

Methodology Matters

Critical appraisal of clinical performance measures in Germany

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Abstract

Background. One of the tasks of the Federal Co-ordinating Committee, as part of the self-governing health care system in Germany, is to develop clinical performance measures (CPMs). As these measures generally exert a strong impact on health care delivery, their methodological quality should meet the highest standards.

Objective. To develop, for use in the German health care system, methodological quality requirements for CPMs and performance assessment programs.

Materials and Methods. We assembled and reviewed internationally available materials on CPMs. From these we prepared lists of requirements for appraising the methodological quality of CPMs and CPM programs.

Products. Lists of criteria for use in appraising the appropriateness of the development, content, format and application of CPMs and their value to the health care system for performance measurement; a checklist for assessing the methodological quality of CPMs/CPM programs.

Conclusion. The methods applied and the products from this project offer a useful framework for prospective CPM/CPM program developers and set a high threshold for the development of methodologically rigorous clinical performance measurement.

Keywords: clinical performance measure, Germany, quality indicator, quality management

An objective assessment of the quality of medical care requires a commonly accepted concept of the term 'quality', for example in the form of evidence-based nominal performance values laid down in clinical guidelines. Actual medical care delivery can then be compared with these nominal performance values. To decide whether nominal and actual performance values match or differ, it is common practice to formulate clinical performance measures (CPMs). (For definitions of this and other special terms used in this paper, see the Appendix.) Any discrepancies between the two values may serve as a good starting point for setting up quality improvement activities.

It appears it is exactly this kind of quality assessment that the German legislature intended to implement in Germany's health care system when passing the Health Care Reform Act of 2000. Article 137e of the 'Fifth Social Code Book' provides that the Federal Co-ordinating Committee—a joint

committee of both the Physicians and Sickness Funds Committee (ambulatory care) and the Hospitals Committee (in-patient care) representing all medical care providers and purchasers at the federal level—should determine, on the basis of evidence-based clinical guidelines, 'criteria' for assessing the appropriate and efficient management of at least 10 diseases per year. Diseases should be selected according to indications that diagnostic or therapeutic approaches to these diseases are underused, overused or misused and that eliminating these deficiencies could have a strong impact on morbidity and mortality in the population [1].

In simple terms, one might say that the outstanding importance of CPMs is due to the widely acknowledged fact that 'what gets measured gets done' [2]. The effects of these measures on the quality of care, however, need not necessarily be positive. On the one hand, official application of particular CPMs in routine care might focus on improving only those

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Table 1 Examples of clinical performance measurement lists and programs that include proposals for methodological quality requirements for clinical performance measures

CPM Program/Name	Source	URL
Computerized Needs Oriented Quality Measurement Evaluation System (CONQUEST)	Agency for Healthcare Research and Quality	www.ahrq.gov
National Library of Quality Indicators	Joint Commission on Accreditation of Healthcare Organizations	www.jcaho.org
ORYX Program	Joint Commission on Accreditation of Healthcare Organisations	www.jcaho.org
Health Plan Employer Data and Information Set (HEDIS®)	National Commission for Quality Assurance	www.ncqa.org
FACCT Quality Measures	Foundation for Accountability	www.facct.org
Quality Indicator Project®	Association of Maryland Hospitals and Health Systems	www.qiproject.org
Acute Health Clinical Indicator Project	Department of Human Services Victoria, Australia	www.dhs.vic.gov.au/ahs/quality/clinical.htm
NHS Performance Indicators	National Health Service Executive	www.doh.gov.uk
Clearing House Databases	UK Clearinghouse on Health Outcomes	www.leeds.ac.uk/nuffield/infoservices/UKCH/home.html
Zurich Indicator Set (in German)	Verein Outcome Zuerich	www.vereinoutcome.ch

aspects that get measured and thus cause a lack of resources that would be required for equally important aspects of care elsewhere. On the other hand, methodologically unsound CPMs can erroneously indicate poor quality of care. Utilizing unsound CPMs could eventually lead to deterioration of the quality of medical care if resources were being used up or health care providers excluded who would otherwise be necessary to maintain high quality of care. For this reason, only rigorous CPMs should be employed to assess the quality of medical care.

So far in Germany no criteria have been available to critically appraise the methodological quality of CPMs. Basing the design of our project on accounts of the experiences with clinical guideline development where the publication of quality criteria did actually lead to better guidelines [3,4], we took it as our objective to promote the development of rigorous high-quality CPMs. We compiled sets of criteria for CPM selection, and formulated methodological quality requirements for individual CPMs and CPM programs. Finally, we developed a checklist as a tool to critically appraise the methodological quality of CPMs.

Materials and methods

We conducted a search for internationally available lists of CPMs and screened them to identify those that proposed

quality requirements for CPMs. Our search strategy was to identify English- and German-speaking organizations generally known to be involved in quality assessment in health care using the keywords: quality indicator, CPM, quality requirement, quality specification, methodological quality, methods, criteria, assessment. The international sources we consulted that proved relevant for this task are listed in Table 1. We then assembled these materials and drew on them to formulate firstly quality requirements for CPM programs (Table 2) and for individual CPMs (Table 3), secondly quality specifications for CPMs and CPM programs (Table 4) (for definitions see Appendix), and thirdly the checklist for the critical appraisal of CPMs presented in Tables 5–7. The process of compilation comprised mainly the sorting out of all methodological quality criteria for CPMs mentioned, striking out duplicates, and classifying the criteria by principal category. To formulate the major categories of the checklist we drew especially on the established German Checklist for Appraising the Quality of Clinical Guidelines [4].

Requirements for clinical performance measures

Before developing CPMs it is important to select carefully those aspects of health care that are worthy of researchers' effort in undertaking the laborious CPM development process. Several criteria for selecting aspects of care suitable for quality assessment have been proposed in the literature [5–8].

Table 2 Quality requirements for clinical performance measure programs

Requirement	Extension
Consensus on the relative importance of aspects of care	National programs for development and use of CPMs should be established and realized only for those aspects of care for which consensus exists among all stakeholders about their impact on the overall quality of medical care. Legal requirements must be taken into account.
Relevance	CPMs/CPM programs must be relevant to health care practice. Target groups and aspects of care that are the focus of CPMs should be clearly defined and described.
Controllability of aspects of care	CPMs/CPM programs should refer to those aspects of care that have a high potential for quality improvement when quality management techniques are employed.
Balance	CPMs/CPM programs should assess the quality of health care in a balanced manner, i.e. their effects and side effects on medical care should be taken into account. Side effects may result from emphasizing certain processes whereas at the same time neglecting other equally important but unmeasured processes. Therefore, sets of CPMs should be used to assess aspects of care if possible.
Cost–benefit ratio	The purpose of CPMs/CPM programs is to improve health care delivery. The cost-effectiveness of applying CPMs or CPM programs should be taken into account in comparison with other methods that are able to improve the aspects of care under consideration.

Table 3 Quality requirements for clinical performance measures

Requirement	Method of address
Comprehensibility	CPMs must be clearly and distinctly defined by using easily comprehensible language and precise terminology.
Validity	CPMs are considered valid if there is sufficient scientific evidence that they truly measure quality of care (internal validity). The measurement activity and subsequent orientation of the care process measured towards established performance thresholds actually should lead to an improvement of medical care delivery and/or of the outcomes of care (external validity).
Reproducibility	CPMs are considered reproducible if different groups of independent experts develop comparable CPMs when using the same scientific evidence and methods.
Reliability	CPMs are considered reliable if different independent users using the same database and methods at different times attain comparable measure values for given quality indicators.
Discrimination	CPMs and related performance thresholds should help to distinguish between ‘good’ and ‘bad’ provision of care. To this end, CPMs must be both sensitive, i.e. able to measure even slight quality differences, and specific, i.e. only react to those cases where true variability exists in quality of care.
Adjustability	CPMs should be formulated in such a way that they measure the quality of specific aspects of care of comparable units (regions, organizations, providers of care). If there is only limited comparability all possible confounders should be identified and statistically adjusted.

These include procedures or processes with the following characteristics.

1. Those with a high frequency of occurrence.
2. Those with high risk for patients.
3. Problem-prone procedures.
4. Those suspected of overuse, underuse or misuse.
5. Those with proven inter-provider variability.

Table 4 Quality specifications for clinical performance measures and clinical performance measure programs

Specification	Specification details
Documentation of CPM program development	Procedures, participants, materials and premises used to develop a CPM program should be documented exactly. The link between CPMs and the best available scientific evidence should also be documented clearly.
Transparency	CPMs/CPM programs should only be implemented if their objectives, methods used and underlying scientific findings, sources, authors and target groups are clearly identified.
Updating/systematic reviewing	CPMs/CPM programs should include information about the date and method for reviewing the methodological quality of CPMs as well as information about the individual(s)/body(ies) performing the review.
Stakeholder and patient involvement	Representatives of stakeholder groups should be involved in CPM/CPM program development. In particular, CPM programs measuring outcomes of care should involve affected patients.
Application of measurement results	CPMs/CPM programs should be complemented with tools that help achieve the objectives of quality measurement, i.e. improve quality of care. Tools may include: user-friendly publications of quality assessments, assessment interpretation guides, educational and training material.

6. Processes of care that have recently undergone major changes.
7. Procedures with a strong financial impact.
8. Processes considered to be measurable or adaptable.
9. Service procedures provided by caregivers favorably disposed to system changes.
10. Those that have the potential to improve health care delivery and outcomes.
11. Those that have high relevance to consumer interests.
12. Those that might be used to improve decision-making processes (for or against specific organizations providing medical care).

By drawing on the sources mentioned above (see Table 1) and by using this list of characteristics to assess a selected number of aspects of care we were able to assemble a list of quality requirements for use in the development of programs to assess quality of care by means of CPMs (Table 2).

Quality requirements for individual CPMs are listed in Table 3 and quality specifications for CPMs/CPM programs in Table 4.

Checklist for appraising the quality of clinical performance measures

The questions in the checklists listed in Tables 5–7 were derived from the quality requirements and specifications for choosing and specifying the aspects of medical care to be measured listed in Tables 2–4. In addition, we included those questions from the German Checklist for Appraising the Quality of Clinical Guidelines [4] that we found useful for formulating CPMs and that had been helpful in evaluating the methodological quality of CPMs in surgical gynecology

[9]. The checklist contains questions concerning development, content, format and application of CPMs. A total of 39 questions promote comprehensive documentation and appraisal of the quality of CPMs (see Tables 5–7).

Conclusion

Given all the criteria established above, both quality requirements presented for CPMs and CPM programs and the checklist derived to document and assess their methodological quality establish a maximum requirement for those developing CPMs and it is unlikely that all these quality requirements can be fulfilled at once. Existing CPMs/CPM programs do not appear to have reached such a high-quality level yet [10]. As a framework for prospective CPM/CPM program developers, though, the quality requirements described above offer the possibility of developing methodologically more rigorous CPMs/CPM programs and a more objective appraisal of the quality of medical care.

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Table 5 Checklist for appraising the quality of clinical performance measures: Part 1, questions concerning the development of clinical performance measures

Responsibility for development of the clinical performance measures	
1.1	Is the institution responsible for development of the clinical performance measures clearly identified?
1.2	Are the individuals and/or bodies involved in development of the clinical performance measures (specialist groups, stakeholders, user and patient groups) clearly identified as to their function and kind of involvement?
1.3	Are details provided about any financial support or any other forms of funding received from a third party for development of the clinical performance measures?
1.4	If there was any sponsorship by commercial stakeholders or any indication of potential obligations and/competing interests, has their potential impact on the clinical performance measures been discussed?
Selection of quality-relevant aspects of health care	
1.5	Has a detailed analysis been performed and documentation provided on the aspect of health care for which clinical performance measures are to be developed?
1.6	Are the sources of information and methods described that were used to retrieve, identify and select clinical practice guidelines for these quality-relevant aspects of health care?
1.7	Are the methods described for obtaining consensus on prioritization of quality-relevant aspects of care?
Identification, formulation and selection of clinical performance measures including related performance thresholds	
1.8	Are the sources of information and methods that were used to search for and identify both potential clinical performance measures and related performance thresholds described?
1.9	Are the methods for selecting existing clinical performance measures described?
1.10	Have the methodological characteristics of clinical performance measures and performance thresholds been systematically reviewed?
1.11	Are the sources of information and methods that were used to search, identify and select the evidence underlying clinical performance measures and performance thresholds described?
1.12	Are the methods used to assess the strength of the evidence specified?
1.13	Are the methods used to obtain consensus on the clinical performance measures and performance thresholds described?
External validation and pilot studies	
1.14	Were the clinical performance measures independently reviewed before publication?
1.15	Are the methods, commentaries and consequences of the review described?
1.16	Have the clinical performance measures been tested or piloted?
1.17	If so, is explicit information provided about both the methods of the pilot tests and the results adopted?
Updating of clinical performance measures	
1.18	Are the individuals or the body responsible for initiating and performing the review and/or updating process clearly identified?
1.19	Are the methods (evaluation plan) for reviewing and/or updating the measures precisely described?
1.20.	Is a specific date for reviewing and/or updating the measures given?
Transparency of the development of clinical performance measures	
1.21	Is a summary given of the methodology used to develop the clinical performance measures (e.g. in the form of a clinical performance measures report)

Table 6 Checklist for appraising the quality of clinical performance measures: Part 2, Questions concerning the content and format of clinical performance measure

Systematic explanation of clinical performance measures	
2.1	Are the clinical performance measures described in unambiguous terms and comprehensible language?
2.2	Are all the terms used in the description clearly defined?
2.3	Are the reasons for applying the clinical performance measures explicitly stated?
2.4	Are the target group(s) (e.g. patients, providers of care, or administrators) of the clinical performance measures identified?
2.5	Is (are) the patient group(s) receiving the care to be measured clearly defined (e.g. as to sex, age, stage of the disease, concomitant diseases, organizational unit, area of health care, region)?
2.6	Are the factors influencing the measure value of clinical performance measures described?
2.7	Are corrective adjustment procedures described that may help to improve the inter-performer comparability of the measure values of clinical performance measures?
2.8	Are the performance thresholds for the clinical performance measures explicitly stated?
2.9	Are the sources used to collect the data for clinical performance measures and their influencing factors clearly specified?

Table 7 Checklist for appraising the quality of clinical performance measures: Part 3, Questions concerning the application of clinical performance measures

Data Management	
3.1	Are practicable and evaluated tools available for collecting the data necessary to estimate the measure values for clinical performance measures (e.g. documentation forms containing instructions, electronic data processing programs, etc.)?
3.2	Is a clear description provided of the data pooling processes that may be required for estimating the measure values for clinical performance measures?
3.3	Are informational and/or training programs available for those involved in the data collection process?
3.4	Are the procedures used to ensure the quality of data described?
3.5	Are the procedures used to ensure technical data security and data protection explicitly stated?
Application of clinical performance measures	
3.6	Is information available about the intended forum for dissemination of the quality evaluation results?
3.7	Is specific information available about the application and/or ownership of the data and results of the analysis?
3.8	Is an estimate available of the financial resources needed for collecting and analysing the data for routine use?
3.9	Are plans available for evaluating the impact that the application of clinical performance measures has on health care?

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Appendix

Definitions

We define here a number of terms relating to quality assessment of medical care as they are used in this paper. Most definitions were derived from the following sources [7,11–14].

Aspects of health care are structures, processes or outcomes of medical care that are considered suitable for assessment in the context of quality management in health care.

Clinical performance measures (CPMs) are algorithms or rules of procedure for measuring aspects of health care service provision (e.g. structures, processes or outcomes) for the purpose of assessing their quality and the need for quality improvement.

Clinical performance measure programs are programs that use sets of CPMs to assess the quality of medical care delivered by different health care providers. The results of the assessments are used for comparative performance reporting. In Germany such programs are run jointly by the Federal associations of health care providers, the German Hospital Association, and the Federal Associations of Sickness Funds. Health care providers showing poor results may have their licence to practice revoked.

Performance thresholds are specific levels on a scale of values that mark the points at which the performance of a health care activity as measured by a quality indicator is assigned a rating such as ‘Good’, ‘Satisfactory’, ‘Poor’, etc.

(Quality) indicators—an alternate term for CPMs—are applied to aspects of care provision to evaluate the quality of structures, processes, or outcomes of medical care.

Quality requirements for CPMs are needs or expectations that are stated, generally implied or obligatory (e.g. as part of the procedural rules of the Federal Co-ordinating Committee) and must be taken under consideration and addressed when selecting performance measures.

Quality specifications are data elements pertaining to the resources and materials used, contributors engaged, groups targeted and results applications produced in the process of performance measures development. These elements and their mode of application to the measure development process should be clearly documented to permit full appraisal of the quality of the measures.

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