

Avoiding Pitfalls in Chronic Disease Quality Measurement: A Case for the Next Generation of Technical Quality Measures

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The true utility of quality measurement lies in its ability to inspire quality improvement, with resultant enhancements in the processes and outcomes of care. Because quality measurement is expensive, it is difficult to justify using measures that are not likely to lead to important improvements in health. Many current measures of chronic disease technical quality, however, have one or more pitfalls that prevent them from motivating quality improvement reactions. These pitfalls include that: (1) measured processes of care lack strong links to outcomes; (2) actionable processes of care are not measured; (3) measures do not target those at highest risk; (4) measures do not allow for patient exceptions; and (5) intermediate outcome measures are not severity adjusted. To exemplify recent advancements and current pitfalls in chronic disease quality measurement, we examine the evolution of quality measures for diabetes mellitus and discuss the limitations of many currently used diabetes mellitus care measures. We then propose more clinically meaningful "tightly linked" measures that examine clinical processes directly linked to outcomes, target populations with specific diagnoses or intermediate disease outcomes that contribute to risk for poor downstream health outcomes, and explicitly incorporate exceptions. We believe that using more tightly linked measures in quality assessment will identify important quality of care problems and is more likely to produce improved outcomes for those with chronic diseases.

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quality of care have shown us that many patients are not receiving indicated care^{2,3} and that some patients may encounter significant medical errors.^{4,5} Furthermore, purchasers of healthcare have called on healthcare organizations, insurers, and managed care organizations to demonstrate the quality of care that they provide so that the purchasers and their employees can make more informed healthcare choices.⁶⁻⁸ The National Committee for Quality Assurance (NCQA) currently collects quality information on more than 300 health plans using effectiveness measures for preventive care and some chronic diseases developed for the Health Plan Employer Data and Information Set (HEDIS).^{9,10} Given the empirical evidence that quality of care could be improved, the national focus on quality issues, and the financial pressures from purchasers of care, the issue for healthcare organizations is no longer *whether* to measure quality of care but rather *how* to measure it accurately, meaningfully, and efficiently.

Most critics of traditional quality monitoring efforts do not debate the need for quality monitoring and improvement. However, they point out that the traditional measures are often inaccurate, lack clinical

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Current Efforts to Measure the Quality of Healthcare

In 1997, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry stated that "[t]he real level of quality in most areas of the country is unknown, but what we do know suggests that we can no longer afford the luxury of ignorance."¹ In fact, multiple studies on

importance, and are expensive to produce. Indeed, developing good quality measures is difficult.^{11,12} Accuracy issues arise when measures do not take exceptions into account (eg, patient refusal or contraindications to treatment),¹³ when outcomes being profiled are not adequately case-mix adjusted,^{14,15} and when the sample size is insufficient.¹⁶⁻¹⁸ In addition, many measures are limited in their clinical usefulness, particularly for chronic diseases. For example, many seemingly reasonable quality measures specify the performance of clinical interventions that have not been sufficiently linked to important patient outcomes. Furthermore, the appropriate quality improvement response to poor performance on many measures is either unclear or of unknown efficacy.¹⁶ Finally, quality monitoring is expensive. Collecting necessary data for a typical HEDIS measure costs a plan \$20,000 to \$700,000.¹⁹ This cost is impossible to justify if there is no potential improvement in patient health outcomes and may still be difficult to justify if the likelihood of improvement is small.

Despite these obstacles, quality measurement has made tremendous advances in the past decade,¹⁶ and the cycle of measurement and feedback has become widespread in US healthcare organizations.²⁰ The HEDIS measures undergo annual revisions and expansions, multiple large research projects have been funded to examine quality measurement issues, and the former Agency for Health Care Policy and Research has been transformed into the Agency for Healthcare Research and Quality.²¹ The NCQA itself has contributed importantly to advancing the field of quality measurement by explicitly acknowledging the need to continually evaluate, revise, and expand its measurement set. In this paper, we discuss how to potentially improve quality measurement for chronic disease by transitioning from traditional measures of technical quality to more clinically meaningful measures. We argue that this next generation of measures should target individuals at highest risk for poor health outcomes; focus on strong process-outcome links; measure critical actions necessary for quality improvement; and incorporate exceptions such as contraindications and patient refusal. To illustrate the pitfalls and advancements in quality measurement, we examine the evolution of measures for diabetes mellitus; propose new measures that link intermediate clinical outcomes and the processes of medical care; and discuss the testing and implementation of such measures in interventions to improve diabetes mellitus care quality.

The Structure of Typical Quality Measures

Measures of technical quality generally define a group of persons who have a specific condition or are candidates for an intervention (the eligible population) and calculate the proportion of those individuals who have achieved a specified criterion.¹⁹ The criterion in question could be a process of medical care (eg, whether blood pressure was checked or aspirin was prescribed), an intermediate outcome (eg, level of blood pressure control), or a downstream health outcome (eg, death, stroke, or functional status).

Good health outcomes are the ultimate goal of the healthcare system, and improving health outcomes should be the driving force for a quality measurement feedback program. However, quality measures based on outcomes have several problems^{19,22,23}: (1) most important outcomes are rare, and thus large sample sizes are necessary to make conclusions about outcome quality; (2) outcomes are affected principally by patient factors (eg, the patient's prehospitalization health status) and only secondarily by provider factors;¹⁵ and (3) for some conditions there is a long lag between the care provided and the outcome itself. For example, end-stage renal disease in people with diabetes mellitus might take more than 20 years to develop, which is a long time to wait to understand whether there are quality problems with a healthcare organization's appropriate use of angiotensin-converting enzyme inhibitor therapy and level of glycemic and blood pressure control.

Intermediate outcomes, such as level of blood pressure control, are more immediately influenced by clinical interventions (eg, treatment with antihypertensive medication) than are downstream health outcomes (eg, end-stage renal disease or stroke). Intermediate outcomes become important once they have clearly been shown to influence downstream health outcomes (eg, level of blood pressure control is clearly linked to incidence of stroke) and are far more common than are the downstream health outcomes of ultimate interest.¹⁹ However, intermediate outcomes, like downstream health outcomes, are also clearly affected by both medical interventions and patient factors.¹⁷

The most commonly used measures are based on processes of care, which are the actual clinical interventions and healthcare services provided to an individual or population.²² For example, whether patients with diabetes mellitus had blood pressure checks at every visit or examinations of their feet are both process-of-care measures. These clinical interventions occur frequently, and the level of their

performance is mainly influenced by the healthcare organization or provider rather than the patient's health status.²³ Clinical interventions that are strongly linked to outcomes are useful to measure because improving the process of care should ultimately improve health outcomes, and differences in performance are much easier to detect than when using outcomes.¹⁸⁻²² For example, prescribing aspirin to patients with known coronary artery disease is a process of care that has been experimentally linked to decreased cardiovascular mortality rates.^{24,25}

Improving Health Through Chronic Disease Quality Measurement: What Are the Pitfalls?

Quality measurement can be used for the purposes of comparing performance and improving quality.¹⁹ Comparisons are valuable if they can be used by consumers (individuals and employers) to make health purchasing decisions or if an entity with sub-par performance is motivated to improve. Ultimately, however, the true utility of quality measurement lies in inspiring quality improvement, with resultant enhancements in processes of care that will ultimately improve health outcomes.^{26,27} For quality profiling to influence the health of a population with an identified chronic disease, efforts should be made to avoid the following 5 main pitfalls common to chronic disease quality measures:

1. *Measured processes of care lack strong links to outcomes.* Many process-of-care measures reflect simple counts of clinical interventions that are supported by expert judgment but are not clearly linked to health outcomes through scientific studies. In some instances, this is done because the data elements required for these measures are relatively easy to obtain and therefore the measures are comparatively inexpensive to construct. For example, most administrative data systems allow a health plan to count how many cholesterol tests were obtained for patients with diabetes mellitus in a given year but do not contain the actual results of the cholesterol tests. Obtaining the results of cholesterol tests often requires expensive medical record review. Although regular cholesterol testing is an important first step, we also need to know whether providers act on the levels because it is controlling the cholesterol level that will reduce morbidity and mortality rates for patients with diabetes mellitus. A measure that is satisfied just because a test was performed encourages more testing but does not necessarily encourage better care.
2. *Actionable processes of care are not measured.* This is especially true both for downstream

health outcomes, where outcomes are often far removed in time from processes of care that might affect them, and for intermediate outcomes, where the actionable process might be clear (eg, starting use of a medication) but often not measured. For example, profiling the proportion of patients with diabetes mellitus who had hypercholesterolemia without knowing how many of these patients are already being treated appropriately does not sufficiently help the organization target a quality improvement intervention.

3. *Measures do not target those at highest risk.* When constructing a quality measure, it is easiest to target eligibility at a broad population. Yet, it is often specific subpopulations of patients who are at highest risk for poor downstream outcomes.^{28,29} For example, it is easier to identify all patients with diabetes mellitus than patients whose diabetes mellitus was diagnosed at an early age, but it is the latter group that is at highest risk for microvascular complications.²⁹ Tailoring monitoring programs to high-risk individuals should markedly improve the efficiency of a quality measure and resultant quality improvement interventions. Constructing measures that balance level of risk, potential benefit, and efficiency is challenging, and further research is needed to evaluate the clinical and economic impact of varying quality measure specifications.
4. *Measures do not allow for patient exceptions.* Identifying exceptions, eg, patient refusal, poor adherence, social factors, or contraindication to specified treatment, often requires extensive medical record review or patient survey. However, profiles created without allowing for exceptions might not accurately reflect healthcare quality. Taking exceptions into account is important for comparisons if one healthcare organization has a higher rate of patient refusal than another (eg, of vaccination). Also, quality measures that do not allow for exceptions might encourage providers to disregard patient preferences and minimize patient autonomy. Finally, opportunities for quality improvement can be greatly overestimated or poorly targeted when patient exceptions are not included in an organization's performance profile. For example, knowing that social factors play a large role in how well a recommended intervention is accepted by patients in a certain health plan would likely change the organization's approach to improving performance for that recommendation. How important exceptions are for any given quality measure is testable and might differ for different populations.
5. *Intermediate outcome measures are not severity adjusted.* Profiles of intermediate outcomes such as levels of hemoglobin A_{1c} (HbA_{1c}, a

measure of glucose control in diabetes mellitus) and blood pressure control are often presented without adjusting for the underlying disease severity in the population.⁹ This is largely because of a lack of severity adjustment tools that can accurately explain an adequate proportion of variation in intermediate outcomes and the complexity of collecting data for severity adjustment.²³ Indeed, the complexity and difficulty of accurately adjusting intermediate and downstream outcomes for the level of underlying disease severity cannot be overstated. Nonetheless, we know that intermediate outcomes are affected not only by clinical actions but also by the underlying severity of disease and by patient comorbidities. Consequently, organizations with the sickest patients might seem to score worse on quality measures of intermediate outcomes than those with healthier patients, even when optimally treating these very sick patients.³⁰

The Current State of the Art in Diabetes Mellitus Quality Measurement: Does It Measure Up?

To exemplify advances, pitfalls, and next-generation solutions in chronic disease technical quality measurement, we examine specifically the status of quality measures for diabetes mellitus, an enormous public health burden. It is estimated that there are 10 to 15 million people with diabetes mellitus in the United States, and care of these patients accounts for approximately 15% of all medical expenditures.³¹⁻³³ The complications of diabetes mellitus can be devastating. Cardiovascular and peripheral vascular disease, visual and other sensory loss, and renal failure are responsible for much of the cost and nearly all of the excess loss of life and functional status associated with diabetes mellitus. Clinical interventions such as tight control of blood pressure, cardiovascular risk management, and control of blood glucose levels (glycemic control), however, can prevent many of these adverse outcomes.^{29,31,34-39} For these reasons, care for diabetes mellitus has been a particular target of quality monitoring efforts.

Quality measurement for diabetes mellitus has made tremendous improvements in the past 5 years, thanks in large part to attention from the HEDIS Committee on Performance Measurement, the Department of Veterans Affairs' External Peer Review Program (EPRP), and the National Diabetes Quality Improvement Program, which began under the sponsorship of a coalition of public and private entities (the American Diabetes Association, the Foundation for Accountability, the Health Care Financing Administration, and the NCQA) and was

joined by the American Academy of Family Physicians, the American College of Physicians, and the Veterans Health Administration.⁴⁰ In 2000, the HEDIS adopted its first "comprehensive set" of measures to be applied to diabetes mellitus care,⁹ based largely on Diabetes Quality Improvement Program measures. These are the first national measures to extend beyond annual retinopathy screening.

Table 1 lists the measures contained in the HEDIS 2000 for diabetes mellitus. Do these measures avoid the pitfalls described previously? First, note that 2 of the 4 process measures (annual retinal examination and annual screening for nephropathy—Measures 2 and 4, Table 1) try to target those at highest risk for the intervention specified. For example, the retinopathy measure states that patients who seem to be at high risk for eye disease should have an annual eye examination, whereas biannual eye examinations are reasonable for those at lower risk. Note, however, that the first 4 measures listed in Table 1 are relatively simple counts of processes of care that have not been shown in randomized controlled trials to influence downstream outcomes. For example, experts agree that it is important to monitor glycemic control (HbA_{1c} levels) and cholesterol levels (low-density lipoprotein [LDL]) in patients with diabetes mellitus. Good control, not simply measurement, of both these factors leads to improved outcomes. No study has clearly linked the frequency of obtaining HbA_{1c} tests or LDL measurements to improved healthcare outcomes. Monitoring is the first step, and, therefore, these measures are wisely included in the HEDIS measurement set. Nonetheless, one has to act on the results of the obtained levels, for example by giving patients appropriate medications to lower LDL level, to improve downstream health outcomes. Similarly, periodic screening for retinopathy might be a necessary step in improving quality, but it is optimally timed photocoagulation that improves outcomes, and frequent screening might be less important than close surveillance of those with known disease.^{41,42}

Unfortunately, a healthcare organization can make large improvements in their performance on these "loosely linked" process measures without significantly affecting the health of their population. For example, an organization can automatically obtain HbA_{1c} levels by an administrative mandate to routinely order a test each time a patient with diabetes mellitus is seen in a physician's office or clinic. If treatment intensity is unaffected by such routine testing, however, the organization's monitoring performance will improve but health outcomes will be

largely unaffected. Therefore, although it is certainly a step forward that national measures for diabetes mellitus have been expanded to focus on more aspects of diabetes mellitus care, these simple counts of processes might not be sufficient to motivate important quality improvement and the resultant improved health outcomes.

Recognizing these factors, the HEDIS comprehensive diabetes mellitus set also includes 2 measures of intermediate outcome, namely, levels of glycemic and LDL control (Measure 5 and 6, Table 1). These measures offer promise because we have strong experimental and epidemiological evidence that

improvements will result in improved downstream patient outcomes. These measures might be especially appropriate for assessing longitudinally the success of internal quality improvement programs. Nonetheless, these measures of intermediate outcome also have some important limitations and risks. First, we know that a provider's ability to control a patient's glucose level is influenced not only by appropriate treatment but also by the patient's biological status (severity of disease), social circumstances, and attitudes and beliefs. These measures, like most current measures of intermediate outcomes, do not take such patient factors into account.

Table 1. Diabetes Mellitus (DM) Measures Contained in the Health Plan Employer Data and Information Set and Their Identified Pitfalls

Measure	Pitfalls				
	Process of Care Lacks Strong Link to Outcomes	Actionable Process of Care Is Not Measured	Measure Does Not Target Those at Highest Risk	Measure Does Not Allow for Many Exceptions	Intermediate Outcome Measure Is Not Severity Adjusted
1. Proportion of patients with DM who had hemoglobin A _{1c} levels measured annually	X		X	X	
2. Proportion of patients with DM who had an annual dilated retinal examination (or biannual for those at lower risk)	X			X	
3. Proportion of patients with DM who had LDL levels measured at least every other year	X		X	X	
4. Proportion of patients with DM who had annual screening for nephropathy (or biannual for those at lower risk)	X			X	
5. Proportion of patients with DM who had hemoglobin A _{1c} levels >9.5% in the reporting year		X		X	X
6. Proportion of patients with DM who had LDL levels >3.36 mmol/L (>130 mg/dL)		X		X	X

LDL=low-density lipoprotein.

Therefore, healthcare organizations or providers who have patients with very complicated diabetes mellitus might seem to perform worse on a measure of intermediate outcome than a healthcare organization or provider with patients who have comparatively mild diabetes mellitus.¹⁷

Furthermore, when using quality measures based on intermediate or biological outcomes, one needs to make a somewhat arbitrary definition of that outcome's desirable level (eg, LDL <3.37 mmol/L [<130 mg/dL]). Healthcare organizations or providers with patients who have complicated diabetes mellitus might make great strides in lowering lipid levels of these patients without being able to achieve the specified levels because of their patients' severity of disease. Lowering a patient's LDL level from 5.17 to 3.49 mmol/L (200 to 135 mg/dL) is much more beneficial than lowering it from 3.49 to 2.33 mmol/L (135 to 90 mg/dL).^{43,44} Yet, the 3.36 mmol/L (130 mg/dL) cutoff value would count the first example as bad care and the latter as good care. Ironically, this quality measure might reinforce the economic incentive for healthcare organizations and providers to avoid patients with severe disease because the easiest way for them to achieve better performance results on intermediate outcome measures is often to limit the number of patients in their panels who have severe disease or social problems that make meeting optimal goals difficult or impossible.¹⁷

Of note, for the glycemic control measure, the specified level (HbA_{1c} <9.5%) is set higher than the identified "ideal" benefit level of near normoglycemia that is based on randomized controlled trials. This is not because the HEDIS Committee on Performance Measurement believed that achieving a level less than 9.5% is adequate for all patients with diabetes mellitus. Rather, the committee recognized the problems of noncomparability in intermediate outcome measures, the motivation for deselection when the bar is set too low, and that patients with HbA_{1c} levels >9.5% make up a large portion of risk for microvascular complications (ie, especially years spent blind) and therefore merit intensive intervention.²⁹

Despite this adjustment, simple measures of intermediate outcomes are fraught with the problems and cautions described in the previous section and do not provide information on the processes of care that might improve the intermediate, and eventually downstream, outcome.

Designing Clinically Meaningful Measures

By establishing a set of quality measures for diabetes mellitus beyond retinopathy and including

measures of intermediate outcome, the Diabetes Quality Improvement Program and the HEDIS have greatly advanced the state of the art for diabetes mellitus quality measurement. Nonetheless, the newer quality assessment measures could be further improved on and expanded. All 4 process measures do not assess a clinical intervention that is strongly and directly linked to improved health outcomes, and the 2 intermediate measures are not case-mix adjusted and do not profile clinical interventions on which one can act. How can we further advance the state of diabetes mellitus and chronic disease quality measurement? We need to develop measures that target high-risk populations and specify clinical interventions that, if fulfilled, have a high likelihood of improving the quality or length of people's lives and that take exceptions, such as patient refusal and contraindications, into account.

Such an approach would go beyond the loosely linked process measures and simple measures of intermediate outcome that have been described in this paper to more tightly linked, actionable, and clinically meaningful measures (Table 2). These tightly linked measures specify processes that are strongly associated with important outcomes, intrinsically take the severity of the patient illness into account, identify appropriate quality improvement responses, and allow for patient exceptions. The measures are "tightly linked" because the link between process and outcomes is clearly established by scientific evidence and because the link between the measure and a potential quality improvement response is evident. Tightly linked measures can be specified in a spectrum of ways. In its most basic form, a tightly linked measure identifies patients who are eligible for a clinical intervention because they have been diagnosed as having a high-risk condition. Such a measure, for example, might determine whether patients with known coronary artery disease are receiving daily aspirin treatment. On the other end of the spectrum are tightly linked measures that involve the measurement of a process of care and an intermediate or downstream outcome.

For example, a tightly linked quality measure that focuses on cholesterol management in patients with diabetes mellitus would report the proportion of patients with diabetes mellitus and high LDL values in the previous year who were not given appropriate medication in the reporting year (with the level of LDL and the appropriate medication response being clearly specified; see measure 1 in Table 3) and who neither had contraindications to nor refused therapy. In this way, the group eligible for the measure is

in part defined by having a poor intermediate outcome (high LDL level), but the measure itself is a process-of-care measure (being given appropriate medication). This construction is likely to identify those at high risk for a poor downstream health outcome (because they have a poor intermediate outcome or a specific diagnosis) and those who have received poor quality of care (because of not having met the technical process-of-care requirement). Finally, the quality improvement intervention that would yield improved results in the intermediate or downstream outcome (eg, giving the patient appropriate medication) is included in the measure. Tightly linked measures could also examine the appropriateness of previous care for persons with poor downstream outcomes. For example, a measure could determine the percentage of patients with diabetes mellitus undergoing amputation who had documentation of specific interventions (eg, monofilament screening, foot care education, and specialty referral) within a year prior to amputation.

Why are tightly linked measures likely to be an important addition to the cadre of loosely linked and intermediate outcome measures? First, because tightly linked measures focus on clinical interventions as opposed to intermediate outcomes, health-care organizations get credit for “doing the right thing,” regardless of the severity of their patient population. This decreases the motivation to rid oneself of complicated patients or those with severe social problems who are never likely to reach “ideal” control levels specified by simple outcome measures. Second, the measures identify those at high risk for poor downstream outcomes and those who would be the most likely to benefit from a quality improvement intervention. Third, unlike simple outcome measures that might identify a high proportion of persons with severe disease regardless of whether appropriate treatment has been attempted, tightly linked measures are likely to identify a high proportion of individuals with actual quality problems. Finally, because tightly linked measures have a strong process-outcome link, the quality improve-

Table 2. Definitions and Examples of Quality Measures in Chronic Disease

Measure Type	Definition	Characteristics	Examples
Loosely linked	Assessment of the performance of a clinical intervention in which the intervention meets professional standards but is not strongly and directly linked to health outcomes by epidemiological studies.	Process not strongly linked to outcomes. May or may not take exceptions into account. May or may not target high-risk populations.	Proportion of patients with DM who have annual HbA _{1c} measures. Proportion of patients with coronary disease who have annual LDL measurements.
Simple outcome	Measure of intermediate or downstream health outcomes without severity adjustment. For intermediate outcomes, epidemiological evidence suggests that improved performance in the intermediate outcome should result in improved downstream health outcomes.	Actionable process not measured. Not severity adjusted. May or may not take exceptions into account. May or may not target high-risk populations.	Proportion of patients with DM who have HbA _{1c} levels >9.5%. Proportion of patients with coronary artery disease who have LDL levels >3.36 mmol/L (>130 mg/dL). Proportion of general population with blood pressure >140/90 mm Hg.
Tightly linked	Assessment of the performance of a clinical intervention in a high-risk population in which the clinical intervention is strongly and directly linked to health outcomes. Eligibility for the measure can be defined by the diagnosis or by a poor intermediate outcome.	Process strongly linked to outcomes. Actionable process measured. Targets high-risk populations. Takes exceptions into account.	Proportion with coronary disease prescribed daily aspirin therapy. Proportion of patients with DM and 2 blood pressure readings >140/90 mm Hg who have adjustment of antihypertensive therapy within 3 mo of a second high reading.

DM=diabetes mellitus; HbA_{1c}=hemoglobin A_{1c}; LDL=low-density lipoprotein.

ment intervention likely to improve patient outcomes is clearly incorporated in the measure.

A potential disadvantage of tightly linked measures, especially those that incorporate outcomes, is that they require more data collection than many simple outcome measures (although case-mix-adjusted measures would require even more data collection than necessary for any tightly linked measure). Table 3 lists 2 tightly linked measures for diabetes mellitus that incorporate intermediate outcomes and the data elements required to calculate them. To calculate a simple intermediate outcome measure on lipid or blood pressure control in a diabetic population, one needs only to identify the data elements contained in column 2 (the eligible population). For a tightly linked measure, one also needs to identify whether the appropriate clinical intervention was done and take into account appropriate exceptions. Although more data collection is required, the measure's utility and accuracy are greatly enhanced, for the reasons enumerated previously. Furthermore, data collection would be greatly simplified by the trend toward complete electronic medical records that include diagnoses; pharmacy

data; laboratory test results; results of diagnostic testing; and extractable data fields for vital signs, important signs and symptoms, contraindications, and patient refusal. Unfortunately, most healthcare organizations' information systems have not developed to this level of sophistication. The current incorporation of tightly linked measures in routine quality monitoring might therefore be cost prohibitive. Nonetheless, as information systems advance, we should consider which data fields are essential to incorporate for efficient and accurate quality monitoring.

Implementing Tightly Linked Measures for Chronic Disease

Although tightly linked measures have not yet been widely implemented for diabetes mellitus, basic tightly linked measures are already in use in multiple settings for a variety of chronic diseases. In fact, among the 15 measures used to assess quality in 7 chronic disease areas in the HEDIS 2000, 3 can be considered basic tightly linked measures. These cover β -adrenergic blocking agent treatment after myocardial infarction, appropriate medication use

Table 3. Data Elements and Their Sources Required for Calculating 2 Composite Tightly Linked Measures for Diabetes Mellitus (DM)

Example Measure	Identify Eligible Population	Identify Intervention	Identify Exceptions
Proportion of patients with DM who had an LDL level >3.36 mmol/L (>130 mg/dL) in the previous year and who meet one of the following criteria in the reporting year: –Started taking cholesterol-lowering medication –Had dose of cholesterol-lowering medication increased –Had repeat measurement of LDL level that is <3.36 mmol/L (<130 mg/dL)	DM diagnosis (ICD-9 code or medical record review). LDL level >3.36 mmol/L (>130 mg/dL) (administrative laboratory data or medical record review).	Lipid-lowering agent in specified time frame (administrative pharmacy data or medical record review).	Allergy. Contraindication (pharmacy records or medical record review). Patient refusal (electronic data capture or medical record review).
Proportion of patients with DM who had 2 blood pressure readings >140/90 mm Hg in the reporting year and who have had either adjustment of antihypertensive medication dose or new medication added within 3 mo of the second reading	DM diagnosis (ICD-9 code or medical record review). Blood pressure readings (electronic data capture or medical record review).	Antihypertensive medication (dose and type) in specified time frame (administrative pharmacy data or medical record review).	Allergy. Contraindication (pharmacy records or medical record review). Patient refusal (electronic data capture or medical record review).

LDL=low-density lipoprotein; ICD-9 = *International Classification of Diseases*, ninth revision.

for persistent asthma, and appropriate continuation phase treatment for clinical depression.⁹ Of note, the HEDIS measures generally rely on hybrid methods involving administrative data (eg, for diagnosis, laboratory data, and/or pharmacy data) and some medical record review. Although the measures include some exceptions, such as noted contraindications to medications (eg, the diagnosis of asthma is a contraindication to β -adrenergic blocking agent use), they do not take patient refusal into account.

At least 2 other national measurement systems have also implemented tightly linked measures: the Veterans Affairs' EPRP and the Joint Commission on Accreditation of Healthcare Organizations performance measurement system. The EPRP, which includes a larger number of measures for chronic disease than does the HEDIS, has developed and applied 7 tightly linked measures. In diabetes mellitus, the EPRP already includes one tightly linked measure—referral to specialist for patients with identified abnormalities on foot examination.⁴⁵ Examples of other tightly linked measures in the EPRP include appropriate thrombolytic, β -adrenergic blocking agent, and aspirin treatment after myocardial infarction. The EPRP relies on administrative data to identify eligible patients, but data used to assess the measures are collected from the medical record. Contraindications, but not patient refusal, are taken into account.

The Joint Commission on Accreditation of Healthcare Organizations is pilot testing a set of performance measures for hospitalized and recently discharged patients. The set includes tightly linked measures such as aspirin use after myocardial infarction and angiotensin-converting enzyme inhibitor use in heart failure. The measures require data collection on contraindications and exceptions.

Several research studies and quality improvement initiatives are developing and implementing tightly linked measures that incorporate both processes and outcomes. For example, the Global Quality Assessment Tool, developed at RAND with funding by the Health Care Financing Administration, the Agency for Healthcare Research and Quality, and the California Health Care Foundation, covers 33 adult chronic diseases, acute conditions, and preventive care.^{12,46,47} The tool's tightly linked measures include indicators for treatment modification of hypercholesterolemia in patients with heart disease who have not achieved adequate LDL levels and treatment escalation for patients with persistent hypertension. The Global Quality Assessment Tool currently relies on medical record abstraction

for data but is designed to be used also with an electronic medical record system that contains extractable data fields. The Global Quality Assessment Tool measures explicitly incorporate exceptions, including contraindications and patient refusals.

The diabetes mellitus research coordinating center of the Veterans Affairs Quality Enhancement Research Initiative (QUERI) is testing tightly linked measures (in addition to several loosely linked and simple outcome measures) for diabetes mellitus in a regional quality improvement project. This project profiles teams of providers on diabetes mellitus quality of care and identifies (for individual providers) patients who might benefit from intensive treatment. The tightly linked measures examine the proportion of patients with diabetes who have specified appropriate treatment for hypertension and hypercholesterolemia. Because of the Department of Veterans Affairs' advanced electronic data systems, these measures are calculated directly from administrative and clinical electronic data, without the need for medical record review. Without medical record review, the measures are not able to take exceptions into account, but the software can easily accommodate documentation of exceptions, and the feasibility of a provider-initiated exception reporting system is being considered.

Conclusions and Next Steps

Ten years ago there were no nationally accepted measures for monitoring and improving chronic disease quality of care. Now, efforts by national organizations such as the NCQA, the Veterans Health Administration, and the Joint Commission on Accreditation of Healthcare Organizations, as well as research funding from the Agency for Healthcare Research and Quality, Veterans Affairs Health Services Research and Development, and other organizations, have provided us with widely applied measures for chronic disease quality assessment. This has been a tremendous first step, but relying only on loosely linked measures of process is not sufficient. Adding simple measures of intermediate outcomes is an improvement but will not guarantee an improvement in health outcomes.

How can we improve our measures of technical quality? First, as the NCQA is already starting to do, we must acknowledge the need to develop and test clinically meaningful measures to yield the most appropriate quality improvement responses. Although this paper has given examples of several such measures, additional measures for various

chronic diseases need to be developed and tested. Testing should establish whether tightly linked measures identify quality problems more amenable to quality improvement interventions than loosely linked measures or those of intermediate outcomes and whether adding the additional clinical detail is worth the added complicity and cost. We also need to evaluate whether using tightly linked, clinically meaningful measures in organizations' profiles or quality improvement initiatives can yield measurable improvement in intermediate and, when possible, downstream health outcomes. The diabetes mellitus QUERI is testing several such measures for diabetes mellitus, but this principle should be examined in other chronic diseases and for social as well as medical barriers to care. Third, we need to promote the development of electronic medical records with extractable data fields and linkage capabilities in and across healthcare organizations.^{48,49} Because tightly linked measures are often more complex, the data required to construct them (eg, laboratory, medication, and diagnoses) are currently often found only in the medical record. However, healthcare organizations that have extensive electronic capture of essential patient information (laboratory results, medications, vital signs, and reliable diagnoses) can often construct composite tightly linked measures from electronic data without the need for medical record review. Furthermore, systems can be established to allow providers to enter contraindications and patient refusal. The widespread adoption of electronic medical records with extractable data fields will allow all quality measures, including composite tightly linked measures, to be constructed more simply and less expensively.

Quality measurement is an important but expensive enterprise. Healthcare organizations that want to measure and improve quality of care with resultant improvements in downstream health outcomes should consider closely how well the measures they choose avoid the pitfalls described in this paper. We believe that using more tightly linked measures in quality assessment will identify important quality of care problems and will better motivate changes in healthcare delivery that result in improved outcomes for those with chronic diseases.

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