless whether their survival status is known or not. Worst-case analysis here means that all patients with unknown survival status will be considered as deceased. Accordingly, the indicator measures actual deaths and deaths that cannot be excluded due to improper documentation within a year after transplantation. A Structured Dialogue will be conducted on this indicator.

Evaluating the results

Considering the overall good, high documentation rate, the aggregate result reveals a deteriorating trend compared to the previous year and continues to be below the reference range. One reason for this was the comparatively poor result for in-hospital mortality in the data collection year 2010. This was scrutinized in the Structured Dialogue on the affected data collection year. Considering the good results on 1- and 2-year survival rates in data collection year 2011 to 2013, an improvement in 3-year survival rate is also expected for data collection year 2014, provided that the documentation rate continues to be good.

Description

Numerator	Patients with information that they are alive 3 years after the transplantation
Denominator	All patients with lung or heart-lung transplantation in data collection year 2010 without retransplantation in 2011 to 2013
Reference range	≥ 60.0 % (tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	51641
Comparability with the previous year's results	Comparable

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	53.5 %	59.1 %	56.3 %
Confidence interval	–	–	47.2–59.7 %	53.0–65.0 %	50.5–61.9 %
Total number of cases	–	–	241	252	286
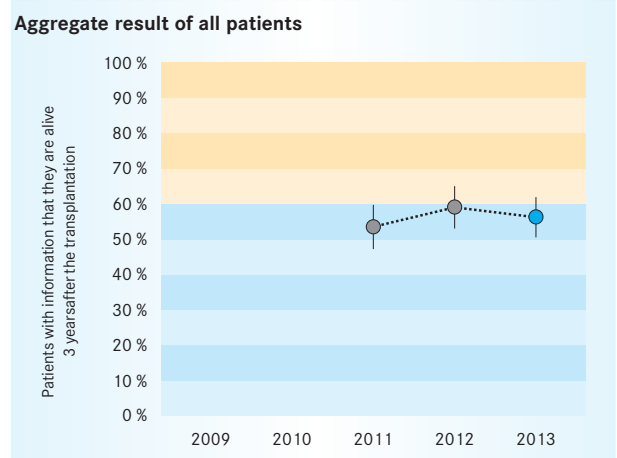
Aggregate result of all patients

Hospital-based results

Target population of all hospitals	12
Number of hospitals with 0 cases	4

4 Hospitals with ≥ 20 cases

Median	46.9 %	Number of computationally discrepant hospitals	4 of 4
Range	39.3 – 66.0 %		

8 Hospitals with 1 to 19 cases

Median	59.1 %	Number of computationally discrepant hospitals	3 of 8
Range	22.2 – 80.0 %		
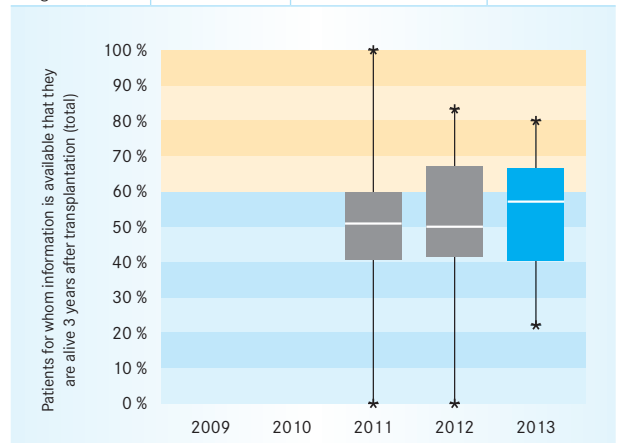
Liver transplantation

Thaddäus Tönnies, Dr. Tonia Kazmaier, Federal Experts' Working Group for Liver Transplantation

Introduction
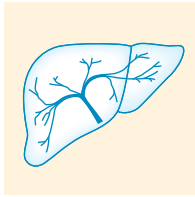
The liver is the most important organ in human metabolism. Patients with chronic or acute liver failure cannot survive without transplantation. The main causes of liver failure are alcoholic liver cirrhosis, hepatocellular carcinoma and chronic viral hepatitis C.

Since 2006, transplantation centers have been required to participate in external hospital quality assurance for the clinical area *Liver transplantation*, which has facilitated the description of quality of care in this sector using quality indicators.

In the presentation of the results for the follow-up survival rates, it must be borne in mind that, in addition to the existing indicators depicting the 1-, 2- or 3-year survival rates for patients with known survival status, the indicator result will also be recorded as a worst-case analysis. This means that all patients with no information on survival status are considered deceased. The indicator therefore measures actual documented deaths as well as deaths that cannot be excluded due to improper documentation. In this way, worst-case indicators provide information on the documentation quality and/or the quality of aftercare in a hospital.

In the results for the previous year, it should be noted that records which had not been supplied in data collection year 2012 can be submitted subsequently. The records submitted subsequently are included in the calculation of the previous year's results presented here, so that there may be results that differ from the Federal Analysis 2012.

Services subject to mandatory documentation

All liver transplantations.

Changes in comparison to the previous year

Two indicators were deleted from each of the indicator groups on survival 1, 2 and 3 years after transplantation. In the calculation of the indicators that have now been omitted, patients who had died in the previous year were excluded (e.g., 1-year survival rate only for patients discharged alive). Thus, the survival rates with known survival status (QI-ID 12349, QI-ID 12365, QI-ID 12385) and those of the worst-case analysis (QI-ID 51596, QI-ID 51599, QI-ID 51602) are retained in each indicator group. The aim of this change is to allow a more comprehensible description for the public.

Results

On the basis of data collection year 2012, there were a total of 32 computational discrepancies in 17 hospitals. More than half of the computational discrepancies (n = 17) were identified in the worst-case indicators. After conclusion of the Structured Dialogue, 13 of these cases were evaluated as "qualitatively discrepant", 3 of these qualitative discrepancies being found in "In-hospital mortality" (QI-ID 2096). Only a few of these discrepancies were of medical origin; the majority were due to missing data. An evaluation was not possible in 7 cases due to improper documentation.

Furthermore, this clinical area was again subjected to a sampling procedure with data synchronization. Compared with the results from the first reverification of data collection year 2010, it can be observed that the data validity of the laboratory values (bilirubin, creatinine and INR) has improved within just 2 years. Nevertheless, it must be borne in mind that the results of the first data collection year are based on data from just one hospital. Despite this positive development, once again there is a need to highlight some data fields that are deemed to be "in need of improvement" due to documentation problems. This applies to 17.6 % of the fields reviewed. The other fields, however, exhibited "good" or "excellent" data validity.

For data collection year 2013, 838 records from 24 hospitals were documented for the clinical area *Liver transplantation*. The case completeness of the follow-up data has improved markedly over the previous years. A total of 3,137 (98.5 %) records were supplied for the data collection year 2013 out of 3,184 expected follow-up records. At the time of the Federal Analysis of the previous year, this proportion was only 88.9 % (2,864 out of 3,222), but this figure increased later to more than 98 % as a result of the subsequent submissions of follow-up records for data collection year 2012. The Federal Experts' Working Group expressly welcomes this development and attributes it to the worst-case analysis that was introduced in the previous year. Due to this development, the results for 1-, 2- and 3-year survival are based on an almost complete data basis. To illustrate this, the 1-year survival rate with known survival status (QI-ID 12349) is contrasted with the worst-case analysis (QI-ID 51596).

An international comparison of the care situation is difficult to establish. In the current discussion, it is sometimes alleged that the results in Germany are not as good as, for example, in other European countries or the United States (e.g., *European Liver Transplant Registry*, *United Network for Organ Sharing*). It should be noted, however, that the quality of donor organs in the USA, for example, is rated substantially higher than the quality of donor organs in Germany. There are also major differences in organ availability. Thus, in countries that regulate organ donation by what is known as the dissent solution, a fundamentally higher organ availability is to be assumed – whereas in Germany an extended consent solution applies.

As the urgency of transplantation is seen as a fundamental criterion for allocating a donor liver, but as a rule the recipient's risk also increases with increasing urgency, better results could probably be achieved if there was a greater willingness for post-mortem donation and, thus, more organs were available. In addition, when comparing outcomes, it is sometimes forgotten how many patients on the waiting list die without having received a liver transplantation. Accordingly, the Federal Experts' Working Group assumes that the in international terms lower survival rates in Germany point less to a deficiency in the quality of medical care, but rather are associated with the different framework conditions such as quality of donor organs and organ allocation.

Liver transplantation

Looking forward

Care is currently provided against a background of long waiting times and constantly older recipients and donors. These factors generally have a major effect on survival rates and must be considered when assessing the results. The Federal Experts' Working Group emphasizes that a comprehensive assessment of the care situation in transplantation medicine is only possible by considering organ allocation and organ quality, as well as the recipient's general health.

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	998	838*	836	100.2 %
Hospitals	24	24	25	96.0 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	900*	100 %
< 1 year	42	4.7 %
1 – 9 years	55	6.1 %
10 – 19 years	22	2.4 %
20 – 29 years	35	3.9 %
30 – 39 years	50	5.6 %
40 – 49 years	132	14.7 %
50 – 59 years	302	33.6 %
60 – 69 years	245	27.2 %
70 – 79 years	17	1.9 %
≥ 80 years	0	0.0 %
Sex		
Male	568	63.1 %
Female	332	36.9 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/LTX/

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* The discrepancy between the number of patients in the basic statistics and the number of records provided in the database arises from the switch from evaluation of the year of surgery to the year of discharge. For further details see section "Data basis".

Liver transplantation

Case-based aggregate results (patients)

| | | | 2012 | 2013 | | | |
| | | | | Cases (patients) | | | |
QI-ID	Name of the quality indicator		Result	Result	Numerator (O | E) *	Denominator	Trend
	In-hospital mortality						
2096	In-hospital mortality	⚠	15.2 %	14.6 %	122	838	→
51594	Ratio of the observed to the expected rate (O / E) of deaths	⚠	1.00	0.92	122 / 132 — 14.56 % / 15.78 %	838	→
2097	Death through surgical complications	⚠	1.4 %	1.7 %	14	838	→
2133	Postoperative length of stay	⚠	23.2 %	23.7 %	180	758	→
	1-year survival						
12349	1-year survival (with known status)	⚠	78.0 %	78.9 %	767	972	→
51596	1-year survival (worst-case analysis)	⚠	77.5 %	78.1 %	767	982	→
	2-year survival						
12365	2-year survival (with known status)	⚠	71.7 %	73.0 %	769	1,054	→
51599	2-year survival (worst-case analysis)	⚠	70.6 %	71.9 %	769	1,070	→
	3-year survival						
12385	3-year survival (with known status)	⚠	69.4 %	67.9 %	754	1,111	→
51602	3-year survival (worst-case analysis)	⚠	66.8 %	66.6 %	754	1,132	→

* for regression-based quality indicators

Liver transplantation

Hospital-based aggregate results for utilization in quality assurance

	QI-ID	Name of the quality indicator	Reference range	2013			
				Hospitals		Evaluation	
				Total	Discrepant (computationally)	Category	Need for action
Indicator group		In-hospital mortality					
	2096	In-hospital mortality	≤ 20.0 % (TO)	24	4	2	A
	51594	Ratio of the observed to the expected rate (O / E) of deaths	n.d.*	24	–	X	X
	2097	Death through surgical complications	≤ 5.0 % (TO)	24	1	1	A
	2133	Postoperative length of stay	≤ 30.0 % (TO)	24	8	2	A
Indicator group		1-year survival					
	12349	1-year survival (with known status)	n.d.*	24	–	X	X
	51596	1-year survival (worst-case analysis)	≥ 70.0 % (TO)	24	4	1	A
Indicator group		2-year survival					
	12365	2-year survival (with known status)	n.d.*	24	–	X	X
	51599	2-year survival (worst-case analysis)	≥ 63.5 % (TO; 10th percentile)	24	5	2	A
Indicator group		3-year survival					
	12385	3-year survival (with known status)	n.d.*	23	–	X	X
	51602	3-year survival (worst-case analysis)	≥ 50.0 % (TO; 10th percentile)	23	1	2	A

TO = Tolerance range; * not defined

Liver transplantation

QI-ID 12349: 1-year survival (with known status)

Description	
Numerator	Patients who are alive 1 year after the transplantation
Denominator	All patients with liver transplantation in data collection year 2012 without retransplantation in 2013 with known follow-up status
Reference range	Not defined
Risk adjustment	No further risk adjustment
QI-ID	12349
Comparability with the previous year's results	Comparable

Case-based results (patients)					
	2009	**2010**	**2011**	**2012**	**2013**
Aggregate result	76.5 %	77.4 %	75.5 %	78.0 %	78.9 %
Confidence interval	73.5–79.4 %	74.7–80.0 %	72.9–77.9 %	75.5–80.4 %	76.2–81.4 %
Total number of cases	814	1,002	1,109	1,066	972

Aggregate result of all patients
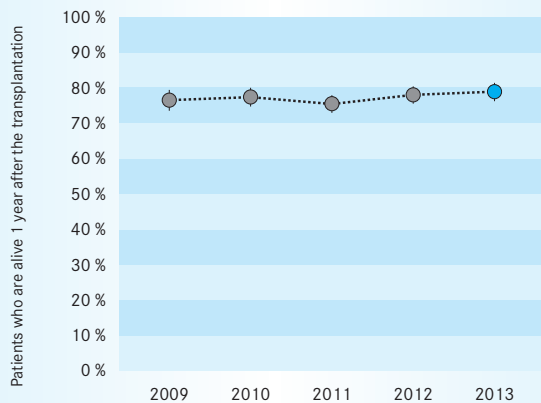
Hospital-based results	
Target population of all hospitals	24
Number of hospitals with 0 cases	0

16 Hospitals with ≥ 20 cases

Median	79.7 %	Number of computationally discrepant hospitals	–
Range	65.1–88.7 %		

8 Hospitals with 1 to 19 cases

Median	79.3 %	Number of computationally discrepant hospitals	–
Range	50.0–100.0 %		
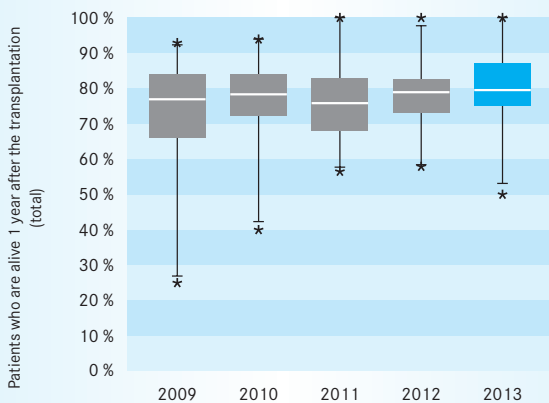
Quality target

As high as possible 1-year survival rate.

Background

Data from the *European Liver Transplant Registry* show that the 1-year survival rate after liver transplantations has increased considerably since the 1990s. It was 75 % in the period from 1988 to 1991 compared to 83 % in the period from 2000 to 2003 and 85 % between 2004 and 2009. A comparable trend is also reported from the USA.

When considering recipients of postmortem donations, the recipient's underlying disease, the age of both recipient and donor and the donor's cause of death exert a major effect on 1-year survival. The performance of the transplantation at a center with comparatively few cases per year is also regarded as a risk factor according to the literature.

In order to identify patients most urgently in need of a transplantation given the limited supply of organs in Eurotransplant, the MELD score[1] is used. The aim is to reduce the waiting time for a donor organ, in particular for those patients who are at especially high risk of dying without a transplant. However, high-risk patients also have a higher risk of dying within the first year after transplantation.

The encouraging improvements in terms of survival rates in the last 20 years demonstrate the particular importance of both peri-transplantation management and good medical care. In addition, the switch to organ allocation based on the MELD score has significantly influenced 1-year survival thanks to more appropriate selection of transplant recipients.

Evaluating the results

The present indicator evaluates the survival of patients in the first year after liver transplantation. Yet, only patients with a known survival status are considered here. In the absence of documentation, therefore, this is only a subset of all transplanted patients – whereas with the following indicator on the worst-case analysis (QI-ID 51596) all cases with a liver transplantation are considered, regardless of whether the survival status is known. The present indicator (QI-ID 12349) is therefore to be interpreted only in conjunction with the subsequent indicator (QI-ID 51596).

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[1] The MELD score (*Model for End-Stage Liver Disease*) is a measure of the risk of a patient dying in the next three months without a liver transplantation.

Liver transplantation

QI-ID 51596: 1-year survival (worst-case analysis)

Quality target

As high as possible 1-year survival rate.

Background

For the target population of this indicator, all cases with liver transplantation are considered, regardless of whether the survival status is known or not. Worst-case analysis means that all patients with unknown survival status are considered deceased. The indicator therefore measures actual deaths and deaths that cannot be excluded due to improper documentation within one year after transplantation.

The unsatisfactory documentation rates one, two and three years after transplantation were the reason for introducing a worst-case analysis. The worst-case analysis should offer an incentive for more thorough aftercare and better documentation of the follow-up records.

Evaluating the results

Of 982 cases considered from data collection year 2013 (i.e., transplanted in 2012), the survival status 1 year later is unknown in only 10 patients (1.0 %). By contrast, at the time of the Federal Analysis of the previous year, the information on survival status was missing for 10.9 % (n = 117) of patients. The Federal Experts' Working Group expressly welcomes this progress towards more complete documentation. It was noticeable in the previous year that there were individual hospitals which provided almost no follow-up data. The relevance of correct and complete documentation was discussed with these hospitals within the Structured Dialogue, which appears to have heightened awareness of this issue. Overall, therefore, the Federal Experts' Working Group regards the introduction of the worst-case analysis as a success, since the 1-year survival results are now based on a valid data basis.

On the basis of the data from 2013, the 1-year survival rate is 78.1 % (QI-ID 51596) and thus within the reference range (≥ 70 %). Four hospitals have a 1-year survival rate of less than 70 %, which needs to be analyzed within the Structured Dialogue. An international comparison of survival rates, however, is difficult in view of different framework conditions (e.g., organ donor rate and allocation). The Federal Experts' Working Group believes that the 1-year survival rate in Germany could probably be even higher if there were a greater willingness for postmortem donation, thus increasing the availability of organs.

Description

Numerator	Patients with information that they are alive 1 year after the transplantation
Denominator	All patients with liver transplantation in data collection year 2012 without retransplantation in 2013
Reference range	≥ 70.0 % (tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	51596
Comparability with the previous year's results	Comparable

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	73.9 %	77.5 %	78.1 %
Confidence interval	–	–	71.2–76.3 %	74.9–79.9 %	75.4–80.6 %
Total number of cases	–	–	1,133	1,074	982

Aggregate result of all patients
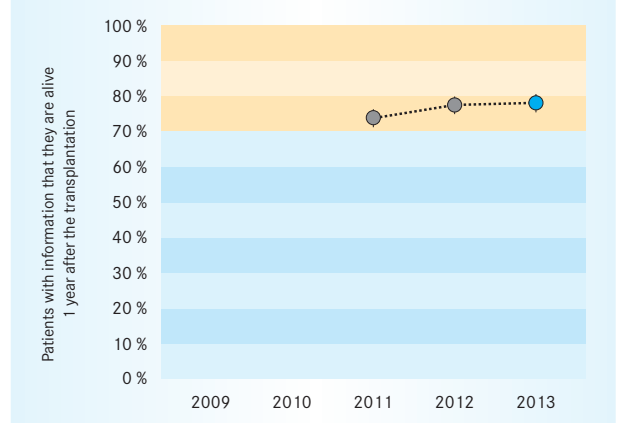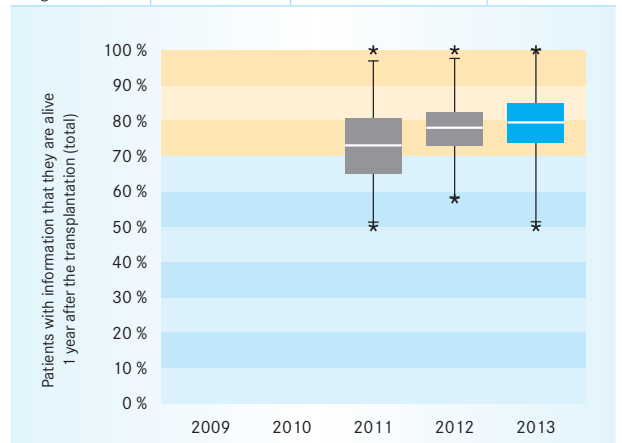

Hospital-based results

Target population of all hospitals	24
Number of hospitals with 0 cases	0

16 Hospitals with ≥ 20 cases

Median	79.7 %	Number of computationally discrepant hospitals	2 of 16
Range	65.1–87.9 %		

8 Hospitals with 1 to 19 cases

Median	79.3 %	Number of computationally discrepant hospitals	2 of 8
Range	50.0–100.0 %		

Living liver donation

Thaddäus Tönnies, Dr. Tonia Kazmaier, Federal Experts' Working Group for Liver Transplantation

Introduction
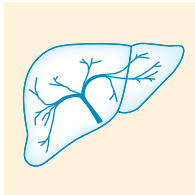
The liver is the most important organ of human metabolism. Patients with chronic or acute liver failure cannot survive without transplantation. Since the number of donor organs is by far not enough to cover the demand, many patients die every year while waiting for a donor organ. A living liver donation from a close person can be a therapy option.

Due to the liver's special multi-segmental anatomic structure and its great regeneration capacity, it is possible to graft part of the liver from a living donor to a recipient. Particularly in pediatric transplantation surgery, the living donation of a liver graft is a way of increasing the availability of organs and thereby enhancing treatment options for hepatically impaired children.

Because these surgeries are performed on healthy individuals, living organ donations are subject to intense ethical debate. To be qualified for the living donation, donors must be in a good state of health and consent voluntarily to the donation. Against this background, the German transplantation law allows living liver donation exclusively to first- and second-degree relatives, spouses and fiancées and other persons "who have an obviously close personal relationship with the prospective donor". To protect the donor, whose safety and health are of the utmost priority, a statement by an independent living donation committee must be obtained prior to each living donation.

The clinical area *Living liver donation* exclusively addresses the donor. In living donations, a high level of safety should be achieved by the best possible quality of medical treatment and by thorough preoperative evaluation of the donor. Protecting the donor from any complications is the highest priority.

In the presentation of the results for survival rates, it must be borne in mind that, in addition to the existing indicators depicting the 1-, 2- or 3-year survival rates for patients with known survival status, the indicator result will also be recorded as a worst-case analysis. This means that all patients with no information on survival status are considered deceased. The indicator therefore measures both actual documented deaths and deaths that cannot be excluded due to improper documentation. In this way, worst-case indicators provide information on the documentation and/or the quality of aftercare in hospitals.

In the results presented for the previous year, it should be noted that records which had not been supplied in data collection year 2012 can be submitted subsequently. The records submitted subsequently are included in the calculation of the previous year's results presented here, so that there may be results that differ from the Federal Analysis 2012.

Services subject to mandatory documentation

All living liver donations.

Changes in comparison to the previous year

In the clinical area *Living liver donation*, the worst-case indicators on the death of the donor 1, 2 and 3 years after living liver donation (QI-ID 51603, QI-ID 51604, QI-ID 51605) have been revised for a more comprehensible depiction to the public. The calculation of the indicators has not been changed, so that the results are comparable with those of the previous year.

The reference range of the indicator "Intervention-specific or general complications requiring treatment" (QI-ID 2128) is this year defined as a sentinel event. In the previous year the reference range was ≤ 5 %.

Results

For data collection year 2013, 83 living liver donations in 10 hospitals were documented for external hospital quality assurance. For the number of data-supplying hospitals and for the number of records submitted, this gives a case completeness of 100 %.

The case completeness of the follow-up data is lower, but has improved markedly over the previous year. A total of 204 (88.3 %) records were submitted out of 231 expected follow-up records. At the time of the Federal Analysis of the previous year, this proportion was only 79.3 % (176 out of 222). The Federal Experts' Working Group welcomes the positive development and attributes it to the worst-case analysis introduced in the previous year to give the hospitals incentives for complete follow-up documentation. Nevertheless, a need for further improvement is seen here.

The result of the indicator for liver function (QI-ID 12617) suggested that this was impaired in one donor 3 years after the donation. The discrepancy, however, was due to a documentation error by the hospital.

There were complications (QI-ID 2128) regarding the living liver donation in 9 donors (10.8 %). This rate is the same level as the previous year (11.1 %). Each complication was the subject of an individual analysis in the Structured Dialogue.

Based on the data from 2012, there were a total of 28 computational discrepancies at 10 hospitals. Following the conclusion of the Structured Dialogue, the Federal Experts' Working Group evaluated 13 computational discrepancies as "qualitatively non-discrepant". Three computational discrepancies from one hospital were classified as "qualitatively discrepant". The Federal Experts' Working Group interpreted the massive under-documentation for the worst-case indicators on survival here as evidence of structural and process deficiencies (e.g., staff bottleneck in relation to documentation). This was described by the hospital concerned in the statement. Twelve computational discrepancies were unevaluable due to missing or improper documentation.

Looking forward

The present results reflect, according to the Federal Experts' Working Group, a very good quality of care: No living donor has died due to the donation and none had to undergo transplantation themselves after the donation. Living liver donation is therefore an acceptable treatment option in the Federal Experts' Working Group's opinion. Nevertheless, the willingness for postmortem organ donation in the population should be

Living liver donation

increased by targeted public interventions, as living liver dona-tion involves a procedure in healthy individuals. Complications cannot altogether be avoided, as the result of the indicator "Intervention-specific or general complications requiring treat-ment" (QI-ID 2 128) shows. Accordingly, a living donation should only be considered if no postmortem donated organ is available (subsidiarity principle of living donation).

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	72	83	83	100.0 %
Hospitals	12	10	10	100.0 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	83	100 %
< 20 years	[ ]*	[ ]*
20 – 29 years	20	24.1 %
30 – 39 years	29	34.9 %
40 – 49 years	17	20.5 %
50 – 59 years	13	15.7 %
60 – 69 years	[ ]*	[ ]*
70 – 79 years	0	0.0 %
≥ 80 years	0	0.0 %
Sex		
Male	33	39.8 %
Female	50	60.2 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/LLS/

* Result not shown on data protection grounds

Living liver donation

Case-based aggregate results (patients)

QI-ID	Name of the quality indicator		2012 Result	2013 Cases (patients)			Trend
				Result	Numerator	Denominator	
2125	In-hospital mortality		0.00 %	0.00 %	0	83	→
2127	Liver transplantation required in the living liver donor		0.00 %	0.00 %	0	83	→
2128	Intervention-specific or general complications requiring treatment		11.11 %	10.84 %	9	83	→
	Death of the donor within the 1st year after living liver donation						
12296	Death of the donor within the 1st year after living liver donation		0.0 %	0.0 %	0	62	→
51603	Death or unknown survival status of the donor within the 1st year after living liver donation		8.57 %	13.89 %	10	72	→
12549	Liver transplantation required in the donor (within the 1st year after living liver donation)		0.00 %	0.00 %	0	62	→
12609	Impaired liver function of donor (1 year after living liver donation)		0.00 %	0.00 %	0	59	→
	Death of the donor within 2 years after living liver donation						
12308	Death of the donor within 2 years after living liver donation		0.0 %	0.0 %	0	64	→
51604	Death or unknown survival status of the donor within 2 years after living liver donation		10.11 %	8.57 %	6	70	→
12561	Liver transplantation required in the donor (within 2 years after living liver donation)		0.00 %	0.00 %	0	64	→
12613	Impaired liver function of donor (2 years after living liver donation)		2.63 %	0.00 %	0	58	→
	Death of the donor within 3 years after living liver donation						
12324	Death of the donor within 3 years after living liver donation		0.0 %	0.0 %	0	78	→
51605	Death or unknown survival status of the donor within 3 years after living liver donation		28.33 %	12.36 %	11	89	→
12577	Liver transplantation required in the donor (within 3 years after living liver donation)		0.00 %	0.00 %	0	78	→
12617	Impaired liver function of donor (3 years after living liver donation)		[ ]*	[ ]*	[ ]*	72	→

Indicator group (left vertical labels for the three grouped sections)

* Result not shown on data protection grounds

Living liver donation

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		Evaluation	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
2125	In-hospital mortality	Sentinel event	10	0	X	A
2127	Liver transplantation required in the living liver donor	Sentinel event	10	0	X	A
2128	Intervention-specific or general complications requiring treatment	Sentinel event	10	7	X	A
	Death of the donor within the 1st year after living liver donation					
12296	Death of the donor within the 1st year after living liver donation	n.d.*	11	–	X	X
51603	Death or unknown survival status of the donor within the 1st year after living liver donation	Sentinel event	12	5	X	A
12549	Liver transplantation required in the donor (within the 1st year after living liver donation)	Sentinel event	11	0	X	A
12609	Impaired liver function of donor (1 year after living liver donation)	Sentinel event	11	0	X	A
	Death of the donor within 2 years after living liver donation					
12308	Death of the donor within 2 years after living liver donation	n.d.*	11	–	X	X
51604	Death or unknown survival status of the donor within 2 years after living liver donation	Sentinel event	11	4	X	A
12561	Liver transplantation required in the donor (within 2 years after living liver donation)	Sentinel event	11	0	X	A
12613	Impaired liver function of donor (2 years after living liver donation)	Sentinel event	11	0	X	A
	Death of the donor within 3 years after living liver donation					
12324	Death of the donor within 3 years after living liver donation	n.d.*	10	–	X	X
51605	Death or unknown survival status of the donor within 3 years after living liver donation	Sentinel event	11	6	X	A
12577	Liver transplantation required in the donor (within 3 years after living liver donation)	Sentinel event	10	0	X	A
12617	Impaired liver function of donor (3 years after living liver donation)	Sentinel event	10	1	X	A

Indicator group (label repeated in left margin for each group)

* not defined

Living liver donation

QI-ID 12296: Death of the donor within the 1st year after living liver donation

Description	
Numerator	Living liver donors who died within the 1st year after the donation
Denominator	All living liver donors from data collection year 2012 with known follow-up-status and excluding domino donors
Reference range	Not defined
Risk adjustment	No further risk adjustment
QI-ID	12296
Comparability with the previous year's results	Comparable

Case-based results (patients)					
	2009	**2010**	**2011**	**2012**	**2013**
Aggregate result	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %
Confidence interval	0.0–12.8 %	0.0–7.9 %	0.0–4.8 %	0.0–5.7 %	0.0–5.8 %
Total number of cases	27	45	77	64	62

Aggregate result of all patients
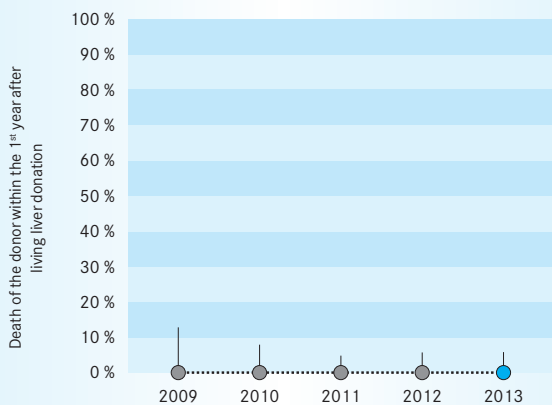
Hospital-based results	
Target population of all hospitals	11
Number of hospitals with 0 cases	0

0 Hospitals with ≥ 20 cases

Median	–	Number of computationally discrepant hospitals	–
Range	–		

11 Hospitals with 1 to 19 cases

Median	0.0 %	Number of computationally discrepant hospitals	0 of 11
Range	0.0–0.0 %		
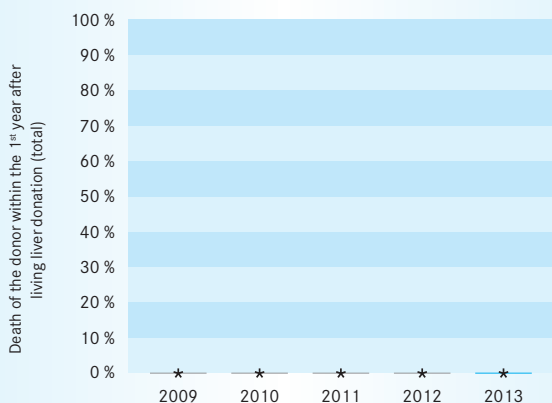
Quality target

No deaths within the 1st year after living liver donation.

Background

Whether potential living organ donors are suitable for the planned intervention is usually assessed in a multi-stage procedure. This involves assessing the transplant recipient's requirement for liver tissue and the expected function of the donor's residual liver after the partial living liver donation and weighing them against one another. In addition, impact factors are identified that may increase the risk for a potentially fatal complication. In accordance with section 8 of the Transplantation Law, organ removal in a living person is only permissible if that person is not put at further risk in addition to the general risk of surgery. The risk must therefore be assessed preoperatively and risk factors for thromboembolic events such as advanced age, smoking, estrogen treatment and obesity must be excluded.

The safety of the living organ donor also has the utmost priority after the organ donation. The risk of dying after a living liver donation is correspondingly small. Various studies report a mortality of between 0.2 % and 0.5 %. Follow-up is required to ascertain whether a patient's death is related to the living liver donation.

Evaluating the results

This indicator covers deaths of patients 1 year after living liver donation. It only includes patients whose survival status is known 1 year after the living liver donation. In data collection year 2013, as in the previous years, no deaths of living liver donors are known 1 year after the living liver donation. In the opinion of the Federal Experts' Working Group, the result is in line with expectations, as any threat to the donor's life can be prevented by careful preoperative evaluation.

As this indicator (QI-ID 12296) only includes patients with a documented survival status, a worst-case analysis is performed in the form of the subsequent indicator (QI-ID 51603), which also includes living donors whose survival status is unknown 1 year after the living liver donation.

Living liver donation

QI-ID 51603: Death of the donor or unknown survival status within the 1st year after living liver donation

Quality target

No deaths within the 1st year after living liver donation.

Background

The indicator covers patients who died within the 1st year of a living liver donation or for whom no information on survival status is available 1 year after living liver donation. This indicator therefore also provides information about the quality of documentation and aftercare.

The reason for introducing the so-called worst-case analysis was the unsatisfactory documentation rates 1, 2 and 3 years after living liver donation. The worst-case analysis should offer an incentive for more thorough aftercare and better documentation of follow-up.

Evaluating the results

Out of a total of 72 living liver donations performed in 2012, the survival status in the first year after the living liver donation, i.e., in data collection year 2013, is known in 62 donors (86.1 %). There is no information on the 1-year survival status of 10 donors (13.9 %) from a total of 5 hospitals. From one of these hospitals, the information is missing for 5 donors. All cases are analyzed within the scope of the Structured Dialogue.

The Federal Experts' Working Group regards it as positive that the proportion of patients with unknown survival status in data collection year 2013 (13.9 %) has fallen markedly by several percentage points compared to the previous year. Nevertheless, a need for further improvement is seen here as the proportion of just under 14 % of patients with an unknown survival status 1 year after the living liver donation seems too high.

The Federal Experts' Working Group, however, also stresses that the transplantation center need not always be responsible for the missing follow-up information. The Structured Dialogue for data collection year 2012 revealed that there are sometimes cases where transplantation centers have made great efforts, but were nevertheless unable to ascertain patients' survival status. This is due among other reasons to the fact that patients usually feel well after a living liver donation and therefore see no need to attend for aftercare. Contact with patients from abroad who had traveled specifically for the living liver donation was also sometimes difficult. In addition, patients in some cases refused any contact with the aftercare transplantation center, for example because the recipient of the living liver donation (usually a near relative) had died after the liver transplantation.

In the view of the Federal Experts' Working Group, the reasons mentioned can be accepted only in exceptional cases and do not justify the proportion of just under 14 % of donors with an unknown survival status.

| Description	
Numerator	Living liver donors who died within the 1st year after the donation or whose survival status 1 year after donation is unknown
Denominator	All living liver donors from data collection year 2012, excluding domino donors
Reference range	Sentinel event
Risk adjustment	No further risk adjustment
QI-ID	51603
Comparability with the previous year's results	Comparable. The result from data collection year 2012 presented here includes records that were not yet available at the time of the Federal Analysis 2012 and were only submitted subsequently (*) in the course of the Structured Dialogue.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	6	10
Confidence interval	–	–	–	–	–
Total number of cases	–	–	–	70	72
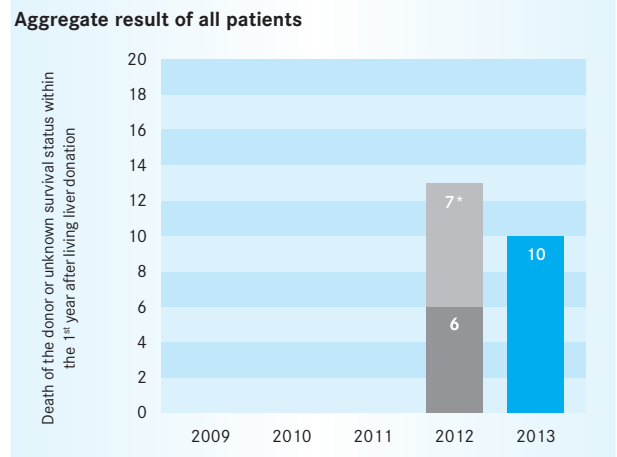
Aggregate result of all patients

Hospital-based results

Target population of all hospitals	12
Number of hospitals with 0 cases	0

0 Hospitals with ≥ 20 cases

Median	–	Number of computationally discrepant hospitals	–
Range	–		

5 Hospitals with 1 to 19 cases

Median	0.00 %	Number of computationally discrepant hospitals	5 of 12
Range	0.00 – 100.00 %		
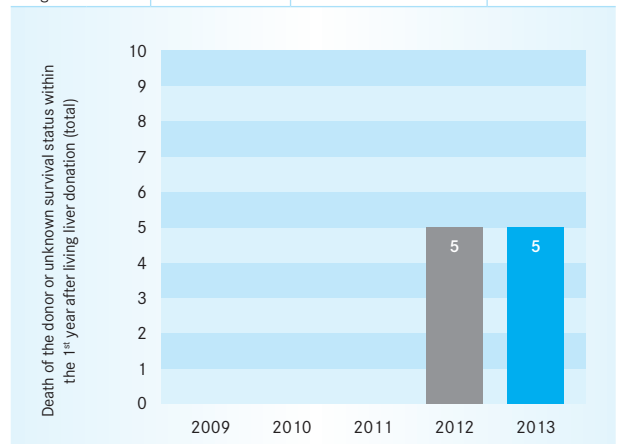
Kidney transplantation

Dr. Klaus Richter, Raphael Held, Theresia Höhne, Federal Experts' Working Group for Kidney and Pancreas Transplantation

Introduction
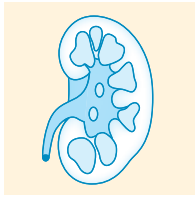
The most common causes of chronic kidney failure are diabetes mellitus, high blood pressure, inflammatory diseases of the "renal corpuscles" (called glomerulonephritis) and congenital diseases such as hereditary polycystic kidney. In end-stage kidney failure, called terminal renal insufficiency, only regular dialysis or a transplant can save the patient's life. Kidney transplantation is a well-established procedure and the best available treatment for patients with terminal renal insufficiency.

While the clinical area *Kidney transplantation* presented here exclusively addresses the organ recipient, the clinical area *Living kidney donation* focuses on the organ donor. Since 2006, all German transplantation centers in the clinical area *Kidney transplantation* must participate in the external hospital quality assurance. Monitoring the clinical course of patients one, two and three years after transplantation is one focus of quality assurance.

As in the previous year, the results for the follow-up survival rates report the indicator result as a worst-case analysis in addition to the existing indicators depicting the 1-, 2- or 3-year survival rates for patients with known survival status. This means that all patients with no information on survival status are considered deceased. The indicator therefore measures actual documented deaths and deaths that cannot be excluded due to improper documentation. In this way, worst-case indicators provide information on the documentation and/or the quality of aftercare in a hospital.

Regarding the previous year's results, records that were not supplied in the data collection year 2012 were subsequently submitted. These records are included in the calculation of the previous year's results presented here, so that the results may differ from those of the Federal Analysis 2012.

Services subject to mandatory documentation

All kidney transplantations must be documented, regardless of the type of donation: living or postmortem donation.

Changes in comparison to the previous year

At the joint meeting of the Federal Experts' Working Group for Transplantation Medicine, it was decided to adapt the indicator groups on survival to allow a more comprehensible depiction to the public. The indicators "1-year survival (for alive discharged patients after transplantation and known status)" (QI-ID 51558) and "1-year survival (for alive discharged patients after transplantation and worst-case analysis)" (QI-ID 51559) have been removed. The more easily understandable indicators "1-year survival (with known status)" (QI-ID 2144) and "1-year survival (worst-case analysis)" (QI-ID 51560) are retained. In addition, it was decided for these indicators to base the reference ranges, which are not uniformly defined, on internationally published outcomes across all clinical areas. For the indicator "1-year survival (worst-case analysis)" (QI-ID 51560), the reference range of ≥ 90 % is retained for the time being. For the indicators QI-ID 51561 and QI-ID 51562 from the indicator groups of 2- and/

or 3-year survival, percentile-based reference ranges have been defined.

The quality indicator "Transplant failure within the first year after kidney transplantation (with known status)" (QI-ID 12809) was also assigned a reference range (95th percentile) by the Federal Experts' Working Group.

Results

The results of the Structured Dialogue based on the data collection year 2012 showed a total of 29 computational discrepancies in 19 out of 40 hospitals providing data. The increase in computational discrepancies over the previous year was primarily due to the introduction of the worst-case indicators on survival. A total of 15 of these 29 computational discrepancies were evaluated as "qualitatively discrepant" by the Federal Experts' Working Group. The statements showed that information on survival status was available in the hospital for several patients but had not ultimately been documented. Some hospitals, moreover, were unaware that study results from other hospitals and physicians involved in aftercare could also be used. However, the current Structured Dialogue already shows a marked improvement in follow-up documentation completeness.

The other qualitatively discrepant results were in particular due to the occurrence of intra- and postoperative complications and to suboptimal donor-recipient selection (e.g., organs from elderly donors to young recipients). Against this background, the results of the indicator "Intra- or postoperative complications" (QI-ID 51557) are presented in detail below.

Due to the constantly decreasing number of postmortem donors, donors with poor health status or older donation age are also increasingly being accepted. Nevertheless, the 1-, 2- and 3-year survival results also show that the quality of care in Germany in respect of kidney transplantation is good in international terms. For example, the results of the indicator "2-year survival (worst-case analysis)" (QI-ID 51561) are presented below.

Looking forward

The worst-case analysis implemented for the second time in the data collection year 2013 shows a marked improvement in the documentation in the 1-, 2- and 3-year follow-up. The Federal Experts' Working Group hopes for a further increase in case completeness for follow-up so that even more valid patient follow-up data can be obtained. An optimal follow-up documentation, however, can only be achieved through a cross-sectoral procedure as well as using health insurance claims data. According to the Federal Experts' Working Group, in order to improve the quality of aftercare, there is an urgent need that transplantation centers increasingly undertake aftercare in the future.

Kidney transplantation

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	2,601	2,189	2,193	99.8 %
Hospitals	40	40	42*	95.2 %
Of which isolated kidney transplantations				
Records	2,446	2,139	n.a.	n.a.

* Two hospitals submitted a wrong declaration of conformity.

Kidney transplantations as well as pancreas and pancreas-kidney transplantations are recorded together in one documentation sheet and will therefore be depicted together in the data basis.

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	2,262	100 %
< 1 year	[ ]*	[ ]*
1 – 9 years	43	1.9 %
10 – 19 years	58	2.6 %
20 – 29 years	182	8.0 %
30 – 39 years	268	11.8 %
40 – 49 years	426	18.8 %
50 – 59 years	570	25.2 %
60 – 69 years	521	23.0 %
70 – 79 years	191	8.4 %
≥ 80 years	[ ]*	[ ]*
Sex		
Male	1,417	62.6 %
Female	845	37.4 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):

www.sqg.de/themen/NTX/

* Result not shown on data protection grounds

Kidney transplantation

Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator		2012 Result	2013 Result	2013 Cases (patients) Numerator	2013 Cases (patients) Denominator	Trend
	2171	In-hospital mortality	!	1.0 %	1.1 %	22	2,046	→
Indicator group		Immediate functionality of the transplant						
	2184	Immediate functionality of the transplant after postmortem organ donation	!	75.0 %	76.4 %	1,004	1,314	→
	2185	Immediate functionality of the transplant after living organ donation	!	96.0 %	95.6 %	679	710	→
Indicator group		Quality of transplant function at discharge						
	2188	Quality of transplant function at discharge after post-mortem organ donation	!	87.2 %	84.6 %	1,073	1,268	→
	2189	Quality of transplant function at discharge after living organ donation	!	97.5 %	96.3 %	680	706	→
	51557	Intra- or postoperative complications	!	17.5 %	19.8 %	405	2,046	→
Indicator group		1-year survival						
	2144	1-year survival (with known status)	!	95.8 %	96.3 %	2,294	2,383	→
	51560	1-year survival (worst-case analysis)	!	95.1 %	95.3 %	2,294	2,408	→
	12809	Transplant failure within the 1st year after kidney transplantation (with known status)	!	5.5 %	5.7 %	133	2,351	→
	12729	Quality of transplant function (1 year after transplantation)	!	97.8 %	97.2 %	2,085	2,145	→
	50065	No rejection requiring treatment within the 1st year after kidney transplantation	!	85.9 %	85.2 %	2,031	2,383	→
Indicator group		2-year survival						
	12199	2-year survival (with known status)	!	94.5 %	94.0 %	2,383	2,536	→
	51561	2-year survival (worst-case analysis)	!	91.0 %	90.8 %	2,383	2,625	→
	12810	Transplant failure within 2 years after kidney transplantation (with known status)	!	8.1 %	6.9 %	171	2,481	→
	12735	Quality of transplant function (2 years after transplant)	!	98.7 %	98.0 %	2,199	2,245	→
Indicator group		3-year survival						
	12237	3-year survival (with known status)	!	91.5 %	92.3 %	2,334	2,528	→
	51562	3-year survival (worst-case analysis)	!	84.3 %	86.1 %	2,334	2,712	→
	12811	Transplant failure within 3 years after kidney transplantation (with known status)	!	9.2 %	9.2 %	229	2,488	→
	12741	Quality of transplant function (3 years after transplant)	!	98.3 %	98.9 %	2,165	2,190	→

Kidney transplantation

Hospital-based aggregate results for utilization in quality assurance

	QI-ID	Name of the quality indicator	Reference range	Hospitals Total	Hospitals Discrepant (computationally)	Evaluation Category	Evaluation Need for action
	2171	In-hospital mortality	≤ 5.0 % (TO)	39	3	1	A
Indicator group		*Immediate functionality of the transplant*					
	2184	Immediate functionality of the transplant after postmortem organ donation	≥ 60.0 % (TO)	39	4	2	A
	2185	Immediate functionality of the transplant after living organ donation	≥ 90.0 % (TO)	38	8	2	A
Indicator group		*Quality of transplant function at discharge*					
	2188	Quality of transplant function at discharge after postmortem organ donation	≥ 70.0 % (TO)	39	1	2	A
	2189	Quality of transplant function at discharge after living organ donation	≥ 80.0 % (TO)	38	1	1	A
	51557	Intra- or postoperative complications	≤ 25.0 % (TO)	39	10	2	A
Indicator group		*1-year survival*					
	2144	1-year survival (with known status)	n.d.*	39	–	X	X
	51560	1-year survival (worst-case analysis)	≥ 90.0 % (TO)	39	4	2	A
	12809	Transplant failure within the 1st year after kidney transplantation (with known status)	≤ 18.1 % (TO; 95th percentile)	39	1	2	A
	12729	Quality of transplant function (1 year after transplantation)	n.d.*	39	–	X	X
	50065	No rejection requiring treatment within the 1st year after kidney transplantation	n.d.*	39	–	X	X
Indicator group		*2-year survival*					
	12199	2-year survival (with known status)	n.d.*	40	–	X	X
	51561	2-year survival (worst-case analysis)	≥ 79.0 % (TO; 10th percentile)	40	3	2	A
	12810	Transplant failure within 2 years after kidney transplantation (with known status)	n.d.*	40	–	X	X
	12735	Quality of transplant function (2 years after transplant)	n.d.*	40	–	X	X
Indicator group		*3-year survival*					
	12237	3-year survival (with known status)	n.d.*	39	–	X	X
	51562	3-year survival (worst-case analysis)	≥ 77.1 % (TO; 10th percentile)	39	4	2	A
	12811	Transplant failure within 3 years after kidney transplantation (with known status)	n.d.*	39	–	X	X
	12741	Quality of transplant function (3 years after transplant)	n.d.*	39	–	X	X

TO = Tolerance range; * not defined

Kidney transplantation

QI-ID 51557: Intra- or postoperative complications

Description

Numerator	Patients with at least one (severe) intra- or postoperative complication
Denominator	All patients with isolated kidney transplantation
Reference range	≤ 25.0 % (tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	51557
Comparability with the previous year's results	Limited comparability

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	16.4 %	17.5 %	19.8 %
Confidence interval	–	–	15.0–17.8 %	16.0–19.1 %	18.1–21.6 %
Total number of cases	–	–	2,651	2,336	2,046

Aggregate result of all patients
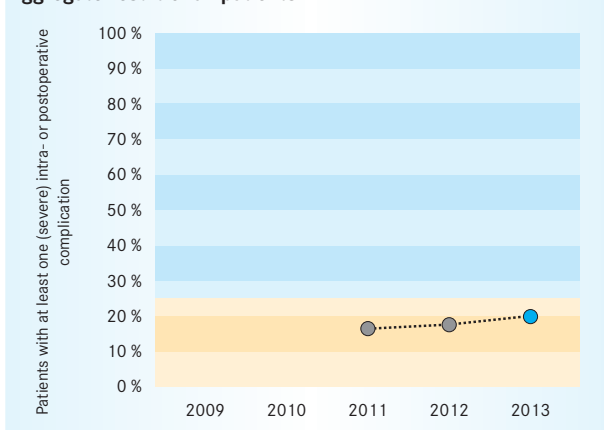
Hospital-based results

Target population of all hospitals	39
Number of hospitals with 0 cases	1

34 Hospitals with ≥ 20 cases

Median	18.8 %	Number of computationally discrepant hospitals	9 of 34
Range	4.8 – 50.0 %		

5 Hospitals with 1 to 19 cases

Median	11.1 %	Number of computationally discrepant hospitals	1 of 5
Range	0.0 – 33.3 %		
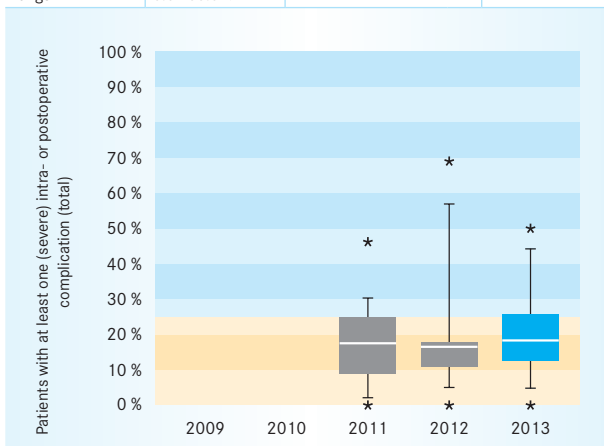
Quality target

Rare (severe) intra- or postoperative complications in kidney transplantation.

Background

Postoperative complication rates are between 2.4 and 14.1 %. Urine leakage is one of the most common early complications. Other frequent intra- or postoperative complications are infections and hemorrhages.

The quality indicator "Intra- or postoperative complications" (QI-ID 51557) is suitable for a comparative assessment of the quality of care in kidney transplantation centers. Such potential complications are monitored and recorded during the hospital stay. To a limited extent they may be unavoidable; however, if they occur to an increased extent, it is suggested that the surgical process, the surgical technique or the experience of the transplant surgeon should be critically reviewed in the Structured Dialogue.

Evaluating the results

Since 2012, only complications that are specifically attributable to surgery are documented. This includes transplantations that require reoperation or more than one blood transfusion, or in which complications occur that can be fatal (e.g., septicemia). However, in addition, fewer severe complications, such as superficial wound infections, were previously recorded by means of the indicator, which explains the high complication rate in many hospitals. The extent to which this state of affairs also applies in the data collection year 2013 must be reviewed in the Structured Dialogue. Whether an adaptation of the indicator for intra- or postoperative complications can lead to an improvement in documentation will be reviewed by the Federal Experts' Working Group following the conclusion of this year's Structured Dialogue within the scope of system maintenance and further development.

The overall rate of hospital results for intra- or postoperative complications of 19.8 % in the data collection year 2013 was slightly higher compared to the previous year (17.5 %). Following an isolated kidney transplant, intra- or postoperative complications were documented in 405 out of 2,046 patients. The very wide range of results (0 % to 50 %) is striking. In 10 out of the total of 39 hospitals, the complication rate was even between 25 and 50 %. Such results are unacceptably high in the view of the Federal Experts' Working Group.

The severe complications documented in the data collection year 2013 were, with a few exceptions, not life-threatening complications. This is shown by the overall rate of the indicator "In-hospital mortality" (QI-ID 2171), which has been stable in recent years at about 1.0 – 1.3 %.

Kidney transplantation

QI-ID 51561: 2-year survival (worst-case analysis)

Quality target

The highest possible 2-year survival rate.

Background

Survival after a kidney transplant is the most important outcome parameter for analyzing transplantation outcomes since, unlike organ survival time, this parameter also takes into account outcomes of treatment-related secondary diseases. On the one hand, adequate immunosuppression is an important determinant in the long-term success of transplantation because acute rejection reactions negatively impact on transplant survival, and on the other hand it is also associated with risks that affect patient survival.

The main causes of death in organ recipients in the first year after transplantation are cardiovascular diseases (26 %) and infections (24 %). Up to 3 years after transplantation, the relative proportion of deaths due to infections decreases, whereas the number of "malignant disease" as a cause of death increases.

While the indicator "2-year survival (with known status)" (QI-ID 12199) shows the survival of patients 2 years after transplantation and only includes patients whose survival status is known after the period concerned, in the worst-case analysis all patients are considered using the indicator described here (QI-ID 51561); patients whose survival status is unknown are regarded as deceased in the worst-case analysis.

Evaluating the results

The overall rate of 2-year survival in hospital in the data collection year 2013 was 90.8 % – i.e., well within the tolerance range of ≥ 79.0 % (10th percentile). Compared with the previous year, the quality of documentation has markedly improved. Although there were no data on survival status for 89 patients (3.4 %), the proportion of patients with an unknown status has fallen considerably compared to the previous year (11.8 %, n = 322). Since almost all missing records in the Structured Dialogue 2013 were subsequently submitted, a valid comparison of the results of data collection years 2012 and 2013 is possible. In the data collection year 2013, only 3 hospitals are "computationally discrepant". The Federal Experts' Working Group expressly welcomes this development.

Compared to international survival rates, the German results achieved reflect a good quality of care. A patient survival rate of more than 90 % is observed 2 years after transplantation and the results for organ survival are also to be warmly welcomed despite the trend to older donors and recipients.

Description

Numerator	Patients for whom information is available that they are alive 2 years after transplantation
Denominator	All patients with isolated kidney transplantation in the data collection year 2011 without retransplantation in the years 2012 and 2013
Reference range	≥ 79.0 % (10th percentile, tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	51561
Comparability with the previous year's results	Comparable. The result from the data collection year 2012 presented here includes records that were not yet available at the time of the Federal Analysis 2012 and were only submitted in the course of the Structured Dialogue.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	87.8 %	91.0 %	90.8 %
Confidence interval	–	–	86.5–89.0 %	89.9–92.0 %	89.6–91.8 %
Total number of cases	–	–	2,577	2,718	2,625

Aggregate result of all patients
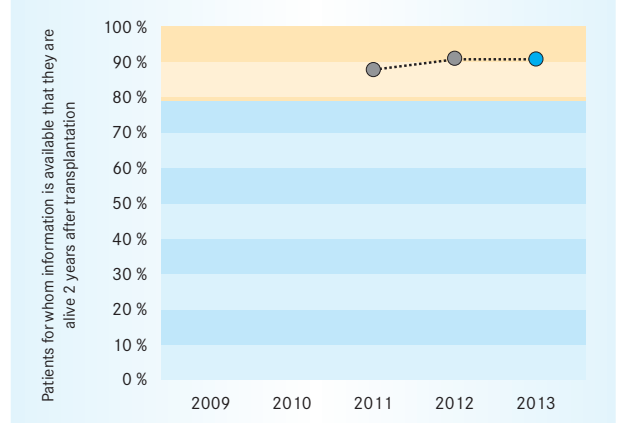
Hospital-based results

Target population of all hospitals	40
Number of hospitals with 0 cases	0

37 Hospitals with ≥ 20 cases

Median	91.8 %	Number of computationally discrepant hospitals	3 of 37
Range	72.7 – 100.0 %		

3 Hospitals with 1 to 19 cases

Median	100.0 %	Number of computationally discrepant hospitals	0 of 3
Range	84.6 – 100.0 %		
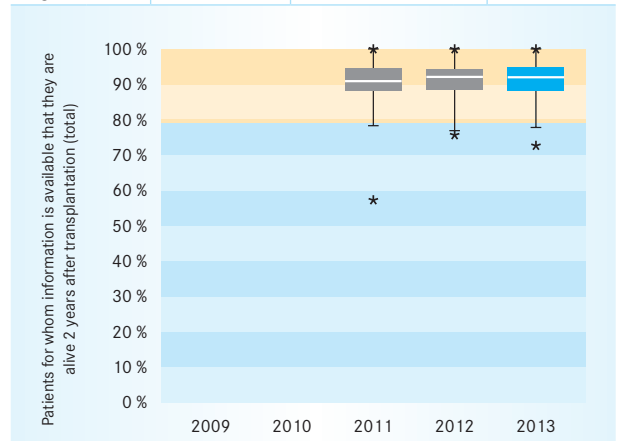
Living kidney donation

Dr. Klaus Richter, Raphael Held, Theresia Höhne, Federal Experts' Working Group for Kidney and Pancreas Transplantation

Introduction
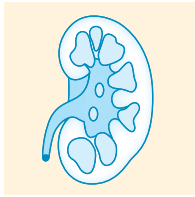
Given the current shortage of organs, the demand for living organ donations on the part of patients and their relatives is growing rapidly. To be qualified for a living donation, donors must be in a good state of health and consent voluntarily to the organ donation; this consent must be reviewed by an independent living donation committee. Against this background, the German Transplantation Law allows living kidney donation exclusively to first- and second-degree relatives, spouses, registered life partners or fiancé(e)s and other persons "who have an obviously close personal relationship with the prospective donor" (Transplantation Law: section 8).

The quality assurance procedure for *Living kidney donation* exclusively addresses the donor. In living donations, a maximum of safety should be achieved by the best possible quality of medical care and thorough preoperative evaluation of the donor's health. It is of major importance that the donor be protected against all complications.

Since 2006, all German hospitals working in the clinical area of *Living kidney donation* have to fulfill the mandatory requirement of participating in external hospital quality assurance. One focus of quality assurance is to monitor the clinical course of patients after one, two and three years (follow-up).

The results for the follow-up survival rates include both the existing indicators showing the 1-, 2- or 3-year survival rates for patients with known survival status and the indicator result, which will also be recorded as a worst-case analysis. This means that all patients with no information on survival status are considered deceased. The indicator therefore measures actual documented deaths and deaths that cannot be excluded due to improper documentation. In this way, worst-case indicators provide information on the documentation and/or the quality of aftercare in a hospital.

In the results for the previous year, it should be noted that records which had not been supplied in data collection year 2012 can be submitted subsequently. These are included in the calculation of the previous year's results presented here, so that there may be results that differ from the Federal Analysis 2012.

Services subject to mandatory documentation

All living kidney donations.

Changes in comparison to the previous year

At the joint meeting of the Federal Experts' Working Group for Transplantation Medicine, it was decided to adapt the title of the worst-case indicator on mortality to allow a more comprehensible description. In addition, starting in the data collection year 2013, albuminuria rather than urine total protein is being recorded as a marker of renal injury to allow a clear conclusion to be drawn about renal impairment. The indicator "Emergent arterial hypertension within the 1st year after living kidney donation" (QI-ID 12667) was amended so as to exclude patients who had hypertension before their admission to hospital until the time of their discharge from the calculation.

Results

The results of the Structured Dialogue based on data collection year 2012 showed a total of 77 computational discrepancies. The increase in computational discrepancies over the previous year was primarily due to the introduction of the worst-case indicators on mortality. Due to insufficient aftercare provision or lack of documentation of the actually known survival status of the donor, 50 of these 77 computational discrepancies were assessed by the Federal Experts' Working Group as "qualitatively discrepant". Some hospitals, moreover, were unaware that study results from other hospitals and physicians involved in aftercare could also be used for documentation. Possible improvement measures were agreed with the hospitals concerned within the Structured Dialogue. However, a marked improvement regarding case completeness of the follow-up documentation was observed in the Structured Dialogue on the basis of data collection year 2013.

Overall, according to the Federal Expert's Working Group, as in the previous year, the available results of the analysis in this clinical area reflect a very good medical quality of care for the donor.

Looking forward

The worst-case analysis used for the second time in the data collection year 2013 shows a marked improvement in the documentation of aftercare of living donors in the 1-, 2- and 3-year follow-up. The Federal Experts' Working Group hopes for a further increase in case completeness for follow-up so that even more valid donor follow-up data can be obtained. Optimal follow-up documentation, however, can only be achieved by using health insurance claims data. To achieve continuous aftercare as far as possible, it is an urgent requirement in the opinion of the Federal Experts' Working Group that in the future this should be undertaken jointly by the inpatient and outpatient sectors. The Federal Experts' Working Group also recommends an extension of aftercare data documentation to 5 or 10 years in the clinical area *Living kidney donation*.

Living kidney donation

Data basis				
	2012	**2013**		
	Reported	Reported	Expected	Case completeness
Records	760	725	726	99.9 %
Hospitals	37	38	38	100.0 %

Basic statistics		
	2013	
	Number	Proportion
Age distribution		
Number of patients	725	100 %
< 20 years	[ ]*	[ ]*
20 – 29 years	20	2.8 %
30 – 39 years	51	7.0 %
40 – 49 years	196	27.0 %
50 – 59 years	285	39.3 %
60 – 69 years	149	20.6 %
70 – 79 years	21	2.9 %
≥ 80 years	[ ]*	[ ]*
Sex		
Male	293	40.4 %
Female	432	59.6 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):

www.sqg.de/themen/NLS/

* Result not shown on data protection grounds

Living kidney donation

Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator		2012 Result	2013 Result	Cases (patients) Numerator	Denominator	Trend
	2137	In-hospital mortality		0.00 %	0.00 %	0	725	→
	2138	Dialysis required in the living donor		0.00 %	0.00 %	0	725	→
	51567	Intra- or postoperative complications		3.2 %	2.2 %	16	725	→
Indicator group		Death of the donor within the 1st year after living kidney donation						
	12440	Death of the donor within the 1st year after living kidney donation		[ ]**	[ ]**	[ ]**	732	→
	51568	Death or unknown survival status of the donor within the 1st year after living kidney donation		4.29 %	3.82 %	29	760	→
	12636	Impaired renal function of the donor (1 year after living kidney donation)		[ ]**	[ ]**	[ ]**	724	→
	51997	Albuminuria within 1 year after living kidney donation		n.c. *	12.6 %	85	673	n.a.***
	12667	Emergent arterial hypertension within the 1st year after living kidney donation		7.5 %	11.3 %	59	524	→
Indicator group		Death of the donor within 2 years after living kidney donation						
	12452	Death of the donor within 2 years after living kidney donation		[ ]**	[ ]**	[ ]**	746	→
	51569	Death or unknown survival status of the donor within 2 years after living kidney donation		7.70 %	6.19 %	49	792	→
	12640	Impaired renal function of the donor (2 years after living kidney donation)		[ ]**	[ ]**	[ ]**	730	→
	51998	Albuminuria within 2 years after living kidney donation		n.c.*	10.0 %	66	663	n.a.***
Indicator group		Death of the donor within 3 years after living kidney donation						
	12468	Death of the donor within 3 years after living kidney donation		0.4 %	1.0 %	6	599	→
	51570	Death or unknown survival status of the donor within 3 years after living kidney donation		22.91 %	10.42 %	69	662	↗
	12644	Impaired renal function of the donor (3 years after living kidney donation)		[ ]**	[ ]**	[ ]**	581	→
	51999	Albuminuria within 3 years after living kidney donation		n.c.*	12.9 %	68	527	n.a.***

* not calculated; ** result not shown on data protection grounds; *** not applicable

Living kidney donation

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		Evaluation	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
2137	In-hospital mortality	Sentinel-Event	38	0	X	X
2138	Dialysis required in the living donor	Sentinel event	38	0	X	X
51567	Intra- or postoperative complications	≤ 10.0 % (TO)	38	4	2	A
	Death of the donor within the 1st year after living kidney donation					
12440	Death of the donor within the 1st year after living kidney donation	n.d.*	37	–	X	X
51568	Death or unknown survival status of the donor within the 1st year after living kidney donation	Sentinel event	37	11	X	A
12636	Impaired renal function of the donor (1 year after living kidney donation)	Sentinel event	37	1	X	A
51997	Albuminuria within 1 year after living kidney donation	n.d.*	37	–	X	X
12667	Emergent arterial hypertension within the 1st year after living kidney donation	n.d.*	36	–	X	X
	Death of the donor within 2 years after living kidney donation					
12452	Death of the donor within 2 years after living kidney donation	n.d.*	40	–	X	X
51569	Death or unknown survival status of the donor within 2 years after living kidney donation	Sentinel event	40	17	X	A
12640	Impaired renal function of the donor (2 years after living kidney donation)	Sentinel event	39	2	X	X
51998	Albuminuria within 2 years after living kidney donation	n.d.*	38	–	X	X
	Death of the donor within 3 years after living kidney donation					
12468	Death of the donor within 3 years after living kidney donation	n.d.*	38	–	X	X
51570	Death or unknown survival status of the donor within 3 years after living kidney donation	Sentinel event	38	18	X	A
12644	Impaired renal function of the donor (3 years after living kidney donation)	Sentinel event	38	2	X	X
51999	Albuminuria within 3 years after living kidney donation	n.d.*	37	–	X	X

Indicator group (rows 12440–12667)
Indicator group (rows 12452–51998)
Indicator group (rows 12468–51999)

TO = Tolerance range; * not defined

Pancreas and pancreas-kidney transplantation

Dr. Klaus Richter, Raphael Held, Theresia Höhne, Federal Experts' Working Group for Kidney and Pancreas Transplantation

Introduction
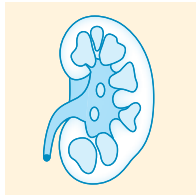
Currently, only type 1 diabetics suffering from end-organ damage after a prolonged course of their underlying disease, particularly with advanced stage of renal impairment, are considered for the transplantation of the pancreas and/or for combined pancreas-kidney transplantation. In this group of patients, the pancreas and the kidney are transplanted together. Such combination transplants not only improve the patient's quality of life, but can also be regarded as a life-saving intervention in that they prevent renewed diabetic damage to the kidney and cut the mortality risk by half. Pancreas transplantation is considered as a treatment of the underlying cause for insulin-dependent diabetes mellitus. The transplantation objective is to restore a sufficient level of endogenous insulin production that eliminates the need for any additional insulin therapy and/or to replace a damaged kidney.

Since 2007, all German transplantation centers working in the clinical area *Pancreas and pancreas-kidney transplantation* have to fulfill the mandatory requirement of participating in external hospital quality assurance. One focus of quality assurance is to monitor the clinical course of patients after one, two and three years (follow-up).

Since 2012, given the overall low number of cases in this clinical area, the cumulative analysis has covered the data from two years. This means that the Structured Dialogue with the hospitals is only conducted every two years as well.

The results for the follow-up survival rates present, in addition to the existing indicators mapping the 1-, 2- or 3-year survival rates for patients with known survival status, the indicator result which is also recorded as a worst-case analysis. This means that all patients with no information on survival status are considered deceased. The indicator therefore measures both actual documented deaths and deaths that cannot be excluded due to improper documentation. In this way, worst-case indicators provide information on the quality of documentation and/or aftercare in a hospital.

In the results of the previous year, it should be noted that records not supplied in data collection year 2012 can be submitted subsequently. Those are included in the calculation of the previous year's results presented here, so that there may be some discrepancy compared to the Federal Analysis 2012.

Services subject to mandatory documentation

All pancreas or combined pancreas and kidney transplantations are to be documented and collected together in one documentation form.

Changes in comparison to the previous year

At the joint meeting of the Federal Experts' Working Group for Transplantation Medicine, it was decided to adjust the indicator groups on survival to allow a more comprehensible depiction to the public. The indicators "1-year survival (for alive discharged patients after transplantation and known status)" (QI-ID 51515) and "1-year survival (for alive discharged patients after transplantation and worst-case analysis)" (QI-ID 51525) were omitted. The indicators "1-year survival (with known status)" (QI-ID 12493) and "1-year survival (worst-case analysis)" (QI-ID 51524) are easier to understand and were kept.

Results

Due to the usually very low number of cases in this clinical area, the power of quality indicators is limited as they are only based on one data collection year. That was why there were no reference ranges defined for the indicators in the past either. In 2011, the Federal Experts' Working Group decided to examine the results for the two data collection years together in order to increase their power.

In the past year, the data from data collection years 2011 and 2012 were aggregated and reference ranges defined. This meant that computationally discrepant results could be analyzed and assessed in the Structured Dialogue 2013 for the first time. The analysis of these data yielded a total of 21 computational discrepancies in 12 of 26 hospitals. The Federal Experts' Working Group evaluated 4 of these computational discrepancies as "qualitatively discrepant" within the Structured Dialogue. The qualitatively discrepant results were mainly due to surgery and missing documentation. In one hospital, prior vascular damage to the pancreas transplant led to complications and ultimately to the death of the patient. The Federal Experts' Working Group considers the results of data collection years 2011 and 2012 at the federal level nevertheless of a predominantly satisfactory quality of care.

Looking forward

The Federal Experts' Working Group for Kidney and Pancreas Transplantation hopes for a further increase in follow-up case completeness so that even more valid patient follow-up data can be obtained. Optimal follow-up documentation, however, can only be achieved with a cross-sectoral procedure or by using health insurance claims data. To improve the quality of aftercare, Federal Experts' Working Group points to the urgent need for transplantation centers to conduct more intensified aftercare in the future.

In this clinical area, the cumulative data over two years are analyzed due to its usually very low number of cases. The same applies to implementation of the Structured Dialogue, which will not take place until 2015, based on results of data collection years 2013 and 2014.

Pancreas and pancreas-kidney transplantation

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	2,601	2,189	2,193	99.8 %
Hospitals	40	40	42*	95.2 %

Of which, isolated pancreas transplants, simultaneous pancreas-kidney transplantations, pancreas transplants after kidney transplantation

Records	152	127	n.a.	n.a.

* Two hospitals submitted a false conformity declaration.

Kidney transplantations and pancreas and pancreas-kidney transplantations are captured together in one documentation sheet and are presented together in the data basis.

Basic statistics

	2012/2013	
	Number	Proportion
Age distribution		
Number of patients	274	100 %
< 1 year	0	0.0 %
1 – 9 years	0	0.0 %
10 – 19 years	0	0.0 %
20 – 29 years	11	4.0 %
30 – 39 years	74	27.0 %
40 – 49 years	103	37.6 %
50 – 59 years	74	27.0 %
60 – 69 years	12	4.4 %
70 – 79 years	0	0.0 %
≥ 80 years	0	0.0 %
Sex		
Male	167	60.9 %
Female	107	39.1 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/PNTX/

Pancreas and pancreas-kidney transplantation

Case-based aggregate results (patients)

| QI-ID | Name of the quality indicator | | 2012/2013 accumulated | | |
| | | | | Cases (patients) | |
			Result	Numerator	Denominator
2143	In-hospital mortality		3.3 %	9	274
2145	Quality of transplant function at discharge		85.0 %	226	266
2146	Removal of the pancreas transplant		10.5 %	29	275
	1-year survival				
12493	1-year survival (with known status)		94.5 %	292	309
51524	1-year survival (worst-case analysis)		93.6 %	292	312
12824	Quality of the transplant function (1 year after transplantation)		84.2 %	251	298
	2-year survival				
12509	2-year survival (with known status)		89.7 %	262	292
51544	2-year survival (worst-case analysis)		86.2 %	262	304
12841	Quality of transplant function (2 years after transplantation)		82.5 %	227	275
	3-year survival				
12529	3-year survival (with known status)		88.5 %	207	234
51545	3-year survival (worst-case analysis)		80.2 %	207	258
12861	Quality of transplant function (3 years after transplantation)		80.0 %	172	215

Indicator group (1-year survival, 2-year survival, 3-year survival)

Pancreas and pancreas-kidney transplantation

Hospital-based aggregate results for utilization in quality assurance

| | | | 2012/2013 accumulated | | | |
| | | | Hospitals | | Evaluation | |
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
2143	In-hospital mortality	n.d.*	26	–	X	X
2145	Quality of transplant function at discharge	n.d.*	26	–	X	X
2146	Removal of the pancreas transplant	n.d.*	26	–	X	X
	1-year survival					
12493	1-year survival (with known status)	n.d.*	26	–	X	X
51524	1-year survival (worst-case analysis)	n.d.*	26	–	X	X
12824	Quality of the transplant function (1 year after transplantation)	n.d.*	26	–	X	X
	2-year survival					
12509	2-year survival (with known status)	n.d.*	25	–	X	X
51544	2-year survival (worst-case analysis)	n.d.*	25	–	X	X
12841	Quality of transplant function (2 years after transplantation)	n.d.*	25	–	X	X
	3-year survival					
12529	3-year survival (with known status)	n.d.*	24	–	X	X
51545	3-year survival (worst-case analysis)	n.d.*	24	–	X	X
12861	Quality of transplant function (3 years after transplantation)	n.d.*	24	–	X	X

Indicator group (1-year survival)
Indicator group (2-year survival)
Indicator group (3-year survival)

* not defined

Breast surgery

Stephanie Wrede, Kathrin Wehner, Federal Experts' Working Group for Breast Surgery

Introduction
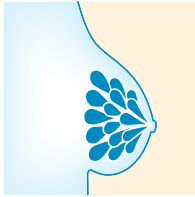
The clinical area *Breast surgery* addresses the treatment of breast cancer (mammary carcinoma, breast Ca). With around 70,000 new cases annually, it is the most common type of cancer in women in Germany. Annually, mammary carcinoma causes approximately 17,000 deaths. In extremely rare cases, this disease can also affect men. About 600 new cases are recorded annually in men through the cancer registry.

Early detection as well as adequate diagnostic procedures and stage-appropriate treatment of breast cancer improve the quality of life of patients and reduce disease-related mortality. Treatment planning should be done comprehensively and meticulously. When selecting treatment options, the patient's individual situation, treatment objective, risk-benefit assessment as well as patient preferences should all be taken into consideration. Important requirements are interdisciplinary and cross-sectoral cooperation between different healthcare providers as well as informed and shared decision-making between the patient and the physician.

A distinction in the surgical treatment options of mammary carcinoma is drawn between breast-conserving surgery and complete removal of the affected breast (mastectomy). Following a mastectomy there is the possibility of the simultaneous or subsequent reconstruction of the breast with the patient's own tissue or implants. The lymph node status, which provides an indication of whether and to what extent tumor invasion of the lymph nodes of the underarm (axilla) has occurred in a patient, can influence both further treatment planning and the course of the disease. In order to assess the lymph node status, removal of the sentinel lymph nodes and in some cases extirpation of the axillary lymph nodes (axillary dissection) may be necessary. Depending on the type of surgery and the extent of the tumor, radiation therapy may be required. Furthermore, treatment of breast cancer can also include chemotherapy, hormone therapy and/or antibody therapy, depending on the type and properties of the tumor.

The consistent application of evidence-based standards in breast cancer therapy and psycho-oncological support of the whole therapeutic process can lead overall to both improvements in the individual prognosis in affected women and an elevation of their quality of life. In every stage of treatment, the quality of care is the deciding factor for survival and quality of life. The indicators of the clinical area *Breast surgery* undergo continuous development in accordance with current national and international guidelines. As such, quality assurance measures play an important role in the implementation of guideline-compliant standards in routine treatment.

Services subject to mandatory documentation

All open biopsies and tumor-resecting and axillary interventions performed to diagnose benign or malignant tumors, precancerous lesions or presumed tumors of the breast.

Changes in comparison to the previous year

The indicator "Pretherapeutic histological diagnosis verification" (QI-ID 51846) was newly introduced as a modification of one indicator of the S3 guideline "Diagnosis, therapy and aftercare of breast cancer". As a result, a joint indicator for palpable and non-palpable findings was used for the first time with a reference range of ≥ 90.0 %. The previous indicator group "Pretherapeutic diagnosis verification" has been omitted.

The indicator "Indication for sentinel lymph node biopsy" (QI-ID 51847) was introduced for the first time instead of the indicator "Sentinel lymph node biopsy with pT1 without lymph node invasion" (QI-ID 2262) and likewise corresponds to an indicator recommended in the S3 guideline. The new indicator now includes tumors of all stages.

Based on the findings from the previous Structured Dialogues, various adjustments have been made to the indicator "Lymph node removal with DCIS and breast-conserving therapy" (QI-ID 50719). For the purposes of increasing accuracy, patients in whom an invasive carcinoma has been identified in the preoperative histological findings and patients with preoperative therapy are now excluded from the indicator. In addition, plausibility rules have been introduced to improve the documentation quality in terms of data on histological findings.

As a result of the revision of the data field for axillary dissection, the indicators "Primary axillary dissection with DCIS" (QI-ID 2163) and "Indication for sentinel lymph node biopsy" (QI-ID 51847) can be mapped more validly in 2013 than in the previous years. Cases with the additional removal of individual, unmarked lymph nodes are now recorded separately and can therefore be included in the corresponding calculation formula. The results of the indicators mentioned are therefore not comparable with those of the previous year. In particular, the marked increase in the overall rate in the indicator for sentinel lymph node biopsy must be interpreted against the background of the different data basis.

The indicators "Metric documenting safety margin with breast-conserving therapy" (QI-ID 2131) and "Metric documenting safety margin with mastectomy" (QI-ID 2162) are no longer recorded. In the opinion of the Federal Experts' Working Group, it may be assumed that the documentation of the metric safety margin in the pathology report is now done extensively and therefore no further potential for improvement is to be expected. In addition, the results and feedback from the Structured Dialogue of the past few years have shown that the majority of all computational discrepancies involved documentation errors and not treatment deficiencies.

Since data collection year 2013, the indicator "Breast-conserving therapy with pT1" (QI-ID 2167) has no longer been a constituent part of the clinical area. In the opinion of the Federal Experts' Working Group, this indicator provides a misincentive to perform breast-conserving surgery too often. In addition, the findings from the Structured Dialogues of previous years have shown that suspected quality deficiencies in terms of the indication for breast-conserving therapy can be identified to only a limited extent with this indicator.

Breast surgery

Furthermore, the indicator "At least 10 lymph nodes removed with lymph node invasion" (QI-ID 11989) is no longer recorded. The benefit of removing at least 10 lymph nodes in the course of axillary dissection is called into question as a result of new study findings and against the background of the risk of morbidity associated with the intervention.

Results

For the clinical area *Breast surgery* a good quality of care may be assumed in large part in terms of the national average. Gratifyingly, the overall rates of all indicators are again within the defined reference ranges.

Some results, however, give cause to focus on certain problems in particular areas of care: thus, a special need for action is seen for the indicator "Lymph node removal with DCIS and breast-conserving therapy" (QI-ID 50719). Against the background of the guideline recommendations, the national overall rate of 16 % indicates that a not inconsiderable proportion of patients considered in the indicator are overtreated. In the opinion of the Federal Experts' Working Group, there is therefore a need to address the care situation at specialist congresses. In addition, the procedure in the cases recorded in the indicator with lymph node removal should be investigated precisely in the Structured Dialogue with computationally discrepant hospitals.

Moreover, the indicators "Pretherapeutic histological diagnosis verification" (QI-ID 51846) and "Indication for sentinel lymph node biopsy" (QI-ID 51847) are classed as having an extended need for action. The reason for this is the clearly deviating values for the group of hospitals with fewer than 20 cases in the target population of the indicator. It should be clarified in greater detail in the Structured Dialogue whether the necessary equipment is available for the procedures concerned.

The trend of the previous years in the results of the indicator group on the time interval between diagnosis and surgery (QI-ID 51370, QI-ID 51371) continues: the proportion of patients undergoing surgery more than 21 days after diagnosis is increasing, whereas the proportion of patients undergoing surgery prior to 7 days after diagnosis is decreasing.

Based on the total of 1,140 computational discrepancies in data collection year 2012, the responsible offices at the state level requested 483 statements from the hospitals concerned. After conclusion of the Structured Dialogue, the evaluation "qualitatively discrepant" was assigned in 79 cases. In the majority of cases, this classification was made based on notices of structural or process deficiencies without further detail from the States. In this respect, particular attention may be drawn to the indicators on pretherapeutic diagnosis verification (QI-ID 50047, QI-ID 50080), for which this classification was assigned 26 times in total.

Looking forward

The indicators in the clinical area *Breast surgery* are constantly undergoing further development according to nationally and internationally valid guidelines. In addition, the quality assurance results are used by medical societies to intensify the discussions on quality of care.

The indicators "Hormone receptor analysis" (QI-ID 2135), "HER-2/neu analysis" (QI-ID 2261), "Metric documenting safety margin with breast-conserving therapy" (QI-ID 2131) and "Metric documenting safety margin with mastectomy" (QI-ID 2162) were suspended in the past two years because it had been possible over time to implement the associated quality aims extensively in clinical practice. For other areas of care yet to be accounted for, the Federal Experts' Working Group sees a need to promote quality improvements by introducing new indicators. As part of the further development, new indicators should be developed on the subjects of HER-2/neu positivity rate, genetic risk screening and indication for wire marking. For the coming data collection year, the calculation formula of the indicator "Intraoperative specimen sonography with sonographic wire marking" (QI-ID 51369) will also be adapted once the requisite data fields have been modified.

For an extensive portrayal of the quality of care in *Breast surgery*, the aim in future should be to introduce a patient survey as an integral component of external hospital quality assurance. This will involve scrupulously weighing up the advantages and disadvantages of diagnostic and therapeutic measures for treating mammary carcinoma with regard to patients' personal preferences and individual quality of life. The informed process of joint decision-making between patient and physician is a fundamental component of treatment planning, therapy and follow-up care. In addition to process quality, e.g., with respect to the joint decision-making process, psycho-oncological care and transfer to neighboring disciplines, aspects of the outcome quality could be recorded by means of a patient survey.

Breast surgery

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	114,400	115,640	115,758	99.9 %
Hospitals	910	904	913	99.0 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Anzahl der Patientinnen	115,399	100 %
< 30 years	3,272	2.8 %
30 – 39 years	5,842	5.1 %
40 – 49 years	20,214	17.5 %
50 – 59 years	28,981	25.1 %
60 – 69 years	26,651	23.1 %
70 – 79 years	22,065	19.1 %
≥ 80 years	8,374	7.3 %
Sex		
Male	990	0.9 %
Female	114,409	99.1 %
ASA classification		
ASA 1: A normal healthy patient	34,882	30.2 %
ASA 2: A patient with mild systemic disease	62,492	54.2 %
ASA 3: A patient with severe systemic disease	17,502	15.2 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	499	0.4 %
ASA 5: A moribund patient who is not expected to survive without the operation	24	< 0.1 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German): *www.sqg.de/themen/18n1/*

Breast surgery

Case-based aggregate results (patients)

			2012	2013			
				Cases (patients)			
	QI-ID	Name of the quality indicator	Result	Result	Numerator	Denominator	Tendenz
	51846	Pretherapeutic histological diagnosis verification	95.9 %	96.1 %	72,223	75,127	→
Indicator group		Intraoperative specimen x-ray and intraoperative specimen sonography					
	303	Intraoperative specimen x-ray with mammographic wire marking [!]	97.1 %	96.7 %	20,568	21,267	→
	51369	Intraoperative specimen sonography with sonographic wire marking	63.5 %	66.7 %	13,191	19,780	↗
	2163	Primary axillary dissection in DCIS	1.7 %	1.1 %	85	7,451	→
	50719	Lymph node removal with DCIS and breast-conserving therapy	18.1 %	16.0 %	866	5,419	↗
	51847	Indication for sentinel lymph node biopsy	87.7 %	93.9 %	34,859	37,106	↗
Indicator group		Interval between diagnosis and surgery					
	51370	Interval below 7 days between diagnosis and surgery	12.3 %	10.5 %	6,598	62,766	↗
	51371	Interval over 21 days between diagnosis and surgery	23.8 %	27.0 %	16,973	62,766	↘

Breast surgery

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
51846	Pretherapeutic histological diagnosis verification	≥ 90.0 % (Z)	807	190	2	B
	Intraoperative specimen x-ray and intraoperative specimen sonography					
303	Intraoperative specimen x-ray with mammographic wire marking	≥ 95.0 % (TA)	593	117	2	A
51369	Intraoperative specimen sonography with sonographic wire marking	n.d.*	564	–	X	X
2163	Primary axillary dissection in DCIS	≤ 5.0 % (TO)	560	39	2	A
50719	Lymph node removal with DCIS and breast-conserving therapy	≤ 29.8 % (TO; 90th percentile)	517	106	2	C
51847	Indication for sentinel lymph node biopsy	≥ 80.0 % (TA)	720	115	2	B
	Interval between diagnosis and surgery					
51370	Interval below 7 days between diagnosis and surgery	≤ 42.1 % (TO; 97.5th percentile)	745	69	3	A
51371	Interval over 21 days between diagnosis and surgery	≤ 55.1 % (TO; 97.5th percentile)	745	29	2	A

Indicator group (51846 row group — left label)

Indicator group (51370/51371 row group — left label)

TO = Tolerance range; TA = Target range; * not defined

Breast surgery

QI-ID 51846: Pretherapeutic histological diagnosis verification

Quality target

As many patients as possible with pretherapeutic histological verification by punch or vacuum biopsy with primary disease invasive mammary carcinoma or ductal carcinoma in situ (DCIS) and primary intervention.

Background

If a tumor has been diagnosed by sonography or mammography, it must be investigated histologically (i.e., in a tissue specimen) for its malignant or benign nature. The diagnosis should be verified before the actual treatment is initiated. It is only in this way that the subsequent course of treatment can be carefully planned and a stage-appropriate treatment ensured in the case of malignant tumors.

The guidelines recommend obtaining tissue for diagnosis verification by means of a punch or vacuum biopsy. This involves taking tissue by means of special needles which are either x-ray controlled (stereotactically) or ultrasound controlled (sonographically), depending on the findings. With the availability now of minimally invasive methods, an open diagnostic excision biopsy performed under general anesthesia, which is more stressful for the patient, must be strictly indicated. It should only be used if a punch or vacuum biopsy is impossible or too risky.

The present indicator was calculated for the first time in data collection year 2013 and used in place of the indicator group "Pretherapeutic diagnosis verification" with the indicators "Pretherapeutic diagnosis verification with palpable malignant neoplasms" (QI-ID 50080) and "Pretherapeutic diagnosis verification with non-palpable malignant neoplasms" (QI-ID 50047). In line with the indicator recommended in the S3 guideline "Diagnosis, therapy and aftercare of breast cancer", stratification by palpable and non-palpable findings has been omitted. Only cases with pretherapeutic diagnosis verification by punch or vacuum biopsy are included in the numerator of the new indicator.

Evaluating the results

The overall rate of the indicator points to a good quality of care in terms of the federal average: in 96.1 % of all patients with mammary carcinoma in 2013, a histological diagnosis verification by punch or vacuum biopsy was performed before the first surgical intervention. This result is clearly within the reference range of ≥90 % recommended by the S3 guideline for the diagnosis, therapy and aftercare of breast cancer and is to be regarded as positive. However, 190 of the 807 hospitals did not achieve the reference range. In particular, the Federal Experts' Working Group adopts a critical view on the results in hospitals with fewer than 20 cases in the target population of the indicator. The median of the indicator for this group is only 87.5 %; with 145 hospitals, more than half of the hospitals in this group are "computationally discrepant".

Based on these results, the indicator is deemed to have an "extended need for action" (category B). The Federal Experts' Working Group suspects that structural problems might be one of the causes for low rates in pretherapeutic histological diagnosis verification. For this reason, in the case of computationally discrepant hospitals the State Administrative Offices for Quality Assurance (LQS) have been asked to investigate specifically in the Structured Dialogue for data collection year 2013 whether the necessary structures and equipment are available for undertaking punch and vacuum biopsies. The results of the quality assurance should also be presented and discussed at specialist conferences.

Description	
Numerator	Patients with pretherapeutic histological diagnosis verification by punch or vacuum biopsy
Denominator	All patients with a primary intervention with primary disease and histology "invasive mammary carcinoma (primary tumor)" or "DCIS"
Reference range	≥90.0 % (target range)
Risk adjustment	No further risk adjustment
QI-ID	51846
Comparability with the previous year's results	The indicator was introduced for the first time and calculated retrospectively for data collection year 2012. It replaces the indicator group "Pretherapeutic diagnosis verification".

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	95.9 %	96.1 %
Confidence interval	–	–	–	95.7–96.0 %	96.0–96.3 %
Total number of cases	–	–	–	74,013	75,127

Aggregate result of all patients
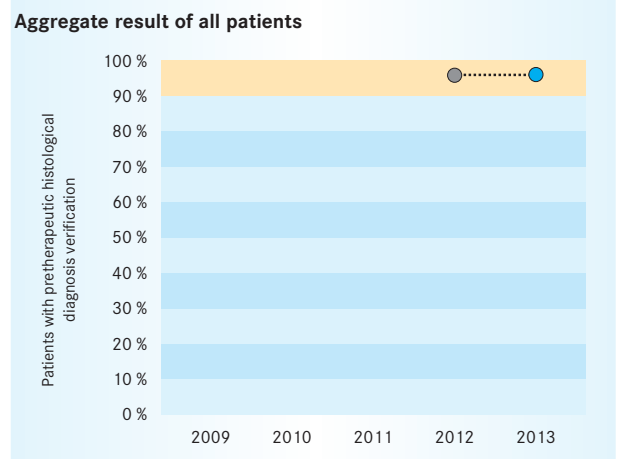
Hospital-based results

Target population of all hospitals	807
Number of hospitals with 0 cases	97

536 Hospitals with ≥ 20 cases

Median	96.9 %	Number of computationally discrepant hospitals	45 of 536
Range	68.0 – 100.0 %		

271 Hospitals with 1 to 19 cases

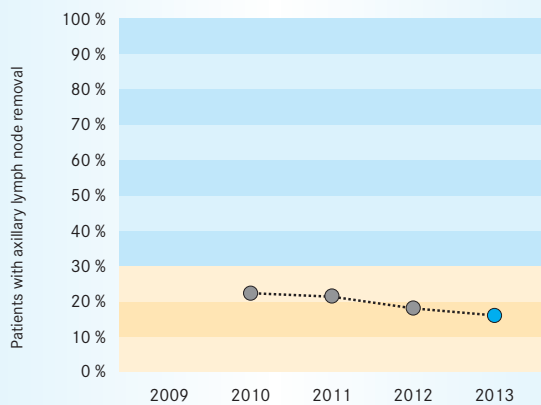| Median	87.5 %	Number of computationally discrepant hospitals	145 of 271
Range	0.0 – 100.0 %		

Breast surgery

QI-ID 50719: Lymph node removal with DCIS and breast-conserving therapy

Description	
Numerator	Patients with axillary lymph node removal
Denominator	All patients with histology "DCIS" and completed surgical therapy with primary disease, breast-conserving therapy and without preoperative tumor-specific therapy, excluding patients with preoperative histology "invasive mammary carcinoma"
Reference range	≤ 29.8 % (90th percentile, tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	50719
Comparability with the previous year's results	Comparable to a limited extent. To improve the validity of the indicator with regard to the recording of patients with histology "DCIS", the calculation formulas have been revised and used for the first time in data collection year 2013. Whereas 2012 was calculated retrospectively using the new calculation formulas, the values for 2010 and 2011 are based on the obsolete calculation formulas.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	22.3 %	21.5 %	18.1 %	16.0 %
Confidence interval	–	21.3–23.4 %	20.5–22.6 %	17.1–19.2 %	15.0–17.0 %
Total number of cases	–	5,650	5,586	5,406	5,419

Aggregate result of all patients

Hospital-based results

Target population of all hospitals	517
Number of hospitals with 0 cases	387

79 Hospitals with ≥ 20 cases
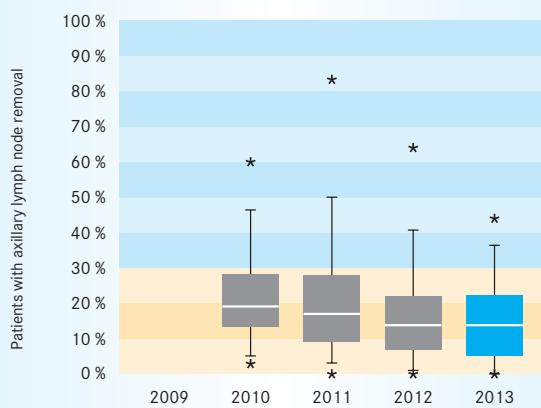
Median	13.8 %	Number of computationally discrepant hospitals	7 of 79
Range	0.0 – 44.0 %		

438 Hospitals with 1 to 19 cases

Median	9.1 %	Number of computationally discrepant hospitals	99 of 438
Range	0.0 – 100.0 %		

Quality target

As few patients as possible with axillary lymph node removal with DCIS and breast-conserving therapy.

Background

The indicator "Lymph node removal with DCIS and breast-conserving therapy" depicts how frequently lymph node removal is performed in patients with ductal carcinoma in situ (DCIS) and breast-conserving therapy. A DCIS is an early breast cancer stage, in which the separating layout from the surrounding tissue has not yet been breached. Tumor involvement of the axillary lymph nodes is excluded, as metastases do not yet spread from carcinomas of this type. In accordance with guideline recommendations, lymph node removal for the determination of lymph node status should therefore generally be avoided in these patients to prevent the occurrence of the associated side effects. Exceptions where lymph node removal by sentinel lymph node biopsy in DCIS is recommended include breast-conserving surgery of large tumors near the axilla and cases involving mastectomy, since here the obligatory subsequent biopsy of the sentinel lymph node is sometimes no longer possible for technical reasons.

Evaluating the results

Axillary lymph nodes were removed in 866 of the total of 5419 cases with the diagnosis of DCIS and breast-conserving therapy considered in the indicator. This corresponds to an overall rate nationwide of 16.0 %. With regard to the requirement (< 5 %) of the S3 guideline and against the background of the changes made to improve the validity of the indicator, the Federal Experts' Working Group regards the federal overall rate as too high. Even when accounting for possible exceptional cases where a sentinel lymph node biopsy may be justified, the Federal Experts' Working Group interprets this result as meaning that a relatively high proportion of women considered here will not receive guideline-compliant treatment. For this reason, a special need for action is seen for this indicator. In addition to the consistent implementation of the Structured Dialogue at State level, the treatment situation should be addressed and discussed at specialist congresses.

In a majority of hospitals considered, fewer than 20 cases are in the target population of the indicator. An assessment of these hospitals is difficult due to the fact that, depending on the reference range, a computational discrepancy may only be present in a single case in the numerator of the indicator. For this reason, the value proposed in the guideline was not chosen for the indicator in data collection year 2013, as had been the case in the previous year, but instead the 90th percentile as a limit for the reference range. A total of 106 of the 517 hospitals considered exceed the calculated value of 29.8 %.

In the Structured Dialogue for data collection year 2012, 70 notices were sent and 42 statements were requested. In conclusion, 7 hospitals were classified as "qualitatively discrepant" since the procedure for the majority of treatment cases could not be comprehensibly justified. An evaluation was not possible in a further 8 hospitals due to improper documentation. The described "problem of small caseloads" with respect to the evaluation of individual hospitals is also apparent in the Structured Dialogue, even with the generous reference range chosen: in 24 statements, the deviating result could be explained by individual cases.

Breast surgery

QI-ID 51847: Indication for sentinel lymph node biopsy

Quality target

As many patients as possible with sentinel lymph node biopsy (SLNB) and without axillary dissection with lymph node–negative (pN0) invasive mammary carcinoma.

Background

Sentinel lymph nodes are described as the first lymph nodes in the lymph drainage of a tumor. If they are tumor-free, it may be assumed that the subsequent lymph nodes are tumor-free as well. Sentinel lymph node biopsy was first introduced in Germany in 2008 as an efficient method for determining the lymph node status.

In order to be able to find the sentinel lymph node or lymph nodes, a weakly radioactive substance is injected into the area of the tumor, which drains out via the lymphatic system and is first taken up by the sentinel lymph nodes. The lymph nodes marked in this way can be detected with a special gamma probe via the radioactive signal and can be removed with a small incision. Sentinel lymph node biopsy replaced the previously customary method of axillary dissection for determining lymph node status, which requires the removal of at least 10 lymph nodes. A basic advantage of the new method is that side effects such as lymphatic congestion, restricted movement or sensory disorders in the arm can be reduced.

The indicator records the number of patients with invasive mammary carcinoma whose lymph nodes had been diagnosed as tumor-free, in whom only a sentinel lymph node biopsy was performed rather than an axillary dissection, which was not indicated in that case. Cases with a sentinel lymph node biopsy are then also included in the numerator if individual unmarked but suspicious lymph nodes have been removed additionally.

Evaluating the results

Following adaptation to the revised S3 guideline, the present indicator was introduced for the first time in 2013 and replaces the indicator "Sentinel lymph node biopsy in pT1 without lymph–node invasion" (QI-ID 2262). The new indicator now takes into consideration tumors of all stages in patients where no lymph node invasion has been diagnosed.

At 93.9 %, the national overall rate for data collection year 2013 is clearly within the reference range recommended by the guideline. This shows that the sentinel lymph node biopsy is now well established in terms of the federal average. However, 115 of the 720 hospitals considered were computationally discrepant (16 %), with 105 hospitals having fewer than 20 cases in the target population of the indicator. The median of the indicator for this group is 87.5 %, whereas in the group of hospitals with at least 20 cases in the target population of the indicator it is 95.1 %. In view of these results, the Federal Experts' Working Group suspects that the structural preconditions for sentinel lymph node biopsy are not present in some hospitals and sees an extended need for action for the indicator. When conducting the Structured Dialogue with computationally discrepant hospitals, the State Administrative Offices for Quality Assurance (LQS) have been requested to specifically question whether these hospitals are properly equipped to perform sentinel lymph node biopsies (cooperation with the nuclear medicine department, presence of a gamma probe). The problem should be discussed at specialist conferences based on the results of quality assurance.

Description

Numerator	Patients with sentinel lymph node biopsy and without axillary dissection
Denominator	All patients with primary disease mammary carcinoma, negative pN staging, completion of surgical therapy and without preoperative tumor-specific therapy
Reference range	≥ 80.0 % (target range)
Risk adjustment	No further risk adjustment
QI-ID	51847
Comparability with the previous year's results	There is no comparability with the previous year's results as the data field for axillary dissection was revised for data collection year 2013. Since then, cases with the additional removal of individual, unmarked lymph nodes have been recorded separately and can therefore be included in the numerator of the indicator.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	87.7 %	93.9 %
Confidence interval	–	–	–	87.4 – 88.0 %	93.7 – 94.2 %
Total number of cases	–	–	–	37,557	37,106

Aggregate result of all patients
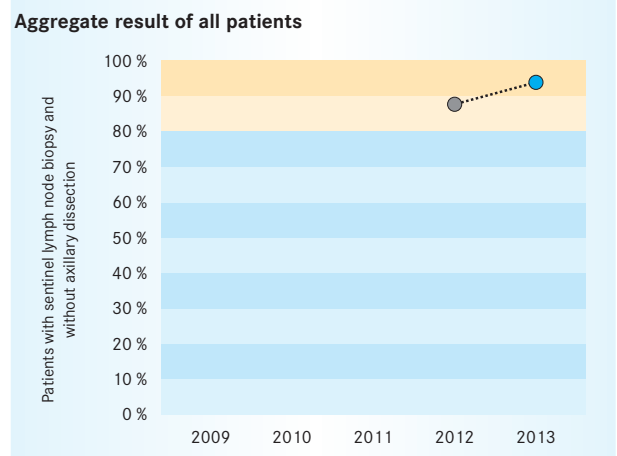
Hospital-based results

Target population of all hospitals	720
Number of hospitals with 0 cases	184

442 Hospitals with ≥ 20 cases
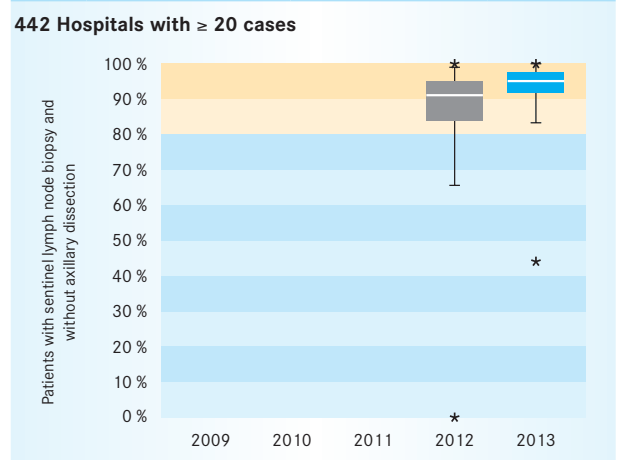
Median	95.1 %	Number of computationally discrepant hospitals	10 of 442
Range	44.1 – 100.0 %		

278 Hospitals with 1 to 19 cases

Median	87.5 %	Number of computationally discrepant hospitals	105 of 278
Range	0.0 – 100.0 %		

Obstetrics

Stefanie Konheiser, Teresa Thomas, Priv.-Doz. Dr. Günther Heller, Federal Experts' Working Group for Perinatal Medicine

Introduction
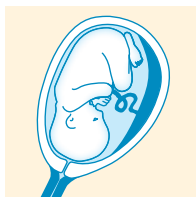
Perinatal medicine covers the period from shortly before to shortly after birth. Since the Munich Perinatal Study (1975 to 1977) and the resultant perinatal census, external comparative quality assessments have been carried out in Germany. Their aim is to exactly collect observed differences in the quality of obstetric care and to improve its quality.

The clinical area *Obstetrics* was initiated nationally in 2001 and it registers all births that have occurred in-hospital in the Federal Republic of Germany. The corresponding quality indicators describe relevant aspects of quality in relation to process and results. For the Structured Dialogue, a series of other quality-related data are available for computationally discrepant hospitals, allowing a differentiated presentation of the care situation in the affected hospitals. In spite of the fact that there is no requirement for births outside hospitals to be registered in this documentation form, the results describe important aspects of obstetric care in Germany.

Services subject to mandatory documentation

All in-hospital births.

Changes in comparison to the previous year

Three new indicators were introduced in data collection year 2013: "Documentation of pH value, but not of base excess value" (QI-ID 51797), "Acidosis in preterm infants with determination of umbilical artery pH" (QI-ID 51826) and "Quality index on critical outcome in mature neonates" (QI-ID 51803). They relate to pre-existing indicators and are intended to supplement and/or specify them, thereby allowing a more comprehensive conclusion regarding quality. The indicator "Documentation of pH value, but not of base excess value" (QI-ID 51797) was introduced to improve the quality of documentation as acid-base balance in the blood in the form of base excess and pH are measured at the same time and should therefore also be documented. To heighten hospitals' awareness of this issue, the indicator will be present in data collection years 2013 and 2014 without a reference range before being deleted again in data collection year 2015 and replaced by the introduction of a suitable plausibility check. To ensure a fair comparison between hospitals, the newly introduced indicators "Acidosis in preterm infants with determination of umbilical artery pH" (QI-ID 51826) and "Quality index on critical outcome in mature neonates" (QI-ID 51803) will be presented risk-adjusted in 2013.

Results

In the *Obstetrics* clinical area, there were just under 659,000 hospital births documented in 2013. This represents an increase of about 7,700 births over the previous year. In the opinion of the Federal Experts' Working Group, the results of the indicators in 2013 again reflect a good care situation on average, even if some hospitals exhibit a large range in terms of their results and some are, therefore, far outside the reference range. In addition, fewer computational discrepancies are observed in the *Obstetrics* clinical area than in the previous year.

The obstetric indicators were generally assessed by the Federal Experts' Working Group as having a need for action level A or B. Only the indicator "Presence of a pediatrician at premature births" (QI-ID 318) was classified as a level C indicator (special need for action). The results indicate structural problems which were particularly observed in hospitals with few births. Compared to the previous year, the results of most indicators show no significant change from the previous year (i.e., an unchanged tendency), while in the indicator "Perioperative antibiotic prophylaxis in cesarean section delivery" (QI-ID 50045) the result has improved markedly.

Findings from the Structured Dialogue from data collection year 2012, however, point to a high rate of improper documentation or software problems for the indicators "Antenatal corticosteroid therapy in premature births with prepartum hospitalization for at least two calendar days" (QI-ID 330) and "D-D time in emergency cesarean section > 20 minutes" (QI-ID 1058). Appropriate measures to tackle these problems have already been introduced and will be reinforced further.

In addition, following the data validation, a sampling procedure with data synchronization was undertaken for the present clinical area for data collection year 2012. A total of 1,040 case records from 53 hospitals underwent reverification on the basis of preselected data fields. Finally, the data validity of 54.2 % of the data fields reviewed were rated as "excellent" and 20.8 % as "good". For the other 25.0 % of the data fields, the classification "requires improvement" had to be assigned due to documentation problems.

Looking forward

For 2014, the introduction of further indicators is planned for 2014. The aim of the indicator "Mother and child discharged home together" is to illustrate the quality of treatment for both mother and child. This aim is also to be pursued in the context of the further development of the clinical area by merging neonatal and perinatal records. In addition, it is also planned in data collection year 2014 to introduce an indicator that is intended to provide information as to whether hospitals should carry out more cesarean sections without the corresponding indication.

A further future topic of the Federal Experts' Working Group is the appropriate selection of reference areas. As part of system maintenance on the procedure, the definition of existing reference areas should be checked and modified where necessary.

Obstetrics

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	651,765	658,822	659,397	99.9 %
Hospitals	764	744	746	99.7 %

Basic statistics

	2013	
	Number	Proportion
Births		
Number of births	658,735	100 %
Singleton pregnancies	646,344	98.1 %
Multiple pregnancies	12,391	1.9 %
Children		
Number of children	671,354	100 %
Live-born infants[1]	668,988	99.7 %
Still births	2,366	0.3 %
Age distribution		
Number of mothers	658,735	100 %
< 18 years	3,843	0.6 %
18 – 29 years	276,636	42.0 %
30 – 34 years	229,805	34.9 %
35 – 39 years	120,586	18.3 %
≥ 40 years	27,865	4.2 %
Weeks of gestation		
Number of children	671,354	100 %
< 28 weeks of gestation	4,102	0.6 %
28 – 31 weeks of gestation	6,163	0.9 %
32 – 36 weeks of gestation	49,573	7.4 %
37 – 41 weeks of gestation	607,701	90.5 %
> 41 weeks of gestation	3,815	0.6 %
Birth weight (children)		
Number of children	671,354	100 %
< 500 g	775	0.1 %
500 – 749 g	1,843	0.3 %
750 – 999 g	1,921	0.3 %
1,000 – 1,499 g	5,209	0.8 %
1,500 – 1,999 g	9,960	1.5 %
2,000 – 2,499 g	29,136	4.3 %
2,500 – 2,999 g	107,535	16.0 %
3,000 – 3,999 g	449,321	66.9 %
4,000 – 4,499 g	57,865	8.6 %
≥ 4,500 g	7,789	1.2 %
Method of delivery (children)		
Number of children	671,354	100 %
Spontaneous delivery	405,716	60.4 %
Cesarean section	204,640	30.5 %
Operative vaginal	44,872	6.7 %
Other method	16,126	2.4 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/16n1/

[1]   n = 840 (0.1 %) of live births died within the first 7 days of life.

Obstetrics

Case-based aggregate results (patients)

QI-ID	Name of the quality indicator	2012 Result	2013 Result	2013 Cases (patients) Numerator (O | E) *	Denominator	Trend
330	Antenatal corticosteroid therapy in premature births with prepartum hospitalization for at least two calendar days	95.7 %	96.1 %	6,953	7,235	→
50046	Antibiotics for premature rupture of membranes	84.0 %	85.9 %	3,480	4,051	→
50045	Perioperative antibiotic prophylaxis in cesarean section delivery	95.5 %	97.4 %	204,814	210,388	↗
1058	D–D time in emergency cesarean section > 20 minutes	0.99 %	0.91 %	74	8,142	→
	Determination of umbilical artery pH in live-born singletons					
319	Determination of umbilical artery pH in live-born singletons	99.1 %	99.2 %	634,621	639,945	→
51797	Documentation of pH value, but not of base excess value	13.6 %	13.2 %	83,767	634,621	↗
	Acidosis in mature singletons with determination of umbilical artery pH					
321	Acidosis in mature singletons with determination of umbilical artery pH	0.2 %	0.2 %	1,064	592,407	→
51397	Ratio of the observed to the expected rate (O / E) of acidosis in mature singletons with determination of umbilical artery pH	1.00	1.02	1,064 0.18 % | 1,043 0.18 %	592,407	→
51826	Acidosis in preterm singletons with determination of umbilical artery pH	0.7 %	0.7 %	277	42,214	→
51831	Ratio of the observed to the expected rate (O / E) of acidosis in preterm singletons with determination of umbilical artery pH	1.00	0.95	277 0.66 % | 291 0.69 %	42,214	→
318	Presence of a pediatrician at premature births	95.6 %	95.5 %	22,955	24,033	→
	Critical outcome in mature neonates					
1059	Critical outcome in mature neonates	0.0 %	0.0 %	181	600,192	→
51803	Quality index on critical outcome in mature neonates	1.00	1.04	4,055 0.69 % | 3,904 0.67 %	584,187.5	→
	Grade III or IV perineal tear					
322	Grade III or IV perineal tear in spontaneous singleton births	1.3 %	1.3 %	5,383	400,538	→
51181	Ratio of the observed to the expected rate (O / E) of grade III or IV perineal tear in spontaneous singleton births	1.00	1.01	5,383 1.34 % | 5,338 1.33 %	400,538	→
323	Grade III or IV perineal tear in spontaneous singleton births without episiotomy	1.0 %	1.0 %	3,337	322,437	→
324	Grade III or IV perineal tear in spontaneous singleton births with episiotomy	2.6 %	2.6 %	2,046	78,101	→
331	Maternal deaths during births	0.00 %	0.00 %	16	658,735	→

* for regression-based quality indicators

Obstetrics

Hospital-based aggregate results for utilization in quality assurance

QI-ID	Name of the quality indicator	Reference range	2013 Hospitals		2013 Evaluation	
			Total	Discrepant (computationally)	Category	Need for action
330	Antenatal corticosteroid therapy in premature births with prepartum hospitalization for at least two calendar days	≥ 95.0 % (TA)	324	85	2	B
50046	Antibiotics for premature rupture of membranes	≥ 95.0 % (TA)	331	174	3	B
50045	Perioperative antibiotic prophylaxis in cesarean section delivery	≥ 90.0 % (TA)	742	44	1	A
1058	D-D time in emergency cesarean section > 20 minutes	Sentinel event	693	57	X	B
	Determination of umbilical artery pH in live-born singletons					
319	Determination of umbilical artery pH in live-born singletons	≥ 95.0 % (TA)	743	12	1	A
51797	Documentation of pH value, but not of base excess value	n.d.*	743	–	X	X
	Acidosis in mature singletons with determination of umbilical artery pH					
321	Acidosis in mature singletons with determination of umbilical artery pH	n.d.*	739	–	X	X
51397	Ratio of the observed to the expected rate (O / E) of acidosis in mature singletons with determination of umbilical artery pH	≤ 1.70 (TO)	739	147	2	B
51826	Acidosis in preterm singletons with determination of umbilical artery pH	n.d.*	737	–	X	X
51831	Ratio of the observed to the expected rate (O / E) of acidosis in preterm singletons with determination of umbilical artery pH	≤ 5.13 (TO; 95th percentile)	737	42	2	A
318	Presence of a pediatrician at premature births	≥ 90.0 % (TA)	570	184	2	C
	Critical outcome in mature neonates					
1059	Critical outcome in mature neonates	n.d.*	739	–	X	X
51803	Quality index on critical outcome in mature neonates	≤ 2.61 (TO; 95th percentile)	740	37	2	B
	Grade III or IV perineal tear					
322	Grade III or IV perineal tear in spontaneous singleton births	n.d.*	739	–	X	X
51181	Ratio of the observed to the expected rate (O / E) of grade III or IV perineal tear in spontaneous singleton births	≤ 2.25 (TO)	739	39	2	A
323	Grade III or IV perineal tear in spontaneous singleton births without episiotomy	n.d.*	739	–	X	X
324	Grade III or IV perineal tear in spontaneous singleton births with episiotomy	n.d.*	734	–	X	X
331	Maternal deaths during births	Sentinel event	743	16	X	A

TO = Tolerance range; TA = Target range; * not defined

Obstetrics

QI-ID 318: Presence of a pediatrician at premature births

Description	
Numerator	Pediatrician present at birth
Denominator	All live-born preterm infants with a gestational age of 24+0 to less than 35+0 weeks, excluding children born before hospital admission
Reference range	≥ 90.0 % (target range)
Risk adjustment	No further risk adjustment
QI-ID	318
Comparability with the previous year's results	Comparable

Case-based results (patients)					
	2009	**2010**	**2011**	**2012**	**2013**
Aggregate result	92.5 %	95.5 %	95.3 %	95.6 %	95.5 %
Confidence interval	92.2–92.9 %	95.2–95.7 %	95.0–95.6 %	95.3–95.8 %	95.2–95.8 %
Total number of cases	24,163	23,566	22,844	23,780	24,033

Aggregate result of all patients
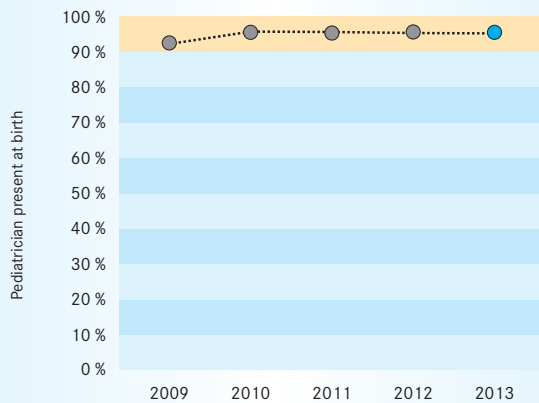
Hospital-based results	
Target population of all hospitals	570
Number of hospitals with 0 cases	174

250 Hospitals with ≥ 20 cases
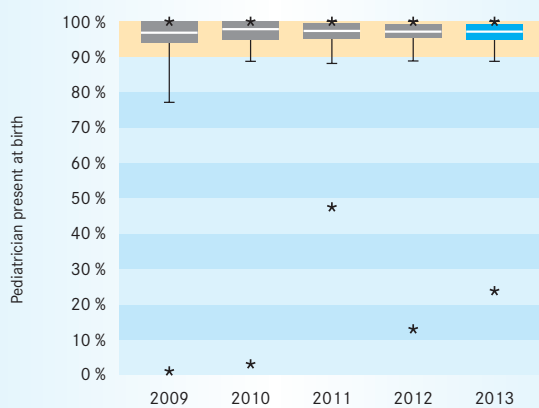
Median	97.1 %	Number of computationally discrepant hospitals	14 of 250
Range	23.8 – 100.0 %		

320 Hospitals with 1 to 19 cases

Median	80.0 %	Number of computationally discrepant hospitals	170 of 320
Range	0.0 – 100.0 %		

Quality target

Frequent presence of a pediatrician at the birth of live-born preterm infants with a gestational age of 24+0 to less than 35+0 weeks.

Background

Preterm infants should be cared for by specialist physicians. A pediatrician (a specialist in child and adolescent medicine) should therefore be present during the birth itself in order to be able to provide pediatric treatment immediately after delivery.

In addition to the presence of a pediatrician, the whole organization of the hospital determines the treatment outcome of preterm infants. What is important here is:

- Staff qualification
- Hospital facilities in terms of equipment and rooms
- Premises in close proximity to one another to avoid having to transport children, where required
- Neonatal intensive care unit located next to the delivery room with its own 24-hour pediatric shift service
- Close cooperation between the Obstetrics and Neonatology Departments
- Individual case analyses and regional conferences
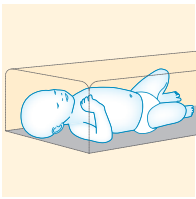- Continuing training of staff

Various studies have shown that the mortality of preterm infants in larger perinatal centers is lower than in smaller clinics, even when accounting for existing risk factors.

Evaluating the results

The result of the indicator "Presence of a pediatrician at premature births" (QI-ID 318) in data collection year 2013 at the federal level is 95.5 % and, thus, within the defined target range of ≥ 90 %. Even though this high outcome rate indicates an appropriate quality of care, it should be kept in mind that hospitals with at least 20 cases show a very wide range of outcomes with 23.8 to 100 %. In hospitals with 1 to 19 cases, the range of 0 to 100 % is even more marked. Furthermore, in data collection year 2013 as in previous years, almost one in three hospitals is computationally discrepant with respect to this indicator (2013: n = 184; 2012: n = 190).

Of the 190 computational discrepancies in data collection year 2012, 17 were classified as "qualitatively discrepant" after the Structured Dialogue had been held; in 21 hospitals, an assessment was not possible due to improper documentation. In the opinion of the Federal Experts' Working Group, the reasons for this are predominantly structural problems in hospitals. Thus, in some federal states, obstetric care is undertaken by physicians with hospital rights or physicians in private practice who work as "part-time specialists" within the scope of an employee relationship. In this context, a conflict of interest is not uncommon when it comes to optimally protecting the outcome for mother or child versus the care-related interest of the specialist in private practice. To draw attention to structural problems and to create the framework for further regulations at a statutory level, the indicator "Presence of a pediatrician at premature births" (QI-ID 318) is classed as having a special need for action level C.

Neonatology

Stefanie Konheiser, Teresa Thomas, Priv.-Doz. Dr. Günther Heller, Federal Experts' Working Group for Perinatal Medicine

Introduction

Neonatology is a branch of applied pediatrics that is concerned with the healthcare and treatment of newborns and preterm infants. The assurance of a good quality of care is of great importance. The treatment of preterm infants in particular poses a special therapeutic challenge.

On the basis of neonatal records (records of neonatal and preterm care provision) of the Federal German States, a national quality assurance procedure *Neonatology* has been developed in recent years and became mandatory on January 1st, 2010. This is an important requirement to ensure the mutual cross-hospital merging of perinatal and neonatal records that was planned several decades ago.

Services subject to mandatory documentation

All neonates admitted within the first seven days of life and who have a length of stay over 12 hours or are transferred to another ward within the first four months and meeting at least one of the following criteria are subject to mandatory documentation:

- Birth weight of less than 2,000 g
- Hospital stay over 72 hours outside of the obstetrics department
- Ventilation for more than an hour
- Serious illness

Furthermore, children who die within the first seven days of life are also subject to mandatory documentation.

Changes in comparison to the previous year

In data collection year 2013, the "Quality index of preterm infant care" (QI-ID 51901) was thoroughly revised and therefore introduced as a new indicator. Because of these adjustments, the result is not comparable with that of the previous year. One fundamental change is that the index refers *exclusively* to non-relocated children. In addition, a logistic regression was calculated for each of the six index levels. As a result, it is possible for the denominators of the individual levels to be based on the associated indicators. In order to avoid duplications within the Structured Dialogue, the non-hierarchical indicators (QI-ID 51837, QI-ID 50050, QI-ID 51843, QI-ID 50051, QI-ID 50053, QI-ID 50052) are presented without a reference range.

In 2013, children for whom no admission temperature was reported were analyzed for the first time by means of a specific indicator ("Admission temperature not reported", QI-ID 51845). The calculation formula of the indicator "Admission temperature > 36.0 degrees" (QI-ID 50064) was adapted accordingly. In addition, for the indicator "Hearing test performed" (QI-ID 50063), the target population was extended to include as far as possible all children cared for by the first admitting hospital.

Results

In data collection year 2012, while the number of computational discrepancies has fallen compared to the previous year (2011: 478; 2012: 360), the number of hospitals classified as "qualitatively discrepant" after conclusion of the Structured Dialogue is higher than in the previous year. In the view of the Federal Experts' Working Group, however, this is due less to a deterioration in the care situation than to the change in the rating system at the end of the Structured Dialogue. Quality deficits were identified within the Structured Dialogue for data collection year 2012 particularly in the indicators "Ratio of the observed to the expected rate (O / E) in ventilated children with pneumothorax (without relocated children)" (QI-ID 50062) and "Admission temperature < 36.0 degrees" (QI-ID 50064). In the case of the first-mentioned indicator, 8 of the 30 computationally discrepant hospitals were classified as "qualitatively discrepant". In the case of the indicator "Admission temperature < 36.0 degrees", 8 hospitals were "qualitatively discrepant" out of 18 computationally discrepant hospitals.

The Federal Experts' Working Group rates the care situation in 2013 as good overall and marks all indicators with a need for action level A or B. In addition, most indicators exhibit no significant change from the previous year. The only deteriorations from the previous year were in the indicators "Admission temperature < 36.0 degrees" (QI-ID 50064) and "Admission temperature not reported" (QI-ID 51845). The retrospective calculation of the new indicator for 2012 shows that the number of children without an admission temperature in data collection year 2013 has doubled from the previous year.

However, it is pleasing to note that overall the results of the quality indicators have improved continuously since the introduction of the clinical area *Neonatology*. This is also apparent with the indicator "Hearing test performed" (QI-ID 50063). The rate of 98.0 % in data collection year 2013 indicates good care, but the large spread (77.5 – 100.0 %) of the results shows that there is still room for improvement in some hospitals. In addition, a scientific evaluation of the quality and results of the examination should be commissioned by the G-BA. This indicator is therefore presented in greater detail below.

Looking forward

The merger of perinatal and neonatal records continues to be of major significance in the further development of the clinical area. This is required in order to incorporate the course of treatment from pregnancy until discharge from the pediatric hospital in the quality assurance. However, the need for case linkage within the clinical area *Neonatology* has also become more pressing. In the course of the voluntary central publication of results on the website *www.perinatalzentren.org*, it has become apparent that the outcomes of treated children must be depicted in order to ensure a fair representation of the results. This is to be implemented in the planned further development. The technical preconditions for case linkage are currently being discussed in the G-BA.

By adapting the QA filter, the aim is to document in future all children dying in the delivery room as well. Since it is not planned to record children born before 22 weeks of pregnancy (gestational age of < 22+0 weeks of pregnancy) in this QA procedure, for these cases, a minimal data set (MDS) must be created from data collection year 2014.

Neonatology

In addition, the Federal Experts' Working Group for Perinatal Medicine is currently consulting on the development of an indicator for the increase in head circumference during the hospital stay. Head circumference is a valid indicator for the child's brain growth. Too small a head circumference affects the development of cognitive abilities.

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	95,214	96,781	96,175	100.6 %
Hospitals	559	567	608	93.3 %

Basic statistics

	2013	
	Number	Proportion
All children	95,580	100 %
Gestational age (completed weeks)[1]		
< 24 weeks of gestation	473	0.5 %
24 – 25 weeks of gestation	1,250	1.3 %
26 – 28 weeks of gestation	2,570	2.7 %
29 – 31 weeks of gestation	5,205	5.5 %
32 – 36 weeks of gestation	33,600	35.3 %
≥ 37 weeks of gestation	52,178	54.8 %
Sex[1]		
Male	52,961	55.6 %
Female	42,299	44.4 %
Indeterminate	16	< 0.1 %
Birth weight[1]		
< 500 g	448	0.5 %
500 – 749 g	1,385	1.5 %
750 – 999 g	1,874	2.0 %
1,000 – 1,249 g	2,043	2.1 %
1,250 – 1,499 g	3,178	3.3 %
1,500 – 2,499 g	28,730	30.2 %
≥ 2,500 g	57,618	60.5 %
Mortality by days of life[1]		
Deceased children	1,093	1.1 %
Of whom up to 7 days of life	668	61.1 %
Of whom 8 – 28 days of life	250	22.9 %
Of whom after 28 days of life	175	16.0 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/NEO/

[1] Excluding n = 304 children who were stillborn or who had a lethal malformation.

Neonatology

Case-based aggregate results (patients)

			2012	2013			
				Cases (patients)			
QI-ID	Name of the quality indicator		Result	Result	Numerator (O | E)*	Denominator	Trend
	Mortality among at-risk live births						
51120	Mortality among at-risk live births	⚠	0.9 %	0.9 %		812	94,803	→
51119	Ratio of the observed to the expected rate (O / E) of deaths in at-risk live births	⚠	1.00	0.90	812 0.86 %	898 0.95 %	94,803	→
51070	Mortality among at-risk live births (without relocated children)	⚠	0.8 %	0.8 %		709	91,476	→
50048	Ratio of the observed to the expected rate (O / E) of deaths in at-risk live births (without relocated children)	⚠	1.00	0.91	709 0.78 %	781 0.85 %	91,476	→
51832	Mortality among very small preterm infants (without relocated children)		4.9 %	4.4 %		419	9,624	→
51837	Ratio of the observed to the expected rate (O / E) of deaths in very small preterm infants (without relocated children)		1.00	0.83	419 4.35 %	506 5.26 %	9,624	→
	Intra- and periventricular cerebral hemorrhage (IVH grade 3 or PVH)						
51076	Intra- and periventricular cerebral hemorrhage (IVH grade 3 or PVH) in very small premature infants (without relocated children)	⚠	4.5 %	4.6 %		435	9,463	→
50050	Ratio of the observed to the expected rate (O / E) of cerebral hemorrhage (IVH grade 3 or PVH) in very small preterm infants (without relocated children)	⚠	1.00	0.98	435 4.60 %	442 4.67 %	9,463	→
	Necrotizing enterocolitis (NEC)						
51838	Necrotizing enterocolitis (NEC) with surgery in very small preterm infants (without relocated children)		1.0 %	1.4 %		130	9,624	→
51843	Ratio of the observed to the expected rate (O / E) of necrotizing enterocolitis (NEC) in very small preterm infants (without relocated children)		1.00	1.31	130 1.35 %	99 1.03 %	9,624	→
	Cystic periventricular leukomalacia (PVL)						
51077	Cystic periventricular leukomalacia (PVL) in very small preterm infants (without relocated children)		2.0 %	2.0 %		173	8,745	→
50051	Ratio of the observed to the expected rate (O / E) of cystic periventricular leukomalacia (PVL) in very small preterm infants (without relocated children)		1.00	1.00	173 1.98 %	173 1.98 %	8,745	→
	Bronchopulmonary dysplasia (BPD)						
51079	Bronchopulmonary dysplasia (BPD) in very small preterm infants (without relocated children)	⚠	8.0 %	8.1 %		781	9,624	→
50053	Ratio of the observed to the expected rate (O / E) of bronchopulmonary dysplasia (BPD) in very small preterm infants (without relocated children)	⚠	1.00	0.99	781 8.12 %	787 8.18 %	9,624	→
	High-grade retinopathy of prematurity (ROP)						
51078	High-grade retinopathy of prematurity (ROP) in very small preterm infants (without relocated children)	⚠	3.4 %	3.2 %		239	7,556	→
50052	Ratio of the observed to the expected rate (O / E) of high-grade retinopathy of prematurity (ROP) in very small preterm infants (without relocated children)	⚠	1.00	0.89	239 3.16 %	268 3.55 %	7,556	→
51901	Quality index of premature infant care		1.00	0.94	1,607 15.71 %	1,708 16.70 %	10,231	→

Neonatology

Case-based aggregate results (patients)

			2012	2013			
				Cases (patients)			
	QI-ID	Name of the quality indicator	Result	Result	Numerator (O | E) *	Denominator	Trend
Indicator group		**Nosocomial infections**					
	51085	Children with nosocomial infections per 1,000 treatment days (without relocated children)	1.11	1.08		1,581	1,459.4 TD	→
	50060	Ratio of the observed to the expected rate (O / E) of children with nosocomial infections per 1,000 treatment days (without relocated children)	1.00	0.95	1,581 1.08	1,672 1.15	1,459.4 TD	→
	51086	Number of nosocomial infections per 1,000 treatment days (without relocated children)	1.31	1.26		1,845	1,459.4 TD	→
	50061	Ratio of the observed to the expected rate (O / E) of number of nosocomial infections per 1,000 treatment days (without relocated children)	1.00	0.92	1,845 1.26	2,004 1.37	1,459.4 TD	→
Indicator group		**Pneumothorax**					
	51087	Pneumothorax in ventilated children	4.9 %	5.0 %		1,240	24,952	→
	50062	Ratio of the observed to the expected rate (O / E) of ventilated children with pneumothorax (without relocated children)	1.00	1.00	1,240 4.97 %	1,241 4.97 %	24,952	→
	50063	Hearing test performed	97.9 %	98.0 %		66,951	68,312	→
Indicator group		**Temperature at admission**					
	50064	Admission temperature < 36.0 degrees	4.4 %	4.8 %		4,208	88,571	↘
	50103	Admission temperature > 37.5 degrees	7.5 %	7.3 %		6,478	88,571	→
	51845	Admission temperature not reported	0.2 %	0.5 %		443	89,014	↘

* for regression-based quality indicators

Neonatology

Hospital-based aggregate results for utilization in quality assurance

	QI–ID	Name of the quality indicator	Reference range	2013 Hospitals Total	2013 Hospitals Discrepant (computationally)	2013 Evaluation Category	2013 Evaluation Need for action
Indicator group		Mortality among at-risk live births					
	51120	Mortality among at-risk live births	n.d.*	519	–	X	X
	51119	Ratio of the observed to the expected rate (O / E) of deaths in at-risk live births	≤ 2.11 (TO)	519	28	1	A
	51070	Mortality among at-risk live births (without relocated children)	n.d.*	515	–	X	X
	50048	Ratio of the observed to the expected rate (O / E) of deaths in at-risk live births (without relocated children)	≤ 2.40 (TO)	515	25	2	A
	51832	Mortality among very small preterm infants (without relocated children)	n.d.*	291	–	X	X
	51837	Ratio of the observed to the expected rate (O / E) of deaths in very small preterm infants (without relocated children)	n.d.*	291	–	X	X
Indicator group		Intra- and periventricular cerebral hemorrhage (IVH grade 3 or PVH)					
	51076	Intra- and periventricular cerebral hemorrhage (IVH grade 3 or PVH) in very small premature infants (without relocated children)	n.d.*	278	–	X	X
	50050	Ratio of the observed to the expected rate (O / E) of cerebral hemorrhage (IVH grade 3 or PVH) in very small preterm infants (without relocated children)	n.d.*	278	–	X	X
Indicator group		Necrotizing enterocolitis (NEC)					
	51838	Necrotizing enterocolitis (NEC) with surgery in very small preterm infants (without relocated children)	n.d.*	291	–	X	X
	51843	Ratio of the observed to the expected rate (O / E) of necrotizing enterocolitis (NEC) in very small preterm infants (without relocated children)	n.d.*	291	–	X	X
Indicator group		Cystic periventricular leukomalacia (PVL)					
	51077	Cystic periventricular leukomalacia (PVL) in very small preterm infants (without relocated children)	n.d.*	271	–	X	X
	50051	Ratio of the observed to the expected rate (O / E) of cystic periventricular leukomalacia (PVL) in very small preterm infants (without relocated children)	n.d.*	271	–	X	X
Indicator group		Bronchopulmonary dysplasia (BPD)					
	51079	Bronchopulmonary dysplasia (BPD) in very small preterm infants (without relocated children)	n.d.*	291	–	X	X
	50053	Ratio of the observed to the expected rate (O / E) of bronchopulmonary dysplasia (BPD) in very small preterm infants (without relocated children)	n.d.*	291	–	X	X
Indicator group		High-grade retinopathy of prematurity (ROP)					
	51078	High-grade retinopathy of prematurity (ROP) in very small preterm infants (without relocated children)	n.d.*	257	–	X	X
	50052	Ratio of the observed to the expected rate (O / E) of high-grade retinopathy of prematurity (ROP) in very small preterm infants (without relocated children)	n.d.*	257	–	X	X
	51901	Quality index of premature infant care	≤ 1.89 (TO)	297	33	2	B

Neonatology

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
	Nosocomial infections					
51085	Children with nosocomial infections per 1,000 treatment days (without relocated children)	n.d.*	466	–	X	X
50060	Ratio of the observed to the expected rate (O / E) of children with nosocomial infections per 1,000 treatment days (without relocated children)	≤ 2.48 (TO)	466	22	2	A
51086	Number of nosocomial infections per 1,000 treatment days (without relocated children)	n.d.*	466	–	X	X
50061	Ratio of the observed to the expected rate (O / E) of number of nosocomial infections per 1,000 treatment days (without relocated children)	≤ 2.33 (TO)	466	24	2	A
	Pneumothorax					
51087	Pneumothorax in ventilated children	n.d.*	357	–	X	X
50062	Ratio of the observed to the expected rate (O / E) of ventilated children with pneumothorax (without relocated children)	≤ 2.53 (TO)	357	35	2	A
50063	Hearing test performed	≥ 95.0 % (TA)	435	55	2	B
	Temperature at admission					
50064	Admission temperature < 36.0 degrees	≤ 11.0 % (TO)	357	17	2	B
50103	Admission temperature > 37.5 degrees	≤ 13.5 % (TO)	357	21	2	B
51845	Admission temperature not reported	≤ 2.3 % (TO)	357	16	2	B

TO = Tolerance range; TA = Target range; * not defined

Neonatology

QI-ID 50063: Hearing test performed

Quality target

Frequent performance of a hearing test.

Background

Adequate hearing is a prerequisite for natural speech acquisition. In Germany, about 1 to 2 in 1,000 children suffer from congenital hearing impairment or deafness. A hearing loss of 35 to 40 decibels is regarded as a critical value during screening for identifying hearing disorders that require treatment.

As well as speech development disorders, cognitive, emotional and psychosocial development disorders are associated with hearing impairment or deafness. The later the condition is diagnosed and appropriate treatment initiated, the more pronounced are usually the negative consequences for development. According to international studies, the age of diagnosis for hearing disorders without neonatal hearing screening is currently about 21 to 47 months. Studies of the benefit assessment of screening indicate that children with hearing disorders have a benefit in terms of speech development if their hearing disorder is discovered during a neonatal hearing screening and treated appropriately.

A neonatal hearing test became mandatory nationwide on September 1st, 2009. The aim of the hearing test is to diagnose primarily congenital bilateral hearing disorders from a hearing loss of 35 decibels by the end of the 3rd month of life and to initiate treatment by the 6th month of life.

Evaluating the results

In data collection year 2013, a hearing test was performed in 98.0 % of children. The overall rate on introduction of the indicator in data collection year 2010 was 95.3 % and has risen slightly since: the results for hospitals with at least 20 cases are between 77.5 % and 100.0 %. This also points to an improvement in the overall result since in data collection year 2010 the range was from 19.2 % to 100.0 %. It should be noted generally that a hearing test is less often performed in particular in those children with only a short stay in hospital.

Although the overall rate of hearing tests performed has increased year on year, the number of computationally discrepant hospitals has risen (2012: 40; 2013: 55). According to the definition of the indicator, the documentation of a hearing test must be done primarily by the first admitting hospital. Because of a change of data field, the calculation formula was modified in data collection year 2013 so that the comparability of the results with those of the previous year is limited. Over the course of the Structured Dialogue 2012, it became clear that documentation errors were the main reason for the computational discrepancies. An assessment was not possible in a total of 9 hospitals because of improper documentation.

The Federal Experts' Working Group recommends a clarification of the computational discrepancies in the Structured Dialogue and discussion at specialist congresses. The indicator is therefore ranked as need for action level B.

Description	
Numerator	Children with hearing test performed
Denominator	All children discharged home alive without lethal malformations with a gestational age of at least 24+0 weeks p.m. who were not relocated
Reference range	≥ 95.0 % (target range)
Risk adjustment	No further risk adjustment
QI-ID	50063
Comparability with the previous year's results	Limited comparability

Case-based results (patients)					
	2009	2010	2011	2012	2013
Aggregate result	–	95.3 %	97.2 %	97.9 %	98.0 %
Confidence interval	–	95.1–95.4 %	97.1–97.3 %	97.8–98.0 %	97.9–98.1 %
Total number of cases	–	68,341	69,695	65,685	68,312

Aggregate result of all patients
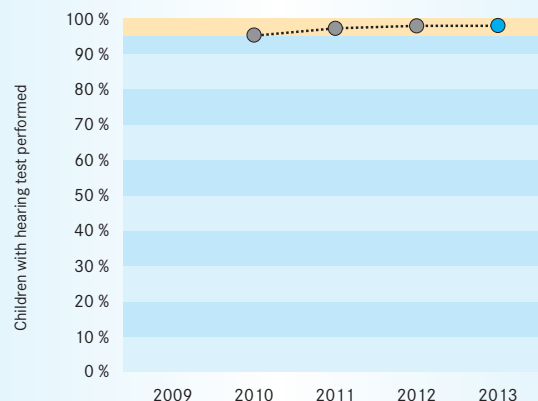
Hospital-based results	
Target population of all hospitals	435
Number of hospitals with 0 cases	132

323 Hospitals with ≥ 20 cases
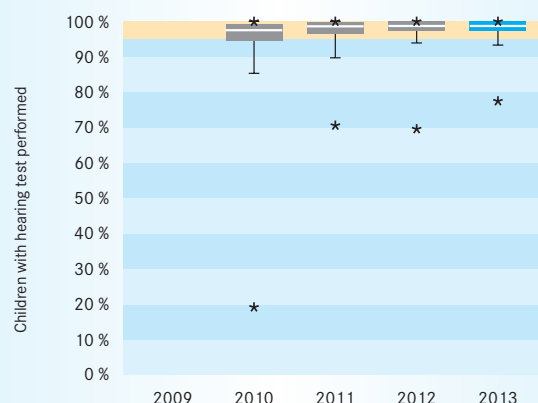
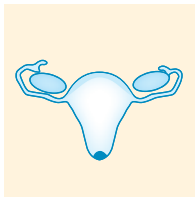| Median	98.7 %	Number of computationally discrepant hospitals	32 of 323
Range	77.5 – 100.0 %		

112 Hospitals with 1 to 19 cases

Median	100.0 %	Number of computationally discrepant hospitals	23 of 112
Range	0.0 – 100.0 %		

Gynecological surgery

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Introduction

Gynecological surgeries fundamentally comprise all surgeries on the female internal sexual organs. However, the clinical area *Gynecological surgery* exclusively covers surgical interventions on the uterus, fallopian tubes and ovaries conducted in the inpatient sector. The majority of surgical interventions involve removal of the ovaries (ovariectomy) and tissue in the area of the cervix (conization).

In the data collection year 2013, there were approximately 151,000 interventions on ovaries and fallopian tubes (adnexal surgery) and approximately 11,000 conizations (removal of tissue from the cervix) documented in the external hospital quality assurance. Starting in the data collection year 2013, removal of the uterus (hysterectomy) is no longer documented in this clinical area, pending the appearance of the new guideline amongst other reasons.

Careful clarification of the need for a surgical intervention is a prerequisite for a high quality of care. The benefits and risks of surgery have always to be balanced and the possibility of a conservative, i.e., non-surgical, treatment has to be assessed as well. An accurate indication is particularly important for a benign disease or a change in the uterus or the ovaries. Therefore, quality assurance in the clinical area of gynecological surgery focuses on the indication for surgery and on the histological evaluation of the removed tissue to confirm the diagnosis.

Different surgical approaches are implemented in gynecological interventions: through the vagina (vaginal), through the abdominal wall (abdominal), or by what is known as keyhole surgery (laparoscopic). The focus in this clinical area is on the quality assurance of laparoscopic surgeries. In general, complications after surgery cannot be excluded, even for minimally invasive surgical procedures such as laparoscopy. Organ injury is one of the most serious complications of laparoscopic surgeries. The organs anatomically closest to the fallopian tubes and ovaries (ureter, bladder and intestine) are most prone to injury. The frequency of organ injuries is documented and analyzed in the external hospital quality assurance.

Services subject to mandatory documentation

All adnexal surgeries and conizations performed in female patients older than 11 years constitute a part of the mandatory documentation. Patients with concurrent cesarean section or certain diagnoses are excluded: malignant neoplasms of the organs of the digestive tract, urinary tract, or lymphatic, hematopoietic, and related tissue, peritoneal mesothelioma, or diverticulosis of the colon.

Changes in comparison to the previous year

The G-BA decided in June 2012 to provisionally discontinue the mandatory documentation of hysterectomies starting in the data collection year 2013. The corresponding indicators "Organ injuries during hysterectomy" (QI-ID 553), "Organ injuries during hysterectomy in patients without carcinoma, endometriosis, or previous surgery" (QI-ID 557), "Antibiotic prophylaxis in

hysterectomy" (QI-ID 235) and "Hysterectomy in patients without malignant findings and below 35 years of age" (QI-ID 672) were therefore eliminated from the set of indicators. In addition, laparoscopic hysterectomies are also no longer included in the indicator group "Organ injuries during laparoscopic surgery".

The rate-based indicator "Organ injuries during laparoscopic surgery" (QI-ID 51417) is risk-adjusted and starting in the data collection year 2013, the indicator is calculated as "Ratio of the observed to expected rate (O / E) of organ injuries during laparoscopic surgery" (QI-ID 51906).

Furthermore, the indicator "Complete removal of the ovaries or adnexa without pathological findings or without specific details on findings" (QI-ID 51907) has been introduced in the data collection year 2013. The numerator of this indicator includes, in addition to the postoperative histological findings "Follicular or corpus luteum cyst" and "Normal findings", non-specific details on histological findings (e.g., changes in the adnexa not depicted by the specific histology codes available).

Results

The Federal Experts' Working Group evaluates the quality of care in the clinical area as good. The results of the indicators in the data collection year 2013 show mostly unchanged rates compared to 2012, indicating a constant and good quality of care of patients undergoing gynecological surgery (interventions on the fallopian tubes, ovaries or cervix).

In the data collection year 2013, at least one neighboring organ was injured in 0.5 % of patients undergoing laparoscopic gynecological surgery (e.g., urinary bladder, ureter or bowel). When compared with previous data collection years, an overall stable situation of care can be observed. The nationwide overall rate of organ injuries during laparoscopic gynecological surgery is also comparable to those in other countries. Due to the importance of this indicator, it will also be reported as risk-adjusted starting in the data collection year 2013 (QI-ID 51906). The number of patients with an organ injury during laparoscopic surgery without carcinoma, endometriosis, or previous surgery in the surgical area has decreased compared to previous years (2013: 153 patients; 2012: 172 patients; 2011: 231 patients; QI-ID 51418).

The overall rate has also remained mostly unchanged from the last two data collection years for the indicators for adnexal surgery, indicating a stable quality of care. The overall rate in the indicator "Missing histology after isolated ovarian surgery with tissue removal" (QI-ID 12874) is stable at 1.6 %. This highlights the constant quality of care over several data collection years in terms of the performance of a postoperative histological examination after isolated ovarian surgery. Similarly, the indicator "Complete removal of the ovary or adnexa without pathological findings" (QI-ID 10211) shows an almost unchanged overall rate. The overall rate of the indicator "Organ conservation in ovarian surgery" (QI-ID 612) is 91 % and it shows that the quality of care in this area has been constantly improving over the last few years (2010: 89.2 %; 2011: 90.1 %; 2012: 90.5 %). With the newly introduced indicator "Complete removal of the ovary

Gynecological surgery

or adnexa without pathological findings or without specific details on findings" (QI-ID 51907), the overall rate is 35.6 %. This indicator is presented in detail below.

The histological examination of the tissue removed by conization showed no statistically significant change compared to the previous year (QI-ID 665). In 3.6 % of patients with an inpatient conization, no pathological findings were present following histopathological preparation of the removed tissue and reporting of the results. The overall rate has remained constant compared to the previous year. In 0.5 % of patients in whom a conization was performed in an inpatient setting, the postoperative histological findings were completely missing (QI-ID 666). Here, as well, there is no clear (statistically significant) difference compared to previous data collection years. Due to the small caseload in the inpatient sector, only limited conclusions about the quality of care of all patients with conization in Germany can be drawn from the overall rates reported.

A total of 1,200 computational discrepancies were the subject of the Structured Dialogue in 2013 on the results of the data collection year 2012. In the Structured Dialogue, 544 notifications were sent to hospitals and 652 statements requested. In conclusion, the Structured Dialogue evaluated 50 computational discrepancies (4.2 %) as "qualitatively discrepant". Evidence on structural or process deficiencies were identified as reasons for the assessment as "qualitatively discrepant" in 33 discrepancies: e.g., inadequate and questionable indication for surgery, problems with service provision by external physicians, frequent change of staff, and in some cases deficiencies in the documentation processes.

Looking forward

Starting in the data collection year 2013, hysterectomies are no longer being documented in this clinical area. The Federal Experts' Working Group adopts a critical view in this concern, as hysterectomy is the most common gynecological intervention in this clinical area. Due to the increasing number of this intervention and the significance of accurate indications, it is essential according to the Federal Experts' Working Group to develop new indicators for hysterectomy as soon as possible. In addition, the inclusion of the patient perspective by means of a patient survey is advocated in order to adequately depict the indication for hysterectomies.

In the area of gynecological surgery, surgical interventions are increasingly being performed in the outpatient sector. Due to an increasing switch of service provision from hospital to the outpatient sector, the Federal Experts' Working Group has for years emphasized the importance of cross-sectoral quality assurance for the clinical area *Gynecological surgery*. With the quality assurance procedure for conization, a first gynecological procedure has already been developed by which the cross-sectoral quality of care can be collected. The Federal Experts' Working Group therefore adopts a critical view of the fact that this quality assurance procedure has not yet been implemented due to different coding practices in the outpatient and hospital sectors. The overall number of inpatient conizations has been decreasing for years, so that it is now almost impossible to draw

a valid conclusion about the quality of care of all patients undergoing conization using the indicators of external hospital quality assurance. As the cross-sectoral quality assurance procedure for conization has not been implemented, the possibility of collecting the quality of care of a major gynecological intervention in the outpatient sector for the first time has not been realized.

The complications resulting from gynecological interventions can currently only be registered in the clinical area if they occur and are diagnosed during the hospital stay. However, patients are often treated for only a few days in hospital after the gynecological intervention, so that complications that occur after discharge are currently not documented. The Federal Experts' Working Group therefore considers it advisable to conduct a follow-up in the form of a follow-up survey– which should also include health insurance claims data, when necessary.

Furthermore, the Federal Experts' Working Group supports the development of cross-sectoral quality assurance procedures on ovarian cancer (ovarian carcinoma) and cervical cancer (cervical carcinoma). Relevant lists of criteria have already been submitted to the G-BA. In addition, the Federal Experts' Working Group recommends the development of a cross-sectoral quality assurance procedure for uterine cancer (endometrial carcinoma): Due to the increasing numbers of endometrial carcinoma and outpatient interventions, endometrial carcinoma represents a relevant subject for cross-sectoral quality assurance in the area of gynecological surgery.

In addition to the proposed developments of cross-sectoral quality assurance procedures, the Federal Experts' Working Group is currently discussing the inclusion of urogynecological interventions in this clinical area. Essentially, these are interventions for urinary incontinence and for the treatment of bladder and/or uterine prolapses.

Data basis

By plenary decision on 21 June 2012, the G-BA decided to discontinue the mandatory documentation of hysterectomies in the clinical area *Gynecological surgery*. For this reason, the number of records has decreased markedly compared to the previous year.

Gynecological surgery

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	259,618	165,724	165,639	100.1 %
Hospitals	1,047	1,028	1,030	99.8 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	165,624	100 %
< 20 years	5,534	3.3 %
20 – 29 years	25,683	15.5 %
30 – 39 years	37,997	22.9 %
40 – 49 years	46,471	28.1 %
50 – 59 years	24,470	14.8 %
60 – 69 years	12,522	7.6 %
70 – 79 years	10,511	6.3 %
≥ 80 years	2,436	1.5 %
ASA classification*		
ASA 1: A normal healthy patient	73,905	44.5 %
ASA 2: A patient with mild systemic disease	79,666	47.9 %
ASA 3: A patient with severe systemic disease	12,155	7.3 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	412	0.3 %
ASA 5: A moribund patient who is not expected to survive without the operation	28	< 0.1 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/15n1/

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*   Since these figures relate to the number of surgery report forms, the total number of patients classified according to ASA differs from the value stated in the age distribution.

Gynecological surgery

Case-based aggregate results (patients)

QI-ID	Name of the quality indicator	2012 Result	2013 Result	2013 Fälle (Patientinnen) Numerator (O | E) *	Denominator	Trend
	Organ injuries during laparoscopic surgeries					
51417	Organ injuries during laparoscopic surgery	0.5 %	0.5 %	446	94,631	→
51906	Ratio of the observed to the expected rate (O / E) of organ injuries during laparoscopic surgery	1.00	0.98	446 0.47 % 455 0.48 %	94,605	→
51418	Organ injuries in patients without carcinoma, endometrio-sis or previous surgery during laparoscopic surgery	0.34 %	0.30 %	153	50,595	→
12874	Missing histology after isolated ovarian surgery with tissue removal	1.6 %	1.6 %	637	40,553	→
	Complete removal of the ovary or adnexa without pathological findings					
10211	Complete removal of the ovary or adnexa without pathological findings	13.6 %	13.5 %	2,470	18,276	→
51907	Complete removal of the ovary or adnexa without pathological findings or without specific details on findings	36.7 %	35.6 %	6,515	18,276	→
612	Organ conservation in ovarian surgery	90.5 %	91.0 %	28,589	31,417	→
	Conization					
665	Conization in ectopy or normal findings	3.5 %	3.6 %	286	7,947	→
666	Missing postoperative histology after conization	0.7 %	0.5 %	36	7,981	→

Indicator group

* for regression-based quality indicators

Gynecological surgery

Hospital-based aggregate results for utilization in quality assurance

	QI-ID	Name of the quality indicator	Reference range	2013			
				Hospitals		Evaluation	
				Total	Discrepant (computationally)	Category	Need for action
Indicator group		Organ injuries during laparoscopic surgeries					
	51417	Organ injuries during laparoscopic surgery	≤ 1.9 % (TO; 95th percentile)	974	38	1	A
	51906	Ratio of the observed to the expected rate (O / E) of organ injuries during laparoscopic surgery	≤ 4.23 (TO; 95th percentile)	974	40	1	A
	51418	Organ injuries in patients without carcinoma, endometriosis or previous surgery during laparoscopic surgery	Sentinel event	963	135	X	A
	12874	Missing histology after isolated ovarian surgery with tissue removal	≤ 5.0 % (TA)	914	89	1	A
Indicator group		Complete removal of the ovary or adnexa without pathological findings					
	10211	Complete removal of the ovary or adnexa without pathological findings	≤ 20.0 % (TO)	855	187	2	A
	51907	Complete removal of the ovary or adnexa without pathological findings or without specific details on findings	≤ 55.9 % (TO; 90th percentile)	855	119	2	X
	612	Organ conservation in ovarian surgery	≥ 77.8 % (TO; 5th percentile)	926	87	2	A
Indicator group		Conization					
	665	Conization in ectopy or normal findings	≤ 11.5 % (TO; 95th percentile)	730	74	2	A
	666	Missing postoperative histology after conization	≤ 5.0 % (TA)	732	19	1	A

TO = Tolerance range; TA = Target range

Gynecological surgery

QI-ID 51907: Complete removal of the ovary or adnexa without pathological findings or without specific details on findings

Quality target

As few patients as possible with isolated ovarian surgery with complete removal of the ovary or adnexa, in whom the main histological finding is reported as "follicular or corpus luteum cyst", normal findings or non-specific details on findings.

Background

The complete removal of the ovary or adnexa should be accurately indicated to confirm the diagnosis; the removed tissue should undergo histological examination and assessment postoperatively by a pathologist. The removal of healthy ovaries or healthy adnexa with normal histological findings should be avoided. The presence of ovarian cysts also does not necessarily indicate the complete removal of the ovary, as most are functional cysts that often have hormonal causes. These "functional" cysts (e.g., follicular, corpus luteum cysts) often develop as a result of the normal menstrual cycle. They are frequently asymptomatic and usually resolve spontaneously. These cysts are considered pathological in particular in the event of pain or bleeding into the cyst.

Monitoring and ultrasound scans (sonography) are particularly recommended for preoperative differentiation. Nevertheless, the differentiation of functional cysts from benign and malignant neoplasms of the ovaries is often difficult. An accurate indication is required in this case to avoid removal of healthy ovaries.

Evaluating the results

In 2013, a complete removal of an ovary or adnexa was performed in a total of 6,515 out of 18,276 patients, even though no pathological findings (follicular or corpus luteum cyst, or normal findings) or specific details on findings were present. This corresponds to an overall rate nationwide of 35.6 %. In total, 119 out of 855 hospitals exceeded the nationwide reference range in 2013 (≤ 90th percentile).

This indicator was first reported in 2013 in order to include cases without specific details on histological findings. Analyses at the federal level have shown that in recent years the non-specific code "Adnexa: changes in the adnexa not covered in codes 10 – 17" has increasingly been documented as postoperative histological findings.

In 2013, no specific histological findings were reported in 4,045 of the 18,276 patients with complete removal of the ovary or adnexa (22.1 %). This proportion is regarded as very high by the Federal Experts' Working Group. There is also uncertainty regarding which cases are documented with the above-mentioned code. Against this background, the Federal Experts' Working Group has formulated a recommendation to the State Administrative Offices for Quality Assurance (LQS) to inquire from computationally discrepant hospitals about cases documented with this code and reasons for the non-specific details on findings.

The Federal Experts' Working Group classifies the indicator as having a need for action X. Depending on the outcome of the Structured Dialogue, the indicator may need to be developed further, or the specification revised.

Description

Numerator	Patients with follicular or corpus luteum cysts or normal findings as the main histological finding, and patients with changes in the adnexa, in whom none of the following is the main histological finding: serous cystoma, mucinous cystoma, dermoid cyst, endometriosis, inflammation, ectopic pregnancy or primary malignant neoplasms, including relapses
Denominator	All patients with isolated ovarian surgery with complete removal of the ovary or adnexa (OPS: 5 - 652.4*, 5 - 652.6*, 5 - 653*) and data on postoperative histology, excluding patients with adnexectomy in association with breast cancer (discharge diagnosis C50* with concomitant documentation of OPS: 5 - 652* or 5 - 653*) or preventive surgery of the ovary due to risk factors associated with malignant neoplasms (discharge diagnosis Z40.01)
Reference range	≤ 55.9 % (90th percentile, tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	51907
Comparability with the previous year's results	The indicator was introduced for the first time in the data collection year 2013 and calculated retrospectively for 2012.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	36.7 %	35.6 %
Confidence interval	–	–	–	36.0 – 37.4 %	35.0 – 36.3 %
Total number of cases	–	–	–	17,843	18,276

Aggregate result of all patients
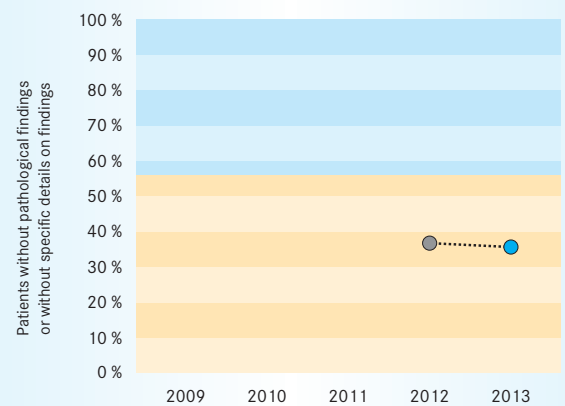
Hospital-based results

Target population of all hospitals	855
Number of hospitals with 0 cases	173

390 Hospitals with ≥ 20 cases
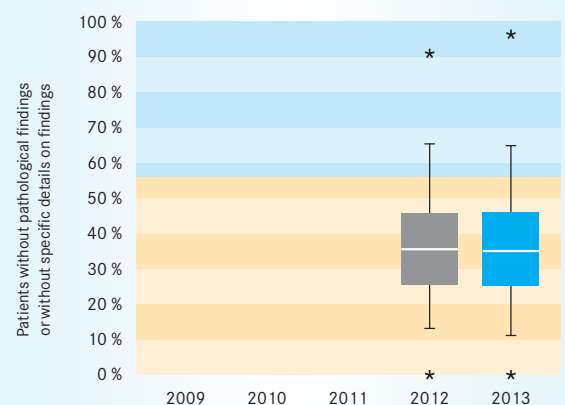
Median	35.0 %	Number of computationally discrepant hospitals	39 of 390
Range	0.0 – 96.3 %		

465 Hospitals with 1 to 19 cases

Median	29.4 %	Number of computationally discrepant hospitals	80 of 465
Range	0.0 – 100.0 %		

Femoral fractures near the hip joint

Cristina Thole, Thorben Breitkreuz, Andrea Wolf, Federal Experts' Working Group for Orthopedics and Trauma Surgery

Introduction
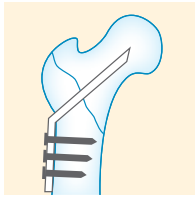
A fracture in the upper femur, i.e., the upper part of the thigh bone, the strongest and largest bone in the human body that connects with the hip joint, is called femoral fracture near the hip joint. In most cases, these fractures are caused by accidents. Depending on the location of the fracture, a distinction is made between fractures of the femoral neck and pertrochanteric fractures. The former type of fractures includes those located between the femoral head and the greater process (trochanter major) of the thigh bone. The latter includes fractures occurring obliquely through the trochanter region of the thigh bone, located below the femoral neck and above the small process (trochanter minor).

With age, the bone loses its strength and stability. Aging can also lead to loss of the bone mass and to porosity (osteoporosis). At the same time, walking becomes uncertain. This is a reason why femoral fractures near the hip joint are a specific and common injury in the elderly. In the elderly, even minor falls, for example, due to uncertain gait can result in femoral fractures. Approximately 85 % of about 100,000 fractures occurring annually are suffered by people aged 70 years and older. Given the demographic changes, the number of femoral fractures is expected to increase.

There are two surgical procedures for treating femoral fractures: femoral head-preserving (osteosynthetic) surgery and procedures involving replacement of the femoral head (total joint replacement). In both cases, the aim is to quickly restore the patients' mobility and physical strength without complications. A rapid recovery is of great importance, particularly for the elderly, in order to restore the patient's self-care, which will decrease the chance for being dependent on long-term nursing care.

Services subject to mandatory documentation

All isolated femoral neck fractures and pertrochanteric femoral fractures without severe concurrent injuries that are treated by osteosynthesis or total joint replacement in patients ≥ 20 years.

Changes in comparison to the previous year

At the beginning of data collection year 2013, the documentation specifications on preoperative length of stay were improved. By exactly documenting time specifications, it is possible to determine the time elapsed between the patient's admission and surgery. This substantially improves the validity of the indicator result. Moreover, the documentation costs are reduced because these data can be gathered directly from the case documentation. Detailed information on the indicator ("Preoperative length of stay over 48 hours after admission", QI-ID 2266) is presented later in this section.

Within the scope of system maintenance, the two quality indicators regarding the ability to walk at discharge (QI-ID 2272 and QI-ID 50874) were adjusted to the direction of the calculation formula. Accordingly, the name of the indicator group was changed from "Limited ability to walk at discharge" to "*In*ability to walk at discharge". Inability to walk was defined as: the pa-

tient is not able to walk at least 50 meters (neither with aid nor with crutches). Furthermore, since data collection year 2013, all patients who were discharged alive after a femoral fracture near the hip joint were included in the calculation formula of the quality indicator. For the current data collection year, this means that the target population for this quality indicator increased by 13,815 patients compared to the previous year.

The reference range for the quality indicator "Ratio of the observed to the expected rate (O / E) of postoperative wound infections" (QI-ID 50889) was redefined. The new definition is based on the infection rates of the National Reference Center (NRZ) for the surveillance of nosocomial infections between 2008 and 2012.

Based on the corresponding non-risk-adjusted indicator (QI-ID 2269) for the risk-adjusted quality indicator "Ratio of the observed to expected rate (O / E) of wound hematomas/postoperative bleeds" (QI-ID 50858), the reference range was redefined as ≤ 3.54. The average was based on the 95th percentile from data collection years 2010 to 2012.

Results

Overall, good quality of care was observed in the clinical area *Femoral fracture near the hip joint*. On federal average, none of the quality indicators fall outside the reference range. The quality indicator "Total joint replacement in patients > 80 years with medial femoral neck fracture (Garden III or IV)" (QI-ID 2115) exceeded the previous year's result with 98.8 % (98.6 %) and reflects a high level of care given that only 3.1 % of hospitals were rated as "computationally discrepant".

This is also true for the indicators "Perioperative antibiotic prophylaxis in osteosynthetic care" (QI-ID 10361) and "Perioperative antibiotic prophylaxis in endoprosthetic care" (QI-ID 10364). Both yielded high rates of 99.0 % (osteosynthetic care) and 99.6 % (endoprosthetic care) respectively, even though there are still some hospitals rated as "computationally discrepant" due to their low rates. These were subject to individual evaluation by the responsible State Administrative Offices for Quality Assurance (LQS) within the Structured Dialogue. Despite the overall very good results, the Federal Experts' Working Group recommends further documentation and evaluation for these important indicators. They should be retained in the indicator set to allow continuous observation on the long-term. As part of system maintenance, it is planned however to revise these indicators against the background of preventing nosocomial infections aiming at collecting data on antibiotic administration, duration, active ingredients and the route of administration (systemic, in the cement, combined).

The good results for all indicators on surgical complications that require intra- or postoperative treatment show almost no change in comparison to the previous year. The indicators "In-hospital mortality for ASA risk factors 1 or 2" (QI-ID 2277) and "In-hospital mortality for risk factor ASA 3" (QI-ID 2276) show a slight, but not statistically significant improvement over data collection year 2012.

Femoral fractures near the hip joint

On the contrary, a slight worsening in the results of the quality indicator "General postoperative complications" (QI-ID 2275) was again observed. This indicator documents, e.g., pneumonia and deep vein thrombosis of the leg/pelvis and lung embolism. In particular, the rate of pneumonia in patients with a femoral fracture has continued to increase as in the previous years (2010: 2.2 %, 2011: 2.3 %, 2012: 2.5 %, 2013: 2.6 %). Based on the results of the Structured Dialogue on the corresponding risk-adjusted indicator (QI-ID 50894) of data collection year 2012, 5 hospitals (out of 62 computationally discrepant) were classified as "qualitatively discrepant". In light of the current discussion on nosocomial infections, the indicator was also categorized by the Federal Experts' Working Group with an extended need for action B and should be monitored intensely.

Only the results of the indicator "Preoperative length of stay > 48 hours after admission to the hospital" (QI-ID 2266) in data collection year 2013 significantly worsened over the previous year. However, it should be noted that the data fields required to calculate the indicator within the scope of system maintenance for the data collection year 2013 were changed. Therefore, a direct comparison with the previous year's results is only conditionally possible.

Compared to other OECD countries (comparative data from 2011) that also measure the 48-hour interval between admission and surgery in patients > 65 years, Germany is in the upper middle in terms of the current values (Fig. 1).

Looking forward

A further development of a hospital follow-up procedure on *Total hip replacement care*, which also had impacts on the clinical area *Femoral fracture near the hip joint*, is planned for the year 2015. Due to the envisioned conversion, the femoral fractures near the hip joint treated by osteosynthesis or total joint replacement will be excluded from this clinical area and presented in a new clinical area *Hip replacement care* in the future. A special analysis will be performed for data collection year 2014 to enable continued diagnosis-related evaluation of the quality of surgical treatment of femoral fractures after femoral head-preserving (osteosynthetic) procedures and procedures involving replacement of the femoral head (endoprosthetic) similar to the previous analyses.

Iceland	95.8 %
Denmark	94.0 %
Sweden	93.4 %
UK	88.4 %
Germany	86.2 %
Czech Republic	85.1 %
New Zealand	84.5 %
Finland	84.2 %
Ireland	83.2 %
Canada	83.2 %
Slovenia	55.6 %
Portugal	46.6 %
Spain	43.2 %
Italy	36.8 %
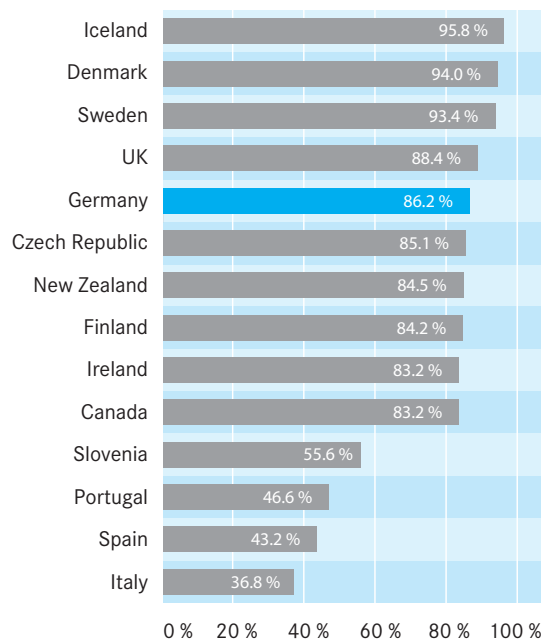
Figure 1: „Hip fracture surgery initiated within 48 hours after admission to the hospital" (OECD 2011)*

* *http://stats.oecd.org* (Health: Health Care Quality Indicators: Acute Care: Hip fracture surgery initiated within 48 hours after admission to the hospital). Accessed on 23 May 2014.

Femoral fractures near the hip joint

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	102,168	107,052	106,216	100.8 %
Hospitals	1,104	1,096	1,093	100.3 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	106,795	100 %
< 50 years	1,936	1.8 %
50 – 59 years	4,628	4.3 %
60 – 69 years	8,827	8.3 %
70 – 79 years	26,410	24.7 %
80 – 89 years	46,881	43.9 %
≥ 90 years	18,113	17.0 %
Sex		
Male	31,536	29.5 %
Female	75,259	70.5 %
General postoperative complications requiring treatment		
At least one complication	13,099	12.3 %
Pneumonia (lung infection)	2,828	2.6 %
Deep vein thrombosis of leg/pelvis	159	0.1 %
Lung embolism	576	0.5 %
Cardiovascular complications (relating to the heart and vascular system)	4,542	4.3 %
Other general postoperative complications	7,413	6.9 %
ASA classification		
ASA 1: A normal healthy patient	2,629	2.5 %
ASA 2: A patient with mild systemic disease	25,996	24.3 %
ASA 3: A patient with severe systemic disease	69,621	65.2 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	8,291	7.8 %
ASA 5: A moribund patient who is not expected to survive without the operation	258	0.2 %

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Further information on the clinical area

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www.sqg.de/themen/17n1/

Femoral fractures near the hip joint

Case-based aggregate results (patients)

			2012	2013			
				Cases (patients)			
	QI-ID	Name of the quality indicator	Result	Result	Numerator (O | E)*	Denominator	Trend
	2266	Preoperative length of stay > 48 hours after hospital admission ⚠	9.5 %	13.0 %	13,935	106,795	↘
	2115	Endoprosthetic care in patients > 80 years with medial femoral neck fracture (Garden III or IV)	98.6 %	98.8 %	22,886	23,165	→
Indicator group		Perioperative antibiotic prophylaxis					
	10364	Perioperative antibiotic prophylaxis in endoprosthetic care ⚠	99.6 %	99.6 %	48,155	48,329	→
	10361	Perioperative antibiotic prophylaxis in osteosynthetic care	98.9 %	99.0 %	56,730	57,299	→
Indicator group		Inability to walk at discharge					
	2272	Inability to walk at discharge	4.7 %	4.8 %	4,819	101,145	→
	50874	Ratio of the observed to expected rate (O / E) of patients with inability to walk at discharge	1.00	1.01	4,819 4.76 % | 4,758 4.70 %	101,145	→
Indicator group		Vessel lesion/nerve damage					
	2271	Vessel lesion/nerve damage	0.1 %	0.1 %	113	106,795	→
	50853	Ratio of the observed to the expected rate (O / E) of vessel lesions/nerve damage	1.00	0.85	113 0.11 % | 133 0.12 %	106,795	→
Indicator group		Implant malposition, dislocation or fracture					
	2267	Implant malposition, dislocation or fracture ⚠	1.0 %	1.1 %	1,128	106,795	→
	50879	Ratio of the observed to expected rate (O / E) of implant malpositions, implant dislocations or fractures ⚠	1.00	1.01	1,128 1.06 % | 1,112 1.04 %	106,795	→
Indicator group		Dislocation of total joint replacement					
	2270	Dislocation of total joint replacement ⚠	0.8 %	0.7 %	348	48,329	→
	50884	Ratio of the observed to the expected rate (O / E) of dislocations of total joint replacements ⚠	1.00	0.91	348 0.72 % | 383 0.79 %	48,329	→
Indicator group		Postoperative wound infection					
	2274	Postoperative wound infection ⚠	1.1 %	1.1 %	1,122	106,795	→
	50889	Ratio of the observed to the expected rate (O / E) of postoperative wound infections ⚠	1.00	0.99	1,122 1.05 % | 1,130 1.06 %	106,795	→
Indicator group		Wound hematomas/postoperative bleeds					
	2269	Wound hematomas/postoperative bleeds	1.7 %	1.5 %	1,633	106,795	→
	50858	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds	1.00	0.90	1,633 1.53 % | 1,810 1.70 %	106,795	→
Indicator group		General postoperative complications					
	2275	General postoperative complications	3.1 %	3.3 %	3,491	106,795	→
	50894	Ratio of the observed to the expected rate (O / E) of general postoperative complications	1.00	1.05	3,491 3.27 % | 3,327 3.12 %	106,795	→
Indicator group		Revision due to complications					
	2268	Revision due to complications ⚠	2.9 %	2.8 %	3,034	106,795	→
	50864	Ratio of the observed to expected rate (O / E) of revisions due to complications ⚠	1.00	0.97	3,034 2.84 % | 3,142 2.94 %	106,795	→

Femoral fractures near the hip joint

Case-based aggregate results (patients)

			2012	2013			
					Cases (patients)		
QI-ID	**Name of the quality indicator**		**Result**	**Result**	Numerator (O | E)*	Denominator	**Trend**
	In-hospital mortality						
2277	In-hospital mortality for ASA risk factors 1 or 2		0.82 %	0.68 %		195	28,625	→
2276	In-hospital mortality for ASA risk factor 3		5.2 %	5.1 %		3,574	69,621	→
2279	In-hospital mortality in osteosynthetic care		4.7 %	4.8 %		2,736	57,299	→
2278	In-hospital mortality in endoprosthetic care		6.1 %	5.9 %		2,872	48,329	→
51168	Ratio of the observed to expected rate (O / E) of deaths		1.00	0.99	5,637 5.28 %	5,677 5.32 %	106,730	→

* for regression-based quality indicators

Femoral fractures near the hip joint

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		Evaluation	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
2266	Preoperative length of stay > 48 hours after hospital admission	≤ 15.0 % (TO)	1,096	357	2	X
2115	Endoprosthetic care in patients > 80 years with medial femoral neck fracture (Garden III or IV)	≥ 90.0 % (TO)	1,036	32	2	A
	Perioperative antibiotic prophylaxis					
10364	Perioperative antibiotic prophylaxis in endoprosthetic care	≥ 95.0 % (TA)	1,088	17	1	A
10361	Perioperative antibiotic prophylaxis in osteosynthetic care	≥ 96.4 % (TO; 5th percentile)	1,039	55	1	A
	Inability to walk at discharge					
2272	Inability to walk at discharge	n.d.*	1,095	–	X	X
50874	Ratio of the observed to expected rate (O / E) of patients with inability to walk at discharge	≤ 3.15 (TO; 95th percentile)	1,095	55	2	A
	Vessel lesion/nerve damage					
2271	Vessel lesion/nerve damage	n.d.*	1,096	–	X	X
50853	Ratio of the observed to the expected rate (O / E) of vessel lesions/nerve damage	≤ 16.06 (TO)	1,096	18	2	A
	Implant malposition, dislocation or fracture					
2267	Implant malposition, dislocation or fracture	n.d.*	1,096	–	X	X
50879	Ratio of the observed to expected rate (O / E) of implant malpositions, implant dislocations or fractures	≤ 1.92 (TO)	1,096	200	2	B
	Dislocation of total joint replacement					
2270	Dislocation of total joint replacement	n.d.*	1,088	–	X	X
50884	Ratio of the observed to the expected rate (O / E) of dislocations of total joint replacements	≤ 6.31 (TO)	1,088	33	2	A
	Postoperative wound infection					
2274	Postoperative wound infection	n.d.*	1,096	–	X	X
50889	Ratio of the observed to the expected rate (O / E) of postoperative wound infections	≤ 2.84 (TO)	1,096	96	2	A
	Wound hematomas/postoperative bleeds					
2269	Wound hematomas/postoperative bleeds	n.d.*	1,096	–	X	X
50858	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds	≤ 3.54 (TO)	1,096	49	2	A
	General postoperative complications					
2275	General postoperative complications	n.d.*	1,096	–	X	X
50894	Ratio of the observed to the expected rate (O / E) of general postoperative complications	≤ 2.64 (TO; 95th percentile)	1,096	56	2	B
	Revision due to complications					
2268	Revision due to complications	n.d.*	1,096	–	X	X
50864	Ratio of the observed to the expected rate (O / E) of revisions due to complications	≤ 4.08 (TO)	1,096	14	2	A

Indicator group

Femoral fractures near the hip joint

Hospital-based aggregate results for utilization in quality assurance

	QI-ID	Name of the quality indicator	Reference range	2013			
				Hospitals		**Evaluation**	
				Total	Discrepant (computationally)	Category	Need for action
Indicator group		In-hospital mortality					
	2277	In-hospital mortality for ASA risk factors 1 or 2	Sentinel event	1,065	160	X	A
	2276	In-hospital mortality for ASA risk factor 3	n.d.*	1,081	–	X	X
	2279	In-hospital mortality in osteosynthetic care	≤ 10.6 % (TO; 95th percentile)	1,039	56	1	A
	2278	In-hospital mortality in endoprosthetic care	≤ 13.3 % (TO; 95th percentile)	1,088	67	2	A
	51168	Ratio of the observed to expected rate (O / E) of deaths	n.d.*	1,096	–	X	X

TO = Tolerance range; TA = Target range; *not defined

Femoral fractures near the hip joint

QI-ID 2266: Preoperative length of stay > 48 hours after hospital admission

Quality target

Short preoperative length of stay.

Background

Any delay in the surgical treatment of a femoral fracture near the hip joint increases the danger for complications, such as thrombosis, embolism or pressure ulcers (decubitus). Accordingly, guidelines recommend that the time of surgery be as early as possible after fractures of the thigh bone near the hip joint (femoral fracture).

Reasons for delaying surgery can include drug-related (e.g., anti-coagulants), internistic and anesthesiological factors, surgical capacities as well as diagnostic waiting times on the one hand. On the other hand, structural factors or legal regulations have also been reported. For example, the time waiting for the informed consent to be given by a legal guardian (of the frequently very elderly patients) may also be a reason for an extended length of hospital stay until the surgery is performed.

Evaluating the results

Although the overall rate of the quality indicator continues to be within the reference range, it has increased to 13.0 %. In data collection year 2013, more patients had to wait longer than 48 hours for surgery than in the previous year (2012: 9.5 %).

Compared to previous years, the preoperative length of stay is no longer documented manually based on three predefined time windows (< 24 hours, between 24 and 48 hours, > 48 hours). Rather, since the data collection year 2013, it has been automatically documented and calculated down to the minute from the admission date/time and commencement of surgery (incision time). One limitation of the new documentation method is that patients who were not admitted for a femoral neck fracture, but fell during their hospital stay, are not correctly documented. The planned documentation adjustments starting in the data collection year 2015 will allow a separate calculation of femoral neck fractures occurring in a hospital stay.

The Federal Experts' Working Group presumes that the use of anti-coagulants in the affected patients was another reason why the 48-hour cutoff was exceeded. A further analysis revealed that most patients with anti-coagulants were operated on within 48 hours (80 %; n = 23,799) – but that they were actually operated on significantly more frequently after 48 hours than were patients without chronic antithrombotic therapy (39.8 % versus 25.6 %). Thereby, a delayed surgery was found to be independent on the drug and not, as was to be expected, only for those with a longer half-life. The Structured Dialogue will clarify these aspects and this might help to further develop the indicator.

An important aspect regarding extended preoperative length of stay is that the proportion of patients admitted on a Friday who had to wait longer than 48 hours for their operation, was remarkably higher this year with 19.2 % (2012: 14.3 %) than on other weekdays (Monday – Thursday on average 11.5 %, Saturday 16.2 %, Sunday 10.2 %). The Federal Experts' Working Group suspects this to be attributable to structural deficiencies caused by limited personnel coverage on weekends.

Description

Numerator	Patients undergoing surgery later than 48 hours after admission
Denominator	All patients > 20 years
Reference range	≤ 15.0 % (tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	2266
Comparability with the previous year's results	Comparable to a limited extent. Instead of collecting data based on three predefined time windows only, the time between admission date/time and commencement of surgery (incision time) has been automatically calculated down to the minute since data collection year 2013.

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	10.7 %	9.9 %	9.6 %	9.5 %	13.0 %
Confidence interval	10.5–10.9 %	9.7–10.1 %	9.4–9.8 %	9.3–9.7 %	12.8–13.3 %
Total number of cases	99,671	104,168	102,001	101,888	106,795

Aggregate result of all patients
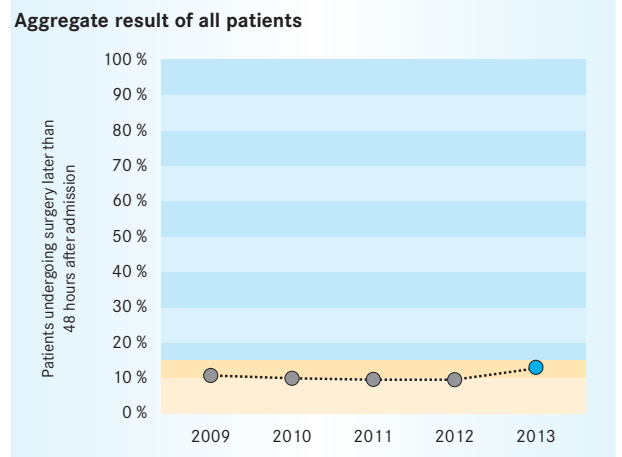
Hospital-based results

Target population of all hospitals	1,096
Number of hospitals with 0 cases	0

983 Hospitals with ≥ 20 cases
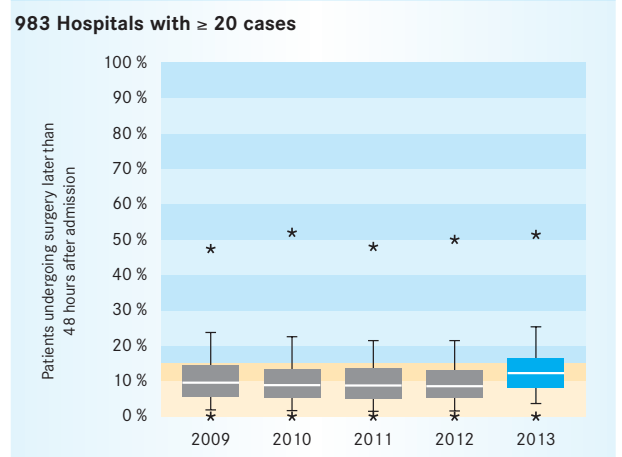
Median	12.2 %	Number of computationally discrepant hospitals	296 of 983
Range	0.0–51.4 %		

113 Hospitals with 1 to 19 cases

Median	16.7 %	Number of computationally discrepant hospitals	61 of 113
Range	0.0–100.0 %		

Hip replacement — Primary implantation

Cristina Thole, Thorben Breitkreuz, Andrea Wolf, Federal Experts' Working Group for Orthopedics and Trauma Surgery

Introduction
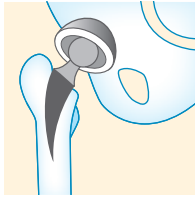
The implantation of an artificial hip joint is one of the most commonly performed surgeries in Germany. The main reason for replacing a hip joint is advanced wear and damage of the joint, especially to the protective cartilage layer between joint head and socket (coxarthrosis). In most cases, the cartilage wear in the hip joint is an age-related condition. Nevertheless, previous diseases, such as malalignment of the skeleton (the bony framework of the body), permanent improper loading or overweight can lead to coxarthrosis.

In the advanced stage of the disease, strong pain and functional impairments can occur. In Germany, more than 150,000 patients undergo this operation annually due to arthrosis of the hip joint – of which approximately two thirds are women.

Just as the "original" hip joint, the artificial hip joint (hip arthroplasty) consists of a joint socket and a joint head, which is seated on the top of the shaft of the thighbone. While total joint replacement is performed on the complete joint, partial replacement only involves replacement of parts of the joint. The aim of a hip replacement is to relieve the patients' pain and restore maximal mobility. Before an implantation is performed, certain preconditions – e.g., pain level, extent of arthrosis and severity of the damage and the impairment of the joint function – must be assessed.

Services subject to mandatory documentation

Primary implantations of non-fracture-related total hip replacement in patients ≥ 20 years.

Changes in comparison to the previous year

In analogy to the other clinical areas in orthopedics and trauma surgery, the documentation forms were restructured. Since data collection year 2013, it is now possible to create what is called a partial record for a hospital case. This means that administrative data, e.g., for a bilateral hip joint replacement for a patient, do not have to be created twice. As a result of this restructuring, an adjustment of the calculation formula for the affected quality indicators was required. Hence, no longer the affected patients, but the primary implantations documented by the hospital are counted since data collection year 2013.

As part of system maintenance, the titles of the two quality indicators on the ability to walk at discharge (QI-ID 264 and QI-ID 50909) were adjusted to the content-related alignment of the calculation formula. The name of the indicator group was changed accordingly: "Limited walking ability at discharge" was renamed "*In*ability to walk at discharge". Inability to walk means that the patient is not able to walk more than 50 meters (neither with an assisting person nor with crutches). Previously, patients who, for example, were discharged to a nursing home, were not considered in the quality indicator. Since data collection year 2013, all patients who were discharged alive after a non-fracture-related primary implantation of a hip replacement have been measured by the calculation formula for the quality indicator. As a result, the target population of the quality indicator grew by 3,034 patients in the current data collection year.

Based on the corresponding non-risk-adjusted indicator "Implant malposition, implant dislocation or fracture" (QI-ID 449) for the risk-adjusted indicator "Ratio of the observed to the expected rate (O / E) of implant malpositions, implant dislocations or fractures" (QI-ID 50919), the reference range was defined as ≤ 4.16. This was based on the average of the 95th percentiles from data collection years 2010 to 2012. A similar procedure was also followed for the indicator "Ratio of the observed to the expected rate (O / E) of dislocations of total joint replacements" (QI-ID 50924).

Results

In data collection year 2013, more records on primary implantations of hip replacements were transmitted than in the previous year. However, this was not due to a higher number of surgeries performed, but to inclusion criteria that were modified compared to data collection year 2012 (for more details, please refer to the German Hospital Quality Report 2012). Compared to data collection years 2011 and 2013, there was a de facto decline in relation to the non-fracture-related primary implantations of hip replacements by around 4 %. The data of the Federal Statistical Office also confirm this trend.

For the most part, the results of the individual quality indicators do not reveal any statistically significant changes over the previous years. On the federal level, the results of the indicators were consistently within the reference ranges, which is why the Federal Experts' Working Group rates the healthcare situation overall as good.

The quality indicator for the indication (QI-ID 1082) shows improvement for a repeated time: In data collection year 2013, 95.2 % of patients receiving primary implantation of a hip replacement fulfilled the indicator criteria. Compared to the previous year, the number of computationally discrepant hospitals has also dropped (2012: n = 220; 2013: n = 186).

A significantly positive trend was shown for the indicator "Range of motion of at least 0/0/70 according to the neutral-zero method" (QI-ID 446). The proportion of patients who achieved this range of motion before discharge from the hospital was 99.1 %. Nevertheless, the data show that the use of the neutral-zero method has declined. The Federal Experts' Working Group views this development as critical which decidedly point to this generally recognized method for evaluating the range of motion of hips.

Overall, the proportion of surgical procedures with at least one postoperative complication (QI-ID 455) showed no marked change over the last years (2013: 1.1 %, corresponding 1,624 cases; 2008: 1.2 %, corresponding 1,942 cases). Postoperative complications include pneumonia, cardiovascular complications, deep vein thrombosis of leg/pelvis and lung embolism. Most frequently (around 70 %), "Other" is stated under the complications but is not entered in the calculation of the indicator.

The other proportion of the patients with non-fracture-related primary implantation of a total hip replacement underwent surgery due to the previous disease coxarthrosis. This did not involve emergency surgeries, but elective interventions, the

Hip replacement — Primary implantation

time point of which is usually freely selectable and plannable. Nevertheless, over 300 patients died during their hospital stay after primary implantation of a total hip replacement. In more than 850 patients, the hospitals established a severe or even life-threatening systemic disease before surgery (e.g., chronic heart failure or kidney failure). The operative risk for these patients is thus particularly high. The Federal Experts' Working Group expects that the indication in patients at particularly high individual risk is rendered with particular scrutiny – at best in conjunction with intensive interdisciplinary collaboration.

Looking forward

The Federal Experts' Working Group welcomes merging of the clinical areas *Hip replacement – Primary implantation* and *Hip replacement – Revision and component exchange* into the clinical area *Hip replacement care* planned to start with data collection year 2015. This merger will lead to a bundled presentation and calculation of the quality indicators. For example, the postoperative complications of the two clinical areas previously considered separately will be merged into one index. The clinical-area-specific quality indicators, for example, the indication for implantation of a hip joint, remain.

In the routine operation 2015, patient-identifying data (PID) as part of the planned merger of the clinical areas are transmitted for the first time in pseudonymized form. Based on these, patients can be tracked, even cross-institutionally, within the scope of quality assurance with a view to a potential revision surgery. The resulting follow-up indicator for revision of an artificial hip joint shall be analyzed starting in 2016.

What is even more conclusive for the inpatient observation is the announced analysis of health insurance claims data: These data could also be used to measure complications that do not emerge until after the acute inpatient clinical treatment. The Federal Experts' Working Group and the AQUA Institute regret that the prerequisites for utilizing the health insurance claims data for external quality assurance in orthopedics and trauma surgery have currently not been created yet. The same applies to the development of a patient survey: The Federal Experts' Working Group once more points to the special meaning of this perspective for quality assurance in the orthopedic and trauma surgery clinical areas.

Hip replacement — Primary implantation

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	152,591	153,324	153,255	100.0 %
Hospitals	1,091	1,075	1,074	100.1 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	152,519	100 %
< 50 years	8,894	5.8 %
50 – 59 years	23,380	15.3 %
60 – 69 years	39,599	26.0 %
70 – 79 years	60,835	39.9 %
80 – 89 years	19,008	12.5 %
≥ 90 years	803	0.5 %
Sex		
Male	63,008	41.3 %
Female	89,511	58.7 %
General postoperative complications requiring treatment		
At least one complication	4,768	3.1 %
Pneumonia (lung infection)	291	0.2 %
Cardiovascular complications (relating to the heart and vascular system)	1,179	0.8 %
Deep vein thrombosis of leg/pelvis	137	0.1 %
Lung embolism	120	0.1 %
Other general postoperative complications	3,354	2.2 %
ASA classification*		
ASA 1: A normal healthy patient	12,705	8.3 %
ASA 2: A patient with mild systemic disease	92,190	60.4 %
ASA 3: A patient with severe systemic disease	46,964	30.7 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	856	0.6 %
ASA 5: A moribund patient who is not expected to survive without the operation	17	< 0.1 %

* As the numbers mentioned here refer to the number of surgeries (several surgery forms can be filled out for one patient), the aggregate sum of patients in the ASA classification deviates from the figure stated in the age distribution.

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):

www.sqg.de/themen/17n2/

Hip replacement — Primary implantation

Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator		2012 Result	2013 Result	2013 Cases (patients) Numerator (O | E)*	Denominator	Trend
	1082	Hip replacement – primary implantation with fulfilled indication criteria	⚠	94.5 %	95.2 %	145,432	152,732	↗
	265	Perioperative antibiotic prophylaxis	⚠	99.7 %	99.7 %	152,282	152,732	→
Indicator group		*Postoperative range of motion*						
	2223	Measuring the postoperative range of motion using the neutral-zero method	⚠	96.8 %	95.9 %	146,461	152,732	↘
	446	Range of motion of at least 0/0/70 according to the neutral-zero method		98.2 %	99.1 %	145,187	146,461	↗
Indicator group		*Inability to walk at discharge*						
	264	Inability to walk at discharge		0.3 %	0.4 %	548	152,207	→
	50909	Ratio of the observed to the expected rate (O / E) of patients with inability to walk at discharge		1.00	1.14	548 0.36 % / 479 0.31 %	152,207	→
Indicator group		*Vessel lesion or nerve damage*						
	447	Vessel lesion or nerve damage		0.3 %	0.3 %	453	152,732	→
	50914	Ratio of the observed to the expected rate (O / E) of vessel lesions or nerve damage		1.00	1.01	453 0.30 % / 447 0.29 %	152,732	→
Indicator group		*Implant malposition, implant dislocation or fracture*						
	449	Implant malposition, implant dislocation or fracture	⚠	1.0 %	1.0 %	1,513	152,732	→
	50919	Ratio of the observed to the expected rate (O / E) of implant malpositions, implant dislocations or fractures	⚠	1.00	1.03	1,513 0.99 % / 1,468 0.96 %	152,732	→
Indicator group		*Dislocation of total joint replacement*						
	451	Dislocation of total joint replacement	⚠	0.3 %	0.3 %	437	152,732	→
	50924	Ratio of the observed to the expected rate (O / E) of dislocations of total joint replacements	⚠	1.00	0.90	437 0.29 % / 488 0.32 %	152,732	→
Indicator group		*Postoperative wound infection*						
	452	Postoperative wound infection	⚠	0.5 %	0.5 %	734	152,732	→
	50929	Ratio of the observed to the expected rate (O / E) of postoperative wound infections	⚠	1.00	1.05	734 0.48 % / 699 0.46 %	152,732	→
Indicator group		*Wound hematomas/postoperative bleeds*						
	454	Wound hematomas/postoperative bleeds		1.0 %	0.9 %	1,339	152,732	→
	50934	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds		1.00	0.88	1,339 0.88 % / 1,514 0.99 %	152,732	↗
Indicator group		*General postoperative complications*						
	455	General postoperative complications		1.1 %	1.1 %	1,624	152,519	→
	50939	Ratio of the observed to the expected rate (O / E) of general postoperative complications		1.00	0.95	1,624 1.06 % / 1,707 1.12 %	152,519	→
Indicator group		*Revision due to complications*						
	456	Revision due to complications	⚠	1.6 %	1.5 %	2,318	152,732	→
	50944	Ratio of the observed to the expected rate (O / E) of revisions due to complications	⚠	1.00	0.97	2,318 1.52 % / 2,381 1.56 %	152,732	→
Indicator group		*In-hospital mortality*						
	457	In-hospital mortality	⚠	0.18 %	0.20 %	312	152,519	→
	50949	Ratio of the observed to the expected rate (O / E) of deaths	⚠	1.00	1.11	312 0.20 % / 280 0.18 %	152,519	→

* for regression-based quality indicators

Hip replacement — Primary implantation

Hospital-based aggregate results for utilization in quality assurance

| | | | 2013 | | | |
| | | | Hospitals | | Evaluation | |
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
1082	Hip replacement – primary implantation with fulfilled indication criteria	≥ 90.0 % (TA)	1,074	186	2	A
265	Perioperative antibiotic prophylaxis	≥ 95.0 % (TA)	1,074	5	1	A
	Postoperative range of motion					
2223	Measuring the postoperative range of motion using the neutral-zero method	≥ 95.0 % (TA)	1,074	250	2	A
446	Range of motion of at least 0/0/70 according to the neutral-zero method	≥ 95.0 % (TA)	1,063	38	1	A
	Inability to walk at discharge					
264	Inability to walk at discharge	n.d.*	1,073	–	X	X
50909	Ratio of the observed to the expected rate (O / E) of patients with inability to walk at discharge	≤ 6.17 (TO; 95th percentile)	1,073	54	2	A
	Vessel lesion or nerve damage					
447	Vessel lesion or nerve damage	n.d.*	1,074	–	X	X
50914	Ratio of the observed to the expected rate (O / E) of vessel lesions or nerve damage	≤ 6.83 (TO)	1,074	47	2	A
	Implant malposition, implant dislocation or fracture					
449	Implant malposition, implant dislocation or fracture	n.d.*	1,074	–	X	X
50919	Ratio of the observed to the expected rate (O / E) of implant malpositions, implant dislocations or fractures	≤ 4.16 (TO)	1,074	72	2	A
	Dislocation of total joint replacement					
451	Dislocation of total joint replacement	n.d.*	1,074	–	X	X
50924	Ratio of the observed to the expected rate (O / E) of dislocations of total joint replacements	≤ 9.39 (TO)	1,074	22	2	A
	Postoperative wound infection					
452	Postoperative wound infection	n.d.*	1,074	–	X	X
50929	Ratio of the observed to the expected rate (O / E) of postoperative wound infections	≤ 6.56 (TO)	1,074	46	2	A
	Wound hematomas/postoperative bleeds					
454	Wound hematomas/postoperative bleeds	n.d.*	1,074	–	X	X
50934	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds	≤ 8.07 (TO)	1,074	7	2	A
	General postoperative complications					
455	General postoperative complications	n.d.*	1,074	–	X	X
50939	Ratio of the observed to the expected rate (O / E) of general postoperative complications	≤ 3.39 (TO; 95th percentile)	1,074	59	2	A
	Revision due to complications					
456	Revision due to complications	n.d.*	1,074	–	X	X
50944	Ratio of the observed to the expected rate (O / E) of revisions due to complications	≤ 5.77 (TO)	1,074	19	2	A
	In-hospital mortality					
457	In-hospital mortality	Sentinel event	1,074	243	X	A
50949	Ratio of the observed to the expected rate (O / E) of deaths	n.d.*	1,074	–	X	X

TO = Tolerance range; TA = Target range; *not defined

Hip replacement — Revision and component exchange

Cristina Thole, Thorben Breitkreuz, Andrea Wolf, Federal Experts' Working Group for Orthopedics and Trauma Surgery

Introduction

The most important indications for revisions of total hip replacements include loosening of individual prosthetic components, severe functional disorders of the implanted joint and infections. A distinction is made between complete revision and component exchange of total hip replacement. If an acute or chronic infection has caused the loosening, a partial exchange or removal of the entire implant may be required, depending on the extent of the defect. Initially, any bony damage is treated and/or missing bone material replaced. This can be done using autologous bone, with natural graft material from a bone bank or with artificial bone cement. After healing and rehabilitation, good joint function is usually possible with both a partial replacement or with the second joint.

The number of revision interventions (revision arthroplasty) performed on artificial hip joints has increased markedly over the past years. Between 2007 and 2013, an increase of over 20 % was registered. Evidence from studies suggests higher complication rates for revision interventions (revision arthroplasty) than first implantations (primary arthroplasty). In some cases, the risk of postoperative hip joint dislocation (dislocation of the prosthesis), implant malpositioning, wound infection or mortality is markedly elevated when a total hip replacement has to be revised.

Services subject to mandatory documentation

All hip replacement revisions and component exchanges in patients ≥ 20 years.

Changes in comparison to the previous year

In analogy to the other clinical areas in orthopedics and trauma surgery, the documentation forms were restructured. Since data collection year 2013, it is now possible to create what is called a partial record for a hospital case. This means that the administrative data on one patient who underwent several revision procedures do not have to be created multiple times. As a result of this restructuring, an adjustment of the calculation formula for the affected quality indicators was required. Accordingly, the affected patients will no longer be counted starting with data collection year 2013, but rather the number of revision interventions documented by the hospital.

Within the scope of system maintenance, the two quality indicators regarding the ability to walk at discharge (QI-ID 10878 and QI-ID 50954) were adjusted to the calculation formula. The name of the indicator group was also changed accordingly: "Limited walking ability at discharge" was renamed "*In*ability to walk at discharge". Inability to walk means that the patient is not able to walk at least 50 meters (neither with an assisting person nor with crutches). Previously, patients who, for example, were discharged to a nursing home, were not considered in this quality indicator. Since data collection year 2013, all patients discharged alive have been accounted for through the calculation formula of the quality indicator. For the current data collection year, this means that the target population of the quality indicator grew by 1,144 patients.

Based on the reference range of the corresponding non-risk-adjusted indicator (QI-ID 463), the reference range for the risk-adjusted quality indicator "Ratio of the observed to the expected rate (O / E) of implant malpositions, implant dislocations or fractures" (QI-ID 50964) was redefined. The average was based on the 95th percentile from data collection years 2010 to 2012.

Since data collection year 2013, data on a new quality indicator "Postoperative wound infections without preoperative signs of infection" (QI-ID 51866) has been collected. Since this quality indicator solely measures infections caused by revision surgery, the Federal Experts' Working Group resolved to categorize it as a sentinel event indicator. The quality indicator "Postoperative wound infection" (QI-ID 466) that existed up to 2012 will continue to be presented as a characteristic number in the Federal Analysis.

In the case of the quality indicator "Hip replacement revision and component replacement with fulfilled indication criteria" (QI-ID 268), the Federal Experts' Working Group did not consider the previous indication criteria to be sufficient, which was why the calculation formula was defined more precisely. For better comparability, the new calculation formula in the present German Hospital Quality Report was also retrospectively applied to data collection year 2012. Further information on this indicator is presented in the following.

Results

After the revision procedures up to 2012 had shown annual growth of approx. 2 %, no further increase was registered from 2012 to 2013. Compared to the previous year, the documentation quality markedly improved (2012: 97.3 %; 2013: 100.3 %).

Most quality indicators (17 of 19) showed no statistically significant changes compared to the previous year. At the federal level, their results are within the reference ranges across the board. A significantly negative trend compared to the previous year was measured in two indicators. Although the result of the indication indicator (QI-ID 268) was within the reference range, the result at the federal level dropped by 0.7 percentage points in data collection year 2013 over 2012 and, thus, has significantly worsened. The same applied to another indicator: Compared to the previous year, the result of the indicator "Revision due to complications" (QI-ID 470) increased by 0.7 percentage points – but has no reference range, which is why no Structured Dialogue will be conducted on it. By contrast, the corresponding risk-adjusted indicator (QI-ID 50989) does have a reference range – it did not worsen compared to the previous year. Factors such as age, classification by ASA scores, wound contamination classification, positively identified pathogen and recurrent dislocation of the prosthesis were used for risk adjustment.

To collect data on nosocomial infections, the quality indicator "Postoperative wound infections without preoperative signs of infection" (QI-ID 51866) was newly introduced. This indicator exclusively accounts for patients whose preoperative laboratory findings yielded no signs of inflammation, whose test for pathogens was negative and whose procedure was classified as aseptic. Retrospective calculation shows that the proportion of nosocomial infections in hip replacement revisions and com-

Hip replacement — Revision and component exchange

ponent exchanges increased by 0.19 percentage points compared to the previous year (equivalent to 140 postoperative wound infections).

In data collection year 2013, 428 patients died (2012: 408) in connection with a revision surgery during their hospital stay (see QI-ID 471). The increase is not statistically significant compared to the previous year. The risk-adjusted quality indicator "Ratio of the observed to the expected rate (O / E) of deaths" (QI-ID 50994) even showed that 3 % fewer patients died during their hospital stays than was statistically expected.

The Federal Experts' Working Group cannot understand how 57 of the 288 hospitals only received a notice regarding mortality in the Structured Dialogue on data collection year 2012 and – in contravention to the Directive on Quality Assurance Measures in Hospitals – were not required to submit a statement.

Looking forward

The Federal Experts' Working Group welcomes the merging of the clinical areas *Total hip replacement – Primary implantation* and *Hip replacement – Revision and component exchange* into the planned clinical area *Hip replacement care* starting with data collection year 2015. This merger will lead to a bundled presentation and calculation of the quality indicators. For example, the postoperative complications of the two previously separate clinical areas will be merged into one quality index. The clinical area-specific quality indicators, as for example, the indication for hip replacement revision or component exchange, remain.

In the process of merging these clinical areas, pseudonymized patient-identifying data (PID) will also be transmitted for the first time as part of routine operation in 2015. Based on the PID, patients can be tracked within the scope of quality assurance with a view to a potential revision surgery, even across healthcare providers. The planned follow-up indicator will be analyzed starting in 2016 and will map the surgeries that led to repeated revisions of artificial hip joints.

Moreover, health insurance claims data provide an important source of information on potential complications that can be used for post-discharge surveillance. The Federal Experts' Working Group and the AQUA Institute hence regret that the prerequisites for utilizing the health insurance claims data for external quality assurance in the orthopedics and trauma surgery areas have currently not been created yet. The same applies to the development of a patient survey: The Federal Experts' Working Group once again points out the special meaning of this perspective for quality assurance in the clinical areas of orthopedic and trauma surgery.

Data basis				
	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	26,400	26,451	26,360	100.3 %
Hospitals	1,049	1,025	1,024	100.1 %

Basic statistics		
	2013	
	Number	Proportion
Age distribution		
Number of patients	26,156	100 %
< 50 years	1,061	4.1 %
50 - 59 years	2,587	9.9 %
60 - 69 years	5,009	19.2 %
70 - 79 years	10,907	41.7 %
80 - 89 years	5,822	22.3 %
≥ 90 years	770	2.9 %
Sex		
Male	10,739	41.1 %
Female	15,417	58.9 %
ASA classification*		
ASA 1: A normal healthy patient	948	3.6 %
ASA 2: A patient with mild systemic disease	11,594	43.6 %
ASA 3: A patient with severe systemic disease	13,218	49.7 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	797	3.0 %
ASA 5: A moribund patient who is not expected to survive without the operation	13	< 0.1 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German): *www.sqg.de/themen/17n3/*

*   As the numbers mentioned here refer to the number of surgeries (several surgery forms can be filled out for one patient), the aggregate sum of patients in the ASA classification deviates from the figure stated in the age distribution.

Hip replacement — Revision and component exchange

Case-based aggregate results (patients)

			2012		2013			
					Cases (patients)			
	QI-ID	Name of the quality indicator	Result	Result	Numerator (O | E)*	Denominator	Trend	
	268	Hip replacement revision and component replacement with fulfilled indication criteria	94.3 %	93.6 %		24,881	26,570	↘
	270	Perioperative antibiotic prophylaxis	99.6 %	99.7 %		26,496	26,570	→
Indicator group		Inability to walk at discharge						
	10878	Inability to walk at discharge	2.0 %	2.1 %		537	25,728	→
	50954	Ratio of the observed to the expected rate (O / E) of patients with inability to walk at discharge	1.00	1.01	537 2.09 %	529 2.06 %	25,728	→
Indicator group		Vessel lesion/nerve damage						
	2221	Vessel lesion/nerve damage	0.6 %	0.6 %		162	26,570	→
	50959	Ratio of the observed to the expected rate (O / E) of vessel lesions/nerve damage	1.00	1.09	162 0.61 %	149 0.56 %	26,570	→
Indicator group		Implant malposition, implant dislocation or fracture						
	463	Implant malposition, implant dislocation or fracture	2.0 %	1.8 %		478	26,570	→
	50964	Ratio of the observed to the expected rate (O / E) of implant malpositions, implant dislocations or fractures	1.00	0.89	478 1.80 %	540 2.03 %	26,570	→
Indicator group		Dislocation of total joint replacement						
	465	Dislocation of total joint replacement	1.8 %	1.9 %		515	26,570	→
	50969	Ratio of the observed to the expected rate (O / E) of dislocations of total joint replacements	1.00	1.06	515 1.94 %	487 1.83 %	26,570	→
	51866	Postoperative wound infections without preoperative signs of infection	1.06 %	1.25 %		140	11,193	→
Indicator group		Wound hematomas/postoperative bleeds						
	468	Wound hematomas/postoperative bleeds	2.8 %	3.0 %		808	26,570	→
	50979	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds	1.00	1.05	808 3.04 %	772 2.90 %	26,570	→
Indicator group		General postoperative complications						
	469	General postoperative complications	3.0 %	3.3 %		864	26,156	→
	50984	Ratio of the observed to the expected rate (O / E) of general postoperative complications	1.00	1.05	864 3.30 %	825 3.15 %	26,156	→
Indicator group		Revision due to complications						
	470	Revision due to complications	6.3 %	7.0 %		1,851	26,570	↘
	50989	Ratio of the observed to the expected rate (O / E) of revisions due to complications	1.00	1.05	1,851 6.97 %	1,768 6.66 %	26,570	→
Indicator group		In-hospital mortality						
	471	In-hospital mortality	1.56 %	1.64 %		428	26,156	→
	50994	Ratio of the observed to the expected rate (O / E) of deaths	1.00	0.97	428 1.64 %	442 1.69 %	26,156	→

* for regression-based quality indicators

Hip replacement — Revision and component exchange

Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
268	Hip replacement revision and component replacement with fulfilled indication criteria	≥ 84.7 % (TO; 5th percentile)	1,024	112	2	B
270	Perioperative antibiotic prophylaxis	≥ 95.0 % (TA)	1,024	17	1	A
	Inability to walk at discharge					
10878	Inability to walk at discharge	n.d.*	1,021	–	X	X
50954	Ratio of the observed to the expected rate (O / E) of patients with inability to walk at discharge	≤ 3.72 (TO; 95th percentile)	1,021	80	2	A
	Vessel lesion/nerve damage					
2221	Vessel lesion/nerve damage	n.d.*	1,024	–	X	X
50959	Ratio of the observed to the expected rate (O / E) of vessel lesions/nerve damage	≤ 3.57 (TO)	1,024	82	2	A
	Implant malposition, implant dislocation or fracture					
463	Implant malposition, implant dislocation or fracture	n.d.*	1,024	–	X	X
50964	Ratio of the observed to the expected rate (O / E) of implant malpositions, implant dislocations or fractures	≤ 3.69 (TO)	1,024	66	2	A
	Dislocation of total joint replacement					
465	Dislocation of total joint replacement	n.d.*	1,024	–	X	X
50969	Ratio of the observed to the expected rate (O / E) of dislocations of total joint replacements	≤ 5.46 (TO)	1,024	49	2	A
51866	Postoperative wound infections without preoperative signs of infection	Sentinel event	864	111	X	A
	Wound hematomas/postoperative bleeds					
468	Wound hematomas/postoperative bleeds	n.d.*	1,024	–	X	X
50979	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds	≤ 4.47 (TO)	1,024	53	2	A
	General postoperative complications					
469	General postoperative complications	n.d.*	1,024	–	X	X
50984	Ratio of the observed to the expected rate (O / E) of general postoperative complications	≤ 3.47 (TO; 95th percentile)	1,024	68	2	A
	Revision due to complications					
470	Revision due to complications	n.d.*	1,024	–	X	X
50989	Ratio of the observed to the expected rate (O / E) of revisions due to complications	≤ 2.40 (TO)	1,024	120	2	A
	In-hospital mortality					
471	In-hospital mortality	Sentinel event	1,024	297	X	A
50994	Ratio of the observed to the expected rate (O / E) of deaths	n.d.*	1,024	–	X	X

TO = Tolerance range; TA = Target range; * not defined

Hip replacement — Revision and component exchange

QI-ID 268: Hip replacement revision and component replacement with fulfilled indication criteria

Quality target

An appropriate indication is rendered as often as possible based on clinical symptoms, radiographic criteria or based on signs of inflammation.

Background

The "survival" (implantation time) of a total hip replacement is usually 10 to 15 years. Revision of a total joint replacement is only indicated when the findings along with the clinical symptoms are confirmed by the appropriate diagnostics.

The most important indications for a hip replacement revision are aseptic or septic loosening of the joint, infection without loosening, periprosthetic fracture, implant fracture, recurrent dislocations, polyethylene insert wear or allergic reactions to the implant prosthesis materials and/or cement components. Suitable laboratory workup, clinical and/or radiographic diagnostics are performed to confirm the medical indication for hip replacement revision.

In order to verify that the indication has been appropriately rendered, the aforementioned reasons mandating a revision are collected via the calculation formula of the quality indicator. Since there are no evidence-based criteria to be applied as a standard for fulfilling the medical indication for hip replacement revision, the Federal Experts' Working Group has selected the 5th percentile as a reference range.

Evaluating the results

On a national average, the overall rate of the quality indicator generally shows a good level of care in the indication for "Hip replacement – Revision and component exchange". Nevertheless, the last 3 years have seen a significant decline in the overall rate – i.e., a trend that fewer hip replacement revisions and component replacements with fulfilled indication criteria are being performed (2011: 95.6 %; 2012: 94.3 %; 2013: 93.6 %).

In the Structured Dialogue on data collection year 2012, the State Administrative Offices for Quality Assurance (LQS) issued the final ranking in relation to the aggregate total of 127 computationally discrepant hospitals as follows: qualitatively discrepant (2), improper documentation (17), qualitatively non-discrepant (25), hospital notified of computationally discrepant result (82), other (1).

Both the State Administrative Offices as well as the Federal Experts' Working Group stress the great importance of determining the correct medical indication. In view of the growing number of very elderly and multimorbid individuals, the decision for surgical intervention must be reviewed more scrupulously and always weigh the risk of surgery against each patient's quality of life.

Description

Description	
Numerator	Surgeries in patients with: Prosthesis (sub)luxation or implant migration/failure/wear and isolated insert or head revision (OPS: 5-821.18, 5-821.2a, 5-821.2b) OR at least one pain criterion and at least one radiographic criterion OR at least one pain criterion and one positively identified pathogen OR laboratory evidence of inflammation and one positively identified pathogen
Denominator	All surgeries in patients ≥ 20 years.
Reference range	≥ 84.7 % (5th percentile, tolerance range)
Risk adjustment	No further risk adjustment
QI-ID	268
Comparability with the previous year's results	Limited comparability

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	92.6 %	95.8 %	95.6 %	94.3 %	93.6 %
Confidence interval	92.2–92.9 %	95.5–96.0 %	95.3–95.8 %	94.0–94.5 %	93.3–93.9 %
Total number of cases	23,145	24,948	25,374	26,127	26,570

Aggregate result of all patients
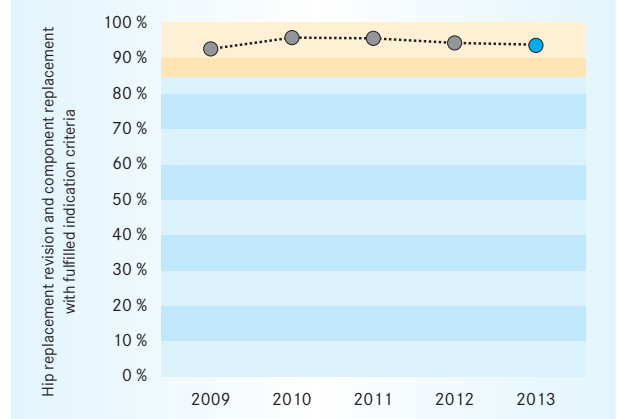
Hospital-based results

Target population of all hospitals	1,024
Number of hospitals with 0 cases	1

437 Hospitals with ≥ 20 cases
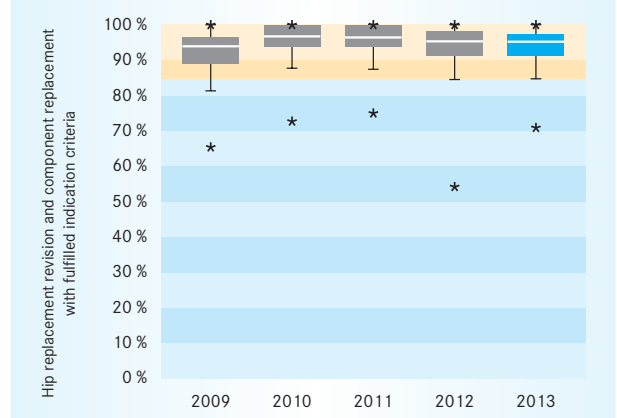
Median	95.2 %	Number of computationally discrepant hospitals	21 of 437
Range	70.9 – 100.0 %		

587 Hospitals with 1 to 19 cases

Median	100.0 %	Number of computationally discrepant hospitals	91 of 587
Range	0.0 – 100.0 %		

Total knee replacement — Primary implantation

Cristina Thole, Thorben Breitkreuz, Andrea Wolf, Federal Experts' Working Group for Orthopedics and Trauma Surgery

Introduction
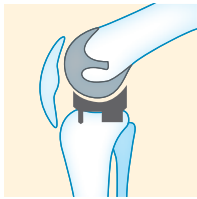
In Germany, the implantation of an artificial knee joint is one of the most commonly performed surgeries. Arthrosis of the knee joint (gonarthrosis) is predominantly caused by permanent and excessive loading (for example due to exercise), malposition, abnormal alignment or formation of the legs ("knock-knees", "bowlegs"), but also injuries, overweight and lack of physical activity. Moreover, gonarthrosis can also manifest with age, absent any of the aforementioned causalities. Going by the available data, more than half of all patients who receive primary implantation of a total knee replacement are 70 years and older.

As wear of the knee joint advances, pain and limitation of movement occur and progressively worsen. For instance, almost 74 % of patients report pain at rest at the preliminary consultation leading up to primary implantation of a total knee replacement. When the wear becomes so far advanced that neither medicines nor physiotherapy nor joint-preserving surgery alleviate the patients' pain and improve their mobility, an artificial joint (total knee replacement, total knee arthroplasty or TKA) may be indicated. The primary implantation of a total knee joint involves replacement of the damaged articular surfaces of the femur and tibia. This procedure can be performed with or without partial replacement of the kneecap.

Services subject to mandatory documentation

All primary implantations of a total knee joint in patients ≥ 20 years.

Changes in comparison to the previous year

Within the scope of system maintenance, the two quality indicators regarding the limited ability to walk at discharge (QI-ID 2288 and QI-ID 51004) were adjusted to the alignment of the calculation formula. Consistent with this, the name of the quality indicator group was changed: "Limited walking ability at discharge" was renamed "*In*ability to walk at discharge". Inability to walk means that the patient is not able to walk at least 50 meters (neither with an assisting person nor with crutches). Since data collection year 2013, all patients discharged alive have, furthermore, been included through the calculation formula of the quality indicator. As a result, the target population of the quality indicator grew by 665 patients in the current data collection year.

In analogy to the other clinical areas in orthopedics and trauma surgery, the documentation forms were restructured. Since data collection year 2013, it has been possible to create what is called a partial record for a hospital case. This means that administrative data for several revision procedures on one patient do not have to be created multiple times. This restructuring makes it is necessary to adapt the calculation formula for all quality indicators. Hence, no longer the affected patients, but the primary implantations documented by the hospital are counted starting in data collection year 2013.

Results

In data collection year 2013, nearly 130,000 individuals were implanted with a total knee replacement for the first time; meaning that the number has declined compared to the previous years. The reason for this is not necessarily a lower number of interventions being performed, but rather might be a change in inclusion criteria (change in ICD codes). Notwithstanding this code change, the Federal Statistical Office, which collects data on all primary implantations of total knee replacements without exception, also registered a decline between 2011 and 2012.

The aggregate results in this clinical area show a good and stable quality of care as all quality indicators are within the specified reference ranges.

If one compares this development with the previous year, 2 quality indicators show a statistically significant positive trend. The indicator "Knee replacement primary implantation with fulfilled indication criteria" (QI-ID 276) confirms that the indication for primary implantation of an artificial knee joint had been rendered correctly in the majority of the cases. This means that the mainly positive trend for this indicator registered since 2008 (92.7 % back then) has continued in 2013 as well. The positive trend seen in the indicator "Postoperative range of motion at least 0/0/90 according to the neutral-zero method" (QI-ID 10953) is gratifying.

By contrast, the 3 quality indicators – QI-ID 2218, QI-ID 51004, QI-ID 51014 – show a significantly negative trend compared to the previous year. Despite a negative trend, the quality target for the indicator "Measuring the postoperative range of motion using the neutral-zero method" (QI-ID 2218) was achieved. Therefore, the Federal Experts' Working Group sees no extended or special need for action. Contrarily, the Federal Experts' Working Group sees an extended need for action (category B) given the increasing number of patients who are unable to walk after a total knee replacement (QI-ID 51004). In comparison, the Federal Experts' Working Group has not reached any conclusions in the case of the risk-adjusted indicator "Ratio of the observed to the expected rate (O / E) of fractures" (QI-ID 51014) regarding a need for action (Category X). This is because the filter necessitated a change in the target population in data collection year 2012, thereby rendering a valid comparison with the previous year impossible.

Looking forward

The Federal Experts' Working Group welcomes the merging of the clinical areas *Total knee replacement – Primary implantation* and *Knee replacement – Revision and component exchange* into the planned clinical area *Knee replacement care* starting with data collection year 2015. This merger will also yield a bundled presentation and calculation of the quality indicators. For example, the postoperative complications of the two clinical areas previously considered separately will be merged into one quality index. The clinical area-specific quality indicators, as for example, the indication for implantation of a knee joint, remain.

Total knee replacement — Primary implantation

In the process of merging these clinical areas, pseudonymized patient-identifying data (PID) will be transmitted for the first time as part of routine operation in 2015. Based on the PID, patients can be tracked within the scope of quality assurance with a view to a potential revision surgery, even across hospitals. The resulting follow-up indicator for revision of an artificial knee joint should be analyzed starting in 2016.

What will provide even more conclusive data on post-discharge observation is the announced analysis of health insurance claims data because these data could also be used to measure complications that do not emerge until after the acute inpatient clinical treatment. The Federal Experts' Working Group and the AQUA Institute regret that the prerequisites for utilizing the health insurance claims data for external quality assurance in the orthopedics and trauma surgery have currently not been created yet. The same applies to the development of a patient survey: The Federal Experts' Working Group once more points to the special meaning of this perspective for quality assurance in the clinical areas for orthopedics and trauma surgery.

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Further information on the clinical area
For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German): *www.sqg.de/themen/17n5/*

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	133,948	127,192	127,077	100.1 %
Hospitals	1,033	1,031	1,027	100.4 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Number of patients	126,898	100 %
< 50 years	3,510	2.8 %
50 – 59 years	17,738	14.0 %
60 – 69 years	35,405	27.9 %
70 – 79 years	54,865	43.2 %
80 – 89 years	15,053	11.9 %
≥ 90 years	327	0.3 %
Sex		
Male	44,955	35.4 %
Female	81,943	64.6 %
General postoperative complications requiring treatment		
At least one complication	3,920	3.1 %
Pneumonia (lung infection)	203	0.2 %
Cardiovascular complications (relating to the heart and vascular system)	802	0.6 %
Deep vein thrombosis of leg/pelvis	533	0.4 %
Lung embolism	191	0.2 %
Other general postoperative complications	2,442	1.9 %
ASA classification*		
ASA 1: A normal healthy patient	6,993	5.5 %
ASA 2: A patient with mild systemic disease	76,587	60.3 %
ASA 3: A patient with severe systemic disease	42,918	33.8 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	543	0.4 %
ASA 5: A moribund patient who is not expected to survive without the operation	10	< 0.1 %

* As the numbers mentioned here refer to the number of surgeries (several surgery forms can be filled out for one patient), the aggregate sum of patients in the ASA classification deviates from the figure stated in the age distribution.

Total knee replacement — Primary implantation

Case-based aggregate results (patients)

| | | | 2012 | 2013 | | | |
| | | | | Cases (patients) | | | |
QI-ID	Name of the quality indicator		Result	Result	Numerator (O | E)*	Denominator	Trend
276	Knee replacement – primary implantation with fulfilled indication criteria	⚠	96.1 %	96.6 %	122,723	127,051	↗
277	Perioperative antibiotic prophylaxis	⚠	99.6 %	99.7 %	126,680	127,051	→
	Postoperative range of motion						
2218	Measuring the postoperative range of motion using the neutral-zero method	⚠	98.3 %	97.5 %	123,880	127,051	↘
10953	Postoperative range of motion at least 0/0/90 according to the neutral-zero method	⚠	90.4 %	91.4 %	113,232	123,880	↗
	Inability to walk at discharge						
2288	Inability to walk at discharge		0.2 %	0.3 %	318	126,773	→
51004	Ratio of the observed to the expected rate (O / E) of patients with inability to walk at discharge		1.00	1.28	318 0.25 % | 248 0.20 %	126,773	↘
	Vessel lesion/nerve damage						
2219	Vessel lesion/nerve damage		0.1 %	0.2 %	218	127,051	→
51009	Ratio of the observed to the expected rate (O / E) of vessel lesions/nerve damage		1.00	1.17	218 0.17 % | 186 0.15 %	127,051	→
	Fracture						
285	Fracture		0.1 %	0.2 %	194	127,051	→
51014	Ratio of the observed to the expected rate (O / E) of fractures		1.00	1.67	194 0.15 % | 116 0.09 %	127,051	↘
	Postoperative wound infection						
286	Postoperative wound infection	⚠	n.c.**	0.3 %	398	127,051	n.a.***
51019	Ratio of the observed to the expected rate (O / E) of postoperative wound infections	⚠	n.c.**	0.97	398 0.31 % | 410 0.32 %	127,051	n.a.***
	Wound hematomas/postoperative bleeds						
288	Wound hematomas/postoperative bleeds		n.c.**	0.9 %	1,117	127,051	n.a.***
51024	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds		n.c.**	0.91	1,117 0.88 % | 1,222 0.96 %	127,051	n.a.***
	General postoperative complications						
289	General postoperative complications		1.3 %	1.3 %	1,615	126,898	→
51029	Ratio of the observed to the expected rate (O / E) of general postoperative complications		1.00	0.97	1,615 1.27 % | 1,660 1.31 %	126,898	→
	Revision due to complications						
290	Revision due to complications	⚠	n.c.**	1.3 %	1,591	127,051	n.a.***
51034	Ratio of the observed to the expected rate (O / E) of revisions due to complications	⚠	n.c.**	1.00	1,591 1.25 % | 1,584 1.25 %	127,051	n.a.***
	In-hospital mortality						
472	In-hospital mortality	⚠	0.08 %	0.10 %	125	126,898	→
51039	Ratio of the observed to the expected rate (O / E) of deaths	⚠	1.00	1.22	125 0.10 % | 103 0.08 %	126,898	→

*   for regression-based quality indicators; ** not calculated; *** not applicable

Total knee replacement — Primary implantation

Hospital-based aggregate results for utilization in quality assurance

	QI-ID	Name of the quality indicator	Reference range	2013 Hospitals Total	2013 Hospitals Discrepant (computationally)	2013 Evaluation Category	2013 Evaluation Need for action
	276	Knee replacement – primary implantation with fulfilled indication criteria	≥ 90.0 % (TA)	1,030	107	2	A
	277	Perioperative antibiotic prophylaxis	≥ 95.0 % (TA)	1,030	8	1	A
Indicator group		Postoperative range of motion					
	2218	Measuring the postoperative range of motion using the neutral-zero method	≥ 90.0 % (TA)	1,030	53	1	A
	10953	Postoperative range of motion at least 0/0/90 according to the neutral-zero method	≥ 80.0 % (TA)	1,030	110	1	A
Indicator group		Inability to walk at discharge					
	2288	Inability to walk at discharge	n.d.*	1,030	–	X	X
	51004	Ratio of the observed to the expected rate (O / E) of patients with inability to walk at discharge	≤ 8.28 (TO; 95th percentile)	1,030	49	2	B
Indicator group		Vessel lesion/nerve damage					
	2219	Vessel lesion/nerve damage	n.d.*	1,030	–	X	X
	51009	Ratio of the observed to the expected rate (O / E) of vessel lesions/nerve damage	≤ 13.66 (TO)	1,030	17	2	B
Indicator group		Fracture					
	285	Fracture	n.d.*	1,030	–	X	X
	51014	Ratio of the observed to the expected rate (O / E) of fractures	≤ 21.91 (TO)	1,030	9	2	X
Indicator group		Postoperative wound infection					
	286	Postoperative wound infection	n.d.*	1,030	–	X	X
	51019	Ratio of the observed to the expected rate (O / E) of postoperative wound infections	≤ 6.20 (TO)	1,030	62	2	A
Indicator group		Wound hematomas/postoperative bleeds					
	288	Wound hematomas/postoperative bleeds	n.d.*	1,030	–	X	X
	51024	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds	≤ 8.32 (TO)	1,030	17	2	A
Indicator group		General postoperative complications					
	289	General postoperative complications	n.d.*	1,030	–	X	X
	51029	Ratio of the observed to the expected rate (O / E) of general postoperative complications	≤ 3.36 (TO; 95th percentile)	1,030	60	2	A
Indicator group		Revision due to complications					
	290	Revision due to complications	n.d.*	1,030	–	X	X
	51034	Ratio of the observed to the expected rate (O / E) of revisions due to complications	≤ 4.81 (TO)	1,030	53	2	A
Indicator group		In-hospital mortality					
	472	In-hospital mortality	Sentinel event	1,030	108	X	A
	51039	Ratio of the observed to the expected rate (O / E) of deaths	n.d.*	1,030	–	X	X

TO = Tolerance range; TA = Target range; * not defined

Total knee replacement — Primary implantation

QI-ID 10953: Postoperative range of motion at least 0/0/90 according to the neutral-zero method

Description

Numerator	Surgeries after which the patient's knee achieved a postoperative range of motion of at least 0/0/90 (at least 0 degrees extension and at least 90 degrees flexion)
Denominator	All surgeries, after which the knee's range of motion in the patient (> 20 years) was measured using the neutral-zero method
Reference range	≥ 80.0 % (target range)
Risk adjustment	No further risk adjustment
QI-ID	10953
Comparability with the previous year's results	Limited comparability

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	86.1 %	88.1 %	89.2 %	90.4 %	91.4 %
Confidence interval	85.9–86.2 %	87.9–88.3 %	89.0–89.4 %	90.2–90.6 %	91.2–91.6 %
Total number of cases	141,890	142,521	142,135	131,460	123,880

Aggregate result of all patients
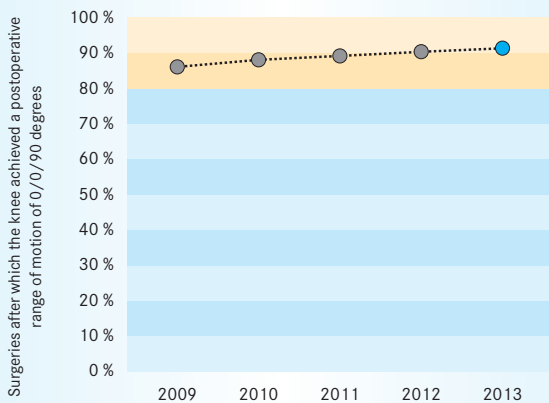
Hospital-based results

Target population of all hospitals	1,030
Number of hospitals with 0 cases	1

939 Hospitals with ≥ 20 cases
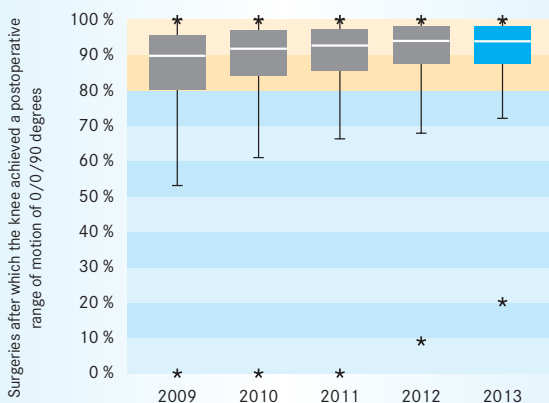
Median	93.9 %	Number of computationally discrepant hospitals	95 of 939
Range	20.2 – 100.0 %		

91 Hospitals with 1 to 19 cases

Median	100.0 %	Number of computationally discrepant hospitals	15 of 91
Range	30.0 – 100.0 %		

Quality target

As often as possible postoperative range of motion of at least 0/0/90 degrees using the neutral-zero method.

Background

A sufficient range of motion in the knee joint is essential for a normal gait and a precondition for further strength-building and preservative exercises during rehabilitation therapy. During the swing phase of a normal gait, the knee joint needs to flex by approx. 67 degrees. The knee joint requires approx. 93 degrees of flexion to get the body up from a chair without assistance. This explains the target postoperative knee joint flexion of > 90 degrees. Hence, the Federal Experts' Working Group requires that each knee joint show a full range of active extension and an active flexion of at least 90 degrees at discharge from the hospital performing the surgery.

The present quality indicator measures the proportion of patients in whom the primary implantation of a total knee replacement was performed and whose knee joints could be actively flexed by at least 90 degrees and fully extended after surgery. The postoperative range of motion of the knee joint is measured by a goniometer, usually using the neutral-zero method.

Evaluating the results

The proportion of patients whose knee joints achieve a postoperative range of motion of at least 0/0/90 degrees at discharge at the latest has risen continually since data collection year 2009. On a federal average, the rate was 91.4 % in data collection year 2013 and thereby clearly within the reference range. Despite these good federal results, 110 of 1,030 hospitals lay outside of the reference range in data collection year 2013. The Structured Dialogue on data collection year 2012 showed that a portion of the computationally discrepant results were attributable to insufficient documentation quality. Of the 129 computational discrepancies back then, 15 (12 %) were classified as "qualitatively discrepant" after conclusion of the Structured Dialogue; 33 were based on improper documentation.

Assessment of quality of care based of the range of motion of 0/0/90 degrees was questioned by several representatives of the State Administrative Offices for Quality Assurance (LQS). Sometimes, functional parameters like independent attention to one's daily personal hygiene are required, for instance. Alternatively, there are proposals to lower the target for the range of motion to, say, 0/10/80 degrees as the postoperative full extension and flexion of 90 degrees cannot always be ensured given today's average duration of stay. The Federal Experts' Working Group cannot follow these arguments: on the one hand because other functional parameters are being measured already, while on the other, sufficient flexion in the knee joint is a precondition to qualify for rehabilitation therapy. Beyond this, the Federal Experts' Working Group points out that some patients are discharged too early, i.e., even before the upper threshold of DRG length of stay elapses. Keeping an eye on the patients' well-being, a too-early discharge is not appropriate unless a sufficient range of motion of the knee is present at this time point. In conclusion, the Federal Experts' Working Group recommends that the range of motion of 0/0/90 degrees continue to be assessed using the neutral-zero method and is pleased about the fundamentally positive overall development of this quality indicator.

Knee replacement — Revision and component exchange

Cristina Thole, Thorben Breitkreuz, Andrea Wolf, Federal Experts' Working Group for Orthopedics and Trauma Surgery

Introduction
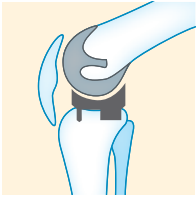
The time between primary and revision surgery of knee replacement (endoprosthesis) is called the implantation time. The majority of primary knee replacements have an implantation time over 10 years before the artificial joint has to be partially or completely replaced. The reasons for (early) revision include: Implant loosening, instability of the artificial joint, extensive bacterial infection and advanced wear of parts of the joint that have not been previously replaced. A strong functional impairment of the artificial joint that is often accompanied by pronounced pain may also require a revision.

Compared to primary implantation, the complete replacement of the prosthesis (revision of total joint replacement) or changing parts of the joint (component exchange) is a technically more sophisticated and considerably more complex procedure. Moreover, revision surgery is associated with a higher risk of bleedings and infections. That is why the outcome achieved is frequently not as satisfactory as that of a primary implantation.

When planning the revision surgery, more attention should be paid to the selection of the implant and the surgical technique as well as the management of any special surgical problems such as compensating for the lost bone mass.

Services subject to mandatory documentation

All knee replacement revisions and component exchanges in patients ≥ 20 years.

Changes in comparison to the previous year

In total, changes were made in three quality indicators. In collaboration with Federal Experts' Working Group, the calculation formula for the indicator "Knee replacement primary implantation with fulfilled indication criteria" (QI-ID 295) was adapted. This was done because the Federal Experts' Working Group deemed the combination of pain and laboratory evidence of inflammation insufficient for determining the proper indication. Starting in the data collection year 2013, this indication was defined more precisely and replaced with "one pain criterion and positively identified pathogen". Moreover, since the data collection year 2013, the presence of inflammation in combination with a positively identified pathogen as indication for revision surgery on the knee joint have been accounted for in the calculation formula.

To identify nosocomial wound infections, the quality indicator "Postoperative wound infections without preoperative signs of infection" (QI-ID 51874) was introduced. It measures the proportion of patients who demonstrated no signs of infection before their revision surgery, but suffered a wound infection as a consequence of the intervention. Since this quality indicator solely measures infections caused by the revision surgery, the Federal Experts' Working Group resolved to categorize it as a sentinel event indicator.

As part of system maintenance, the titles of the two quality indicators on the limited walking ability at discharge (QI-ID 2291 and QI-ID 51044) were adjusted to the content-related alignment of the calculation formula. Consistent with this, the indicator group "Limited walking ability at discharge" was renamed "*In*ability to walk at discharge". Inability to walk means that the patient is not able to walk more than 50 meters (neither with aid nor with crutches). Previously, patients who, for example, were discharged to a nursing home, were not considered in the quality indicator. Since the data collection year 2013, all patients discharged alive were included in the calculation. As a result, the target population of the quality indicator grew by 225 patients in the report year.

Similar to the other clinical areas in orthopedics and trauma surgery, the documentation forms were restructured. Since the data collection year 2013, it is now possible to create a partial record for a hospital case. This means that administrative data for several revision procedures on one patient do not have to be created multiple times. This restructuring makes it is necessary to modify the calculation formula for all quality indicators. Therefore, starting with the data collection year 2013, the affected patients are no longer counted, rather the number of the revision procedures documented by the hospital.

Results

In the data collection year 2013, 17,428 records were delivered, which is nearly equivalent to the number of the previous year. The aggregate results of the quality indicators show that the quality of care is good and has remained stable. As in the previous year, all indicators lie within the pre-defined reference ranges. Based on the high level of care on the federal level, the Federal Experts' Working Group does not see an extended or special need for action in any of the quality indicators; therefore, all are classified as category A.

The analysis of the data collection year 2013 showed that 72 patients died (2012: 62 patients) in relation to a revision surgery (QI-ID 476) during their hospital stay. Thereby, the proportion of deceased is 0.42 %, which corresponds to an increase of 0.06 percentage points compared to the previous year's value, yet the difference is not statistically significant. Based on the risk profile, the corresponding risk-adjusted quality indicator (QI-ID 51069) on in-hospital mortality reveals that 3 % more patients died than would have been expected.

The Structured Dialogue revealed 6 of 56 computationally discrepant hospitals in the data collection year 2012 that only received notices regarding the indicator "In-hospital mortality" (QI-ID 476), instead of being requested to submit a written statement due to its classification as a sentinel event. The Federal Experts' Working Group stated that this procedure was not justified as it disagrees with the requirements of the directive on external hospital quality assurance.

Looking forward

The Federal Experts' Working Group is pleased about the overall good quality of care in the clinical area *Knee replacement – Revision and component exchange*. Given the exceptionally low rate in the quality indicator "Vessel lesion or nerve damage" (QI-ID 2220), this quality indicator is under consideration to be

Knee replacement — Revision and component exchange

classified as a sentinel event next year.

The Federal Experts' Working Group recommends merging the clinical areas *Total knee replacement – Primary implantation* and *Knee replacement – Revision and component exchange* into the planned clinical area *Knee replacement care* starting with the data collection year 2015. This will lead to a focused presentation and calculation of the quality indicators. For example, the postoperative complications of the two previously separate clinical areas will be merged into one quality index. Moreover, it is planned to re-include surgeries for implanting sled prostheses which had formerly been subject to mandatory documentation. The clinical area-specific quality indicators, for example, the indicator "Knee replacement primary implantation with fulfilled indication criteria" (QI-ID 295), remain.

For routine operation in 2015, patient-identifying data will be transmitted for the first time in pseudonymized form as part of implementing this merger of the clinical areas. Based on these data, the associated patients can be followed up on, also cross-disciplinarily, within the scope of quality assurance with a view to potential revision surgery. The corresponding follow-up indicator for revision of an artificial knee joint will be analyzed starting with reporting year 2016.

What would provide even more conclusive data on post-discharge observation will be the announced analysis of health insurance claims data as these data could also be used to measure complications that do not emerge until after the acute inpatient clinical treatment. The Federal Experts' Working Group and the AQUA Institute regret that the prerequisites for utilizing the health insurance claims data for external quality assurance in the orthopedics and trauma surgery have currently not been created yet. The same applies to the development of a patient survey: The Federal Experts' Working Group once more points to the significant importance of this perspective for quality assurance in the orthopedic and accident surgery clinical areas.

Data basis

| | 2012 | 2013 | | |
	Reported	Reported	Expected	Case completeness
Records	17,281	17,428	17,376	100.3 %
Hospitals	968	972	969	100.3 %

Basic statistics

| | 2013 | |
	Number	Proportion
Age distribution		
Number of patients	17,224	100 %
< 50 years	741	4.3 %
50 - 59 years	2,683	15.6 %
60 - 69 years	4,506	26.2 %
70 - 79 years	6,852	39.8 %
80 - 89 years	2,338	13.6 %
≥ 90 years	104	0.6 %
Sex		
Male	6,486	37.7 %
Female	10,738	62.3 %
ASA classification*		
ASA 1: A normal healthy patient	699	4.0 %
ASA 2: A patient with mild systemic disease	9,170	52.9 %
ASA 3: A patient with severe systemic disease	7,240	41.8 %
ASA 4: A patient with severe systemic disease that is a constant threat to life	201	1.2 %
ASA 5: A moribund patient who is not expected to survive without the operation	10	0.1 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/17n7/

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* As the numbers mentioned here refer to the number of surgeries (several surgery forms can be filled out for one patient), the aggregate sum of patients in the ASA classification deviates from the figure stated in the age distribution.

Knee replacement — Revision and component exchange

Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator		2012 Result	2013 Result	2013 Cases (patients) Numerator (O | E)*		Denominator	Trend
	295	Knee replacement primary implantation with fulfilled indication criteria	⚠	93.2 %	92.9 %		16,096	17,320	→
	292	Perioperative antibiotic prophylaxis	⚠	99.6 %	99.8 %		17,281	17,320	→
Indicator group		*Inability to walk at discharge*							
	2291	Inability to walk at discharge		0.5 %	0.6 %		104	17,152	→
	51044	Ratio of the observed to the expected rate (O / E) of patients with inability to walk at discharge		1.00	1.08	104 0.61 %	96 0.56 %	17,152	→
	2220	Vessel lesion or nerve damage		0.2 %	0.2 %		43	17,320	→
Indicator group		*Fracture*							
	300	Fracture		0.4 %	0.5 %		80	17,320	→
	51049	Ratio of the observed to the expected rate (O / E) of fractures		1.00	1.07	80 0.46 %	74 0.43 %	17,320	→
	51874	Postoperative wound infections without preoperative signs of infection		0.64 %	0.47 %		40	8,477	→
Indicator group		*Wound hematomas/postoperative bleeds*							
	473	Wound hematomas/postoperative bleeds		2.3 %	2.2 %		374	17,320	→
	51054	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds		1.00	0.91	374 2.16 %	409 2.36 %	17,320	→
Indicator group		*General postoperative complications*							
	474	General postoperative complications		1.8 %	1.8 %		303	17,224	→
	51059	Ratio of the observed to the expected rate (O / E) of general postoperative complications		1.00	0.98	303 1.76 %	311 1.80 %	17,224	→
Indicator group		*Revision due to complications*							
	475	Revision due to complications	⚠	3.6 %	3.6 %		625	17,320	→
	51064	Ratio of the observed to the expected rate (O / E) of revisions due to complications	⚠	1.00	0.96	625 3.61 %	651 3.76 %	17,320	→
Indicator group		*In-hospital mortality*							
	476	In-hospital mortality	⚠	0.36 %	0.42 %		72	17,224	→
	51069	Ratio of the observed to expected rate (O / E) of deaths	⚠	1.00	1.03	72 0.42 %	70 0.41 %	17,224	→

* for regression-based quality indicators

Knee replacement — Revision and component exchange

Hospital-based aggregate results for utilization in quality assurance

| | | | 2013 | | | |
| | | | **Hospitals** | | **Evaluation** | |
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
295	Knee replacement primary implantation with fulfilled indication criteria	≥ 77.6 % (TO; 5th percentile)	970	76	2	A
292	Perioperative antibiotic prophylaxis	≥ 95.0 % (TA)	970	12	1	A
	Inability to walk at discharge					
2291	Inability to walk at discharge	n.d.*	970	–	X	X
51044	Ratio of the observed to the expected rate (O / E) of patients with inability to walk at discharge	≤ 6.86 (TO; 95th percentile)	970	56	2	A
2220	Vessel lesion or nerve damage	≤ 2.0 % (TO)	970	30	1	A
	Fracture					
300	Fracture	n.d.*	970	–	X	X
51049	Ratio of the observed to the expected rate (O / E) of fractures	≤ 9.36 (TO)	970	39	2	A
51874	Postoperative wound infections without preoperative signs of infection	Sentinel event	828	36	X	A
	Wound hematomas/postoperative bleeds					
473	Wound hematomas/postoperative bleeds	n.d.*	970	–	X	X
51054	Ratio of the observed to the expected rate (O / E) of wound hematomas/postoperative bleeds	≤ 6.35 (TO)	970	39	2	A
	General postoperative complications					
474	General postoperative complications	n.d.*	970	–	X	X
51059	Ratio of the observed to the expected rate (O / E) of general postoperative complications	≤ 4.61 (TO; 95th percentile)	970	58	2	A
	Revision due to complications					
475	Revision due to complications	n.d.*	970	–	X	X
51064	Ratio of the observed to the expected rate (O / E) of revisions due to complications	≤ 3.19 (TO)	970	94	2	A
	In-hospital mortality					
476	In-hospital mortality	Sentinel event	970	66	X	A
51069	Ratio of the observed to expected rate (O / E) of deaths	n.d.*	970	–	X	X

TO = Tolerance range; TA = Target range; *not defined

Nursing: Prevention of pressure ulcers

Karen Pottkämper, Svetlana Rasch, Kathrin Rickert, Federal Experts' Working Group for Nursing: Prevention of pressure ulcers

Introduction
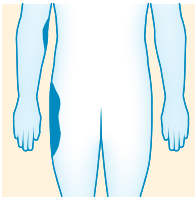
A pressure ulcer is a skin wound that develops on the skin and/or in the underlying tissues and is caused by prolonged pressure. This type of tissue damage is also called pressure sores, decubitus ulcers or bedsores. These complications occur in patients receiving nursing care and need to be taken very seriously. Pressure ulcers can accompany severe diseases and can be a result of longer periods of impairment to mobility or consciousness. Accordingly, the elderly are affected by pressure ulcers with a particularly high frequency. A pressure ulcer is very painful for the affected patient, is associated with a very high degree of suffering, restricts quality of life and usually requires months of care.

Alongside complicated wound treatment, extreme cases may also require plastic surgery to reconstruct the area where the skin lesion or soft tissue defect developed. From an ethical, medical, nursing and economic perspective, the targeted prevention of pressure ulcers (decubitus prophylaxis) should be an issue of major concern.

By measuring how frequently pressure ulcers develop during a hospital stay (incidence of pressure ulcers), we can gather evidence as well as arrive at conclusions about the implemented preventative measures and the timely initiation of treatment modalities. Internationally, the incidence of pressure ulcers counts as a result-orientated quality indicator of patient safety in hospitals.

The degree of severity of a pressure ulcer is categorized on a scale of 1 to 4. This classification scheme is based on the International Statistical Classification of Diseases and Related Health Problems – German Modification.

Classification scheme for decubitus ulcer and pressure area by L89 (ICD-10-GM 2014)	
Stage 1 Pressure ulcer	Decubitus [pressure] ulcer limited to erythema only
Stage 2 Pressure ulcer	Decubitus [pressure] ulcer with abrasion or blister, partial-thickness skin loss involving epidermis and/or dermis or skin loss, no other specification
Stage 3 Pressure ulcer	Decubitus [pressure] ulcer with full thickness skin loss involving damage or necrosis of subcutaneous tissue extending to underlying fascia
Stage 4 Pressure ulcer	Decubitus [pressure] ulcer with necrosis of muscle, bone or supporting structures (i.e., tendon or joint capsule)
Pressure ulcer and pressure area, unspecified	Decubitus [pressure] ulcer without mention of stage

In clinical practice, there is often uncertainty when delineating a stage 1 pressure ulcer from simple skin redness (erythema). Therefore, only data on higher stage (from stage 2 pressure ulcers) are collected and analyzed in the clinical area *Nursing: Prevention of pressure ulcers*.

Services subject to mandatory documentation

New since data collection year 2013: All inpatient patients aged 20 years and older who develop a stage 2 pressure ulcer or higher during a hospital stay. To be able to guarantee proper risk adjustment, all hospitals that have treated inpatient cases (patients) ≥ 20 years are required to transmit the risk statistic.

Changes in comparison to the previous year

It is not possible to compare the results with those of the previous year for the quality indicators in the clinical area *Nursing: Prevention of pressure ulcers* because data collection using the available claims data of the healthcare providers did not take place until 2013. The data fields "Was a pressure ulcer present on admission?" and "Was the pressure ulcer present on discharge?" were the only fields that could not be automatically extracted from the claims data and, therefore, must continue to be documented by the healthcare providers.

Moreover, starting in data collection year 2013, a more comprehensive target population will be considered. Whereas last year, first-quarter data from patients aged 75 years and older, including stage 1 pressure ulcers, were only available for quality assurance, now data collection encompasses all patients ≥ 20 years and covers the entire year. Nevertheless, the collection of more cases is associated with lower cost for healthcare providers because patients without pressure ulcers no longer have to be documented. Only those with stage 2, 3 and 4 pressure ulcers and "stage not specified" have to be documented, while most data are extracted from the claims data. However, aggregated basic information in the form of risk statistics for the entire target population of the clinical area is required in addition to this.

In the first year of new data collection with routine data, evaluation of the results is only possible to a limited extent because no comparative data are available yet. International results on routine pressure ulcer data collected in the USA and Canada ("Patient Safety Indicators #3 – Pressure Ulcer" reported by the *Agency for Healthcare Research and Quality* (AHRQ)) are based on such different invoicing principles (ICD-9-CM) and inclusion/exclusion rules that they cannot be used for comparison purposes. The literature does not contain any comparative data for collecting pressure ulcer rates from routine data either.

Results

Neither a direct comparison with the previous year's results nor a final interpretation is possible due to the extensive changes (target population, use of claims data, risk adjustment based on the risk statistic of the hospitals). On January 20, 2015, the available results and evidence from the Structured Dialogue were deliberated comprehensively at the conference on the prevention of pressure ulcers in Berlin, which brings the federal and state levels together.

In data collection year 2013, pressure ulcers contracted in hospital were documented in less than 1 % of the hospital cases considered. Due to the high number (2,442 cases) of stage 4 pressure ulcers acquired in hospital, the results of this quality indicator (QI-ID 52010) will be addressed in more detail in a later section.

Nursing: Prevention of pressure ulcers

Data collection year 2012 had a total of 259 computational discrepancies, of which 44 (17.0 %) were evaluated as "qualitatively discrepant" after conclusion of the Structured Dialogue: In 36 cases, there was evidence of structural and process deficiencies which, for example, manifested as unknown and/or not implicit responsibilities for the nursing, wrong risk assessment or too late or inconsistent positioning. Six hospitals gave no (sufficiently explanatory) reason for their computational discrepancies, and 2 cases were classified as "qualitatively discrepant for other reasons".

Special emphasis should be given to the numerous initiatives and measures performed at the state level within the scope of the Structured Dialogue. For example, state experts' working groups have developed structured surveys on the implementation of expert standards and of all prophylactic measures in order to achieve more targeted quality improvement measures. Furthermore, the Bremen Experts' Working Group has made substantial efforts to improve documentation quality in the past years. The federal states of Baden-Württemberg, Hamburg and Hessen collect additional indicators on the state level or do analyses based on the entire year and give feedback to the hospitals on the departmental level as well. Nearly half of the federal states include stage 3 pressure ulcers in addition to the sentinel event indicator "Emergent stage 4 pressure ulcers in patients without pressure ulcers at admission" (QI-ID 2118). The Federal Experts' Working Group expressly welcomes this initiative.

Looking forward

Since the mapping of nursing quality in hospitals cannot be subsumed under the development of pressure ulcers alone, the Federal Experts' Working Group believes that it is urgently necessary to develop a set of quality indicators that can more comprehensively map the quality of nursing care in hospitals. This deserves emphasis, especially in these times of staff cutbacks particularly affecting the nursing sector and in the face of the current political discussion about transparency and quality at hospitals. The Federal Experts' Working Group feels strongly about changing the fact that only one of the 30 clinical areas deals with in-hospital nursing quality. They have already drafted concrete proposals (fall prevention, nursing-based pain management and discharge management).

Moreover, the Federal Experts' Working Group would like to stress the need to also examine pressure ulcer prevention across hospitals' inpatient departments and recommends including domestic nursing care and geriatric nursing in quality assurance.

Nursing: Prevention of pressure ulcers

Data basis

	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	1,227,501	262,305	264,831	99.0 %
Hospitals	1,658	1,511	1,534	98.5 %

Basic statistics

	2013	
	Number	Proportion
Age distribution		
Age distribution in patients with pressure ulcer		
Number of patients	261,765	100 %
20 – 29 years	1,184	0.5 %
30 – 39 years	1,888	0.7 %
40 – 49 years	6,150	2.3 %
50 – 59 years	16,991	6.5 %
60 – 69 years	32,685	12.5 %
70 – 79 years	79,837	30.5 %
80 – 89 years	92,064	35.2 %
≥ 90 years	30,966	11.8 %
Age distribution in patients with at least one emergent pressure ulcer		
Number of patients	73,754	100 %
20 – 29 years	421	0.6 %
30 – 39 years	624	0.8 %
40 – 49 years	1,861	2.5 %
50 – 59 years	5,339	7.2 %
60 – 69 years	10,334	14.0 %
70 – 79 years	23,563	31.9 %
80 – 89 years	24,297	32.9 %
≥ 90 years	7,315	9.9 %
Sex		
All patients ≥ 20 years with pressure ulcer		
Male	124,941	47.7 %
Female	136,818	52.3 %
Unknown	6	< 0.1 %
All patients ≥ 20 years with at least one emergent pressure ulcer		
Male	36,638	49.7 %
Female	37,114	50.3 %
Unknown	[ ]*	[ ]*

* Result not shown on data protection grounds

Basic statistics

	2013	
	Number	Proportion
Pressure ulcer status on admission		
No pressure ulcer on admission		
Aggregate	78,428	100 %
Stage 2	62,481	79.7 %
Stage 3	10,970	14.0 %
Stage 4	2,370	3.0 %
Pressure ulcer, stage not specified	2,607	3.3 %
Pressure ulcer present on admission		
Aggregate	236,669	100 %
Stage 2	139,856	59.1 %
Stage 3	57,853	24.4 %
Stage 4	30,869	13.0 %
Pressure ulcer, stage not specified	8,091	3.4 %
Unknown pressure ulcer status on admission		
Aggregate	5,476	100 %
Stage 2	3,896	71.1 %
Stage 3	910	16.6 %
Stage 4	341	6.2 %
Pressure ulcer, stage not specified	329	6.0 %

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Further information on the clinical area

For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German):
www.sqg.de/themen/DEK/

Nursing: Prevention of pressure ulcers

Case-based aggregate results (patients)

| | | 2012 | 2013 | | | |
| | | | | Cases (patients) | | |
QI-ID	Name of the quality indicator	Result	Result	Numerator (O | E)*	Denominator	Trend
	All pressure ulcers acquired in-hospital in patients ≥ 33 years (highest stage per patient)					
52008	All pressure ulcers acquired in-hospital (excluding stage 1 pressure ulcers)	n.c.**	0.5 %		71,898	14,532,477	n.a.***
52009	Ratio of the observed to expected rate (O / E) of pressure ulcers acquired in-hospital (excluding stage 1 pressure ulcers)	n.c.**	1.00	71,898 0.49 %	71,646 0.49 %	14,532,477	n.a.***
52010	All stage 4 pressure ulcers acquired in-hospital (in patients ≥ 20 years)	n.c.**	0.01 %		2,442	16,506,988	n.a.***

* for regression-based quality indicators; ** not calculated; *** not applicable

Hospital-based aggregate results for utilization in quality assurance

| | | | 2013 | | | |
| | | | Hospitals | | Evaluation | |
QI-ID	Name of the quality indicator	Reference range	Total*	Discrepant (computationally)	Category	Need for action
	All pressure ulcers acquired in-hospital in patients ≥ 33 years (highest stage per patient)					
52008	All pressure ulcers acquired in-hospital (excluding stage 1 pressure ulcers)	n.d.**	1,609	–	X	X
52009	Ratio of the observed to expected rate (O / E) of pressure ulcers acquired in-hospital (excluding stage 1 pressure ulcers)	≤ 2.16 (TO; 95th percentile)	1,609	80	2	A
52010	All stage 4 pressure ulcers acquired in-hospital (in patients ≥ 20 years)	Sentinel event	1,694	671	X	B

TO = Tolerance range; ** not defined

* Not just QA documentation alone, but also the risk statistic is relevant to the indicators listed here. For that reason, number of hospitals stated at this juncture may deviate from the number entered in the data basis.

Nursing: Prevention of pressure ulcers

QI-ID 52010: All stage 4 pressure ulcers acquired in-hospital

Quality target

No emergent stage 4 pressure ulcers in patients with no pressure ulcer present on admission or for whom no pressure ulcer status was stated on admission.

Background

This quality indicator measures the rate of patients with stage 4 pressure ulcers that was newly emergent during their hospital stay. This includes all patients 20 years and older.

Stage 4 pressure ulcers are an extremely serious complication associated with a very high degree of personal suffering, pain and protracted course of healing for the patients, but which can usually be prevented by efficacious prophylaxis. Hence, the quality target is to prevent the emergence of a stage 4 pressure ulcer during a patient's hospital stay. To find out whether any serious quality problems exist, the emergence of a high-stage pressure ulcer (stage 4) is collected as a sentinel event. This triggers an analysis within the Structured Dialogue under all circumstances.

In special isolated cases, pressure ulcers can nevertheless not be prevented in spite of proper nursing care. This can apply to patients, e.g., in whom prophylactic care interventions are contraindicated because they cannot tolerate positional changes due to severe pain or are incapable of micro-movements. Moreover, there are also patients in whom nursing prophylactic care interventions are ineffective (e.g., those with severe circulatory disorders or taking medicines that impair skin circulation). As a rule, these are patients who have cumulative risk factors for the emergence of pressure ulcers while concomitantly suffering very serious, life-threatening events. It should be stressed that this involves a very small group of patients. Generally, targeted prophylactic interventions are also successful in patients at high risk for pressure ulcers.

Evaluating the results

No direct comparison with the previous year's results is possible due to the extensive changes (target population, use of claims data, risk adjustment based on the risk statistic of the hospitals). The documentation using claims data shows a high number of patients (2,442) with stage 4 pressure ulcer, newly acquired in the hospital. Therefore, the Federal Experts' Working Group classifies the need for action as Category B and requested the federal states to analyze the reasons in the Structured Dialogue and to intensively search for options to improve quality.

Description

Numerator	Patients ≥ 20 years with stage 4 pressure ulcers acquired in-hospital or for whom no pressure ulcer status was stated on admission
Denominator	All patients in the risk statistics receiving fully hospitalized treatment
Reference range	Sentinel event
Risk adjustment	No further risk adjustment
QI-ID	52010
Comparability with the previous year's results	Not calculated in the previous year

Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	–	–	–	–	2,442
Confidence interval	–	–	–	–	–
Total number of cases	–	–	–	–	16,506,988

Aggregate result of all patients
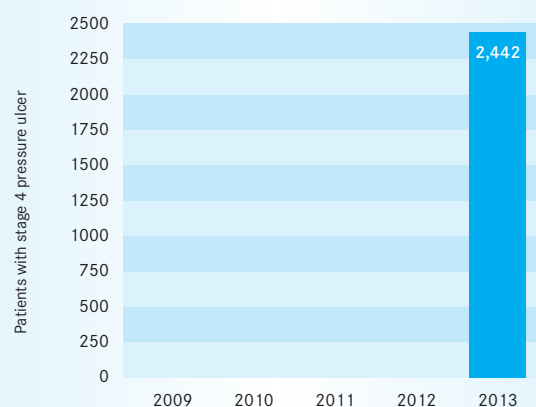
Hospital-based results

Target population of all hospitals	1,694
Number of hospitals with 0 cases	0

1,612 Hospitals with ≥ 20 cases

Number of computationally discrepant hospitals	655 of 1,612

82 Hospitals with 0 to 19 cases*

Number of computationally discrepant hospitals	16 of 82
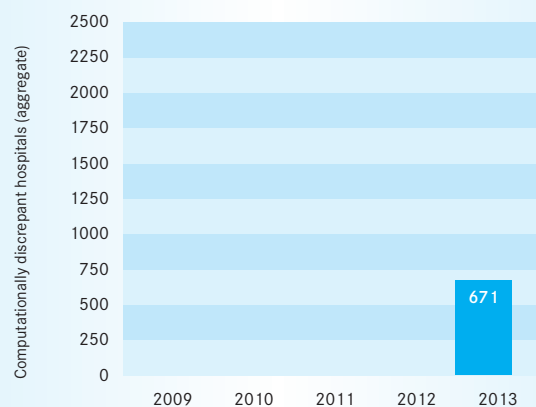
* As the provided number refers to the QA documentation, a hospital can also be discrepant although no risk statistic has been transmitted.

Background

Further reading

External quality assurance

Björn Broge

Task and objectives

In sections 135 ff. of the German Social Code, Book Five (SGB V), the legislator has defined the key objectives of quality assurance in medicine. As the joint self-governing body, the Federal Joint Committee (German abbreviation G-BA, for Gemeinsamer Bundesausschuss) is responsible for important tasks in quality assurance. Since September 1, 2009, the G-BA has been supported by the AQUA Institute, as the professionally independent institution defined in section 137a SGB V.

To avoid discontinuities arising in the future, particularly through the periodically pending new calls for tender, the legislator is planning to transfer the tasks currently commissioned to the AQUA Institute to a newly established foundation after the ongoing term of contract expires (i.e., after 2016). Section 137a SGB V was newly amended in this context, but had not yet gone into force at the time the present German Hospital Quality Report went to print. Therefore, the explanations below refer to the legislation valid at that time.

Pursuant to section 137a SGB V, the AQUA Institute is commissioned to develop preferably cross-sectoral indicators and instruments for the measurement and presentation of the quality of care. Furthermore, the necessary documentation should be developed paying particular consideration to the principle of data economy. Additionally, the AQUA Institute should participate in the implementation of cross-institutional quality assurance and publish the results using appropriate means.

Key framework conditions, such as data flows that are of importance for the AQUA Institute are set forth in the directives of the G-BA. Currently, the following distinctions should be made:

- Development of new cross-sectoral quality assurance according to the German Directive on Cross-institutional and Cross-sectoral Quality Assurance (Qesü-RL).
- Further development and implementation of current procedures of inpatient quality assurance according to the German Directive on Quality Assurance Measures in Hospitals (QSKH-RL)

- Further directives of the G-BA, insofar as they concern quality assurance measures (rules for hospitals governing the preparation of quality reports (Qb-R); Directive for the Care of Preterm Infants and Neonates (QNeu-RL) among others).

The scope and content of the commissioned tasks are governed by the contract between the G-BA and the AQUA Institute (Figure 1).

Description of commissioned activities

Like the Institute for Quality and Efficiency in Health Care (IQWiG), which particularly supports the G-BA in assessing medical examination and treatment methods, the AQUA Institute has laid down the principles of its conceptual and scientific work in a Methods Paper.

The Methods Paper describes, among others, how quality indicators for cross-sectoral measurement of quality of care are developed, and gives reasons for the steps chosen. Moreover, the transparent representation of basic working methods allows a public discussion on the further development of legally mandated quality assurance. The Methods Paper thus represents not a static but a dynamic concept, which will be correspondingly adapted in pace with new findings and new research results. The plan is to carry out an update every two years. Each updated version is published on the internet at *www.sqg.de*.

In addition to the provision of development services, the AQUA Institute is also involved in implementing quality assurance. This comprises the existing QA procedures for external hospital quality assurance, including their system maintenance and further development, for which the AQUA Institute has been responsible since 2010.
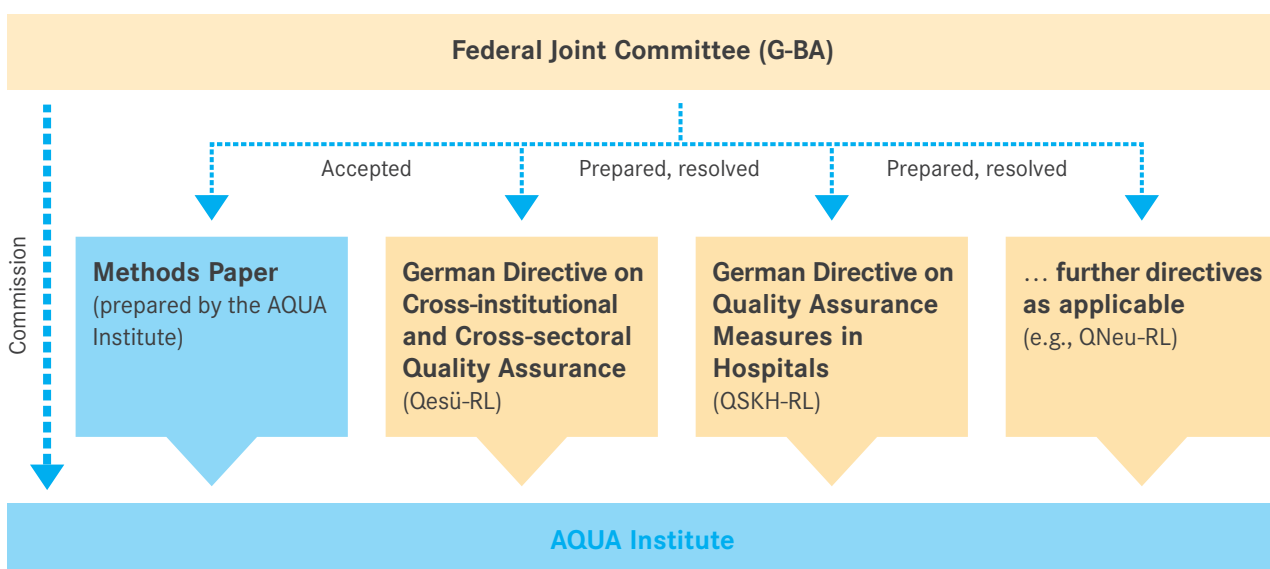
Figure 1: Fundamentals for the AQUA Institute's work

External quality assurance

AQUA Institute

AQUA – Institute for Applied Quality Improvement and Research in Health Care is an independent and neutral service provider. The institute was founded in Göttingen, Germany, in the year 1995. With a stronghold in science, the AQUA Institute specializes in quality improvement projects in the health sector. Some key services the institute provides – alongside the development of a data-driven quality management system – include support of medical quality circles, evaluating new care models, developing and implementing quality indicators and patient surveys. Since the end of 2009, the AQUA Institute has been setting up a nation-wide, cross-institutional and cross-sectoral quality assurance program for the health sector pursuant to section 137a of the German Social Code, Book Five (SGB V) as commissioned by the Federal Joint Committee.

Federal Joint Committee (G-BA)

The Federal Joint Committee (German abbreviation G-BA, for Gemeinsamer Bundesausschuss) is the supreme decision-making body of the joint self-governing bodies of doctors, dentists, psychotherapists, hospitals and statutory health insurance (SHI) funds in Germany. By issuing directives, the G-BA defines the catalogue of services to be provided by the SHI funds and thereby determines which medical care services are reimbursed by them. In addition, it passes resolutions on quality assurance measures for the inpatient and outpatient sectors of the health-care system. The G-BA was established on January 1st, 2004, as mandated by the German Statutory Health Insurance Modernization Act (GMG). It assumes and unifies the tasks of the different committees of mutual self-government that had been active heretofore. Although legally the G-BA reports to the Federal Ministry of Health, it is not a subordinate authority. The legal basis for the work of the G-BA is laid down in the SGB V.

Implementing external hospital quality assurance

Since January 2010, the AQUA Institute has been supervising the currently existing 30 clinical areas of external hospital quality assurance (Table 1). Annually, a Federal Analysis is conducted on each clinical area (QA procedure). These Federal Analyses contain the uncommented results of all quality indicators for the individual QA procedures. Each of these reports also contains a "basic analysis" with descriptive statistics. The Federal Analyses constitute an essential basis for the AQUA Institute's and Federal Experts' Working Groups' commentary on the results. These are published at *www.sqg.de*.

The current German Hospital Quality Report presents the results of quality assurance in a form that is more "readable" by the interested general public. It contains a description of all the QA procedures that were subject to mandatory documentation in data collection year 2013. In addition to an overview of all the results for quality indicators on the clinical area, patient and hospital level, detailed presentations of specific indicators are presented that are of particular interest by virtue of the comments made by the Federal Experts' Working Groups.

Alongside data receipt and preparation of reports on the federal and/or state level, implementation of existing quality assurance procedures comprises further tasks. These include:

■ Preparation of feedback reports for the participating hospitals (benchmark reports)

■ Conduct of the Structured Dialogue (see chapter "Structured Dialogue")

■ Implementation of the data validation procedure (see chapter "Data validation")

For clinical areas with small caseloads (e.g., *Heart transplantation*), for which analysis on the state level does not produce conclusive findings, the aforementioned tasks will be carried out directly by the AQUA Institute (called direct QA procedures). For other clinical areas, these tasks will initially be implemented on the state level by the State Administrative Offices for Quality Assurance (LQS) and the results will be reported to the AQUA Institute (called indirect QA procedures). Preparation of imple-

mentation of the quality assurance procedures takes place in close coordination between the federal and state levels, within various working groups (State Working Group, Data Validation Project Group, representatives of State Experts' Working Groups in the Federal Experts' Working Groups).

Major support for the AQUA Institute's work comes from the Federal Experts' Working Groups. They advise the AQUA Institute, particularly on the evaluation of the quality assurance results and the implemented quality improvement measures as well as with regard to any QA procedural update requirements. They are set up on a specialty-specific basis, and can cover several QA procedures and/or clinical areas whenever the topics fit together. The Federal Experts' Working Groups are constituted of experts appointed by the member organizations of the G-BA and by the AQUA Institute. As far as clinical areas of the inpatient sector are involved, the appointing organizations presently include:

■ The German Hospital Federation (DKG)

■ The National Association of Statutory Health Insurance Funds (GKV-SV)

■ Patient representatives pursuant to section 140f SGB V

■ The German Medical Association (BÄK)

■ The German Nursing Council (Deutscher Pflegerat)

The German Medical Association additionally appoints representatives of the medical societies. During the implementation of quality assurance, especially for the so-called indirect or state-related QA procedures, there is a need for close coordination with the state level. In agreement with the State Administrative Offices for Quality Assurance, a working group has been established to incorporate the states' expertise in implementing quality assurance for system maintenance and further development, but also to coordinate measures involved with the Structured Dialogues and the corresponding reporting.

External quality assurance

Table 1: *Clinical areas relating to external hospital quality assurance in data collection year 2013*

Clinical area	Procedures		Federal Experts' Working Group
	Direct	Indirect	
Cholecystectomy		■	Abdominal surgery
Carotid artery revascularization		■	Vascular surgery
Community-acquired pneumonia		■	Pneumonia
Pacemaker – Implantation		■	Pacemaker/ cardioverter defibrillators
Pacemaker – Replacement of generator/battery		■	
Pacemaker – Revision/system replacement/removal		■	
Implantable cardioverter defibrillators – Implantation		■	
Implantable cardioverter defibrillators – Replacement of generator/battery		■	
Implantable cardioverter defibrillators – Revision/system replacement/removal		■	
Coronary angiography and percutaneous coronary intervention (PCI)		■	Cardiology
Coronary surgery, isolated	■		Heart Surgery
Aortic valve surgery, isolated	■		
Combined coronary and aortic valve surgery	■		
Heart transplantation	■		Heart and Lung Transplantation
Lung and heart-lung transplantation	■		
Liver transplantation	■		Liver Transplantation
Living liver donation	■		
Kidney transplantation	■		Kidney and Pancreas Transplantation
Living kidney donation	■		
Pancreas and pancreas-kidney transplantation	■		
Breast surgery		■	Breast Surgery
Obstetrics		■	Perinatal Medicine
Neonatology		■	
Gynecological surgery		■	Gynecology
Femoral fracture near the hip joint		■	Orthopedics and Trauma Surgery
Hip replacement – Primary implantation		■	
Hip replacement – Revision and component exchange		■	
Total knee replacement – Primary implantation		■	
Knee replacement – Revision and component exchange		■	
Nursing: Prevention of pressure ulcers		■	Nursing

External quality assurance

Further developments in quality assurance

In addition to establishing prerequisites for the cross-institutional longitudinal observation, a focus of the past year's further developments has been the development of a cross-sectoral procedure on *Arthroscopy of the knee joint*.

Establishing cross-institutional longitudinal observations (follow-ups)

In order to better capture treatment outcomes in the future, all stakeholders at the G-BA agree that the highest-priority objective is to expand quality measurement beyond any individual outpatient or inpatient treatment. To this end, various milestones have been reached.

The year 2015 will mark the nascent start of data collection in various clinical areas of external hospital quality assurance (esQS) that will be analyzed on a routine basis to enable a longitudinal link of documentation across various inpatient healthcare providers. Before the corresponding resolution by the G-BA (see QSKH-RL for 2015), there was a trial of the technically necessary conversions in the QA documentation (AQUA 2013a) as well as preparatory work regarding the corresponding quality indicators (AQUA 2013b; AQUA 2013c). The following clinical areas of esQS (Appendix 1 of the planned QSKH-RL) are affected:

- Hip replacement care (Hip replacement – Primary implantation including endoprosthetic care of femoral fracture, Hip replacement – Revision and component exchange)
- Knee replacement care (Total knee replacement – Primary implantation including sled prostheses for knees, Knee replacement – Revision and component exchange)
- Pacemaker care (Pacemaker – Implantation, Pacemaker – Replacement of generator/battery, Pacemaker – Revision/system replacement/removal)

When based solely on documentation by the hospitals, the mapping of longitudinal courses is foreseeably limited. Therefore, emphasis shall additionally be placed on substantive and technical preparations for routinely procuring claims data from the health insurance companies. Specifically, the quality indicators on the topic PCI and coronary angiography developed in 2011 were reviewed to determine the degree to which they can be mapped on the basis of such data (AQUA 2014). At the same time, the stakeholders agreed to develop a technical specification for the future routine collection of such data (AQUA 2013d). The results of these projects form an important foundation for the intensive use of routine data planned to be implemented in many topical areas. This not only aims to improve how quality is measured, but also lower documentation cost incurred by healthcare providers.

New development Arthroscopy of the knee joint

A preliminary report on Arthroscopy of the knee joint submitted in 2011 led to the conclusion that the establishment of cross-sectoral quality assurance in this area solely on the basis of documentation by the hospitals is subject to extreme substantive limitations, while at the same time being associated with high cost for data collection.

Therefore, in 2013, the G-BA commissioned a revision of quality indicators on this subject with an amended objective: The addi-

tional documentation cost for the purposes of quality assurance on the part of the healthcare providers should be kept as low as possible and/or avoided entirely. Instead, more resources should be invested in an intensive workup of the results of quality indicators aimed at initiating quality improvements. These objectives shall be achieved through the following measures:

- Obviating documentation by the hospitals (QA documentation) for measuring quality indicators, instead:
- Using health insurance claims data
- Patient surveys
- Establishing a new instrument („Peer assessment") to initiate quality improvement and promotion measures
- Selection of the hospitals for quality assurance measures via a quality index made up of all quality indicators developed instead of individual quality indicators

The final report was submitted to the G-BA on July 14, 2014.

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Data basis

Klaus Rittmeier

Legal basis

The 2013 Federal Data Pool comprises all data documented by hospitals licensed under section 108 of the German Social Code, Book Five (SGB V) within the scope of external hospital quality assurance pursuant to section 137 subsection (1) sentence 3 no. 1 SGB V in conjunction with section 135a SGB V. This data pool forms the data basis for the analyses generated on the hospital, state and federal levels. The German Directive on Quality Assurance Measures (QSKH-RL) for hospitals licensed under section 108 SGB V was promulgated in 2012; Annex 1 thereto defines the clinical areas subject to mandatory documentation in data collection year 2013.

Determining the obligation to mandatory documentation

A specification provided by the AQUA Institute defines the criteria for the software. Called the QA filter, the software verifies the mandatory documentation requirements for the services rendered in each hospital case (patients). This verification comprises two steps:

■ **Checking the requirements for mandatory documentation:** Based on defined inclusion and exclusion criteria, the QA filter software tests whether a hospital case is subject to mandatory documentation. This check is performed during the provision of services and utilizes the data documented at the hospital, including, among others, the admission date or the diagnostic and procedural codes (ICD, OPS). Once all conditions are met, documentation of the respective case is triggered during the provision of services.

■ **Creation of the target caseload:** The target caseload determines the total number as well as the number of cases to be documented per clinical area. At the end of the data collection year, it is generated by the QA filter at the hospital. Additionally, the hospital's management signs a conformity declaration which confirms that the numbers in the target caseload are consistent with the hospital's internal records. This target caseload is used to calculate the sum of the records to be expected in the respective clinical area for that data collection year.

The classification systems used in data collection year 2013 for encoding diagnoses, procedures and remuneration are valid nationwide and define the requirements for mandatory documentation of the services covered (Table 1).

Table 1: Nationwide diagnosis, procedures and remuneration catalogues for data collection year 2013

Source	Link
ICD-10-GM 2013	*www.dimdi.de/static/de/klassi/ icd-10-gm/kodesuche/onlinefassungen/ htmlgm2013/index.htm*
OPS 2013	*www.dimdi.de/static/de/klassi/ ops/kodesuche/onlinefassungen/ opshtml2013/index.htm*
DKR 2013	*www.g-drg.de/cms/inek_site_de/ G-DRG-System_2013/Kodierrichtlinien/ Deutsche_Kodierrichtlinien_2013*

Generating risk statistics

For the first time, all German hospitals that treated full inpatients > 20 years were required to submit a risk statistic for data collection year 2013 in addition to target caseloads by February 2014. The risk statistic, which also stands on its own, supplements the QA documentation pursuant to QSKH-RL for the clinical area *Nursing: Prevention of pressure ulcers*. This measurand alone supplies important information for risk adjustment and permits hospitals to be compared fairly. To reduce documentation costs, since data collection year 2013 only those patients in the clinical area *Nursing: Prevention of pressure ulcers* have to be documented manually who are diagnosed with a pressure ulcer.

Unlike the former procedure, the data collected not only include clinical cases of patients aged over 75 years from the first quarter of the affected year, but, through the risk statistic, all patients who were aged over 19 years and treated and discharged during the entire data collection year.

Data management

The technical requirements for data collection, plausibility testing and data transmission are defined in a formal regulation called a specification. It is valid throughout the entire data collection year and is updated annually by the AQUA Institute. The respectively valid specification describes the triggers, records, key definitions, plausibility rules and export formats for all clinical areas. The corresponding version for data collection year 2013 (Service Release 3) is available at the following link: *www. sqg.de/datenservice/spezifikationen-downloads/verfahrens-jahr-2013*.

For data collection year 2013, all patients with an admission date between Jan. 1 and Dec. 31, 2013 and a discharge date prior to Jan. 31, 2014 were subject to mandatory documentation. In derogation from this time frame, the so-called overstayers in the clinical area *Neonatology* were also subject to mandatory reporting. This means that the affected clinical areas not only have to account for patients admitted in data collection year 2013, but also for those admitted in the previous year 2012 as long as they were discharged in 2013.

In the clinical areas of transplantation medicine, this is the first year that the surgery date was no longer a decisive assignment criterion for the analyses, but the year of discharge instead. This conversion ensures that the patients have been discharged by conclusion of data receipt and the corresponding documents have been prepared under all circumstances. In the wake of this conversion, a one-off special rule was made for the 2013 analysis that the Transplantation medicine overstayers from 2012 who were discharged in 2013 will no longer be considered if the cases had already been analyzed in 2012. The described changes mean that the same analysis allocation rule is applied to all clinical areas with overstayers (transplantations, *Neonatology*, *Nursing: Prevention of pressure ulcers*). In these clinical areas, the decisive criterion for the target caseload and the analyses is the year of discharge. One important advantage of this new rule is that sufficient time is allotted for the timely documentation, irrespective of the discharge date.

Data basis

Data transfer and import

The data are transferred in two different ways, depending on whether a direct or indirect procedure is involved.

- **Direct procedures** (currently clinical areas relating to transplantations or cardiac procedures and surgeries): The hospitals transfer their records for these procedures directly to the Federal Analysis Office (since January 1, 2010 that is the AQUA Institute). This affects clinical areas that are subject to mandatory documentation, but have such relatively low caseloads that consideration at the state level would not make sense.

- **Indirect procedures** (all other clinical areas): The hospitals send the records from the indirect procedures to the responsible State Administration Offices (LQS) which forward them to the AQUA Institute as Federal Analysis Office by the deadline of March of the subsequent year.

In February of the following year, the hospitals send their **target caseload** and **risk statistics** data to the responsible State Administrative Offices which are then passed on to the Federal Analysis Office. If a hospital does not transmit its target caseload by the deadline, it receives a reminder pursuant to section 24 (1) QSKH-RL with a four-week grace period within which it must submit the data. In the event of non-compliance, this could mean that a binding data basis might not be available for the target caseload at the state and federal level until early April of the next year.

Data protection

Since the healthcare sector handles sensitive data and information, the guarantee of data protection is of utmost priority. Above and beyond the contractual obligations of all participants to comply with the statutory data protection regulation, various security measures are necessary to ensure that every participating level is only provided with the directly required data and only authorized parties are allowed access to patient-identifying data (PID).

Prior to transmission, the patient data are pseudonymized at the hospitals. At the state or federal level, the case can no longer be traced to a specific patient. Only the reporting hospital itself can make this assignment. At the state level, the institutional ID numbers of the reporting hospitals are similarly pseudonymized prior to transmission to the AQUA Institute. This way, for all indirect procedures at the federal level, it is not possible to determine which hospital the respective records came from. In general, all records are encoded prior to transmission (e.g., between hospitals and State Administrative Offices) to prevent any access during transmission.

Extent of the 2013 Federal Data Pool

In data collection year 2013, external hospital quality assurance covered 30 clinical areas nationwide that are subject to mandatory documentation according to QSKH-RL.

For data collection year 2013, a total of 1,743 hospitals transmitted the target caseload. Of these, 1,557 hospitals rendered services subject to mandatory documentation requirements. 186 hospitals submitted what is called a "zero report", i.e., these hospitals were not subject to mandatory documentation.

Based on the consideration of overstayers in individual clinical areas, not only cases from 2013, but also from the previous year 2012 were reviewed as to whether they are subject to mandatory documentation in data collection year 2013 and were counted separately for the first time in the target caseload 2013. In the end, this added up to 3,148,852 cases identified with the help of the QA filter as subject to mandatory documentation out of the 19,727,986 tested inpatient cases in data collection year 2013 and the 10,783,986 cases admitted in the previous year from a total of 30,511,972 cases. Compared to the total number of 21,865,202 from the German Hospital Quality Report 2012, with the new procedure markedly more cases from the previous year were considered in testing and were counted than had been the case previously.

A total of 1,557 licensed hospitals transferred 3,153,099 QA records to the Federal Data Pool (Table 2). Since data collection year 2011, the number of reporting hospitals can be determined more precisely than in the previous years, thanks to an improved method of comparison with the data from the State Administrative Offices. A 99.0 % case completeness was determined on this basis. As in the previous year, the ratio of reported to expected records was around 100 % across all clinical areas.

Table 2: Federal Data Pool relating to data collection year 2013

	Reported	Expected	Case completeness
Records	3,153,099	3,148,852	100.1 %
Hospitals	1,557	1,573	99.0 %

The case completeness, i.e., the documentation rate, is measured separately on the level of each hospital and for each clinical area based on the ratio of the number of actually transmitted records to the target value calculated from the target caseload. Pursuant to section 137 SGB V, these figures are also to be published in the hospitals' quality reports. Moreover, the power of the analyses can be judged at the state and federal level.

Based on the target caseload, the total number of hospitals declined by 27 compared to the previous year and the number of hospitals providing services subject to mandatory documentation by as much as 101. At the same time, the number of cases subject to mandatory documentation declined markedly by over 1 million. The main reasons for these dramatic reductions were the changes in the clinical area *Nursing: Prevention of pressure ulcers* introduced in data collection year 2013.

Within the scope of converting the clinical area *Nursing: Prevention of pressure ulcers* over to the greater use of routine data, the QA data were supplemented by the new risk statistic for the first time in data collection year 2013. Formerly, only the first quarter was documented and the hospitals were required to document approx. 1.2 million cases "by hand"; introduction of the risk statistic markedly lowered the cost here. The hospitals were additionally required to submit the (automatically generated) risk statistic. But after conversion to the new procedure in data collection year 2013, only around 300,000 pressure ulcer cases needed to be documented – and that with a markedly larger number of patients, namely around 16.5 million hospital cases.

Data basis

For data collection year 2013, a total of 1,646 hospitals transmitted a risk statistic. Considering the target caseload numbers mentioned above, around 94 % of all hospitals had already submitted a risk statistic in the introductory year. This was clearly a great success. In aggregate, the 2013 risk statistics delivered more than 6 million records for proper risk adjustment.

Case completeness

Case completeness and plausibility are tested on the criteria defined in the specification, in the indirect procedures by the State Administrative Offices for Quality Assurance, and in the direct procedures by the AQUA Institute as Federal Analysis Office.

Since data collection year 2010, the documentation rate has been calculated separately for every clinical area of a hospital. Computational discrepancies, i.e., values below 95 % or over 110 % are discussed within the Structured Dialogue. Since data collection year 2011, section 8 (4) of the Hospital Remuneration Act (KHEntgG) in conjunction with section 137 (1) 2. SGB V requires that hospitals pay a quality assurance fine for cases that are subject to mandatory documentation but were not documented. In all clinical areas of transplantation medicine, special quality assurance fines were defined to be additionally

Table 3: Case completeness by indirect and direct clinical area

Procedures	Clinical area	Short term	Case completeness
Indirect	Cholecystectomy	12/1	100.3 %
	Carotid artery revascularization	10/2	99.4 %
	Community-acquired pneumonia	PNEU	100.7 %
	Pacemaker – Implantation	09/1	100.0 %
	Pacemaker – Replacement of generator/battery	09/2	101.5 %
	Pacemaker – Revision/system replacement/removal	09/3	99.3 %
	Implantable cardioverter defibrillators – Implantation	09/4	99.9 %
	Implantable cardioverter defibrillators – Replacement of generator/battery	09/5	100.3 %
	Implantable cardioverter defibrillators – Revision/system replacement/removal	09/6	100.4 %
	Coronary angiography and percutaneous coronary intervention (PCI)	21/3	100.5 %
	Breast surgery	18/1	99.9 %
	Obstetrics	16/1	99.9 %
	Neonatology	NEO	100.6 %
	Gynecological surgery	15/1	100.1 %
	Femoral fractures near the hip joint	17/1	100.8 %
	Hip replacement – Primary implantation	17/2	100.0 %
	Hip replacement – Revision and component exchange	17/3	100.3 %
	Total knee replacement – Primary implantation	17/5	100.1 %
	Knee replacement – Revision and component exchange	17/7	100.3 %
	Nursing: Prevention of pressure ulcers	DEK	99.0 %
Direct	Heart surgery clinical areas (aggregate)*	HCH	99.8 %
	Heart transplantation	HTX	103.8 %
	Lung and heart-lung transplantation	LUTX	101.5 %
	Liver transplantation	LTX	100.2 %
	Living liver donation	LLS	100.0 %
	Living kidney donation	NLS	99.9 %
	Kidney transplantation, Pancreas and pancreas-kidney transplantation (aggregate)*	NTX, PNTX	99.8 %

* Certain clinical areas are documented together on one documentation sheet. Here, the case completeness is expressed as "aggregate".

Data basis

Table 4: Case completeness in coronary surgery by clinical area for target caseload

Clinical areas for target caseload	Short description pursuant to target caseload	Case completeness
Aortic valve surgery, isolated – conventional	HCH_AORT	101.0 %
Aortic valve surgery, isolated – catheter-supported endovascular	HCH_AORT_KATH_ENDO	97.5 %
Aortic valve surgery, isolated – catheter-supported transapical	HCH_AORT_KATH_TRAPI	100.0 %
Combined coronary and aortic valve surgery	HCH_KOMB	99.8 %
Coronary surgery, isolated	HCH_KORO	100.1 %

levied starting with data collection year 2013 whenever the documentation rate is less than 100 % (section 24 QSKH-RL).

Table 3 lists the case completeness at the federal level by clinical area for data collection year 2013. The case completeness of the individual clinical areas ranged from 99.0 % to 103.8 %, again showing slight improvement over the previous year.

■ **Particulars:** The QA filter for all three clinical areas in cardiac procedures and surgeries that are subject to mandatory documentation is triggered by the same algorithm. Therefore, they are documented together on the same documentation sheet and evaluated mutually for case completeness (Table 3). The concrete allocation to each clinical area (*Aortic valve surgery, isolated*, *Coronary surgery, isolated* and/or *Combined coronary and aortic valve surgery*) is not performed until the analysis. The same applies to the clinical areas *Kidney transplantation* and *Pancreas and pancreas-kidney transplantation*.

To refine the analysis of cardiac procedures and surgeries, the target caseload in data collection year 2010 identified for the first time two so-called "clinical areas for target caseloads" belonging to the catheter-supported interventions. Each target number in these clinical areas for target caseload is based on specific surgery data defined in the QA filter specification (OPS procedure codes). On the other hand, the data from these clinical areas for target caseload are recorded on the uniform documentation sheet such that each value represents a subset of all cardiac surgery records.

Whereas the launch in data collection year 2010 was still affected by some transitional difficulties, implementation in the years 2011 to 2013 showed that this procedure can effectively map the aforementioned types of interventions – and that despite expansion to a total of 5 clinical areas for target caseload. In each clinical area for target caseload, the case completeness averaged between 97.5 % and 101.0 %.

The distribution of records across the corresponding clinical areas for target caseload shows that 59 % of all interventions can be assigned to the clinical area *Coronary surgery, isolated* (Fig. 1). In relation to all cardiac procedures and surgeries, the clinical area *Aortic valve surgery, isolated* takes up a proportion of 30 %. It is divided into three clinical areas for target caseload: conventional (15 %), catheter-supported endovascular (11 %) and catheter-supported transapical (4 %).
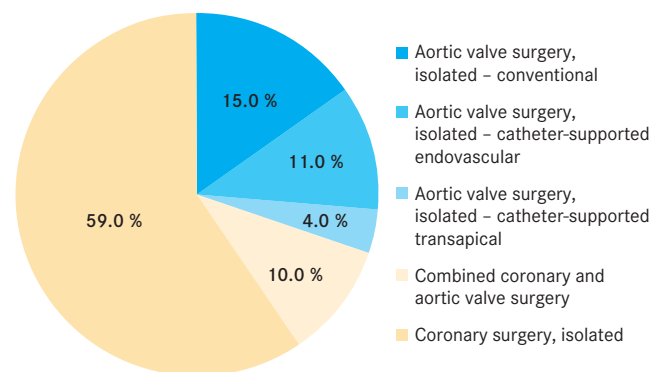
Figure 1: Cardiac procedures and surgeries (%) in data collection year 2013 – proportion of delivered records based on clinical areas for target caseload

Over- and under-documentation

The number of documented records should equal the number of records subject to mandatory reporting, i.e., the documentation rate should be 100 %. In individual clinical areas, over- and/or under-documentation occurred in relation to the number of hospitals as well as to the number of records for the following reasons:

■ **Documentation errors:** Due to coding errors or software problems, hospitals reported records to be documented in their target caseloads, although they did not render these services.

■ **Over-reported target caseloads:** Because they changed their hospital identifier (ID number), hospitals transmitted their target caseload twice.

■ **Over-reported data deliveries:** Because they changed their ID number or documentation software, hospitals transmitted their QA data twice without canceling their previous transmission.

■ **Deviating ID numbers:** The records were transmitted with the ID number of a higher-ranking hospital, even though the correct ID number of the respective hospital was indicated in the target caseloads. This inconsistency can also occur in indirect procedures, for instance, when several operational sites with the same ID number send separate pseudonyms to the Federal Analysis Office. On the other hand, several hospitals generated their target caseloads for a group of several affiliated hospitals.

Data basis

- **Overstayers in transplantation clinical areas:** In transplantation clinical areas, the number of patients called "overstayers" has also been reported since data collection year 2009; overstayers are patients discharged after January 31 of the year after their admission. In several cases, errors in calculating target numbers and determining case completeness were identified that ultimately resulted from a wrong target caseload in data collection year 2013. At several hospitals, no or too few cases with an admission in 2012 were considered in the data basis on target caseload. This meant that overdocumentation could erroneously result for overstayers even though the QA documentation of the hospital was performed correctly and completely. On the other hand, the software did not properly convert all cases to the calendar year of discharge in accordance with the data specification for the target caseload 2013. Due to this error, patients discharged in January 2014 were counted in the target, although these clinical cases had formerly belonged to the analysis of the next data collection year. This constellation might result in isolated cases of apparent under-documentation due to an erroneous target caseload, even though the hospital had completely documented all cases belonging to the data collection year. This problem will be discussed with the hospitals within the scope of the Structured Dialogue.

  Another particular issue with transplantations derives from converting the analysis from the year of surgery to the year of discharge. These treatments are excluded from the current data basis in this case only so that the data from patients with admission in 2012 and discharge in 2013 previously contained in the analysis on data collection year 2012 are not reviewed once more within the Structured Dialogue. In the case of liver transplantations, for example, this ultimately led to a total of 101 documented transplantations where the patients were admitted in 2012 and discharged in 2013. Of them, 67 had already been included in the last analysis, leaving a total of the 34 overstayers remaining in the current data basis. Moreover, comparison with the target number shows that not all overstayers can be completely mapped at the present.

  For illustration purposes, Table 5 compiles all data available on discharges in calendar year 2013.

- **Overstayers in the clinical area _Neonatology_:** In the clinical area _Neonatology_, overstayers have likewise been documented since data collection year 2011. In the 2012 analysis, the conversion to year of discharge led to several overstayers still being excluded that were already contained in the 2011 analysis. By contrast, the current 2013 analysis gives full consideration to all cases with discharge in calendar year 2013 in both the expected (target) as well as the observed data (actual).

- **Overstayers in the clinical area _Nursing: Prevention of pressure ulcers_:** Unlike data collection year 2012, where all patients > 75 years with admission in the 1st calendar quarter and discharge by the end of April were subject to the nationwide obligation to mandatory documentation pursuant to QSKH-RL, the conversion in this clinical area led to all patients with pressure ulcers and discharge by December 31, 2013 having to be considered in the 2013 target

caseload. Similar to the procedure previously described for transplantations, several hospitals also counted patients not discharged until January 2014 in their target caseload. This was in contradiction to the data specification. After timely consultation with the participating State Administrative Offices, however, it was shown that the error could have resulted from software, but also from user errors at the hospitals, depending on the individual case. As it turned out, various software suppliers were affected, although the error did not occur at all customers. In the end, the wrong target caseload might lead to apparent under-documentation here as well, even though the hospital fully documented all cases belonging to that data collection year.

Table 5: Allocation of transplantations with admission in 2012 and discharge in 2013 (overstayers)

Overstayers in …	Expected (target)	Received (aggregate)	Of which previously considered for 2012	Of which analyzed in 2013
Liver transplantation	95	101	67	34
Heart transplantation	100	108	29	79
Lung and heart-lung transplantation	42	50	32	18
Kidney transplantation, pancreas and pancreas-kidney transplantation	78	106	104	2
Aggregate	**315**	**365**	**232**	**133**

- **Deviating Eurotransplant (ET) numbers:** For transplantations and living donations, the data on surgeries and follow-up of patients after 1, 2 and 3 years were merged using the ET numbers assigned by the _Eurotransplant_ organization. The wrong entry of ET numbers during documentation causes problems when merging the data for evaluation of the longitudinal course. Therefore, to improve data quality, follow-up survey data have since January 2012 no longer been accepted unless plausible data on the respective surgery are available. Thanks to this extended plausibility control, errors in both follow-up surveys and in surgery data can be identified effectively.

- **Deviating case numbers:** The patients are identified by a unique case number from admission to discharge through all treatment steps of a clinical area. Nevertheless, in isolated cases, software or documentation errors can lead to generation of new case numbers when the data are updated. Such errors can lead to apparent over-documentation.

Minimal data set

A minimal data set is created when certain medical circumstances prevent documentation in the respective clinical area from being sufficiently complete (e.g., in incorrect triggering by

Data basis

the QA filter). In data collection year 2013, a total of 5,101 minimal data sets were transmitted by 486 hospitals. Compared to last year, the number of minimal data sets thus rose slightly by around 4 %. The highest number of minimal data sets was generated in the clinical area *Neonatology*, whereby the proportion of all minimal data sets dropped from 34 % to 24 % compared to the previous year. The number of minimal data sets increased in the clinical areas *Community-acquired pneumonia*, *Hip replacement – Primary implantation* and *Total knee replacement – Primary implantation*. The minimal data sets are always included for determining the case completeness.

Notes on the evaluation

Any differences between the present and the previous German Hospital Quality Report are due to an updated data basis (e.g., post-documentation on long-term inpatients with transplantations) or modified mathematical principles (e.g., changes in computational rules, rounding of decimal places). The results in this report refer to the Federal Analysis of the clinical areas valid at the time this report went to press. If any changes are made retrospectively, the status of the Federal Analysis published at *www.sqg.de* supersedes the data published in this report.

Follow-up pursuant to QSKH-RL

Besides the previously described routine operation within the scope of a follow-up procedure pursuant to Annex 2 of QSKH-RL, the merging of individual treatments using pseudonymized patient data has been under testing for selected clinical areas since 2010. For this testing, the QSKH-RL requires the hospitals to collect patient data in the selected procedures in orthopedics and perinatal medicine alongside the QA data. These data are collected in the form of PID fields that are pseudonymized, but also allow links to longitudinal observations. This testing focuses on the inclusion of a newly founded trust center as well as the conversion of the export format to XML.

During the special export in 2013 of data collection year 2012, the data-supplying hospitals and the delivered records increased both in number and in proportion compared to the previous year. Assessment of the substantive results produced linkage rates in the orthopedic clinical areas that were to be expected based on the pretest. For instance, repeat interventions involving prosthesis and component exchange in the same calendar year could be assigned to 1.7 % of primary total hip replacements performed in data collection year 2012. The data from the special export 2013 have once more confirmed that the process of linking mother and child by way of the mother's pseudonymized PID is not possible in the clinical area of perinatal medicine because the information on the mother necessary for pseudonymization is not automatically collected during the neonatological treatment of the child. From a technical perspective, however, the second special export worked better than the first. Hence, there are no more problems regarding the XML export format.

More comprehensive information on this project is published at the following link: *www.sqg.de/entwicklung/technische_entwicklung/stationaere_qs/projekt-follow-up-uebersicht.html.*

Concluding notes and looking forward

For more than four years now, the AQUA Institute has been functioning as Federal Analysis Office in the sector of external hospital quality assurance pursuant to section 137a SGB V. In close cooperation with the State Administrative Offices for Quality Assurance, software producers and the associated hospitals, the documentation of the data basis has been successfully further developed and optimized. For coordination purposes, meetings take place at least twice a year with the State Administrative Offices and the software suppliers.

The current analyses reveal that, although the determination of the target caseload in connection with overstayers continues to improve, isolated documentation errors still keep occurring. Despite complete QA documentation by the hospital, these implementation errors potentially lead to apparent over- or underdocumentation. These differences not only impact the quality of the data basis, but could also result in relevant sanctions being imposed on budget negotiations. To improve this situation, attempts are being made to get all stakeholders – software suppliers and hospitals – to focus more intensively on the problem so as to effect a solution for future target caseload reports. The AQUA Institute believes that the harmonization of the rules governing all overstayer procedures already accomplished is a first step in this direction. Moving forward, this process could be extended to all clinical areas, thereby turning the calendar year of discharge into the uniform basis for target caseloads and analyses.

The reliable quality of QA data as a basis for information gains even greater significance in light of the outcomes connected with the allocation of donor organs ("organ donor scandal") at some German hospitals. In previous years, deviating ET numbers proved a common source of error during the follow-up of transplantation patients. Due to the extended, year-on-year plausibility check made upon data receipt that the AQUA Institute introduced in early 2012, there has been a trend towards a substantial minimization in these errors. With regard to improved documentation of follow-up data, the follow-up monitor, which the AQUA Institute provides to all participating hospitals on a regular basis, has established itself as an important tool for supporting the hospitals. This tool summarizes the key data on all patients in the clinical areas of transplantations and living donation over a period of four years. It thereby gives the hospitals an important foundation for the planning and documentation of follow-ups. The next step intends to test whether the future plausibility check for the ET numbers can already be reviewed when the data on the index service are received.

In addition to optimizing existing processes, new procedures for harmonizing data flows and expanding the data basis have been and are being developed intensively. This also particularly applies to the XML export format conversion resolved by the G-BA as well as the inclusion of health insurance claims data pursuant to section 299 SGB V. In this area, obvious progress has been made since the last German Hospital Quality Report. That is why the AQUA Institute anticipates that the export format will be converted to XML starting in data collection year 2015 and the first claims data will be incorporated starting in 2016.

Maintenance of current clinical areas (system maintenance)

Mareike Steen, Claudia Ammann, Almut Seyderhelm, Stephanie Vey

The primary mission of quality assurance is to measure and present the quality of care. The results are reported on both the state and federal level as well as by the hospitals themselves. They provide the basis for comparing healthcare providers and treatment options, while also serving as a helpful guide for patients. Therefore, it is important that quality assurance itself is also constantly monitored and updated. For example, the critical question must be asked as to whether good results actually reflect a good healthcare situation or whether limiting factors exist which have to be accounted for when interpreting the results and, in turn, necessitate the adjustment of an existing clinical area (QA procedure). The concept of control and updating is called system maintenance and serves to align quality assurance procedures with current medical developments and knowledge from prior implementation.

System maintenance is based on the following questions:

■ Have proposed changes been submitted, e.g., by experts of the Federal Experts' Working Groups or the State Administrative Offices for Quality Assurance (LQS)? How have they been assessed? Which form of implementation is appropriate?

■ Have hospitals reported documentation problems that mandate a change in data collection or evaluation?

■ Have new guidelines been developed or existing ones updated for the medical healthcare service under consideration? Do the existing quality indicators continue to measure the quality of care properly, do they need to be adapted to current recommendations or should new indicators be developed?

■ Can potential quality deficits be mapped sufficiently or is a further development or realignment of the existing QA procedure necessary, e.g., by including the outpatient sector, by a patient survey or longitudinal observation (follow-up)?

■ Is a fair comparison of hospitals possible based on existing quality indicators or do patient-related factors impacting treatment outcomes nevertheless exist that healthcare providers cannot influence and which were previously unaccounted for? Is risk adjustment indicated?

■ Is the target population (caseload) of the quality indicators sufficiently large enough to prevent the results from being coincidence-dependent, i.e., is the discriminatory power sufficient enough?

■ Is the target population (caseload) of the quality indicators sufficiently large enough to prevent the results from being coincidence-dependent, i.e., is the discriminatory power sufficient enough?

■ Is the QA procedure influenced by legislative amendments or modifications to the classification?

■ Is it possible to conduct the QA procedure with an improved cost-benefit ratio and lower the documentation cost for the hospitals without detracting from the power of quality assessment? Is a harmonization with other data collection systems in the healthcare system possible (e.g., cancer registries)?

■ Does evidence gathered during the Structured Dialogue with the hospitals or during quality control of the data (data validation) suggest that there is a need to change the quality indicators or the data collection procedure?

■ Are there technical reasons that mandate adjustments in relation to collection, export or transmission of the data?

■ Which institutions should be included (e.g., DIMDI[1] when changes are indicated in the classification of diagnoses)?

■ Have changes in the way data were collected in the years before made it necessary to adjust the calculation formulas?

As these myriad questions suggest, system maintenance is a continual process involving many stakeholders where a broad number of quality assurance elements (e.g., descriptions of the indicators, calculation formulas, trigger criteria, documentation forms) have to be considered. There is a set sequence and precise timing according to which the required adjustments and modifications are made in the QA procedures. For example, the conditions for data collection and transmission, called the data specification, must be published six months before the respective data collection year commences. This gives the software suppliers enough time to implement the changes. Conversely, the rules for calculating quality indicators will not be published until after the respective data collection year is over. This allows the results of the reported data and feedback from the hospitals to be included.

Table 1 lists the elements of quality assurance requiring changes within the scope of system maintenance, whenever regulations in the healthcare system are amended, but also when changes in the clinical areas mandate it as well. It becomes obvious that every data collection year has a lead-in and follow-up phase and therefore, the entire process is spread out over a total of 4 years. This is the reason why evidence and resolutions relating to one data collection year can often not be implemented until 2 or 3 calendar years later. For example, if evaluation of the indicator results for data collection year 2013 exposes a need for adjustment in spring 2014 that also affects data collection, then this change cannot be implemented for data collection until calendar year 2016 and cannot be presented in the results reports before calendar year 2017. To illustrate the essentially needed amount of time, an excerpt from Table 1, namely the preparation, coordination, publication and implementation of the data specification, has been presented in more detail in Table 2.

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1 DIMDI: German Institute of Medical Documentation and Information

Maintenance of current clinical areas (system maintenance)

Table 1: System maintenance: Relevant processes for data collection year 2013
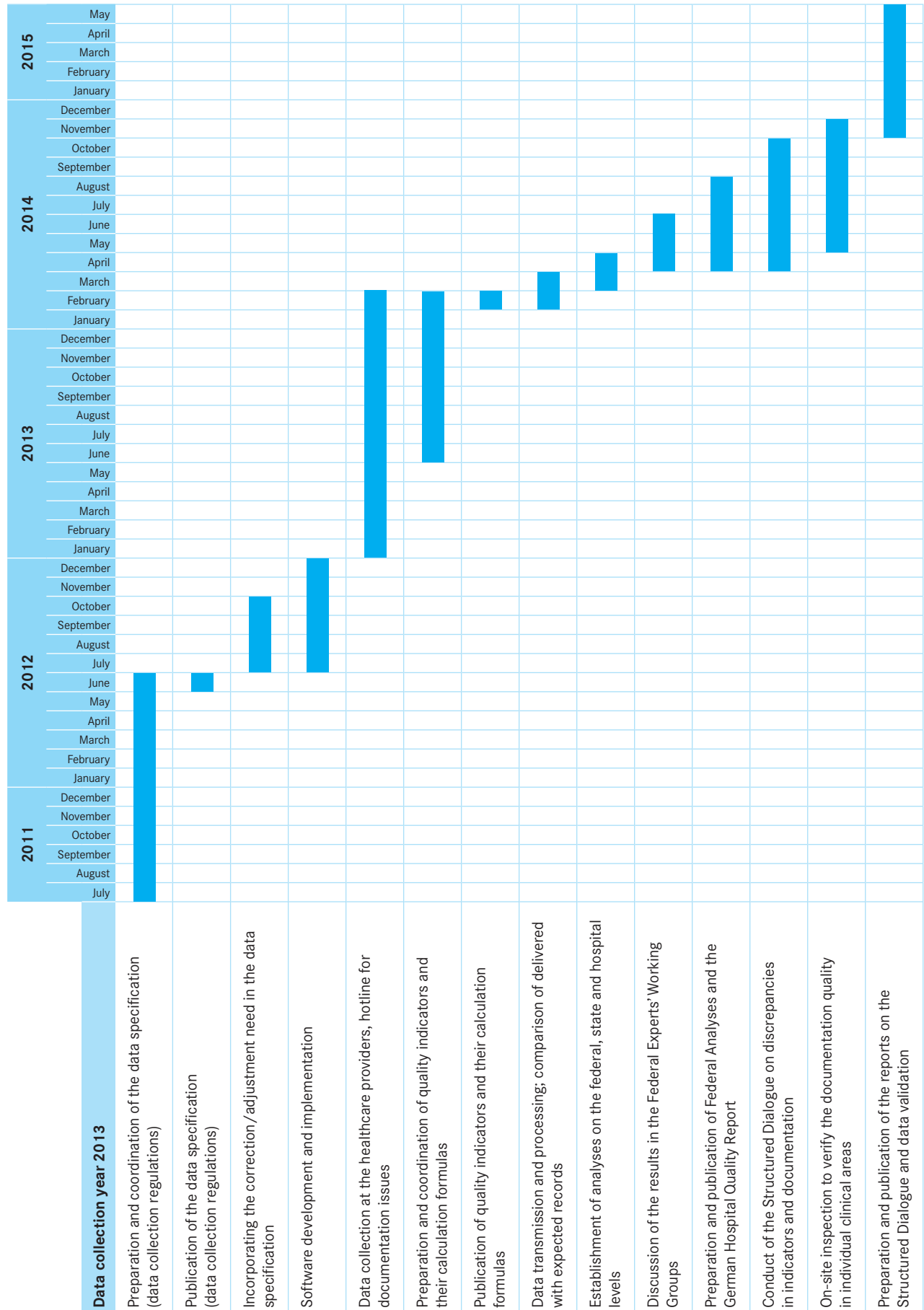
Maintenance of current clinical areas (system maintenance)

Table 2: Processes ranging from the preparation to the commencement of data collection on January 1 of a data collection year (status: May 2014)

	July	August	September	October	November	December	January	February	March	April	May	June	July	August	September	October	November	December
Viewing (internally and externally) proposed changes received up to 30th June	X																	
Internal, cross-clinical area testing by the team of experts		X	X	X														
Agreement of the need for change between the Federal Experts' Working Groups (BFG), software suppliers (SWS), state level and any other stakeholders			X	X														
Internal testing of technical implementation options and feedback from the BFG, SWS, the state level and any other stakeholders			X	X														
Compilation of the need for change in a report					X	X												
Dispatch of recommendations on the data specification to the G-BA							X											
Informing SWS, the state level and any other stakeholders about the recommendations							X											
Deliberation in the G-BA's committees								X	X	X								
Checking compliance of proposed changes with data protection laws								X	X									
Coordination with SWS, the state level and any other stakeholders (data collection offices, trust center)								X	X	X								
Preparing the publication of the data specification, technical implementation, if applicable publication of an alpha version								X	X	X								
Amending the respective directive(s)								X	X	X								
Resolution by the G-BA											X							
Incorporation of deviations between recommendations and resolution											X							
Publication of the data specification												X						
Collecting feedback on the published data specification													X	X	X			
Preparation and implementation of the need for correction/amendment													X	X	X	X		
Publication of a new version of the data specification (error correction)															X			
Checking whether the ICD/OPS catalogues published by DIMDI need amending															X	X		
Publication of a new version of the data specification (including ICD/OPS updates)																X		
Development, testing and implementing of the software												X	X	X	X	X	X	X

In the German Hospital Quality Report 2012 an example is used to illustrate that many potential solutions exist for each issue, each of which variously impacts other areas. One reason for the complexity of system maintenance is the intermeshing of rules on data collection, Structured Dialogue, data validation and directive regulations. Another component is the plethora of coordination processes required among the stakeholders.

Even the further developments in existing clinical areas affect the complexity of system maintenance and its time expenditure by raising new issues and needs for rules and governance. Examples of further developments are the introduction of a follow-up in the clinical areas of pacemaker, total hip and knee replacement care; also, the clinical area for heart transplantation was extended to cover heart support systems/artificial hearts, while health insurance claims data are used in the clinical area *Cholecystectomy*.

Maintenance of current clinical areas (system maintenance)

Moreover, the requirements for the existing system maintenance processes are growing irrespective of the envisioned further developments. For example, a final compilation and justification for all data fields is required prior to any resolution on amendments to the QSKH-RL. This is intended to allow them to be tested for compliance with data protection laws before the directive goes into effect.

To counteract the elevated coordination need and shorten the associated processing deadlines, the following measures have been undertaken in relation to data collection year 2015:

- In the fall of 2013, a schedule was mutually agreed with the G-BA that plans for any future resolutions modifying the QSKH-RL data specification to take place as early as May, instead of June of the year prior to the respective data collection year. This enables responses to consultation results and any possible deviations from the resolution on recommendations.

- So that the various G-BA committees can deliberate and the data protection law-related testing can be implemented in a timely manner, preparations for amending the directive for data collection year 2015 were already initiated in the fall of 2013. Against this background, the recommendations for data specification 2015 and the overview of data fields to be collected and their intended purposes were already made available to the G-BA in January 2014.

- In order to enable a coordinated and timely implementation for data collection year 2015, the results of the further development project on considering heart support systems/artificial hearts in the clinical area of heart transplantation in relation to data collection was already presented to the G-BA's working group for "External hospital quality assurance" some time before the project was finished.

- To be able to publish a coordinated data specification in a timely manner, the required structural changes in data collection were presented to the software suppliers and different technical solutions were discussed at several supplementary online conferences and workshops early on. The publication of an alpha specification for data collection year 2015 based on the current state of deliberations (May 2014) and the decoupling of an update for correcting errors from the ICD/OPS code updates (first update on data specification 2015 in September 2014) are further means to permit early testing and incorporation into the software products.

- To integrate new stakeholders in the process and to clarify implementation issues, further workshops will be conducted with representatives from the federal and state level, data collection offices, trust center and software suppliers.

- Work meetings with representatives of the State Administrative Offices for Quality Assurance (LQS) and of the AQUA Institute were set up to draft proposals as to how current substantive and technical requirements can be coordinated and integrated into routine operation as promptly as possible.

Table 2 details the impacts of these precautions on the schedule.

Synthesis and looking forward

Established quality assurance procedures need continual maintenance and review, always taking into account new medical knowledge, new methods of quality assurance and experiences with their prior implementation. The results of this system maintenance may relate to different aspects of the quality verification procedure, for instance to analyses, data collection or quality assurance measures. Accordingly, the potentially affected group of individuals to be involved in the preparation and coordination of recommendations is very large.

There is an especially high need for coordination in relation to the data to be collected at the hospitals. Besides substantive clarification, changes at this juncture need specifications for their technical implementation, a review of their compliance with data protection laws and as to whether any extra costs will be incurred. The various associated processes are dependent on one another.

The longer the technical and legal preparations take, the less likely it is that a quality verification procedure can be maintained to the current level of medical knowledge. Whether this leads to a conflict among the various objectives (the most currently updated versions, the most error-free technical specifications and maximum legal security), depends how detailed the legal specifications are.

The specifications for data collection in external hospital quality assurance have been described in great detail in the Directive since data collection year 2014. That limits our present ability to account for the knowledge and findings from the ongoing data collections in the coming year. In the interests of a high level of acceptance at the documenting hospitals, it would be important in the future to draft directives such that minor changes and corrections can be implemented as promptly as possible.

Structured Dialogue

Martina Köppen, Julia Ruppel, Dr. Tonia Kazmaier

The Structured Dialogue, the central instrument for implementing quality assurance and improvement, now marks its 13th year of application. Its key objectives are anchored in the German Directive on Quality Assurance Measures in Hospitals (QSKH-RL). QSKH-RL governs the responsibilities, clinical areas, handling of computational discrepancies and the concrete implementation of the individual trial steps and measures to be undertaken.

Objectives and background

The objective of the Structured Dialogue is to elucidate whether a result on a quality indicator that lies outside the reference range should actually be evaluated as "qualitatively discrepant". Whenever quality deficits are determined, the experts and the respectively competent bodies provide advisory support to the hospitals to help them eliminate deficiencies and introduce measures to improve quality. The Structured Dialogue thereby supports hospitals in their continual drive to improve the quality of processes and outcomes.

Responsibilities and timelines

In external hospital quality assurance, one differentiates between direct and indirect clinical areas. The former comprise 10 clinical areas with comparably low caseloads (organ transplants and coronary surgery) and are supervised directly by the AQUA Institute. The respective State Administrative Offices for Quality Assurance (LQS) in the individual federal states are responsible for the 20 indirect clinical areas with higher caseloads.

In direct procedures, overall responsibility for the Structured Dialogue lies with the G-BA's Subcommittee for Quality Assurance. The steering committees of the federal states (section 14

of QSKH-RL; Fig. 1) are responsible for the clinical areas covered by the indirect procedures.

The Structured Dialogue follows a detailed pre-defined schedule from data receipt to publication of the results (Fig. 2).

The QA data documented by the respective hospital are transmitted to the external offices – either to the State Administrative Offices for Quality Assurance or to the AQUA Institute – where they are analyzed according to predefined criteria.

The results of these analyses are initially returned to the hospitals in the form of benchmark reports. Should the results of the quality indicators expose evidence for potential quality deficits, the Structured Dialogue is initiated to clarify the causes of any discrepancies that have occurred (sections 10–15 QSKH-RL; Fig. 3). In this case, the results and anonymized statements of the affected hospitals are presented to the expert groups for further review and assessment.

Depending on the deficiencies identified, the experts and representatives of the hospitals mutually agree on concrete target agreements. These are designed to improve internal hospital quality and will be reviewed over the further course.

Reviewing computationally discrepant results

During implementation of the Structured Dialogue in calendar year 2013, a new nationwide uniform system was used for the first time to evaluate the results. This new system more exactly stipulates when to initiate the Structured Dialogue and which options are available to conclusively evaluate the result (Fig. 4).

The decision as to whether a computationally discrepant quality indicator result should only lead to a notice being sent to the

Direct procedure   **Indirect procedure**

The G-BA's Subcommittee for Quality Assurance

Steering Committee

AQUA Institute ←→ Federal Experts' Working Groups

LQS ←→ Experts' working groups and task forces

Structured Dialogue

Healthcare providers

Figure 1: Structured Dialogue – participants and responsibilities

Structured Dialogue

Data collection year

| 1 | QA documentation data receipt |

Year of procedure

| 2 | January | February | March | April | May | June | July | August | September | October | November | December |

End of data receipt

Start of the Structured Dialogue

Implementation of the Structured Dialogue

Conclusion of the Structured Dialogue

Report year

| 3 | January | February | March | April | May | June | July | August | September | October | November | December |

State-level reports for indirect procedures

Federal-level report for direct procedures

Federal-level summarizing report

Figure 2: *Structured Dialogue – timeline*

Computational discrepancy

No measure

(in justified cases according to section 10 (3) QSKH-RL)

Measures

Notice

Statement　　　**Clarification**

Not accepted

Accepted

Meeting　　　**On-site inspection**

Not accepted

Accepted

Target agreement

Not accepted

Accepted

Conclusion of the Structured Dialogue

Deliberation in the G-BA's subcommittee or steering committee
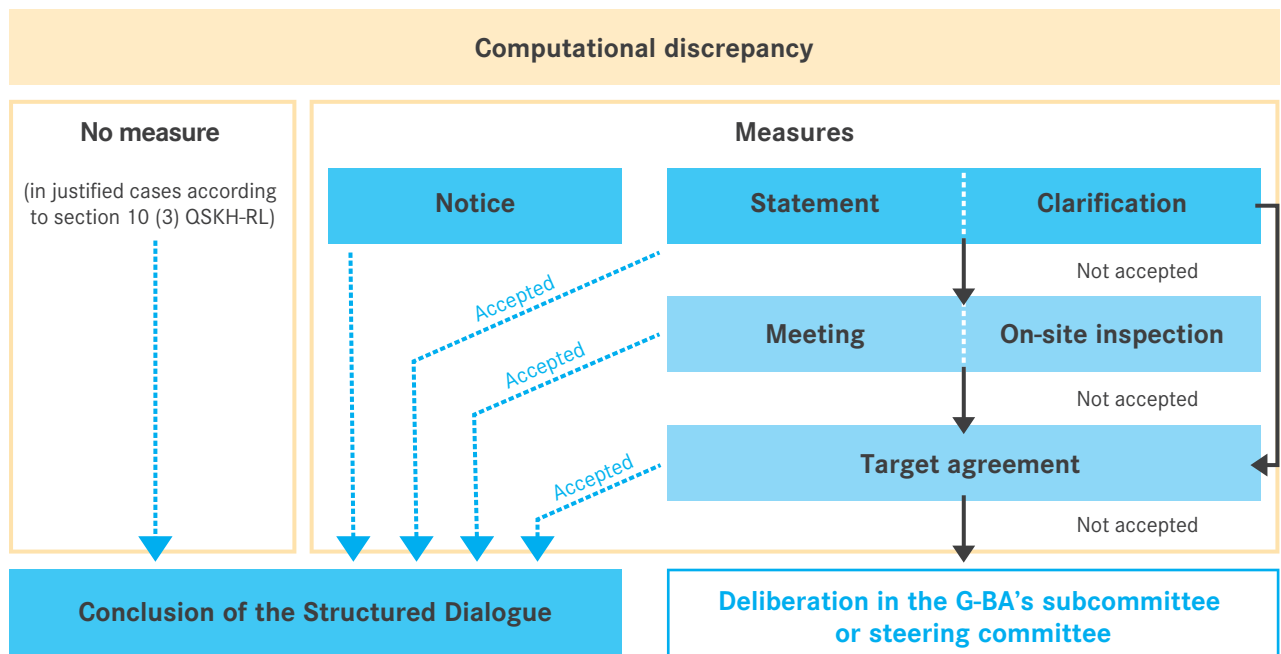
Figure 3: *Structured Dialogue – overview of the measures available*

Structured Dialogue

Result of a quality indicator or discrepancy criterion

Category | ranking (justification)

Review phase 1

Evaluation planned?

No → **N** Evaluation **not** planned
(justification 01/02/99)

Yes ↓

Result within reference range?

Yes → **R** Result within **reference range**
(justification 10)

No ↓

Triggers the Structured Dialogue

↓

Review phase 2

Measure initiated?

No → **S** **Other**
(justification 90)

Yes ↓

Statement requested?

No → **H** Hospital **notified** of computation-
ally discrepant result
(justification 20/99)

Yes ↓

→ **U** Ranked as qualitatively **non-
discrepant** after Structured Dialogue
(justification 30/31/32/99)

→ **A** Ranked as qualitatively **discre-
pant** after Structured Dialogue
(justification 40/41/42/99)

→ **D** Evaluation not possible due to
improper **documentation**
(justification 50/51/99)

→ **S** **Other**
(justification 91/99)

Figure 4: Structured Dialogue – trial steps and classification of hospital-based results (U30 and A40 are exclusively relevant to discrepancy criteria within the scope of data validation)

Structured Dialogue

hospital or whether a statement should be requested is left to the discretion of the responsible experts' working group giving consideration to the QSKH-RL specifications. In every case of what are called sentinel event indicators, however, it is mandatory to request a statement. Pursuant to section 10 (3) QSKH-RL, initiation of the Structured Dialogue can be obviated whenever the computational discrepancy is only due to one case per quality indicator (single-case rule). In the event of all other computational discrepancies, statements must be requested from the affected hospitals.

The transmitted, anonymized statements of the hospitals are then comprehensively reviewed by the expert groups according to the following criteria:

■ Was the queried result critically analyzed, reflected and discussed at the hospital?

■ Was the result in this indicator similarly discrepant the year before?

■ What do the results of the other quality indicators in this clinical area look like?

■ Are the results of the relevant discrepancy criteria of the data validation plausible in connection with the result of that indicator?

■ Is it a care and/or a documentation problem?

■ Was the problem with its associated need for action recognized by the hospital?

■ Have solutions to improve the results already been prepared and initiated?

■ Do the planned measures promise to be successful?

■ Have the initiated measures been conclusively checked by the hospital?

Conclusion of the Structured Dialogue

If the answers of the hospital are conclusive enough to classify the reason for the computational discrep-ancy, the final evaluation is carried out according to the new systematics first introduced in calendar year 2013 (Table 1).

Table 1: Categories for ranking the results after conclusion of the Structured Dialogue

Category	Ranking	Number	Justification
N	Evaluation not planned	01	Quality indicator without a result because no corresponding cases occurred
		02	Reference range not defined for this indicator
		99	Other (explained in the comments)
R	Result within reference range	10	Result computationally non-discrepant, therefore no Structured Dialogue required
H	Hospital notified of computation-ally discrepant result	20	Hospital's internal quality management requested to analyze the computational discrepancy
		99	Other (explained in the comments)
U	Ranked as qualitatively non-discrepant after Structured Dialogue	31	Special clinical situation
		32	The deviating result explained by isolated cases
		99	Other (explained in the comments)
A	Ranked as qualitatively discrepant after Structured Dialogue	41	Notices on structural or process deficiencies
		42	No (sufficiently explanatory) reasons known for the computational discrepancy
		99	Other (explained in the comment)
D	Evaluation not possible due to improper documentation	50	Incomplete or erroneous documentation
		51	Software problems caused erroneous documentation
		99	Other (explained in the comments)
S	Other	90	Measures in the Structured Dialogue waived
		91	Structured Dialogue not concluded yet
		99	Other (explained in the comments)

Structured Dialogue

Results of the Structured Dialogue 2013 based on the data from 2012

Computational discrepancies and initiated measures

For data collection year 2012, 4,188,762 records from a total of 1,658 hospitals licensed pursuant to section 108 SGB V were transmitted to the commissioned bodies. Following initial verification, 17,686 computational discrepancies resulted for the 30 clinical areas subject to mandatory documentation.

The identified computational discrepancies were processed using the testing scheme shown above (Fig. 4). Any additional measures were waived for 12 computational discrepancies because they derived from departments that had meanwhile been closed, among others. Notices regarding 7,459 computationally discrepant results were sent to the hospitals. Generally, the notices pointed out that the hospitals should analyze the reasons for discrepant results within their own internal quality management. Statements on 10,168 computational discrepancies were requested from the affected hospitals. After analysis

of the transmitted statements, additional measures were carried out with 115 hospitals. On-site inspections regarding 43 computational discrepancies were conducted at 12 hospitals. "Colleague-to-colleague" talks were held with 103 hospitals on another 278 computational discrepancies. This is approximately equivalent to the previous year's number where 290 computational discrepancies triggered "colleague-to-colleague" talks and on-site inspections at a total of 129 hospitals.

Figure 5 contrasts the measures initiated in data collection year 2012 with the previous year (data collection year 2011).

Table 2 shows the results for data collection year 2012 based on each clinical area. The respectively initiated measures and the number of qualitative discrepancies determined after conclusion of the Structured Dialogue are presented in addition to the number of computational discrepancies. The percentages indicated for qualitative discrepancies refer to the number of computational discrepancies.
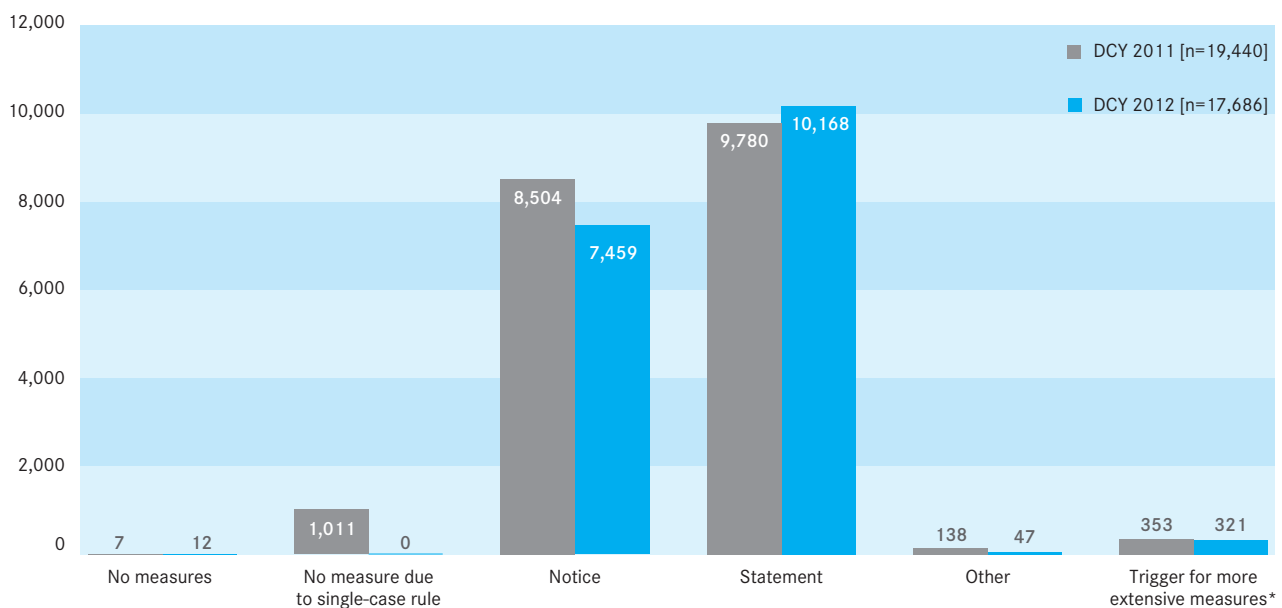
Figure 5: Measures initiated on computational discrepancies found in data collection years 2011 and 2012

DCY = Data Collection Year;
* More extensive measures: Consultations and on-site inspections

Structured Dialogue

Table 2: *Measures and results of the Structured Dialogue for data collection year 2012 per clinical area*

Clinical area	Computational discrepancy	Measure				More extensive measure*			Qualitative discrepancy**
		No measure	Notice	Statement	Other	Trigger for consultation	Trigger for on-site inspection	Target agreement	
Cholecystectomy	840	0	271	567	2	4	0	19	3.3 %
Carotid artery revascularization	125	0	43	82	0	6	0	7	8.0 %
Community-acquired pneumonia	3,302	2	1,387	1,900	13	43	0	235	17.6 %
Pacemaker – Implantation	849	0	402	447	0	24	0	32	10.7 %
Pacemaker – Replacement of generator/battery	814	0	450	364	0	12	0	26	12.2 %
Pacemaker – Revision/system replacement/ removal	748	0	343	405	0	19	1	27	10.8 %
Implantable cardioverter defibrillators – Implantation	770	0	348	422	0	8	0	20	4.8 %
Implantable cardioverter defibrillators – Replacement of generator/ battery	313	0	126	187	0	1	0	4	11.5 %
Implantable cardioverter defibrillators – Revision/system replacement/removal	263	0	102	161	0	3	0	1	2.7 %
Coronary angiography and percutaneous coronary intervention (PCI)	1,074	0	428	646	0	30	0	50	7.9 %
Coronary surgery, isolated	15	0	1	14	0	1	0	1	46.7 %
Aortic valve surgery, isolated	26	0	2	24	0	2	0	2	46.2 %
Combined coronary and aortic valve surgery	17	0	2	15	0	1	0	1	41.2 %
Heart transplantation	22	0	0	22	0	4	0	6	27.3 %
Lung and heart-lung transplantation	14	0	0	14	0	1	0	1	7.1 %
Liver transplantation	32	0	0	32	0	0	0	0	40.6 %
Living liver donation	28	0	0	28	0	0	0	0	10.7 %
Kidney transplantation	29	0	0	29	0	3	0	3	51.7 %
Living kidney donation	77	0	0	77	0	3	0	3	64.9 %
Pancreas and pancreas-kidney transplantation	21	0	0	21	0	2	0	2	19.0 %
Breast surgery	1,140	0	630	483	27	29	18	55	6.9 %
Obstetrics	826	4	206	616	0	20	22	49	20.6 %
Neonatology	360	0	126	231	3	3	0	12	9.4 %
Gynecological surgery	1,200	2	544	652	2	9	2	14	4.2 %
Femoral fracture near the hip joint	1,108	0	432	676	0	10	0	27	8.1 %
Hip replacement – Primary implantation	1,180	0	472	708	0	15	0	63	5.8 %
Hip replacement – Revision and component exchange	1,226	0	615	611	0	13	0	17	4.2 %
Total knee replacement – Primary implantation	524	0	187	337	0	6	0	25	5.9 %
Knee replacement – Revision and component exchange	484	0	286	198	0	0	0	6	3.3 %
Nursing: Prevention of pressure ulcers	259	4	56	199	0	6	0	6	17.0 %
Aggregate	17,686	12	7,459	10,168	47	278	43	714	10.2 %

* The additional measures refer to individual quality indicators.   ** The percentages (%) refer to the number of computational discrepancies determined.

Structured Dialogue

Results after conclusion of the Structured Dialogue
All hospital-based results undergo a final evaluation by the experts in the working groups and experts' working groups. The comprehensive results and evaluations of the Structured Dialogue from data collection year 2012 are contained in a separate report, available on the AQUA Institute's SQG website (*http://www.sqg.de/themen/strukturierter-dialog/berichte-strukturierter-dialog/index.html*).

The newly designed evaluation system was extremely important for the Structured Dialogue on data collection year 2012. The previous evaluation system, which evaluated the discrepancies using numerical key codes 1–14, cannot be unequivocally transferred to the new evaluation categories. Alongside lettered allocation options, the new evaluation system allows categorization by means of predefined justification texts (Table 1). The aim here is to achieve the highest possible federal uniformity.

Figure 7 shows the summarized percentages of the assigned evaluation categories for all computational discrepancies in data collection year 2012. Figure 6 presents the previous year's evaluations.

Table 3: Contrasting the evaluation systems

Evaluation key up to data collection year 2011	Evaluation categories starting from data collection year 2012
–	Notices [H20/H99]
Qualitatively non-discrepant [1]	Qualitatively non-discrepant [U31/U32/U99]
Qualitatively non-discrepant with special monitoring [2]	–
Qualitatively discrepant [3, 4, 5]	Qualitatively discrepant [A41/A42/A99]
Qualitatively discrepant due to improper documentation [13, 14]	–
–	Evaluation not possible due to improper documentation [D50/D51/D99]
Other [9]	Other [S90/S99]
Structured Dialogue not yet concluded [0]	Other [S91]

- ■ Qualitatively non-discrepant [1]
- ■ Qualitatively non-discrepant with special monitoring [2]
- ■ Qualitatively discrepant [3, 4, 5]
- ■ Qualitatively discrepant due to improper documentation [13, 14]
- ■ Other [9]
- ■ Structured Dialogue not yet concluded [0]
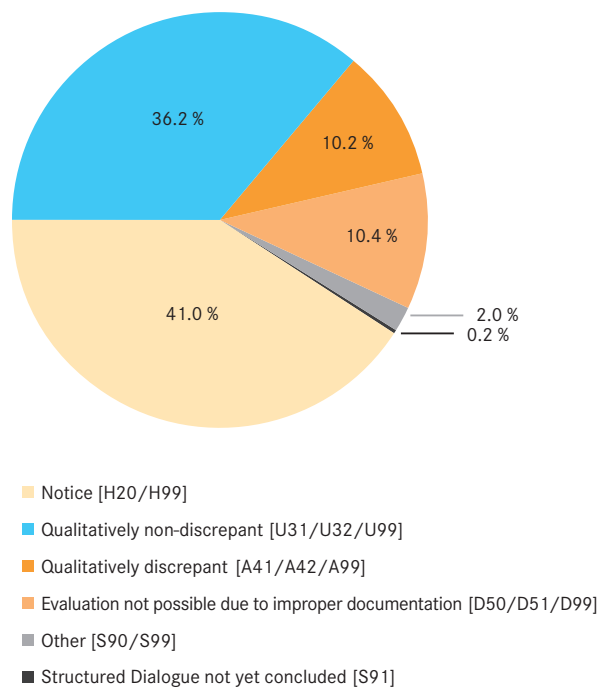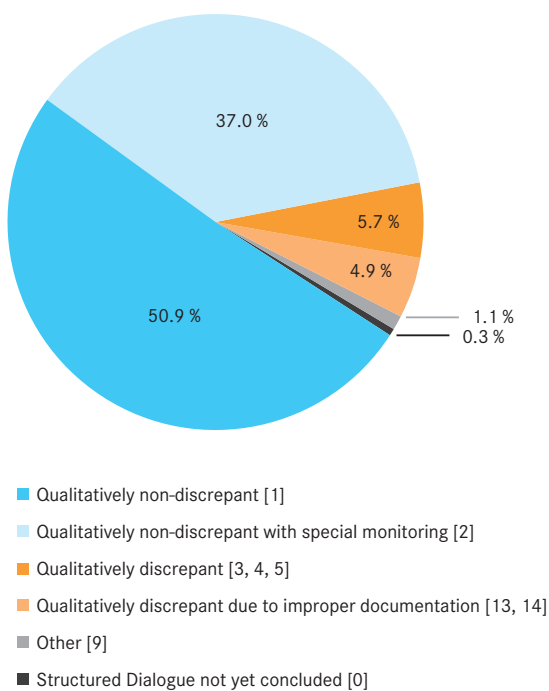
Figure 6: Result rankings after conclusion of the Structured Dialogue (data collection year 2011)

- ■ Notice [H20/H99]
- ■ Qualitatively non-discrepant [U31/U32/U99]
- ■ Qualitatively discrepant [A41/A42/A99]
- ■ Evaluation not possible due to improper documentation [D50/D51/D99]
- ■ Other [S90/S99]
- ■ Structured Dialogue not yet concluded [S91]

Figure 7: Result rankings after conclusion of the Structured Dialogue (data collection year 2012)

Structured Dialogue

Conclusion and looking forward

By applying the new evaluation categories this year, the proportion of qualitatively discrepant results nearly doubled across all clinical areas. This increase is most likely attributable to the fact that the new evaluation system no longer contains the key code 2 ("The result is classified as qualitatively non-discrepant after conclusion of the Structured Dialogue. The results will be subject to special monitoring in the follow-up.") In the past, this evaluation key was frequently used for cases that could not be unequivocally allocated. The revised evaluation categories no longer allow borderline cases of this type. The statements must now be evaluated more concretely after review. The extent to which improvement with regard to differentiation options is necessary will be addressed in the User Guide Project Group[1].

Furthermore, it was found that regarding up to approx. 40 % of the computational discrepancies only one notice was sent. Further analyses show that there are certain indicators in which the proportion of sent notices turns out to be comparably high. The Federal Experts' Working Groups of the affected clinical areas need to analyze the reasons for the increased number of notices sent in order to identify any optimization potentials derivable therefrom that might lead to methodological further developments for the affected quality indicators. Table 4 lists the indicators that produced the classification H20 or H99 in at least 75 % of the computational discrepancies, i.e., only 1 notice was sent.

After conclusion of the Structured Dialogue on data collection year 2011, nearly 5 % of the results were classified as "Qualitatively discrepant due to improper documentation". The similar ranking "Evaluation not possible due to improper documentation" was assigned twice as many times under the new evaluation system. Further analyses showed that large differences between the indicators can be found here as well. Table 5 lists all indicators where at least 40 % of the computational discrepancies could not be evaluated.

These results will be re-addressed in the corresponding Federal Experts' Working Groups. In particular, the discussion aims to check whether the instructions on how to fill in the data fields relating to that quality indicator need to be revised.

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[1] User Guide Project Group: Is constituted of members of the LQS and AQUA Institute, who deal with further development and implementation of measures within the Structured Dialogue.

Table 4: Proportion of sent notices (≥ 75 %) in relation to the total number of computational discrepancies determined per quality indicator

Clinical area	Quality indicator	Computationally discrepant Number	Sent notices Number	Sent notices Proportion
Breast surgery	QI-ID 51370: Interval below 7 days between diagnosis and surgery	76	69	90.8 %
Hip replacement – Revision and component exchange	QI-ID 270: Perioperative antibiotic prophylaxis	24	21	87.5 %
Implantable cardioverter defibrillators – Implantation	QI-ID 50007: Duration of intervention up to 75 minutes for a single-chamber system (VVI) implantation	33	28	84.8 %
Pacemaker – Revision/system replacement/removal	QI-ID 585: Revised ventricular leads with intracardiac signal amplitude ≥ 4 mV	30	25	83.3 %
Pacemaker – Replacement of generator/battery	QI-ID 480: Lifetime of the old pacemaker generator/battery > 6 years in a single-chamber system (AAI, VVI)	66	54	81.8 %
Pacemaker – Replacement of generator/battery	QI-ID 481: Lifetime of the old pacemaker generator/battery > 6 years in a dual-chamber system (VDD, DDD)	27	22	81.5 %
Pacemaker – Replacement of generator/battery	QI-ID 210: Duration of intervention up to 60 minutes	27	22	81.5 %
Community-acquired pneumonia	QI-ID 2012: Early mobilization within 24 hours after admission for risk class 1 (CRB-65 SCORE = 0)	158	121	76.6 %
Breast surgery	QI-ID 51371: Interval over 21 days between diagnosis and surgery	41	31	75.6 %
Knee replacement – Revision and component exchange	QI-ID 292: Perioperative antibiotic prophylaxis	24	18	75.0 %
Community-acquired pneumonia	QI-ID 2019: Review of the diagnostic or therapeutic strategy in risk class 3 (CRB-65 SCORE = 3 or 4)	32	24	75.0 %

Structured Dialogue

Table 5: Proportion of quality indicators (≥ 40 %) not evaluable due to improper documentation

Clinical area	Quality indicator	Computationally discrepant	Not evaluable due to documentation errors	
		Number	Number	Proportion
Living liver donation	QI-ID 12613: Impaired liver function of donor (2 years after living liver donation)	1	1	100.0 %
Living liver donation	QI-ID 12617: Impaired liver function of donor (3 years after living liver donation)	2	2	100.0 %
Liver transplantation	QI-ID 51595: 1-year-survival (patients discharged alive after transplantation with worst-case analysis)	12	7	58.3 %
Total knee replacement – Primary implantation	QI-ID 2218: Measuring the postoperative range of motion using the neutral-zero method	47	24	51.1 %
Living liver donation	QI-ID 51604: Death of donor within 2 years after living liver donation or assumed death of donor with unknown survival status after 2 years	6	3	50.0 %
Living liver donation	QI-ID 51605: Death of donor within 3 years after living liver donation or assumed death of donor with unknown survival status after 3 years	8	4	50.0 %
Lung and heart-lung transplantation	QI-ID 51637: 1-year-survival (patients discharged alive after transplantation with worst-case analysis)	2	1	50.0 %
Coronary angiography and percutaneous coronary intervention (PCI)	QI-ID 2062: PCI despite lack of clinical and/or non-invasive signs of ischemia	58	28	48.3 %
Obstetrics	QI-ID 319: Determination of umbilical artery pH in live-born singletons	11	5	45.5 %
Hip replacement – Primary implantation	QI-ID 265: Perioperative antibiotic prophylaxis	9	4	44.4 %
Implantable cardioverter defibrillators – Revision/system replacement/removal	QI-ID 50039: Intraoperative amplitude measurement of the atrial lead	10	4	40.0 %
Pancreas and pancreas-kidney transplantation	QI-ID 51525: 1-year-survival (patients discharged alive after transplantation with worst-case analysis)	5	2	40.0 %

During the preparation of the report on the Structured Dialogue (data collection year 2011), it emerged that more computational discrepancies had been included in total in the Structured Dialogue than were identified back in the Federal Analysis and/or in the German Hospital Quality Report. To analyze the reasons for this deviation, the AQUA Institute first determined the deviations per federal state, clinical area and indicator. Then, it reflected them back to the State Administrative Offices for them to check the facts internally. The following causalities were identified:

- Differences in the number of decimal places used in the computations
- Deviating definitions for units of analysis
- Federal-state-specific reference ranges
- Receipt of records after deadline
- Erroneous entry in the database used for the report on the Structured Dialogue

Commencing with the current year, this will be the first time that the QA data of the discharging location will be collected as units of analysis. This is particularly relevant for hospitals with multiple locations, but invoicing under one hospital identifier. The modified presentation of location-related results after conclusion of the Structured Dialogue is anticipated for this report format in 2016.

Aimed at making the Structured Dialogue even more effective overall, the G-BA established three new project groups in calendar year 2013. These project groups discussed new trigger mechanisms, reviewed the individual process and implementation steps and elucidated reporting styles. The optimization potentials identified and the recommendations made by the three project groups are currently being addressed in the respectively responsible G-BA working groups.

Data validation

Janina Schubert, Anja Kaiser, Dr. Tonia Kazmaier

Background

The data are validated on the basis of the most currently amended version of the German Directive on Quality Assurance Measures in Hospitals (QSKH-RL) and in close coordination with the Data Validation Project Group. This group is constituted of representatives of State Administrative Offices for Quality Assurance (LQS), the member organizations of the Federal Joint Committee (G-BA) as well as of the patient representative. It normally convenes twice annually, chaired by the AQUA Institute.

Apart from their evidence base, the quality of the data on which quality indicators are calculated is crucial for their power. Data collected within the QA documentation are of high documentation quality if they are characterized by:

- **Plausibility,** i.e., the data recorded on a case are plausible
- **Record completeness,** i.e., all data on a case have been documented
- **Case completeness,** i.e., all cases of a clinical area subject to mandatory documentation have been reported
- **Correctness,** i.e., the data documented on a case are correct

A number of measures have been taken to ensure high documentation quality in external hospital quality assurance. Figure 1 shows the systematic of the measures based on the data processing phase along with the parties instrumental in the respective phase.

As part of in-hospital data collection, the QA filter software (for particulars, see chapter "Data basis") helps ensure complete collection of cases by prompting the hospital when a case in a particular clinical area is subject to mandatory documentation.

During data entry, data are examined for plausibility and record completeness. The plausibility check focuses on whether the data meet formal criteria, e.g., that a patient's admission date is before the discharge date. The same check is conducted once more during data export and when the data are received by the data-receiving bodies (the AQUA Institute or the LQS) depending on the clinical area). The test algorithms required for this are provided in the QA documentation software specification.

In spite of these supporting measures during data collection and data transfer, errors can occur within this complex process, e.g., due to improper data entry or processing. As part of data entry control, additional tests are conducted to be able to assess how good the quality of the data used to calculate quality indicators is.

Case completeness in QA documentation is verified by performing a target-vs.-actual comparison for each clinical area. Here, the data on a certain clinical area delivered by the hospitals ("actual") are synchronized with the number of cases that should have been documented according to the QA filter software ("target", for particulars, see chapter "Data basis"). This comparison is performed routinely by the AQUA Institute as part of each data collection and/or data analysis.

The correctness and completeness of the data are checked within a data validation procedure specifically developed for this purpose. The results are primarily used to initiate targeted measures for optimizing documentation processes on the hospital level. Moreover, data validation provides important findings for the further development of the verified clinical areas on the federal level.

Data processing phase **Implementation under QSKH-RL**
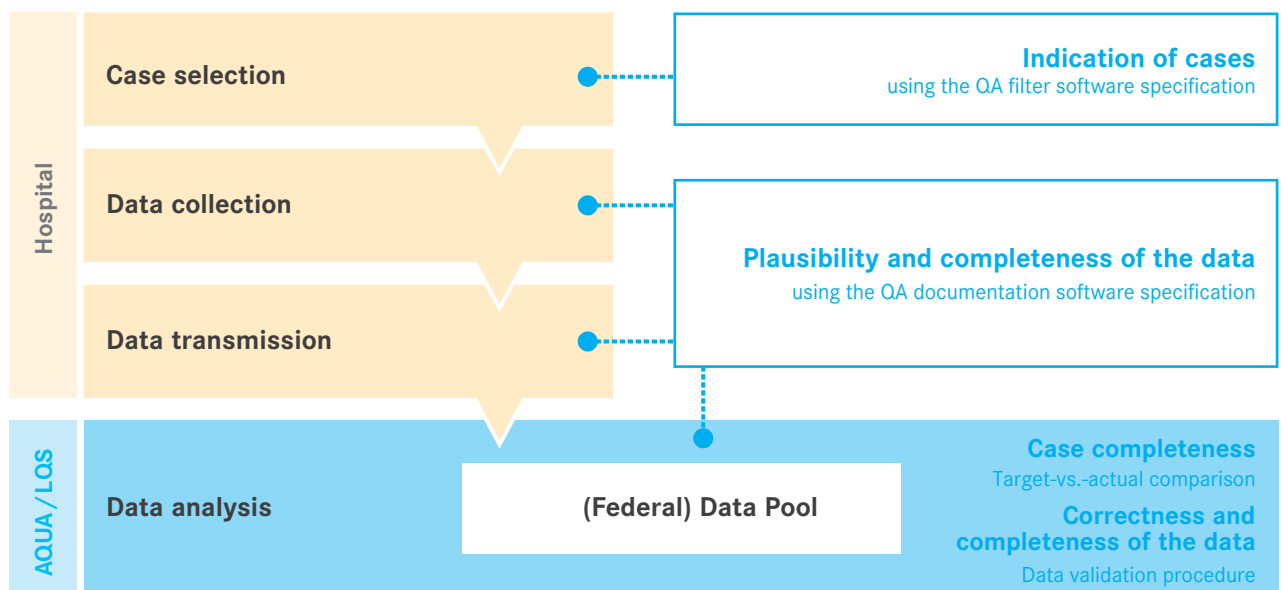
Figure 1: Ensuring documentation quality in external hospital quality assurance

Data validation

Methodology

The data validation procedure comprises two segments: Basic Statistical Testing with Structured Dialogue and sampling with data synchronization. They differ in both their primary objectives as well as in their methods (Fig. 2).

Basic Statistical Testing
with Structured Dialogue

Sampling Procedure
with data synchronization

Basic Statistical Testing
of QA data using discrepancy criteria

Random sample
from all hospitals

Element 1:	Element 2:	Element 3:
Discrepancy criteria for case completeness	Discrepancy criteria for data plausibility and record completeness (continuation)	Discrepancy criteria for data plausibility and record completeness (primary application)

Discrepancy in data validation?

Reverification of selected data fields and data synchronization

Structured Dialogue
"Data validation"

Report
Combining the results and annual public reports

Figure 2: Data validation procedure

Basic Statistical Testing with Structured Dialogue

The Basic Statistical Testing with Structured Dialogue aims to identify entries of incompletely, improperly counted and/or improperly documented data within the QA data and initiate specific measures to improve documentation quality. For this purpose, a statistical analysis is carried out according to pre-defined discrepancy criteria. These criteria test for data plausibility, record completeness and case completeness. When applying them for the first time, an analysis is carried out as to whether these discrepancy criteria are suitable for continuous application in the subsequent years (continuation). Based on their characteristics, discrepancy criteria are assigned to one of the three elements:

- **Element 1: Discrepancy criteria for case completeness**
  Since data collection year 2011, discrepancy criteria for case completeness have been applied in all clinical areas. The data basis for this comprises all data sets delivered by a hospital in a clinical area (actual inventory) as well as the data on the target caseload (target inventory). Based on the target-vs.-actual comparison, one discrepancy criterion per clinical area is applied to under-documentation (ratio of actual/target < 95 % per clinical area) and one discrepancy criterion to over-documentation (ratio of actual/ target > 110 % per clinical area). Additionally – since data collection year 2011 – a discrepancy criterion for the mini-

mal data set (AK MDS) has been used in all clinical areas; the clinical area *Neonatology* as well as the clinical areas of orthopedics, trauma surgery and transplantations have been excluded from this. Because follow-up data were collected for transplantations as well as for living donations, additional discrepancy criteria have been introduced, which examine the documentation rate and any unknown survival status.

- **Element 2: Discrepancy criteria for data plausibility and record completeness (continuation)**
  Since data collection year 2010, discrepancy criteria proving suitable in the year of their primary application continued to be applied in the subsequent years following annual review within the scope of Basic Statistical Testing. That way, computational discrepancies that point to improper documentation can be tracked beyond the year of their primary application.

- **Element 3: Discrepancy criteria for data plausibility and record completeness (primary application)**
  Besides the discrepancy criteria governing record completeness and continual discrepancy criteria on plausibility and record completeness, a comprehensive set of new discrepancy criteria is developed every year and applied to selected clinical areas for the first time.

Data validation

In their presentation, discrepancy criteria are rate-based (numerator/denominator) and have a reference range. Hospitals outside of the reference range are rated computationally discrepant in terms of documentation quality. These hospitals were suspected of improper documentation in the data fields under consideration. Once a hospital becomes computationally discrepant, a Structured Dialogue is initiated to validate the data. As a rule, a written statement is requested from the affected hospitals to determine the reason for the computational discrepancy. Optimization measures are triggered whenever the QA data of a hospital prove incomplete, improperly counted and/or improperly documented.

Sampling procedure with data synchronization

The sampling procedure with data synchronization is designed to make quantitative statements about documentation quality. It aims to answer the question as to how good the documentation quality is in a certain clinical area. Various data fields of the QA documents are selected for reverification against the patients' medical records.

A two-stage random sample is drawn for this reverification. For this purpose, in compliance with section 9 QSKH-RL, the indirect procedures first select 5 % of the hospitals per federal state and clinical area which service the clinical area and reported the corresponding data. The direct procedures stipulate that the sampling procedure with data synchronization in the selected clinical areas is to be performed at no less than 5 % of the hospitals. For each clinical area, the sampling procedure should include at least 4 hospitals and at least 40 cases in relation to the cases documented by all hospitals in the selected clinical area. Next, both the direct and the indirect procedures draw up to 20 clinical cases from each of the randomly selected hospitals. These cases are then used to synchronize the data from the reverification with those from the QA documentation obtained during the on-site inspection. The medical records are the reference standard. If there are discrepancies in documentation, i.e., large deviations between the medical records and the QA documentation, a Structured Dialogue to validate the data may be introduced for the respective hospital.

Since 2011, the results from both procedures have been provided to the public in an annual report posted on the website: *www.sqg.de*.

Results of data validation based on data collection year 2012

Basic Statistical Testing with Structured Dialogue

- Element 1: Discrepancy criteria for case completeness
  Applying the discrepancy criteria for case completeness to the Federal Data Pool of 2012 revealed a total of 1,131 computational discrepancies. Compared to last year, a marked decline is identifiable, particularly in the discrepancy criterion on under-documentation. Overall, written statements were requested for 840 of these computational discrepancies (Table 1). The reasons for the computational discrepancies listed in the statements included technical difficulties, e.g., software problems. On the other hand, however, circumstances such as internal communication problems, personnel bottlenecks, processing errors due to restructuring (e.g., merging locations and/or departments), deficiencies in structural and process quality and improper documentation were also cited.

- Element 2: Discrepancy criteria for data plausibility and record completeness (continuation)
  For data collection year 2012, continued discrepancy criteria were applied in 16 clinical areas to check plausibility and record completeness of the data. Up to 201 computational discrepancies were identified per clinical area. The discrepancies were determined at the hospital level and for each discrepancy criterion. This means that a hospital can be computationally discrepant in terms of multiple discrepancy criteria. Overall, 1,037 computational discrepancies were identified. A written statement was requested from 914 hospitals and 122 received a notice. Analysis of the statements showed that 27.2 % of the computational discrepancies are attributable to documentation errors (Table 2). Measures to optimize documentation quality have already been taken in some hospitals (e.g., staff training).

- Element 3: Discrepancy criteria for data plausibility and record completeness (primary application)
  For data collection year 2012, discrepancy criteria were developed for the clinical areas *Implantable cardioverter defibrillators – Implantation*, *Obstetrics* and *Liver transplantation* and applied for the first time as part of Basic Statistical Testing. It was not deemed purposeful to develop new discrepancy criteria for the clinical area Heart transplantation. Table 3 shows the number of these criteria per clinical area as well as the number of hospitals and documented records (except for minimal data sets) included in the Basic Statistical Testing. Applying the discrepancy criteria to the 2012 Federal Data Pool revealed between 14 and 132 computational discrepancies per clinical area. These were also determined for each discrepancy criterion at the hospital level. Within the Structured Dialogue, written statements were requested for 182 of the total of 235 computational discrepancies. A notice was sent to 52 computationally discrepant hospitals and the initiation of measures was refrained from at one other hospital. The Structured Dialogue showed that 53.8 % of the computational discrepancies for which a statement was requested were due to improper documentation (Table 4). The remaining computationally discrepant hospitals verified proper documentation, gave other answers or failed to respond to the statement request. Improper documentation was caused by both technical problems and human error, e.g., transmission errors from the medical records into the QA documentation.

Data validation

Table 1: Selected measures for Basic Statistical Testing with Structured Dialogue – case completeness

Clinical area	Computational discrepancies	Statements requested
Cholecystectomy	35	26
Carotid artery revascularization	43	37
Community-acquired pneumonia	114	103
Pacemaker – Implantation	58	46
Pacemaker – Replacement of generator/battery	35	24
Pacemaker – Revision/system replacement/removal	74	56
Implantable cardioverter defibrillators – Implantation	37	27
Implantable cardioverter defibrillators – Replacement of generator/battery	13	11
Implantable cardioverter defibrillators – Revision/system replacement/removal	30	20
Coronary angiography and percutaneous coronary intervention (PCI)	63	54
Coronary surgery (aggregate)*	3	3
Heart transplantation	10	10
Lung and heart-lung transplantation	5	5
Liver transplantation	35	18
Living liver donation	7	0
Living kidney donation	28	2
Kidney transplantation, Pancreas and pancreas-kidney transplantation (aggregate)*	40	38
Breast surgery	46	41
Obstetrics	10	10
Neonatology	86	50
Gynecological surgery	25	23
Femoral fractures near the hip joint	51	37
Hip replacement – Primary implantation	43	31
Hip replacement – Revision and component exchange	83	61
Total knee replacement – Primary implantation	20	15
Knee replacement – Revision and component exchange	38	25
Nursing: Prevention of pressure ulcers	99	67

* Certain clinical areas are documented together on one documentation sheet. Here, the case completeness is expressed as "aggregate".

Data validation

Table 2: Selected measures and results for the Basic Statistical Testing with Structured Dialogue – continuation

Clinical area	Discrepancy criteria Number	Computational discrepancies Number	Requested Statements Number	Documentation verified as improper	
				Number	Proportion
Cholecystectomy	2	201	192	24	12.5 %
Carotid artery revascularization	1	24	20	1	5.0 %
Pacemaker – Implantation	2	25	23	14	60.9 %
Coronary angiography and per-cutaneous coronary intervention (PCI)	1	32	30	4	13.3 %
Coronary surgery, isolated	3	7	7	3	42.9 %
Aortic valve surgery, isolated – Conventional	3	8	8	2	25.0 %
Aortic valve surgery, isolated – Catheter-supported	3	25	24	13	54.2 %
Combined coronary and aortic valve surgery	1	1	1	0	0.0 %
Breast surgery	2	69	62	28	45.2 %
Obstetrics	1	97	70	36	51.4 %
Neonatology	3	118	109	21	19.3 %
Gynecological surgery	2	149	116	15	12.9 %
Femoral fractures near the hip joint	1	9	9	5	55.6 %
Hip replacement – Primary implantation	2	47	40	16	40.0 %
Hip replacement – Revision and component exchange	2	144	126	41	32.5 %
Total knee replacement – Primary implantation	2	81	77	26	33.8 %

Table 3: Basic Statistical Testing – Number of hospitals, records (excluding minimal data sets) and discrepancy criteria in the clinical areas subject to data validation

Clinical area	Hospitals	Records	Discrepancy criteria
Implantable cardioverter defibrillators – Implantation	654	29,574	5
Obstetrics	764	651,696	3
Liver transplantation	24	987	1

Table 4: Selected measures and results for the Basic Statistical Testing with Structured Dialogue – primary application

Clinical area	Computational discrepancies Number	Statements requested Number	Computational discrepancies with verified improper documentation	
			Number	Proportion
Implantable cardioverter defibrillators – Implantation	132	98	56	57.1 %
Obstetrics	89	70	42	60.0 %
Liver transplantation	14	14	0	0.0 %

Data validation

Sampling procedure with data synchronization

In addition to Basic Statistical Testing with Structured Dialogue, a sampling procedure with data synchronization was carried out on-site for the clinical areas *Implantable cardioverter defibrillators – Implantation*, *Obstetrics*, *Heart transplantation* and *Liver transplantation*. Table 5 presents the number of clinical cases per clinical area that were subjected to reverification against the medical records. It additionally shows the number of hospitals among which the cases were distributed along with the number of data fields per clinical area selected for reverification.

Based on the results of the sampling procedure with data synchronization, the data validity of each data field was evaluated according to a specific rating system. Figure 3 summarizes the results of this rating for all verified data fields of each clinical area. Overall, the majority of the data fields appears to be rated "good" or "excellent". However, some data fields were subject to documentation problems, so that their data validity had to be rated "requires improvement".

The documentation problems are mainly attributable to misinterpretations with regard to fill-in instructions, insufficient knowledge of the documenting staff as well as other internal structural problems in the hospitals. In the following, some of the identified documentation problems are discussed. A comprehensive analysis of the individual data fields is found in the "Data Validation Report 2013 – data collection year 2012", which can be viewed on the website *www.sqg.de*.

Table 5: *Basic Statistical Testing – Number of visited hospitals, collected clinical cases and synchronized data fields in the clinical areas subject to data validation*

Clinical area	Hospitals	Clinical cases	Selected data fields
Implantable cardioverter defibrillators – Implantation	37	596	36
Obstetrics	53	1,040	24
Heart transplantation	4	40	14
Liver transplantation	4	69	19
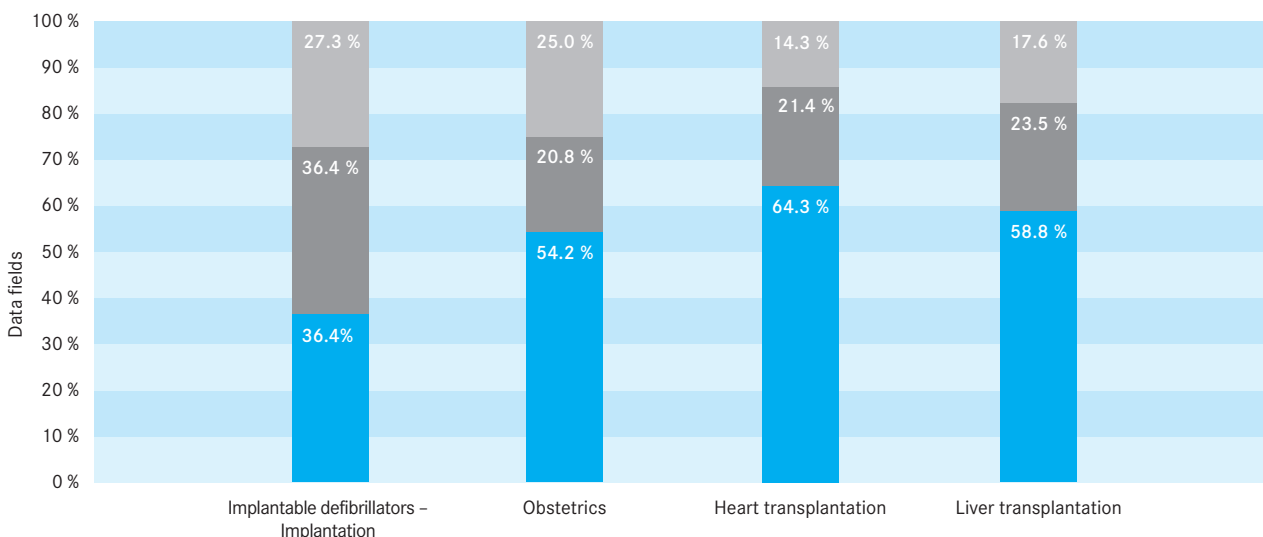
Figure 3: *Sampling procedure with data synchronization – Data validity based on data fields**

■ **Requires improvement** = consistency rate and/or sensitivity and/or specificity < 80 %
■ **Good** = consistency rate and/or sensitivity and/or specificity ≥ 80 % and < 90 %
■ **Excellent** = consistency rate and/or sensitivity and specificity ≥ 90 %

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* In the clinical area *Implantable cardioverter defibrillators – Implantation*, the individual perioperative complications were combined within the scope of the analysis. Furthermore, the data fields were grouped by location of the lead dislodgement and lead dysfunction for the analysis. Thus, 22 data fields were used in the analysis as a basis for calculation.

In the clinical area *Liver transplantation*, the serum creatinine value or the bilirubin value can be reported according to the documentation sheet in both mg/dl and µmol/l. Since all data are reported in mg/dl, only the results in this unit of measure are discussed. Thus, 17 data fields were used in the analysis as a basis for calculation.

Data validation

In the clinical area *Implantable cardioverter defibrillators – Implantation*, the data field "Perioperative complication(s)" showed that, incorrectly, only intraoperative complications were documented instead of all perioperative complications. The deviations in the data field "Probable need for atrial stimulation" resulted primarily from the fact that in some hospitals, no indications about the probable need for atrial stimulation are found in the records although this field is documented in the QA form. In this regard, the doctors of the hospitals declared unanimously this is a purely clinical assessment that cannot be measured.

In the future, a uniform rule regarding the reference document to be used aims to prevent the discrepancies in the data field "Pregnancy risks" in the clinical area *Obstetrics*. The affected hospitals were recommended to transfer the information about pregnancy risks from the maternity passport to the QA documentation.

The improvement-worthy data validity of the data field "Lung vessel resistance value" in the clinical area *Heart transplantation* was caused by hospitals not always complying with the fill-in instructions when reporting the last measured value before the transplantation within the scope of QA documentation.

In the clinical area *Liver transplantation*, deviations were observed frequently in the data field "Indication for liver transplantation". The inconsistencies resulted from the fact that, at some of the inspected hospitals, the indication in the patient file was found in text form and not according to the ELTR code[1] as required for the QA documentation. This led to reassessment during the comparison for these cases and, at the same time, depicts the complexity of the ELTR coding as well as the associated difficulties.

Conclusion and looking forward

A valid data basis is crucial for the calculation of quality indicators. The results of the sampling procedure in the clinical areas *Implantable cardioverter defibrillators – Implantation*, *Obstetrics*, *Heart transplantation* and *Liver transplantation* again underscored the necessity and relevance of a data validation procedure in this year as well. Within the scope of the data validation procedure for data collection year 2012, marked differences in data validity were revealed; this applied across the individual data fields as well as across the clinical areas. At the same time, the effectiveness of the sampling procedure with data synchronization was verified on the clinical area *Liver transplantation*. This area had already been subjected to a sampling procedure with data synchronization in data collection year 2010. When comparing the results of the two years, one finds that data validity of the laboratory values improved (bilirubin, serum creatinine, and INR) within just two years.

Moreover, the use of discrepancy criteria for Basic Statistical Testing helped identify any problems with documentation quality and allowed them to be clarified with the hospitals within the Structured Dialogue. Whenever documentation errors were found, the hospitals had already initiated improvement measures. In addition, optimization measures had already been initiated at the federal level (e.g., modification of the fill-in instructions).

To continue to track computational discrepancies indicating improper documentation in the years to come, the discrepancy criteria used for the first time in the clinical areas *Implantable cardioverter defibrillators – Implantation*, *Obstetrics* and *Liver transplantation* were tested with regard to their suitability for identifying improper documentation in coordination with the Data Validation Project Group. In conclusion, in the clinical area *Obstetrics* all 3 and in the clinical area *Implantable cardioverter defibrillators – Implantation*, 4 of the 5 discrepancy criteria used for the first time were recommended for continuation. The discrepancy criterion used in the clinical area Liver transplantation proved to not serve the intended purpose in practical application.

Since the discrepancy criteria for plausibility and record completeness (continuation) have to be reviewed annually in terms of adjustment and reliability, several changes resulted for data collection year 2013. These included modifications to some of the discrepancy criteria, but also temporary suspension or even obviation of the repeat application of certain other discrepancy criteria.

The G-BA selected the clinical areas *Carotid artery revascularization*, *Knee replacement – Revision and component exchange* as well as *Lung and heart-lung transplantation* for validating the data from data collection year 2013.

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[1] ELTR = *European Liver Transplant Registry*

Public reporting at hospital level

Kathrin Rickert, Priv.-Doz. Dr. Günther Heller

Since 2005, the hospitals have been legally bound by section 137a of the German Social Code, Book Five (SGB V) to prepare regularly a structured quality report based on the specifications of the Federal Joint Committee (G-BA) regarding content, scope and data format. Initially, this was supposed to happen every two years. In 2013, the G-BA enacted the specifications of the Act Amending the Act on the Prevention and Control of Infectious Disease in Man and Other Laws, which mandate annual reports. In addition to information on structure, performance data and quality management of the respective hospital, results of quality indicators from external hospital quality assurance are to be published in section C-1.2 of the report.

Commission

In October 2010, the G-BA's plenum unanimously resolved to commission the AQUA Institute to test and evaluate all indicators of external hospital quality assurance with regard to their suitability for public reporting by April 2011. Given the short time frame, it was not possible back then to conduct a fully comprehensive review, but only an "expeditious evaluation".

As part of its follow-up contract from the G-BA, the AQUA Institute was commissioned to announce by March 2013 which indicators newly developed since the "expeditious evaluation" as well as which indicators not subject to mandatory reporting thus far could be recommended as suitable for reporting in the future.

Consistent with these recommendations, the review and evaluation procedures used for the quality indicators of data collection year 2013 were updated with regard to their suitability for public reporting by March 2014.

Methodology

In general, quality indicators are not reviewed until their data collection year, i.e., indicators are not published in their first year of data collection.

All quality indicators were reviewed which underwent "expeditious evaluation" in 2011 or had not yet been reviewed in 2012. Moreover, all quality indicators were reviewed that had not been recommended for mandatory reporting within the review in 2012, but had been revised since then. This evaluation was based on an expert survey administered using questionnaires as well as on statistical testing.

Expert survey

In an anonymous survey, the members of the Federal Experts' Working Groups were each requested to rate the corresponding quality indicators in their clinical areas. In addition, the 17 State Administrative Offices for Quality Assurance (LQS) were surveyed in relation to state-related procedures affecting them.

Based on concrete questions, the experts evaluated the indicators newly developed since 2012 and, thus, reviewed them for the first time according to a total of 9 criteria (relevance, comprehensibility, validity etc.) on a scale from 1 to 9 (1 = poorest, 9 = best). In addition to the actual questions, each evaluation sheet contained a description of the indicator as well as an appendix with explanations of the indicators' scientific backgrounds (rationale).

For the analysis, arithmetic means of the results were calculated: If the mean was 5.0 or lower, the result was rated as "poor". A value between 5.1 and 6.0 produced a rating of "moderate". Between 6.1 and 7.0, the indicator was rated "good". Values above this were rated "very good".

A shorter questionnaire was selected for assessment of the indicators that were not subject to mandatory reporting after the first review in 2012, but which had been revised since then and, therefore, had to be re-reviewed in 2013. The overall estimation was used for the analysis, in which the respondents could answer under the heading "Suitability for public reporting" with "yes, unrestrictedly"/"yes, restrictedly"/"no". If more than 50 % of the respondents answered with "yes, unrestrictedly", the indicator was recommended for mandatory reporting.

Statistical testing

Statistical testing of the quality indicators was used to verify the quality indicators to be evaluated in terms of their discriminatory power. The discriminatory power of an indicator expresses the extent to which the quality indicator can be used to conclusively capture the quality beyond random impacts. The results on discriminatory power are categorized into "good", "moderate" or "weak".

Categorization

The mutually independent results of the expert survey and the statistical testing were combined in a cross table for evaluation purposes. Based on this evaluation schema, it was possible to assign every indicator included to one of the following categories:

- **Category 1:** "Mandatory reporting recommended"
- **Category 2:** "Mandatory reporting recommended, explanation and/or slight adaptation necessary"
- **Category 3:** "Reporting not recommended at the current time, review following revision where applicable"
- **Category 4:** "Reporting not recommended"

In some previously defined borderline cases (e.g., expert evaluation: "very good"/statistically: "moderate"), scientists at the AQUA Institute, with the involvement of each of the coordinators of the Federal Experts' Working Groups, discussed and finally assigned the affected indicator to one or the other category.

Results

An evaluation of the suitability for public reporting at hospital level is available for 392 of a total of 434 quality indicators evaluated for data collection year 2013. In 2013, 49 indicators were reviewed: 46 quality indicators for the first time and 3 quality indicators for a repeated time. The other 343 indicators had already been evaluated within the scope of the "expeditious evaluation" in 2011 or by the review in 2012. No review was carried out on 42 indicators used for the first time or substantially modified in data collection year 2013.

Across all clinical areas, a questionnaire return rate of 56.8 % was achieved, which, depending on the clinical area, varied between 42.9 % and 69.7 %. Seven of a total of 46 first-time-reviewed quality indicators were rated very good with regard to their suitability for public reporting, 25 indicators received

Public reporting at hospital level

a good and 14 a moderate rating. None of these indicators received a good and 14 a moderate rating. None of these indicators received a poor rating. Three quality indicators were re-reviewed, with less than 50 % of those surveyed rating each of them as suitable for the hospital-level public reporting.

Statistical testing produced a weak rating for 16 (32.7 %) of the 49 tested indicators. 9 indicators (18.4 %) were rated moderate and 24 indicators (49.0 %) good.

In its corresponding report on data collection year 2013, the AQUA Institute recommended 296 of the 434 indicators in total for public reporting on the hospital-level overall:

- 92 indicators (21.2 %) "Mandatory reporting recommended"
- 204 indicators (47.0 %) "Mandatory reporting recommended, explanation and/or slight adaptation necessary"
- 50 indicators (11.5 %) "Reporting not recommended at the current time, review following revision where applicable"
- 46 indicators (10.6 %) "Reporting not recommended"
- The remaining 42 indicators have not yet been reviewed with regard to their suitability for public reporting because they were substantially modified or used for the first time in data collection year 2013.

Based on recommendations by the AQUA Institute, the G-BA amended the regulations governing the hospitals' quality reports (Qb-R) on June 19, 2014 and specified the indicators subject to mandatory reporting (Table 1). Deviating from the recommendations submitted in mid-March 2014 by the AQUA Institute to the G-BA, 2 indicators for the clinical area *Coronary angiography and percutaneous coronary intervention (PCI)* were not rated as "unrestrictedly suitable for reporting". The data field conversion had led to a higher frequency of errors in the documentation of transfer services. This meant that the correct representation of the quality of treatment and care could not be guaranteed in every case. Because the AQUA Institute was not in possession of any data beforehand, it was not possible to include these data until after publication of the report on QI testing in 2013.

Moreover, one quality indicator for the clinical area *Aortic valve surgery, isolated* had been ranked by the G-BA as "unrestrictedly suitable for reporting", against the recommendation of the AQUA Institute. As this indicator has been fundamentally revised, it was formally treated as a new indicator in data collection year 2013. Therefore, no review was performed. By contrast, the Federal Experts' Working Group for Coronary Surgery had previously judged reporting of the indicator to be sensible already for the first year because the Group was of the opinion that this indicator was important and its informative value had been improved by its revision.

Conclusion

Whereas the findings on a maximum of 29 quality indicators had to be reported up to 2011, the number rose to 182 indicators in 2011 after "expeditious evaluation" by the AQUA Institute. This is equivalent to 46.7 % of the quality indicators calculated for data collection year 2010. QI review in 2012 raised the number to 289 (62.3 %) quality indicators. In 2014, 295 (68.0 %) quality indicators will be subject to mandatory reporting (Fig. 1). That signifies a marked elevation in the transparency of quality in the healthcare system. Patients and referring doctors thus have the opportunity to inform themselves comprehensively about the quality of the hospitals and use this as a selection basis for impending treatments.
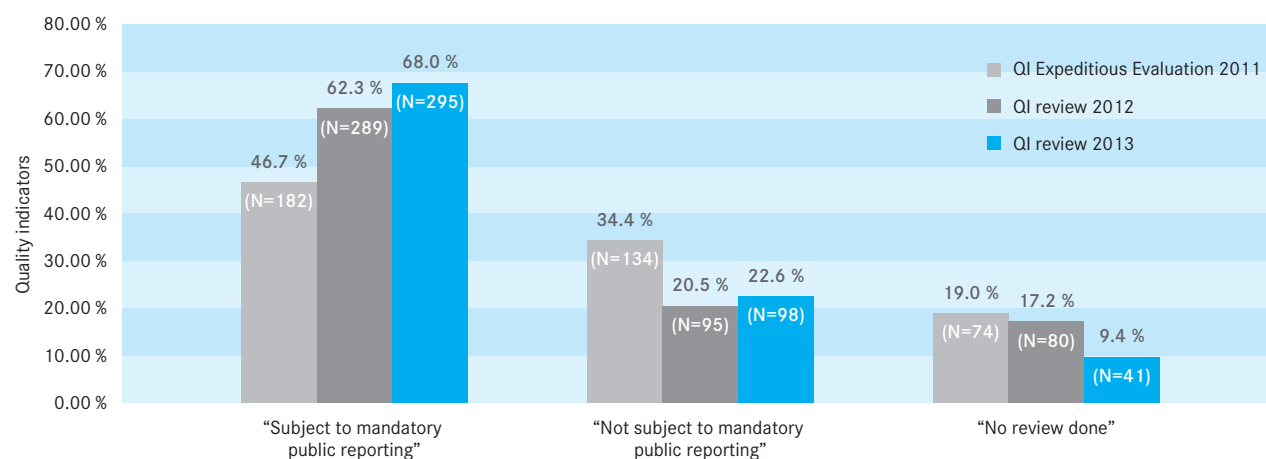
Figure 1: Reporting requirement for quality indicators from data collection years 2011 – 2013

Public reporting at hospital level

Table 1: *Indicators subject to mandatory reporting in data collection year 2013 (Qb-R, Appendix 3 to Attachment 1)*

Clinical area	Subject to mandatory reporting Number	Not subject to mandatory reporting Number	No review done Number
Cholecystectomy	8	4	0
Carotid artery revascularization	9	5	4
Community-acquired pneumonia	17	0	0
Pacemaker – Implantation	11	0	1
Pacemaker – Replacement of generator/battery	4	8	0
Pacemaker – Revision/system replacement/removal	6	5	3
Implantable cardioverter defibrillators – Implantation	12	0	1
Implantable cardioverter defibrillators – Replacement of generator/battery	6	3	1
Implantable cardioverter defibrillators – Revision/system replacement/removal	9	0	3
Coronary angiography and percutaneous coronary intervention (PCI)	16	7	0
Coronary surgery, isolated	6	3	0
Aortic valve surgery, isolated	11	4	4
Combined coronary and aortic valve surgery	5	3	0
Heart transplantation	9	0	0
Lung and heart-lung transplantation	7	0	0
Liver transplantation	10	0	0
Living liver donation	15	0	0
Kidney transplantation	19	0	0
Living kidney donation	13	0	3
Pancreas and pancreas-kidney transplantation	12	0	0
Breast surgery	1	3	4
Obstetrics	11	3	4
Neonatology	19	2	6
Gynecological surgery (without hysterectomies)	5	2	2
Femoral fracture near the hip joint	15	10	0
Hip replacement – Primary implantation	13	9	0
Hip replacement – Revision and component exchange	10	8	1
Total knee replacement – Primary implantation	10	10	0
Knee replacement – Revision and component exchange	6	9	1
Nursing: Prevention of pressure ulcers	0	0	3
Aggregate (of 434 quality indicators)	**295**	**98**	**41**

Risk adjustment and caseload-prevalence problem

Dr. Thomas König, Linda Barnewold, Priv.-Doz. Dr. Günther Heller

Two methodologically challenging issues are a frequent subject of international debate in medical quality assurance: The first issue looks at the risk adjustment of hospital-based results as indispensable to comparing hospitals in a fair manner; the second is the widely acknowledged caseload-prevalence problem. The latter derives from the fact that inherently low caseloads at medical centers make it difficult to distinguish problematic hospital-based results from purely random results by using statistical methods alone.

This chapter presents the fundamental methods for risk adjustment and for handling the caseload-prevalence problem. Subsequently, concrete examples are shown of how the AQUA Institute deals with each of these problems.

Risk adjustment

The quality of medical services rendered and treatment outcomes delivered by various hospitals can only be compared fairly when the preconditions for achieving these results are equivalent. Accordingly, it is very important to account for patient-related risks such as age or previous diseases. Such risks can lead to different outcomes although the same quality of care was given. For instance, without risk adjustment, a hospital that treats many elderly patients or patients suffering from a variety of diseases will score worse on an inter-hospital comparison than a hospital with a younger or healthier clientele of patients, even though both provided the same quality of care.

Risk adjustment accounts for the individual and patient-related risks that the hospitals cannot influence when computing the quality indicators. Risk adjustment compensates for the differences in the patient mix of the different hospitals.

The aim of risk adjustment is to permit an unbiased comparison of medical healthcare institutions, even when the patients treated at these hospitals are identified to have different risk structures. This context becomes relevant whenever the aim is to compare treatment outcomes. Conversely, risk adjustment can usually be obviated when evaluating quality characteristics relating to diagnostic or therapeutic processes (process quality) or to a hospital's equipment and staff (structural quality) (Iezzoni 2013: 206).

Which risk adjustment methods to use?

A variety of methods are employed for risk adjustment. For example, risk adjustment starts as early as in the phase of developing quality indicators. Moreover, indicators can be stratified or risk adjusted using regression analyses or multilevel models.

Definition of quality indicators

Defining the target population of a quality indicator is an initial type of risk adjustment because not all cases or patients of a hospital are compared with each other, but only patients with certain illnesses and receiving certain therapies. In addition, only precisely defined events are considered as quality indicators. This means that the comparability of the cases and, consequently, the comparability of the results for the treating hospitals is generally given.

Stratification (subgroup analysis)

If only a few influencing variables are known with a limited number of effects, then the risk can be adjusted by dividing the considered cases into strata: This stratification divides the patient population into subgroups, e.g., based on age and gender, representing similar treatment risks (Johnston 2003: 102). The treatment outcome and/or the value of an indicator are calculated individually for each subgroup. This enables the comparison of homogeneous subgroups.

One example of this type of stratification is the differentiation of patients using the classification system developed by the *American Society of Anesthesiologists* (ASA) for estimating perioperative risk. Stratification according to the ASA classification is intended to ensure that only treatment outcomes of patients with comparable health status are compared. In total, six categories are differentiated (Heinrichs 2010: S43):

- ASA 1: A normal healthy patient
- ASA 2: A patient with mild systemic disease
- ASA 3: A patient with severe systemic disease
- ASA 4: A patient with severe systemic disease that is a constant threat to life
- ASA 5: A moribund patient who is not expected to survive without the operation
- ASA 6: A declared brain-dead patient

Exemplary for data collection year 2012, Table 1 breaks down the patients in the clinical area Femoral fracture near the hip joint into ASA classes.

Table 1: Clinical area "Femoral fracture near the hip joint": In-hospital mortality

	Data collection year 2013		
	Treated patients	Number of deaths	Deaths in percent
All patients	106,795	5,650	5.3 %
Outcomes stratified by ASA classification			
ASA 1 – 2	28,625	195	0.7 %
ASA 3	69,621	3,574	5.1 %
ASA 4	8,291	1,771	21.4 %
ASA 5	258	110	42.6 %

Various hospitals are compared with each other (cross-institutional comparison) in order to account for each of the individual results in the corresponding subgroups.

Additive scoring, by contrast, involves assigning a value to different characteristics and/or risk factors and then adding up these values to obtain a sum for each individual patient. One example is the CRB-65 score used in the clinical area *Community-acquired pneumonia*.

Risk adjustment and caseload-prevalence problem

Letter	Description	Value
C	Pneumonia-related disorientation in time, place or person („**C**onfusion")	1
R	Respiratory rate ≥ 30 / min („**R**espiratory Rate")	1
B	Low blood pressure. Diastolic blood pressure (DBP) ≤ 60 mmHg or systolic blood pressure (SBP) < 90 mmHg („**B**lood Pressure")	1
65	Age ≥ **65** years	1

This score is applied to predict the patients' prognosis (i.e., expected mortality) for each risk class:

Table 3: Expected mortality in community-acquired pneumonia according to CRB-65 score

Total CRB-65 score	Expected, study-derived mortality
0	0.9 %
1	5.2 %
2	12.0 %
3 – 4	31.2 %

Here, risk groups based on additive scores are indicated as subgroups in the clinical area and these only are accounted for in the inter-hospital comparison. In other words, additive scores are analyzed as a stratification.

Regression analyses

If the impact of many variables, both categorical (e.g., gender) and continuous (e.g., blood pressure), are to be accounted for at the same time in a risk adjustment, then it is common to use regression analyses. Multiple logistic regressions examine the impact of multiple risk factors on a binary quality indicator (e.g., "patient died": yes/no). A comprehensive presentation including additional information about the computation, results and their interpretation can be found in the 2009 German Hospital Quality Report (AQUA 2010).

In the clinical area *Neonatology*, a Poisson regression is additionally used to calculate an indicator that does not refer to the number of persons, but to the number of infections per 1,000 treatment days.

Calculating individual patient risks and risk-adjusted indicator values

Using risk adjustment, the expected probability of the predicted event (e.g., "in-hospital mortality") can be determined by accounting for the patient's risk profile. This expected event probability (E) is then set in relation to the actually observed event rate (O). In this context, calculating the O / E ratio is a common way to compare hospitals (Ash et al. 2013: 342). This measure is also called the *standardized mortality rate* (SMR). It is not

only used to measure mortality, but morbidity and complication rates as well: An O / E ratio of 1 indicates that a hospital is within the risk-adjusted average, whereas an O / E ratio of 2 points to a (risk-adjusted) doubling of the hospital-specific outcome with respect to the analyzed indicator. By contrast, an O / E of 0.5 signifies a (risk-adjusted) halving of this outcome. These numbers need to be interpreted cautiously, as explained below in the section on the caseload problem.

Further development of existing monitoring methodology and risk adjustment

Regression-based methods allow for a more comprehensive and precise risk adjustment than stratifications and additive score (Jin et al. 2005). Therefore, the AQUA Institute strives to risk-adjust as many outcome indicators as possible (additionally) on the basis of statistical models over the long term.

The adjustment variable selection is of elementary importance and must be undertaken individually for each quality indicator. Under certain circumstances, additional adjustment variables must be identified and the suitability of previously used variables reverified. The influencing variables should be selected according to both substantive as well as statistical criteria.

It is crucial to select factors that the hospital itself cannot influence, e.g., patient characteristics at the time of hospital admission. By contrast, factors that a hospital can indeed influence, such as waiting times until surgery, may not be adjusted, because it is exactly these influenceable factors that reflect the quality differences between hospitals and, consequently, must remain identifiable. Potential influencing factors on patient level can be divided into the following categories:

- Demographic factors (e.g., age, gender)
- Clinical factors (e.g., co-morbidity)
- Socioeconomic factors (e.g., education)
- Health-related behaviors (e.g., smoking)

The risk adjustment of quality indicators requires the availability of the most comprehensive database that can be collected at reasonable cost. Access to health insurance claims data plays a key role here because it allows cost-effective consideration of numerous influencing variables which, beyond this, are only partially contained in the current data set available within the quality assurance framework.

The aforementioned example of ASA classifications points to such potential risk adjustment problems. For instance, it is generally known that classification by ASA scores has been variously understood and documented (Ranta et al. 1997; Haynes et al. 1995). Such classifications may even encumber any between-hospital comparability. This situation shall be taken into account in the further development of the existing clinical areas by converting to risk-adjusted quality indicators.

Adapting the existing risk adjustment using the example of the aortic valve score 2.0

In addition to introducing new risk adjustment models, the existing ones are also subject to constant monitoring. Every year, the AQUA Institute tests the risk factors of existing risk adjust-

Risk adjustment and caseload-prevalence problem

ment models to determine whether they continue to have a statistically relevant, i.e., significant, influence on the related complication. Attention is not only paid to whether a risk factor continues to influence the occurrence of a complication, but also as to how strong this influence is. That is why new coefficients for the risk factors are calculated and published each year based on the previous year's data. It is particularly important to monitor existing risk adjustment models whenever extreme changes occur in the clinical areas of quality assurance. Such changes can diminish the influence of certain risk factors, whereas others can cause other risk factors to gain importance and/or influence.

In the clinical area *Aortic valve surgery, isolated*, the catheter-supported method has increasingly established itself within the last years alongside conventional (open) surgery. In the last years, the caseloads of this new method have increased continuously and markedly: Data collection year 2008 saw the development of the aortic valve score (AKL score), previously used for the risk adjustment of mortality. In the same year, 529 cases involving catheter-supported interventions were documented (4.5 % of all aortic valve interventions), in 2013 there were 10,441 cases (51.3 %). Moreover, several of the previously used risk factors were repeatedly unable to detect any statistically significant influence on mortality. In fall 2013, therefore, the aortic valve score 2.0 for estimating the probability of in-hospital death after an intervention on the aortic valve was developed in collaboration with the Federal Experts' Working Group for Coronary Surgery.

The model for the new aortic valve score 2.0 was developed based on a 50 % sample of all primary interventions on the aortic valve (conventional and catheter-supported) performed in data collection years 2011 and 2012. This mainly accounted for all of the over 30 potential risk factors contained in the documentation. This included general vitals (e.g., age), diseases (e.g., pulmonary hypertension, diabetes mellitus) and the patient's current medical condition (e.g., status post resuscitation), among others. Although the score was newly developed, several risks associated with aortic valve replacement remained unchanged. That meant that many risk factors of the previously used AKL score recurred in the new aortic valve score 2.0. Hence, the following describes a sampling of the most important changes only:

- Age remains one major risk factor. Nevertheless, the risk can be estimated more accurately by including accurate age data compared to the previously used age groups. The same applies to patients with a body mass index (BMI) > 39, i.e., patients who are morbidly obese.

- In contrast to the previously used model, certain preoperative events suggesting a poor general health status of the patients were not subsumed into one combined factor "Critical preoperative status", but incorporated separately in the risk adjustment because extreme differences between the influences of individual events had been found.

- The following have been newly included in risk adjustment:
  - Angina pectoris during mild exertion or at rest (CCS III or IV),
  - ASA classification 4 or 5,
  - Coronary angiography findings and main branch stenosis,
  - Diabetes mellitus (insulin-treated or untreated).

- The following are no longer considered in risk adjustment:
  - Myocardial infarction up to 21 days in the past,
  - Lung diseases,
  - Emergency interventions.

Development of risk adjustment

In 2013, the general overhaul of the AKL score was the most complicated risk adjustment change. However, as each year, the influence of various risk factors was reviewed in the other clinical areas as well and, as appropriate, adapted to more recent developments.
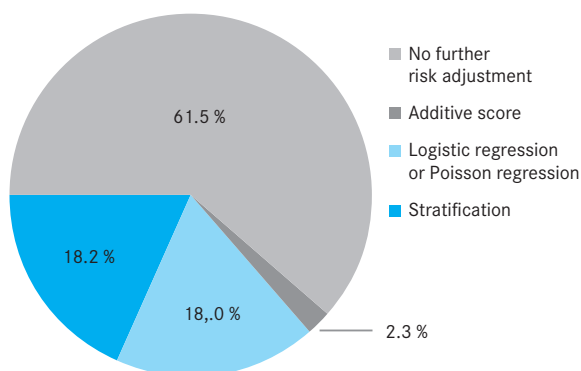
Figure 1: Risk adjustment method for quality indicators

Figure 1 illustrates the current distribution of risk adjustment methods across all 434 indicators of external hospital quality assurance: 79 of these indicators were risk-adjusted by stratification, 76 by logistic regression, 2 by Poisson regression and 10 using an additive score. This leaves 267 indicators without further risk adjustment; many of these – in particular in the transplantation-related clinical areas – have such small overall caseloads that regression models cannot be applied due to statistical limitations. It is noteworthy, however, that the proportion of variables risk-adjusted by regression methods has almost tripled since the AQUA Institute took over from the BQS Institute for Quality and Patient Safety in Health Care (from around 6 % up to nearly 18 %).

Considering that indicators on medical indication and process quality ought not to be risk-adjusted for ethical reasons, only 334 indicators are available for risk adjustment. On top of that, it is not possible to determine the prevalence that is important for public reporting from the results of the observed to the expected rate O / E. For that reason, an indicator of the raw rates, which, by definition, is not risk-adjusted, is listed next to every indicator risk-adjusted by regression analysis. In other words, now 65.2 %, i.e., almost two-thirds of the indicators theoretically accessible to a risk adjustment, are risk-adjusted. The overwhelming portion of the 89 remaining outcome indicators has such small caseloads that a risk adjustment is hardly possible for statistical reasons.

Caseload-prevalence problem

Besides risk adjustment, the solution to the caseload-prevalence problem is an equally methodologically demanding challenge. The majority of quality indicators have "unfavorable" statistical properties, particularly due to especially low and/

Risk adjustment and caseload-prevalence problem

or especially high frequencies of the events to be measured. Depending on the indicator, these low or high frequencies may indeed be intentional: Outcome indicators ought to point out quality deficiencies, i.e., preferably rare events. On the other hand, process indicators, for example, examine compliance with medical guidelines: Hence, these indicators are often close to 100 %. The largest caseload possible is required to be able to factually differentiate hospitals without quality deficiencies from those with potential quality deficiencies.

If the number of patients (caseload) receiving certain treatments in a hospital is low, then the probability that an observed rare event (e.g., complications) occurred by chance is high. Low caseloads and rarely occurring events encumber the statistical reliability of conclusions about the quality of treatment and lead to the caseload/frequency problem (Heller 2010).

International quality assurance research is aware of this dilemma. In the USA, for example, the discriminatory power of the indicators was assessed as sufficient only in a single one out of seven surgical clinical areas, namely bypass surgery (Dimick et al. 2004). The discriminatory power of an indicator is defined as its suitability to provide conclusions about not merely random, but actually existing differences of data/results. Several years ago, outcome quality indicators from various inpatient clinical areas were similarly studied in Germany, too. Second-generation Helios indicators, selected BQS indicators as well as certain indicators of the project "Quality assurance with routine data (QSR)" were investigated in this context. Here, serious problems were identified for the majority of indicators with regard to their power to reliably distinguish hospital-specific outcomes from one another (Heller 2010).

To answer the pivotal question as to whether an indicator measures actual deviations or merely random fluctuations, several years ago, scientists investigated the discriminatory power of quality indicators by proposing the following hypothesis (Dimick et al. 2004): Hospitals with poor performance defined as having mortality rates of at least double the national average should also achieve actually below-average treatment outcomes at a 95 % significance level and be detected with a probability of 80 %. Based on this hypothesis, the minimum caseload needed was calculated and the number of hospitals which actually achieved these caseloads determined. For the example indicator "Mortality among at-risk live births", a minimum required caseload of 1,055 results from the data from external hospital quality assurance. In data collection year 2012, only one out of 517 hospitals met the caseload. This suggests that the power of this quality indicator is unsatisfactory.

Within the scope of the review and assessment of indicators for external quality assurance of inpatients with respect to their suitability in public reporting at the hospital level, the AQUA Institute analyzed a total of 302 indicators for external hospital quality assurance using the described methods (AQUA 2011). 44 % of the indicators on the reporting hospitals do not possess sufficient discriminatory power. For 87 % of the indicators, less than half of the hospitals have the necessary discriminatory power. Based on the above-mentioned criteria, only 7 % of the indicators analyzed proved to have sufficient discriminatory power for more than 75 % of the hospitals (Fig. 2).
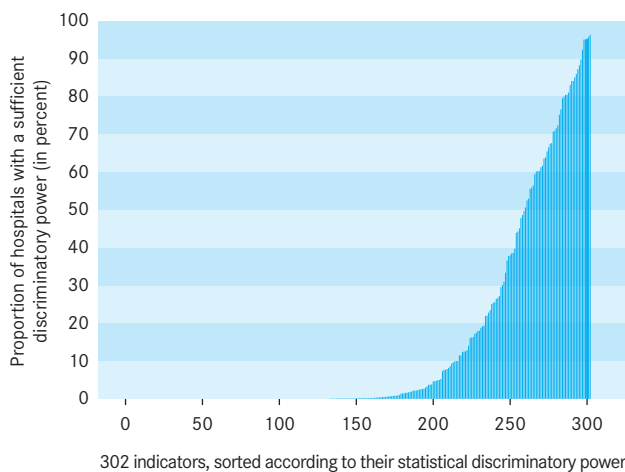
Figure 2: *Quality indicators in ascending order of discriminatory power (AQUA 2011)*

Solution approaches

Multiple approaches have been proposed to solve the widespread problem of indicators with poor discriminatory power:

- The caseloads can be multiplied by analyzing longer time periods, i.e., by combining several data collection years (*pooling*). The analysis of *moving averages* and the generation of cumulative sum plots resp. *quality control charts* similarly belong to this category (Tekkis et al. 2003). Combining individual healthcare providers into healthcare provider groups is another way of increasing the caseload. This includes, e.g., volume-outcome analysis, regional overviews or analysis of one healthcare provider's various locations.

- Multilevel and empirical Bayesian analyses can be applied as an approach to solving the caseload-prevalence problem. Here, in addition to the calculated value for a hospital, it is assumed that prior information (*Informative Prior*) exists, which is the global mean in an empirical Bayesian analysis. Distributions are calculated based on this informative prior, which can reduce variance and possibly lead to better predictive ability of healthcare provider-related outcomes (Ash et al. 2013; Dimick et al. 2010).

- Combining multiple quality indicators into a quality index is a further possibility for solving the caseload/frequency problem (Iezzoni 2013: 198; Heller et al. 2012; Heller 2010; Heller 2008). In earlier publications, the term "complication index" was used instead of "quality index". However, the term complication index becomes too narrow whenever the aim of treatment or medical indication quality is made the subject of quality analysis in addition to complications. The expression *composite measure* is also used internationally in this context (Iezzoni 2013; Dimick et al. 2012; AHRQ 2011; Staiger et al. 2009). However, the term is often used to describe measured values combined across several clinical areas.

Caseload increase and CUSUM presentation

A simple method for improving the discriminatory power was used in the clinical area *Pancreas and pancreas kidney transplantation*: The caseloads were approximately doubled by analyzing two data collection years together. The transplantation

Risk adjustment and caseload-prevalence problem

clinical areas have comparatively high prevalence rates in terms of mortality. This is due to the severity of the underlying disease, the nature of the surgical intervention itself, the low willingness of the populace to make postmortem donations and the associated suboptimal donor-recipient organ allocation. In-hospital mortality is a very important indicator and can be reliably measured by the comparably high event prevalence with a sufficient discriminatory power.

Furthermore, this area is designed to also map cumulative sums in form of what is called CUSUM charts (Page 1954). The data presented in a CUSUM or *CUmulative SUM* chart do not merely constitute the cumulative sum of the measured data, but represent the cumulative sum of the mean-adjusted differences between the measured data. This method exposes changes in a rate (e.g., mortality rate) over time and can thereby point to any confounding deviations. Moreover, it can be easily visualized (Grigg et al. 2003) and is thereby suited for public reporting. Originally developed for laboratory experiments, control charts are increasingly being used for quality monitoring and health-related research as well (Woodall 2006).

Likewise in the clinical area *Nursing: Prevention of pressure ulcers*, the number of cases has grown since now younger patients are being included in quality assurance, thereby allowing consideration of a more comprehensive target population: Whereas in the previous year, only data from the first quarter from patients > 75 years were available for quality assurance, data collection now encompasses all patients > 20 years and covers the entire year. The risk adjustment here is based on aggregated basic data which are required in the form of risk statistics for the entire target population of the clinical area; the hospitals are required to compile these basic data together with their target caseloads.

Indexing

A more elegant, but markedly more complicated solution to the caseload-prevalence problem is indexing. Indexing was applied to external hospital quality assurance for the first time in data collection year 2011 for the clinical area *Neonatology* as the indicator "Quality index of preterm infant care" (QI-ID 51174).

In the clinical area *Obstetrics*, the "Quality index of premature infant care" (QI-ID 51803) was developed for data collection year 2013: This index covers four levels in descending order of severity:

1. The ratio of the observed to the expected rate (O / E) of pediatric deaths: The death of a neonate is without doubt the most serious event as an outcome of a birth.

2. The ratio of the observed to the expected rate (O / E) of children with a 5-minute Apgar score < 5: Established decades ago, the Apgar score (Apgar 1953) is a simple instrument used to measure the "vitality" of a newborn infant. The baby's heart rate, respiratory effort, muscle tone, reflex irritability, and skin color are rated with 0 to 2 points. The sum of points gained ranges between 0 and 10, with 10 being the best score. The 5-minute Apgar score especially correlates with later mortality (Casey et al. 2001; Toh 2000; Portman et al. 1990; Nelson et al. 1981; Drage et al. 1964; Apgar 1953) and morbidity (Toh 2000; Portman et al. 1990; Drage et al. 1966). Neonates with scores of < 5 are clearly at higher

risk than those with a higher score (Vahabi et al. 2010; Marrin et al. 1988).

3. The ratio of the observed to the expected rate (O / E) in children with *base excess* < 16 mmol/l: The *base excess* is employed to measure acid-base disorders. Such metabolic disorders often lead to neurological and other late sequelae (Williams et al. 2002; Toh 2000; Low 1997; Low et al. 1995; Low et al. 1994). The *base excess* is determined in the plasma of whole blood and represents an important diagnostic parameter that can provide conclusions about the acid-base balance in the blood. The reference range is -2 to +2 mmol/l. A strongly negative base excess < 16 mmol/l indicates metabolic acidosis, which is often associated with other late sequelae (Goldaber et al. 1991).

4. The ratio of the observed to the expected rate (O / E) in children with acidosis (pH < 7): Other types of acidosis are also associated with high morbidity, although not all children are affected (Sehdev et al. 1997; van den Berg et al. 1996; Gilstrap et al. 1989). Therefore, this is the indicator with the lowest ranking.

All of the mentioned end points were risk adjusted using multinomial logistic regression for the calculation of the quality index. Figure 3 shows the distribution of the hospital-specific frequencies for the "Quality index of premature infant care" (QI-ID 51803). The lightly shaded area represents the result for individual hospitals and the darkly shaded area the lower limit of the 95 % confidence interval according to Wilson (1927). The vertical line marks the computationally discrepant hospitals to the left of the black line; the horizontal yellow line visualizes the discrepancy criterion at an O / E that is above 2.61. The 95 % confidence interval covers results which were better than average at only 2 of the 38 computationally discrepant hospitals. This means that there were only 2 cases where it can be assumed that the result was no worse than average with an estimated probability of > 2.5 %. 11 of the 38 hospitals achieved a result at the same significance level that was at least twice as bad as the average result (Fig. 3). Measured on the study of Dimick et al. (2004), these results show very good discriminatory power: It can be assumed that actual quality deficits to be solved in the Structured Dialogue were also responsible for the computational discrepancies.
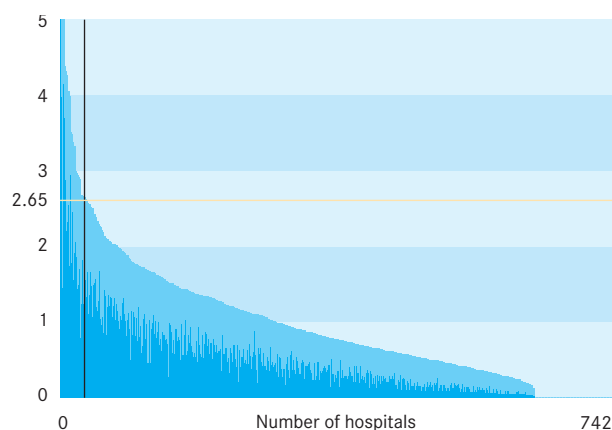

Figure 3: Hospital-specific prevalence of the quality index in mature neonates

Risk adjustment and caseload-prevalence problem

The discriminatory power is much lower when the individual indicators are viewed in isolation. For example, the result occurring with the rarest frequency – death of a neonate – demonstrates a statistically significant result at 3 computationally discrepant hospitals. Even if the indicator with the highest prevalence, the ratio of the observed to the expected rate (O / E) in children with *base excess* < -16, is considered, then only 20 of the 38 hospitals had a significantly poorer result than average on the 95 % level. Hence, this index delivers much more robust results for comparing hospitals without loss of information because the results of the individual indicators are identified separately. Moving forward, the AQUA Institute is therefore also planning to develop quality indices in other clinical areas.

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Secondary data use

Dr. Thomas König

The quality, case completeness and record completeness of the data collected for quality assurance are all high. Thanks to the over ten-year history of external hospital quality assurance, we now also have a large pool of longitudinal data. These quality assurance data are, thus, excellently suited for use in scientific studies on questions outside of the statutory quality assurance pursuant to sections 137ff of the German Social Code, Book Five (SGB V). Consistently, this type of secondary use is also expressly codified in law.

Within the scope of the G-BA resolution on the procedure for the secondary use of data from external hospital quality assurance, the AQUA Institute systematized the handling of secondary data back in 2011.

The application forms co-developed for this purpose by the AQUA Institute are available at *http://www.sqg.de/datenservice/sekundaernutzung*. Every application is subjected to a uniform process, which verifies that the prerequisites are met for scientific, non-commercial use in compliance with all data protection regulations. Provided that the prerequisites stipulated by the G-BA are met, the data collected within the scope of quality assurance can be made available for secondary analysis.

In the past years, the majority of applications for data analysis were submitted from the clinical area Obstetrics. In 2013, the applications covered a more diverse range of subjects across all clinical areas. Overall, seven applications for secondary data analysis were approved by the G-BA in 2013. The specific applications are listed below:

Table: *Applications for secondary data analysis approved by the G-BA in 2013*

Topic	Applicant	Clinical area
Healthcare reality in revision surgery for hip and knee joint replacements in the Federal Republic of Germany	Rüdiger Smektala, University Clinic for Surgery, Department of Trauma Surgery, Knappschafts Hospital Bochum	*Complete revision or component exchange of a hip arthroplasty; Revision or component exchange of a total knee replacement,* data collection years 2006 to 2010
Evidence-based minimum caseload at breast centers	Günther Flämig, Alfried Krupp Hospital, Bochum	*Breast surgery,* data collection years 2006 to 2011
Change in access for hysterectomy in benign indications and evaluation of the complication rates in different surgical methods	Klaus Joachim Neis, Gynecologist Team Staden, Saarbrücken Felix Neis, Gynecology Department, Tübingen University Hospital	*Gynecological surgery,* data collection years 2003 to 2012
Induction of labor after 40+7 weeks of pregnancy to reduce perinatal mortality	Christiane Schwarz, Doctoral Candidate, Witten/Herdecke University	*Obstetrics,* data collection years 2005 to 2013
Determinants for elevated mortality in community-acquired pneumonia	Klaus Richter, Federal Experts' Working Group for Pneumonia, AQUA Institute, Göttingen	*Community-acquired pneumonia,* data collection years 2008 to 2012
Lung transplants – Building blocks for successful therapy	Marc Hartert, Department of Cardiac, Thoracic and Vascular Surgery, University Clinic, Mainz	*Lung transplantation,* data collection years 2004 to 2012
Research contract for volume trending in the G-DRG system	Jonas Schreyögg, Hamburg Center for Health Economics, Hamburg University	All clinical areas, data collection years 2006 to 2012

The following results of secondary data analyses from the applications of previous years were published in 2013:

Ewig, S; Bauer, T; Richter, K; Szecsenyi, J; Heller, G; Strauss, R; Welte, T. (2013). Prediction of In-Hospital Death from Community-Acquired Pneumonia by Varying CRB-Age groups. Eur Respir J 41(4): 917-922

Markewitz, A (2013). Jahresbericht 2011 des Deutschen Herzschrittmacher- und Defibrillatorregisters. Teil 1: Herzschrittmacher. Fachgruppe Herzschrittmacher [2011 Annual Report of the German Pacemaker and Cardioverter Defibrillator Registry. Part 1: Pacemakers. Experts' Working Group for Pacemakers]. Göttingen: AQUA – Institute for Applied Quality Improvement and Research in Health Care

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Results of external hospital quality assurance on nosocomial infections

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Introduction

Infections are termed nosocomial if they demonstrate a chronological relationship to a medical intervention in an inpatient or outpatient setting, i.e., were acquired at healthcare facilities (section 2 of the German Protection against Infection Act (IfSG); Geffers et al., 2002). Even in highly developed healthcare systems like in Germany, nosocomial infections still pose a significant threat to patients. They entail an increased disease burden, which in many cases also results in increased mortality. This problem is exacerbated by the fact that nosocomial infections are induced by bacteria that are resistant to antibiotics more often than other infections. In the healthcare system, nosocomial infections result in high costs due to the need for additional treatments, often involving prolonged or repeated hospital stays (Geffers et al. 2002). Appropriate measures for reducing nosocomial infections and the development of antibiotic resistance include, among others, strict compliance with rules of hygiene and avoiding the inappropriate administration of antibiotics.

A current representative cross-sectional study by the National Reference Center (NRZ) for the surveillance of nosocomial infections of the Robert Koch Institute (RKI) reports the frequency of nosocomial infections in German hospitals at any particular time (point prevalence) to be 5.1 % in fully hospitalized patients, with 3.4 % of all patients acquiring their infection during their current hospital stay (Behnke 2013). Given that about 19.1 million patients are fully hospitalized annually, about 975,000 patients contracted one or more hospital-acquired infections in 2012 (Destatis 2013). With 24.3 %, postoperative wound infections make up the highest proportion of all nosocomial infections. This is followed by urinary tract infections 23.2 %, infections of the lower respiratory tract (pneumonia) 21.7 % and blood poisoning (primary catheter-related sepsis) 5.7 % (Behnke 2013).

For several years, special attention in the healthcare system has been focused on the prevention of nosocomial infections. In addition to other surveillance systems, statutory quality assurance pursuant to section 137a of the German Social Code, Book Five (SGB V) also collects and evaluates data on the occurrence of nosocomial infections and the use of antibiotics in German hospitals related to certain services included in statutory quality assurance. The prevalence of nosocomial infections and the use of antibiotics, classified according to the current quality-assured clinical areas and types of infection recorded in external hospital quality assurance (esQS) are described here. The aim hereby is to help in assessing the health care situation specific to Germany in 2013. In addition to the special chapter in the Quality Report 2012, the AQUA Institute has issued a special report on nosocomial infections, which was published in May 2014 (AQUA 2014).

Methodology

In the following, the results of indicators related to nosocomial infections from the various clinical areas of external hospital quality assurance on the basis of data collection year 2013 are compared with those of the previous years. They are based on data routinely collected and evaluated in all German hospitals. These include infection rates as well as analyses of antibiotic use.

Within the scope of this review, special emphasis will be placed primarily on the federal results of the indicators; further details can be found in the chapters on the respective clinical areas. In addition to the general comparison of the indicator results, individual data fields relating to nosocomial infections and the use of antibiotics in different clinical areas are also presented. These data fields do not primarily form the basis of a specific indicator for nosocomial infections, but are accounted for in the calculation of summarizing indicators, among others (e.g., "postoperative complications"), as part of a sum of different types of complications, including non-infectious ones.

Result

The results of external hospital quality assurance are presented below in the order of prevalence of the individual types of nosocomial infection (Behnke 2013). These are followed by the results for antibiotic use as prophylaxis.

Postoperative wound infections

Postoperative wound infections are typical complications of surgical interventions. With 24.3 %, they constitute today's most common nosocomial infections (Behnke 2013). Wound infection is caused by the penetration of pathogens (mainly bacteria) into a surgical wound via the outer skin layer or the inner mucous membranes. These pathogens proliferate, triggering a local reaction and/or a reaction of the whole body, which in the worst case can result in septic shock and hence in organ failure.

To monitor the occurrence of postoperative wound infections, the RKI recommends that wound infections be classified according to the definition established by the *Centers for Disease Control and Prevention* (CDC). According to this definition, all postoperative wound infections acquired up to 30 days after surgery are considered nosocomial. Deep wound infections after implant operations (e.g., in endoprosthetics and artificial heart valves) are considered nosocomial infections up to 365 days after surgery (NRZ 2011).

The rate of postoperative wound infections varies depending on medical specialization and surgical procedure. The highest wound infection rates occur during abdominal surgery, followed by coronary surgery, vascular surgery and orthopedics/accident surgery (NRZ 2014). In external hospital quality assurance, indicators for postoperative wound infections are currently recorded following orthopedic/trauma and cardiac surgical interventions (see Tables 1 and 2). Colon surgery, which is associated with particularly high postoperative wound infection rates, will only be included in the statutory quality assurance with the proposed new cross-sectoral development "Prevention of nosocomial infections: Postoperative wound infections".

To date, only postoperative wound infections occurring prior to hospital discharge have been recorded in statutory quality assurance. Since, however, the average hospital stay of 8 to 10 days is considerably shorter than the CDC definition intervals for nosocomial postoperative wound infections (30 days or 1 year), the frequency of postoperative wound infections within the scope of external quality assurance is currently underestimated; see also comparison between inhouse and total infection rates in OP-KISS (NRZ 2014). This must be taken into

Results of external hospital quality assurance on nosocomial infections

consideration when interpreting the results – a limitation that can only be eliminated by the proposed cross-sectoral QA procedure, which can ensure adequate follow-up over time.

In 2013, postoperative wound infections in the orthopedic/ trauma surgery clinical areas occurred only rarely during the initial hospital stay (Table 1). This reflects a good care situation. Both after surgery on femoral fractures near the hip joint as well as after total hip and knee replacements, the national averages for data collection year 2013 were not significantly different from those of data collection year 2012, where comparable indicators were available. The risk-adjusted national averages do not differ significantly for those two years either. The rates of postoperative wound infections following orthopedic/trauma surgery derived from external hospital quality assurance in Germany are comparable with the in-house infection rates registered by the German Hospital Infection Surveillance System (KISS) (NRZ 2014) and with the results from Switzerland (Ruef et al. 2013) and Great Britain (HPA 2012).

The two indicators for postoperative wound infections in the clinical area *Total knee replacement – Primary implantation* were suspended in 2012 but continued in 2013. The non-risk-adjusted wound infection rate in data collection year 2013, with a national average of 0.3 %, was at a similarly low level as in data collection years 2011 and 2010.

In 2013, four indicators for postoperative wound infections in the clinical areas *Hip replacement – Revision and component exchange* and *Knee replacement – Revision and component exchange* were discontinued. Instead, a new indicator was introduced into both clinical areas to measure the rate of postoperative wound infections only for all patients without preoperative signs of infection. This resulted in a focus on postoperative nosocomial wound infections. At the same time, these were defined as sentinel events so that now each wound infection recorded by these indicators following revision will also be considered in the Structured Dialogue.

Table 1: Indicators for postoperative wound infections in orthopedics and trauma surgery

Name of the quality indicator	2012		2013				Trend
	Reference range	Result	Reference range	Result	Cases (patients)		
					Numerator (O | E) *	Denominator	
Femoral fractures near the hip joint							
Postoperative wound infections (QI-ID 2274)	n.d.**	1.1 %	n.d.**	1.1 %	1,122	106,795	→
Ratio of the observed to the expected rate (O / E) of postoperative wound infections (QI-ID 50889)	≤ 4.33 (TO)	1.00	≤ 2.84 (TO)	0.99	1,122 / 1.05 %	1,130 / 1.06 %	106,795	→
Hip replacement – Primary implantation							
Postoperative wound infections (QI-ID 452)	n.d.**	0.5 %	n.d.**	0.5 %	734	152,732	→
Ratio of the observed to the expected rate (O / E) of postoperative wound infections (QI-ID 50929)	≤ 5.71 (TO)	1.00	≤ 6.56 (TO)	1.05	734 / 0.48 %	699 / 0.46 %	152,732	→
Total knee replacement – Primary implantation							
Postoperative wound infections (QI-ID 286)		Not calculated, because discontinued	n.d.**	0.3 %	398	127,051	n.a.***
Ratio of the observed to the expected rate (O / E) of postoperative wound infections (QI-ID 51019)		Not calculated, because discontinued	≤ 6.20 (TO)	0.97	398 / 0.31 %	410 / 0.32 %	127,051	n.a.***
Hip replacement – Revision and component exchange							
Postoperative wound infections without preoperative signs of infection (QI-ID 51866)	QI new 2013	1.06 % Retrospective calculation	Sentinel event	1.25 %	140	11,193	→
Knee replacement – Revision and component exchange							
Postoperative wound infections without preoperative signs of infection (QI-ID 51874)	QI new 2013	0.64 % Retrospective calculation	Sentinel event	0.47 %	40	8,477	→

TO = Tolerance range, * for regression-based quality indicators; ** not defined; *** not applicable

Results of external hospital quality assurance on nosocomial infections

In the orthopedic/trauma surgery clinical areas, in addition to the data from external hospital quality as-surance for each post-operative wound infection, the wound infection depth is also recorded in three levels (NRZ 2011) in accordance with the CDC definition of surgical site infections (SSI):

- A1: Superficial incisional SSI
- A2: Deep incisional SSI
- A3: Organ/space SSI

The majority of postoperative wound infections documented after surgery of a femoral fracture near the hip joint or after implantation, revision or component exchange of a hip or total knee replacement were classified as deep wound infections (54 %) or as an infection of an organ (in this case bone) or of a space (in this case joint cavity) (7 %). Only 39 % of the documented wound infections were considered to be superficial incisional SSI. This result did not change significantly over the previous year (Fig. 1). The analyzed results of external hospital quality assurance are consistent with the OP-KISS reference data on surgical site infection depths based on the wound infection rates documented at the participating hospitals (in-house) (NRZ 2014).

Figure 1: Infections by wound depth in the orthopedic/trauma surgery clinical areas
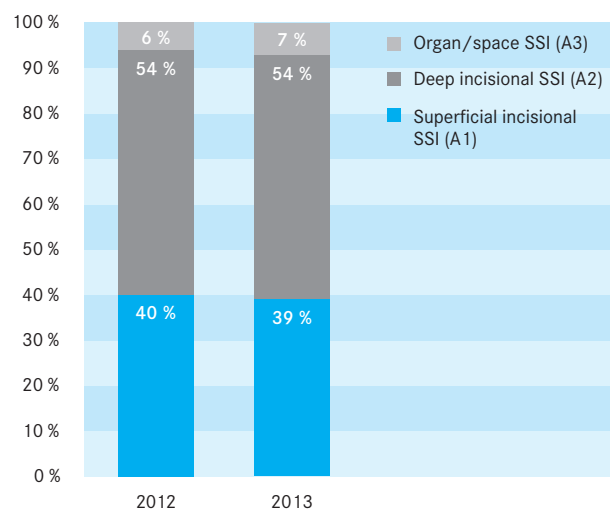
Because of the high morbidity and mortality (Filsoufi et al. 2009), deep wound infection after cardiac surgery – mediastinitis – constitutes a particularly important clinical complication. Here, a serious infection in the chest develops around the heart, between the lungs (mediastinum). In the cardiac surgery clinical areas, two indicators relating to these infections are designated for each of three types of surgery. Here again, post-operative mediastinitis is only recorded if it has developed prior to hospital discharge. Both the risk-adjusted and the non-risk-adjusted indicators showed no statistically significant change over the previous year. The indicators "Postoperative mediastinitis after elective/urgent surgery" (QI-ID 2263, QI-ID 2256 and QI-ID 2283) of the clinical areas *Aortic valve surgery, isolated*; *Coronary surgery, isolated* and *Combined coronary and aortic valve surgery* reveal mediastinitis rates of between 0.2 % and 0.3 % in data collection year 2013. Postoperative mediastinitis in aortic valve surgery was documented least often (0.2 %),

while the rate in coronary surgery and also in combined coronary and aortic valve surgery was slightly higher at 0.3 %. The mediastinitis rates in cardiac surgery recorded within the scope of external hospital quality assurance were comparable to those of KISS (NRZ 2014). Overall rates with follow-up were reported as 1.8 to 3.6 % (Filsoufi et al. 2009; Graf et al. 2009; Lucet et al. 2006); because of the longer observation period, they were markedly higher than the mediastinitis rates observed within the scope of external hospital quality assurance. The indicators for "Postoperative mediastinitis in risk class 0 or 1 (NNIS[1]) (QI-ID 2280, QI-ID 2257 and QI-ID 2284) are risk-adjusted indicators as they only include patients of risk class 0 or 1 (NNIS[1]). In contrast to the non-risk-adjusted indicators, they also include infection rates after emergency surgery.

The frequency of postoperative wound infections can also be illustrated on the basis of the existing data fields for the areas *Pacemakers*, *Defibrillators*, *Obstetrics* and *Breast surgery*. The results show that post-operative wound infections occurred rarely in 2013 and no changes were found over the previous year. The wound infection rate during the initial hospital stay in data collection year 2013 in the clinical area *Breast surgery* was 0.72 % (2012: 0.74 %) and therefore twice as high as the comparable in-house wound infection rate of OP-KISS (0.34 %) (NRZ 2014). In contrast to the esQS, the OP-KISS reference data relate exclusively to voluntarily participating hospitals with at least 30 breast surgery operations (NRZ 2014). In the clinical area *Obstetrics*, the wound infection rate following cesarean section deliveries was 0.13 %. This shows a positive development compared with previous years. Following pacemaker or defibrillator interventions, the wound infection rate was less than 0.1 % (Fig. 2). The Federal Experts' Working Group stated that this low wound infection rate may be explained primarily by the restriction to data collection during primary hospitalization, i.e., by the lack of follow-up.

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[1] NNIS risk index category 0 or 1 (NNIS = National Nosocomial Infections Surveillance): This involves an additive score used for risk adjustment: one risk point is respectively assigned whenever ASA ≥ 3, duration of surgery > 75th percentile of the distribution of the duration of the procedure for the type of surgery under review, and/or the intervention is contaminated or septic.
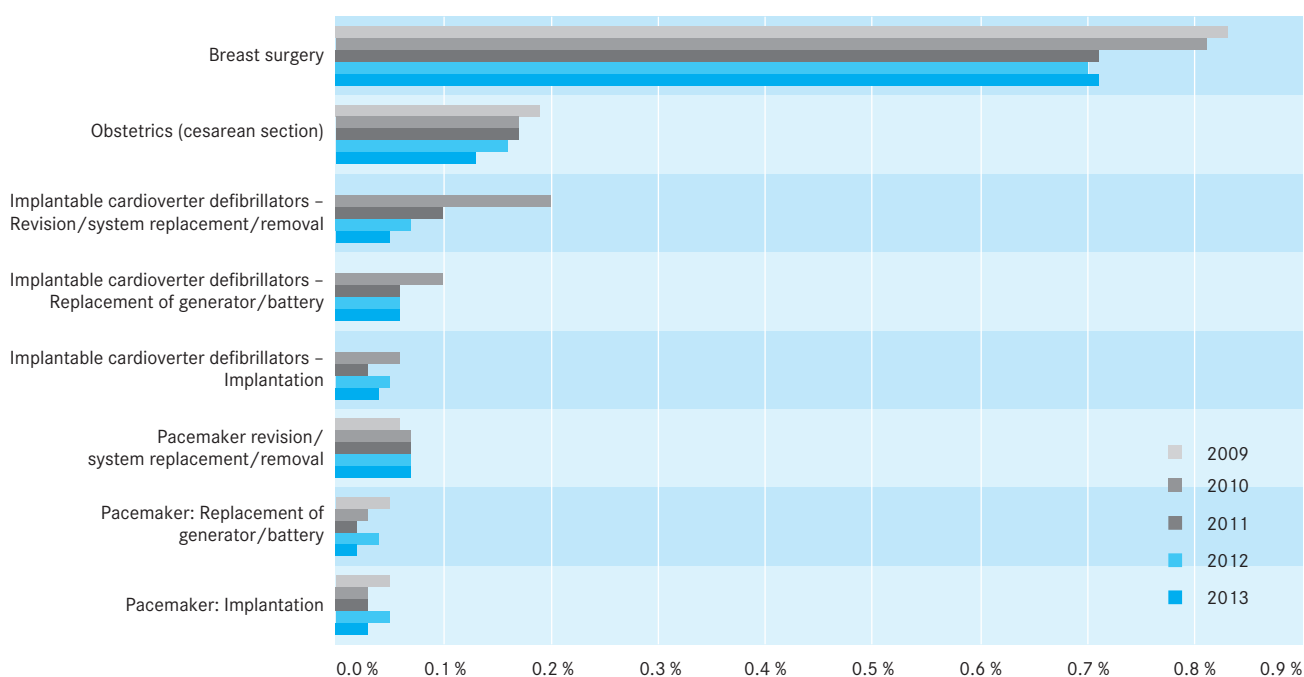
Results of external hospital quality assurance on nosocomial infections

Table 2: Postoperative wound infections in coronary surgery

Name of the quality indicator	2012		2013				Trend
					Cases (patients)		
	Reference range	Result	Reference range	Result	Numerator	Denominator	
Aortic valve surgery, isolated – conventional							
Postoperative mediastinitis after elective/urgent surgery (QI-ID 2263)	n.d.*	0.3 %	n.d.*	0.2 %	19	9,493	→
Postoperative mediastinitis in risk class 0 or 1 (NNIS[1]) (QI-ID 2280)	≤ 1.0 % (TO; 95th percentile)	0.2 %	≤ 1.2 % (TO; 95th percentile)	0.2 %	15	7,719	→
Coronary surgery, isolated							
Postoperative mediastinitis after elective/urgent surgery (QI-ID 2256)	n.d.*	0.4 %	n.d.*	0.3 %	116	33,798	→
Postoperative mediastinitis in risk class 0 or 1 (NNIS) (QI-ID 2257)	≤ 1.2 % (TO; 95th percentile)	0.4 %	≤ 1.3 % (TO; 95th percentile)	0.3 %	97	31,301	→
Combined coronary and aortic valve surgery							
Postoperative mediastinitis after elective/urgent surgery (QI-ID 2283)	n.d.*	0.6 %	n.d.*	0.3 %	20	6,381	→
Postoperative mediastinitis in risk class 0 or 1 (NNIS) (QI-ID 2284)	≤ 2.9 % (TO; 95th percentile)	0.5 %	≤ 2.2 % (TO; 95th percentile)	0.3 %	14	5,204	→

[1] NNIS risk index category 0 or 1 (NNIS = National Nosocomial Infections Surveillance): This involves an additive score used for risk adjustment: one risk point is respectively assigned whenever ASA ≥ 3, duration of surgery > 75th percentile of the distribution of the duration of the procedure for the type of surgery under review, and/or the intervention is contaminated or septic.

TO = Tolerance range; * not defined

Figure 2: Rate of postoperative wound infections (%) – Special assessment of certain data fields collected within the scope of QA documentation

Results of external hospital quality assurance on nosocomial infections

Table 3: Infection as indication for follow-up intervention

| | 2012 | | 2013 | | | | |
| | | | | | Cases (patients) | | |
Name of the quality indicator	Reference range	Result	Reference range	Result	Numerator	Denominator	Trend
Implantable cardioverter defibrillators – Revision/system replacement/removal							
Infection as indication for follow-up intervention (QI-ID 52002)	Not comparable because of restructuring of indicator		≤ 4.3 % (TO; 95th percentile)	1.1 %	400	37,877	n.a.*

TO = Tolerance range; * not applicable

For example, patients only stay an average of three days postoperatively in the hospital following implantation of a pacemaker (according to data from external hospital quality assurance). However, since infections often do not occur until several days or weeks after an intervention, there is also the problem that such infections are not completely documented due to the fact that the inpatient stays are short and analyses in statutory quality assurance have until now exclusively concentrated on the first hospital stay.

In the clinical area *Implantable cardioverter defibrillators – Revision/system replacement/removal*, data are collected on infections in the area of the generator/battery or lead requiring a revision. The indicator "Infection as indication for follow-up intervention" (QI-ID 52002) reflects the proportion of revisions caused by infections within 2 years after the primary intervention in comparison with all primary implantations performed in the same hospital. In 2013, it was 1.1 % (Table 3). This long-term wound infection rate is comparable to the rates described in the international literature (0.48 % to 1.21 %; Klug et al., 2007; Johansen et al., 2011). This indicator was restructured for data collection year 2013 and is therefore no longer comparable with that of the previous year. The newly developed indicator includes infections of the lead up to 1 year and infections of the generator/battery pouch up to 2 years after the primary intervention. It thus encompasses both nosocomial (up to 1 year) and non-nosocomial (after more than 1 year) postoperative wound infections. This "late" postoperative wound infection rate is about 10 times higher than the wound infection rate in the initial hospital stay and expressly points to the need for systematic follow-up data collection.

Urinary tract infections

At 23.2 %, urinary tract infections represent the second largest proportion of all nosocomial infections (Behnke 2013). Usually, these are associated with bladder catheters (transurethral indwelling catheters), which provide a portal of entry for pathogens into the urethra.

Nosocomial, postoperative or postpartum (occurring after birth) urinary tract infections are collected in three clinical areas (*Gynecological surgery*, *Cholecystectomy* and *Obstetrics*) as part of external hospital quality assurance (Fig. 3). These clinical areas involve on average very short periods of hospitalization, a factor that contributes to the low infection rates documented up until discharge.

Overall, the rate of urinary tract infections during the initial hospital stay is low. After laparoscopic cholecystectomy (removal of the gall bladder), the rate of urinary tract infections has remained relatively constant over the years at about 0.2 %. After open cholecystectomy, these infections occurred in 0.9 % of cases in 2013 (2012: 1.1 %). The main reasons for the higher urinary tract infection rate after open surgery are found in patients with poor postoperative health status and longer hospital stay.

After the birth of a child, the rate of urinary tract infections that emerged during hospitalization has also remained constantly low over the years at about 0.1 %. The overall rate after gynecological surgery was several times higher than for the other interventions cited, but decreased steadily from 1.1 % to 0.8 % between 2008 and 2012. In 2013, the rate has again fallen substantially to 0.5 %. However, the change in data collection is responsible for this: Since 2013, patients who have undergone removal of the uterus (hysterectomy) are no longer recorded in the clinical area *Gynecological surgery*. As more postoperative urinary tract infections occur after this intervention than after the other interventions, their exclusion resulted in decrease of the overall rate.
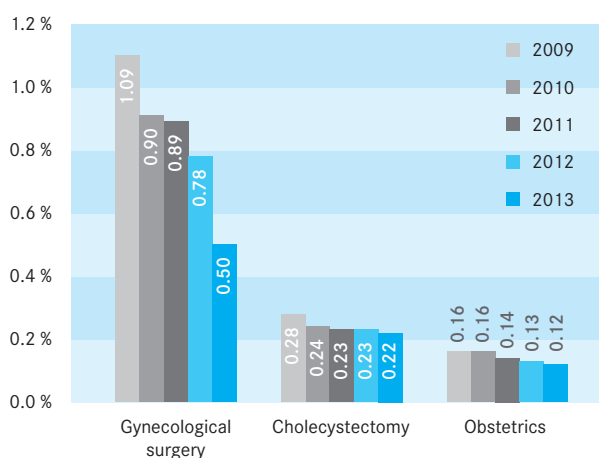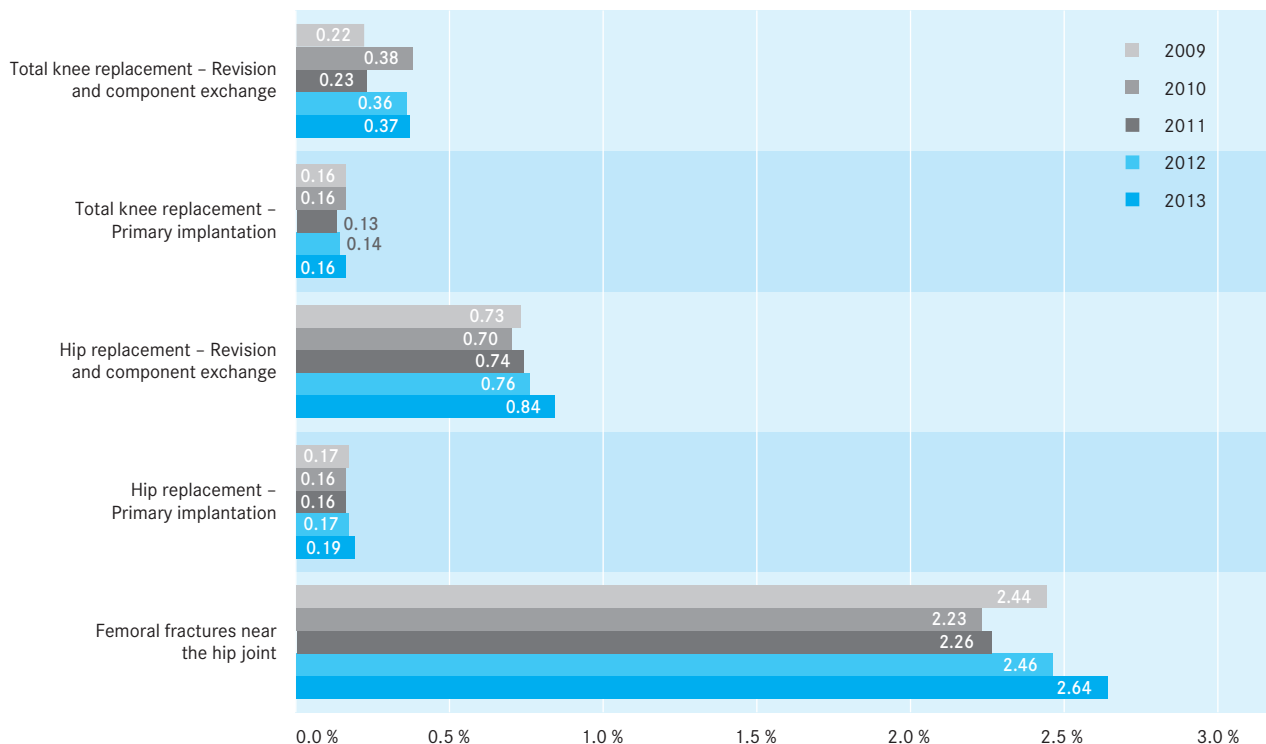

Figure 3: Rate of postoperative/postpartum urinary tract infections (%) – Special assessment of certain data fields collected within the scope of QA documentation

Results of external hospital quality assurance on nosocomial infections

Figure 4: *Rate of postoperative pneumonia (%) – Special assessment of certain data fields collected within the scope of QA documentation. Differences from the data in the 2012 Quality Report may be due to rounding effects or changed target populations and associated recalculations.*

Pneumonia (lung infection)

With 21.7 %, lower respiratory tract infections represent the third largest group of all nosocomial infections (Behnke 2013). Nosocomial lung infections are often associated with artificial ventilation of patients (ventilator-associated pneumonia). They therefore count among the characteristic complications in intensive care units besides urinary and vessel catheter-associated infections (Geffers et al. 2002). Apart from the generally increased risk of infection in artificially ventilated patients, pneumonia may also have other causes. It frequently occurs in immunocompromised and mainly older, bed-ridden patients, in whom perfusion and ventilation of the lungs as a whole deteriorates due to immobility, which in turn can promote the proliferation of invading pathogens.

Among the nosocomial infections, pneumonia should be singled out not only due to the frequency of its occurrence, but also because it is associated with both significantly longer periods of hospitalization – e.g., in intensive care units – as well as with increased mortality (Geffers et al. 2002).

In the orthopedic/trauma surgery clinical areas, substantially more cases of postoperative pneumonia occur following surgery on femoral fractures near the hip joint than following elective hip or knee replacements. In the last three years, the postoperative pneumonia rate following surgery on femoral fractures near the hip joint has increased constantly from 2.26 % (2011) to 2.64 % (2013) (Fig. 4). This increase is associated with a continuous growth in the proportion of patients over 90 years of age from 15.9 % in 2011 to 16.5 % in 2012 and 17.0 % in 2013. Accordingly, the proportion of severely ill patients (ASA 3 and above) increased from 71.9 % in 2011 to 73.2 % in 2012 and 73.3 %

in 2013. Subsequent to statistical testing and in the opinion of the Federal Experts' Working Group, the increase in the rate of pneumonia over the last three years cannot be explained entirely by a change in the risk structure of the patient population. The older age of patients and the increasing severity of the disease both point to the increased significance of pneumonia prevention measures (e.g., breathing exercises, mobilization). In order to be able to improve the healthcare situation related to postoperative pneumonia following femoral fracture near the hip joint through targeted benchmarking and a Structured Dialogue, the AQUA Institute recommends the introduction of an appropriate indicator in this clinical area.

The annual comparison reveals that the calculations for the primary implantation of hip or total knee replacements show consistently low postoperative pneumonia rates of up to 0.2 % (Fig. 4). The postoperative pneumonia rates following (component) exchange of a total knee replacement are twice as high as after primary implantation of the replacement concerned and about four times as high in the case of a total hip replacement.

Sepsis in neonates

Healthy neonates cared for in the maternity ward's "nursery" during the first few days after birth are not counted. In neonates, infections occurring later than 72 hours after birth (*late onset*) during inpatient treatment are considered nosocomial. The indicators in the clinical area *Neonatology* describe the number of infections or the number of infected neonates per 1,000 treatment days in the hospital. While the results of the risk-adjusted indicators for nosocomial septic infections in 2012 were already 14 % (QI-ID 50060) and 18 % (QI-ID 50061) lower than those in 2011, in 2013 they again fell slightly, albeit

Results of external hospital quality assurance on nosocomial infections

Table 4: Indicators for nosocomial infections in neonates receiving inpatient treatment (without neonatal transfer)

Name of the quality indicator	2012		2013				Trend
					Cases (patients)		
	Reference range	Result	Reference range	Result	Numerator (O | E)	Denominator	
Neonatology							
Children with nosocomial infections per 1,000 treatment days (without relocated children) (QI-ID 51085)	n.d.*	1.11	n.d.*	1.08	1,581	1,459.4 TD[1]	→
Ratio of the observed to the expected rate (O / E) of children with nosocomial infections per 1,000 treatment days (without relocated children) (QI-ID 50060)	≤ 2.25 (TO; 95th percentile)	1.00	≤ 2.48 (TO)	0.95	1,581 1.08	1,672 1.15	1,459.4 TD	→
Number of nosocomial infections per 1,000 treatment days (without relocated children) (QI-ID 51086)	n.d.*	1.31	n.d.*	1.26	1,845	1,459.4 TD	→
Ratio of the observed to the expected rate (O / E) of number of nosocomial infections per 1,000 treatment days (without relocated children) (QI-ID 50061)	≤ 2.23 (TO; 95th percentile)	1.00	≤ 2.33 (TO)	0.92	1,845 1.26	2,004 1.37	1,459.4 TD	→

TO = Tolerance range; * not defined   [1] 1,000 Treatment Days

not significantly (Table 4). Statistically, 1.08 neonates suffered from nosocomial sepsis per 1,000 treatment days in 2013 (QI-ID 51085). Since some neonates suffered successive multiple septic infections during their hospital stay, the average number of nosocomial septic infections per 1,000 treatment days was 1.26 in 2013 (QI-ID 51086). Overall, the results in this clinical area show an unchanged quality of care compared to the previous year.

Transplantations

Infections are particularly dangerous for patients with organ transplantations as they are taking drugs that weaken the functions of the immune system (immunosuppressives) in order to prevent organ rejection.

In Germany between 2009 and 2013, a total of 2,069 patients (isolated) received a lung transplant. About 9.2 % (190) of these patients died during their initial hospital stay. About one in eight of these deaths was due to infections. Despite the increased risk of infection, the proportion of patients who died from an infection during their initial hospital stay after lung transplantation is still comparatively small. While the proportion of infection-related deaths following lung transplantation has remained at about the same level over the years, the total proportion of deaths following lung transplantation has increased slightly (Fig. 5).

Antibiotic prophylaxis

For interventions with a high risk of infection, preventive antibiotics (antibiotic prophylaxis) are recommended to reduce the risk of postoperative wound infections occurring. Guideline-compliant antibiotic prophylaxis – that considers the indication, choice of suitable drug, timing, dosage and duration of anti-

biotic administration – is moreover an important component for preventing the development of resistant pathogens. In external hospital quality assurance, data on perioperative antibiotic prophylaxis in approx. 640,000 interventions and births with premature rupture of fetal membranes are collected and measured by indicators (Table 5).
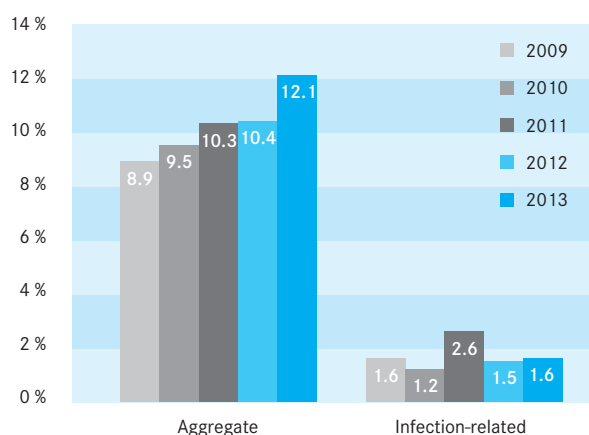
Figure 5: Death rate after lung transplantation (%) – Special assessment of certain data fields collected within the scope of QA documentation

In the clinical area *Obstetrics*, the administration of antibiotics within 24 hours of premature rupture of fetal membranes (QI-ID 50046) and perioperative antibiotic prophylaxis for cesarean section delivery (QI-ID 50045) are documented. Premature rupture of fetal membranes can promote ascending infections from

Results of external hospital quality assurance on nosocomial infections

Table 5: Indicators for perioperative antibiotic prophylaxis

| Name of the quality indicator | 2012 | | 2013 | | | | |
| | Reference range | Result | Reference range | Result | Cases (patients) | | Trend |
					Numerator	Denominator	
Obstetrics							
Antibiotics for premature rupture of fetal membranes (QI-ID 50046)	n.d.*	84.0 %	≥ 95.0 % (TA)	85.9 %	3,480	4,051	→
Perioperative antibiotic prophylaxis for cesarean section delivery (QI-ID 50045)	≥ 90.0 % (TA)	95.5 %	≥ 90.0 % (TA)	97.4 %	204,814	210,388	↗
Femoral fractures near the hip joint							
Perioperative antibiotic prophylaxis in endoprosthetic care (QI-ID 10364)	≥ 95.0 % (TA)	99.6 %	≥ 95.0 % (TA)	99.6 %	48,155	48,329	→
Perioperative antibiotic prophylaxis in osteosynthetic care (QI-ID 10361)	≥ 96.4 % (TO; 5th percentile)	98.9 %	≥ 96.4 % (TO; 5th percentile)	99.0 %	56,730	57,299	→
Hip replacement – Primary implantation							
Perioperative antibiotic prophylaxis (QI-ID 265)	≥ 95.0 % (TA)	99.7 %	≥ 95.0 % (TA)	99.7 %	152,282	152,732	→
Hip replacement – Revision and component exchange							
Perioperative antibiotic prophylaxis (QI-ID 270)	≥ 95.0 % (TA)	99.6 %	≥ 95.0 % (TA)	99.7 %	26,496	26,570	→
Total knee replacement – Primary implantation							
Perioperative antibiotic prophylaxis (QI-ID 277)	≥ 95.0 % (TA)	99.6 %	≥ 95.0 % (TA)	99.7 %	126,680	127,051	→
Knee replacement – Revision and component exchange							
Perioperative antibiotic prophylaxis (QI-ID 292)	≥ 95.0 % (TA)	99.6 %	≥ 95.0 % (TA)	99.8 %	17,281	17,320	→

TO = Tolerance range; TA = Target range; * not defined

the lower genital tract. Such infections can result, for example, in premature births, which in turn are associated with an increased risk of further complications. In this case, administration of antibiotics in a timely manner can have a preventive effect. The proportion of patients receiving antibiotic prophylaxis in this indication is 85.9 % in terms of the national average. It thus remains well below the defined reference range of ≥ 95 % and has not significantly changed over the previous year. Delivery by cesarean section is associated with a high risk for the mother of developing an infection after childbirth. The national value for the indicator "Perioperative antibiotic prophylaxis for cesarean section delivery" (QI-ID 50045) in 2013 was 97.4 % and thus significantly higher than in the previous year (95.5 %).

As mentioned before, hysterectomies (i.e., removals of the uterus) have no longer been recorded in the clinical area *Gynecological surgery* since data collection year 2013. For this reason, the indicator "Antibiotic prophylaxis in hysterectomy"

(QI-ID 235), which was still recorded in the previous year, has been dropped and not replaced.

In the orthopedic / trauma surgery clinical areas, a total of six indicators are recorded for perioperative antibiotic prophylaxis. The unchanged results compared to the previous year (99.0 – 99.8 %) reflect a very high level of the medical indication for antibiotic prophylaxis.

For all indicators for antibiotic prophylaxis, however, one limitation must be noted in that the QA documentation records whether antibiotic prophylaxis was administered, but not which antibiotic was given. An extension of data collection in this respect is being discussed this year in conjunction with system maintenance.

In addition to the indication for antibiotic prophylaxis, the frequency of antibiotic treatment is regarded as an important as-

Results of external hospital quality assurance on nosocomial infections
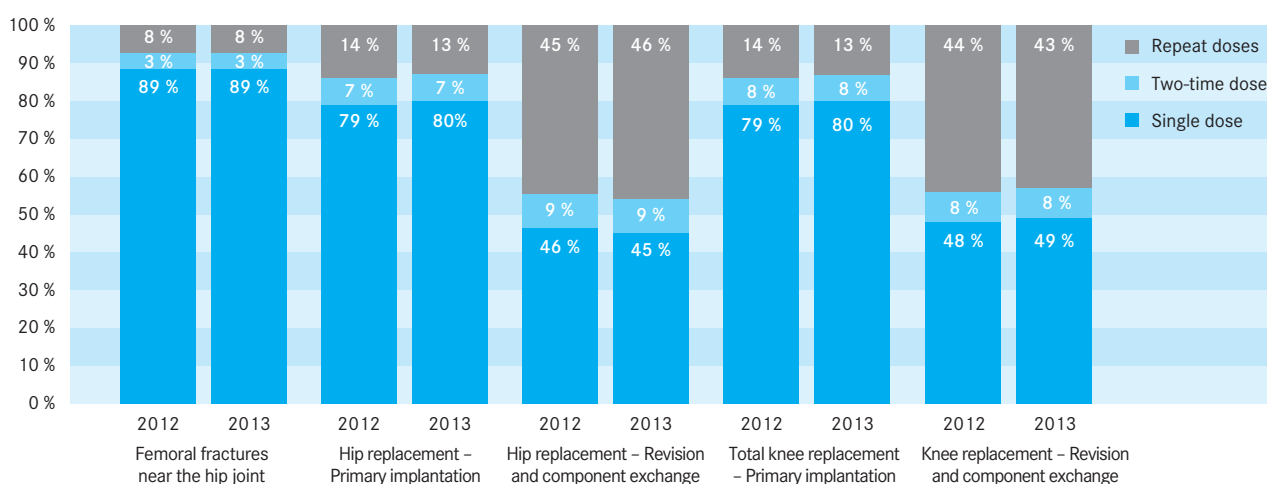
Figure 6: Comparison of proportions of frequencies of prophylactic antibiotic administration in the orthopedic/trauma surgery clinical areas in 2012 and 2013 – Special assessment of certain data fields collected within the scope of QA documentation

pect of guideline-compliant treatment. According to the guidelines, a single dose of certain antibiotics is usually sufficient for effective prophylaxis (AWMF 2012; Wacha et al. 2010). Although a second dose may be indicated during longer surgery times (usually more than 4 hours), any administration of prophylactic antibiotics beyond this should be avoided as it may promote the development of resistant hospital bacteria.

In many cases, however, antibiotic prophylaxis is administered longer than this at German hospitals (Hohmann et al. 2012). Analysis of the corresponding data fields from external hospital quality assurance has yielded this conclusion as well. In data collection year 2013, between 8 % and 45 % of patients received more than two prophylactic antibiotic treatments in the orthopedic/trauma surgery clinical areas (Fig. 6). Compared with the previous year, no relevant differences are observed in the frequency of prophylactic antibiotic administration. Especially in revision surgeries, prophylactic antibiotics seem to be administered more frequently over longer periods.

Synthesis and looking forward

In this overview, the data on nosocomial infection rates and on the use of antibiotics in external hospital quality assurance are presented for the second time. These data have been recorded for many years; they currently consist of many hundreds of thousands of cases in the areas of orthopedics/trauma sur-gery, cardiovascular surgery, gynecology, obstetrics and neonatology from all hospitals licensed pursuant to section 108 SGB V. They are primarily used for quality assurance in relation to postoperative wound infections and postoperative pneumonia.

However, data on postoperative urinary tract infections or nosocomial sepsis are also collected in individual clinical areas. The results are essentially comparable with the hospital infection rates of other surveillance systems (e.g., OP-KISS) in Germany (NRZ 2014). They show largely unchanged low infection rates during hospital stays over recent years.

When comparing the results of 2013 and 2012, attention should be drawn to the fact that the rate of nosocomial pneumonia following orthopedic surgery is tending to increase, but this is due largely to a different age and risk distribution. Essentially, what is apparent is that the risk of postoperative infection depends on the type and extent of surgery as well as on age.

In international comparision, the results point to a fundamentally good care situation in Germany, yet further improvements are possible (ECDC 2013). The risk of nosocomial infections increases with the patient's age. Against the background of demographic change and the increased emergence of resistant bacteria, an increase in nosocomial infections must therefore be expected in future unless effective countermeasures are adopted. Since many years, it is known that the excessive use of antibiotics in patient care in hospitals has contributed to the increased development of bacteria resistant to multiple antibiotics, i.e., multiresistant pathogens. Data from external hospital quality assurance show again that properly indicated perioperative antibiotic prophylaxis is indeed administered in a very high number of cases, but the potential for improvement exists to the extent that sensible antibiotic prophylaxis should not be continued for an unnecessarily long period.

The available external hospital quality assurance data also show the methodological limits of existing data collection instruments and, hence, the limitations in the assessment of quality of care. Only those infections diagnosed during the primary hospital stay can be documented within the scope of external hospital quality assurance. Data on infections acquired in the hospital, but not manifesting in the outpatient setting until after hospital discharge or during rehospitalization have not been systematically collected in any German surveillance system to date. In view of the increasingly shorter hospital stays, this aspect gains particular weight. Moreover, the incubation period for deep nosocomial wound infections after implant surgery (e.g., total hip replacements) as defined by the CDC can be up to one year. Against this background, the G-BA commissioned the AQUA Institute to develop two quality assurance procedures

Results of external hospital quality assurance on nosocomial infections

on the prevention of nosocomial infections (vessel-catheter associated infections and postoperative wound infections). The occurrence of postoperative wound infections can be recorded over the complete definition interval of nosocomial wound infections (up to 1 year after surgery). In addition to wound infection rates, hygiene-related processes among healthcare providers will also be considered in the planned procedure. The final reports of both developments have already been approved by the G-BA and published (AQUA 2012; AQUA 2013). The further development stages commissioned by the G-BA are currently underway – feasibility testing and empirical testing of the health insurance claims data included.

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Presenting the quality of care in preterm infants transparently online

Teresa Thomas, Stefanie Konheiser, Priv.-Doz. Dr. Günther Heller

Background

Every year, around 9,000 children are born weighing less than 1,500 g. Ensuring good care in the treatment of preterm infants with very low birth weight is of significant importance. That is the reason why these children are treated in specially equipped intensive care units for preterm infants (*Neonatal Intensive Care Units*, NICU). For several years now, these Level I and II perinatal centers had been required to publish data on quality assurance and outcome quality of the prior 5 years based on neonatal collection data (Phase A). However, relevant evidence suggested major deficiencies in data collection: For example, documentation of preterm infant deaths has tended to be incomplete in the past years (Hummler et al. 2011). Yet, conclusive statements about the quality of care can only be made on the basis of reliable data and completely counted records and cases.

The AQUA Institute was therefore commissioned by the G-BA in March 2011 to describe results relating to the quality of care at Level I and II perinatal centers in layman terms and make them available on a publically accessible website (Phase B, project: NICU website). Supplementing cases of death based on inpatient claims data should guarantee valid conclusions regarding the quality of care.

Target groups

The NICU website is intended for various target groups:

- The website is primarily aimed at expectant parents. When confronted with the fact that they might potentially suffer a premature birth, they can access information and decision-making aids to help them find a suitable hospital.
- Other target groups are the contracted physicians and insurance companies. The website can give them orientation for the further treatment of pregnant women.
- Furthermore, perinatal centers are a target group. They are offered the opportunity to present the quality of their performance transparently as well as in a risk-adjusted manner and to compare each other among themselves.

Timeline and methodology

Since February 2014, the website *www.perinatalzentren.org* has been available with the following information on the quality of care of perinatal centers:

1. Number of treated preterm infants with very low birth weight
   – < 1,250 g
   – between 1,250 – 1,499 g

2. Survival of preterm infants

3. Survival of preterm infants without serious diseases (cerebral hemorrhage, colitis requiring surgery, retinopathy requiring laser or cryotherapy as well as chronic lung disease requiring supplemental oxygen at home following discharge)

4. Record completeness analysis of the development diagnostic follow-up examination at the maturity-corrected age of 2 years

Hospital-derived figures from the last 5 years are required to compute quality data. These are transmitted once a year to the AQUA Institute by the respective State Administrative Office for Quality Assurance (LQS) and/or by the responsible State Chambers of Physicians (LÄK). This does not entail any great extra cost since both the LQS and LÄK are already in possession of the data from the voluntary neonatal data collection and from the clinical area *Neonatology*.

Finally, the completely counted mortality data will undergo data validation by cross-checking against external claims data pursuant to section 21 Hospital Remuneration Act (KHEntgG). Using Merge Tool Box record linkage software (Schnell et al. 2005), the raw data are supplemented by deaths from claims data not assignable to any cases from the neonatal collection.

In order to enable a fair comparison of the hospitals and account for the different risk profiles of the patients treated, the data on quality are analysed using logistic regression. This accounts for relevant factors potentially affecting the result of quality data like weight at admission or gender.

Website design

The quality information for the website is prepared giving specific consideration to the different levels of knowledge of laypersons and experts. The start page features the option to search for a hospital geographically by entering a postal code or the name of a city or by restricting the search to a certain distance from the designated location. The results overview gives the layperson an easy-to-understand comparison of hospitals in relation to the quality data mentioned (Fig. 1).

For illustration purposes and to comparatively estimate the quality of care, the data are presented in bar charts. Additionally, the national average and the national minimum and maximum are displayed next to the hospital's result. The results can be sorted in ascending or descending order or a new search started. An accompanying glossary explains the key terms, while the search result is graphically displayed on a map of Germany.

The quality data for physicians, other medical specialists and experts are presented in varying degrees of detail (Fig. 2). A bar chart presents the result for the selected hospital in comparison with the national average. The confidence intervals for the determined values are indicated in the expert information. Moreover, a graphical display of the frequency distribution of data (histogram) shows how the results of all hospitals compare with the selected one. A variance diagram illustrates the survival rate and the distance for the selected hospital. That way the reader can tell at a glance how much it would cost (distance it would take) to reach a hospital with better outcomes.

Besides comparing the quality of the hospitals, the website also provides the layperson with easy-to-understand information on premature birth and data on the origin of and/or computation method for the data used. The website provides the specialist audience with expert information on the timeline and methodology of the project.

Presenting the quality of care in preterm infants transparently online

Current trends

On February 28, 2014, the website went online for the first time and the response was very positive. The participation of hospitals in the centralized publication of results is voluntary: Currently, outcome data on 90 of the approx. 180 to 200 perinatal centers are published on the portal.

Within the scope of voluntary publication of results, deaths were cross-checked against claims data pursuant to section 21 KHEntgG. However, the result was only reported to the hospitals. The deviations occurring are intended to be clarified with the affected perinatal centers during routine operation by means of a special data validation procedure.

Publication of the website triggered intense discussions in the medical community. In particular, suggestions were made to establish routine operation as quickly as possible in order to map all perinatal centers. Moreover, it was recommended that further development also consider the transfer/referral experience which cannot be mapped within the scope of present quality assurance.

On February 28, 2015, the results of data collection years 2009 – 2013 from the voluntarily participating hospitals were published on *www.perinatalzentren.org*. The G-BA is planning a routine operation involving mandatory participation of all perinatal centers starting in 2015 to enable publication of the results on data collection years 2010 – 2014 as soon as possible.

Conclusion and looking forward

The adequate care of preterm infants with very low birth weight has long been in the spotlight of health services research and policy. Here, the central question is who can provide the most optimal care of these children. A high validity and reliability of the data as well as risk-adjusted analysis are all required to guarantee a fair comparison of the results. The website primarily aims to contribute to elevating transparency and comparability with regard to the quality of care. Together with a presentation of results geared towards laypersons, the website takes a new and further step in the direction of more quality transparency.
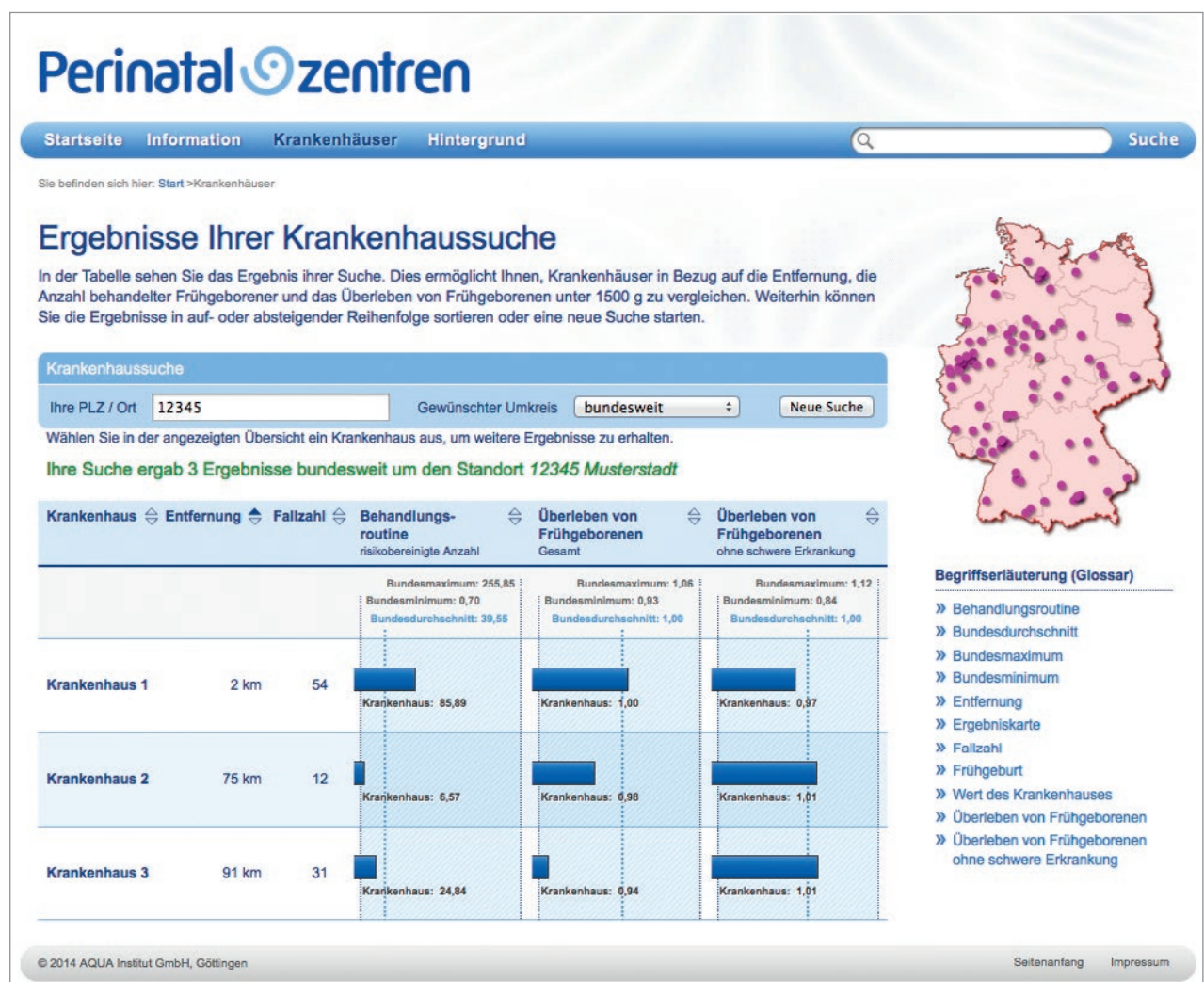
Figure 1: *How the overview of results is presented*

Presenting the quality of care in preterm infants transparently online
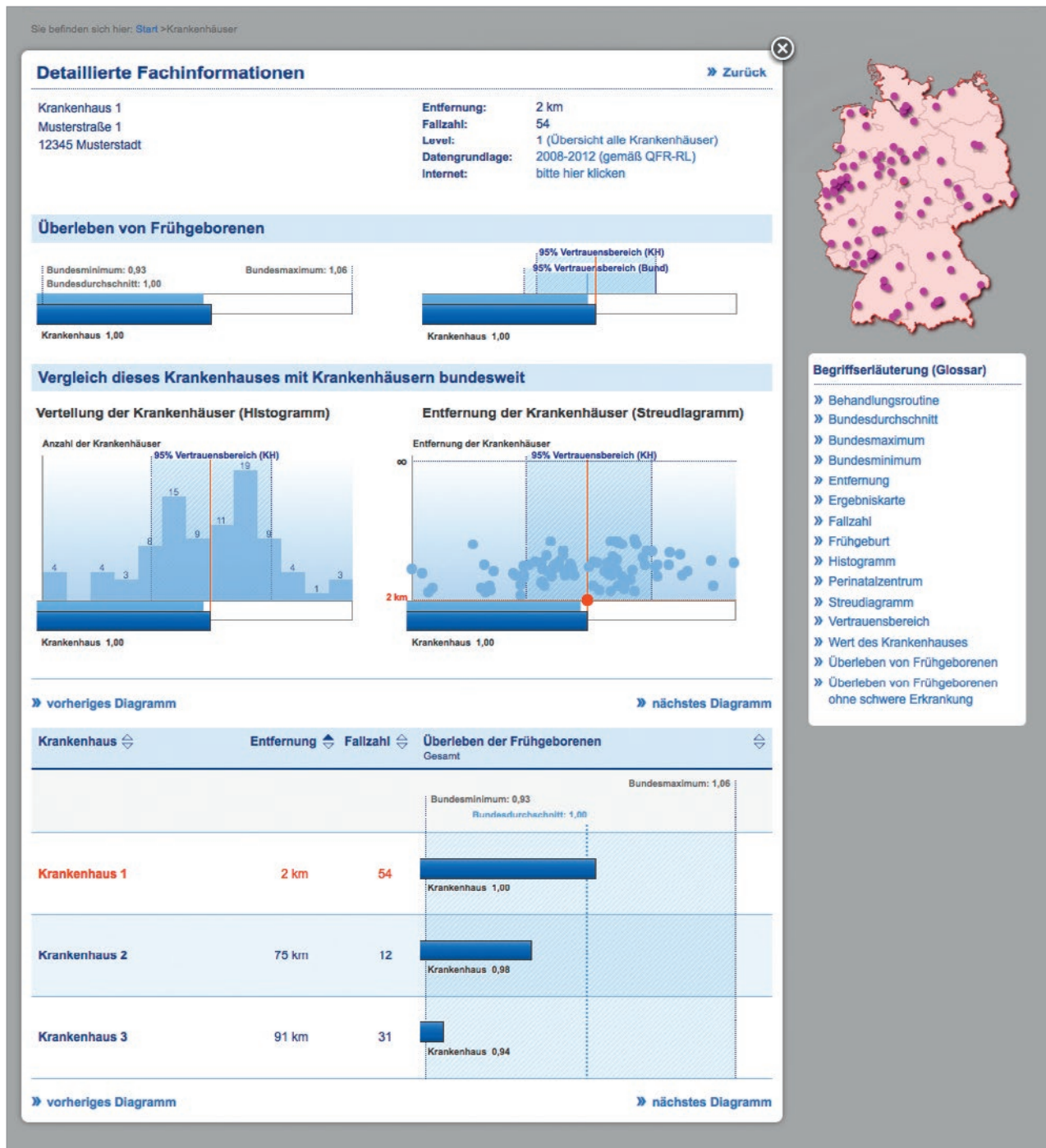
Figure 2: *How information for experts is presented*

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From the hospital onto the Web — making quality assurance data public

Robert Deg, Linda Barnewold, Uta Buch

Transparency is one of the most important demands that both politics and numerous lobbyists and advocates in the health-care system place on quality assurance. Since 2005, hospitals have been required to publish their results on quality indicators subject to mandatory reporting. The legal basis for this is anchored in the regulations governing the hospitals' quality report (Qb-R) defined by the Federal Joint Committee (G-BA).

The hospital quality reports have often been the subject of criticism. The reason behind this is that the results are outdated because hospitals only have to make their results public at two-year intervals. The G-BA modified the corresponding legislative amendment and shortened the intervals for annual reporting. Another point of criticism was that proportionately little information was known from the hospitals. In 2008, the at that time responsible BQS Institute for Quality and Patient Safety in Health Care recommended 29 quality indicators for public reporting. The G-BA responded in this concern and commissioned the AQUA Institute with examining all indicators (see chapter "Public reporting at hospital level"). Based on this, AQUA Institute recommended to the G-BA indicators suitable for publications. The G-BA followed this recommendation and this resulted in a total of 295 indicators being subject to mandatory reporting in data collection year 2013.

As previously mentioned, since many years all hospitals are obligated to prepare and publish quality reports. Since data collection year 2012, the reports are no longer transmitted and published as PDFs. Health insurance companies are still required to post their quality results on the Internet in compliance with the G-BA's specifications. Moreover, hospitals continue to have the option to publish their quality reports on a voluntary basis, e.g., on their own homepage. These QA data, however, can also be used by health companies and other organizations.

Collecting QA data

The G-BA defines in a directive, which clinical areas have to be documented nationwide by hospitals. In data collection year 2013, quality assurance comprised a total of 30 clinical areas. The AQUA Institute defined specifications as to how documentation is to be structured in the respective clinical areas. With regard to system maintenance and the further development of external hospital quality assurance, the AQUA Institute is advised by the Federal Experts' Working Groups where patient representatives and experts from various disciplines are represented.

Delivery – direct and indirect

Depending on the clinical area, the hospitals deliver their QA documentation directly or indirectly through the State Administrative Offices for Quality Assurance (LQS) to the AQUA Institute as the institution pursuant to section 137a SGB V.

Data processing and the Internet

Data collection in the hospital and posting on the Internet takes more than one year. This will be explained with the example of data from the data collection year 2013. The delay arises from the following necessary steps: Delivery of data (by March 2014), data testing, computation of quality indicators, evaluation of the results (by June 2014), conduct of the

Structured Dialogue in cases of computational discrepancies (closure by October 2014) and final evaluation. Finally, the data (December 2014) are forwarded to the Information Technology Service Center of the Statutory Health Insurance (ITSG).

In addition to QA data, the hospitals also collect structural data (bed capacity, number of physicians etc.) and transmit these to the ITSG, which, in turn processes these data for further use as commissioned by the G-BA. Structural data, like QA data, are provided to the ITSG (15 December 2014).

After performing these necessary steps (starting January 2015) the QA results are available for publication. The ITSG then makes the quality reports available unchanged to the organizations and institutions in section 6 Qb-R, including the G-BA as well. Upon receipt and without delay, the G-BA reproduces and transmits the data at the same time to the German Hospital Association, the National Association of Statutory Health Insurance Physicians, the German Federal Association of Sick Fund Dentists, the patient representative organizations and self-help organizations for chronically ill and handicapped persons pursuant to section 140 SGB V and to the additionally participating organizations pursuant to section 137 SGB V. Moreover, the suppliers of hospital guidebooks can procure information from the G-BA and use it on their websites (Fig. 1).

From the hospital onto the Web — making quality assurance data public

Table 1: Selection of internet sites that include results of statutory quality assurance:

Quelle	Link
General Statutory Health Insurance Fund (AOK)	www.aok-gesundheitsnavi.de
BARMER GEK	weisse-liste.barmer-gek.de
The Bertelsmann Foundation and umbrella organizations of patient advocate organizations	www.weisse-liste.de
Company health insurance funds (Betriebskrankenkassen, BKK)	www.bkk-klinikfinder.de
German Health Insurance Company for Salaried Employees (Deutsche Angestellten Krankenkasse, DAK)	www.dak-krankenhauskompass.de
German Hospital Association and State Hospital Associations	www.deutsches-krankenhaus-verzeichnis.de
Health Insurance Fund for Commerce (hkk)	weisse-liste.krankenhaus.hkk.de
Hanseatic Health Insurance Fund (HEK)	klinikfinder.hek.de
HKG Health Services	www.hamburger-krankenhausspiegel.de
Ruhr Initiative Group	www.kliniken-rhein-ruhr.de
Commercial/clerical statutory health insurer (Kaufmännische Krankenkasse, KKH)	klinikfinder.kkh.de
Hospital Association of the Free Hanseatic City of Bremen (HBKG)	www.bremer-krankenhausspiegel.de
Rhineland Special Purpose Association	www.klinikfuehrer-rheinland.de
Technicians' Health Insurance Fund (TK)	www.tk.de/tk/klinikfuehrer
Association of Health Insurance Companies (vdek)	www.vdek-kliniklotse.de
Association of Private Health Insurance Companies (PKV)	www.derprivatpatient.de/services/krankenhaussuche
4QD – Qualitätskliniken.de	www.qualitaetskliniken.de

Hospital: Data collection
(2013)

QA data — **Structural data**

AQUA/LQS: Data processing
Data entry by March of the following year (2014)

AQUA/LQS: Structured Dialogue
Concluded by end of October of the following year (2014)

ITSG: Merging of the data
Data entry by end of the following year (Dec 15, 2014)
Provision to recipients pursuant to section 6 Qb-R (Jan 31, 2015)

G-BA: Provision (e.g., for Internet portals)
QA and structural data jointly available starting January 31 (2015)

"Publication on portals"
(e.g., via health insurance companies)

Figure 1: Timeline – Example from data collection year 2013

Status and perspectives of quality assurance

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Statutory quality assurance is constantly subject to increasingly higher requirements. The necessary realignment of quality assurance towards a cross-sectoral perspective commenced in 2009 has not been concluded yet. Nevertheless, new tasks are already being discussed, for example, in connection with hospital financing and planning. This stands in contrast with the criticism that quality assurance has long been confronted with, its costs being too high and its benefits too low.

Hence, it appears appropriate to put under greater scrutiny how the quality assurance of the past years has further developed, which deficits still exist and what conclusions can be drawn for the future. This discussion focuses on four central quality assurance objectives:

- Quality verification and improvement
- Fair and conclusive comparisons of hospitals
- Transparency and orientation for users
- Improvement in cost-benefit ratios

Quality verification and improvement

The central objectives of quality assurance are to promote and improve quality where deficits have been identified and to maintain the existing high-level quality of treatment.

Results of quality assurance

In order to test whether the objectives of quality assurance have, in fact, been achieved, the quality assurance measures that were introduced pursuant to section 137b of the German Social Code, Book Five (SGB V) should be evaluated for effectiveness. From that, the recommendations should be drafted for cross-sectoral and cross-disciplinary quality assurance in the healthcare system that is aligned along uniform principles, including its implementation. Concrete projects on quality assurance evaluation, however, are still pending.

This is why, at present, the evaluation can only be carried out based on the results and evidence obtained from quality assurance itself. Judging on this basis, the objectives of quality assurance have been fulfilled in broad areas: For most quality indicators, the general quality level is high and, moreover, improvements continue to be achieved in many areas (e.g.,for 40 quality indicators in 2013).

Since all healthcare providers are required to participate in quality assurance measures, it is not methodologically possible to differentiate the influence of quality assurance from general trends. Thus, the question as to whether comparable results would have been achieved without established quality assurance measures and/or what exact share quality assurance had in the achieved results, cannot be answered at this time. To do so, evaluation projects would be necessary with adequate study designs that are implemented either before or while establishing a QA procedure.

Quality improvement

Individualized, healthcare provider-specific analyses of the results of quality indicators and supplementary data build the foundation for all quality assurance measures. Initially, they are aimed at all hospitals and intended for use, for example, within the scope of each provider's internal quality managements.

More extensive measures are aimed at providers that produce discrepant results in their quality indicators. How these measures are concretely designed varies depending on the guideline, but generally involves initiating a process that helps clear up the discrepancies, thereby enabling the introduction of suitable measures to improve quality.

In the inpatient quality assurance sector, responsibility for implementing quality assurance measures (there: "Structured Dialogue") is distributed across the federal or state levels, depending on the clinical area. Ten of the 30 clinical areas in total are managed directly by the AQUA Institute within the scope of the Structured Dialogue. This is because implementation on the state level does not seem to make sense, given the comparatively small caseloads (transplantations, coronary surgery). In the past, there was a problem in that each of the responsible parties would interpret and implement the guideline-specified measures and evaluation categories in varying ways. That limited comparability of the results on the federal level.

For that reason, the **evaluation procedure after conclusion of the Structured Dialogue was modified** in collaboration with representatives of the State Administrative Offices for Quality Assurance (LQS). This modified evaluation was used for the first time in calendar year 2013. The aim was to achieve the most clear-cut allocation to the categories "qualitatively non-discrepant" and "qualitatively discrepant" and thereby facilitate comparisons on the federal level. Besides harmonizing evaluation methods, the use of **new evaluation categories** also nearly doubled the proportion of qualitatively discrepant results across all clinical areas. This increase is most likely attributable to the fact that the new evaluation system eliminated the option of not having to clearly assign certain cases ("Result after Structured Dialogue computationally non-discrepant with special monitoring"). Regarding the indicators subject to mandatory reporting, the results of quality assurance not only have to be published, but the evaluations must be published in each hospital's individual quality reports after conclusion of the Structured Dialogue as well.

With a view to further developing quality assurance measures, particular efforts are being made to increasingly rely on direct, personal talks with the responsible parties representing the healthcare providers. For example, a threshold criterion based on quality indicators was developed in the planned cross-sectoral QA procedure for *Arthroscopy of the knee joint* (ASK). Consequently, this threshold criterion did not trigger the testing procedure of the Structured Dialogue, but rather a so-called "peer assessment". Each case involves a personal talk aimed at deriving concrete quality improvement measures from the results. Here as well, however, the adage applies that the effectiveness of such measures has to be tested within suitable evaluation projects so as to obtain sound conclusions about how to properly structure these quality-assuring measures.

Fair and conclusive comparisons of healthcare providers

All objectives connected with quality assurance pursuant to section 137a SGB V stand or fall with the question of whether indicators successfully enable fair and conclusive quality comparisons between the healthcare providers operating within the

Status and perspectives of quality assurance

healthcare system. It is therefore no wonder that the process of developing quality indicators – the foundation of quality assurance – has been subjected to the most changes over the past years. Here, one distinguishes between various fields of action:

Alignment along relevant quality potentials and objectives

The conclusiveness of the quality assurance procedures to be developed primarily depends on whether indicators can be used to map relevant quality targets and quality improvement potentials. Therefore, the scientific testing of planned QA procedures that directly incorporate medical expertise and include various QA perspectives, e.g., the patient's perspective, takes place early in the development process. In past years, evidence researching has been optimized and more strongly aligned along available quality potentials.

Likewise, the structured and increasingly earlier inclusion of specialists' expertise and patient's perspectives has been intensified and optimized over the past years. This has taken place in scoping workshops, focus groups or on expert panels – all of which have contributed to indicator development in multi-stage development procedures.

Despite intensive research, it has been shown that questions from a quality assurance perspective – e.g., what quality differences exist between healthcare providers or which measures can achieve quality improvements – can only be answered satisfactorily at best on the basis of available studies and guidelines. In that respect, it is desirable from the perspective of quality assurance to pursue further guideline development more intensively in the future and to align research projects, especially those on health services research, along their potential benefit for quality assurance. This might be given consideration in G-BA-funded health services research projects.

Under the given framework conditions, the (early) inclusion and/or the empirical (pre)testing of potential QA procedures based on routine data play a central role in identifying quality assurance potentials prior to implementation of a QA procedure. Moreover, such a data basis can be used to verify whether target populations, interventions and other quality-relevant events are unequivocally delimitable and/or measurable. Presently, the use of anonymized routine data for the development of quality assurance procedures, however, has not yet been institutionalized on a permanent basis, but needs to be built up on a project basis, which oftentimes leads to time delays.

Improving and broadly implementing risk adjustment

Another key requirement for a fair between-hospital comparison is the computational consideration of patient-related risks, e.g., age or pre-existing diseases. It will never be possible to account for all possible risk factors and thereby achieve the perfect risk adjustment. Nevertheless, the fundamental aim should be upheld to use all suitable risk factors that are collected within the scope of quality assurance and/or mapped by routine data in order to perform risk-corrected and/or risk-adjusted comparisons of quality of care data. Against this background, the primary mission was and is the further development and broader application of a detailed and more comprehensive **risk adjustment** driven by regression-based procedures. Whereas only very few (2009: n = 10) indicators of external hospital quality

assurance had been risk-adjusted in this sense in the past, this number has risen markedly in recent years due to the development and introduction of new risk-adjusted quality analyses (2013: n = 78).

Improving the validity of collected data

Tests on documents used in quality assurance show that, as before, the quality of the data needs to be improved in order to heighten the power of the quality indicators (AQUA 2014). Therefore, the measures for verifying documentation quality have been continuously intensified over the past years.

A **process-concurrent test for plausibility and record completeness** based on nationwide harmonized criteria is already performed at the hospitals during their collection of QA data. The introduction of the XML data specification has made a test program additionally available for this. The aim is to identify and/or avoid any data collection errors as early as possible.

Above and beyond this, a systematic analysis based on (rate-based) discrepancy criteria was established in all existing clinical areas of quality assurance. For example, since 2011, one discrepancy criterion per clinical area has been applied to under-documentation (ratio of actual/target < 95 % per clinical area) and one discrepancy criterion to over-documentation (ratio of actual/target > 110 % per clinical area). The target-vs.-actual comparison has been used as a basis for this. Additionally, since data collection year 2011, a discrepancy criterion for the frequency of minimal data sets has been used in many clinical areas. In the areas of transplantations and living donations, moreover, additional discrepancy criteria for follow-up have been introduced to examine documentation rates and information about unknown survival status. Here as well, a Structured Dialogue takes place with the hospitals that are computationally discrepant in this regard.

The sanctions for incomplete documentation have also been sharpened. The routine comparison between the QA data delivered by the hospitals ("actual") and the number of cases that should have been documented according to the QA filter software ("target") took place earlier and was performed mutually across all clinical areas. Meanwhile, the case completeness is now evaluated, as far as technically possible, on the level of each individual clinical area. Non-documented cases in clinical areas with small caseloads (e.g., *Heart transplantation*) can thus no longer be "compensated for" by documentation in clinical areas with higher caseload (e.g., *Hip replacement – Primary implantation*). Another approach is currently being followed in the clinical areas of transplantations. To achieve the highest case completeness rates in follow-up, missing survival status data on patients will be interpreted to the detriment of the hospital (called worst-case analysis).

Each year, additional specific discrepancy criteria are being developed for selected clinical areas. Here as well, the discrepancies are cleared up in the Structured Dialogue. Whenever a further need for action is identified, these criteria are continued, i.e., also applied in the subsequent years. Beyond this, annual on-site inspection takes place at 5 % of the hospitals in at least three selected clinical areas. During this inspection, the QA documentation data are compared against the hospital's records on the patients (Sampling procedure with data synchronization).

Status and perspectives of quality assurance

Within the project on transparency in the quality of care of pre-term infants (*www.perinatalzentren.org*) routine data were used for the first time (in this case, data pursuant to section 21 (3) of the Hospital Remuneration Act (KHEntgG)) to verify the plausibility and record completeness of the QA documentation. Herein lies great potential for evolving documentation quality verification methods.

Improving the discriminatory power of indicators

In addition to compensating for systematic errors in quality measurement through risk adjustment and continually improving data validity, care must be taken to ensure that random errors confound the quality measurement as marginally as possible. In other words, the reliability of the measurement should be as high as possible. Since numerous outcome quality indicators map rather rare events (e.g., complications) and the number of treated cases in many hospitals beyond this tends to be low, computational discrepancies arise that cannot be explained by quality deficiencies. In the past, this so-called caseload-prevalence problem had been dramatically underestimated in Germany (Dimick et al. 2004; Heller et al. 2008; Heller 2010).

From a statistical perspective, sufficiently high caseloads are needed to ensure the **discriminatory power of indicators**. In the meantime, to counteract the problem of too small caseloads, indicators are increasingly being combined into an index and/or into one measurand. On the one hand, this **indexing** leads to a higher prevalence in indicators with low caseloads. That reduces statistical estimation problems and enhances the validity of conclusions regarding quality. On the other hand, indexing allows broader conclusions to be made on quality. The initial measures implementing such indices were undertaken in 2012 and/or 2013 in the clinical areas *Neonatology* and *Obstetrics*. As a threshold criterion for the planned on-site inspections, indexing is also relevant to the development of indicators in the planned clinical area *Arthroscopy of the knee joint*. Further possibilities to increase the discriminatory power of indicators include evaluations of longer analysis intervals, e.g., when producing cumulative sums, multi-year mappings (AQUA 2013a), but also the consideration of cross-institutional longitudinal observations. Because of their more expansive importance, these will be described in more detail in the following section.

Establishing cross-institutional longitudinal observations (follow-ups)

To date, external quality assurance has been almost exclusively based on case-related documentation relating to those certain inpatient services rendered exactly during that hospital stay. Presently, a long-term observation of survival is only carried out for the clinical areas of transplantation, albeit based on follow-up by the hospitals themselves. Due to the high cost associated with it, among others, this concept is not transferrable to other clinical areas. Disregarding the above-mentioned exception, the following general statements are valid otherwise: Quality assurance ends once the patient leaves the hospital.

Quality assessment that solely examines one treatment or one hospital stay is clearly limited. Late complications, longitudinal observations of survival and other important clinical outcomes have evaded consideration thus far. One high-priority objective of the past years has been to overcome these limits. Important sub-objectives have now been achieved.

Initially, the established survey instrument of QA documentation, i.e., data collection at the hospitals, was implemented technically in such a way that it was possible to link various treatment episodes across hospital and sectoral limits. These technical preconditions were created by the AQUA Institute in 2012 based on national and international standards. Parallel to this, the G-BA set up a trust center that performs pseudonymization of the identifying features necessary to link a patient's QA data. After various trial projects, the new XML interface will be implemented in the routine operation of inpatient quality assurance starting 2015. At the same time, longitudinal observations have been established in various clinical areas. From a technical point of view and in terms of data protection laws, this means that the fundamental basics are also available for cross-sectoral collection as long as documentation is intended to be hospital-based.

That said, the trigger for the documentation requirement is still subject to major limitations in many cases. This particularly applies to the outpatient sector, both in terms of collectively as well as selectively contracted services. At present, outpatient claims diagnoses are frequently unsuitable for permitting sufficiently accurate identification of the target population of a quality assurance procedure. On the one hand, this is especially due to the difficulty in accurately assigning times to diagnoses and, on the other, because of the different invoicing rules prevailing nationwide (particularly in the selectively contracted sector). Because mandatory documentation triggering is ultimately linked to claims for services rendered, the option of establishing that kind of quality assurance procedure is severely restricted. For that reason, cross-sectoral approaches are currently being followed; this particularly applies to the outpatient surgery sector. Thanks to the mandatory documentation of surgery and procedure codes, a more exact mapping of the clinical experience is usually achieved there.

The most important requirement for overcoming the aforementioned limitations to QA documentation is for quality-relevant parameters to be better illustrated on the invoice than has hitherto been the case. The corresponding proposals from the quality assurance side, however, have not yet been successful – the requirements of quality assurance have not been accounted for – neither in connection with a better mapping of cataract surgery aftercare nor in the proposed introduction of a *Present on Admission* label in the clinical area *Nursing: Prevention of pressure ulcers*. Presumably, this will not change until a statutory framework has been created.

A second, complementary option for simplifying longitudinal surveys would be to make a note on the German Electronic Health Card (eGK) that a quality assurance-relevant service, i.e., one subject to mandatory documentation, has been rendered. That way, outpatient and inpatient follow-up treatments could be detected and documented even without specific invoicing codes. Unfortunately, this approach is also not being pursued any further at present.

Despite the objective of further improving cross-institutional longitudinal observations, the current emphasis, rather, is being placed on the establishment of new survey instruments, namely on the collection of routine data through health insurance companies and on the conduct of patient surveys.

Status and perspectives of quality assurance

Establishing new survey instruments: Routine data and patient surveys

Since the establishment of cross-sectoral quality assurance was commenced, the utilization of routine data from the health insurance companies and from patient surveys has been a key objective. Both collection instruments have the advantage that different treatment episodes can be mapped beyond hospital-related and sectoral limits. Moreover, they have other specific advantages:

■ Patient surveys are particularly suited for measuring various patient-relevant end points (e.g., pain or everyday activities) that otherwise cannot be collected at all or can only be collected with difficulty via other instruments. Moreover, this is the (only) way to incorporate the patients' experiences in the treatment process.

■ Routine health insurance claims data have the special advantage that their collection incurs no added cost for the healthcare providers. Moreover, this data source provides information on patient survival – a parameter that is an important treatment aim in many clinical areas.

In the context of quality assurance, the term "routine data" generally refers to already available data relevant in this connection (e.g., claims data), i.e., data that do not have to be collected specifically for quality assurance purposes. In the past, the AQUA Institute (as commissioned and after testing) was already able to utilize the inpatient claims data pursuant to section 21 (3a) Hospital Remuneration Act (KHEntgG) for quality assurance purposes. In addition, it is also possible to collect routine data in an automated way directly through hospitals, e.g., as implemented in the clinical area *Nursing: Prevention of pressure ulcers*.

One new feature is the utilization of routine data pursuant to section 299 (1a) SGB V (health insurance claims data). In 2012, the statutory basis was created for this by extending the scope of section 299 SGB V. Only data of this kind currently enable cross-hospital and cross-sectoral longitudinal observation, while containing additional information on patient survival.

After the statutory basis was established, the AQUA Institute was commissioned in 2013 to develop technical and content recommendations using the example of the planned cross-sectoral QA procedure *Percutaneous coronary intervention (PCI) and coronary angiography* in coordination with the statutory health insurance companies. The corresponding reports were accepted by the G-BA in June 2014. Further commissions to develop quality indicators that account for health insurance claims data are being processed (e.g., for the clinical areas *Aortic valve surgery, isolated* and *Coronary surgery, isolated*) and/or have been completed (*Cholecystectomy*, *Arthroscopy of the knee joint*). After setting up a data collection office for health insurance claims data and the envisioned testing of data flows in 2015, the first routine operations with health insurance claims data incorporated in quality assurance are planned for 2016.

In addition, patient surveys will also be established successively as quality assurance survey instruments. In March 2013, the G-BA commissioned the AQUA Institute to prepare instruments on the mapping of patient perspective ("Therapeutic experiences and results from the patient perspective") for the planned quality assurance procedures *Arthroscopy of the knee joint* and *Percutaneous coronary intervention (PCI) and coronary angiography*.

The objective is to develop and validate procedure-specific, quality-focused instruments on public reporting according to the prevailing scientific standards as an integral component of the specific quality assurance procedures.

The development of patient surveys as a data source for quality assurance is associated with special challenges. In particular, this applies to the development of the contents of the questionnaire. Here, it is initially decisive that the instrument is substantively valid, i.e., that it is suitable for mapping the procedure-specific objectives and/or the quality potentials. In order to obtain the most valid answers from patients, special requirements need to be placed on the development. The comprehensibility of the questions is pivotal for patients, which is why they are involved both in the early phase of development (implementation of focus groups) as well as in the later validation steps (cognitive pretests). Both experts and patient representatives are included in the development process for medical validation of the contents, but also regarding concrete implementation questions (e.g., as to the right survey time point).

Presently, the two commissioned patient surveys are being empirically validated, e.g., to determine the required sample sizes to achieve a sufficient discriminatory power of the results between hospitals. The results on this were presented in November 2014 (*Percutaneous coronary intervention (PCI) and coronary angiography*) and/or June 2015 (*Arthroscopy of the knee joint*). In parallel, the G-BA is devising the necessary framework conditions, for example, regarding the question as to who should send the surveys and which data flows ought to be established for this purpose.

Transparency and orientation for users

The results of quality assurance are used by different potential user groups whose information needs vary. Not only patients, but also referrers search for specific quality data to select a hospital for treatment. By contrast, specific quality data can be useful for health insurance companies, for instance, when negotiating selective contracts or quality-oriented remuneration. Indeed, hospitals themselves can also find out valuable information about the quality of other hospitals, e.g., to help their own quality improvement or strategic alignment.

Reporting of quality indicators at hospital level

Prerequisite to the use of quality data is, firstly, that the results on quality assurance indicators are reported at the hospital level. In the sector of inpatient quality assurance, the hospitals' quality reports serve this purpose. However, not all of the current 434 quality indicators (in data collection year 2013) in the 30 clinical areas are suitable for hospital-level public reporting. The reasons for this might be, for example, that the necessary risk adjustment has not (yet) been implemented, that some indicators have no statistical power due to small caseloads or their publication is not indicated due to deficient data quality.

One first step taken in the past years has therefore been to establish a systematic testing process that supports decision-

Status and perspectives of quality assurance

making about which quality indicators are sufficiently valid for comparing hospitals and are thereby suitable for hospital-level public reporting. The AQUA Institute has been examining this suitability regularly since 2011 by means of **expert surveys and based on statistical criteria** (for particulars, see chapter "Public reporting at hospital level"). This process has also had a major impact on the further development of existing quality indicators. Up to 2011, it was only possible to publish the results on a maximum of 29 quality indicators. In the meantime, this number has reached 295 (data collection year 2013), which makes up around 70 % of all indicators. That markedly elevates the transparency of quality in the healthcare system. While substantial efforts are still needed to present the results in ways that are genuinely understandable to laypersons, referring physicians and interested patients will meanwhile find a much improved foundation to inform themselves about the quality of hospitals and use this as a selection basis for impending treatments.

A further step in this direction was taken in 2013 when the terms and descriptions of all indicators subject to mandatory reporting were **reviewed for general understandability** by the AQUA Institute. During this review, a large proportion of the indicators were rewritten and/or renamed. Whenever indicators from different clinical areas measured the same content, the names where harmonized. These generally understandable terms and descriptions were taken on by the G-BA as recommendations for the hospitals to use in their quality reports.

Target-group oriented work-up and presentation

It is not self-evident that the growing scope of available results on quality assurance also translates into better orientation for users. For example, the publication of standardized mortality rates is good for the purpose of quality assurance but, on its own, not sufficient for informing patients. Other important aspects for a target-group orientated work-up and presentation from the patient's perspective include focusing the presentations of the results on particularly relevant parameters. This approach not only involves an alignment along specific information needs, but should also question whether a hospital even has any experience at all with the treatment of patients in that particular individual risk category.

The G-BA has taken one big step in this direction by commissioning a project to establish a website that provides information on the quality of care of very small preterm infants at German perinatal centers (*www.perinatalzentren.org, in German*): Expecting parents and referring physicians can view the outcome data of hospitals licensed for the care of preterm infants and neonates with very low birth weights. Essentially, the website gives users the option to sort hospitals – thus far participating on a voluntary basis – according to their clinical routine, i.e., according to the number of cases they treat, and the respective outcomes (e.g., survival after preterm birth without serious disease), and select the hospitals by name, region and distance. The high click rates on this website registered since early 2014 reflect the considerable interest in transparent and comparative presentations of quality. After the successful pilot phase with voluntary participants, all clinics caring for preemies and neonates are required to publish their data and results at *www.perinatalzentren.org.*

Improvement in cost-benefit ratios

To date, no comprehensive model for evaluating costs and benefits in quality assurance has been established. Approaches towards systematic analysis exist with regard to costs only (e.g., within the scope of determining the costs of bureaucracy). Here, the analysis previously focused on the time expended by healthcare providers (e.g., for generating documents). The objective is to keep these costs as low as possible in order to make fundamentally scarce medical resources available for their core mission, i.e., patient care.

Given these conditions, the improvement in the cost-benefit ratio is presently focused on the following aspects:

- Avoiding (hand-written) documentation by the healthcare providers
- Focusing quality assurance on areas where quality improvements are possible (quality potentials)

Use of hospitals' routine data
Particularly by establishing the new survey instruments "Health insurance claims data" and "Patient surveys", documentation costs at the healthcare providers can be lowered. The current implementation status of these instruments is illustrated above.

Beyond the still-to-be-established use of routine data pursuant to section 299 (1a) SGB V, the AQUA Institute has made **major improvements** in the **cost-benefit ratio** of hospital quality assurance in the existing clinical area *Nursing: Prevention of pressure ulcers* by using routine data from the hospitals themselves. These data are automatically generated by the hospital information system. Last year, more than 1.2 million cases had to be documented by hand and irrespective of the presence of a pressure ulcer (AQUA 2012). Starting with data collection year 2013, only cases with the presence of a pressure ulcer (approx. 300,000) have to be documented at present. Additionally, data collection has now been extended to cover 16.5 million patients and one total data collection year (previously: quarterly random sample) (AQUA 2013b). This means that approx. 80 % of inpatient care is now subject to quality assurance. To obtain the basic risk adjustment data imperatively required for this clinical area, the AQUA Institute has specified a **risk statistic** to be supplied by the hospitals once a year.

Development of new QA procedures
An alignment on quality potentials is undertaken to achieve maximum benefits in the development of new QA procedures. Concept sketches are an intermediate step in this development process.

They provide a decision-making basis for the G-BA that reveals whether the commissioned objectives are prospectively achievable with the existing instruments (survey instruments and quality assurance instruments) and/or what the anticipated costs will be and what the associated (implementation) risks would be to achieve the objectives, and whether these costs are justified when weighed against the relevance of the topic to healthcare.

This step is designed to avoid running a potential QA procedure through the complete process of development only to find out at the end that it does not have the required healthcare rel-

Status and perspectives of quality assurance

evance, is not implementable or is deemed too expensive for implementation.

Meanwhile, the AQUA Institute has prepared a variety of such concept sketches – e.g., on the subject of stroke and on two proposals from the field of dentistry. Further preliminary studies on the subject of tonsillectomy, the outpatient psychotherapy of patients insured under the statutory health insurance and discharge management are in processing and/or have been commissioned. These preliminary studies prove to deliver very valuable decision-making aids, in particular when anonymized routine data are available to evaluate aspects of healthcare relevance and implementability. One disadvantage, however, is that the intermediate steps (required) for getting the submitted reports approved and deciding on further procedure have markedly increased the time needed overall to establish QA procedures.

Looking forward

In the past years, there have been many necessary and fundamental developments to help better achieve the objectives of quality assurance. Major advances have been achieved, particularly in terms of more conclusive power on the part of the quality indicators. At the same time, the documentation load at the hospitals has been reduced and the transparency on the results of quality assurance has been heightened. Key requirements nevertheless remain outstanding if the aim is to fulfill all the expectations placed on quality assurance:

■ The access to anonymized routine data has been essential for the desired alignment of new quality assurance procedures along quality potentials and to comprehensively avoid "manual" data collection. The so far necessary project-related establishment of data access has considerably delayed the development of the QA procedures. The statutory fundamentals are lacking here; this particularly applies to an extension of the regulations set forth in section 299 (1a) SGB V which would enable institutionalized access to such data for the further development of quality assurance (and not only, as previously, for already-established QA procedures).

■ Because the topic of routine data is gaining increasing significance in quality assurance, it is important that central, quality-relevant contents be mapped therein. Presently, further developments in invoicing claims systems and quality assurance are mostly taking place separately from one another.

■ Evaluation projects are necessary to give the discussion about the benefits of quality assurance a rational foundation. It is important that such projects are prepared before or during the establishment of new QA procedures in order to create study designs that can differentiate general trends from the effects of quality assurance.

■ Moving forward, core topics of quality assurance must be given stronger consideration in health services research. For further developing quality assurance, it is important to obtain research findings that are helpful for its development and implementation (e.g., conclusions about the quality potentials of hospitals, options for assigning responsibilities in the event of deficits, valid survey instruments, expectations about the success of specific quality improvement measures). This also means intensifying and professionalizing the essentially valuable guideline development process.

Not all of the aforementioned fields of action are in the direct purview of the G-BA. The support of multiple stakeholders is necessary to implement the aforementioned items.

Finally, it should be pointed out that the planned innovations in the QA procedures create costs for implementation at the healthcare providers and for establishing the necessary structures on the level of federal states (e.g., software, need for training). This should be considered if successful establishment is to be achieved.

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Appendix

Instructions to the reader and glossary

Appendix

Instructions to the reader and glossary

Instructions to the reader

Presentation of results by clinical area

The following instructions to the reader are designed to explain tables and graphics used in the chapter "Analysis 2013". The results for each clinical area are presented on the basis of quality indicators on both the patient and hospital level. For some of the clinical areas (quality assurance procedures), comprehensive results are presented for individual quality indicators wherever they exhibit a trend towards significant changes or a detailed presentation of them seemed to be of special interest in terms of their general importance. The glossary below explains the main technical terms that are key to understanding the text.

Text: **Introduction**

At this point the subject of the clinical area in question and the reasons for its inclusion in external quality assurance are explained in the most understandable layman terms.

Text: **Services subject to mandatory documentation**

An exact delineation of the services subject to mandatory documentation is not only important for reasons of data economy, but also in order to obtain valid and reproducible findings and to categorize the result correctly.

Text: **Changes in comparison to the previous year**

This is where changes over the previous year are presented in an abbreviated overview (modified calculation formula, introduction of risk adjustment, etc.). Each quality indicator is listed along with its identification number (abbreviated QI-ID) under which it can be found in other places (e.g., database, Federal Analysis, benchmark report, etc.).

Text: **Results**

The Federal Experts' Working Groups responsible for the respective clinical area assist the AQUA Institute in interpreting the results. The key aspects are summarized here. Beyond this, the outcome of the Structured Dialogue from the previous year is also discussed.

Text: **Looking forward**

Recommendations on the need for action from the point of view of the AQUA Institute and from that of the respective Federal Experts' Working Group are formulated on the basis of the indicator results, supplemental data from the Federal Analyses and backed by each group's special expertise.

Table: **Data basis**

Data basis				
	2012	**2013**		
	Reported	Reported	Expected	Case completeness
Records	[Number]	[Number]	[Number]	[Value]
Hospitals	[Number]	[Number]	[Number]	[Value]

This table provides information on the data basis from the Federal Analysis for each clinical area on which this report was based in both the current and previous data collection year. The following information is presented in the table: Number of records (including the so-called minimal data sets), number of hospitals as well as a value for the case completeness for the current data collection year. It is expressed as the proportion of the delivered data (numerator) over the expected data (denominator), for more details, see chapter "Data basis".

Table: **Basic statistics**

Basic statistics		
	2013	
	Number	Proportion
Age distribution		
[Age]	[Value]	[Value]
Sex		
[Sex]	[Value]	[Value]
ASA classification and/or risk classes		
[Name]	[Value]	[Value]

This table contains important patient-related data and figures (absolute number and relative proportion) for the respective clinical area, e.g., total number of patients, age and gender distribution as well as any ASA classification for them and/or the corresponding risk classes. The sum of the individual values given may differ slightly from 100 % to the right of the decimal point as a result of rounding.

In some clinical areas the sum total of the number of patients as given in the tables stating age and sex may vary from the values given for ASA classification and/or risk classes. This may be the case if, e.g., the last mentioned value refers to the number of surgical operations (see, e.g., chapter "Hip replacement – Primary implantation").

Instructions to the reader

Presentation of results by clinical area

Table: Project leaders at the AQUA Institute

Project leaders at the AQUA Institute	
[Name]	[Name]

This is where the AQUA Institute's staff members are listed who are responsible for the respective clinical area.

Table: Members of the Federal Experts' Working Group

Members of the Federal Experts' Working Group	
[Name], *[City]*	[Name], *[City]*

The related table lists all the external members of the Federal Experts' Working Group. A corresponding note will be entered if any member leaves the group prematurely or a new member is appointed.

Table: Further reading

Further information on the clinical area
For a detailed description of the indicators (including references) and the 2013 Federal Analysis, please visit this website (in German): *[Link to the clinical area at www.sqg.de]*

Interested readers can find more comprehensive information made available to the public as stated in the table.

Table: Case-based aggregate results (patients)

	QI-ID	Name of the quality indicator	2012 Result	2013 Result	Cases (patients) Numerator (O | E) *	Denominator	Trend
		[Indicator group name]					
Indicator group	[QI-ID]	[Quality indicator within a group]	[Value]	[Value]	[Value]	[Value]	↗
	[QI-ID]	[Quality indicator within a group]	[Value]	[Value]	[Value]	[Value]	↘
	[QI-ID]	[Quality indicator] ⚠	n.c.**	[Value]	[ ]***	[Value]	n.a.****
	[QI-ID]	Ratio of the observed to the expected rate (O / E) of …	[Value]	[Value]	Numerator O Rate O (%)	Numerator E Rate E (%)	→

*   for regression-based quality indicators presented as the ratio of O / E;
** not calculated; *** result not shown on data protection grounds; **** not applicable

For every clinical area, the results of the quality indicator are computed based on the cases (patients) and listed in this table. The official name of the indicator is preceded by its identification number (QI-ID). This nomenclature also facilitates comparison across the various years. The QI-ID is stored in the matching databases and Federal Analyses.

Several substantively interrelated indicators are subsumed into indicator groups which are not only flagged by the matching header "**Indicator group** name", but also by a vertical label ("Indicator group").

The quality indicator values (e.g., in percent, minutes, days) are presented for data collection years 2012 and 2013. Any deviations from the descriptions given in previous German Hospital Quality Reports are explained at the appropriate place. As in the case of transplantations, these may be due to recalculations, modified calculation formulas or roundings.

Rounding is done according to the type of indicator to one (with rate-based or median-based indicators) or two (with risk-adjusted and sentinel event indicators) decimal places to the right of the decimal point. For data collection year 2013, numerators and denominators are additionally indicated to convey an impression of the number of cases. The numerator states the number of patients who meet the criteria for the quality indicator (deaths, patients with intact organ function, etc.). The denominator indicates how many cases were included for the affected quality indicator overall. This is equivalent to what is termed the target population or N.

The result for risk-adjusted quality indicators is given as the **ratio of the observed to expected rate (O / E)**. Additionally, the numerator of the observed number of events (numerator O), plus the corresponding number of cases and its rate (rate O) are indicated alongside the number of events expected because of the risk profile (numerator E) plus the corresponding number of cases and their rate (rate E).

Instructions to the reader

Presentation of results by clinical area

The **trend arrows** show whether an indicator's quality of care comparing 2012 to 2013 shows a positive (upward arrow) or negative (downward arrow) trend or whether it has remained the same, i.e., no significant changes were detected (horizontal arrow). The significance is evaluated based on the confidence intervals of the indicator values. Detailed information on the confidence intervals is given in the Federal Analysis 2013 on each clinical area. No trend is indicated (n.a., not applicable), if the preceding year's result was not calculated or is not comparable (e.g., due to the implementation of new data fields).

In the present German Hospital Quality Report, all quality indicators in the individual clinical areas evaluated by the Federal Joint Committee (G-BA) as unrestrictedly suitable for reporting are flagged in the "Case-based aggregate results (patients)" table by a symbol (🗈) inserted after the name of each indicator. For more information on the **reporting requirement**, please refer to the website of the G-BA under "Regelungen zum Qualitätsbericht der Krankenhäuser (Qb-R)" [German for "Regulations governing the hospitals' quality reports"]. These reports must be prepared annually.

Table: Hospital-based aggregate results for utilization in quality assurance

			2013			
			Hospitals		**Evaluation**	
QI-ID	Name of the quality indicator	Reference range	Total	Discrepant (computationally)	Category	Need for action
[QI-ID]	[Quality indicator]	[Range]	[Value]	[Value]	[Value]	[Value]

Alongside the reference range, the table presents the total number of hospitals reporting cases on the quality indicator in question, the number of computationally discrepant hospitals, the evaluation category and the estimation of the need for action by the Federal Experts' Working Group.

In terms of **reference ranges,** a distinction is made between a target range (TA) and tolerance range (TO). For indicators without a specified reference range, "n.d." (not defined) is entered in the "Reference range" column. If the quality indicator represents a very rare, severe event, the term "sentinel event" is listed in the "Reference range" column.

The column headed "**Discrepant (computationally)**" indicates the number of hospitals whose result is located outside of the reference range. Every hospital with at least one sentinel event is considered discrepant (computationally). The column "Discrepant (computationally)" remains empty for quality indicators with an undefined reference range.

The last two columns in the table, "Category" and "Need for action", present an evaluation of the quality indicators for data collection year 2013. These are computed evaluation categories and rankings of the need for action by the responsible Federal Experts' Working Group expressed in letters or numbers explained as follows.

Category (computed)

1: The aggregate result of the quality indicator is non-discrepant, is located in the reference range and the proportion of hospital-based results significantly discrepant from the reference range or the federal average is less than 5 %.

2: The aggregate result is non-discrepant and is located in the reference range, but the proportion of hospital-based results significantly discrepant from the reference range or the federal average ranges between 5 % and 25 %.

3: The aggregate result is discrepant and is located outside of the reference range and/or the proportion of hospital-based results significantly discrepant from the reference range or the federal average is larger than 25 %.

X: The quality indicator is a sentinel event indicator or no reference range has been defined.

## Need for action (as deemed necessary by the Federal Experts' Working Group)

A: **Standard need for action:** Computational discrepancies will be resolved in the Structured Dialogue.

B: **Extended need for action:** Computational discrepancies will be resolved in the Structured Dialogue; additionally, the discrepant results will be discussed as key topics at expert conferences and in academic and scientific publications. The societies and professional associations will be informed about the need for action.

C: **Special need for action:** Same as B, but additionally with the need for targeted support in implementing existing directives and/or for updating them or developing new directives. An analysis will be performed as to whether the results might be caused by wrong incentives within the remuneration system.

X: **No statement on the need for action:** Currently, no reference range defined, or evidence for limited data validity.

Instructions to the reader

Presentation of the results by quality indicator

① Description

Numerator	[Description of the numerator]
Denominator	[Description of the denominator (i.e., target population)]
Reference range	[Information on the reference range], see glossary "Reference range"
Risk adjustment	[Risk adjustment method], see Chapter "Risk adjustment and caseload-prevalence problem"
QI-ID	[Identification number of the quality indicator]
Comparability with the previous year's results	[Note on comparability of the computational basis with the previous year]

② Case-based results (patients)

	2009	2010	2011	2012	2013
Aggregate result	[Value of the indicator]	s. glossary "Aggregate result"	s. glossary "Aggregate result"	s. glossary "Aggregate result"	s. glossary "Aggregate result"
Confidence interval	[Lower and upper limit of the confidence interval]	s. glossary "Confidence interval"	s. glossary "Confidence interval"	s. glossary "Confidence interval"	s. glossary "Confidence interval"
Total number of cases	[Value of the denominator]	[Value of the denominator]	[Value of the denominator]	[Value of the denominator]	[Value of the denominator]

Aggregate result of all patients
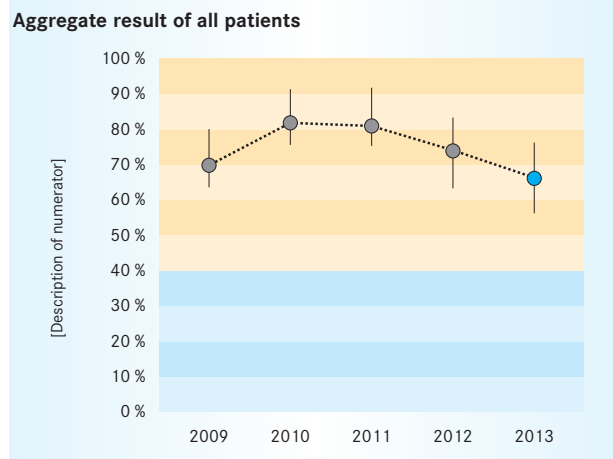
③ Hospital-based results

Target population of all hospitals	[Number]
Number of hospitals with 0 cases	[Number]
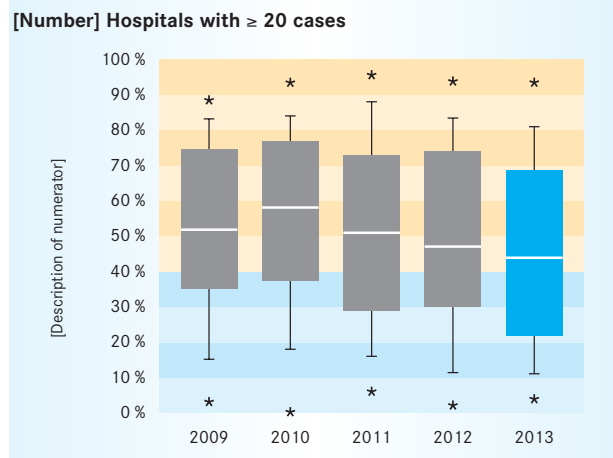
[Number] Hospitals with ≥ 20 cases

Median	s. glossary "Median"	Number of computationally discrepant hospitals	[Number] of [Number of hospitals with ≥ 20 cases]
Range	s. glossary "Range"		

[Number] Hospitals with 1 to 19 cases

Median	s. glossary "Median"	Number of computationally discrepant hospitals	[Number] of [Number of hospitals with 1 to 19 cases]
Range	s. glossary "Range"		

1. Description

The numerator and denominator are stated under the name of the quality indicator. Whenever defined, the reference range applicable to the indicator is listed there, too. Similarly, the risk adjustment method used, if any, is stated for this quality indicator. The description contains a note on the comparability of the data with the previous year's results, i.e., regarding mathematical principles, data basis or method changes.

2. Case-based results (patients)

The table and its matching chart (see "4. Error bar plots") show the federal results obtained for data collection years 2009, 2010, 2011, 2012 and 2013. Bar charts are used instead of line or error bar diagrams for certain quality indicators (e.g., sentinel events). An existing reference range is highlighted in yellow as the target or tolerance range.

3. Hospital-based results

The tables and diagrams show the results obtained for a quality indicator on the hospital level. The "target population of all hospitals" comprises the number of hospitals that delivered cases for this indicator. Not all hospitals that, in principle, could have rendered treatments in the clinical area will have necessarily done so in data collection year 2013. Therefore, the number of hospitals that have not documented any cases relevant to that indicator is additionally listed ("Number of hospitals with 0 cases"). The sum of the two entries equals the number of hospitals listed in the data basis and is consistently the same for all indicators depicting the respective clinical area.

Up to five box-and-whisker plots are included below these two lines of information. These charts show the distributions of the hospital-based results for data collection years 2009, 2010, 2011 and 2012 (gray) and 2013 (blue). If not noted otherwise, these charts normally only account for hospitals reporting at least 20 cases. These presentations can be used to evaluate the trends developing in the hospital-based results.

- Changes in the middle position of the results can be identified by an up or down shift in the median.

- Changes in variance mean that the differences in treatment quality between the hospitals increased or decreased. Such changes can be detected when the boxes are longer or shorter and/or whenever the range increases or decreases, i.e., the distance between the minimum and maximum of the result value changes.

Further information on the hospital-based results for data collection year 2013 is listed below the box-and-whisker plots. This information is presented for two subgroups: Hospitals with at least 20 clinical cases (directly below the graphics) and hospitals with 1 to 19 cases. For descriptions of the terms "Median", "Range" and "Discrepancy (computational)", please refer to the glossary.

Instructions to the reader

## Presentation of the results by quality indicator

4. Error bar plots

Error bar plots are used to present the case-based aggregate results (patients). This way, the quality of care mapped by the indicator can be compared directly based on values from the years 2009 to 2013. The confidence intervals for annual values are plotted as vertical lines. However, a confidence interval may sometimes not be discernible because its limits are located very close to each other, depending on the scale of the y-axis. This is the case whenever they are located within a circle marking the aggregate result. If a reference range is defined for the quality indicator, it appears as a target or tolerance range correspondingly highlighted in yellow.
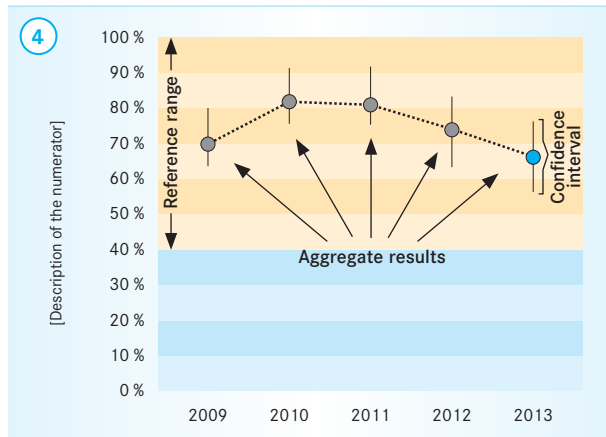
5. Box-and-whisker plots

Box-and-whisker plots are used to visualize the distribution of hospital-based results. This form of presentation clearly shows at a glance the range within which the overwhelming proportion of the hospitals' results are located. On the box-and-whisker plot, the box includes all values between the 25th and the 75th percentile and thereby covers the interquartile range. Fifty percent of all values of a distribution are located within this area. The box for data collection years 2009, 2010, 2011 and 2012 is highlighted in gray and that for the current data collection year 2013 in blue. The median of the values, i.e., the 50th percentile, is indicated as a horizontal white dividing line. It divides the upper 50 % of the values from the lower 50 %. Vertical lines (whiskers) connect the center of the box to the 5th or 95th percentiles (small dashes) of the hospital distribution. The minimum (lowest value) and maximum (highest value) are indicated by ✶. Whenever the minimum or maximum falls together with the minimum and maximum of the potential value range for the indicator (e.g., 0 % or 100 %), the ✶ symbol will appear on the upper or lower limit of the margin and may therefore be less clearly identifiable. When defined, the reference range here is also correspondingly highlighted in yellow as a target or tolerance range.
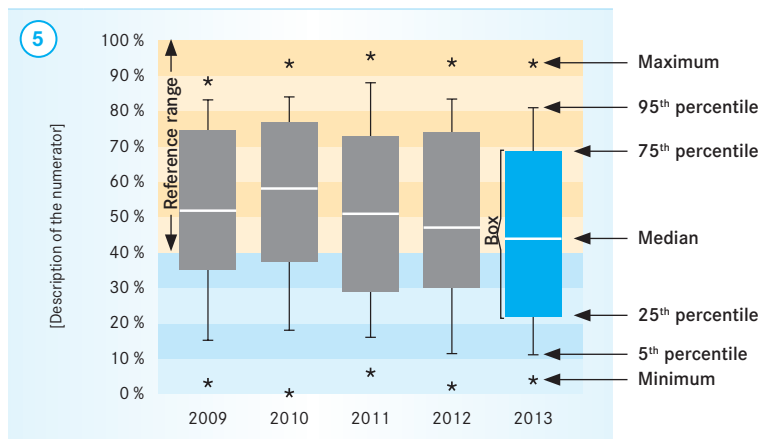
6. Bar charts

a) For sentinel event indicators, bar charts present the (absolute) number of sentinel events (on the patient level) and/or the (absolute) number of hospitals with sentinel events. No distinction is made here with regard to the number of documented cases.
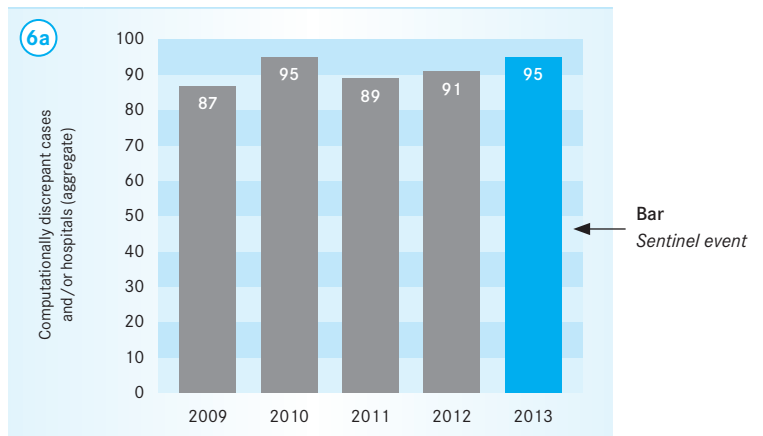
b) For risk-adjusted indicators which express the ratio of the observed (O) to expected (E) rates, the difference from the O and E ratio for the respective year is presented as a column in order to map the trend over the years. When the observed rate (O) of events equals the expected rate (E), then the difference (O – E) between the observed (O) and expected (E) rates is zero. The regression coefficients used are based on the year that the respective quality indicator was introduced.
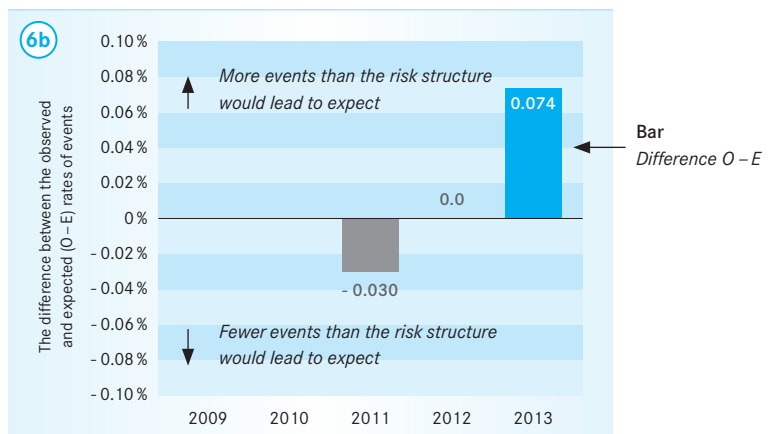
Instructions to the reader

Glossary

Aggregate result

For the present quality report the aggregate result was determined on the basis of patients (cases). Only the cases reported by the affected hospital are used to calculate a hospital-based result.

ASA

Physical status classification system of the *American Society of Anesthesiologists* (ASA). The subsequent nomenclature is that used in the specification for data collection year 2013.

- ASA 1: A normal healthy patient
- ASA 2: A patient with mild systemic disease
- ASA 3: A patient with severe systemic disease
- ASA 4: A patient with severe systemic disease that is a constant threat to life
- ASA 5: A moribund patient who is not expected to survive without the operation

Case completeness and record completeness

Case completeness: When all clinical cases subject to mandatory documentation have been gathered, we speak of a case completeness. The ratio of the number of delivered to the number of expected clinical cases subject to mandatory documentation is also referred to as the documentation rate.

Record completeness: When all data on a clinical case have been gathered completely, we speak of records being complete.

Clinical area

Sometimes also referred to as (QA) procedure or module. Clinical areas involve the medical services which are subject to mandatory documentation in accordance with the "German Directive on Quality Assurance Measures in Hospitals" (QSKH-RL).

Here, we differentiate between direct and indirect procedures:

- Due to small case numbers or a small number of implementing hospitals, **direct procedures** relate to the national level. These procedures are directly monitored by the institution mandated by section 137a of the German Social Code, Book Five (SGB V; previous version of section 137a, as of 01/01/2012), i.e., the AQUA Institute.
- **Indirect procedures** are covered by clinical areas with comparatively high numbers of cases and are therefore monitored on the state-level by the State Administrative Offices for Quality Assurance (LQS).

Clinical area for target caseload

For clinical areas that are surveyed using a mutual documentation form (e.g., heart surgery), the clinical area for a target caseload is designed for allocation to a certain sub-clinical area (e.g., catheter supported operations in the clinical area *Aortic valve surgery, isolated*).

Confidence interval

The confidence interval describes an interval around a calculated result value, e.g., the aggregate result of a quality indicator. In simple terms, the confidence interval indicates an interval in which the actual value of a quality indicator is located, whilst taking all random events into consideration (e.g., documentation errors) with a specific, predefined probability.

The scope of the confidence interval is a function of the number of cases (e.g., the number of operated-on patients) and the probability limit. The Federal Analyses that form the foundation of this German Hospital Quality Report used a probability of 95 %.

Correctness

The data documented on a case are correct as long as they are also verifiable in the patient's medical records.

Data collection year

The data collection year refers to the year in which the data are collected and upon which the results of the quality indicators are based. The criteria for delineating the data collection year are defined in the specification for the target caseload.

Data field

The smallest unit of a record (e.g., gender information on the documentation form).

Data validation

Checking the data transmitted by the healthcare providers for accurateness; this covers plausibility, case completeness, record completeness as well as correctness. The corresponding procedure for data validation is detailed in the G-BA's directives (for more information, see chapter "Data validation").

Discrepant (computationally)

A computational discrepancy exists when the value of a quality indicator, i.e., the aggregate result based on all cases in the Federal Republic of Germany or the result of a hospital lies outside of the reference range. Computational discrepancies can trigger the Structured Dialogue.

See also: Reference range

Documentation rate

See: Case completeness

Federal Data Pool

The quality assurance data documented by the hospitals are compiled in a Federal Data Pool to permit their analysis.

Federal Joint Committee (G-BA)

The Federal Joint Committee (German abbreviation G-BA for Gemeinsamer Bundesausschuss) is the supreme decision-making body of the joint self-governing bodies formed by the

Instructions to the reader
Glossary

national associations of doctors, dentists, psychotherapists, hospitals and statutory health insurance funds in Germany. By issuing directives, the G-BA defines the catalogue of services to be provided by the statutory health insurance funds for more than 70 million insured and thereby determines which medical care services are reimbursed by the statutory health insurance funds. In addition, it passes resolutions on quality assurance measures for the inpatient and outpatient sectors of the healthcare system.

Follow-up

Healthcare services, the quality of which (e.g., a successful outcome) is not measured once, but at different points in time during follow-up, i.e., aftercare period.

Health insurance claims data

With the revision of section 299 (1a) SGB V, it became possible in early 2012 to also use health insurance claims data on insured individuals in pseudonymized form for quality assurance purposes. In a narrower sense, this involves claims data for medical treatments as well as some insurance master data sets, i.e., health insurance claims data are typical routine data.

Incidence

The number of new cases of a disease occurring during a certain period in a defined population (more accurately, incidence rate).

Indicator (quality indicator)

A quality indicator allows us to "translate" a quality target such as "Always perform the first blood gas analysis or pulsoxymetry within 8 hours after admission of the patient" into a number, i.e., to quantify it. Not until this has been done is it possible to conclude the degree to which the medical care at an individual center (or in a territory) is distant from a quality target or has achieved the target. Such quantifications rely on the data gathered on patients and clinical courses within the scope of quality assurance. Frequently, the indicator is expressed in percent and will chiefly be referred to as "rate": For reasons of continuity, we will stick to the term as much as possible (*see also: Rate*). The numerator of the percentage is the number of patients for whom the quality target was achieved or not achieved, depending on the objective of the quality indicator. The denominator is the total number of all patients who received the treatment in question. Each quality indicator is allocated an identification number, called the quality indicator ID (QI-ID).

Median

The median is variously termed the 50th percentile. The median splits a distribution in equal halves such that (when ranked) half of all values are above this value and half are below: 50 % of the hospitals achieve values that are smaller than or equal to the median, whilst the values of the other 50 % are greater than or equal to the median.

The median allows characterization of the "medium" strength of the distribution of a value set, even when the distribution is asymmetrical and extreme values occur; in other words, compared to the mean, the advantage of the median is that it is not susceptible to extremely small or extremely large values (outliers).

See also: Percentiles

Minimum and maximum

The minimum is the smallest value in a set. The definition of "smallest" value is predicated on the assumption that the values can be ranked and allows more than one unit in the set studied (e.g., case, patient, hospital) to have the same value (that is smaller than all the other values).

The maximum is the largest value in a set. The definition of a maximum value also requires that the values can be ranked. Like the minimum, several units in the set studied may exhibit the maximum value.

See also: Range

Multiple logistic regression

Multiple logistic regression is a statistical risk adjustment method used to analyze the impact that various variables (e.g., age, gender, or concomitant diseases) have on a binary target variable, i.e., a variable permitting only one of two options (e.g., "Patient died?": yes/no). Each patient at a hospital is only compared with patients with influencing variables of the same nature (e.g., the same gender and age groups, the same concomitant diseases).

Number of cases

Number of patients treated, e.g., per clinical area in one hospital. If the number of cases is less than four, the result is not stated for reasons of privacy protection ([ ]*).

O / E and/or O − E

The ratio of the observed (O) to the expected (E) rate is an important figure in risk adjustment. The value O represents the actual rate of observed events (raw, i.e., without risk adjustment) in the respective data collection year. E represents the expected rate of events in the data collection year. Regression models are used to calculate the risk profile, using data from the previous year. An O / E value of 1.20 indicates that the observed rate is 20 % higher than the expected rate. On the other hand an O / E value of 0.90 indicates that the observed rate is 10 % smaller than the expected rate. The O / E value is dimensionless and will be given with two decimal places.

To map a trend over several years, the difference derived from the O and E values are presented for each year. When the observed rate (O) of events equals the expected rate (E), then the difference (O − E) from the observed rate (O) and expected rate (E) is zero.

Instructions to the reader

Glossary

Percentiles

Percentiles are used to describe the rank position of individual hospital-based results relative to the results of all other hospitals. Percentiles subdivide values in a set by size into one hundred equally sized areas. The 25th percentile, the 50th percentile (median) and the 75th percentile are also termed quartiles because they divide the data array into four equally sized quarters.

The xth percentile of the hospital-based results is defined such that x % of the hospital-based results are smaller or equal to the xth percentile. For example, if 25 % of the investigated hospitals report a wound infection rate of 1.5 % or less, then 1.5 % corresponds to the 25th percentile.

The use of percentiles permits the interquartile range to be stated as a measure of the variance of a distribution; in contrast to range, outliers do not affect this unit. The interquartile range is limited by the 25th and the 75th percentile; it encompasses 50 % of all values. In a plot of a distribution, it is represented as a box in a box-and-whisker plot.

The computation of percentiles can become troublesome, when the distribution contains many equal values (plateau formation). This happens particularly frequently with outcome quality indicators and hospitals with low numbers of cases. In the event of plateau formation, the value less critical to the reference range (not "computationally discrepant") is assumed.

Prevalence

The number of cases of a disease that are present in a population at a specified time (more accurately, prevalence rate).

Prophylactic therapy

Measures undertaken to prevent a specific disease.

Pseudonymization

Involves replacing the name and other identifying features with a label intended to prevent or significantly hamper the identification of the person involved (section 3 (6 a) of the German Federal Data Protection Act (BDSG)).

QA documentation

Refers to the gathering of treatment data by healthcare providers for the purpose of external comparative quality assessments. QA documentation is currently the major source of data for computing quality indicators.

Quality target

A quality target defines the specific requirements placed on the quality of a medical treatment. The responsible Federal Experts' Working Groups set quality targets for their clinical area. One or several quality indicators can be developed for each quality target. Based on the indicator values, conclusions can be drawn whether and to what extent hospitals in the healthcare system have achieved the defined quality targets.

Range

The range (R) of an array of indicator values is a measure that can easily be derived using the minimum and maximum. It is the difference between the largest and the smallest value:

$$R = x_{max} - x_{min}$$

The range is strongly dependent on outliers (extremely large or extremely small values). This parameter is suited to characterize how sets of measured values from small sample sizes are scattered: when the sample sizes are large, the information content is correspondingly low.

Rate

The term "rate" is used to refer to results obtained on quality indicators. The result at the federal level is the overall rate for that quality indicator.

Record

A predefined quantity of data fields assigned to one case (e.g., a patient). A record is generated using a documentation form within the scope of QA documentation.

Reference range

The reference range indicates whether the result of an indicator is computationally discrepant or non-discrepant. In the event that results lie outside the reference range, an analysis within the Structured Dialogue is usually initiated. Currently, a distinction is made between target ranges and tolerance ranges:

- **Target range:** Evidence-based studies are used to define which result can be interpreted to reflect good quality. For these indicators, a fixed value is set as the reference range limit.

- **Tolerance range:** If no corresponding value is known from the scientific literature, the reference range is empirically defined such that it delineates especially discrepant results. This can be done using either a fixed value or a percentile (percentile reference range).

Risk adjustment

Risk adjustment is primarily required for quality indicators that refer to treatment outcomes. For a fair comparison of treatment outcomes from various hospitals, consideration is given to the severity of the disease of the treated patients based on risk adjustment features. For this purpose, risk adjustment methods are employed to ensure that only patients with the same degree of severity are compared with each other (for more details, see chapter "Risk adjustment and caseload-prevalence problem").

With reference to the present clinical areas, a distinction is made between the following methods:

- Additive score
- Stratification
- Multiple logistic regression
- Poisson regression
- Multinomial logit modell

Instructions to the reader
Glossary

Routine data

The term routine data designates already existing data that do not have to be separately gathered for quality assurance purposes (e.g., claims data). The AQUA Institute is currently able to use inpatient claims data according to section 21 (3a) of the Hospital Remuneration Act (KHEntgG) for purposes of quality assurance. Corresponding legal prerequisites have been established in 2012 for data according to section 299 (1a) of the German Social Code, Book Five (health insurance claims data). Implementation is currently carried out. Routine data can also be gathered directly, in an automated process, at the health-care provider as is, for example, the case with the clinical area *Nursing: Prevention of Pressure Ulcers*.

Sentinel event, sentinel event indicators

Sentinel event indicators cover rare, severe events (sentinel events) of special importance. Each case represents a discrepancy that mandates an isolated case analysis within the Structured Dialogue (see chapter "Structured Dialogue"). In the results table, the term "sentinel event" is entered under the reference range column for such quality indicators.

Specification

Description of a record, i.e., defines how mandatory documentation is triggered, which data fields of the QA documentation are collected and how and which instruments are suitable for this (e.g., for plausibility tests).

Structured Dialogue

The Structured Dialogue is triggered by computational discrepancies found in the results of a quality indicator. The Structured Dialogue investigates whether the computational discrepancies are qualitatively discrepant or non-discrepant. For existing clinical areas, the Structured Dialogue supports hospitals in the continual improvement of processes and quality.

Survey instrument

Specification of the way and means of collecting data (for external quality assurance) and/or including data sources or making them utilizable. Examples:

- Documentation forms for collecting data through the health-care providers (QA documentation)
- Questionnaires for collecting data on patients
- Technical specifications for collecting routine data (e.g., from health insurance claims data)

Target caseload

At the end of the data collection year, the target caseload is generated by the hospitals in accordance with the specification for the QA filter and confirmed in a written conformity declaration. This forms the basis for computing the sum of records to be expected for the data collection year as well as for the case completeness check within the scope of data validation. The target caseload is used to derive any differences between the number of actually documented cases and the expected rates of cases to be documented (invoiced) at one hospital per clinical area.

Target range (TA)

See: Reference range

Tolerance range (TO)

See: Reference range

Trend

Trends are indicated by arrows (*Table: Case-based aggregate results (patients)*). They indicate whether the indicator-related quality of care shows a positive trend (upward arrow) or negative trend (downward arrow) or whether it has remained the same (horizontal arrow). For example, there is no statistically significant difference (horizontal arrow) when there is an overlap between the confidence intervals of the respective results.

Worst-case indicator

A worst-case indicator counts all patients without any survival data available as deceased. Accordingly, actual deaths and deaths that cannot be ruled out due to lack of documentation are measured. Thereby, they allow conclusions about the documentation and aftercare quality of the hospitals.

Legal notice

Göttingen, April 2015 (German version: August 2014)

1/04.2015

Up-to-date information on the implementation of external hospital quality
assurance and the development of cross-sectoral quality assurance in
the German healthcare system is available (in German) at:

www.sqg.de

Institute for Applied Quality
Improvement and Research
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German Hospital Quality Report 2013