

No consistent association between processes-of-care and health-related quality of life among patients with diabetes: a missing link?

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ABSTRACT

Purpose: Health-related quality of life (HRQoL) is considered a representative outcome in the evaluation of chronic disease management initiatives emphasizing patient-centered care. We evaluated the association between receipt of processes-of-care (PoC) for diabetes and HRQoL.

Methods: This cross-sectional study used self-reported data from non-institutionalized adults with diabetes in a Swiss canton. Outcomes were the physical/mental composites of the short form health survey 12 (SF-12) physical composite score, mental composite score (PCS, MCS) and the Audit of Diabetes-Dependent Quality of Life (ADDQoL). Main exposure variables were receipt of six PoC for diabetes in the past 12 months, and the Patient Assessment of Chronic Illness Care (PACIC) score. We performed linear regressions to examine the association between PoC, PACIC and the three composites of HRQoL.

Results: Mean age of the 519 patients was 64.5 years (SD 11.3); 60% were male, 87% reported type 2 or undetermined diabetes and 48% had diabetes for over 10 years. Mean HRQoL scores were SF-12 PCS: 43.4 (SD 10.5), SF-12 MCS: 47.0 (SD 11.2) and ADDQoL: -1.6 (SD 1.6). In adjusted models including all six PoC simultaneously, receipt of influenza vaccine was associated with lower ADDQoL ($\beta=-0.4$, $p\leq 0.01$) and foot examination was negatively associated with SF-12 PCS ($\beta=-1.8$, $p\leq 0.05$). There was no association or trend towards a negative association when these PoC were reported as combined measures. PACIC score was associated only with the SF-12 MCS ($\beta=1.6$, $p\leq 0.05$).

Conclusions: PoC for diabetes did not show a consistent association with HRQoL in a cross-sectional analysis. This may represent an effect lag time between time of process received and health-related quality of life. Further research is needed to study this complex phenomenon.

BACKGROUND

The number of people living with diabetes mellitus (DM) continues to rise, with an estimated 371 million individuals around the

Key messages

- ▶ In this study, processes of care for diabetes were not consistently associated with health-related quality of life when adjusting for patient and disease characteristics.
- ▶ There was similarly no association or trend towards a negative association when these processes of care were analyzed as combined measures.
- ▶ These findings prompt further diabetes research to focus on the effects of processes-of-care on health-related quality of life and other patient-reported outcomes, from a patient-centered perspective, taking a longitudinal approach.

world who were affected by the illness in 2012.¹ The consequences of diabetic illness, such as blindness and kidney disease, place a high toll on patients and the social system, not only in terms of functional life years lost, but also in terms of the morbidity that leads to disability and decreased quality of life.¹⁻⁴ Given the significant impact of diabetes on patient lives and the responsibility of disease self-management on the individual with diabetes, health-related quality of life (HRQoL) is acknowledged as an important outcome to consider when developing and assessing interventions targeting these patients.⁵ Furthermore, novel chronic disease management initiatives emphasize a more 'patient-centered' model,⁶ with increased attention to patient reported outcome measures (PROMs) such as HRQoL.⁷

However, although HRQoL is accepted as a diabetes-relevant outcome, having demonstrated positive associations with patients' daily life-functioning, disease management and prognosis,^{5 8-10} efforts for assessing the quality of diabetes care have primarily focused on the development and monitoring of process measures and clinical outcomes. For almost two decades, system initiatives in the USA and across the globe have poured



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resources into the implementation of specific process measures^{11–13} that improve relevant intermediate and ultimate end points such as glycated hemoglobin (HbA1C), and diabetic complications, comorbidities and overall prognosis, respectively.^{12 14 15} However, it is not yet known how these process measures affect PROMs in patients with diabetes, such as HRQoL.

Since process indicators are accepted as measures of high-quality diabetes care,¹⁶ we ask whether these established measures also ultimately translate into an improved patient-centered outcome. Therefore, the aim of this study was to examine whether receipt of highly utilized process(es)-of-care (PoC) measures was related to the HRQoL in patients with diabetes. We hypothesised that there would be a positive association between patient's receipt of PoC, as measured by individual and combined measures and HRQoL outcomes.

METHODS

Study design

We used data from a cross-sectional survey of patients with diabetes.

Setting, population and recruitment

In the fall of 2011 and summer of 2012, patients with diabetes were recruited by community-based pharmacies registered in the canton of Vaud, Switzerland, a large French-speaking canton (state) with over 720 000 inhabitants.¹⁷ Patients were eligible if they came to the pharmacy with a prescription for oral hypoglycemics, insulin, glucometer and/or glucometer strips and had a diagnosis of diabetes for at least 12 months, were aged ≥ 18 and non-institutionalized. Patients not residing in the canton of Vaud, not speaking or understanding French well enough, or those presenting with obvious cognitive impairment were excluded, as well as women with gestational diabetes. During this two-phase process, 85 pharmacies agreed to help recruit patients for the study and 519 eligible patients consented to the study, and completed and returned the questionnaire. Further details about recruitment and participation may be found in the published study about the original survey.¹⁸

Measures

Data were self-reported and collected using a paper mail-in survey that was given to patients during their visit to the pharmacy. It addressed the following themes: diabetes illness and care management, lifestyle, health status and sociodemographics.

Dependent variables

The main dependent variables of our study were two HRQoL measures, one generic and one disease-specific: the SF-12 and the Audit of Diabetes-Dependent Quality of Life (ADDQoL), respectively. We considered the mental composite score (MCS) and physical composite score (PCS) of the SF-12 rating, which each range from 0

(worst) to 100 (best).¹⁹ The 19-item ADDQoL instrument,^{20 21} which is highly tailored to important issues of daily life for patients with diabetes, has been used among various types of populations, and is considered one of the few disease-specific tools with adequate psychometric properties.^{22 23} The 19-item ADDQoL global score ranges continuously from -9 (worst) to 3 (best). Validation analyses for this project of the present French for Switzerland version showed a CFI (goodness-of-fit index) of 0.80, and a Cronbach's α of at least 0.90 for all items.

Exposure variables

PoC: individual measures

Our main exposure variables were six individual PoC that are routinely used to monitor quality of diabetes care in practice and in research studies.^{12 24} The diabetes-specific patient-reported process measures were: HbA1C check (yes, 1 \times /year; yes $>1\times$ /year; no; unknown), retinal eye examination by ophthalmologist (yes, <1 year ago; yes, 1–2 years ago; yes, >2 years ago; never; unknown), annual urine microalbuminuria screen (yes; no; unknown), annual foot examination by physician (yes; no; unknown), annual lipid test (yes; no; unknown) and annual influenza vaccination (yes; no; unknown). Owing to a skip question survey method, receipt of HbA1c check was only asked to those reporting knowing what HbA1c was (HbA1c-aware). However, multiple categories were created for the HbA1c PoC variable, to include the patients who did not know about HbA1c (HbA1c-unaware). The HbA1c variable categories were as follows: (1) HbA1c-aware and HbA1c was checked; (2) HbA1c-aware and HbA1c was not checked; (3) HbA1c-aware and do not know if HbA1c was checked; (4) HbA1c-unaware (not HbA1c-aware or do not know if HbA1c-aware). The reference category was 'HbA1c-aware and HbA1c was not checked.'

PoC: combined measures

We also used two combined measures for the PoC indicators.²⁵ These combined measures were restricted to HbA1c-aware patients with no missing data, since these respondents were asked about HbA1c check and had answered all of the other PoC questions. This means that HbA1c-unaware patients and patients with missing and 'do not know' answers for any other PoC were not included in the following two combined measures:

1. Mean percentage of recommended care: the sum of received PoC (number of 'yes' responses per patient), divided by six possible processes.
2. Percentage of patients receiving all of recommended care: percentage of patients receiving six process measures (patients with all 'yes' responses), with reference to those not receiving all process measures (patients with 'no' for any of the six indicators).

Patient Assessment of Chronic Illness Care measure

Our last exposure variable was the Patient Assessment of Chronic Illness Care (PACIC) global score (range from

1-never to 5-always), which was used as an overall PoC measure, assessing to what extent current care is congruent with the Chronic Care Model.²⁶ It does not incorporate the aforementioned PoC variables but, rather, bases its metrics on an evidence-based theoretical framework for chronic disease care.

Covariates

We considered other patient and clinical variables given their potential confounding with the association between PoC receipt and HRQoL.^{5 27–29} These variables included (1) demographics: age, gender, education (primary, secondary, tertiary), quartiles of monthly income level in CHF (≤ 3499 , 3500–5499, 5500–9499, ≥ 9500), living companion (lives with someone at home, yes/no), (2) medical history: alcohol consumption (history of alcohol problems, yes/no), smoking (currently smoking, yes/no), body mass index (underweight/normal, overweight, obese), physical inactivity (no physical activity, yes/no), number of medical/psychiatric comorbidities and (3) diabetes characteristics and disease severity: diabetes type (type 2/undetermined, type 1), treatment (on insulin, yes/no), diabetes complications (presence of at least one of the following diabetes complications: cardiovascular disease, stroke, retinopathy, chronic kidney insufficiency, regular dialysis or kidney transplant, neuropathy, foot ulcer/wound, lower extremity amputation and severe hypoglycemia or hyperglycemia,) and duration of diabetes illness (10 years or more, yes/no). In order to not lose cases in fully adjusted models, missing and ‘do not know’ responses (if these two totaled over 10) were incorporated into a separate category for each variable.

Statistical analysis

First, we conducted descriptive analyses to describe the population, as well as HRQoL scores and PoC received. Next, we performed bivariate analyses to examine the association between each of the three HRQoL outcomes (SF12-MCS, SF12-PCS, ADDQoL) and each single PoC indicator. Using the ANOVA test, we assessed whether there were any differences in HRQoL mean scores between respondents for each PoC indicator, comparing report of receipt and no receipt of each PoC.

We then performed linear regressions of HRQoL outcomes and PoC. First, crude linear regression models for each of the three outcomes simultaneously included the six individual PoC (no covariates). All models were then adjusted for demographics, medical history and diabetes characteristics variables. Second, we used the two PoC combined measures and the PACIC to examine the association with the three HRQoL outcomes, in crude and adjusted models.

Finally, we performed a sensitivity analysis for the combined PoC measures to include all patient cases. This consisted of creating a combined measure to include patients with missing data as well as HbA1c-unaware patients who were not asked the HbA1c-receipt question (because they responded ‘no’ or ‘do not know’ to

awareness about HbA1c). In this sensitivity analysis (worst case scenario), the HbA1c-unaware patients were assumed as not having an HbA1c screen. Similarly, all patients with missing/‘do not know’ responses for each of the other indicators were counted as ‘no’ answers, thus giving a complete observation set of 519 patients for this combined measure sensitivity analysis. The sum of received PoC (number of ‘yes’ responses) was computed. We then used this combined measure to examine the association with the three HRQoL outcomes, in crude and adjusted models.

Checks for linearity and colinearity were performed in initial bivariate analyses. Residuals in each linear regression model were tested for normality and for homoscedasticity. We crosschecked all model results using transformed versions of the dependent variables, and these did not differ from the initial findings, nor did they provide a better residual distribution, which confirmed results of the original models used. To take into account the intragroup correlation of individuals within pharmacies, the clustered sandwich estimator was used to estimate the variance–covariance matrix (VCE). STATA V.12.0 was used for all analyses.

Written informed consent was obtained from all participants, and data were kept confidential.

RESULTS

Description of the study population is shown in table 1. Among respondents, mean age was 64.5 years and almost 60% were men. The majority had a high school equivalent education or above (81%) and lived with someone at home (73%). While 17% were current smokers, 47% were classified as obese and nearly 30% were physically inactive. The average number of comorbidities per patient was 1.8. The majority of patients reported having type 2 diabetes (67%), 12.7% reported type 1 diabetes; diabetes type diagnosis was unknown by 20% of respondents. Almost 50% required insulin treatment and close to half self-reported at least one diabetes-related complication. The highest-reported diabetes complications were eye problems (with attention to the retina; 18%), stroke or ischemic heart disease (15%) and hypoglycemia or hyperglycemia (11%). Finally, 48% of patients had had a diabetes diagnosis of greater than 10 years.

Table 2 presents the HRQoL outcomes and PoC results. Mean SF-12 MCS and PCS scores were 47.0 (SD 11.2) and 43.4 (SD 10.6), respectively, and mean ADDQoL score was -1.6 (SD 1.6). For individual process variables, about 98% of HbA1c-aware patients had had at least one HbA1c screen during the past 12 months. During that same time period, while screening for lipids was similarly high (94.2%), around 60–70% of the patients reported having received the other four individual process indicators, with the lowest corresponding to microalbuminuria screening (63.3%). Combined PoC measures show that HbA1c-aware individuals received about 86% of the six PoC indicators

Table 1 Characteristics of included patients with diabetes (n=519)

| Demographics | |
|-----------------------------------------|----------------|
| Mean age (n=519) | 64.5 (SD 11.3) |
| Male (n=519) | 59.7% |
| Education (n=504) | |
| Primary | 18.9% |
| Secondary | 56.2% |
| Tertiary | 25.0% |
| Monthly income (CHF; n=486) | |
| <3499 | 21.2% |
| 3500–5499 | 26.5% |
| 5500–9499 | 27.8% |
| ≥9500 | 17.3% |
| ‘do not know’ | 7.2% |
| Lives with someone (n=516) | 73.2% |
| Medical history | |
| Current smoker (n=509) | 17.3% |
| History of alcohol problems (n=505) | 5.9% |
| BMI (n=481) | |
| Underweight | 0.8% |
| Normal | 17.1% |
| Overweight | 35.3% |
| Obese | 46.8% |
| Mean number of comorbidities (n=505) | 1.8 (SD 1.3) |
| Physically inactive (n=494) | 29.8% |
| Diabetes characteristics | |
| Diabetes type 2 or undetermined (n=519) | 87.3% |
| Diabetes requiring insulin (n=516) | 48.8% |
| Any diabetes complications* (n=505) | 46.7% |
| Diabetes duration (n=511, years) | |
| 1–5 | 27.6% |
| 6–10 | 24.5% |
| 11–15 | 18.6% |
| 16–20 | 11.9% |
| over 20 | 17.4% |

*At least one diabetes complication: cardiovascular disease, stroke, retinopathy, chronic kidney insufficiency, dialysis, neuropathy, ulcer, amputation and severe hypoglycemia or hyperglycemia.

BMI, body mass index.

considered, and about 40% of these patients received all six PoC. Results of the combined sensitivity analysis considering all 519 patients showed that at least 18.9% patients received six of the six processes-of-care; this is a result that tests a ‘worst-case’, where HbA1c-unaware for HbA1c, and missing and ‘don’t know’ responses for any PoC receipt are considered as a ‘no’ answer.

The comparisons of mean HRQoL scores across categories of patients having reported (+) or not (–) a specific PoC are shown in table 3. Only a few comparisons were statistically significant. On the one hand, patients who received the influenza vaccine compared to those who did not, had lower ADDQoL scores (–1.7 vs –1.3, respectively) and lower PCS scores (41.8 and 46.2, respectively), and those receiving the retinal examination reported worse ADDQoL score (–1.7), compared to those who did not receive this examination (–1.2). On the other hand, patients with HbA1c checks

reported better ADDQoL than those who did not report any HbA1c check during the past 12 months. Of note, there were no significant differences in HRQoL outcomes between the HbA1c-aware and the HbA1c-unaware groups (data not shown).

Crude and adjusted linear regressions of models including all individual PoC (table 4) suggest that while there were no associations between the receipt of single PoC and SF-12 MCS, receiving a foot examination by a physician was negatively associated with the SF-12 PCS score (ie, worse HRQoL: $\beta=-1.8$) in the fully adjusted model. Also, receipt of influenza vaccine was associated with lower ADDQoL in crude and in adjusted models ($\beta=-0.4$).

Regarding combined measures of PoC (table 5), there was no association with HRQoL in the adjusted models. However, the sensitivity test (‘worst case’) did show that each additional PoC received was associated with a decrease in ADDQoL score ($\beta=-0.1$).

Finally, PACIC was positively associated with HRQoL, with an increase in the SF-12 MCS score ($\beta=1.6$) for each additional point on the PACIC global score (table 5).

DISCUSSION

The results of this study suggest that overall there were no consistently significant associations between patients’ self-report of receipt of diabetic PoC and HRQoL. In fact, save for the PACIC score showing that care more congruent with the Chronic Care Model was positively associated with better SF-12 MCS score, and HbA1c being positively associated with better ADDQoL global score, there was either no association or a trend towards the negative. The findings were similar when we tested process indicators as combined measures.

These findings were somewhat unexpected since we hypothesized that receipt of PoC would lead, ultimately, to better clinical outcomes, and thus better HRQoL. Indeed, PoC have been shown to improve diabetic clinical markers such as HbA1c levels and cardiometabolic risk factors,³⁰ thereby decreasing morbidity and mortality.^{14 31 32} Since less morbid patients report a better HRQoL,^{5 33 34} we expected to see a positive association between PoC and HRQoL.

One possible reason for this discordance is that, in fact, receipt of PoC does not always translate to an observation of improved clinical outcomes for diabetes. In the third National Health and Nutrition Examination Survey (NHANES III), rates of health services use and diabetic complications screening and hyperglycemia, high-blood pressure and cholesterol treatment/therapy in patients with type 2 diabetes were high; however, despite the rise of these indicators, health status and outcomes did not reflect a significant improvement.³⁵ Hypotheses for this finding included patient and healthcare system factors that did not allow for appropriately meeting patients’ needs. Similarly, in the Translating Research Into Action

Table 2 HRQoL scores and processes-of-care among included patients with diabetes (n=519)

| HRQoL outcomes | (n) | Mean (SD) |
|-------------------------------------------------------------------|-----|----------------------------------|
| SF-12 MCS | 496 | 47.0 (11.2) |
| SF-12 PCS | 498 | 43.4(10.6) |
| ADDQoL | 512 | -1.6 (1.6) |
| Individual process-of-care (at least one check in last 12 months) | | Percentage that received process |
| Hemoglobin A1c among 'aware' patients | 282 | 98.3 |
| Lipid | 513 | 94.2 |
| Urine microalbumin | 512 | 63.3 |
| Foot examination by physician | 510 | 66.5 |
| Retinal eye examination (in last 24 months) | 511 | 75.7 |
| Flu vaccination | 514 | 63.8 |
| Combined process-of-care measures | | |
| Mean percentage of recommended care* | 236 | 85.9 |
| Percentage of patients receiving all care* | 236 | 41.5 |
| PACIC | | Mean (SD) |
| Global score | 503 | 2.8 (0.95) |

*Complete observations with no missing data (among HbA1c-aware patients only).

ADDQoL, Audit of Diabetes-Dependent Quality of Life; HRQoL, health-related quality of life; PACIC, Patient Assessment of Chronic Illness Care; SF-12, short form-12

(TRIAD) study, though an average of one additional documented PoC for each patient in a group or plan was associated with significantly lower mean low-density

lipoprotein cholesterol levels, this was not observed with HbA1c, systolic blood pressure or high-density-lipoprotein cholesterol levels.²⁴ Finally, in a review of 24

Table 3 HRQoL outcome across individual processes-of-care, for those reporting it as having been performed (+) or not (-)

| | Health-related quality of life measures | | p Value* |
|--------------------------------|-----------------------------------------|-------------------------------|----------|
| | Mean (SD) PoC not reported (-) | Mean (SD) PoC reported (+) | |
| Lipids | | | |
| SF-12 MCS | 48.4 (9.1) | 46.9 (11.3) | 0.68 |
| SF-12 PCS | 42.2 (11.8) | 43.5 (10.5) | 0.76 |
| ADDQoL | -1.5 (1.4) | -1.6 (1.6) | 0.77 |
| Urine microalbumin | | | |
| SF-12 MCS | 46.6 (11.4) | 47.4 (11.1) | 0.54 |
| SF-12 PCS | 41.6 (9.8) | 44.0 (10.6) | 0.12 |
| ADDQoL | -1.5 (1.5) | -1.6 (1.6) | 0.48 |
| Foot examination | | | |
| SF-12 MCS | 46.7 (11.0) | 47.2 (11.2) | 0.66 |
| SF-12 PCS | 44.1 (9.0) | 43.1 (11.2) | 0.59 |
| ADDQoL | -1.5 (1.4) | -1.6 (1.6) | 0.72 |
| Retinal eye examination | | | |
| SF-12 MCS | 47.8 (10.6) | 46.9 (11.3) | 0.39 |
| SF-12 PCS | 43.8 (11.0) | 43.2 (10.5) | 0.38 |
| ADDQoL | -1.2 (1.5) | -1.7 (1.6) | 0.01 |
| Hemoglobin A1c† | | | |
| SF-12 MCS | 42.0 (10.1) | 46.6 (11.6) | 0.64 |
| SF-12 PCS | 30.0 (14.9) | 43.7 (10.9) | 0.18 |
| ADDQoL | -2.8 (0.98) | -1.8 (1.7) | 0.01 |
| Flu vaccination | | | p value‡ |
| SF-12 MCS | 47.4 (10.9) | 46.8 (11.3) | 0.58 |
| SF-12 PCS | 46.2 (9.9) | 41.8 (10.6) | 0.000 |
| ADDQoL | -1.3 (1.3) | -1.7 (1.7) | 0.001 |

*F-test for ANOVA.

†Results displayed for HbA1c-aware patients only.

‡Two sample t tests with equal variances.

ADDQoL, Audit of Diabetes-Dependent Quality of Life; ANOVA, analysis of variance; HbA1c, glycated hemoglobin; MCS, mental composite score; PCS, physical composite score; PoC, processes-of-care; SF-12, short form-12.

Table 4 Linear regression models of HRQoL and individual processes-of-care in crude and adjusted models

| Process indicators† | HRQoL outcomes | | | | | |
|------------------------------------------------------------|----------------|----------|-------------------|----------|--------|----------|
| | MCS | | PCS | | ADDQoL | |
| | β= | | β= | | β= | |
| | Crude | Adjusted | Crude | Adjusted | Crude | Adjusted |
| Lipids | -2.6 | -3.4 | -0.05 | 2.1 | -0.005 | -0.03 |
| Urine microalbumin | 1.2 | 0.95 | 1.8 | 0.5 | -0.1 | 0.05 |
| Foot examination by physician | 1.1 | 0.9 | -1.5 | -1.8* | -0.1* | 0.2 |
| Retinal eye examination (in past 24 months) | -0.7 | -0.2 | -0.5 | 1.1 | -0.3 | -0.2 |
| Flu vaccination | -0.3 | -0.8 | -4.2 ^α | -1.4 | -0.4** | -0.4** |
| Hemoglobin A1c‡ | | | | | | |
| HbA1c-aware and HbA1c was checked | 4.8 | 1.4 | 14.9* | 3.5 | 1.2 | 0.3 |
| HbA1c-aware and do not know if HbA1c was checked | 1.5 | -2.7 | 19.1* | 4.6 | 2.2 | 0.8 |
| HbA1c-unaware (not aware or do not know if aware of HbA1c) | 6.2 | 0.5 | 13.7* | 3.8 | 1.6 | 0.4 |
| <i>Adjusted. R² for full model</i> | 0.11 | | 0.39 | | 0.21 | |

Crude model=all process indicator in one model, no other covariates.
 Adjusted model=all process indicators+14 covariates (demographics, medical history and diabetes characteristics).
 Covariates:
 Demographics: Age, Male, Education levels, Income levels, Living companion.
 Medical hx: hx of alcohol problems, smoker, BMI category, comorbidities, physical activity.
 Diabetes: type 2 or undetermined, on insulin, DM complications, DM over 10 years.
 *p≤0.05; **p≤0.01; ^αp≤0.001.
 †Reference: no care received for individual process-of-care.
 ‡Reference: HbA1c-aware and did not receive HbA1c screen/check.
 HbA1c, glycated hemoglobin; HRQoL, health-related quality of life.

studies looking at the association of diabetes quality-of-care with surrogate and clinical outcomes, high-quality studies specifically examining process indicators (number of tests or visits) showed mostly inconsistent or negative associations.³⁶ Perhaps we could not find an improvement in HRQoL because the patients observed in this study did not clinically benefit from the PoC received at the time of the survey.

Another postulation is the confounding of severity of disease with more intense PoC, and thus low HRQoL.

We did try to control for this by adjusting for diabetes-specific characteristics and comorbidity; it is, however, still possible that we did not sufficiently account for all aspects of illness severity that are linked to lower HRQoL. In addition, increased medical treatment (such as increased doctor visits and medical testing) may lead to patient worry and inconvenience, and decreased patient HRQoL. Although we did not find studies documenting the effects of PoC on patient stress levels, the intensification of some medical treatment (such as the

Table 5 Crude and adjusted linear regression models of (1) HRQoL and combined processes-of-care, (2) HRQoL and PACIC, in crude and adjusted models

| | HRQoL outcomes | | | | | |
|----------------------------------------------|----------------|----------|-------|----------|--------|----------|
| | MCS | | PCS | | ADDQoL | |
| | Crude | Adjusted | Crude | Adjusted | Crude | Adjusted |
| Mean percentage of recommended care† | 5.9 | 4.5 | -4.0 | -2.1 | -1.4 | -0.8 |
| <i>Adjusted R² for full model</i> | 0.18 | | 0.35 | | 0.19 | |
| Receiving all recommended care† | 0.3 | 0.1 | -0.7 | 0.1 | -0.4 | -0.2 |
| <i>Adjusted R² for full model</i> | 0.17 | | 0.35 | | 0.19 | |
| Sensitivity analysis‡ | -0.1 | 0.2 | -0.4 | -0.3 | -0.2 | -0.1* |
| <i>Adjusted R² for full model</i> | 0.12 | | 0.39 | | 0.21 | |
| PACIC score | 0.96 | 1.6* | 0.5 | -0.6 | -0.1 | -0.1 |
| <i>Adjusted R² for full model</i> | 0.13 | | 0.39 | | 0.20 | |

Crude model=combined process-of-care measure, no other covariates.
 Adjusted model=combined measure +14 covariates (demographics, medical history and diabetes characteristics).
 Covariates:
 Demographics: Age, Male, Education levels, Income levels, Living companion.
 Medical hx: hx of alcohol problems, smoker, BMI category, co-morbidities, physical activity.
 Diabetes: type 2 or undetermined, on insulin, DM complications, DM over 10 years.
 *p≤0.05.
 †Complete case: yes=1; no=0; all other answers=missing.
 ‡Worst case: yes=1; all other answers (HbA1c-unaware for HbA1c; no, missing, do not know for all other PoC)=0.

transition from oral hypoglycemics to insulin) has been linked to higher stress and worry and lower HRQoL among patients with type 2 diabetes, though this relationship was inconsistent.⁵

One more readily possible explanation is that the lack of association represents an effect lag time between time of process received and impact on HRQoL; cross-sectional data are not ideal to detect such an effect. Other studies have also described the need to measure quality of care and patient outcomes, over time, in order to most accurately reflect these relationships.^{10 37 38} As such, the relationship between PoC and HRQoL might be further elucidated through a longitudinal examination, and thus should be a priority for future diabetic cohort studies.

Owing to this possible time-effect issue, one postulation was that receipt of PoC could be associated with a more immediate surrogate of patients' experiences, such as patient satisfaction. For example, the TRIAD study showed that the number of care processes documented was associated with patient satisfaction measures and self-rated quality of diabetes care.²⁴ In post hoc analyses, we indeed observed a similar positive trend between PoC and 'very good/excellent' patient ratings on care satisfaction (vs 'bad/medium/good') and feeling 'very well/well informed' (vs 'very bad/bad/medium'), across individual and combined PoC measures, as well as the PACIC global score.

This study is unique in that we attempted to examine the specific association between PoC and HRQoL among a population-based sample of patients with diabetes, a topic that, to the best of our knowledge, has not yet been studied. We employed generic as well as diabetes-specific HRQoL outcomes, and a range of measurement for PoC (individual, combined, PACIC). However, our results need to be interpreted in light of the following limitations. First, since we used a cross-sectional design, we cannot make conclusions about causal associations even though exposure to PoC was measured, retrospectively, for the previous year(s). Second, our sample size, calculated for getting appropriate precision around our primary outcomes, may have been too small to detect significant associations in secondary analysis. Another sample issue is that our combined analyses were limited to 236 of the 519 patients because of the skip question method for the question of HbA1c check receipt. In order to not eliminate the HbA1c-unaware patients from the combined measures, we constructed a third measure that was tested in the analysis where patients who responded 'no' or 'do not know' to knowing about HbA1c were assumed to not have received an HbA1c screen. A further point to consider is the relation between PoC measures and quality of life for patients with a specific complication (ie, how is quality of life affected in patients with retinopathy who receive an annual retinal examination compared to patients with diabetes who do not have retinopathy and receive annual retinal examinations?). Unfortunately, the sample size for many of these specific complication groups is much too small for further reliable analysis.

Third, the generalizability of these results is limited because the studied population may not be representative of the true population of patients with diabetes. We are nevertheless confident that our population-based sampling method, which utilized community pharmacies in the recruitment process, ensured the representativeness of patients with diabetes in the community (not just in clinic and hospital settings). Furthermore, characteristics of our patients with diabetes were similar to those reported from a population-based cohort study conducted in the same area.³⁹ Last, we used self-reported data that may be prone to recall bias; however, supplementary analyses for this project demonstrated good correlation between patient-reported data and physician records for simple PoC, when data was supplied by the treating physician for a fraction of the cohort.⁴⁰

In conclusion, further research should focus on the effects of PoC on patient-reported outcomes, particularly from a patient-centered perspective. Our study probes healthcare stakeholders to look beyond the presence of PoC procedures as the sole measurement of 'good care.' Additional studies, specifically with longitudinal data, are needed to examine the way in which PoC will translate into better health for patients with diabetes and, ultimately, a better quality of life. This includes looking into the way these PoC are conducted, how often they are delivered and what clinical cut-offs are being used. Although our study is a 'first look,' and more investigation is needed, we demonstrated that a list of achieved PoC is not a simple surrogate for gauging improvement on patient quality of life. Health systems and providers must ensure that diabetic care resources are allocated appropriately and organized effectively, so that patients with diabetes are able to thrive in life despite their illness.

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