Measuring, Monitoring, And Managing Quality In Germany's Hospitals

Germany has made progress in measuring quality in hospitals and is extending its effort into its statutory health insurance system.

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ABSTRACT: In German hospitals, quality measurement, monitoring, and management have undergone considerable development. This includes an array of mandatory measures, including a nationwide benchmarking exercise based on 194 indicators. Because of better and deeper coding of diagnoses, procedures, and demographic information since the introduction of the diagnosis-related group (DRG) system, two further "generations" of instruments have been developed: quality measurement performed at the provider (hospital) level using administrative data, and long-term performance measurement using administrative data at the payer level. All three approaches have specific pros and cons concerning validity regarding final outcomes and resistance against manipulation. [*Health Affairs* 28, no. 2 (2009): w294–w304 (published online 27 January 2009; 10.1377/hlthaff.28.2.w294)]

ENSURING THE QUALITY OF CARE HAS BECOME a major concern in the United States as well as in European countries.[1] To do this, quality has to be measured with reliable and valid indicators, monitored, and managed, all of which present challenges. In this paper we examine the respective requirements and developments in the German hospital sector over the past two decades, placing particular emphasis on three "generations" of quality documentation and analysis: one routinely in place, one used on a voluntary basis, and one in a developmental stage. The latter two are closely linked to the nationwide implementation of the diagnosis-related group (DRG) system, which has facilitated both the advancement of the coding systems (especially regarding diagnoses and procedures) and the depth of the information (for example, number of secondary diagnoses), which has become available in administrative data systems at the provider and payer levels.[2]

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The German Health System And Its Main Actors

The German health system is dominated by its statutory health insurance (SHI), making it a "Bismarckian" system based on self-governance and self-regulation within a legal framework. Membership in one of Germany's 200 "sickness funds" is compulsory for workers with gross incomes below a specified level, unemployed and retired people, and certain other population groups (such as farmers, artists, and students). Workers with incomes above the threshold may be voluntary members if they have been members before. Contributions are set as a percentage of income. Around 86 percent of the population is covered by the SHI; 10 percent is covered by private insurance.[3] The main actors involved in the SHI system are as follows. (1) The Federal Association of Sickness Funds (GKV-Spitzenverband) is the central organization established in July 2008 to represent all sickness funds. (2) The Federal Chamber of Physicians (Bundesärztekammer) is responsible for the qualification of specialists; together with the medical societies, it develops medical guidelines. By law, all physicians are members of their respective regional physicians' chambers. (3) The Federal Association of SHI Physicians (Kassenärztliche Bundesvereinigung, or KBV) represents all physicians who participate in outpatient contracts with the sickness funds. These physicians are mandatory members of their respective regional associations, which act as intermediate contractors with the sickness funds. (4) The German Hospital Federation (Deutsche Krankenhausgesellschaft, or DKG) represents all public, not-for-profit, and for-profit hospitals in Germany. All three types of hospitals treat SHI-insured as well as privately insured patients. (5) The Federal Joint Committee (Gemeinsamer Bundesausschuss, or G-BA) is the highest decision-making body in the SHI system and is responsible, among others, for defining quality standards for health care services. When it was founded in 2004, it subsumed the tasks of several (former) committees that had been involved with the promotion and implementation of quality assurance systems. Its decisions are published in the form of binding directives.

(6) The Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, or IQWiG) is a foundation founded and funded by the institutions forming the G-BA; that is, it is independent of government and funded through the SHI system. Its tasks include the compilation of scientific reports, opinions, and statements on the quality and efficiency of services provided under the SHI system; recommendations on disease management programs; evaluation of evidence-based guidelines for epidemiologically important diseases; and the provision of information to patients on quality of health care. (7) The Federal Office for Quality Assurance (Bundesgeschäftsstelle Qualitätssicherung, or BQS) currently concentrates on measuring quality in hospitals. In the future, it will cover ambulatory services as well.[4]

History And Current Status Of Mandatory Quality Assurance Activities

Within the medical profession, approaches to measuring quality have typically been based on separate data collection processes, which are set up for specific diseases or procedures. Disease- or procedure-specific registers are often dedicated not only to epidemiological but also to quality issues, which sets them apart among data collection initiatives. Early examples in Germany were the perinatal registers established in most federal states since the 1970s.

Based on experience gained through these initiatives, Germany's external quality assurance system (as opposed to the internal systems of individual hospitals) was developed and made mandatory in the 1990s. Since 2001, the BQS has managed its development and implementation. The external system involves the documentation of quality indicators, a process supported by regional offices for quality assurance in all federal states.

The BQS is responsible for defining procedures or diseases (known as "modules"), which are the subject of quality measures; defining related data to be sampled; and deriving quality indicators from these data. In 2007 (the latest published data), the BQS collected quality information for twenty-six mandatory modules with 194 indicators. Most are based on procedures (for example, cholecystectomy, hip replacement, some types of heart surgery, pacemaker implantation, or deliveries); very few are based on diagnoses (for example, community-acquired pneumonia). Hospitals that fail to collect data as required by law face financial penalties. If they report fewer than 80 percent of cases (determined through the number of respective reimbursed cases), payment is cut by 150 euro (US$235) per missing case.

Data from some 3.6 million inpatient cases (around 20 percent of all German inpatient cases) in more than 1,600 acute care hospitals were captured by this process in 2007.[5] It is assumed that this is the largest database monitoring quality in the world. Almost all indicators refer to the hospital stay only, because follow-up investigations require high effort. Therefore, follow-up information after discharge is collected only for very complex and less frequent procedures—for example, thirty-day mortality in coronary surgery and some one-year results for organ transplantation. However, one-year follow-up for liver transplant donors could be completed for only 67.5 percent of all 2006 donors. For renal transplant recipients, only fourteen of forty-five hospitals performing this procedure could deliver the required 90 percent follow-up rate.

Data are compiled and analyzed at the national level, and the findings are fed back in the form of reports and recommendations to individual hospitals and made publicly available (anonymously in aggregate format) in an annual quality report.[6] Hospitals that are identified by the BQS as "underperforming" are required to explain this result (in a nonpublic process) and, if deemed necessary, take appropriate action to improve performance. Thus, this quality assurance

process was not primarily intended to provide comparative information on hospital performance. Rather, it has served as an intraprofessional tool for physicians, helping them determine their own relative position with respect to implementing standard treatment processes and identifying important complications.

Considering the time scale of development, this process could be viewed as a "first generation" of quality measurement. The process has its pros and cons. The pros are that physicians can theoretically define any kind of quality measure, because all necessary information is specifically collected, and that physicians can examine the relation of a possible complication to the performed procedure (or treated disease) during the data collection process. The cons are as follows. (1) Considering the increased availability of medical data in administrative systems, the effort for collecting separate data redundantly is too great. (2) The detection of quality problems depends largely on participants' honesty. If the information is used for public benchmarking, there is a strong incentive for manipulation, which can easily be done by omitting complications or by not documenting certain cases at all. (3) Outcome information is mostly restricted to the inpatient episode. Follow-up cannot be widely established because of the enormous effort needed; it also would be prone to loss of cases because of underreporting and reporting bias.

New Developments In Quality Measurement

■ **"Second generation"—quality indicators derived from administrative data at the hospital level.** Apart from political and other factors, the development of quality measurement methods is also driven by the availability of data. Before 1986, coded information about diagnoses or procedures performed in hospitals was not available outside some research projects. In 1986, documentation of diagnoses based on the *International Classification of Diseases*, Ninth Revision (ICD-9) was introduced; in 2000 it was updated to ICD-10. The use of a procedure coding system derived from the World Health Organization's *International Classification of Procedures in Medicine* (ICPM) became mandatory in 1995.

Starting in 2003, Germany introduced a DRG system as a reimbursement method for all acute care inpatient services except psychiatry. Its introduction was accompanied by the implementation of strict coding guidelines and regulations for controlling the quality of coding. Thus, the quality of medical data available in administrative information systems has improved greatly.

The quality of coding for major secondary diagnoses, which contains information about complications as well as comorbidities needed for risk adjustment, has also improved, because such information is used for severity adjustment. Empirical analyses have shown that the quality of coding comorbidities is often better within the administrative systems.[7] However, some physicians remain skeptical.[8]

Coded information from administrative systems has been used for defining quality indicators. In the United States, inpatient quality indicators (IQI) are available from the Agency for Healthcare Research and Quality (AHRQ), covering

nineteen diseases or procedures with thirty-two indicators.[9] Since 2000 the German HELIOS Hospital Group has independently developed quality and volume indicators.[10] The published version (2.1) of these indicators currently covers thirty diseases and procedures with 142 indicators (a more extensive version is in preparation; internally more than 700 indicators are used by the company).[11] On average, around 30 percent of HELIOS hospitals' patients are covered by this approach—many more than are covered by the BQS. HELIOS has published the results as measured by these indicators for all of its hospitals since 2001. Meanwhile, other hospitals have followed this approach and either use the indicators internally or also publish their results.

Both approaches (AHRQ and HELIOS) cover important diseases and major procedures such as acute myocardial infarction (AMI), heart failure, stroke, pneumonia, and cholecystectomy. The definitions used are slightly different. In some cases, the HELIOS system is more differentiated than the IQI. The HELIOS indicators also provide information about cardiac pacemaker implantations, colorectal surgery, mechanical ventilation, and other diseases or procedures that are not yet included in the IQI. The HELIOS approach has been used by Switzerland as the basis for the development of its national quality indicator system.[12]

Inpatient mortality is a dominant, although not the only, outcome measure in the HELIOS system. The advantage is that mortality data are nearly safe from manipulation, although the possibility of some case shifting (shifting critical cases to another diagnosis) remains. This, however, would often be detected within the billing process, because it would result in the wrong DRGs.

Information concerning complications could theoretically also be derived from administrative data, because it can either be directly coded via the ICD-10 or be indirectly detected via coded procedures that are necessary to treat a complication (such as re-operations). If wanted, more detailed information about complications could be collected within administrative systems by integrating the corresponding codes into the official coding systems. Thus, the information collected in the "first-generation" approach could also be included in any "second-generation" methods. However, coding of direct complications again is prone to undercoding, which may lead to an underestimation of complication rates. Furthermore, the tremendous effort associated with a too-detailed approach of collecting quality information has to be considered.

From a strictly scientific point of view, mortality information derived from administrative hospital data is not exact. Because each individual length-of-stay is different, mortality even within the same disease cannot be standardized to a certain amount of time, such as thirty-day mortality. However, this problem applies also to the "first-generation" approach as long as no follow-up is included. In the United States, Medicare has overcome this problem by adding a mortality indicator to the Medicare Provider Analysis and Review (MEDPAR) data set.

Despite these limitations, the HELIOS hospital group has successfully worked

with these indicators by combining their use with an internal auditing process. In hospitals with mortality ratios markedly above the national average, case-by-case reviews of critical cases by experienced peers have usually found major deficiencies in treatment processes for a sizable share of cases. Peers are chairs of related departments of other HELIOS hospitals, and the case review is based on patient records. If the underperforming departments were obligated to improve identified weaknesses within their processes and compliance were controlled via the quality indicators, outcomes could be greatly improved (Exhibit 1).

Because management processes such as benchmarking or peer review to improve outcomes may run parallel with other management processes to improve outcomes, it is difficult, if not impossible, to identify the effects of benchmarking per se on improved outcomes. Only scientifically controlled experiments in which all other factors driving outcomes can be held constant could do that. However, the experience of HELIOS has been that marked improvements in outcomes result

EXHIBIT 1
Changes In Inpatient Mortality In The United States (Medicare) And Within Germany's HELIOS Hospital Group After The Introduction Of Quality Management, Selected Years 1998–2006

	Percent change in inpatient mortality		Standardized mortality rate	
Indication	U.S. (Medicare), 1998–2003 (5 years)	Germany (HELIOS), 2003–2006 (3 years)	2003	2006
Pneumonia 95% CI No. of cases	−15.2	−26.2	1.02 [0.93–1.13] 395 of 3,604	0.76 [0.67–0.85] 286 of 3,832
AMI 95% CI No. of cases	−18.4	−18.1	0.93 [0.83–1.03] 326 of 3,363	0.76 [0.68–0.85] 282 of 3,325
Stroke 95% CI No. of cases	−12.8	−24.5	1.12 [1.03–1.22] 523 of 4,145	0.85 [0.77–0.93] 411 of 4,317
CHF 95% CI No. of cases	−30.1	−24.2	1.00 [0.91–1.11] 394 of 3,575	0.76 [0.69–0.83] 431 of 5,292
AA 95% CI No. of cases	−7.0	−13.3	4.84%[a] [2.39%–8.69%] 9 of 186	4.22%[a] [1.73%–8.58%] 6 of 143
Hip fracture 95% CI No. of cases	–[b]	−16.5	6.67%[a] [5.18%–8.43%] 61 of 915	5.57%[a] [4.22%–7.10%] 51 of 916

SOURCES: U.S. data are based on Medicare Payment Advisory Commission, *Healthcare Spending and the Medicare Program: A Data Book* (Washington: MedPAC, 2005). Data for Germany are previously unpublished HELIOS data, based on twenty-two hospitals that continuously belonged to HELIOS from 2003 to 2006.

NOTES: CI is confidence interval. AMI is acute myocardial infarction. CHF is congestive heart failure. AA is aortic aneurysm.

[a] A risk-adjusted standardized mortality ratio (SMR) calculation is not yet possible for these combinations of diseases and procedures, because case-based or risk-stratified federal data are not publicly available for these indicators. Therefore, only crude rates are presented.

[b] Not available.

in increased case numbers within one to two years after initiating changes. Although not a proof, this is convincing to hospital management. It is possible that this effect is not only a direct consequence of the publication of outcome indicators. In Germany, outpatient physicians admitting patients to a hospital usually are different from those employed by hospitals. Therefore, the various improvements within a department might also be recognized more informally by admitting physicians (for example, improved treatment processes might become evident from the medical report, the experience of fewer complications, or better adherence to the medication suggested by the hospital).

The "second-generation" approach also has its pros and cons. The pros are as follows: (1) No additional effort is required for data sampling besides the effort needed for the reimbursement process (that is, no redundant data collection). (2) All inpatient cases are included; thus, there can be no manipulation by not reporting critical cases. (3) Basically, indicators could be defined for all types of hospital cases, if meaningful measures are available, without causing additional efforts in the hospital. The cons are as follows: (1) Information is restricted to "codeable" diagnoses and procedures—that is, those covered by the coding system. However, these could be modified to obtain better information about quality-related events. Already, the German coding system is more sophisticated than the U.S. ICD-9-CM (Clinical Modification) and thus allows for more detailed evaluations. (2) Outcome information is restricted to the inpatient episode, unless additional effort is put into follow-up. An ambivalent argument is that the definition of indicators is strictly algorithmic, based on computerized data. This is seen as a pro by those who demand rational controls but as a con by physicians who want to have control over the question of whether, in an individual case, a certain complication is related to the tracer or not—usually the argument is that every patient is different and that there is at least one who would not fit into a given algorithmic definition.

■ **"Third generation"—quality indicators derived from administrative data at the sickness-fund level.** As a part of the billing process, coded information about demographics, diagnoses, and procedures is transmitted to the sickness funds by electronic data interchange, which was introduced in 1995 but became fully operational only after DRGs were introduced. Thus, a data set similar to MEDPAR is available at this level. It can be used to compute the same indicators as with the "second-generation" method. However, insurance data offer a far more extensive perspective by linking a start event (for example, a myocardial infarction or a hip replacement) with subsequent mortality information as well as treatment episodes containing all information about diagnoses, procedures performed, and so on.

For hip replacement, major complications within any defined time frame can easily be identified—for example, readmissions due to thrombosis, prosthesis dislocation, femoral shaft fracture, or a complete replacement of the prosthesis would appear in the data available at the sickness funds. Complications can be recognized even if the patient was readmitted to a different hospital. The detection of

medium- or long-term complications does not depend on coding by the treating physician; that is, the method is highly resistant to manipulation. If data on the exact type and manufacturer of an implant would also be collected, a follow-up could easily show problems related to medical devices.

Because there is almost complete follow-up of all patients, such evaluations could provide often more complete insights than a procedure-specific register can provide. In Germany, the only losses to follow-up result from insured persons' changing their sickness funds (around 6 percent annually).[13] Thus, the follow-up rate is much higher than in cases of additional data collection. The follow-up rate could be increased to 100 percent if data from all German sickness funds were pooled. Such a data pool currently exists only for hospitals, but one could theoretically be generated for sickness funds.

For chronic diseases, recurrent and first-ever events can be separated even if the information is not directly coded within the single episodes. If for a certain tracer event, such as stroke, all patients were excluded who had been admitted for the same event within a defined interval before the current admission, then the remaining cases would be first-ever events (if a sufficiently large interval is chosen).[14]

The Allgemeine Orts-Krankenkasse (AOK) group of sickness funds, the Scientific Institute of the AOK, the HELIOS group, and the research institute Forschungs- und Entwicklungsinstitut für das Sozial- und Gesundheitswesen Sachsen-Anhalt (FEISA) have jointly developed such a system based on the AOK data.[15] A core task of the first phase was to develop data extraction and evaluation methods, which include all techniques necessary to extract data from the AOK's computer systems, and to link the patient episodes as well as the computational logic to define the start events (called tracers), risk-adjustment methods, and outcome indicators.

Within this first phase, eight tracers were covered: AMI, congestive heart failure (CHF), stroke, colorectal resection for cancer, appendectomy, elective hip replacement, hip replacement for trauma, and knee replacement. Indicators currently include volume of cases, short- and medium-term mortality (thirty days, ninety days, one year), specific complication rates, and information about comorbidities. The methodology will be extended to other indications.

Starting in spring 2008, the AOK has made specific annual reports about these outcome indicators available to all German hospitals. A consumer-oriented publication is intended for a second phase after more experience has been gathered with the current system.

Currently the method is used by the AOK only. This largest group of German sickness funds covers about 33 percent of all insured Germans and, because of the above-average age structure, about 40 percent of all inpatient cases. Theoretically, such a system could be applied in the future to all patients from all sickness funds.

This method can be used for more than to compare hospitals. It also allows the

comparison of medical treatment methods at the national level with respect to medium- and long-term outcomes. The pros of this method are as follows. (1) Long-term outcomes of a medical treatment can be investigated without additional data collection effort. (2) Data are available across all hospitals (at least from all that treat patients insured by the respective payer). (3) The method is highly resistant to manipulation. The one argument against is that as with the "second-generation" approach, information is restricted to "codeable" information.

Hospital Quality Reports

Measuring quality is one issue; making results publicly available is another. Since 2005, hospitals have been required by law to publish standardized quality reports every two years. The reports are made accessible online, enabling the public to search for information on quality by hospital or location (although direct comparison is often not possible). While providing comprehensive information, the 2005 reports have been criticized because they do not include outcomes data. In addition to structural information (type of departments, licensed beds, and so on), hospitals were required only to publish some volume information for the ten most frequent diagnoses, procedures, and DRGs per department.

Since 2007, the publication of twenty-seven quality parameters out of the BQS modules has become mandatory. Most of these, however, are related to process information, not to outcomes. One example is the question of whether receptor status has been determined in breast cancer surgery patients. Hospitals can publish additional information voluntarily. However, because this is not standardized, it is not available in comparable form—for example, via Internet search engines.

Application And Consequences

The development of quality measurement, monitoring, and management has made great progress in Germany. Besides the current mandatory system to measure quality, which is based on separately collected data, new methods have evolved that use readily available administrative data and therefore provide additional information. The latest version, based on insurance data, represents a new and promising method for measuring long-term outcomes. Because of the relatively coherent data structures within the SHI system, these methods could be applied to nearly the whole population, if legal obstacles could be overcome. This would open new possibilities for quality measurement at the provider level as well as the federal level concerning follow-up and the comparison of outcomes.

A problem for the use of disease- or procedure-specific quality indicators to compare providers relates to statistical power. Especially in cases of important but rarely performed procedures, or in small hospitals with comparatively small case numbers, the proof even of major deviations of complication rates from the national average can be difficult. As a result, small providers might never show "poor outcomes." In part, this problem can be overcome by pooling more than one

year's data. This will improve statistical significance but will provide less information about short-term changes in quality.

However, the calculations done by the AOK show that for every outcome indicator—for example, the standardized mortality ratio—in 4–10 percent of hospitals even the lower limit of the 95 percent confidence interval (CI) will exceed the national average.[16] Thus, quality indicators can help identify the "black sheep." No political method has yet been established to deal with this situation, although the results provoke the question of whether failure to publish and act in the case of hospitals showing, for example, highly and significantly elevated mortality for certain diseases or procedures is ethically justifiable. Based on the experience in New York State after the publication of coronary artery bypass graft (CABG) mortality data, it could be expected that the public availability of this information would improve the quality of these providers or force them to discontinue the services.[17] Other experiences from the United States confirm these results.[18]

The experience of the HELIOS group has shown that competition and the definition of companywide goals for important indicators combined with a peer-review process can improve outcomes. The peer-review process reduces statistical problems. Because it identifies treatment errors or weaknesses in the treatment process on a case-by-case basis, the statistical significance of the results becomes less relevant. Experience from the 100,000 Lives campaign of the Institute for Healthcare Improvement (IHI) in the United States confirms the finding that management processes can considerably improve outcomes.[19]

The long-term results of the "third-generation" indicators are also valuable for evaluating results at the national level. The AOK alone has around 50,000 cases of elective hip replacement and 67,000 cases of AMI annually. The implementation of new treatment procedures that have proved effective in scientific studies and their outcomes under routine conditions can be analyzed using these data. The U.S. Food and Drug Administration seems to have taken a step in this direction.[20] Furthermore, U.S. Medicare has initiated a comparable program by sampling the Chronic Condition Warehouse (CCW) data set; however, this is much more restricted than the German approach.[21] It is a 5 percent sample of Medicare data and refers to twenty-one conditions only. By contrast, the AOK project covers all AOK insured with all hospital or health system encounters of any type.

Thus, the development of "third-generation" indicators—especially if enriched by information previously confined to the "first generation"—may help establish a new type of quality assessment, in both Germany and the United States. Germany seems to be on the way, with the legal requirement for quality indicators to span across sectors introduced in 2007.

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