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Relation Between Quality-of-Care Indicators for Diabetes and Patient Outcomes: A Systematic Literature Review

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Abstract

The authors conducted a systematic literature review to assess whether quality indicators for diabetes care are related to patient outcomes. Twenty-four studies were included that formally tested this relationship. Quality indicators focusing on structure or processes of care were included. Descriptive analyses were conducted on the associations found, differentiating for study quality and level of analysis. Structure indicators were mostly tested in studies with weak designs, showing no associations with surrogate outcomes or mixed results. Process indicators focusing on intensification of drug treatment were significantly associated with better surrogate outcomes in three high-quality studies. Process indicators measuring numbers of tests or visits conducted showed mostly negative results in four high-quality studies on surrogate and hard outcomes. Studies performed on different levels of analysis and studies of lower quality gave similar results. For many widely used quality indicators, there is insufficient evidence that they are predictive of better patient outcomes.

Keywords

health care quality, quality of care, quality indicators, outcome, assessment, diabetes mellitus

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Introduction

Quality indicators are used to identify and reward providers who meet predefined standards of quality of care, and by health care providers for internal quality assessment and improvement initiatives. They are commonly divided into indicators of structure, process, and outcome (Donabedian, 1988). Outcome indicators measure the results of care, including surrogate and hard clinical outcomes. The main difficulty when using outcome indicators is that—in contrast to structure and process indicators—outcomes are not a direct measure of actions of health care providers and can be influenced by other factors that are not under the control of the organization or clinician (Mant, 2001). Therefore, structure and especially process indicators are often used to assess the quality of care (Chassin, Loeb, Schmaltz, & Wachter, 2010; De Vos et al., 2009; Saaddine et al., 2006). It is not always clear, however, whether better performance as measured by structure and process indicators is indeed related to improved patient outcomes.

Structure indicators include organizational aspects of health care as well as material and human resources. Such indicators measure, for example, the adequacy of facilities, equipment, logistics, or registration, or the qualification of medical staff. Structure indicators aim to evaluate the conditions that are considered relevant for delivering the required standards of care. They can be derived from theoretical models, based on the consensus of experts, or on studies showing that interventions aimed at improving specific aspects of the structure of care lead to better processes or outcomes of care (Australian Primary Health Care Research Institute, 2006; Wensing, Wollersheim, & Grol, 2006).

Process indicators reflect actions of health care professionals and organizations, such as the number or quality of consultations, prescriptions, laboratory tests, or physical examinations. They depict actions that clinicians can control most directly. They are usually based on the recommended actions in clinical guidelines. In turn, such guideline recommended actions are usually based on findings from clinical trials and scientific rationale endorsed by quality improvement organizations (Agency for Healthcare Research and Quality [AHRQ], 2009; National Committee for Quality Assurance [NCQA], 2010; The NHS Information Centre, Prescribing Support Unit [NHS], 2009). Given these underlying rationales, many indicators are considered to have content validity, and several have also been tested for face validity and operational feasibility. This does not ensure, however, that they also have predictive validity. The question is whether high scores on structure and process indicators are associated with better patient outcomes in actual practice. This is especially relevant for indicators used for accountability (Campbell, Braspenning, Hutchinson, & Marshall, 2002). Such measures should not only be sufficiently evidence based but also accurately capture the process as well as focus on processes that are proximate to beneficial outcomes without leading to unintended outcomes when implemented in practice (Chassin et al., 2010). Some studies have shown associations between the process of care for hypertension or secondary prevention care, and surrogate outcomes, such as achieving blood

pressure or low-density lipoprotein (LDL)-cholesterol targets (Asch et al., 2005; Asch, Kerr, LaPuerta, Law, & McGlynn, 2001; Ho et al., 2006). Process indicators have also been linked to survival, as was shown for the ACOVE (Assessing Care of Vulnerable Elders) quality criteria (Higashi et al., 2005). On the other hand, for the Quality and Outcome Framework indicators used in the United Kingdom, associations with emergency admissions and mortality were found to be small and inconsistent (Downing et al., 2007).

New Contributions

Various indicators for measuring quality of diabetes care have been developed, which focus on the structure or the process of care (American Diabetes Association [ADA], 2009; AHRQ, 2009; NCQA, 2010; NHS, 2009; Calvert, Shankar, McManus, Lester, & Freemantle, 2009; Martirosyan et al., 2008; Nicolucci, Greenfield, & Mattke, 2006; Wens, Dirven, Mathieu, Paulus, & Van Royen, 2007). Findings of clinical trials and scientific rationale by experts form the basis for these indicators. The usefulness of these indicators depends on their impact on patient outcomes when implemented in actual practice (Campbell et al., 2002, Chassin et al., 2010), but the evidence supporting this appears to be limited (Borgermans et al., 2008). Therefore, we conducted a systematic literature review to assess what is currently known about the relationship between structure and process indicators for diabetes care and patients outcomes. The objectives were to evaluate to what extent commonly used structure and process indicators have been tested and shown to be related to surrogate or hard clinical outcomes in actual practice situations.

Conceptual Model

The conceptual model for organizing the review is based on the Donabedian model of structure–process–outcome, which has been used for many studies addressing quality and outcomes (Donabedian, 1988). Its three dimensions can be seen as independent but interrelated, where it is expected that good structure increases the likelihood of good process, and good process increases the likelihood of good outcome. Figure 1 depicts those elements of diabetes care for which quality indicators have been developed and for which there is underlying evidence or expert consensus of their relevance for beneficial patient outcomes. First of all, there is evidence from intervention studies that the implementation of specific structure of care elements related to quality assurance, coordination of care, and information systems can be effective in improving processes and surrogate outcomes of diabetes care (Renders et al., 2001; Tsai, Morton, Mangione, & Keeler, 2005). There is also evidence from clinical trials showing that intensive drug treatment has beneficial effects on surrogate and hard outcomes (Turnbull et al., 2009; UK Prospective Diabetes Study Group, 1998a; 1998b). Furthermore, there is consensus that risk factors, such as HbA1c, blood pressure, and lipid levels, need to be tested to monitor whether patients are adequately treated or

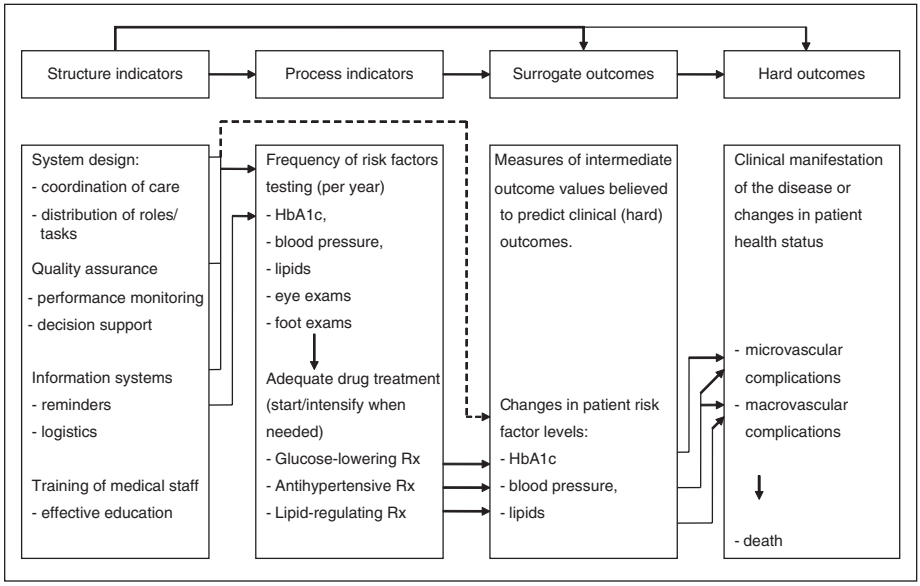

Figure 1. Relationships between quality indicators and outcomes

treatment adjustments are necessary (AHRQ, 2009; NCQA, 2010; NHS, 2009). Most diabetes guidelines also have recommendations regarding the frequency of such risk factor testing (ADA, 2009; Calvert et al., 2009; Nicolucci et al., 2006; Wens et al., 2007), but the scientific rationale is based mostly on the consensus of experts. The predictive validity of these risk factor levels on various diabetes complications is recognized (Baigent et al., 2005; Gilbert, Jasik, DeLuise, O'Callaghan, & Cooper, 1995; Stratton et al., 2000). However, the relationship between some surrogate and hard outcomes is a matter of debate in the management of diabetes and related cardiovascular risk factors, for example, changes in HbA1c may not reflect cardiovascular protection in the long run.

Method

We conducted a systematic search of MEDLINE and Embase until May 1, 2010, to identify studies focusing on the relationship between quality indicators and outcomes for diabetes care (Figure 2). Two reviewers independently screened the titles and abstracts of the 3,296 retrieved publications (664 with MeSH terms from MEDLINE, 2632 from Embase). A snowballing procedure was used to find studies not covered by our search strategy. In addition, we hand-searched the web pages of professional organizations that have sets of quality indicators in the United States and the United Kingdom (AHRQ, 2009; NCQA, 2010; NHS, 2009).

The following combination of MeSH terms was used for MEDLINE:

"Quality Indicators, Health Care"[Majr]

OR "Outcome and process Assessment (Health Care)"[Majr]

OR "Quality of Health Care"[Majr]

AND "Outcome Assessment (Health Care)"[Mesh]

AND "Diabetes Mellitus"[Mesh].

The following combination of EMTREE terms was used for an combined search of EMBASE and MEDLINE using embase.com:

'health care quality'/de AND 'diabetes mellitus'/de AND [1999-2009]/py

Figure 2. Search strategy

Studies were included when they formally tested the relationship between a quality indicator of the structure or processes of diabetes care and patient outcomes. This included prospective and retrospective observational studies testing predictive validity, that is, the extent to which a score on the indicator can predict future (clinical) outcomes. We decided to include also cross-sectional studies testing only associations. The decision to include studies with this weak design methodology was based on preliminary searches, which suggested that there might be few prospective or retrospective studies focusing on the predictive validity of structure measures.

Studies were excluded if they (a) did not formally assess the quality of care or (b) did not test the relationship between the quality indicator and an outcome measure. This implies that (randomized) trials evaluating the effect of an organizational, educational, or treatment intervention on patient outcomes were not included, since they do not assess the predictive validity of a quality indicator. Such studies can provide the evidence base for an indicator but do not address the other criteria relevant for the validity of the indicator, such as accurately capturing structure or process of care, and addressing aspects of care that by themselves have sufficient impact on patient outcomes without leading to unintended outcomes when implemented in practice (Chassin et al., 2010). Furthermore, published studies or reports from quality improvement organizations that only describe (parallel) changes in process and outcome measures were not included, since they do not establish the validity in a formal statistical sense.

When screening the studies, we used a stepwise procedure judging whether the study included any quality indicators and whether the relationship between these quality indicators and patient outcomes was tested, for which full text screening was often needed. Data were extracted by two reviewers using a standardized extraction form. Possible disagreements were decided by consensus. Items extracted included quality

indicator type (structure, process, outcome), patient outcome (surrogate, hard outcomes), study design (cohort, case–control, cross-sectional), level of analysis (patient, health care provider, hospital/medical center, multilevel), number of participants, statistical methods, setting (country and/or health care system), period of study, source of quality indicator (derived from guidelines, literature), data collection (self-report, medical records, claims database), results, and conclusion.

The cohort and case–control studies were graded on their quality, using the Newcastle–Ottawa Scale (Wells et al., 2003). This is a "star-rating" system, where a study is judged on three domains: selection of the study groups (maximum of three stars for representativeness, definition cases/controls, or ascertainment cohort exposure), comparability of the groups (maximum of two stars for controlling for confounding), and reliable assessment exposure for case–control or outcome for cohort and adequate patient follow-up (maximum of three stars). In our review, exposure concerns the quality assessment, whereas outcomes can be surrogate or hard patient outcomes. When looking at the associations at individual patient level, matching or adjusting for confounders is extremely important since the likelihood to receive specific care may depend on the health status of the patient. For example, sicker patients may receive more tests and more drug treatment, which would result in a negative association between the process of care quality and patient outcomes. When looking at the associations at the provider level, confounding with unmeasured disease severity will usually not occur, but sufficient adjusting for case-mix differences remains important. Therefore, we extended the rating for comparability to a maximum of four stars, where a study can receive one star when it controls for each of the following: (a) the patient's age; (b) other possibly related general characteristics, including marital status, economic status, residence, or education in combination with measures of health care utilization; (c) comorbidity status; (d) specific relevant clinical factors, including disease severity, related complications, related drug use. This resulted in an overall quality score ranging from 0 to 11 stars for cohort and case–control studies. We divided the studies into three groups: high quality (9-11), medium quality (6-8), and low quality (0-5).

For cross-sectional studies, one star was assigned, when analyses were conducted at practice or provider level, thereby avoiding part of the endogeneity likely to be present at the patient level. Similar to cohort and case–control studies, one star was assigned when the included patients were considered (somewhat) representative of the patients with diabetes in the community, one star when the quality indicator was assessed through secure records or structured interview or questionnaire, and one star when the outcome was assessed through secure records or structured interview or questionnaire. This resulted in an overall quality score ranging from zero to four stars for cross-sectional studies, where four stars are considered as sufficient quality, three as medium quality, and one or two as low quality.

Structure indicators were subdivided into measures focusing on available technical and clinical facilities, logistics and coordination or care, data registration and

documentation, quality assurance programs and tools, and qualification and training of medical staff. Process indicators were subdivided into measures of drug treatment prescribing (number of) visits or tests/examinations conducted. Surrogate outcomes included measurements of HbA1c, glucose, cholesterol (high-density lipoprotein [HDL], LDL, total), proteinuria, or blood pressure. Hard outcomes included health status, (hospitalizations for) metabolic, microvascular, and macrovascular complications, cardiovascular events, heart and kidney disease, amputations, and death.

Descriptive analyses were first conducted on the relationships found in case–control and cohort studies supporting predictive validity, and second in cross-sectional studies. Distinctions were made according to study quality and the level of analysis. The level of analysis is important because relationships found at patient level may be absent at the higher level, such as the health care provider or hospital or medical center, because of differences in variability and effects of confounding variables. Based on the identified studies, we describe the relationships between (see also Figure 1):

- structure indicators and surrogate or hard outcomes
- process indicators and surrogate outcomes
- process indicators and hard outcomes
- composite measure (of process indicators and surrogate outcomes) and hard outcomes

It was not possible to pool study results in a meaningful way because of the diversity in quality indicators, outcome measures, and study designs.

Results

We identified 24 articles satisfying our inclusion criteria, testing a wide range of structure and process of care indicators (Table 1). Nineteen studies were conducted in the United States, 2 in the United Kingdom, 2 in the Netherlands, and 1 in Italy. There were 10 cohort and 4 case–control studies, 8 of which were considered to be of high quality, whereas the other six studies received medium-quality scores (Table 2). The remaining 10 studies had a cross-sectional design, of which 7 were classified within this category as sufficient quality, 1 as medium quality, and 2 as low quality. Eleven studies conducted the analysis only at patient level, whereas 7 studies conducted a multilevel analysis to take into account the clustering of patients at health care centre or provider level. Three studies conducted analysis at both levels and another 3 only at health care centre or provider level. Data for structure of care were usually collected using self-report survey tools. Data for processes and outcomes of care were collected in most studies from medical records or claims data. The number of patients included ranged from 244 to >100,000, whereas the number of practices or providers ranged from 10 to 626.

Table 1. Quality Measures Included in Reviewed Articles

Author	Type of Indicator	Indicators
Barr et al. (2001)	Structure indicators	Total and component scores evaluating the hospital bedside glucose testing program, including policy/administration, training program, authorization, daily operations, quality assurance, equipment validation
Solberg et al. (2008)	Structure indicator	Physician practice connections—Readiness Survey total and 5 separate domain scores, derived from the chronic care model (health system, delivery system redesign, clinical information system, decision support, self-management support)
Sperl-Hillen et al. (2004)	Structure indicator	Chronic care model components (see above)
Wrobel et al. (2003)	Structure indicators	Site visit ranking (assessment of medical center's foot care program), programming coordination FootSAT score (10 items on standardization of work and skills), feedback coordination FootSAT score (29 items on supervision, exchange information)
Nutting et al. (2007)	Composite structure indicator	9 items score covering the following domains of chronic care model: clinical information system, decision support, self-management support, delivery system design
Dunn and Pickering (1998)	Structure indicators	Register of diabetic patients under GP follow-up, recall system, one partner sees all diabetics, doctor with postgraduate training in diabetes, nurse with postgraduate training
	Process indicators of visits and tests/ exams	Whether patient visit health care provider or not, blood glucose done, HbA1c done, creatinine done, cholesterol done, urine analysis done, blood pressure done, foot examination done, full eye examination done, smoking history recorded, weight done
Pringle et al. (1993)	Structure indicators	Practice questionnaires about presence of 16 items of equipment
	Process indicators of visits and tests/ exams	Number of general practice consultations in previous 2 years, frequency of urine testing, composite measure of testing of 14 diabetes-related examinations (from visual acuity and foot pulses to random blood sugar and urine analysis)
Schectman et al. (2002)	Structure indicator	Proportion of visits to single physician (continuity of care index)
	Process indicators of visits and tests	1. Number of clinic visits 2. Number of HbA1c tests

(continued)

Table 1. (continued)

Author	Type of Indicator	Indicators
Berlowitz et al. (2005)	Process indicator of drug treatment	Patient-specific score expressing relative number of medication changes during 1- to 1.5-year follow-up (intensity of glucose-lowering therapy)
Selby et al. (2009)	Process indicator of drug treatment	Treatment intensification rate, i.e., proportion of patients receiving increase in number of drug classes, dosage of at least one medication, or a switch to another medication within 3 months following an initial observation of poor control
Sperl-Hillen and O'Connor (2005)	Process indicators of drug treatment	Treatment intensifications: addition of metformin; addition of sulfonylurea; start of statin use
Van Bruggen et al. (2009)	Process indicators of drug treatment	Treatment intensification (glucose-lowering drugs, antihypertensives, lipid-lowering drugs)
Ziemer et al. (2005)	Process indicators of drug treatment	Frequency of intensification of diabetes care defined as an increase in the dosage or number of hypoglycemic agents that the patient was taking
Helmer et al. (2008)	Process indicators of visits and tests	1. Number of quarterly diabetes visits 2. Number of quarterly HbA1c testing
Li et al. (2008)	Process indicator of tests	Patients receiving ≥2 HbA1c tests per year
Schade and Hannah (2007)	Process indicators of tests/exams	Quartile class performance regarding annual HbA1c testing, eye exam in 2 years, and lipid test in 2 years
Mayfield et al. (2000)	Process indicator of exams	One or more preventive foot examination within a period of 36 months
Harman et al (2010)	Composite process of tests/exams	Process of care composite score, including HbA1c testing, eye examinations, LDL screening and monitoring nephropathy
Ackerman et al. (2006)	Composite process of tests/exams and drug treatment	Score (0-7 point scale) for assessing/performing HbA1c test, LDL-cholesterol test, proteinuria test, foot exam, eye exam, aspirin advise or use, influenza immunization (1 point each)
Ashton et al. (1995)	Composite process of tests/exams	Percentage of applicable admission workup criteria that is met (47 criteria on, for example, history, physical examination, and initial tests)

(continued)

Table 1. (continued)

Author	Type of Indicator	Indicators
	Composite process of drug treatment	Percentage of applicable treatment criteria that is met (42 criteria for evaluation and treatment during the stay)
Geraci et al. (1999)	Composite process of tests/exams	Percentage of applicable admission work-up criteria that is met (40 criteria on, for example, admission history, physical examinations, basic laboratory investigations)
	Composite process of drug treatment	Percentage of applicable treatment criteria that is met (35 criteria on, for example, treatment start or intensification when indicated during the hospital stay)
Lipner et al. (2007)	Composite process of tests/exams	Patients receiving annual HbA1c, lipids, eye, and foot exams (all 4)
	Composite process of drug treatment	Patients receiving aspirin and/or statin treatment when eligible
Goudswaard et al. (2003)	Composite structure and process	Score (0-11 point scale) for recording data on family history, smoking, duration of diabetes, height, weight, blood pressure, HbA1c, total cholesterol, serum creatinine, fasting blood glucose, annual review
De Berardis et al. (2008)	Composite process of tests/exams and drug treatment and surrogate outcomes	Score (0-40 range scale) for assessing HbA1c (5 points), lipids (5 points), microalbuminuria (MA; 5 points), blood pressure (BP; 5 points), treating MA with ACE inhibitor (10 points), achieving HbA1c < 8% (10 points), BP < 140/90 mmHg (10 points), LDL cholesterol < 130 mg/dl (10 points)

Note. LDL = low-density lipoprotein; GP = general practitioner; ACE = angiotensin-converting enzyme.

Table 2. Quality Assessment of Included Studies Using the Newcastle–Ottawa Scale

Study	Population	Level of Analysis	Newcastle–Ottawa Quality Assessment Scale			
Cohort Studies			Selection	Comparability	Outcome	Total
Berlowitz et al. (2005)	12,523 patients	Patient	4	3	2	9
De Berardis et al. (2008)	785/2,448 providers, 3,235 patients	Patients clustered within provider	4	3	3	10
Geraci et al. (1999)	559 patients	Patient	3	3	2	8
Harman et al. (2010)	7,804 patients	Patients clustered within provider	3	4	2	9
Li et al. (2008)	13,033 patients	Patient	4	2	2	8
Schectman et al. (2002)	726 patients	Patient	3	3	3	9
Selby et al. (2009)	35 facilities, around 250-8,500 patients per facility	Patients clustered within provider	4	2	3	9
Sperl-Hillen and O'Connor (2005)	5,610-7,650 patients (years 1994 to 2003)	Patient	4	3	2	9
Van Bruggen et al. (2009)	161 patients for HbA1c, 701/568 for SBP/DBP, 686 for TC	Patients clustered within provider	4	0	2	6
Ziemer et al. (2005)	12 providers, 2,341 patients	Patient and Provider	2	2	3	7
Case–Control Studies			Selection	Comparability	Exposure	Total
Ashton et al. (1995)	593 patients	Patient	4	2	2	8
Helmer et al. (2008)	2,714 cases and 10,856 controls	Patient	4	3	2	9
Mayfield et al. (2000)	61 cases and 183 controls	Patient	3	2	2	7
Schade and Hannah (2007)	409 cases and 409 controls	Patient	3	4	2	9
Cross-Sectional Studies		Analysis	Selection	Exposure	Outcome	Total
Ackerman et al. (2006)	8,733 patients	Patients clustered within provider	1	1	1	4

(continued)

Table 2. (continued)

Study	Population	Level of Analysis	Newcastle–Ottawa Quality Assessment Scale			
Cross-Sectional Studies		Analysis	Selection	Exposure	Outcome	Total
Barr et al. (2001)	450 patients	Patient	0	0	1	1
Dunn and Pickering (1998)	37 practices, 3,974 patients	Patient and Provider	1	1	1	4
Goudswaard et al. (2003)	52 practices, 1,641 patients	Patient and Provider	1	1	1	4
Lipner et al. (2007)	626 physicians, 12,927 patients	Patients clustered within provider	1	1	0	2
Nutting et al. (2007)	30 practices, 1,059 clinicians, 886 patients	Patients clustered within provider	1	1	1	4
Pringle et al. (1993)	32 practices, 11 GPs, 318 patients	Patient	0	1	1	3
Solberg et al. (2008)	40 practices	Provider	1	1	1	4
Sperl-Hillen et al. (2004)	17 primary care clinics	Provider	1	1	1	4
Wrobel et al. (2003)	10 medical centers	Provider	1	1	1	4

Note. GP = general practitioner.

Structure Indicators Related to Surrogate and/or Hard Outcomes

Structure indicators were tested in one high-quality cohort and seven cross-sectional studies, five of which were considered of sufficient quality (Table 3). No association was found in the cohort study at patient level (Schectman, Nadkarni, & Voss, 2002), whereas in the cross-sectional studies of sufficient and medium quality, some relationships were observed between structure indicators and surrogate outcomes at provider and at patient level (Dunn & Pickering, 1998; Nutting et al., 2007; Pringle et al., 1993; Solberg, Asche, Pawlson, Scholle, & Shih, 2008; Sperl-Hillen et al., 2004; Wrobel et al., 2003). There was a wide variation in both the selection and definition of structure indicators.

The high-quality study only assessed one structure of care aspect concerning continuity of care. This was expressed as the proportion of visits to a single physician, which was not associated with better HbA1c levels (Schectman et al., 2002). Other aspects of structure of care were only tested in studies with weak designs. In three of these studies, measures covering different components of the structure of care were evaluated, based on the chronic care model (Nutting et al., 2007; Solberg et al., 2008; Sperl-Hillen et al., 2004). One other study also included several of such components (Dunn & Pickering, 1998). The components related to "quality assurance programs and tools" showed correlations with HbA1c and LDL-cholesterol outcomes in one study at provider level but not in two other studies at provider or patient level (Dunn & Pickering, 1998; Solberg et al., 2008; Sperl-Hillen et al., 2004). The component related to "logistics and coordination of care" showed similar mixed results (Dunn & Pickering, 1998; Pringle et al., 1993; Sperl-Hillen et al., 2004, Solberg et al., 2008, Wrobel et al., 2003). A composite measure of components of the chronic care model showed associations with lower HbA1c and cholesterol levels in one study at patient level but not in another at provider level (Nutting et al., 2007; Solberg et al., 2008). Better staff training was found to be associated with lower amputation rates at provider level and better HbA1c at patient level in two studies but not with other surrogate outcomes at both levels in another study (Dunn & Pickering, 1998; Pringle et al., 1993; Wrobel et al., 2003). Better equipped practices showed a significant relationship with better glycemic control at patient level (Pringle et al., 1993).

Process Indicators Related to Surrogate Outcomes

We identified six cohort and five cross-sectional studies assessing the relationship between various process indicators and surrogate outcomes (Table 4). Five cohort studies focused on the process of drug treatment prescribing, three of which were of high quality showing positive associations between drug treatment prescribing and surrogate outcomes. Indicators of drug treatment tested in high-quality studies focusing on glucose-lowering treatment showed significant associations with improvements in HbA1c both at patient and provider levels. Patients receiving more intensive drug treatment had better HbA1c outcomes (Berlowitz et al., 2005), facilities with a

Table 3. Associations Between Structure Indicators and Patient Outcomes

Quality Indicator Type	Study	Level of Analysis	Study Quality	Blood Glucose or HbA1c	LDL Cholesterol/ Lipid Ratio	Blood Pressure	Creatinine, Proteinuria	Hard Outcomes
Technical or clinical facilities	Pringle et al. (1993)	Patient	3 of 4[a]	+				
	Barr et al. (2001)	Patient	1 of 4[a]	–				– (LHS)
Logistics and coordination	Schectman et al. (2002)	Patient	9 of 11	–				
	Solberg et al. (2008)	Provider	4 of 4[a]	–	–	–		
	Sperl-Hillen et al. (2004)	Provider	4 of 4[a]	+	–			
	Wrobel et al. (2003)	Provider	4 of 4[a]					+/– (LEA)
	Dunn and Pickering (1998)	Patient and provider	4 of 4[a]	–	–	–	–	
	Pringle et al. (1993)	Patient	3 of 4[a]	+				
	Barr et al. (2001)	Patient	1 of 4[a]	~				– (LHS)
Data registration and documentation	Dunn and Pickering (1998)	Patient and provider	4 of 4[a]	–	–	–	–	
	Solberg et al. (2008)	Provider	4 of 4[a]	–	–	–		
	Sperl-Hillen et al. (2004)	Provider	4 of 4[a]	–	–			
Quality assurance program and tools	Solberg et al. (2008)	Provider	4 of 4[a]	+	+	–		
	Sperl-Hillen et al. (2004)	Provider	4 of 4[a]	–	–			
	Barr et al. (2001)	Patient	1 of 4[a]	–				– (LHS)
Qualification and training of staff	Dunn and Pickering (1998)	Patient	4 of 4[a]	–	–	–	–	
	Wrobel et al. (2003)	Provider	4 of 4[a]					+ (LEA)
	Pringle et al. (1993)	Patient	3 of 4[a]	+				
	Barr et al. (2001)	Patient	1 of 4[a]	–				~ (LHS)
Composite measure	Nutting et al. (2007)	Patient	4 of 4[a]	+	+			
	Solberg et al. (2008)	Provider	4 of 4[a]	–	–	–		

Note. LDL = low-density lipoprotein; LHS = length of hospital stay; LEA = lower extremity amputations; + = significant positive, +/– = mixed associations and ~ = significant weak, and – = not significant.

a. Cross-sectional studies.

Table 4. Associations Between Process Indicators and Surrogate Outcomes

Quality Indicator Type	Study	Level of Analysis	Study Quality	HbA1c	Blood Pressure	LDL or HDL Cholesterol	Creatinine, Proteinuria	Composite Surrogate
Drug treatment	Berlowitz et al. (2005)	Patient	9 of 11	+				
	Selby et al. (2009)	Patient	9 of 11	+				
	Sperl-Hillen and O'Connor (2005)	Patient	9 of 11	+		+		
	Ziemer et al. (2005)	Patient and provider	7 of 11	+				
	Van Bruggen et al. (2009)	Patient	6 of 11	–	–	+		
	Lipner et al. (2007)	Patient	2 of 4[a]					+
Visits	Schectman et al. (2002)	Patient	9 of 11	–				
	Pringle et al. (1993)	Patient	3 of 4[a]	–				
HbA1c tests	Schectman et al. (2002)	Patient	9 of 11	–				
	Dunn and Pickering (1998)	Patient and provider	4 of 4[a]	–	–	–	–	
Other or composite tests/exams	Goudswaard et al. (2003)	Patient and provider	4 of 4[a]	–				
	Dunn and Pickering (1998)	Patient and provider	4 of 4[a]	–	–	–	–	
	Pringle et al. (1993)	Patient	3 of 4[a]	–				
	Lipner et al. (2007)	Patient	2 of 4[a]					+
Composite tests and prescribing	Ackerman et al. (2006)	Patient	4 of 4[a]	–	–	+/–		–
	Pringle et al. (1993)	Patient	3 of 4[a]	–				

Note. LDL = low-density lipoprotein; HDL = high-density lipoprotein; + = significant positive association; +/– = mixed association; – = nonsignificant (or negative) association.
a. Cross-sectional study.

larger increase in drug treatment intensification had a greater likelihood of patients with adequate HbA1c control (Selby et al., 2009). In a somewhat smaller high-quality cohort study, it was found that intensification of drug treatment with either a sulfonylurea or metformin or a statin was related to greater HbA1c or LDL-cholesterol improvement at patient level (Sperl-Hillen & O'Connor, 2005). Among medium-quality studies, the association between process indicators focusing on drug treatment and improvements in surrogate outcomes was also shown to some extent. Providers who intensified drug treatment more often had lower HbA1c level in their patients (Ziemer et al., 2005), whereas intensification of lipid-lowering, glucose-lowering, and antihypertensive treatment demonstrated improvements in total cholesterol but not in HbA1c and blood pressure levels at patient level (Van Bruggen, Gorter, Stolk, Klungel, & Rutten, 2009).

Process indicators focusing on conducting regular tests or exams were studied in one high-quality cohort study at patient level and three cross-sectional studies, two of which were of sufficient quality showing mostly negative results at provider and patient levels. The high-quality cohort study, including a relatively small number of patients from the indigent population, observed no significant relationship between process indicators focusing on number of visits and HbA1c tests and changes in HbA1c control at patient level (Schectman et al., 2002). One cross-sectional study of sufficient quality evaluating a composite indicator, which included conducting and recording of 11 relevant tests and exams, also showed no correlation with HbA1c levels at patient or at provider level (Goudswaard, Lam, Stolk, & Rutten, 2003). Another cross-sectional study of sufficient quality looked at a composite process measure of recommended tests and prescription of aspirin, which was associated with significantly lower LDL-cholesterol levels but not with HDL cholesterol, HbA1c, or systolic blood pressure at patient level (Ackermann et al., 2006). Analysis of associations between various process and outcome criteria in two other cross-sectional studies did not reveal any statistical significance at patient or provider level (Dunn & Pickering, 1998; Pringle et al., 1993).

Process Indicators Related to Hard Outcomes

The relationship between process indicators and hard outcomes was tested in three cohort and four case–control studies, which were all conducted at patient level. A process measure focusing on adequate drug treatment of patients hospitalized for diabetes was associated with fewer treatment-related complications in one medium-quality study (Geraci et al.,1999) but was not associated with fewer readmissions to a hospital in another (Ashton, Kuykendall, Johnson, Wray, & Wu, 1995). No associations were observed for numbers of visits, tests, or exams conducted in two high- and one medium-quality studies, whereas another high-quality and three medium-quality studies found mixed results (Table 5).

For more HbA1c testing, no associations were observed with fewer hospitalizations because of metabolic complications and fewer lower extremity amputation (LEA) rates

Table 5. Associations Between Process Indicators and Hard Outcomes

Quality Indicator Type	Study	Level of Analysis	Study Quality	Hospitalization, Complications of Treatment or Disease	Microvascular Complications LEA, or CKD	Macrovascular Complications	Death	Composite PCS/MCS Score
Drug treatment	Geraci et al. (1999)	Patient	8 of 11	+				
	Ashton et al. (1995)	Patient	8 of 11	–				
Visits	Helmer et al. (2008)	Patient	9 of 11	–				
HbA1c tests	Schade and Hannah (2007)	Patient	9 of 11		–			
	Helmer et al. (2008)	Patient	9 of 11	–				
	Li et al. (2008)	Patient	8 of 11		+/–	+	–	
Other or composite tests/ exams	Schade and Hannah (2007)	Patient	9 of 11		+/–			
	Harman et al. (2010)	Patient	9 of 11					+/–
	Geraci et al. (1999)	Patient	8 of 11	–				
	Ashton et al. (1995)	Patient	8 of 11	–				
	Mayfield et al. (2000)	Patient	7 of 11		–			

Note. LEA = lower extremity amputations; CKD = chronic kidney disease; PCS = physical component score; MCS = mental component score. + = significant positive association; +/– = mixed association; – = nonsignificant (or negative) association.

in two high-quality case–control studies (Helmer et al., 2008; Schade & Hannah, 2007). One of these studies even showed that having no HbA1c tests was associated with fewer hospitalizations for metabolic complications (Helmer et al., 2008). Furthermore, lipid testing, but not eye exams, was associated with fewer LEAs (Schade & Hannah, 2007). Another large medium-quality cohort study showed a significant association between HbA1c testing and a decrease in macrovascular complications and kidney disease, but not with other microvascular complications or death (Li et al., 2008). Of other process indicators, receiving at least semiannual diabetes visits was not associated with fewer hospitalizations for metabolic complications (Helmer et al., 2008) and receiving foot care examination was not associated with fewer LEAs (Mayfield, Reiber, Nelson, & Greene, 2000).

One high-quality study did show a relation at patient level of a composite process of care score, including HbA1c testing, eye examination, LDL screening, and nephropathy monitoring with improvements on the mental but not the physical component of health status scores as measured with the SF-36 (Harman et al., 2010). A composite measure of nondefined tests and exams was not associated with treatment-related complications and fewer readmissions to a hospital in two medium-quality studies (Ashton et al., 1995; Geraci et al., 1999).

Composite Measure Related to Hard Outcomes

There was one high-quality cohort study that assessed predictive validity of a composite measure of processes and surrogate outcomes of care on hard outcomes at patient level (De Berardis et al., 2008). The composite measure included risk factor testing, drug treatment with angiotensin-converting enzyme (ACE) inhibitors and achieving target levels of HbA1c, LDL cholesterol, and blood pressure. This composite was used to divide patients into three classes of achieved quality. The risk of any cardiovascular event was higher in patients in the two lower classes, as compared with those with the highest scores (De Berardis et al., 2008).

Discussion

Our review shows that there is insufficient evidence that structure quality indicators or process indicators focusing on number of tests, exams, and visits predict patient outcomes. The observed inconsistent and negative results for structure indicators are partly because of the lack of well-designed studies. In addition, the variability in selection and definition of these indicators and their indirect relationship with the type of patient outcomes measured may explain these results. For process indicators focusing on conducting tests, exams, or visits, possible residual confounding, even in the higher quality studies, forms a problem. In addition, the focus was mainly on HbA1c testing. Process indicators assessing drug treatment intensification, on the other hand, showed predictive validity at both patient and provider levels, but again focusing mainly on glycemic control. This was established in three high-quality studies and supported

by studies of lower quality. A composite measure of testing, drug treatment, and achieving surrogate outcomes of care was predictive of hard outcomes in one high-quality study. Overall, it seems that there were no differences in terms of positive or negative results in studies conducted at different levels of analysis.

As far as structure indicators, we did not find any firm evidence supporting a clear relationship with patient outcomes. Almost all studies had a cross-sectional design showing mixed results at both patient and provider levels. The only one high-quality cohort study did not show a significant association at patient level (Schectman et al., 2002). This latter study, however, only looked at one structure of care aspect. There is a need for a systematic development of structure of care indicators. In three studies, a theoretical model was used to cover a number of structure aspects for quality of chronic care resulting, however, in different instruments that may not adequately capture all relevant aspects (Nutting et al., 2007; Solberg et al., 2008; Sperl-Hillen et al., 2004). Given the variable results, which are also mirrored in intervention studies aimed at improving the structure of care (Renders et al., 2001; Shojania et al., 2006), it is important to differentiate between different domains. This will enable to pinpoint those domains that really matter for patient outcomes. Furthermore, it is important to look more closely at the different steps from the Donabedian framework. Following this model, one would expect that better structure of care will have an indirect impact on patient outcomes through the process of care (Donabedian, 1988). The studies that looked at this intermediate step were all cross-sectional, making it impossible to draw conclusions about the direction of the observed associations. The results suggest, however, that the structure indicators are slightly more often associated with process than outcome measures (Dunn & Pickering, 1998; Nutting et al., 2007; Solberg et al., 2008; Sperl-Hillen et al., 2004).

With regard to process indicators, we did find evidence that indicators focusing on drug treatment prescribing are related to better patient outcomes, but there was no such evidence for indicators focusing on number of tests, exams, and visits regardless of level of analysis. Process indicators focusing on drug treatment intensification in patients with poor glycemic control are related to improved risk factor control at provider and patient levels, based on three high-quality studies in samples that were representative of the diabetes population in the United States (Berlowitz et al., 2005; Selby et al., 2009; Sperl-Hillen & O'Connor, 2005). One might think that this is an expected result, since clinical trials have demonstrated that intensified drug treatment improves risk factor control and hard outcomes in patients with diabetes (Gaede, Lund-Andersen, Parving, & Pedersen, 2008; UK Prospective Diabetes Study Group, 1998a, 1998b). Such findings from trials, however, do not necessarily imply that higher rates of drug treatment measured at population or provider level are equivalent to better patient outcomes in actual practice. It is possible that the wrong patients receive drug treatment or that the quality indicator does not adequately assess drug treatment quality. It has been recognized that process indicators can have unintended consequences when patients with uncertain diagnoses or contraindications are inadvertently included (Chassin et al., 2010). There are many quality indicators for drug treatment

prescribing in diabetes care. Some focus on first-choice drugs or drugs to be avoided and others on whether drug treatment is prescribed when indicated (Martirosyan et al., 2010). We only found studies that evaluated this last type of drug treatment quality indicator, showing predictive validity on surrogate outcomes. There is evidence that this type of indicators is also associated with surrogate outcomes in patients without diabetes who have poorly controlled hypertension or hyperlipidemia (Selby et al., 2009). Such quality indicators assessing intensification of drug treatment thus appear to be valid for assessing preventive treatment more in general. They have previously been advocated for use in improving quality of care, since they capture possible clinical inertia and may provide a more meaningful judgment than indicators looking at the number of patients treated (Asch et al., 2001, Voorham, Denig, Wolffenbuttel, & Haaijer-Ruskamp, 2008). So far, however, there is no evidence that such indicators are also associated with hard patient outcomes.

We found no evidence from high-quality studies that more HbA1c testing at patient or provider level leads to better patient outcomes, despite the fact that regular testing of HbA1c is recommended by diabetes guidelines (ADA, 2009; Calvert et al., 2009; Martirosyan et al., 2008; Nicolucci et al., 2006; Wens et al., 2007). Although it seems obvious that for risk factor management, one needs to measure the risk factor, there appears to be no clear foundation for the number of tests needed per year. This is partly because of problems with confounding, which complicate observational studies evaluating the effect of testing. Since one can expect that poorly controlled patients or patients with more severe diabetes may receive more HbA1c tests, it is important that studies sufficiently adjust for this type of confounding. The inconsistent results in studies with medium quality or weak designs can be explained by insufficient adjustment for confounding. For several of the positive associations observed in these studies, a direct causal effect was not very likely. For example, HbA1c testing was associated with less macrovascular but not less microvascular complications (Li et al., 2008). Something similar was observed for other risk factors, where more lipid testing was associated with fewer amputations (Schade & Hannah, 2007). But also after adjusting for many relevant confounders in a high-quality case–control study, a positive association was found between receiving no HbA1c tests and having a lower risk of metabolic complications (Helmer et al., 2008). This indicates that there may still be unmeasured confounding at patient level for evaluating the effect of testing on hard outcomes. It could be that instead or in addition to adjusting for age, the duration of diabetes also needs to be taken into account. Furthermore, the frequency of risk factor testing is expected to be more directly related to the process of intensifying drug treatment and subsequently changes in the surrogate outcomes than to hard outcomes. Surprisingly, none of the rigorously designed studies used surrogate outcomes, such as changes in the level of HbA1c, to assess the predictive validity of the frequency of testing. This would be a more direct causal effect of the process of care assessed, since regular testing of HbA1c is expected to lead to better control of HbA1c levels.

We found no evidence that foot examinations reduce the risk of LEA. Performance of annual foot examination is included in many diabetes care guidelines (ADA, 2009;

Wens et al., 2007), but some have argued that this is not a well-defined and accurately documented clinical test (Nicolucci et al., 2006). The one study addressing foot examinations did try to distinguish between different types of foot examinations but was not able to demonstrate an effect of foot care examinations on LEA (Mayfield et al., 2000). This was, however, a medium-quality study in a very small patient sample that had selection bias problems.

Furthermore, we found no evidence that more patient visits will lead to better patient outcomes, based on two high-quality studies (Helmer et al., 2008; Schectman et al., 2002). This is in contrast with a previous study in patients with ischemic heart disease, where the number of outpatient visits was associated with better control of blood pressure and LDL cholesterol (Ho et al., 2006). This study, however, used a cross-sectional design, which introduces many problems with confounding. For example, it is possible that patients who visit the outpatient clinic regularly are also more compliant to medication or lifestyle advice.

A composite measure of testing, drug treatment, and achieving surrogate outcomes of care showed good predictive associations with reduced cardiovascular events (De Berardis et al., 2008). This makes this indicator of interest for external quality assessment. It is not clear, however, which of the elements included in this composite measure are relevant for better outcomes. For internal quality improvement programs, composite indicators are of limited value, since it is hard to say which aspect of care is in need of improvement.

So far, most attention has been given to indicators focusing on glycemic control. The HbA1c level was frequently included as outcome, whereas other surrogate outcomes were much less included. Although this is understandable given the focus of many diabetes guidelines on achieving specific HbA1c targets and its relevance for the prevention of microvascular complications, glycemic control is just one part of adequate diabetes management. The impact of intensive glycemic control on preventing major macrovascular events and mortality seems variable, depending on factors such as duration of diabetes, age, and absence or presence of cardiovascular complications at baseline (Selvin, Marinopoulos, Berkenblit, Rami, & Golden, 2004; Turnbull et al., 2009).

Important criteria for quality indicators is that they are based on scientific evidence, can be measured reliably, and have predictive validity (Campbell et al., 2002). In our review, we focus on this predictive validity. Recently, two more specific criteria were proposed for accountability measures that address processes of care (Chassin et al., 2010). These criteria can be expanded to cover both structure and process of care aspects and include (a) that the measure addresses a care aspect that has few intervening care processes that must occur before the improved outcome is realized and (b) that implementing the measure has little or no chance of inducing unintended adverse consequences. As indicated, for many structure and process indicators, there may be problems with the first "proximity" criterion. It is clear that both structure indicators and process indicators focusing on tests, exams, or visits can be far away from the desired outcome and will not lead to beneficial effects when the necessary follow-up steps are not taken. To ensure better quality of care, they should at least be coupled with indicators that measure processes of care that are more closely related to patient outcomes (Chassin

et al., 2010). The other criterion is most likely to affect process indicators related to invasive tests or treatments that can harm patients. This could be relevant for the drug treatment indicators included in our review. However, these indicators all incorporate a "treated when indicated" definition, which should prevent that they lead to unnecessary drug prescribing.

Strengths and Limitations

Although we searched two electronic databases and two reviewers independently screened the search results, we identified relatively few relevant studies of high quality. There were many studies and reports looking at changes in process and outcome measures in a descriptive way without reporting any statistical testing of possible associations between a measure of quality and patient outcomes. Such studies often show positive changes in the quality of care as well as the patient outcomes over time (Club Diabete Sicilia, 2008; Harwell, McDowall, Gohdes, & Helgerson, 2002). As such they may be quite compelling and influential in affecting provider behavior, but they are not sufficient to support the assumption that there is a direct relationship between quality of care and patient outcomes. Several studies that did test for associations were considered to be of medium or low quality. We base our findings primarily on the eight high-quality studies using a cohort or case–control design, but even these studies had some weaknesses, either not fully adjusting for possible confounding or lacking information on patients' follow-up or response rate. The high-quality studies all tested for associations at patient level, and only three adjusted for clustering at provider level. It is important to distinguish between the levels of analysis when drawing conclusions about the associations found. Associations found at patient level may be absent at provider level, because of differences in variability or confounding. We did not find clear indications that inconsistent results could be explained by differences in the level of analysis. Most studies on provider level, however, had a weak (cross-sectional) design limiting the ability to draw firm conclusions at this level. Evidence at this higher level is important because the indicators are being used by payers and health care providers to identify those providers who do or do not meet predefined standards of quality.

Finally, most of the studies were conducted and published in the United States. There can be loss of external validity since these studies used samples from a single health care system. More studies are therefore needed in other health care settings to test which quality of care indicators predict relevant patient outcomes.

Conclusion

Both structure of care indicators, for example, measuring resources or organizational aspects, and process of care indicators, focusing on number of tests, exams, or visits conducted, appear not to be good predictors of patient outcomes. This is partly due to insufficient good quality studies that have looked at this relationship up to now and

probably also due to the selected indicators that may not have a direct relationship to patient outcomes. For structure of care, new studies are badly needed with adequate designs and covering all relevant structure aspects. For process of care, it seems that the number of tests, exams, or visits to the doctor in itself does not ensure better patient outcomes, whereas the indicators that describe the drug treatment intensification may play a role, especially in glycemic control. Better studies are needed testing the predictive validity of the indicators at the provider level. In general, more evidence is needed to support or refute the assumption that there is close relationship between quality of diabetes care as currently assessed and patient outcomes. This is of extreme importance since many quality improvement programs using indicators carry enormous efforts of health care providers and patients as well as costs for society.

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