

The advantages and disadvantages of process-based measures of health care quality

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Abstract

As consumers, payers, and regulatory agencies require evidence regarding health care quality, the demand for process of care measures will grow. Although outcome measures of quality represent the desired end results of health care, validated process of care measures provide an important additional element to quality improvement efforts, as they illuminate exactly which provider actions could be changed to improve patient outcomes. In this essay, we discuss the advantages and disadvantages of process measures of quality, and outline some practical strategies and issues in implementing them.

Keywords: outcomes, performance improvement, quality

Quality of health care has become a national and international policy issue. Decades of study indicate that quality of care needs improvement all over the world, and therefore sentiment has grown that public disclosure of information about quality of care should be one component of clinical governance [1]. The United States government has developed the Agency for Healthcare Research and Quality (AHRQ) and the National Quality Forum to promote the development and reporting of quality measures [2].

Readers of this journal are well aware that more than thirty years ago, Donabedian proposed that we can measure the quality of health care by observing its structure, its processes, and its outcomes [3]. The Institute of Medicine (IOM) in the US has defined health care quality 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’ [4]. The IOM’s definition and framework thus incorporate two of Donabedian’s three elements in a broad approach to measuring health care quality: (1) determining effects of health care on desired outcomes, including a relative improvement in health, and in consumer evaluations or experience of health care and (2) assessing the degree to which health care adheres to processes that are proven by scientific evidence, professional consensus to affect health, or that concur with patient preference [5–7]. The IOM has further suggested that health care should have the

six aims of being effective, safe, patient-centered, timely, efficient, and equitable [4]. Whereas the aims of effectiveness and safety of health care are nearly universal, societies and cultures around the world differ more in how much they emphasize the additional aims of patient-centeredness, timeliness, efficiency, and equity. Process of care measures of quality assess the degree to which providers perform health care processes demonstrated to achieve the desired aims and the degree to which they avoid processes that avert the desired aims.

Public agents and payers’ ultimate concern rests with providers’ impact on patient outcomes, and most of their measures of quality to date have focused on this. For example, the Center for Medicare and Medicaid Services (CMS formerly the Health Care Financing Administration, HCFA), which administers the Medicare entitlement program for the elderly in the US, began by releasing mortality rates for hospitals [8]. The need for risk adjustment when comparing different providers became evident, and subsequent efforts attempted this. For example, several US state governments including New York, Pennsylvania, and California provided their citizens with publicly available report cards containing risk-adjusted mortality rates for cardiac surgery by hospital and surgeon [9–12].

Measures of the process of care that affect outcomes were initially considered too technical for public or regulatory use.

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Theoretically, providers would respond to publicly reported outcome measurement by developing and implementing their own internal report cards focused on evidence-based process measures. However, given the complexity and expense of developing clinical guidelines and process measures and keeping them updated, and the infancy of clinical information systems that would track the clinical process routinely, individual provider organizations have had difficulty incorporating process measurement into their operations. In the last five years, joint efforts by providers, professional societies, monitoring agencies, and quality-of-care experts have begun to assist in identifying and implementing appropriate process-of-care measures. In addition, government and payers have a better understanding of the difficulty of risk-adjustment for outcome measures such as mortality rates, and their own interest in process of care measures of quality has grown. The National Committee on Quality Assurance (NCQA) in the United States collects data on HEDIS[®] quality measures and includes evidence-based measures of health plan processes of care [13]. In the US, these measures are part of NCQA's health plan accreditation program and are used by some employers, insurers, and government payers to choose participating health plans. CMS (formerly HCFA) in the US has also proceeded from reporting on Medicare beneficiary mortality rates to developing, measuring, and reporting on evidence-based hospital and outpatient care processes [14]. Although HCFA has released data on indicator performance to the public only by state and not by provider, several US states have passed or are considering legislation to collect and publish the same indicators for hospitals and practices in those states (B. Miller, Maryland Hospital Association, personal communication).

In the US, where employer-provided health insurance is the norm, consortia of employers are also using quality measures to assess and select providers, and these are also beginning to incorporate some evidence-based measures of structure and process. Whereas the first effort of this type, the Cleveland Health Quality Choice program [15], focused on outcome measures, newer efforts are now including evidence-based, validated structure and process measures. For example, The Leapfrog group [16], a health care purchasing consortium representing Fortune 500 companies, has developed a national measure of quality of intensive care unit (ICU) care and provides incentives for their employees to purchase health care from hospitals that meet this standard. In the area of validated structural and process measures, the standard includes whether intensive care specialists are monitoring the ICU, which has been demonstrated to improve patient outcomes [17].

Health care quality measures, including process measures, are developed for varied audiences who may wish to use them for health care purchasing, utilization, or performance improvement. For all these purposes it is imperative that they are meaningful, scientifically sound, generalizable, and interpretable [18]. To achieve this, quality measures must be designed and implemented with scientific rigor. In this essay, we present an overview of the advantages and disadvantages of using process measures as quality of care measures, and

discuss practical strategies for using quality measures for improvement.

Advantages and disadvantages of process measures of quality of care

There is considerable debate regarding whether quality measures should evaluate processes or outcomes of care. Before proceeding to develop process indicators, those considering this may find it useful to understand their strengths and limitations. Within the categories of process and outcome, there are good and bad measures, but some specific advantages and disadvantages apply broadly to all process measures compared with outcomes (Table 1).

On the plus side, process measures can be used to provide feedback for quality improvement initiatives. Because many factors can influence patient outcomes, process measures have the potential to identify for clinicians exactly which processes they followed or didn't follow that had the potential to affect patient outcomes. Process measures provide information that is actionable; i.e. what is being done well and what needs improvement. When process measures are developed well, so that they accurately reflect the care that clinicians are delivering, clinicians feel accountable for them. In contrast, many other factors affect health care outcomes that are beyond the provider's control. When a clinician discovers that his patient had worse outcomes than another clinician's patients, it is unclear what he or she should be doing about it. When data collection about process of care is generated unobtrusively simply by an electronic patient record when a provider performs the process, these measures become even more attractive and feasible because they eliminate burdensome additional data collection.

Secondly, most process measures require less risk adjustment for patient illness than do most outcome measures. The use of a process measure requires defining a population that is eligible to receive the process such as which patients with asthma should receive anti-inflammatory medications or which patients should receive beta-blockers or aspirin after myocardial infarction. Once the eligible population is specified, further risk adjustment is generally not required, although it can be useful. In contrast, comparing mortality rates or other outcomes for specific clinical conditions requires risk adjustment. Risk adjustment requires definition and measurement of many patient characteristics, including physiological, anatomical, and health status data that are not part of routine administrative databases at present, that may not be part of medical records, and that may be expensive to collect. In addition, existing risk adjustment models often perform poorly when applied to new data sets, limiting application of a common risk adjustment model to all providers [19,20]. The development of new risk adjustment models is analytically complex, requiring expert statistical analytical resources and a large sample of patients available for the development process. Using process measures applied to an accurately defined population avoids some of the time and expense that risk adjustment entails.

Table 1 Advantages and disadvantages: comparison of process and outcome measures

	Process measures	Outcome measures
Resources		
Need for updating and maintenance of measures	Require updating and maintenance of guidelines, review criteria, instruments and software according to advances in treatment	Known risk factors and models may require some updating, generally less often than updates to process measures are needed
Need for development of risk adjustment models and collection of risk data	Most measures do not require the use of extensive risk adjustment models; however, require good definition of eligible patients	Risk adjustment is difficult; need different models for each outcome
Time needed for measurement	Takes less time to accumulate, smaller sample needed, less observation time needed for processes occurring during provider contact	Due to need for risk adjustment a larger sample is needed; also many outcomes of interest are long-term such as five- or ten-year survival requiring long period of observation
Size of population needed for measurement	Can use a smaller sample size as all included patients experience the process and once eligible patients are defined, only descriptive statistics are needed	Due to need for risk adjustment a larger sample is usually needed for comparisons among providers or treatments
Need for additional follow-up tracking of patients for later data collection	Data collection can be done when clinical process is occurring	Requires follow-up for measurement of short- and long-term outcomes at time when routine data collection not occurring
Use of routinely collected data	Has the potential to be abstracted from data already recorded for clinical and administrative use, and ultimately to be completely integrated into such data collection	Often requires collection of data elements that are not being recorded for clinical or billing purposes such as long-term survival or patient-reported health and well-being on standardized scales
Need for advanced statistical consultation for development of measures and analysis of data	Not needed in general	Needed to create risk adjustment models and evaluate them when analyzing data
Validity		
What patients care about	Often inaccessible to patients who often do not understand the significance of a specific component of care	The generic outcomes of survival, health and well-being are what patients care about and measures of these can be used to validate process changes. More specific or proxy outcomes may not be accessible to patients
What providers care about	Face validity with providers; relates directly to what the provider is doing	Providers are wary of outcome measures that are influenced by many other things besides what they do; must measure performance of risk adjustment models
Ease of use		
Ease of specification and identification of population at risk	Difficult to specify population eligible for a process; there can be many exclusions, contraindications and special outcomes, and many important process measures are specific for a single disease	Easy to define population for which want to measure an outcome; many important outcomes are generic and can be compared across several conditions
Creation of valid summary measures	Difficult to summarize process measures in a valid way as they are rarely comprehensive	Many important outcome measures, such as survival, health and well-being, are both global and generic and can be compared across conditions and processes
Interpretability of feedback for quality improvement	Provides clear and interpretable feedback for quality improvement about what providers are actually doing; easy to benchmark	Most measures cannot be used to give feedback to providers about how to improve what they are doing as rarely is an outcome always a consequence of a particular faulty process; benchmarking is needed for comparisons among groups and adjusted outcomes can be difficult to understand

Thirdly, process measures can usually be collected more quickly than outcome data for two reasons. Firstly, outcome events may be rare where only a small percentage of the patients have the outcome, requiring one to accrue a larger sample of patients. In addition, many outcomes that are important to patients, such as quality of life and functional status, may require years after the illness to evaluate, increasing the time for measurement. In contrast, care delivery occurs in a shorter period of time, and every eligible patient receives the specific process of care being evaluated.

On the other hand, there are several disadvantages to process measures. Firstly, to be valid, there must be a strong relationship between the process and outcome measures. These links between process and outcomes can come from previously published evidence, or may be demonstrated for the group whose quality of care is being evaluated. The prior evidence supporting the relationship may be weak or non-existent for many processes even when they are truly linked to outcomes. Even when studies have been carried out, they may not demonstrate true process–outcome linkages. For example, observational studies may show paradoxical associations of good care with inferior outcomes because of confounding by indication. In confounding by indication, sicker patients (who subsequently have worse outcomes) receive more or better care, setting up the paradoxical observation that good care is linked to inferior outcomes. This phenomenon is particularly problematic for patients with chronic illnesses such as asthma, for which measures of intrinsic disease severity are poor. Therefore, it may be difficult to find evidence to support valid process measures.

Secondly, when evidence linking process and outcomes is absent yet providers believe the process is important, or even if such evidence is available, providers may desire to demonstrate the relationship between a process and outcome measure in their organization. This need may be especially strong when a clinical unit or quality improvement effort is requesting additional resources from their administrators to support an evaluation effort or a change in process. If the professional and scientific community has not conducted the needed studies, or these studies are thought to be inapplicable to a specific organization's population, then demonstrating the link between process and outcome is prohibitively expensive and often impossible to achieve for any one organization.

Thirdly, while providers may care about process measures, patients and non-clinicians generally place little value on them; they care about outcomes and believe it is the provider's responsibility to perform the appropriate processes and to avoid harmful ones. Therefore, the measures mean little to consumers or purchasers for plan or provider selection, and may be less useful to a provider organization in its marketing efforts.

Fourthly, most feasible process measures are usually indicators for a very specific element of the care process rather than comprehensive measures of how care is delivered. For example, national asthma guidelines recommend a comprehensive approach to care, including appropriate medication use, periodic assessment of disease status, patient education

for self-management, and identification and avoidance of asthma triggers. While this comprehensive approach may represent ideal care, it may be feasible to measure only whether certain medications have been dispensed by a pharmacy, which provides a narrow perspective on overall asthma care. Feasibility of certain measures may be limited by what information is usually collected in a patient record. For example, while many clinicians will document laboratory testing or use of medications, it is rare to document conversations in which patients are educated about care of their illness. Thus, use of certain processes as indicators of care may be dictated by availability of data, rather than the relative importance of the element of care. In addition, a provider may adhere well to one part of the process but not to another. Therefore, if process measures are not comprehensive and do not cover all the important parts of the process that can affect outcomes, they may be misleading to users.

Practical strategies for developing quality measures

As we have discussed previously, the audience for and use of the quality measure will influence how the measure is developed and how the results are presented. Quality measures are in general used by provider or care management organizations to evaluate and enhance performance through quality improvement initiatives, by purchasers and patients to inform health care decision making, or by accreditors and regulators to monitor organizations.

Internal quality improvement initiatives

For internal organizational quality improvement initiatives, more detailed, less aggregated measures of quality may be more helpful than summary measures. Providers want information regarding how to improve specific processes. As such, the unit of analysis for these initiatives tends to be small, such as the individual unit, practice, or clinician. These types of measure often require significant technical detail. An important consideration in these types of measure is that clinicians believe that the process is related to the outcome such that improvement in the process will result in improvement in outcomes. Without this belief, it is often necessary to establish the link between process and outcome. Data collection for quality improvement can be made part of routine care by existing staff and thus marginal costs are minimal. Electronic medical record systems play a very important role here, and whenever possible, quality assessment efforts should attempt to obtain needed data by replacing usual clinical data collection with collection of standardized data elements. Finally, when used internally for quality improvement, the statistical significance of the results is often less important than the practical interpretation or the visual impact of differences in a graphic presentation. For example, data from these initiatives are often presented as run charts, indicating a rate or score trend over time, with clinically important changes illustrated as crossing lines

representing acceptable upper or lower bounds rather than statistically significant differences.

Purchasers and patients

If the audience for the measures is purchasers or patients and the intent to provide information for health care purchasing decisions, summary or aggregated data are more helpful. These groups may prefer a comprehensive measure that is presented in a way that is understandable to patients, benefit managers, and enrollees. For these groups, it is important that the process measure is already demonstrated to have a strong link to outcome, as they do not perceive it as their role to conduct clinical studies establishing these links. It is more important for these audiences that patients and enrollees rather than providers believe the measure evaluates an important domain of quality. Statistical significance among groups becomes increasingly important; patients and enrollees want to know 'which is better'. Despite this, further research is needed to design and present quality measures that enable patients to make informed decisions regarding quality of care.

Accreditation and regulatory

For an accreditation or regulatory audience, summary measures for the relevant unit of analysis are helpful. For example, in the US an organization such as the NCQA that accredits health plans will use health plans as the unit of analysis. These groups generally present summary measures and the measures must be strongly linked to outcomes. For these uses, acceptance by the clinical community is also important, and providers often assist in the development of the accreditation policies. Finally, the burden on clinicians to collect and analyze the data must be low, as results are not used for direct clinical feedback. Unfunded mandates can place an increased burden on a taxed health care system, potentially mitigating the benefits of assessing quality.

Conclusion

In this essay, we have discussed the advantages and disadvantages of process measures of quality, and some strategies for implementing them for different purposes or audiences. Process measures are highly acceptable to providers because they demonstrate clearly how providers can improve their outcomes. Clinicians are also more accountable for the process of care than its outcomes, which are affected by many other things. As electronic medical records become more common, process measures can be unobtrusively tracked as part of routine clinical care, which will aid in their implementation. Process measures that are incorporated into routine clinical data collection also provide a constant educational reminder to clinicians about the correct process, and eliminate duplicative data collection for quality assessment. On the other hand, implementing process measures can be difficult because they require constant updating as the science of medicine advances. Joint efforts among providers, professional societies, and external government or payer agencies

to develop and maintain process measures have made them more feasible. To be valid, process measures should have links to important outcomes, or should at least be determined by consensus methods to be judged by clinical experts to be important to patient outcomes. The past decade has brought a greater emphasis on synthesizing the evidence basis for how process of care affects outcomes and has made this information more readily available to the provider community as well as the public. In the future this will provide the ultimate base for the development of process measures of quality.

Finally, practical strategies were reviewed for various uses of process of care measures for internal quality improvement, for choice of providers by patients or purchasers, and for accreditation and regulatory purposes.

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