

Methodology Matters

Defining and classifying clinical indicators for quality improvement

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Abstract

Objective. This paper provides a brief review of definitions, characteristics, and categories of clinical indicators for quality improvement in health care.

Analysis. Clinical indicators assess particular health structures, processes, and outcomes. They can be rate- or mean-based, providing a quantitative basis for quality improvement, or sentinel, identifying incidents of care that trigger further investigation. They can assess aspects of the structure, process, or outcome of health care. Furthermore, indicators can be generic measures that are relevant for most patients or disease-specific, expressing the quality of care for patients with specific diagnoses.

Conclusions. Monitoring health care quality is impossible without the use of clinical indicators. They create the basis for quality improvement and prioritization in the health care system. To ensure that reliable and valid clinical indicators are used, they must be designed, defined, and implemented with scientific rigour.

Keywords: clinical indicators, definitions, outcome measures, performance measures, quality improvement, quality of care

The quality of health care is on the agenda in most health care systems. Much of this interest in quality of care has developed in response to recent dramatic transformations of health care systems, accompanied by new organizational structures and reimbursement strategies that may affect quality of care. However, only of late has systematic evidence about quality of care begun to be collected in most health care systems; in most countries there is no mandatory national system to track the quality of care delivered to the citizens. The question, therefore, is what do we know about the quality of health care? The literature indicates [1–4]: (i) a lack of documentation about how major illnesses are treated in most health care systems; (ii) a lack of systematic outcome assessment; (iii) a lack of resource evaluation related to quality for specific diseases; (iv) persisting variations among providers in care for similar patients; and (v) that few formal monitoring systems are in place by health care providers or regulators. For most diseases, potential quality problems and their prevalence and incidence are unknown in many countries.

Assessing the quality of care has become increasingly important to providers, regulators, and purchasers of care. In recent years, providers have begun to be interested in evidence-based medicine and purchasers have begun to focus on the cost-effectiveness of health care in producing health outcomes.

Indicators for performance and outcome measurement allow the quality of care and services to be measured. This assessment can be done by creating quality indicators that describe the performance that should occur for a particular type of patient or the related health outcomes, and then evaluating whether patients' care is consistent with the indicators based on evidence-based standards of care.

This paper aims to define clinical indicators in a standard way for a global audience, and to review a few classifications of clinical indicators that may be useful to those who wish to measure quality of care.

Terminology, concepts, and definitions

Definitions

Quality of care can be defined as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge' [5], and can be divided into different dimensions according to the aspects of care being assessed [6]. This paper will focus on clinical indicators that describe the performance of health care and related outcomes.

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Indicators have been defined in several different ways:

1. As measures that assess a particular health care process or outcome [7].
2. As quantitative measures that can be used to monitor and evaluate the quality of important governance, management, clinical, and support functions that affect patient outcomes [8].
3. As measurement tools, screens, or flags that are used as guides to monitor, evaluate, and improve the quality of patient care, clinical support services, and organizational function that affect patient outcomes [9].

Indicators provide a quantitative basis for clinicians, organizations, and planners aiming to achieve improvement in care and the processes by which patient care is provided.

Indicator measurement and monitoring serve many purposes. They make it possible to: document the quality of care; make comparisons (benchmarking) over time between places (e.g. hospitals); make judgments and set priorities (e.g. choosing a hospital or surgery, or organizing medical care); support accountability, regulation, and accreditation; support quality improvement; and support patient choice of providers. The use of indicators enables professionals and organizations to monitor and evaluate what happens to patients as a consequence of how well professionals and organizational systems function to provide for the needs of patients. Indicators are, however, not a direct measure of quality. Because quality is multidimensional, understanding quality requires many different measures.

Indicators are based on standards of care. These can be evidence-based and derived from the academic literature (see, for example, Cochrane Collaboration literature syntheses, meta-analyses, or randomized controlled trials) or, when scientific evidence is lacking, determined by an expert panel of health professionals in a consensus process based on their experience. Thus, indicators and standards can be described according to the strength of scientific evidence for their ability to predict outcomes [10].

Key characteristics of an ideal indicator

An ideal indicator would have the following key characteristics: (i) indicator is based on agreed definitions, and described exhaustively and exclusively; (ii) indicator is highly or optimally specific and sensitive, i.e. it detects few false positives and false negatives; (iii) indicator is valid and reliable; (iv) indicator discriminates well; (v) indicator relates to clearly identifiable events for the user (e.g. if meant for clinical providers, it is relevant to clinical practice); (vi) indicator permits useful comparisons; and (vii) indicator is evidence-based. Each indicator must be defined in detail, with explicit data specifications in order to be specific and sensitive. This is discussed in greater detail in a companion paper [10].

Indicators may vary in their validity and reliability. Validity is the degree to which the indicator measures what it is intended to measure, i.e. the result of a measurement corresponds to the true state of the phenomenon being measured. A valid indicator discriminates between care otherwise known

to be of good or bad quality and concurs with other measures that are intended to measure the same dimension of quality. Reliability is the extent to which repeated measurements of a stable phenomenon by different data collectors, judges, or instruments, at different times and places, get similar results. Reliability is important when using an indicator to make comparisons among groups or within groups over time. A valid indicator must be reproducible and consistent.

Indicators should be based on the best available evidence. Sackett *et al.* describe this as ‘the integration of best research evidence with clinical expertise and patient values’ [11]. The strength of evidence for an indicator will determine its scientific soundness or the likelihood that improvement in the indicator will produce consistent and credible improvements in the quality of care.

Types of indicators

Table 1 lists a few different classifications of indicators that may be useful when considering which should be used for a given purpose.

Rate-based versus sentinel indicators

A rate-based indicator uses data about events that are expected to occur with some frequency. These can be expressed as proportions or rates (proportions within a given time period), ratios, or mean values for a sample population. To permit comparisons among providers or trends over time, proportion- or rate-based indicators need both a numerator and a denominator specifying the population at risk for an event and the period of time over which the event may take place.

A sentinel indicator identifies individual events or phenomena that are intrinsically undesirable, and always trigger further analysis and investigation. Each incident would trigger

Table 1 Categories of clinical indicators

Rate-based or sentinel
Related to structure/process/outcome
Generic or disease-specific
Type of care
Preventive
Acute
Chronic
Function
Screening
Diagnosis
Treatment
Follow up
Modality
History
Physical examination
Laboratory/radiology study
Medication
Other interventions

an investigation. Sentinel events represent the extreme of poor performance and they are generally used for risk management.

Table 2 shows examples of rate-based and sentinel indicators [12]. Rate-based and sentinel indicators can be generic or disease-specific, and related to either structure, process, or outcome (see below).

Indicators related to structure, process, and outcome

Indicators can be related to structure, process, or outcome of health care [13,14]. ‘Structure’ denotes the attributes of the settings in which care occurs. This includes the attributes of material resources (such as facilities, equipment, and financing), of human resources (such as the number and qualifications of personnel), and of organizational structure (such as medical staff, organization, methods of peer review, and methods of reimbursement). Examples of structural indicators are listed in Table 3.

‘Process’ denotes what is actually done in giving and receiving care, i.e. the practitioner’s activities in making a diagnosis, recommending or implementing treatment, or other interaction with the patient.

‘Outcome’ measures attempt to describe the effects of care on the health status of patients and populations. Improvements in the patient’s knowledge and salutary changes in the patient’s behavior may be included under a broad definition of outcome, and so may represent the degree of the patient’s satisfaction with care.

In order for a process indicator to be valid, it must previously have been demonstrated to produce a better outcome. Similarly, using structural indicators for quality assessment is possible only if structural components have been shown to increase the likelihood of either a good outcome, or a process that has previously been shown to yield better outcomes. It is necessary, then, to have established such relationships before any particular component of structure or process is used to assess quality. These linkages may be based on scientific literature; if little evidence exists, professional experience concerning these linkages can be distilled using consensus methods. Only clinical indicators that are evidence-based have had

the linkage between structure or process and patient health outcomes confirmed [15]. The ability to assess the quality of medical technical care is bounded by the strengths and weaknesses of clinical science.

Structural indicators

‘Structure’ refers to health system characteristics that affect the system’s ability to meet the health care needs of individual patients or a community. Structural indicators describe the type and amount of resources used by a health system or organization to deliver programs and services, and they relate to the presence or number of staff, clients, money, beds, supplies, and buildings. Examples of structural indicators are listed in Table 3 [4,16]. The assessment of structure is a judgement on whether care is being provided under conditions that are either conducive or inimical to the provision of good care.

Process indicators

Process indicators assess what the provider did for the patient and how well it was done. Processes are a series of inter-related activities undertaken to achieve objectives. Process indicators measure the activities and tasks in patient episodes of care. Examples of process indicators are listed in Table 3.

Some authors include the patient’s activities in seeking care and carrying it out in their definition of the health care process. Others limit this term to care that health care providers are giving. It may be argued that providers are not accountable for the patient’s activities and these, therefore, do not constitute part of the quality of care, but rather fall into the realm of patient characteristics and behavior that influence patients’ health outcomes.

Outcome indicators

Outcomes are states of health or events that follow care, and that may be affected by health care. An ideal outcome indicator would capture the effect of care processes on the health and

Table 2 Examples of rate-based and sentinel indicators

Rate-based indicators

Clean and contaminated wound infection

- (1) Numerator: the number of patients who develop wound infection from the fifth post-operative day after clean surgery
- (2) Denominator: the total number of patients undergoing clean surgery within the time period under study who have a post-operative length of stay of ≥ 5 days.

Hospital-acquired bacteraemia[12]

- (1) Numerator: total number of patients who acquire bacteraemia
- (2) Denominator: total number of patients in hospital during the study period

Sentinel indicators

Numbers of patients who die during surgery

Numbers of patients who die during the perinatal period

Table 3 Examples of indicators related to structure, process, and outcome

Structure
Proportion of specialists to other doctors
Access to specific technologies (e.g. MRI scan)
Access of specific units (e.g. stroke units)
Clinical guidelines revised every 2nd year
Physiotherapists assigned to specific units
Process
Proportion of patients with diabetes given regular foot care
Proportion of patients with myocardial infarction who received thrombolyses
Proportion of patients assessed by a doctor within 24 hours of referral
Proportion of patients treated according to clinical guidelines
Outcome
Intermediate
HbA1c results for diabetics
Lipid profile results for patients with hyperlipidemia
Blood pressure results for hypertensive patients
End result (should be specified for diseases)
Mortality
Morbidity
Functional status
Health status measurement
Work status
Quality of life
Patient satisfaction

wellbeing of patients and populations. Outcomes can be expressed as ‘The five Ds’ [5]: (i) death: a bad outcome if untimely; (ii) disease: symptoms, physical signs, and laboratory abnormalities; (iii) discomfort: symptoms such as pain, nausea, or dyspnea; (iv) disability: impaired ability connected to usual activities at home, work, or in recreation; and (v) dissatisfaction: emotional reactions to disease and its care, such as sadness and anger. Examples of outcome indicators are listed in Table 3.

Intermediate outcome indicators reflect changes in biological status that affect subsequent health outcomes. Some outcomes can only be assessed after years (e.g. 5-year cancer survival). It is therefore important to assess intermediate outcome indicators. They should be evidence-based and reflect the outcome (e.g. HbA1c in diabetes). They can be regarded as short-term outcomes [17,18]. Examples are listed in Table 3.

Risk adjustment

In most cases, multiple factors contribute to a patient’s survival and health outcomes. Figure 1 illustrates potential factors that might contribute to the outcome of care [4,19]. Therefore, outcome measures must be adjusted for factors outside the health system, if fair comparisons are to be made. In quality assessment, components that relate to the medical care system should be isolated, which is accomplished by controlling for significant confounding factors that contribute to the outcome.

Factors that are frequently included in risk adjustment models include patient demographic, psychosocial characteristics (such as age, sex, and functional status), lifestyle factors (smoking, alcohol use), severity of the illness that is the focus for measurement, health status, and co-morbid conditions. Risk adjustment is essential before comparing patient outcomes across hospitals or providers [20,21].

Risk adjustment may be most important for outcome indicators [22,23]. There are also other methods for ensuring that other differences among patient groups are not influencing comparisons of process or outcome indicators. For example, the population of patients for whom the indicator is measured can be carefully restricted. Alternatively, stratified analyses can be performed to examine specific types of patients within an overall sample.

Structure, process, and outcome: which measures should be chosen?

Of the structural indicators, measures that predict variations in processes or outcomes of care have the greatest utility, and such measures often focus on hospital or provider characteristics [16]. Regarding pediatric quality of care, one consistent finding has been that hospitals caring for higher volumes of patients with similar conditions have better adjusted mortality rates, which is also true for surgical procedures [18,24]. Fourteen structural characteristics that have been demonstrated to be related to evidence-based processes or to outcomes have been identified [16].

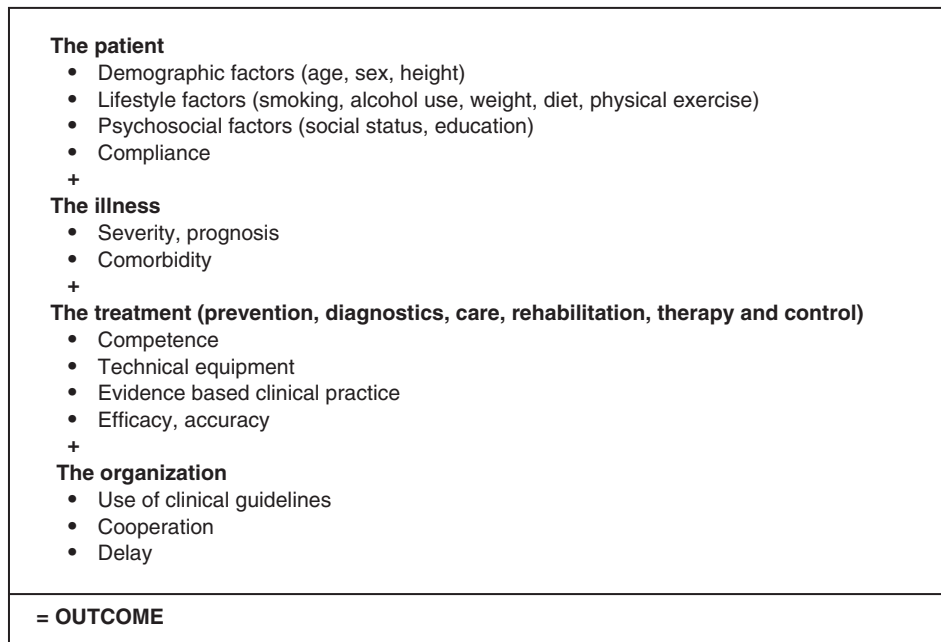


Figure 1 Factors determining the outcome of care.

The advantages and disadvantages of process versus outcome measures have been recently reviewed [22,23,25]. The following points may be worth reiterating. First, as others have also noted, elements of the process of care do not signify quality until they are validated by demonstrating their relationship to desirable outcomes [14,16]. Once it has been established that certain procedures used in specified situations or for certain patients are clearly associated with good results, the presence or absence of these procedures for such patients or situations can be accepted as evidence of good or bad quality [6,13,14]. Such evidence-based structural or process indicators may be referred to as ‘outcome-validated’ and represent direct measures of quality [25].

Process indicators are especially useful when [15]: quality improvement is the goal of the measurement process; an explanation is sought for why specific providers achieve particular outcomes; short time frames are necessary; performance of low volume providers is of interest; and when tools to adjust or stratify for patient factors are lacking.

Comparisons of process data are easier to interpret and more sensitive to small differences than comparisons of outcomes data. A process indicator can measure whether or not a stroke patient receives the right medication, whereas 30-day mortality rates from stroke patients may be difficult to interpret.

Palmer suggests that outcomes data are useful if [15]: outcomes can be measured that are affected by health care; long time-frames are possible; performance of whole systems should be studied; or if a high volume of cases is available. Outcomes data are most useful for tracking care given by high-volume providers over long periods of time, and for detecting problems in implementation of processes of care.

Figure 1 indicates that the outcome of care is determined by several factors related to the patient, the illness, and health care. Differences in outcome may be due to case mix and other confounding factors. Standardized data collection and risk adjustment are therefore important for interpreting outcomes data. Outcome indicators could be used when variations in health care might result in significant variations in health outcome, and where the occurrence is sufficiently common, the outcome indicators will have power to detect real differences in quality [25]. In general it can be recommended that the broader the perspective required, the greater the relevance of outcome indicators. As the perspective narrows to hospitals and departments or providers, outcome measures become less useful, although still important.

A reasonable strategy is to select measures that meet the needs of each particular condition or treatment; sometimes these will be structure or process measures, and sometimes outcomes measures. More often, they will be a combination of the two.

Regardless of whether structural, process or outcome indicators are chosen, feasibility of measurement is always a key consideration. In addition, the frequency with which an event occurs in the population available for study may affect the usefulness of an indicator, unless it is a sentinel event as described previously.

Generic and disease-specific indicators

Generic indicators measure aspects of care that are relevant to most patients, while disease-specific indicators are diagnosis-specific and measure particular aspects of care related to specific diseases. Both generic and disease-specific indicators can focus on structure, process, or outcome. Table 4

lists examples of generic and disease-specific indicators. As indicated, generic indicators may be difficult to interpret, especially when making comparisons among hospitals or providers, because there may be profound differences in patient mix. Disease-specific outcome indicators can be used to compare hospitals and plans, when data are risk-adjusted. Confounding factors, such as prognostic factors for specific diseases, are likely to be found in the scientific literature for these diseases, thereby indicating the need for risk adjustment.

Indicators related to type of care, function, and modality

Indicators can be classified according to type of care, function, and modality [26]. Indicators classified by type of care may be preventive, acute, or chronic. Function of care can relate to screening, diagnosis, treatment, and follow-up. The modality by which care can be delivered relates to physical examination of the patient, laboratory or radiology study, or prescription of medication, for example [26]. Table 5 illustrates

Table 4 Examples of generic and disease-specific indicators

Generic indicators			
Proportion of specialists to other doctors			
Registered patients in the emergency department > 6 hours			
Unscheduled returns to the operating room			
In-patient mortality			
Disease-specific indicators			
Proportion of cardiologists to other doctors treating patients with heart failure at the department of cardiology			
Proportion of patients with stroke treated with thrombocyte inhibitor < 24 hours after admission			
Proportion of patients with hip fracture who need a second operation			
Proportion of patients with lung cancer who are alive 30 days after surgery			
Proportion of patients with myocardial infarct who receive a beta-blocker within 24 hours of admission			
Proportion of patients with diabetes mellitus who receive a retinal exam annually			

Table 5 Example of indicators classified according to type of care, function, and modality

Indicator	Type of care	Function	Modality
Sickle cell disease: children with a positive sickle cell	Chronic	Treatment	Medication screen or children suspected of being positive for sickle cell disease should be placed on daily penicillin prophylaxis from at least 6 months of age until at least 5 years of age
Urinary tract infection: children with a diagnosed urinary tract infection should be reassessed at 48 hours to determine if there is clinical improvement	Acute	Follow up	Other contact
Well-child care: the child's weight should be measured at least four times during the first year of life. This information must either be plotted on a growth curve or be recorded with the age/gender percentile	Preventive	Screening	Physical examination

Adapted with permission [26]

trates how indicators can be classified into these three groups. The example is modified from work by Schuster *et al.* [26], and illustrates how indicators can be classified in a quality of care measurement system to cover multiple clinical topics.

Conclusion

Clinical indicators measure the extent to which set targets are achieved. They are expressed as numbers, rates, or averages that can provide a basis for clinicians, organizations, and planners aiming to achieve improvement in care and the processes by which patient care is provided. They can be measures of structure, process, and outcome, either as generic measures relevant for all diseases, or disease-specific measures that describe the quality of patient care related to a specific diagnosis.

In general, indicator data are of interest to patients, purchasers, and providers. Outcomes may be of major interest to consumers and payers of care, while providers who are receiving data for quality improvement purposes need detailed data about the process of care to make the information credible and possible to act upon.

Clinical indicators should be valid and sensitive to the events and changes they are intended to detect. Furthermore, clinical indicators should be clearly defined in order to avoid the measurement of changes in the patient's status arising from external factors not related to objectives and targets. Only evidence-based clinical indicators predict patient outcomes and are true measures of quality, although indicators based on professional consensus without evidence may be all that is feasible for certain conditions, treatments or patient populations. Patient health outcomes are determined by many other factors besides the quality of health care. Risk adjustment therefore plays an important role in comparison using outcomes data, in order to adjust for confounding factors.

The surveillance of health care quality is greatly aided by the use of relevant quantitative indicators, supplementing other approaches that may include qualitative analyses of specific events or processes. For the healthy population, indicators can also be important with regard to prevention, quality of life, and satisfaction with health care.

References

- Schuster MA, McGlynn EA, Brook RH. How good is the quality of health care in The United States? *Milbank Q* 1998; **76**: 517–563.
- Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. *J Am Med Assoc* 1998; **280**: 1000–1005.
- President's Advisory Commission on Consumer Protection and Quality First. *Better Health Care for All Americans. Final Report to the President of the United States*. Washington, DC: President's Advisory Commission on Consumer Protection and Quality First, 2000.
- Mainz J, Bartels PD, Laustsen S *et al.* The National Indicator Project for monitoring and improving medical technical care [in Danish]. *Ugeskr Laeger* 2001; **163**: 6401–6406.
- Lohr KN (ed.) *Medicare: A Strategy for Quality Assurance*. Vols I and II. Washington, DC: National Academy Press, 1990.
- Donabedian A. The quality of medical care. *Science* 1987; **200**: 856–864.
- Worning AM, Mainz J, Klazinga N, Gotrik JK, Johansen KS. Policy on quality development for the medical profession [in Danish]. *Ugeskr Laeger* 1992; **154**: 3523–3533.
- JCAHO. Characteristics of clinical indicators. *Qual Rev Bull* 1989; **11**: 330–339.
- Canadian Council on Health Services Accreditation. A guide to the development and use of performance indicators. Ottawa: Canadian Council on Health Services Accreditation, 1996. Available at <http://www.cchsa.ca> (last accessed 31 July 2003).
- Mainz J. Developing clinical indicators. *Int J Qual Health Care* 2003; **15** (suppl. 1): i5–i11.
- Sackett DL, Straus SE, Richardson WS *et al.* *Evidence-Based Medicine: How to Practice and Teach EBM*, 2nd edition. London: Churchill Livingstone, 2000.
- Ansari, MZ, Collopy BT. Nosocomial infection indicators in Australian hospitals: Assessment according to hospital characteristics. *J Qual Clin Practice* 1997; **17**: 73–82.
- Donabedian A. The quality of care. How can it be assessed? *J Am Med Assoc* 1988; **260**: 1743–1748.
- Donabedian, A. Evaluating the quality of medical care. *Milbank Mem Fund Q* 1966; **44**: 166–206.
- Palmer RH. Using health outcomes data to compare plans, networks and providers. *Int J Qual Health Care* 1998; **10**: 477–483.
- Palmer RH, Reilly MC. Individual and institutional variables which may serve as indicators of quality of medical care. *Med Care* 1979; **17**: 693–717.
- McGlynn EA. The outcomes utility index: will outcomes data tell us what we want to know? *Int J Qual Health Care* 1998; **10**: 485–490.
- Mangione-Smith R, McGlynn EA. Assessing the quality of health care provided to children. *Health Serv Res* 1998; **33**: 1063–1090.
- Sackett D, Haynes RB, Guyatt GH, Tugwell P. *Clinical Epidemiology. A Basic Science for Clinical Medicine*. 2nd edition. Boston, MA: Little, Brown and Company, 1991.
- Iezzoni LI. The risks of risk adjustment. *J Am Med Assoc* 1997; **278**: 1600–1607.
- Iezzoni, LI. 100 Apples divided by 15 red herrings: A cautionary tale from the mid-19th century on comparing hospital mortality rates. *Ann Intern Med* 1996; **124**: 1079–1085.
- Rubin HR, Pronovost P, Diette GB. The advantages and disadvantages of process-based measures of health care quality. *Int J Qual Health Care* 2001; **13**: 469–474.
- Rubin HR, Pronovost P, Diette GB. From a process of care to a measure: the development and testing of a quality indicator. *Int J Qual Health Care* 2001; **13**: 489–496.

24. Shahian DM, Normand SL. The volume-outcome relationship: from Luft to Leapfrog. *Ann Thorac Surg* 2003; **75**: 1048–1058.
25. Mant J. Process versus outcome indicators in the assessment of quality of health care. *Int J Qual Health Care* 2001; **13**: 475–480.
26. Schuster MA, Asch SM, McGlynn EA, Kerr EA, Hardy AM, Gifford DS. Development of a quality of care measurement system for children and adolescents. Methodological considerations and comparisons with a system for adult women. *Arch Pediatr Adolesc Med* 1997; **151**: 1085–1092.

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