

# Cross-Sectional Versus Sequential Quality Indicators of Risk Factor Management in Patients with Type 2 Diabetes

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**Background:** The fairness of quality assessment methods is under debate. Quality indicators incorporating the longitudinal nature of care have been advocated but their usefulness in comparison to more commonly used cross-sectional measures is not clear.

**Aims:** To compare cross-sectional and sequential quality indicators for risk factor management in patients with type 2 diabetes.

**Methods:** The study population consisted of 1912 patients who received diabetes care from one of 40 general practitioners in The Netherlands. Clinical outcomes, prescriptions, and demographic data were collected from electronic medical records. Quality was assessed for glycemic, blood pressure, and lipid control using indicators focusing on clinical outcomes, and treatment in relation to outcomes. Indicator results were compared with a reference method based on national guidelines for general practice.

**Results:** According to the reference method, 76% of the patients received management as recommended for glycemic control, 58% for blood pressure control, and 67% for lipid control. Cross-sectional indicators looking at patients adequately controlled gave estimates that were 10–25% lower than the reference method. Estimates from indicators focusing on uncontrolled patients receiving treatment were 10–40% higher than the reference method for blood pressure and glycemic control. Sequential indicators focusing on improvement in clinical outcomes or assessing treatment modifications in response to poor control gave results closer to the reference method.

**Conclusions:** Sequential indicators are valuable for estimating quality of risk factor management in patients with diabetes. Such indicators may provide a more accurate and fair judgment than currently used cross-sectional indicators.

**Key Words:** quality indicators health care, diabetes mellitus, quality of health care, outcome and process assessment (health care)

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Quality of diabetes care has received a lot of attention over the past decade, and room for improvement of glycemic, blood pressure, and lipid management has repeatedly been shown.<sup>1–6</sup> There is, however, debate about the fairness of indicators used to assess quality of care, especially for external accountability.<sup>7–10</sup> Many studies looking at quality of care use a cross-sectional approach where processes and outcomes of care are measured at one point in time.<sup>2–6,11–13</sup> This approach may be limited, because it does not take the longitudinal nature of chronic patient care into account. One study showed that, although quality of care may seem to improve over time using cross-sectional assessments, a longitudinal approach can show that specific patient groups are not benefiting.<sup>9</sup> There are also discrepancies between indicators based on process and outcome measures. It has been shown that only looking at outcomes of care can result in an inaccurate view.<sup>14,15</sup> Such indicators do not differentiate between patients receiving suboptimal care and patients that are difficult to manage or noncompliant. Therefore, these indicators are affected by case-mix differences. Indicators reflecting risk factor management in relation to specific outcomes have been advocated to overcome this problem.<sup>14,16–20</sup> Especially, the ability to recognize the failure to initiate or intensify treatment when indicated could provide insights important to target interventions.<sup>10,18,19,21,22</sup> Rodondi et al<sup>14</sup> have argued that care provided by a physician should be evaluated using a decision tree in which actions and events that do imply appropriate care, despite a target level not being achieved, are acknowledged.

To better understand the added value of such an approach, we examined the possible benefits of sequential over cross-sectional quality indicators of risk factor management by comparing both to a reference method. This reference method was based on a detailed assessment of relevant actions and events at the individual patient level.

## METHODS

In a cohort study, the quality of glycemic, blood pressure, and lipid management was assessed for patients with type 2 diabetes. We evaluated indicators focusing on clinical outcomes (HbA1c, systolic blood pressure, total cholesterol), and indicators focusing on treatment related to these outcomes, using target levels from national guidelines for clinical practice. Percentages of patients with risk factor management according to these guidelines were determined using a common cross-sectional indicator and several newly devel-

oped sequential indicators, and compared with the reference method. Calculations were made at the aggregated level, which is common for external quality assessment, and at the individual patient level, because quality indicators may also be used for internal purposes to identify patients not receiving optimal care.<sup>23</sup>

The study was conducted conforming to the Dutch guidelines on the use of medical data for scientific research. For medical record research of anonymous data, no Institutional Review Board approval is needed.

**Study Population and Setting**

Our study population consisted of 1912 patients who received diabetes care from one of 40 general practitioners (GPs) participating in a regional project in 2004 and 2005.<sup>24</sup> All patients with a diagnosis of type 2 diabetes at the beginning of 2004 were included. Among participating GPs, 20% practiced in a rural area, 18% worked in a solo practice, and 16% were dispensing.

In our study area, a regional diabetes facility offers support to GPs; primary care patients with type 2 diabetes can be referred to the diabetes facility. This outpatient facility conducts simple physical examinations and laboratory tests of blood and urine during 3-monthly and yearly diabetes follow-up visits on behalf of the GPs. They report results back to the GP, who remains responsible for further treatment of the patient. All GPs prescribe electronically, and all clinical information is stored in electronic patient records at the GP

practices and an electronic diabetes registry at the diabetes facility.

For the drugs included, there was no copayment because they were all priced below the maximum reimbursement limits set by the Dutch government for both public and private health insurance funds. All drugs can be prescribed by GPs according to the guideline recommendations.

**Data Collection and Quality Indicators**

Clinical outcomes, prescriptions, coronary comorbidity (angina pectoris, myocardial infarction, heart failure, coronary artery bypass graft, coronary angioplasty, atrium fibrillation), other diabetes-related conditions (stroke, transient ischemic attack, peripheral arterial disease, neuropathy, amputations, retinopathy), and demographic data were collected for the period January 2003 until June 2005. Prescriptions collected include all GPs' medication orders. Information was extracted by automatic data collection from the electronic patient record systems at the general practice office and the regional diabetes facility. The data extraction method relies on text recognition to ensure retrieval of information from "free text" segments of patient records in addition to data collection from structured tables. This approach is comparable to manual patient record abstraction, and was found to be 94–100% sensitive to detect the clinical outcomes relevant for this study, irrespective of registration method or information system used by the GP.<sup>25</sup>

**TABLE 1. Quality Indicators of Risk Factor Management**

Indicators Focusing on Clinical Outcomes	
A Patients "controlled"	
Numerator	Patients with measurement at or below target level in evaluation year
Denominator	All patients with measurements
B Uncontrolled patients "achieving control"	
Numerator	Patients with measurement below the target level in evaluation year
Denominator	Patients above target in preceding year
C Uncontrolled patients with "improvement"	
Numerator	Patients with clinically relevant improvement in measurements between evaluation and preceding year
Denominator	Patients above target level in preceding year
D Patients "controlled or improving"	
Numerator	Patients with measurement above target level in preceding year and clinically relevant improvement in evaluation year, or with measurement below target level in both years
Denominator	All patients with measurements
Indicators Focusing on Treatment in Relation to Outcomes	
E Uncontrolled patients "treated"	
Numerator	Patients treated in evaluation year
Denominator	Patients with measurement above target level in evaluation year
F Patients "uncontrolled then treated"	
Numerator	Patients treated in evaluation year
Denominator	Patients with measurement above target level in preceding year
G Patients with "treatment modified when indicated"	
Numerator	Patients started or intensified treatment in evaluation year
Denominator	Patients with last measurement above target in preceding year

We evaluated 4 quality indicators focusing on clinical outcomes, and 3 indicators focusing on treatment related to outcomes (Table 1). For both aspects, the most commonly used cross-sectional indicator was included. The other selected indicators were sequential indicators that incorporate different levels of the longitudinal aspect of patient care, as identified in other studies looking at the evaluation of appropriate care.<sup>14,15,21,26</sup> Table 1 describes for each indicator the patients included in the numerator and denominator.

The last measurement of a risk factor in a year was used for all indicators. Patients were included with at least 1 risk factor measurement in 2003 and in 2004 to allow for sequential assessments. We excluded patients without risk factor measurements from both the tested indicators and the reference method, because in both cases they would fall in the same category of inadequate care.

Based on the national guidelines for general practice at the time of the study, the following target levels were used to identify controlled risk factors: HbA1c <7.0%, systolic blood pressure <140 mm Hg, and total cholesterol <5.0 mmol/L. Changes in risk factor level considered clinically relevant were set at 0.3% for HbA1c, 5 mm Hg for systolic blood pressure, and 0.5 mmol/L for total cholesterol.

The cross-sectional indicator on clinical outcomes is the most widely used measure of patients “controlled” (indicator A) (eg, in the United States, United Kingdom, and The Netherlands).<sup>27–30</sup> This indicator looks at patients below target level as a proportion of all patients. The sequential indicators B and C focus on patients that were previously insufficiently controlled.<sup>9,21</sup> Indicator B identifies patients “achieving control,” that is, patients moving from being uncontrolled in the preceding year to controlled in the current year. Indicator C acknowledges patients with any clinically relevant “improvement” in risk factor level. Indicator D is a combined measure identifying patients “controlled or improving” as a proportion of all patients.

The indicators looking at treatment in relation to outcomes focus on patients who are in need of treatment, that is, insufficiently controlled patients. The cross-sectional indicator identifies all of such patients concurrently “treated” (indicator E). This is a generic approach for assessing guideline compliance to the recommendation that patients with diabetes with uncontrolled risk factors should receive treatment.<sup>1,31</sup> This indicator has been proposed by the Dutch Institute for Healthcare in their recent set of quality indicators for diabetes management.<sup>32</sup> Both sequential indicators (F and G) look at treatment in reaction to elevated risk factor levels, thus incorporating the time sequence of observation and action in contrast to the cross-sectional indicator. Patients who receive treatment after being uncontrolled in the preceding period are identified with the “uncontrolled then treated” indicator F. Finally, indicator G also acknowledges cases of “treatment intensified when indicated” by identifying all uncontrolled patients not on maximal medication for whom treatment is either initiated or intensified.

## Treatment Definitions

Treatment modifications were determined by comparing changes in prescriptions during the evaluation year

with treatment observed in the final 6 months of the preceding year. A treatment modification was considered intensification when a new drug class was started or added or the dosage of medication was increased. A switch to insulin was considered intensification, but switches to other drug classes without continuation of the original medication were not considered treatment intensification, because such switches could be due to side effects. A prescription was considered discontinued if it was not repeated within 120 days from the calculated end date.

For glucose-lowering medication, we included 6 drug classes (insulin, metformin, sulfonylureas, acarbose, thiazolidinediones, and repaglinide), for antihypertensive medication 5 classes (centrally acting antihypertensives, diuretics, beta-blockers, calcium-channel blockers, and renin-angiotensin system inhibitors), and for lipid-lowering medication 5 classes (statins, fibrates, bile acid sequestrants, nicotinic acid derivatives, and ezetimibe).

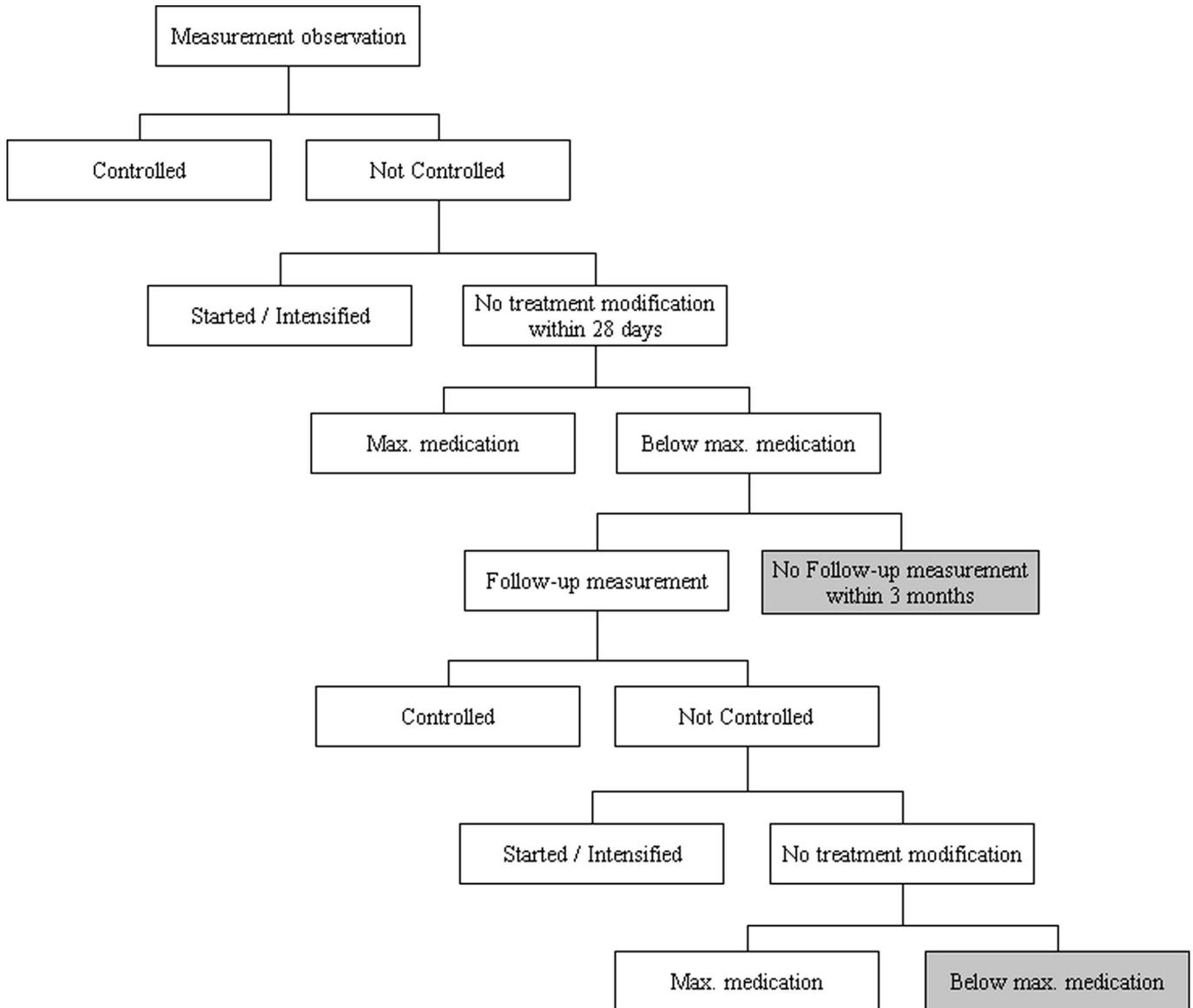
The definitions for maximal medication were derived from treatment recommendations for general practitioners. For glucose-lowering medication, prescription of insulin was defined as having reached maximal medication. For blood pressure lowering medication, 3 or more drug classes prescribed at maximum maintenance dosage was considered as maximal medication. For lipid-lowering medication, prescribing the maximum dosage of a drug was considered maximal medication. Combination of lipid-lowering drugs is not recommended in general practice. Dosage recommendations were obtained from the *Dutch Pharmacotherapy Compendium*.<sup>33</sup>

## Reference Method

The reference method involved a stepwise review of care as documented in the electronic patient records. Events and actions were assessed at the individual patient level, using all information on changes in prescriptions and relevant clinical outcomes using an automated procedure (Fig. 1). This method acknowledges to some extent that care can be appropriate in patients not reaching strict target levels, by focusing on the recommended management in relation to outcomes, as has been advocated before.<sup>14,16–20</sup> It builds upon the work described by Rodondi et al,<sup>14</sup> extended with a follow-up observation to accept management as being in line with guideline recommendations when patients achieved target levels during a monitoring period or medication was modified after a follow-up measurement of the risk factor.

Management was assessed for each of the risk factors separately. The following situations were considered as management as recommended in the guidelines:

1. Risk factor was at or below target level, and therefore adequately controlled,
2. Risk factor was above target level but medication was started or intensified within 28 days,
3. Risk factor was above target level but maximal medication according to guideline recommendations for general practice was already being prescribed,



**FIGURE 1.** Decision tree used in the Reference Method for assessing risk factor management; gray boxes indicate patients who are considered as being not managed according to the guideline recommendations.

4. Risk factor was above target level but target level was achieved during a monitoring period of not more than 120 days,
5. Risk factor was above target level but medication was started or intensified after a monitoring period during which the risk factor was measured again.

Because diabetes consultations should occur 4 times a year according to the diabetes guidelines, we used a monitoring period of 120 days, allowing for some variation in the period between 2 regular consultations. The data origin and collection method were equal for the reference method and the tested indicators, ensuring that differences observed were due to indicator definitions and not to differences in completeness of data collection.

**Analysis**

Percentages of all patients with management as recommended were calculated per risk factor using the reference method. Quality assessments according to each of the indicators A to G were compared with results of the reference method in the same patient population. The absolute difference as well as percentages of disagreement between both estimates were calculated. Significance of differences was assessed by the McNemar statistic for paired proportions. To test whether the results might be sensitive to the set target levels or population case-mix, we repeated the analyses using levels of poorly controlled patients instead of adequately controlled patients, that is, HbA1c >8.5%, systolic blood pressure >160 mm Hg, and

total cholesterol >6.0 mmol/L, and after stratification on comorbidity (yes/no).

Positive and negative likelihood ratios were calculated with 95% confidence intervals. These ratios express the ability of an indicator to predict the quality assessment at the individual patient level. Likelihood ratios combine sensitivity and specificity into 1 measure, and are insensitive to the underlying probability of risk factor management according to the guidelines. Likelihood ratios between 0.5 and 2 were considered to reflect poor predictors, whereas ratios below 0.2 or above 5 indicate moderate to strong predictors.

## RESULTS

### Study Population

Demographic characteristics, degree of control, and treatment in the study population are presented in Table 2. Respectively 83%, 88%, and 73% of the 1912 patients had at least 1 measurement of HbA1c, blood pressure, and total cholesterol recorded in 2004. Mean risk factor levels were 7.1% for HbA1c, 146.6 mm Hg for systolic blood pressure, and 4.9 mmol/L for total cholesterol. The average 10-year absolute risk for coronary heart disease according to the UK Prospective Diabetes Study risk engine<sup>34</sup> was 23.4%. Glucose-lowering medication was prescribed to 83.6%, antihypertensive medication to 71.2%, and lipid-lowering medication to 46.9% of the patients. Coronary comorbidity and other diabetes-related conditions were each recorded in 15% of the patients.

### Reference Method

According to the reference method, 75.8% of the patients received management as recommended for glycemic

control, 58.3% for blood pressure control, and 66.4% for lipid control. Of patients with the recommended glycemic management, 71.5% were already on target, treatment was started or intensified in another 8.8%, 13.8% were on maximal medication, 2.4% returned on target, and 3.5% received a change in medication during follow-up. For blood pressure, 54.3% of such patients were already on target, in 7.4% treatment was started or intensified, 22.9% were already on maximal medication, 11.1% returned to target, and 4.3% received a change in medication during follow-up. For lipid control, 83.6% were on target, treatment was started or intensified in 10.2%, only 0.1% were on maximal medication, 4.1% returned to target, and 2.0% received a change in medication during follow-up.

Of patients who were above target, 52.8%, 61.0%, and 75.0% did not receive any action for glycemic, blood pressure, and lipid control respectively. These patients were considered as being not managed according to the guideline recommendations.

### Comparison at the Aggregated Level

Table 3 shows the differences in percentages of patients assessed as receiving the recommended risk factor management according to the indicators in comparison to the reference method. When looking only at clinical outcomes (indicators A–D), the cross-sectional indicator looking at patients “controlled” (A) and the indicator focusing on patients “achieving control” (B) gave lower estimates than the reference method. For instance, indicator A gave a result for blood glucose management that was almost 22% lower than the reference. For indicator B the absolute difference was 32%. For all 3 risk factors, assessments obtained with sequential indicators focusing on patients with improved outcomes (C and D) gave results considerably closer to the reference method. Indicator C, however, showed higher percentages of disagreement than indicator D. Comparing the indicators with identical patient populations (pairs B,C and A,D) showed that the more complex indicators (C and D) provided results that were significantly different from the simple indicators and closer to the reference method for all 3 risk factors.

The cross-sectional indicator focusing on uncontrolled patients “treated” (E) and the sequential indicator of patients “uncontrolled then treated” (F) gave estimates 34–48% higher than the reference method for blood pressure and glycemic management (Table 4). For these risk factors, the indicator looking at “treatment modified when indicated” (G) resulted in better estimates, although still 15% lower than the reference method. Also, the percentage disagreement was smallest for this indicator. For lipid control, the indicator of patients “uncontrolled then treated” (F) produced an assessment equal to the reference method, but the percentage disagreement was similar to the other indicators. Comparing the treatment indicators with identical patient populations (pair F,G) showed significant differences in favor of the more complicated indicator (G) for glycemic and blood pressure management.

**TABLE 2.** Baseline Characteristics for 1912 Patients with Type 2 Diabetes

	Percentage/Mean (SD)
Age (yr)	66.8 (12.4)
Male gender (%)	45.4
Diabetes duration (yr)	5.7 (5.4)
HbA1c (%)	7.1 (1.1)
Systolic blood pressure (mm Hg)	146.6 (20.0)
Total cholesterol (mmol/L)	4.9 (1.0)
HDL-cholesterol (mmol/L)	1.3 (0.4)
LDL-cholesterol (mmol/L)	2.8 (0.9)
Triglycerides (mmol/L)	2.0 (1.2)
Body mass index (kg/m <sup>2</sup> )	29.5 (5.4)
UKPDS 10-yr overall cardiovascular risk (%)	23.4 (15.8)
Presence of coronary conditions (%)	15.3
Presence of other DM-related conditions (%)	14.6
Not using glucose lowering medication (%)	17.4
Only using oral glucose lowering medication (%)	65.4
Only using insulin (%)	7.4
Using insulin + oral agents (%)	9.8
Using blood pressure lowering medication (%)	71.2
Using lipid lowering medication (%)	46.9
No. chronic medicines used	3.4 (1.9)

**TABLE 3.** Overview of the Results of the Indicators A to G, Compared to the Reference Method\*

	Glycemic Management 75.8% as Recommended (n = 1359)				Blood Pressure Management 58.3% as Recommended (n = 1513)				Lipid Management 66.4% as Recommended (n = 1096)			
	Δ	% FP	% FN	n	Δ	% FP	% FN	n	Δ	% FP	% FN	n
A Patients “controlled”	-21.7 <sup>†</sup>	0	21.7	1359	-26.9 <sup>†</sup>	0	26.9	1513	-11.1 <sup>†</sup>	0	11.1	1096
B Patients “achieving control”	-31.7 <sup>†</sup>	0	31.7	731	-29.7 <sup>†</sup>	0	29.7	1102	-15.9 <sup>†</sup>	0	15.9	687
C Patients with “improvement”	-10.9 <sup>†</sup>	13.8	24.8	731	1.3	18.1	16.9	1102	-1.4	16.0	17.5	687
D Patients “controlled or improving”	-10.5 <sup>†</sup>	7.4	18.0	1359	-4.4 <sup>†</sup>	13.2	17.6	1513	-2.1	10.0	12.1	1096
E Uncontrolled patients “treated”	48.0 <sup>†</sup>	49.5	1.5	729	39.9 <sup>†</sup>	44.5	4.4	1150	13.0 <sup>†</sup>	19.2	6.3	624
F Patients “uncontrolled then treated”	34.7 <sup>†</sup>	36.8	2.2	768	33.8 <sup>†</sup>	39.8	5.7	1096	0.7	14.9	14.1	673
G “Treatment modified when indicated”	-16.1 <sup>†</sup>	9.5	25.7	768	-15.3 <sup>†</sup>	6.3	21.6	1096	-19.8 <sup>†</sup>	5.2	25.0	673

\*Assessments made for all patients with recorded risk factor measurements.

<sup>†</sup>Difference between indicator and reference is significant at *P* < 0.05 level.

Δ, Difference between reference and indicator estimates of percentages of patients with the recommended management; % FP, percentage of false positives; % FN, percentage of false negatives; n, number of patients.

**TABLE 4.** Likelihood Ratios (with 95% Confidence Intervals) for the Different Indicators

Indicator	Glycemic Management		Blood Pressure Management		Lipid Management	
	Negative	Positive	Negative	Positive	Negative	Positive
A Patients “controlled”	0.28 (0.26–0.31)	—	0.47 (0.44–0.49)	—	0.16 (0.15–0.18)	—
B Patients “achieving control”	0.47 (0.43–0.52)	—	0.58 (0.55–0.61)	—	0.29 (0.26–0.31)	—
C Patients with “improvement”	0.64 (0.54–0.75)	1.49 (1.27–1.76)	0.53 (0.46–0.59)	1.80 (1.59–2.04)	0.49 (0.42–0.58)	1.90 (1.62–2.22)
D Patients “controlled or improving”	0.34 (0.30–0.39)	2.44 (2.13–2.79)	0.44 (0.40–0.49)	2.22 (2.00–2.46)	0.26 (0.22–0.30)	2.55 (2.19–2.97)
E Uncontrolled patients “treated”	0.52 (0.28–1.36)	1.03 (0.46–2.27)	0.42 (0.31–0.56)	1.22 (0.90–1.61)	0.34 (0.28–0.41)	2.93 (2.44–3.51)
F Patients “uncontrolled then treated”	0.63 (0.33–1.22)	1.02 (0.53–1.97)	0.50 (0.38–0.66)	1.16 (0.89–1.51)	0.45 (0.39–0.51)	2.58 (2.24–2.97)
G “Treatment modified when indicated”	0.56 (0.49–0.63)	2.38 (2.11–2.69)	0.51 (0.47–0.56)	4.54 (4.19–4.91)	0.64 (0.59–0.70)	4.58 (4.22–4.97)

**Sensitivity Analysis**

When comparing the assessments using higher target levels, both cross-sectional indicators (A and E) showed results that were at least 10% closer to the reference method for glycemic and blood pressure management. The sequential indicators of patients with “improvement” (C) and “treatment modified when indicated” (G) deteriorated in most cases, implying that for assessing poor risk factor management such sequential indicators were not superior to cross-sectional indicators.

The analyses stratified for patients with or without coronary and/or diabetes-related comorbidity showed almost identical results for most indicators. As expected, estimates from indicators A and B were slightly lower in patients with comorbidity. For the sequential indicators C and G, differences in percentages between the 2 cohorts were small (1–6%).

**Comparison at the Individual Patient Level**

For indicators A and B, positive likelihood ratios could not be calculated because all patients assessed as being managed in line with the guideline recommendations fall by definition into the same category for the reference method. The indicator of patients with “improvement” (C) showed positive likelihood ratios between 1.5 and 2, implying it to be a poor predictor for risk factor management according to the

guidelines (Table 4). The indicator of patients “controlled or improving” (D) performed significantly better with ratios between 2 and 3. The negative likelihood ratios were between 0.2 and 0.5 for most of these indicators, signifying weak predictors for identifying individual patients not receiving management as recommended in the guidelines. The sequential indicators did not perform significantly different from the cross-sectional indicators regarding these values.

For the indicators focusing on treatment, the “treatment modified when indicated” indicator (G) showed positive likelihood ratios between 2 and 5, indicating a weak predictor for identifying patients receiving risk factor management as recommended. The other indicators performed significantly worse, with positive likelihood ratios below 2 except for lipid control. For predicting risk factor management not in line with the recommendations at the individual patient level, all indicators performed equally with negative likelihood ratios of around 0.5 (Table 4).

**DISCUSSION**

This study showed that the commonly used quality indicator focusing on the number of patients controlled may lead to inaccurate judgments of risk factor management. The simple sequential indicator looking at patients switching from above to below target levels also gave low estimates of the

quality of such care, similar to the cross-sectional indicator that only looks at the current risk factor level. More complex indicators that focus on uncontrolled patients with clinical improvements provided quality estimates that corresponded better with a detailed evaluation of risk factor management. Furthermore, our results showed the limited value of the cross-sectional indicator looking at uncontrolled patients treated. The observation that a patient with an elevated risk factor level is receiving medication is a poor predictor of management according to guideline recommendations, and will result in high estimates of quality. But again, results of a simple sequential indicator looking at uncontrolled patients subsequently treated were only slightly different from this cross-sectional indicator. Focusing on intensification of treatment in uncontrolled patients led to clearly better quality assessments. At the individual patient level, we observed that the more complex sequential indicators were superior in identifying patients receiving risk factor management as recommended. For assessing the quality of treatment focusing on poorly instead of adequately controlled patients, however, simple cross-sectional indicators seemed to be equally sufficient.

Ideally, one might want to assess the quality of risk factor management by looking at detailed clinical and therapeutic information for each patient over time. This approach has resulted in the development of clinically detailed indicators that require individual patient chart review.<sup>35–37</sup> This is time-consuming and difficult to implement when using automated data for quality assessment. Our reference method involves detailed individual patient assessment over time but is not feasible to conduct on a large scale. Therefore, we evaluated several simpler alternatives on their ability to correspond with this reference method.

The quality assessments observed in our study using simple cross-sectional indicators were similar to those found previously in other studies. The percentages of patients with adequate blood pressure control (32%), lipid control (56%), and glycemic control (54%) were within the range of outcomes reported in recent studies with comparable patient groups and target levels in the United States,<sup>3,6,17,38</sup> Italy,<sup>39</sup> and The Netherlands.<sup>40,41</sup> Also, percentages of patients treated (95%, 79%, and 38%) were within ranges observed in other studies for these risk factors.<sup>3,6,38</sup>

The clear advantage of sequential indicators is that they are capable of quantifying alterations in outcomes and processes of care in response to outcomes. The indicator of patients “controlled or improving,” and especially the indicator “treatment modified when indicated” incorporate several factors important to quantify adequate risk factor management, as pointed out by others.<sup>14,15,18,21,42</sup> Using these indicators can be expected to result in a reduction of the negative incentives to avoid patients that are more difficult to control. Our study demonstrated that such indicators can be applied in practice using routinely recorded information on treatment and outcomes, and are valuable for estimating quality of diabetes management at the aggregated level.

For our primary analyses we used target levels as indicated by the national guidelines for general practice.

However, the use of strict target levels for the entire patient population is under debate.<sup>43</sup> We tested the indicators also with high target levels. The proportion of patients that would not benefit from achieving those targets is smaller, and patient case-mix is therefore less important than when focusing on aggressive management. We found that the advantage of sequential indicators was larger when using strict target levels. This could imply that sequential indicators may counteract some of the case-mix problems observed in commonly used indicators focusing on strict target levels.

The assessed indicators performed comparably for glycemic and blood pressure control, but for lipid control the differences between the indicators were less pronounced. This could be due to physicians reacting less to elevated cholesterol levels than to elevated HbA1c and blood pressure levels. Although the national guidelines at the time of our study recommended that lipid lowering treatment should be guided by cholesterol levels, there were already recommendations that all patients with diabetes are eligible for such treatment.<sup>44</sup>

## Limitations

Both the reference method and the indicators were tested in a population that included patients that may not benefit from (aggressive) treatment. This implies that justifiable decisions not to manage risk factors are not captured as being in line with guideline recommendations. We did not have information on contraindications or circumstances, such as patients’ limited life expectancy or treatment refusal, or competing demands, which could justify nonintervention. There may be other conditions that warrant more immediate attention at a particular visit than risk factor management. Although our reference method allows for an extended period of 120 days in which actions can be taken, some patients may still be incorrectly classified as being in need of additional treatment. This problem is not specific for our study but affects quality assessments in general. When sufficient information is available, it can be solved by excluding these patients from the indicators. For our study, we expect that comparisons between the indicators and the reference method maintain their validity, because this lack of information will affect the tested indicators similarly. The stratified analysis confirmed that our comparative findings were robust for variations in patient population regarding comorbidity.

Furthermore, our data did not allow assessing actions taken regarding lifestyle, treatment compliance, insulin regimen intensifications, or referrals to a medical specialist. Therefore, we considered patients that were uncontrolled but on maximal medication—as defined in this study—as receiving management as recommended. In some cases, however, further actions might have been warranted and possible.

The feasibility of using sequential indicators is expected to be good. The data required for their calculation include risk factor measurements and medication treatment information in 2 concurrent years, which are usually registered during regular care.

## Implications for Quality Assessment

Quality indicators can be used for internal quality improvement and for external purposes. For internal use, it is helpful to identify patients who possibly receive suboptimal management. Our study showed that for this purpose the simple, commonly used indicators performed as well as the more complex indicators. In other words, to optimize patient care at the individual level sequential indicators do not provide a clear benefit.

For external use, such as public accountability, indicators need to provide a fair view of the risk factor management. Indicators looking only at patients below strict target levels may underestimate the quality of care. Substitution of such indicators with the sequential “controlled or improving” indicator, which considers both patients that maintain control and those that achieve clinically relevant improvements, can provide a more meaningful assessment of risk factor management.

Indicators focusing on the percentage of uncontrolled patients receiving medication overestimate treatment quality, because they do not take any recommendations for treatment intensification into account. For assessing treatment quality we recommend the use of a sequential indicator measuring the modification of treatment when indicated. The advantage of including also the “controlled or improving” indicator is that this considers all patients, and not just the ones who are uncontrolled as is done in the treatment oriented indicators. As has been stated before, good quality of risk factor management incorporates achieving control in uncontrolled patients as well as maintaining control in those controlled.<sup>9,14</sup>

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