

24

Measuring Diabetes Quality of Care: Clinical Outcomes, Cost-Effectiveness, and Patient Experience of Care

Patrick J. O'Connor, Katherine Diaz Vickery, and Todd P. Gilmer

Chapter Objectives

- To discuss advantages and challenges of measuring outpatient diabetes care quality.
- To identify and discuss key quality measures for outpatient diabetes care including single-domain and composite measures of glucose, blood pressure (BP), lipids, weight, tobacco use, and appropriate use of antithrombotic medications.
- To identify emerging opportunities and challenges related to assessment of patient experience of care, shared decision-making, and burden of treatment.
- To discuss factors that influence the costeffectiveness of diabetes care and to discuss the cost-effectiveness of diabetes case management, clinical decision support, and shared decisionmaking strategies.

a narrow set of diabetes quality measures that are directly and strongly linked to major clinical outcomes is desirable.

- Recent data indicate wide variation in care quality across clinicians after adjustment for patient factors. This information can be used to guide clinician-specific quality improvement and learning interventions.
- In settings with high-quality diabetes care, there is as much as 300% variation in costs. Thus, identifying maximally cost-effective treatment pathways is an area of needed clarity.
- Improving shared decision-making and patient experience of care and reducing treatment burden may improve treatment adherence, continuity of care, and clinical outcomes.

Concluding Remarks

- Providing simple and understandable measures of diabetes care quality to clinicians, patients, and the public may be associated with improved diabetes care quality in some settings.
- Clinicians and care systems often direct available resources to improve what is measured, so selecting

Center for Chronic Care Innovation, HealthPartners Institute, Minneapolis, MN, USA e-mail: patrick.j.oconnor@HealthPartners.com

K. D. Vickery

T. P. Gilmer

Box 24.1 Implementing a Diabetes Composite Quality of Care Measure

- Step I: Identify all adult patients with a diagnosis of diabetes and with two or more visits to the clinic in the last 12 months. This is the denominator.
- Step II: (a) Classify each patient in the denominator as meeting or not meeting each of these five clinical goals in the past 12 months. (b) If the patient is excluded (criteria for exclusion noted below), they get credit for that clinical goal. (c) If there is no BP measure, A1c test, documentation of use of antithrombotic or lipid lowering therapy, or documentation of tobacco use status within 12 months, they are classified as not meeting that clinical goal.
 - Most recent glycated hemoglobin (A1c) measure done within 12 months is <8%.
 - Most recent systolic BP measure within 12 months is <140 mmHg.

P. J. O'Connor (🖂)

University of Minnesota Department of Medicine, and Health, Homelessness, and Criminal Justice Lab, Hennepin Healthcare Research Institute, Minneapolis, MN, USA

University of California San Diego, San Diego, CA, USA

[©] The Author(s), under exclusive license to Springer Nature Switzerland AG 2023 J. Rodriguez-Saldana (ed.), *The Diabetes Textbook*, https://doi.org/10.1007/978-3-031-25519-9_24

- Patient is currently prescribed a moderate or high-dose statin or other lipid-lowering medication. (Exclude: LDL < 100 mg/dL, documented lipid-lowering medication intolerance; women of child-bearing potential.)
- If the patient has diagnosed atherosclerotic cardiovascular disease, they are taking daily antithrombotic medication. (Exclude: those with no prior diagnosis of cardiovascular disease and those at high risk of gastrointestinal bleed.)
- Chart documentation that the patient is currently a nonsmoker.
- Step III: The patent is counted in the numerator only if they meet all five clinical goals as specified.
- Step IV: Divide the numerator by the denominator and multiply by 100 to calculate the percentage of diabetes patients at the composite diabetes goal.
- Step V: This measure can be used (a) to compare quality of diabetes care across care systems, clinics, clinicians, or groups of patients, and (b) to inform patient or payer selection of preferred clinicians based on quality of care. Adjustment of results based on patient factors (such as age, race, sex, education, income, or insurance status) may be considered.

Introduction

It is widely recognized worldwide that the quality of care provided to those with diabetes mellitus is far from optimal. To guide quality improvement efforts in an efficient way, it is important to identify and target key aspects of diabetes care, track valid measures of care quality over time, and use these measures to direct improvement efforts and assess their results. Here we will discuss the strengths and weaknesses of current measures of diabetes care quality and comment on current challenges that face those engaged in this effort, including developers of quality measures, users of such measures to improve clinical care delivery, or users of such measures to monitor population health. For the sake of brevity, we will focus on outpatient care of adults with type 2 diabetes and limit our attention in this chapter to selected measures of clinical outcomes, cost of care, and patient care experience.

Measuring Clinical Quality of Care: Accountability Versus Improvement Measures

Data from the United States suggest that diabetes leads to about a 5 year loss of life expectancy and a 10 year loss of disability-free life expectancy [1, 2]. A key question for both clinicians and public health leaders is to identify effective prevention or treatment strategies that mitigate these losses both at the population level and for each individual patient.

The most effective way to mitigate the loss of life expectancy and disability-free life expectancy from diabetes is to prevent or delay the onset of type 2 diabetes. This is the topic of several chapters in this book. It is clear from large randomized trials such as the Diabetes Prevention Program and similar programs in Scandinavia and China that both lifestyle interventions and certain pharmacologic agents are somewhat effective in this regard [3, 4]. It is clear that primary prevention of type 2 diabetes should be a very high priority for both clinicians and public health policy makers, and studies to improve the effectiveness of both lifestyle and pharmacologic interventions to prevent diabetes are needed [5].

Once a patient develops type 2 diabetes, the question becomes how to prevent or delay downstream diabetesrelated complications and mitigate the adverse impact that diabetes often has on length and quality of life. Microvascular complications such as retinopathy (that may lead to blindness), nephropathy (that may lead to dialysis or renal transplantation), and neuropathy (which may cause pain and lead to falls or amputations) affect a high proportion of adults with type 2 diabetes. The occurrence of these microvascular complications typically increases with the duration of diabetes and is often accelerated by tobacco use and by inadequate control of glucose and blood pressure. However, while trials of intensive glucose and blood pressure (BP) control have shown some benefit on delaying the onset and progression of these microvascular complications, there is little hard evidence to show an impact on reduced rates of the end-stage microvascular complications such as blindness, end-stage renal disease (ESRD), or amputation [6-8]. Moreover, lifetime occurrence of these three end-stage microvascular complications is much lower than is the lifetime risk of a fatal or nonfatal macrovascular complications of myocardial infarction or stroke in adults with type 2 diabetes [1, 2].

The occurrence of macrovascular complications of myocardial infarction and stroke in those with diabetes has been improving in the last 20 years but is still about twice as high as in those without diabetes. These major cardiovascular events account for the majority of excess deaths and excess costs attributable to type 2 diabetes [9, 10]. Thus, in measuring quality of diabetes care, control of multiple major risk factors that are the principal drivers of microvascular and especially macrovascular complications should be the focus of clinical and public health attention.

In recent years, a composite quality measure often used to assess care of adults with diabetes consists of the proportion of diabetes patients who simultaneously meet all five of these clinical measures: adequate BP control, glucose control, and tobacco control, plus appropriate use of lipid medications and antithrombotic medications. Many experts support this "composite measure" of these five clinical domains, calculated as the proportion of diabetes patients seen at least twice in 12 months in a given care system who meet these five measures (based on most recent measure available within the 12-month period): nonsmoker, A1c < 8%, BP < 140/90 mmHg, on lipid medication if tolerated, and on antithrombotic medication such as asprin (which applies only to patients with atherosclerotic cardiovascular disease) [11]. Box 24.1 below describes how this composite measure can be computed and used.

When a diabetes composite measure was first introduced in 2003 in the United States, less than 5% of US adults with diabetes had all five components at the goals proposed in Box 24.1. The proportion of diabetes patients with all five components at these proposed goals rose to about 30% in the United States by 2015–2018 [12], with major variation from less than 5% to about over 50% across care delivery systems, clinics, individual clinicians, and subgroups of patients. Levels of risk factor control are significantly lower in younger adults versus older adults and lower for Blacks, Latinos, and Native Americans compared to non-Latino Whites. With the onset of the COVID-19 pandemic, there has been a decrease in the proportion of diabetes patients meeting these composite quality measure goals, mostly due to decreased A1c and BP measurement related to reduced access to care [13].

There are several factors to consider when comparing clinicians, clinics, or delivery systems performance using various diabetes or other clinical quality measures. First, if the goal is to incent clinicians to improve care, it may be important to adjust content and interpretation of quality measures based on (a) socioeconomic or clinical characteristics of patients, and (b) availability of technology such as A1c testing available at primary care facilities [14-16]. Otherwise, facilities with less access to technology and/or clinicians who take care of low income or less educated patients (who may have more difficulty getting to clinical goals for a variety of reasons) will be penalized by the quality measures. This issue is especially important if quality measures are publicly reported or if performance on the quality measures is linked to financial compensation [15]. The counter argument is that adjusting quality measure thresholds based on patient characteristics may lead to a double standard of care, with implicit acceptance of lower quality care for more challenging patient populations.

Another consideration related to use of a composite quality measures is whether to weight the components of the composite measure equally or unequally. Are they all equally important? The impact of BP control, lipid control, and tobacco control on life expectancy and major cardiovascular (CV) events in those with diabetes has historically been much greater than the impact of glucose control, unless glucose control is especially poor [17–20]. However, some research suggests that not only the most recent values, but also past values of A1c, BP, lipids, and tobacco use may impact subsequent health outcomes [21]. Moreover, the relative benefit of improving A1c, BP, lipid, or tobacco control varies across patients; in general, the further from goal a patient is on a given measure the greater the potential benefit after effective control is achieved.

These considerations would favor a weighted approach to quality measures, with the weight of each component of the composite measure proportional to the potential benefit of that component. Ideally, the weights should vary based on the clinical circumstances of an individual patient (in some patients, control of very high A1c may confer the most benefit). Technology to enable prioritization of treatment options for individual patients with and without diabetes has recently become available [22-25]. However, the use of individualized care quality measures, although logical and potentially useful, is complex to operationalize and therefore has not vet been widely used. As this science matures, it may be possible to measure diabetes quality at the patient level not only by achievement of threshold levels of A1c, BP, or lipid control but also by estimating change over time in a patient's CV risk, using equations such as the American College of Cardiology/American Heart Association (ACC/AHA) CV disease risk equations, the UKPDS Outcome Model 2 prediction equations, or a combination of these [26, 27].

Just as there is wide variation across clinicians, medical groups, and care delivery system in composite measures of diabetes care quality, so too there is wide variations in the five specific components of the composite measure. For example, some clinicians do a better job with BP control than with glucose control. There are few studies that investigate in detail this variation at the clinician level in patterns of risk factor control. Some of the variation is likely attributable to variation in patients' health literacy, numeracy, or overall educational or poverty level. Thus, when assessing variation in diabetes care quality across clinicians and delivery systems, some experts suggest that credibility requires that the differences adjusted analysis be for in patient characteristics.

Another factor linked to variation in quality of diabetes care is a long delay in clinician recognition or management of changing levels of glucose, BP, lipids, or other clinical parameters. Deterioration in glucose control, for example, may be due to progression of diabetes, nonadherence to medications, lapses in dietary practices, stress, occult infections, or other factors. When patients well-controlled on glucose, BP, or lipids deteriorate, clinicians who delay addressing the underlying reasons and adjust pharmacotherapy if needed in a timely way will, on average, have lower proportions of their diabetes patients at goal. Delayed adjustment in treatment, often referred to as "clinical inertia," is associated with poor clinician performance on key measures of diabetes quality of care and adverse clinical outcomes [28]. Quality measures that assess clinical inertia have been proposed by some but are time consuming to measure and report and may not adequately consider patient-related financial, social, and psychological constraints that sometimes present barriers to optimal care [29–31].

There are hundreds of "evidence-based" components of diabetes care, but not all are of equal benefit to a given patient at a given point in time, and the strength of the supporting evidence from randomized trials varies widely. Thus, all evidence-based aspects of diabetes care are *not* suitable for selection as quality measures. It is best to focus attention on clinical domains that need improvement, have a major direct impact on important health outcomes, have affordable and available management strategies, and can be easily measured.

It is also important to keep in mind that once a clinical quality measure is adopted as a publicly reported accountability measure, clinicians and health care systems tend to narrowly focus on measuring and improving that aspect of care. This can lead to unintended consequences. For example, in the 1990s in the United States, the first publicly reported diabetes quality measure was retinopathy screening—because in the pre-electronic medical record era, it could be accurately and inexpensively measured from insurance claims data. Delivery systems devoted immense resources to improving eye exam rates, while largely ignoring poor glucose or BP control clinical factors that cause retinopathy. That early quality measure may well have *increased* the prevalence of retinopathy by drawing attention away from glucose and BP control.

Thus, we propose a small core set of "accountability measures" that can be used to publicly report diabetes care quality, and a larger set of "improvement measures" that are not publicly reported, but that can be used privately by clinicians and care delivery organizations, as needed, to improve care by pinpointing specific barriers to higher quality diabetes care. If a clinician, clinic, or care system is doing poorly on *accountability measures* such as those listed in Box 24.1, it may be helpful to deploy a set of more detailed *improvement measures* to identify care improvement opportunities related to glucose, BP, lipid, or other clinical goals. Improvement measures are designed to (a) identify *why* a particular clinician may have suboptimal accountability measures and (b) point to clinician-specific or clinic-specific "care improvement opportunities" that can reasonably be expected to improve quality of care. Prior work provides some empiric support for this approach [32, 33].

Clinicians with similar levels of performance on accountability measures may have substantially different patterns in associated improvement measures. This observed variation in patterns of care across clinicians is illustrated in Table 24.1 and suggests the potential usefulness of tailoring quality improvement and learning strategies to clinician-specific "care improvement opportunities." The definition of a "care improvement opportunity" for a specific clinician may be as simple as identifying performance on improvement measures relative to the median of their peer group's performance (Table 24.2). In settings where electronic health records or other sophisticated health information technology is available, collecting detailed clinical data on specific patterns of care at the clinician level is increasingly feasible.

When improvement measures are assessed, it is important to consider how best to share such information with clinicians, clinic leaders, or others. Several characteristics increase the effectiveness of feedback, such as timeliness, regularity over time, positive feedback alongside feedback on sub-optimal performance, feedback to a supervisor as well as the front-line clinician, providing feedback in both

Table 24.1 Examples of variation in percentages of PCC-specific care improvement opportunities (CIOs) in study-eligible patients from a larger algorithmically defined set. Columns represent the percentage of

patients with each CIO within PCC percentiles, and a ratio of COIs in 90th to 10th percentile PCCs

CIO topic	CIO description	10th	25th	50th	75th	90th	Ratio
Thiazide diuretic under use	% of patients with uncontrolled BP and adequate renal function not on a thiazide	16.3	18.9	23.1	27.6	30.3	1.9
ACEI/ARB under use	% of patients with uncontrolled BP who are not on ACEI/ARB use	13.7	15.5	20.0	24.7	27.9	2.0
Use of 3 or more BP medications	% of patients with uncontrolled BP on three or more medications	1.0	1.9	3.0	4.3	6.0	6.1
Hypertension recognition	% of patients meeting BP criteria without a problem list diagnosis	9.6	12.6	16.0	19.4	23.9	2.5
Use of moderate or high intensity statins when indicated	% of patients meeting ACC/AHA criteria for statin use with ASCVD risk \geq 10% on less than moderate intensity statin	12.6	16.3	23.7	32.3	42.9	3.4
Statin initiation when indicated	% of patients meeting ACC/AHA criteria for statin use but not on a statin	17.1	21.2	27.8	37.3	47.5	2.8
Antithrombotic underuse	% of patients meeting criteria for antithrombotic use, but not on an antithrombotic	7.5	9.5	13.0	18.2	22.3	3.0
Antithrombotic overuse	% of patients not meeting criteria for antithrombotic use, but on an antithrombotic	5.0	6.3	9.5	12.3	15.9	3.2
Screening for diabetes when indicated	% of patients meeting USPSTF criteria for diabetes screening without tests in 3 years	6.5	9.2	12.6	17.0	20.3	3.1

Abbreviations: CIO care improvement opportunity, PCC primary care clinician, BP blood pressure, ACEI angiotensin converting enzyme inhibitor, ARB angiotensin receptor blocker, ACC/AHA American College of Cardiology/American Heart Association, ASCVD atherosclerotic cardiovascular disease, USPSTF United States Preventive Service Task Force

Table 24.2 Prototype content of PPF feedback to PCC and their supervisor, updated every 2 months

Selected care improvement	You're doing better than	Number of patients	% of your patients with opportunity to improve care			
opportunity (CIO) from a set of 30	this % of PCP peers	evaluated in past 2 months	You now	Your goal ^a		
Use thiazide diuretics	8	50	38%	23%		
Initiate statin treatment when indicated	11	24	35%	28%		
Refer smokers to cessation programs	23	14	24%	16%		
Hypertension recognition	71	61	12%	☺ Great job!		
Screening for diabetes when indicated	83	33	9%	☺ Great job!		
Antithrombotic underuse	94	17	8%	☺ Great job!		

^a This is performance level of median PCC

verbal and written form, feedback that is actionable, and setting specific goals for improvement with repeat measurement to assess progress [34]. In a time of widespread clinician and health worker burnout, feedback must be provided as sensitively as possible.

Measuring Patient Experience of Care

Diabetes is a complex chronic disease, and clinicians are faced with the daunting challenge of dealing with a myriad of effects that diabetes may have on many dimensions of a patient's life. In addition to its direct biological, psychological, and financial impact on patients, diabetes also may significantly impact the family, friends, employers, and caregivers of those with the illness. The social and economic impact of diabetes on direct medical care costs, indirect costs, and workforce productivity is also substantial. A fundamental question related to measurement of diabetes quality of care is this: how wide a net do we want to cast? Can we hold the care delivery system accountable for the myriad impact of diabetes on a person's life? Should governments, employers, schools, or nursing homes be held accountable for accommodating the needs of those with diabetes?

There is increasing attention to integration of health care with behavioral health and social services for vulnerable persons or families, which would include many individuals or families affected by diabetes. Diabetes may be associated with increased work absenteeism or presenteeism, decreased income, high medication costs, high health-care costs, and decreases in physical, emotional, and social function. The strongest evidence exists for integration of psychological and diabetes care in models such as Collaborative Care [35]. In many communities, social services are available to provide necessary assistance with income, housing, food, safety, or health-care costs. However, integration of social services with primary health care services is often incomplete, and better access to and coordination of services is often needed [36, 37]. Although integration of health-care services and behavioral health and social services may be beneficial for many patients with diabetes, holding clinicians or clinics responsible for delivery of integrated services may not be well accepted by some clinicians and may not be feasible in some rural or under-resourced areas. Moreover, quality measures that assess integration and coordination of care are not yet fully developed and validated.

Quality measures that focus on *patient experience of care* are now being used in some care delivery systems. Important aspects of patient experience of care include a timely access to necessary health-care services, clear and comprehensible communication from clinicians, an active role in care decisions, and satisfaction with clinical care provided.

Collecting patient-reported information on experience of care, patient-centered care, or shared decision-making may require surveys, conversations, electronic communication, and analysis of verbal or questionnaire data. This can be quite time consuming and expensive. Although representative random sampling of patients may reduce the resources required for such measures, accuracy may be compromised if sampling is done in a biased way, if response rates are low, or if the sample size is insufficient to draw reliable conclusions.

Nonetheless, a number of survey instruments have been reasonably well validated to measure patients' experience of care, diabetes distress (Problem Areas in Diabetes/PAID), patient-centered care, shared decision-making, and self-efficacy (Diabetes Empowerment Scale/DES); some of these are available in validated Spanish versions [38–40].

Shared Decision-Making and Treatment Burden

Shared decision-making (SDM) can be informally defined as timely sharing of information between patients and clinicians that empowers patients to actively participate (if so desired) in selecting from a set of evidence-based treatment options, those that best reflect their values and personal preferences. Shared decision-making is an intrinsic and necessary part of primary care practice but is often neglected [41]. One study found that primary care clinicians provided basic information on newly prescribed medications—the name of the medication, frequency of dosing, duration of use, intended benefits, and major side effects—only about 20% of the time [42]. This lack of basic information precludes shared decision-making and has been linked to low medication adherence and increased mortality in some studies [21]. The impact of shared decision-making on diabetes-related clinical outcomes is an area of active research [43].

Some thought leaders have recently proposed that treatment regimens be designed to minimize the burden of care imposed on the patient by their diabetes treatment [44]. This is a neglected but important aspect of care; the typical adult with diabetes takes seven to eight medications a day in the United States, and glucose monitoring, dietary considerations, and frequent office visits increase time and resources devoted to diabetes care [45, 46]. For example, treatment with insulin often imposes burdens related to blood glucose monitoring, disruption of daily routines, risks of hypoglycemia, and high out-of-pocket costs for insulin and associated supplies and equipment. Use of sophisticated insulin delivery systems and continuous glucose monitoring may confer clinical benefits for some patients, while adding different care requirements, concerns, and expense. Some data suggest that minimizing the burden of care may improve treatment adherence, timely follow-up care, and reduce patient stress [44, 47]. For these reasons, some experts suggest that measuring burden of care is justified and that development of creative strategies to minimize burden of care may improve care, adherence, and long-term clinical outcomes [48].

Shared decision-making may help reduce the burden of care [49] and can be used to develop individualized care goals and care plans for complex patients [50–52]. Note that quality measurement becomes more complicated if it must accommodate patient-specific clinical goals. One possible solution to this problem is to select clinical goals for quality measure that are more generalizable, such as an A1c goal of <8% rather than A1c<7%, to accommodate patient-specific variation in clinical goals [53, 54].

It is of particular concern that many clinicians (and patients) overestimate treatment benefits, often by an order of magnitude. For example, in the UKPDS, intensive glucose treatment for about 18 years led to an additional 90–180 days of quality-adjusted life [55]. In the ACCORD randomized trial, intensive glucose control significantly increased death rates by 18–20% compared to moderate glucose control [17, 56]. How many patients, with this information in mind, would opt for intensive glucose treatment using the medications available when those studies were conducted? Fortunately, newer classes of drugs such as GLP-1RA and SGLT2i appear to confer impressive clinical benefits on many diabetes patients who also have cardiovascular disease, chronic kidney disease, or congestive heart failure [57, 58].

These considerations underscore the complexity of shared decision-making and patient-centered care. That complexity

P. J. O'Connor et al.

has led to increased interest in use of web-based decision support algorithms and risk equations that can be used to accurately estimate and compare the potential benefits of various evidence-based treatment options for a specific patient [59]. Observing and understanding the treatment preferences of well-informed patients can, in turn, improve our understanding of what factors influence treatment preferences and lead to improved approaches to shared decisionmaking [22, 23, 25, 60].

Measuring Affordability and Cost-Effectiveness of Diabetes Care

Several studies document that health-care costs of those with diabetes are more than double the health-care costs of ageand sex-matched patients without diabetes [9]. Higher costs are driven by several factors, including pharmaceutical and equipment costs, more outpatient visits, and more frequent and longer hospitalizations across a wide range of admission diagnoses [61]. From the clinical point of view, the major driver of excess, potentially avoidable costs is major cardio-vascular events, including admissions for congestive heart failure, myocardial infarction, stroke, peripheral arterial disease, and revascularization procedures.

Although cost of care is generally higher for those with diabetes, studies indicate that there is a wide variation in costs of care not only across patients but also across care delivery systems for similar patients. This has led many experts to speculate that more attention should be devoted to identifying optimal "care pathways" that combine clinical success with low costs. For example, suppose a patient requires two glucose-lowering agents to achieve their evidence-based glucose goal, the cost to the care delivery system (insurer or government) for various combinations of effective glucose-lowering medications may vary as much as 50-fold with generic metformin and sulfonylureas being least expensive, and SGLT2i and GLP-1RA being most expensive drug classes. Likewise, out-of-pocket cost to the patient may vary widely by care system and insurance arrangements [62].

Insulin acquisition costs are another example of variability in cost to the delivery system, and in some cases to patients. Recent analysis indicates up to tenfold variation in insulin costs in the United States based on the type of insulin (human vs. analog) and delivery system (vial versus cartridges). Thus, judicious use of analog insulins, perhaps reserving them for patients at high risk of serious hypoglycemia, could be a policy that substantially lowers costs [63–65].

The analysis of cost-effectiveness in diabetes care is even more complicated. The threshold of costs per qualityadjusted life year (QALY) that purchasers are willing to pay varies substantially by country, by payer, and by year. The cost of complications such as an amputation or myocardial infarction also varies greatly across nations and across delivery systems within nations. Moreover, pharmaceutical corporations may agree to very different acquisition costs for a given medication in different countries, and within some countries, in different delivery systems. All these factors complicate efforts to accurately estimate cost-effectiveness of diabetes care across time, nations, and delivery systems.

Despite challenges, it is instructive for delivery systems to estimate cost per QALY gained, for various treatment pathways (human vs. analog insulin, vials vs. pen insulin delivery systems, use vs. nonuse of continuous glucose monitoring in stable type 2 diabetes, expensive vs. less expensive noninsulin glucose-lowering drugs, various lipid lowering treatment strategies, various visit intervals, in-person vs. virtual clinical encounters). Doing so and using these data to identify optimal treatment pathways for various groups of diabetes patients, and to aggressively negotiate drug acquisition costs with suppliers, may well reduce the cost and improve the cost-effectiveness of diabetes care in some clinically defined groups of patients.

The recent demonstration that selected GLP-1 receptor agonists (GLP-1RA) and SGLT2 inhibitors may significantly reduce major CV events and CV mortality and preserve renal function, which will complicate efforts to assess optimal treatment pathways from the cost and cost-effectiveness point of view. The cost-effectiveness of these new medication classes will be driven both by their clinical benefits and by their variable but generally high acquisition costs. Also, important to consider are cost-sharing arrangements with patients, whose ability to afford substantial out-of-pocket costs typically varies widely by income.

At the population level, a certain fraction of diabetes patients will require intensive interventions to achieve and maintain glucose, BP, and lipid care goals. Intensive interventions that can be deployed in a targeted way across a population of diabetes patients and can range from intensive, individual level interventions such as nurse case management combined with peer-led, collaborative diabetes education and self-management training to web-based clinical decision support delivered through the electronic health record at primary care encounters. Diabetes care management including diabetes self-management education and peer support is more expensive at the individual level but has been shown to produce more significant improvements in clinical risk factors including A1c [66-68]. Clinical decision support requires a substantial initial investment, but that can be spread over a large population resulting in low individual level costs, although with smaller clinical effects. These two intervention strategies have been shown to be similarly costeffective and can be used in a coordinated, complementary way [69].

Finally, it is important to note that the cost-effectiveness of type 2 diabetes prevention has been thoroughly studied and in most scenarios is either cost saving or highly costeffective, whether accomplished via lifestyle change programs or by using medications such as metformin [70]. Very few things in health care are cost saving, so investments in type 2 diabetes prevention programs is increasingly recognized as a good investment by various private and public care delivery systems [71].

Summary

Systematic measurement of diabetes care quality can identify important gaps in clinical care, map variation in quality of care across clinicians and delivery systems, and provide useful information to guide care improvement efforts. A wide range of diabetes quality measures are available. Selection of a parsimonious set of accountability measures that are causally related to key clinical outcomes is a top priority. A larger set of optional improvement measures can be used to map care improvement opportunities that, if addressed, will improve accountability measures. Measures that assess patient experience of care, shared decisionmaking, and cost of care may also be considered. However, resources needed for quality measures can be considerable and may reduce resources available for direct patient care. Measures that can be extracted from electronic clinical databases are generally much less expensive than measures that require patient-reported data. Ongoing efforts are needed to optimize diabetes quality measures and develop new measures of patient-centered care, efficient use of resources, and patient-reported outcomes and to identify effective strategies for primary prevention of type 2 diabetes.

Multiple Choice Questions

- Clinical measures that are causally related to major microvascular and macrovascular diabetes complications are often selected for clinical quality of care measures. Such clinical measures might include all the following except:
 - (a) Antithrombotic use
 - (b) Cholesterol control
 - (c) Blood pressure control
 - (d) Annual diabetes patient education
 - (e) Glucose control
 - (f) Nonuse of tobacco

Comment: Diabetes patient education is extremely important, but in randomized trials it has only a marginal impact on glucose, BP, lipid, or tobacco control and is not casually related to lower rates of major diabetes complications. Thus, the other aspects of care listed here are more suitable for diabetes quality of care measures.

- Regarding the cost-effectiveness of electronic health record (EHR)-linked clinical decision support and diabetes case management, which of the following statements is false:
 - (a) Case management is much more expensive on a perpatient basis,
 - (b) Over the long run, clinical decision support may be cost-saving.
 - (c) They are about equally cost-effective.
 - (d) Most patients resist active case management as an invasion of privacy.
 - (e) Clinical decision support has high initial implementation costs.

Comment: In large studies of diabetes case management, about 2/3 of high-risk diabetes patients engage in the case management process.

- 3. Reasons to measure diabetes care quality at the clinician level include all the following except:
 - (a) There is significant variation in patterns of care at the clinician level.
 - (b) It is often difficult to link individual patients to a single responsible clinician.
 - (c) Many clinicians like to know how they are doing compared to their peers.
 - (d) Such information can guide clinician-specific learning interventions.
 - (e) Electronic data make this easier to do than in the past. Comment: Well over 90% of patients can be linked to

a usual primary care clinician in most health care systems, based on frequency of visits with various clinicians and/or patient designation of a usual primary care clinician in electronic health record systems.

- 4. Which one of the following statements about the relationship of outpatient cost of diabetes care to outpatient quality of diabetes care is false:
 - (a) Quality of care is not related to cost of care at the clinic level.
 - (b) High-quality care costs more.
 - (c) Low-quality care can be as expensive as high-quality care.
 - (d) Cost of care is important both to the patient and to the care delivery system.
 - (e) Costs of care vary widely across patients with diabetes.

Comment: There is abundant evidence that there is not a strong association of outpatient costs of diabetes care with quality of outpatient diabetes care.

References

 Gregg EW, Li Y, Wang J, Burrows NR, Ali MK, Rolka D, et al. Changes in diabetes-related complications in the United States, 1990-2010. N Engl J Med. 2014;370(16):1514–23.

- Gregg EW, Zhuo X, Cheng YJ, Albright AL, Narayan KM, Thompson TJ. Trends in lifetime risk and years of life lost due to diabetes in the USA, 1985-2011: a modelling study. Lancet Diabetes Endocrinol. 2014;2(11):867–74.
- Knowler WC, Fowler SE, Hamman RF, Christophi CA, Hoffman HJ, Brenneman AT, et al. 10-year follow-up of diabetes incidence and weight loss in the diabetes prevention program outcomes study. Lancet. 2009;374(9702):1677–86.
- Herman WH, Hoerger TJ, Brandle M, Hicks K, Sorensen S, Zhang P, et al. The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. Ann Intern Med. 2005;142(5):323–32.
- Lee CG, Heckman-Stoddard B, Dabelea D, Gadde KM, Ehrmann D, Ford L, et al. Effect of metformin and lifestyle interventions on mortality in the diabetes prevention program and diabetes prevention program outcomes study. Diabetes Care. 2021;44(12):2775–82.
- Montori VM, Fernandez-Balsells M. Glycemic control in type 2 diabetes: time for an evidence-based about-face? Ann Intern Med. 2009;150(11):803–8.
- Brito JP, Montori VM, ACP Journal Club. Intensive BP control and/ or glucose control did not reduce microvascular events in hypertensive type 2 diabetes. Ann Intern Med. 2012;157(8):JC4–7.
- O'Connor PJ, Ismail-Beigi F. Near-normalization of glucose and microvascular diabetes complications: data from ACCORD and ADVANCE. Ther Adv Endocrinol Metab. 2011;2(1):17–26.
- Gilmer TP, O'Connor PJ, Manning WG, Rush WA. The cost to health plans of poor glycemic control. Diabetes Care. 1997;20(12):1847–53.
- Desai JR, Vazquez-Benitez G, Xu Z, Schroeder EB, Karter AJ, Steiner JF, et al. Who must we target now to minimize future cardiovascular events and total mortality?: lessons from the surveillance, prevention and management of diabetes mellitus (SUPREME-DM) cohort study. Circ Cardiovasc Qual Outcomes. 2015;8(5):508–16.
- O'Connor PJ, Bodkin NL, Fradkin J, Glasgow RE, Greenfield S, Gregg E, et al. Diabetes performance measures: current status and future directions. Diabetes Care. 2011;34(7):1651–9.
- Wang L, Li X, Wang Z, Bancks MP, Carnethon MR, Greenland P, et al. Trends in prevalence of diabetes and control of risk factors in diabetes among US adults, 1999–2018. JAMA. 2021;326(8):1–13.
- Patel SY, McCoy RG, Barnett ML, Shah ND, Mehrotra A. Diabetes care and glycemic control during the COVID-19 pandemic in the United States. JAMA Intern Med. 2021;181(10):1412–4.
- 14. World Health Organization. International diabetes federation HEARTS D: diagnosis and management of type 2 diabetes. Geneva: World Health Organization; 2020. https://www.who.int/ publications/i/item/who-ucn-ncd-20.1
- National Quality Forum. Social risk trial final report. Washington, DC: National Quality Forum; 2017. https://www.qualityforum.org/ Publications/2017/07/Social_Risk_Trial_Final_Report.aspx.
- National Quality Forum. Best practices for developing and testing risk adjustment models. Washington, DC: National Quality Forum. https://www.qualityforum.org/ProjectDescription. aspx?projectID=93616.
- Gerstein HC, Miller ME, Genuth S, Ismail-Beigi F, Buse JB, Goff DC Jr, et al. Long-term effects of intensive glucose lowering on cardiovascular outcomes. N Engl J Med. 2011;364(9):818–28.
- Patel A, MacMahon S, Chalmers J, Neal B, Woodward M, Billot L, et al. Effects of a fixed combination of perindopril and indapamide on macrovascular and microvascular outcomes in patients with type 2 diabetes mellitus (the ADVANCE trial): a randomised controlled trial. Lancet. 2007;370(9590):829–40.
- Patel A, MacMahon S, Chalmers J, Neal B, Billot L, Woodward M, et al. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. N Engl J Med. 2008;358(24):2560–72.
- Azad N, Agrawal L, Bahn G, Emanuele NV, Reaven PD, Hayward R, et al. Eye outcomes in veteran affairs diabetes trial (VADT) after 17 years. Diabetes Care. 2021;44(10):2397–402.

- Ho P, Rumsfeld J, Masoudi F, McClure D, Plomondon M, Steiner J, et al. Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. Arch Intern Med. 2006;166(17):1836–41.
- 22. O'Connor PJ, Sperl-Hillen JM, Rush WA, Johnson PE, Amundson GH, Asche SE, et al. Impact of electronic health record clinical decision support on diabetes care: a randomized trial. Ann Fam Med. 2011;9(1):12–21.
- Sperl-Hillen JM, Crain AL, Margolis KL, Ekstrom HL, Appana D, Amundson GH, et al. Clinical decision support directed to primary care patients and providers reduces cardiovascular risk: a randomized trial. J Am Med Inform Assoc. 2018;25(9):1137–46.
- 24. Gold R, Larson AE, Sperl-Hillen JM, Boston D, Sheppler CR, Heintzman J, et al. Effect of clinical decision support at community health centers on the risk of cardiovascular disease: a cluster randomized clinical trial. JAMA Netw Open. 2022;5(2):e2146519.
- 25. Rossom RC, Crain AL, O'Connor PJ, Waring SC, Hooker SA, Ohnsorg K, et al. Effect of clinical decision support on cardiovascular risk among adults with bipolar disorder, schizoaffective disorder, or schizophrenia: a cluster randomized clinical trial. JAMA Netw Open. 2022;5(3):e220202.
- 26. Goff DC Jr, Lloyd-Jones DM, Bennett G, Coady S, D'Agostino RB, Gibbons R, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. Circulation. 2014;129(25 Suppl 2):S49–73.
- 27. Hayes AJ, Leal J, Gray AM, Holman RR, Clarke PM. UKPDS outcomes model 2: a new version of a model to simulate lifetime health outcomes of patients with type 2 diabetes mellitus using data from the 30 year United Kingdom prospective diabetes study: UKPDS 82. Diabetologia. 2013;56(9):1925–33.
- O'Connor PJ, Vazquez-Benitez G, Schmittdiel JA, Parker ED, Trower NK, Desai JR, et al. Benefits of early hypertension control on cardiovascular outcomes in patients with diabetes. Diabetes Care. 2013;36(2):322–7.
- Phillips LS, Branch WT, Cook CB, Doyle JP, El-Kebbi IM, Gallina DL, et al. Clinical inertia. Ann Intern Med. 2001;135(9):825–34.
- Shippee ND, Shah ND, May CR, Mair FS, Montori VM. Cumulative complexity: a functional, patient-centered model of patient complexity can improve research and practice. J Clin Epidemiol. 2012;65(10):1041–51.
- 31. The Lancet. 50 years of the inverse care law. Lancet. 2021;397(10276):767.
- 32. Sperl-Hillen J, O'Connor P, Rush W, Asche S, Appana D, Rudge A, et al. Simulated diabetes training helps providers bring patients to goals: a cluster randomized trial diabetes. Philadelphia, PA: American Diabetes Association—72nd Scientific Sessions; 2012. p. A307.
- O'Connor PJ, Sperl-Hillen JM, Johnson PE, Rush WA, Asche SE, Dutta P, et al. Simulated physician learning intervention to improve safety and quality of diabetes care: a randomized trial. Diabetes Care. 2009;32(4):585–90.
- 34. Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD, et al. Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2012;6:Cd000259.
- 35. Katon WJ, Von Korff M, Lin EH, Simon G, Ludman E, Russo J, et al. The pathways study: a randomized trial of collaborative care in patients with diabetes and depression. Arch Gen Psychiatry. 2004;61(10):1042–9.
- Vickery KD, Shippee ND, Guzman-Corrales LM, Cain C, Turcotte Manser S, Walton T, et al. Changes in quality of life among enrollees in hennepin health: a medicaid expansion ACO. Med Care Res Rev. 2020;77(1):60–73.
- 37. Vickery KD, Shippee ND, Menk J, Owen R, Vock DM, Bodurtha P, et al. Integrated, accountable care for medicaid expansion enroll-

ees: a comparative evaluation of hennepin health. Med Care Res Rev. 2020;77(1):46–59.

- Anderson RMFJ, Gruppen LD, Funnell MM, Oh MS. The diabetes empowerment scale—short form (DES-SF). Diab Care. 2003;26:1641–3.
- Welch GW, Jacobson AM, Polonsky WH. The problem areas in diabetes scale: an evaluation of its clinical utility. Diab Care. 1997;20:760–6.
- 40. Sperl-Hillen J, Beaton S, Fernandes O, Von Worley A, Vazquez-Benitez G, Parker E, et al. Comparative effectiveness of patient education methods for type 2 diabetes: a randomized controlled trial. Arch Intern Med. 2011;171(22):2001–10.
- Desai JR, Sperl-Hillen JM, O'Connor PJ. Patient preferences in diabetes care: overcoming barriers using new strategies. J Comp Eff Res. 2013;2(4):351–4.
- Tarn DM, Heritage J, Paterniti DA, Hays RD, Kravitz RL, Wenger NS. Physician communication when prescribing new medications. Arch Intern Med. 2006;166(17):1855–62.
- 43. Elliott TE, Asche SE, O'Connor PJ, Dehmer SP, Ekstrom HL, Truitt AR, et al. Clinical decision support with or without shared decision making to improve preventive cancer care: a cluster-randomized trial. Med Decis Mak. 2022;42(6):808–21.
- 44. Spencer-Bonilla G, Quinones AR, Montori VM, International Minimally Disruptive Medicine W, Assessing the burden of treatment. J Gen Intern Med. 2017;32(10):1141–5.
- 45. Schmittdiel JA, Raebel MA, Dyer W, Xu S, Goodrich GK, Schroeder EB, et al. Prescription medication burden in patients with newly diagnosed diabetes: a SUrveillance, PREvention, and ManagEment of Diabetes Mellitus (SUPREME-DM) study. J Am Pharm Assoc (2003). 2014, 54(4):e251–e9.
- 46. Shubrook JH, Brannan GD, Wapner A, Klein G, Schwartz FL. Time needed for diabetes self-care: nationwide survey of certified diabetes educators. Diabetes Spectr. 2018;31(3):267–71.
- Boehmer KR, Shippee ND, Beebe TJ, Montori VM. Pursuing minimally disruptive medicine: disruption from illness and health care-related demands is correlated with patient capacity. J Clin Epidemiol. 2016;74:227–36.
- 48. Greenfield S, Kaplan SH, Ware JE Jr, Yano EM, Frank HJ. Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. J Gen Intern Med. 1988;3(5):448–57.
- Rodriguez-Gutierrez R, Gionfriddo MR, Ospina NS, Maraka S, Tamhane S, Montori VM, et al. Shared decision making in endocrinology: present and future directions. Lancet Diabetes Endocrinol. 2016;4(8):706–16.
- McCoy RG, Van Houten HK, Ross JS, Montori VM, Shah ND. HbA1c overtesting and overtreatment among US adults with controlled type 2 diabetes, 2001-13: observational population based study. BMJ. 2015;351:h6138.
- 51. Schroeder EB, Xu S, Goodrich GK, Nichols GA, O'Connor PJ, Steiner JF. Predicting the 6-month risk of severe hypoglycemia among adults with diabetes: development and external validation of a prediction model. J Diabetes Complicat. 2017;31(7):1158–63.
- 52. Ismail-Beigi F, Moghissi E, Tiktin M, Hirsch IB, Inzucchi SE, Genuth S. Individualizing glycemic targets in type 2 diabetes mellitus: implications of recent clinical trials. Ann Intern Med. 2011;154(8):554–9.
- 53. LaVecchia CM, Montori VM, Shah ND, McCoy RG. Values informing the development of an indicator of appropriate diabetes therapy: qualitative study. BMJ Open. 2020;10(12):e044395.
- Rodriguez-Gutierrez R, Millan-Alanis JM, Barrera FJ, McCoy RG. Value of patient-centered glycemic control in patients with type 2 diabetes. Curr Diab Rep. 2021;21(12):63.
- 55. Clarke P, Gray A, Adler A, Stevens R, Raikou M, Cull C, et al. Cost-effectiveness analysis of intensive blood-glucose control with metformin in overweight patients with type II diabetes (UKPDS no. 51). Diabetologia. 2001;44(3):298–304.

- 56. Margolis KL, O'Connor PJ, Morgan TM, Buse JB, Cohen RM, Cushman WC, et al. Outcomes of combined cardiovascular risk factor management strategies in type 2 diabetes: the ACCORD randomized trial. Diabetes Care. 2014;37(6):1721–8.
- 57. Zhu J, Yu X, Zheng Y, Li J, Wang Y, Lin Y, et al. Association of glucose-lowering medications with cardiovascular outcomes: an umbrella review and evidence map. Lancet Diabetes Endocrinol. 2020;8(3):192–205.
- 58. Tsapas A, Avgerinos I, Karagiannis T, Malandris K, Manolopoulos A, Andreadis P, et al. Comparative effectiveness of glucose-lowering drugs for type 2 diabetes: a systematic review and network meta-analysis. Ann Intern Med. 2020;173(4):278–86.
- O'Connor PJ, Sperl-Hillen JM, Fazio CJ, Averbeck BM, Rank BH, Margolis KL. Outpatient diabetes clinical decision support: current status and future directions. Diabet Med. 2016;33(6):734–41.
- 60. Mayo Knowledge and Evaluation Research (KER) Unit. Diabetes medication choice decision conversation aid: mayo foundation for medical education and research.
- Selby JV, Ray GT, Zhang D, Colby CJ. Excess costs of medical care for patients with diabetes in a managed care population. Diabetes Care. 1997;20(9):1396–402.
- Institute of Medicine. Guidelines we can trust 2012. http://iom.edu/ Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx.
- Lipska KJ, Hirsch IB, Riddle MC. Human insulin for type 2 diabetes: an effective, less-expensive option. JAMA. 2017;318(1):23–4.
- 64. Neugebauer R, Schroeder EB, Reynolds K, Schmittdiel JA, Loes L, Dyer W, et al. Comparison of mortality and major cardiovascular events among adults with type 2 diabetes using human vs analogue insulins. JAMA Netw Open. 2020;3(1):e1918554.
- 65. Schroeder EB, Neugebauer R, Reynolds K, Schmittdiel JA, Loes L, Dyer W, et al. Association of cardiovascular outcomes and mortality with sustained long-acting insulin only vs long-acting plus shortacting insulin treatment. JAMA Netw Open. 2021;4(9):e2126605.
- 66. Gilmer TP, Roze S, Valentine WJ, Emy-Albrecht K, Ray JA, Cobden D, et al. Cost-effectiveness of diabetes case management for low-income populations. Health Serv Res. 2007;42(5):1943–59.
- 67. Gilmer T, Burgos JL, Anzaldo-Campos MC, Vargas-Ojeda A. Costeffectiveness of a technology-enhanced diabetes care management program in Mexico. Value Health Reg Issues. 2019;20:41–6.

- 68. Ye W, Kuo S, Kieffer EC, Piatt G, Sinco B, Palmisano G, et al. Cost-effectiveness of a diabetes self-management education and support intervention led by community health workers and peer leaders: projections from the racial and ethnic approaches to community health Detroit trial. Diabetes Care. 2021;44(5):1108–15.
- 69. Gilmer TP, O'Connor PJ, Sperl-Hillen JM, Rush WA, Johnson PE, Amundson GH, et al. Cost effectiveness of an electronic medical record based clinical decision support system. Health Serv Res. 2012;47(6):2137–58.
- Herman WH, Edelstein SL, Ratner RE, Montez MG, Ackermann RT, Orchard TJ, et al. Effectiveness and cost-effectiveness of diabetes prevention among adherent participants. Am J Manag Care. 2013;19(3):194–202.
- 71. Gilmer T, O'Connor PJ, Schiff JS, Taylor G, Vazquez-Benitez G, Garrett JE, et al. Cost-effectiveness of a community-based diabetes prevention program with participation incentives for medicaid beneficiaries. Health Serv Res. 2018;53:4704–24.

Further Reading

- O'Connor PJ, Bodkin NL, Fradkin J, Glasgow RE, Greenfield S, Gregg E, et al. Diabetes performance measures: current status and future directions. Diabetes Care. 2011;34(7):1651–9. [This article presents an overview of important issues and choices related to measuring diabetes quality of care, with author perspectives representing a wide range of stakeholders.]
- Greenfield S, Kaplan SH, Ware JE Jr, Yano EM, Frank HJ. Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. J Gen Intern Med. 1988;3(5):448–57. [This pivotal article showed that patient-centered care and shared decision making are linked to better glucose control, higher satisfaction with care, and better quality of life for adults with diabetes. Electronic health record (EHR)-linked clinical decision support systems can process patient-specific date, identify evidence-based care options, and present care options to both the patient and clinician at the point of care, enabling more efficient and consistent shared decision making.]