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Intensified follow-up of patients with type 1 diabetes and poor glycaemic control: a multicentre quality improvement collaborative based on data from the Norwegian Diabetes Register for Adults

Tone Vonheim Madsen,[1,2] John Graham Cooper,[1] Siri Carlsen,[3] Karianne Loevaas,[1] Magne Rekdal,[4] Jannicke Igland,[5] Sverre Sandberg,[1,5,6] Grethe Åstrøm Ueland,[1] Marjolein Memelink Iversen,[2] Una Sølvik[5]

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For numbered affiliations see end of article.

Correspondence to
Tone Vonheim Madsen; tone.vonheim.madsen@noklus.no

ABSTRACT

Background Patients with type 1 diabetes mellitus (T1DM) and poor glycaemic control are at high risk of developing microvascular and macrovascular complications. The aim of this study was to determine if a quality improvement collaborative (QIC) initiated by the Norwegian Diabetes Register for adults (NDR-A) could reduce the proportion of patients with T1DM with poor glycaemic control (defined as glycated haemoglobin (HbA1c)≥75 mmol/mol) and reduce mean HbA1c at participating clinics compared with 14 control clinics.

Method Multicentre study with controlled before and after design. Representatives of 13 diabetes outpatient clinics (n=5145 patients with T1DM) in the intervention group attended four project meetings during an 18-month QIC. They were required to identify areas requiring improvement at their clinic and make action plans. Continuous feedback on HbA1c outcomes was provided by NDR-A during the project. In total 4084 patients with type 1 diabetes attended the control clinics.

Results Between 2016 and 2019, the overall proportion of patients with T1DM and HbA1c≥75 mmol/mol in the intervention group were reduced from 19.3% to 14.1% (p<0.001). Corresponding proportions in the control group were reduced from 17.3% (2016) to 14.4% (2019) (p<0.001). Between 2016 and 2019, overall mean HbA1c decreased by 2.8 mmol/mol (p<0.001) at intervention clinics compared with 2.3 mmol/mol (p<0.001) at control clinics. After adjusting for the baseline differences in glycaemic control, there were no significant differences in the overall improvement in glycaemic control between intervention and control clinics.

Conclusions The registry linked QIC did not result in a significantly greater improvement in glycaemic control at intervention clinics compared with control clinics. However, there has been a sustained improvement in glycaemic control and importantly a significant reduction in the proportion of patients with poor glycaemic control at both intervention and control clinics during and after the QIC time frame. It is possible that some of this improvement may be due to a spillover effect from the QIC.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ A high proportion of patients with type 1 diabetes mellitus have poor glycaemic control (defined as glycated haemoglobin (HbA1c)≥75 mmol/mol). Improved blood glucose control reduces the risk of developing microvascular and macrovascular complications and decreases the mortality rate in these patients. Quality improvement collaborative (QIC) can promote quality improvement in healthcare by bringing together healthcare providers to focus on a common problem.

WHAT THIS STUDY ADDS

⇒ Contemporaneously with a QIC initiated and coordinated by a national diabetes registry, the proportion of patients with HbA1c≥75 mmol/mol and mean clinic HbA1c decreased significantly both at intervention and control clinics. A lack of a significantly greater improvement in glycaemic control at intervention clinics compared with control clinics could possibly be partly explained by spillover effects from the QIC mediated by easy access to online monthly updated outcome measures at both intervention and control clinics. The study also discusses the problems associated with analysing the effects of QICs in a complex and changing medical environment.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our experiences with this nationwide QIC will be of interest to others who are planning similar quality improvement initiatives.

BACKGROUND

The Diabetes Control and Complications trial demonstrated that improved glycaemic control over an average of 6 years significantly reduced the risk of developing microvascular complications of diabetes.[1] Intensive therapy

also reduces the incidence of cardiovascular disease in type 1 diabetes mellitus (T1DM) that persisted for up to 30 years[2] and reduces the mortality rate after 27 years.[3] A registry-based observational study of adults with T1DM in Sweden demonstrated a substantial increase in all-cause mortality with higher mean glycated haemoglobin (HbA1c) levels.[4] Norwegian diabetes guidelines recommend a HbA1c target of about 53 mmol/mol for patients with diabetes, as long as it can be obtainable with a good quality of life and without unacceptable hypoglycaemic episodes.[5] A registry-based study from Norway in 2012 revealed that 22% of patients with T1DM≥18 years had a HbA1c≥75 mmol/mol.[4 6] Comparable results have been reported from other European countries[7 8] and the USA.[9]

Quality improvement collaboratives (QIC)s have been widely adopted as an approach to share learning and improvement in healthcare. A systematic review of QICs published in 2018 found that an improvement was reported for one or more of the study's primary effect measures in 32/39 hospital based QICs.[10] Furthermore, a systematic review and meta-analysis from 2012 found that QI strategies or financial intensives targeting health systems, healthcare professionals or patients reduced HbA1c by a mean difference of 0.37% (4 mmol/mol).[11] Experience from Sweden has also shown that a systematic QIC in combination with national quality registers can improve clinical results.[12 13]

Healthcare services in Norway such as outpatient treatment, diabetes medication, insulin pumps and monitoring devices are largely state-funded. Annual personal payment for healthcare is limited to approximately US$250. The majority (>90%) of the Norwegian patients with T1DM attend diabetes outpatient clinics at hospitals, and a patient with T1DM will typically have one annual consultation with a doctor and two with a nurse. The consultations are mostly carried out by endocrinologists and diabetes nurses.

The Norwegian Diabetes Register for adults (NDR-A) is a nationwide quality register that collects data from patients with T1DM aged 18 years and older. The NDR-A report from 2015 showed that the proportion of patients with T1DM with poor glycaemic control (defined as HbA1c≥75 mmol/mol) in diabetes outpatient clinics varied between 5% and 30% (mean 19%), and that only 23% attained a target of HbA1c≤53 mmol/mol.[14] These annual report data from 2015 highlighted the need for improvement in glycaemic control.

The aim of the present study is to determine whether the QIC initiated by the NDR-A reduced the proportion of patients with poor glycaemic control and reduced mean HbA1c in patients with T1DM attending hospital outpatient clinics that participated in the intervention compared with a control group of clinics.

METHODS

The NDR-A and the registry linked structured diabetes electronic patient record

The NDR-A was established in 2006 as a national quality registry. The registry developed, together with Emetra AS, a structured diabetes electronic patient record (EPR) that contains predefined variables that enables online collection of registry data (DIPS FastTrak). The diabetes EPR is partially integrated into the hospitals' main EPR. All clinics that report patient data to the registry must use the diabetes EPR. A prerequisite for data transfer during this project was that patients had given written informed consent to be registered in NDR-A. The proportions of clinics reporting data to NDR-A increased from 72% of all clinics in Norway in 2016 to 98% in 2019 (total number of clinics in Norway was 52 in 2019).

Study design

The present study is a multicentre, non-randomised registry-based intervention study with a controlled before and after design. A total of 15 outpatient clinics were invited to participate in the intervention (QIC) and 13 accepted the invitation. The clinics were invited if they met two eligibility criteria: they had to have reported more than 50 patients with T1DM to the NDR-A in 2016 and they also had to be one of the 15 clinics with the highest proportion of patients with an HbA1c≥75 mmol/mol. One clinic declined to participate as they were unable to assign two healthcare professionals to the collaborative due to a lack of resources, the other clinic declined because the post of endocrinologist at the hospital was vacant. The two that declined, and an additional 12 clinics were used as a control group of non-participating centres. At inclusion all the clinics in the control also had to report more than 50 patients with T1DM to the NDR-A in 2016. At inclusion (2016), the clinics in the intervention group had a total of 5145 patients with T1DM and control clinics had a total of 4084 patients with T1DM.

Intervention

The intervention (the QIC) was planned with input from the Breakthrough Series Collaborative Method, a model for achieving breakthrough improvement and was planned in three phases: the preparation phase, the active project phase and the follow-up phase (figure 1).

The preparation phase (September 2016–January 2017)

A project management team comprising two endocrinologists, a diabetes nurse and a biomedical laboratory scientist was established within the NDR-A. Each participating clinic designated two healthcare professionals (endocrinologist and diabetes nurse) as project coordinators at their own clinic. The project coordinators were required to attend four national project meetings.

The active project phase (February 2017–April 2018)

This phase included a kick-off meeting, two workshops and a concluding meeting (figure 1).

The project management team encouraged the clinics to make individual action plans that were both appropriate and feasible. The team recommended that clinics used specific quality improvement processes both to develop and implement the action plans. To achieve this the agenda at the kick-off meeting and subsequent meetings included talks and discussions about several

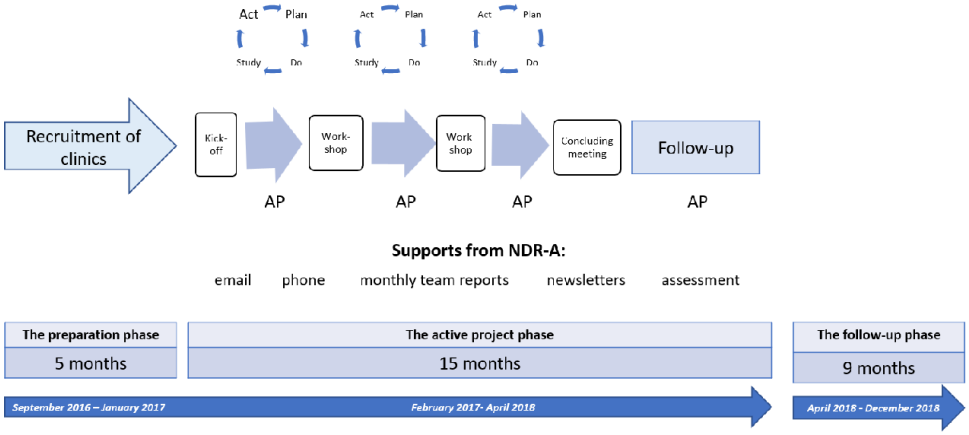

Figure 1 Flow chart illustrating the time line of the project with three phases: (1) The Preparation phase (September 2016–January 2017) where the project team was established, a plan for the intervention was developed and recruitment of clinics was performed. (2) The active project phase (February 2017–April 2018) with meetings and workshops and active periods (AP) where the clinics identified problems and improvement areas at their centre, created action plans after the kick-off meeting, tested changes, evaluated and followed up on the results. (3) Follow-up phase (April 2018–December 2018) with implementation and follow-ups of successful changes. AP, active periods; NDR-A, The Norwegian Diabetes Register for Adults.

improvement methodologies including brainstorming, using a prioritisation matrix, driver diagrams, action plans and the use of plan-do-study-act (PDSA) cycles.[15] The agendas also included professional updates about the best available treatment strategies to lower HbA1c, sharing experiences between the clinics and how to focus on the quality challenge and improved teamwork.

Clinics were required to submit action plans that included measures that could potentially reduce HbA1c values in patients with poor glycaemic control. Clinics were advised to use a PDSA model for improvement,[16] to arrange frequent team meetings to evaluate the improvement-process based on process measurements and to assess the need for adjustment to the action-plans within each clinic. Examples of actions were: more frequent use of short consultations,[1] supplementary telephone-consultations, more frequent blood glucose measurement,[17] use of continuous glucose monitoring (CGM) devices,[18] modifying insulin regimens[19–23] and structured training in self-treatment of diabetes.[24] To evaluate progress during the project the clinics received local reports including aggregated monthly data extracted from the diabetes EPR, showing the proportion of patients at their clinic with HbA1c≥75 mmol/mol. Healthcare workers could also access this data on an online graphical interface (dashboard) that was automatically updated from the diabetes EPR. In addition, this electronic dashboard solution provided benchmarking with other clinics in the QIC. Participating clinics were encouraged to study processes related to their local action plan, for example, monitoring the number of short and/or telephone consultations with patients with poor glycaemic control. However, these process-measurements are not included in this manuscript as they were not collected by the NDR-A.

The follow-up phase (from April 2018 to December 2018)

During this phase, there was ad hoc telephone and email contact between the clinics and the NDR-A. The participating clinics were encouraged to incorporate successful improvement strategies into the clinics day-to-day practices.

Patient and public involvement

The Norwegian Diabetes Association supported the project on behalf of its members and advised the project management team in the planning phase of the project. Members of the Association participated in the workshops as observers and wrote subsequently an article about the project in its member magazine.

Funding of the project

The project was funded with a grant of 1.1 million NOK from the Center for Clinical Documentation and Evaluation (SKDE), a national coordinating body for all quality registries that contributes to equal health services of good quality no matter where the patients live. The funding covered salaries for the project management, development of software for monthly reports as well as four workshops for the participants. There was no funding for additional resources at participating clinics.

Outcome measures

The primary outcome measure was the overall proportion of patients with poor glycaemic control (defined as HbA1c≥75 mmol/mol) in the intervention group compared with the control group at the following points in time: before the intervention (2016), at the completion of the active phase (2018) and 1 year later (2019). The secondary outcome measure was to compare mean HbA1c in the intervention and control groups at the same time points. Differences in change over time between the intervention clinics and the control clinics were tested by

including an interaction term between time and group in the generalised estimating equations (GEEs) models.

Data collection

The following diabetes-related variables were imported from the diabetes EPR to the NDR-A: age, sex, body mass index, smoking habits, HbA1c (both point of care and laboratory values), diabetes duration, systolic blood pressure, data on insulin treatment, percentage of patients using CGM, microalbuminuria, retinopathy requiring treatment, myocardial infarction and stroke.

To measure how the QIC progressed healthcare personnel at each clinic in the intervention group reported the self-assessed level of progress three times during the project. The question used to measure the level of impact was a five-point Likert scale (1–5) developed by the Norwegian national patient safety campaign 'In safe hands' (online supplemental file 1).[25] The target level was 4 or 5 at the end of the project.

At the end of the project healthcare personnel at the clinics in the intervention group responded to a questionnaire designed to map how work routines had changed when treating patients with poor glycaemic control (online supplemental file 2).

Finally, the proportion of patients with HbA1c≥75 mmol/mol (monthly aggregated data) were imported directly from the structured diabetes EPR for both the clinics in the intervention and control group.

Statistical analysis

The continuous variables were approximately normally distributed, and Student's t-test and χ^2 were used to test for differences between intervention- and control group at baseline. We used the differences in the proportion of patients with HbA1c≥75 mmol/mol and mean HbA1c in 2016, 2018 and 2019 as effect measures. Since there is a large but not complete overlap in patients included for the three calendar years, GEEs were used to account for repeated measurements on the same patients. We specified an unstructured correlation structure in all models. Change in average HbA1c was analysed with continuous HbA1c as dependent variable and year as a categorical independent variable with normal distribution and identity as link function. Change in proportion with HbA1c≥75 mmol/mol was analysed with the binary HbA1c variable as dependent variable and year as a categorical variable with binomial distribution and log as link function. Exponentiated regression coefficients from the models with binomial distribution and log-link were reported as risk ratios (RRs) with 95% CIs. RR from the within-group analyses describes how much the proportion with HbA1c≥75 mmol/mol is reduced (eg, RR=0.70 means that the proportion with HbA1c≥75 mmol/mol is reduced by 30%). Differences in change over time between the intervention clinics and the control clinics were tested by including an interaction term between time and group in the GEE models. The regression coefficients for the interaction terms can be interpreted as the difference in change over time between the intervention group and the control group. Due to differences in inclusion criteria for the intervention group and the control group, the difference in mean HbA1c and proportion with HbA1c≥75 mmol/mol at baseline was not random. To adjust for higher mean HbA1c and proportion with HbA1c≥75 mmol/mol at baseline in the intervention group and to take into account regression to the mean, we performed additional analyses where we omitted the main effect of group from the models.[26] For analyses of continuous HbA1c the coefficient for the interaction term at each time point can be interpreted as difference in mean Hba1c between the intervention group and the control group, conditioning on equal means at baseline. For analyses of proportion with HbA1c≥75 mmol/mol the exponentiated coefficient for the interaction term can be interpreted as relative difference in proportion with HbA1c≥75 mmol/mol in the given calendar year, conditioning on equal proportions at baseline. The p value from the Wald test for the interaction terms were used as a measure of significance for between-group difference.

As the number of people with diabetes in the QIC increased by 53% in the intervention group and 32% in the control group, we also performed a sensitivity analysis where we have only included patients that are included in the NDR-A all 3 years.

Statistical significance was assigned as p≤0.05. All statistical analyses were performed by using SPSS V.26.

To visualise longitudinal changes in the proportion of patients with HbA1c≥75 mmol/mol before and after introduction of the intervention, we constructed run-charts (statistical process control (SPC)) for participating and non-participating centres based on monthly measurements of the proportion of patients with HbA1c≥75 mmol/mol in the period 31 January 2015–31 October 2022.[27–29]

RESULTS

Demographic and clinical characteristics at baseline are presented in table 1.

The overall proportion of patients with T1DM and HbA1c≥75 mmol/mol in the intervention group at baseline (2016), at the end of the active phase (2018) and 1 year later (2019) were 19.3%, 15.5% and 14.1% (table 2). There was a reduction of 3.8% from 2016 to 2018, RR 0.77 (95% CI 0.70 to 0.85) and 5.2% from 2016 to 2019, RR 0.71 (95% CI 0.66 to 0.77). Corresponding proportions in the control group were 17.3%, 14.7% and 14.4%. This was a reduction of 2.6% from 2016 to 2018, RR 0.83 (95% CI 0.77 to 0.89) and 2.9% from 2016 to 2019, RR 0.77 (95% CI 0.69 to 0.86). In an unadjusted analysis, the reduction between 2016 and 2019 was significantly larger in the intervention group compared with the control group (p-interaction>0.001). However, the proportion with HbA1c≥75 mmol/mol at baseline was higher in the intervention group compared with the control group. In an additional analysis that was adjusted

Table 1 Characteristics of patients with type 1 diabetes in the intervention and control group at baseline (2016) for all included patients and the subsample of patients with HbA1c≥75 mmol/mol

	All patients with type 1 diabetes			Patients with type 1 diabetes and HbA1c≥75 mmol/mol		
	Control	Intervention		Control	Intervention	
Characteristics	All (n=4084)	All (n=5145)	P value*	All (n=692)	All (n=973)	P value*
Sociodemographic variables						
Age, years, mean (SD)	44 (16)	44 (16)	0.644	39 (16)	40 (11)	0.710
Female, %	45	48	0.129	46	43	0.184
Lifestyle characters						
BMI, mean (SD)	26 (5)	26 (4.6)	0.259	27 (7.5)	27 (5.0)	0.157
Smokers, %	13.2	16.3	0.012	22	25	0.246
Clinical variables						
HbA1c, mean (SD)	62 (14)	64 (14)	<0.001	86 (12)	86 (11)	0.710
Diabetic duration, years, mean (SD)	21 (14)	21 (14)	0.579	22 (15)	22 (15)	0.579
Systolic blood pressure, mean (SD)	128 (16)	128 (16)	0.663	128 (15.3)	128 (15.3)	0.647
Insulin treatment						
Insulin pen, %	63	69	<0.001	59	67	0.030
Insulin pump, %	36	31	<0.001	41	33	0.030
Continues glucose monitoring (CGM), %	20	17	0.020	18	14	0.119
Microvascular complications						
Microalbuminuria, %	6.5	4.9	0.001	9.2	8.2	0.477
Treated for retinopathy, %	15.4	14.2	0.140	17.0	18.0	0.519
Macrovascular complications						
Heart attack, %	5.7	5.0	0.115	6.0	5.9	0.967
Stroke, %	1.9	1.6	0.233	2.4	1.7	0.312

The amount of missing data was modest ranging from minimum 2% (HbA1c) to maximum 28% (use of CGM).
*Student's t-test for continues variables and χ^2 test for categorical variables.
BMI, body mass index; HbA1c, glycated haemoglobin.

for the baseline differences in the proportion of patients with HbA1c≥75 mmol/mol, the difference between the intervention group and the control group became non-significant (RR interaction=0.93, p-interaction=0.09).

The reduction in the proportion of patients with HbA1c≥75 mmol/mol from 2016 to 2018 was significant (p<0.05) for 6 of the 13 clinics in the intervention group, and for 8 clinics from 2016 to 2019. Seven of these eight clinics reported that they had reached the targeted level of progress in the QIC (level 4 or 5) at the end of the project (table 2).

In the control group, the reduction in the proportion of patients with HbA1c≥75 mmol/mol from 2016 to 2018 was significant (p<0.05) for 3 of the 14 clinics, and for 5 clinics from 2016 to 2019 (online supplemental file 3, table 1).

Mean HbA1c values for all patients in the intervention group were 64.3 mmol/mol (2016), 61.9 mmol/mol (2018) and 61.4 mmol/mol (2019) (table 3). This was a 2.6 mmol/mol (95% CI −3.2 to −2.0) (p<0.001) reduction in mean HbA1c of from 2016 to 2018, and 2.8 mmol/mol reduction (95% CI −3.2 to −2.5 mmol/mol) (p<0.001) from 2016 to 2019. In the control group mean HbA1c values were 63.1 mmol/mol (2016), 61.7 mmol/mol (2018) and 61.0 mmol/mol (2019). This was a 1.6 mmol/mol (95% CI −2.0 to −1.3) (p<0.001) reduction of mean HbA1c from 2016 to 2018, and 2.3 mmol/mol (95% CI −2.6 to −2.9) (p<0.001) reduction from 2016 to 2019. In an unadjusted analysis the reduction in mean HbA1c between 2016 and 2019 was significantly larger in the intervention group when compared with the control group (2.8 mmol/mol vs 2.3 mmol/mol (p=0.012).

However, the mean HbA1c at baseline was higher in the intervention group compared with the control group. In an additional analysis that was adjusted for the baseline differences in the mean HbA1c, the difference between the intervention group and the control group became non-significant (0.2 mmol/mol, p=0.456).

Table 3 shows that for eight of the 13 intervention clinics the reduction in mean HbA1c from 2016 to 2018 was significant (p<0.05). From 2016 to 2019, the reduction in mean HbA1c was significant for 11 of the 13 clinics. Eight of these 11 clinics reported self-assessed level of impact of

Table 2 Percentage of patients with type 1 diabetes and HbA1c≥75 mmol/mol at the diabetes outpatient clinics in the intervention and control group in 2016, 2018 and 2019, difference after intervention (2018) and 1 year after intervention (2019) from baseline (2016)

				Difference 2018–2016		Difference 2019–2016		
Intervention diabetes outpatient clinic	2016, % (n)	2018, % (n)	2019, % (n)	In percentage	RR (95% CI)	In percentage	RR (95% CI)	Level of progress December 2018
1	23.6 (152)	17.2 (174)	17.3 (205)	−6.4	**0.71* (0.61 to 0.83)**	−6.3	**0.75* (0.64 to 0.88)**	**5**
2	17.1 (72)	12.0 (56)	12.1 (63)	−5.1	**0.70* (0.54 to 0.91)**	−5.0	**0.70* (0.55 to 0.90)**	**5**
3	14.9 (35)	12.3 (44)	10.6 (41)	−2.6	0.82 (0.59 to 1.13)	−4.3	0.70 (0.48 to 1.03)	3
4	10.1 (7)	11.4 (19)	15.6 (30)	+1.3	1.08 (0.54 to 2.14)	+5.5	1.51 (0.74 to 3.08)	3
5	22.1 (73)	19.2 (71)	15.5 (70)	−2.9	−2.90.85 (0.68 to 1.07)	−6.6	**0.67* (0.53 to 0.85)**	**4**
6	23.4 (78)	14.5 (58)	10.7 (46)	−8.9	**0.60* (0.48 to 0.75)**	−12.7	**0.43* (0.33 to 0.57)**	**5**
7	19.4 (30)	13.6 (105)	13.1 (126)	−5.8	**0.68* (0.49 to 0.95)**	−6.3	**0.64* (0.47 to 0.87)**	**3**
8	23.4 (69)	19.1 (69)	16.2 (63)	−4.3	0.82 (0.65 to 1.02)	−7.2	**0.68* (0.52 to 0.90)**	**4**
9	19.9 (40)	18.1 (38)	14.8 (36)	−1.8	0.90 (0.65 to 1.26)	−5.1	0.81 (0.57 to 1.14)	3
10	17.1 (35)	19.0 (44)	15.6 (41)	+1.9	1.04 (0.78 to 1.37)	−1.5	0.86 (0.62 to 1.19)	Missing
11	21.6 (119)	17.9 (113)	15.0 (103)	−3.7	**0.81* (0.67 to 0.97)**	−6.6	**0.67* (0.55 to 0.82)**	**5**
12	14.8 (161)	12.6 (169)	11.5 (165)	−2.2	**0.84* (0.72 to 0.97)**	−3.3	**0.78* (0.66 to 0.92)**	**5**
13	20.3 (102)	18.9 (95)	17.7 (95)	−1.4	0.97 (0.83 to 1.14)	−2.6	0.89 (0.73 to 1.07)	4
All intervention clinics (n=13)	19.3 (973)	15.5 (1055)	14.1 (1084)	−3.8	**0.77* (0.70 to 0.85)**	−5.2	**0.71* (0.66 to 0.77)**	
All control clinics (n=14)	17.3 (692)	14.7 (730)	14.4 (760)	−2.6	**0.83* (0.77 to 0.89)**	−2.9	**0.77* (0.69 to 0.86)**	
Interaction test between groups (unadjusted for baseline HbA1c)					0.96 (0.87 to 1.05)		**0.88* (0.79 to 0.97)**	
Interaction test between groups (adjusted for baseline HbA1c)					1.01 (0.94 to 1.10)		0.93 (0.86 to 1.01)	

Level of progress in the QIP reported from the clinics after intervention (2018).
*p<0.05. RR of having HbA1c≥75 mmol/mol. Level of progress: Level 1: The team has not started. Plans and ideas, but no activity, Level 2: Activity without improvements. Meetings, mapping, preparation of schemes, review of previous results, various measurements, but no change in practice, Level 3: Some improvements. Changes in practice compared with baseline, Level 4: Significantly improvements obtained. Changes have resulted in measurable improvements compared with baseline, Level 5: Significantly improvements obtained, and the improvements have attained breakthrough in the system. The changes have been standardised in the system and will be continued after the end of the project.
HbA1c, glycated haemoglobin; QIP, quality improvement project; RR, relative risk.

the project in the clinic as level 4 or level 5 at the end of the project (2018).

In the control clinics, the reduction in mean HbA1c from 2016 to 2018 was significant (p<0.05) for 6 of the 14 clinics, and for 7 of the 14 clinics from 2016 to 2019 (online supplemental file 3, table 2).

Figure 2 shows SPC run-chart trends in the proportion of patients with HbA1c≥75 mmol/mol at intervention and control clinics from 31 January 2015 to 31 October 2022. The figures show a pronounced decline in the proportion of patients with HbA1c≥75 mmol/mol at intervention clinics that started when the QIC was initiated (2016). Control clinics had a similar decline in the proportion of patients with an HbA1c≥75 mmol/mol that commenced at a later stage (2018).

Sensitivity analysis

The number of people with diabetes in the QIC increased by 53% in the intervention group and 32% in the control group during the study period. This could lead to concerns that the reductions in HbA1c were due to new patients with lower HbA1c. We have, therefore, performed a sensitivity analysis (online supplemental file 4, tables 1 and 2) where we have only included patients that are included in the NDR-A all three years (2016, 2018 and 2019). The results of the sensitivity analysis show that the reduction in the proportion of patients with HbA1c≥75 mmol/mol and mean HbA1c in both groups persist.

Summary of the action plans from the clinics in the intervention group

A systematic summary of the clinic's action plans (online supplemental file 3) showed that intensified follow-up of the patients with HbA1c≥75 mmol/mol with more frequent consultations was one of the main initiatives. The additional consultations were usually short, typically lasting approximately 15–30 min, and were combined with telephone consultations every 3–4 weeks. Increased use of Diasend (Glooko, Mountain View, California, USA) to transfer blood glucose levels from the patient to the clinic before the consultations was also prioritised. In the action plans many of the clinics stated that they would attempt to improve focus on medical treatment, diet and

Table 3 Mean HbA1c in patients with type 1 diabetes in the intervention and control group in 2016, 2018 and 2019, difference in mean HbA1c after intervention (2018) and 1 year after intervention (2019) from baseline (2016)

Intervention diabetes outpatient clinic	Mean HbA1c, mmol/mol			Difference in mean HbA1c, mmol/mol		Level of progress
	2016 (n)	2018 (n)	2019 (n)	Difference 2018–2016 (95% CI)	Difference 2019–2016 (95% CI)	December 2018
1	65.9 (643)	63.1 (1012)	62.7 (1184)	**–2.8* (–3.8 to –1.8)**	**–2.9* (–4.9 to –1.9)**	**5**
2	63.0 (421)	60.3 (468)	60.0 (520)	**–2.7* (–3.8 to 1.6)**	**–2.9* (–4.0 to –1.8)**	**5**
3	61.6 (235	60.5 (358)	59.6 (388)	–1.1 (–2.4 to 0.2)	**–1.6* (–3.1 to –0.04)**	**3**
4	60.4 (69)	59.0 (166)	60.1 (192)	–1.4 (–3.7 to 0.8)	– 0.2 (–2.8 to 2.4)	3
5	65.0 (331)	62.7 (370)	62.2 (451)	**–2.3* (–3.5 to –1.1)**	**–2.8* (–4.1 to –1.4)**	**4**
6	65.8 (333)	61.5 (399)	59.3 (428)	**–4.3* (–5.6 to –3.0)**	**– 6.7* (–8.1 to –5.2)**	**5**
7	64.5 (155)	61.0 (770)	61.4 (963)	**–3.5* (–5.5 to –1.4)**	**–3.2* (–5.4 to –1.1)**	**3**
8	64.9 (295)	62.8 (361)	62.4 (388)	**–2.2* (–3.4 to –0.9)**	**–2.8* (–4.3 to –1.3)**	**4**
9	63.7 (201	62.8 (210)	62.4 (244)	–0.9 (–2.5 to 0.7)	–0.7 (–2.5 to 1.0)	3
10	64.2 (204)	63.2 (232)	61.7 (262)	–1.0 (–2.6 to 0.6)	**–2.1* (–3.7 to –0.5)**	missing
11	65.5 (550)	62.4 (631)	61.8 (686)	**–3.1* (–4.2 to –2.0)**	**–4.0* (–5.3 to –2.8)**	**5**
12	62.8 (1089)	61.5 (1324)	60.5 (1434)	**–1.2* (–1.9 to –0.6)**	**–2.0* (–2.6 to –1.4)**	**5**
13	64.1 (503)	63.7 (502)	62.6 (538)	–0.5 (–1.5 to 0.5)	**–1.5* (–2.6 to –0.4)**	**4**
All clinics in the intervention group (n=13)	64.3 (5029)	61.9 (6803)	61.4 (7678)	**–2.6* (–3.2 to –2.0)**	**–2.8* (–3.2 to –2.5)**	
All clinics in the control group (n=14)	63.1 (4000)	61.7 (4968)	61.0 (5276)	**–1.6* (–2.0 to –1.3)**	**–2.3* (–2.6 to –1.9)**	
Interaction test between groups (unadjusted for baseline HbA1c)				–0.5 (–0.9 to 0.03)	**–0.8* (–1.4 to –0.2)**	
Interaction test between groups (adjusted for baseline HbA1c)				–0.2 (–0.6 to 0.2)	–0.2 (–0.7 to –0.3)	

Level of progress in the QIP reported from the intervention clinics.
*p<0.05. Level of progress of the intervention self-reported from the clinics: Level 1: The team has not started. Plans and ideas, but no activity, Level 2: Activity without improvements. Meetings, mapping, preparation of schemes, review of previous results, various measurements, but no change in practice, Level 3: Some improvements. Changes in practice compared with baseline, Level 4: Significantly improvements obtained. Changes have resulted in measurable improvements compared with baseline, Level 5: Significantly improvements obtained, and the improvements have attained breakthrough in the system. The changes have been standardised in the system and will be continued after the end of the project.
HbA1c, glycated haemoglobin; QIP, quality improvement project.

technical equipment as well as offering patients' courses in carbohydrate estimation and the use of insulin pumps/CGM. Professional development and improved teamwork were mentioned in all the action plans.

Clinics were advised to use a PDSA method for improvement and to study processes related to their local action plans. Our impression is that most clinics implemented multiple changes at one time and that PDSA cycles were used to a slightly lesser extent than we had anticipated.

What worked well—expressed by participating clinics in the intervention group:

Feedback from meetings suggested that the following initiatives contributed to positive outcomes at most clinics:

- Participating in the workshops together with other diabetes clinics and exchanging experiences about the best way to support the patients with poor glycaemic control.
- Monthly update reports on the proportion of patients with T1DM and HbA1c≥75 mmol/mol and clinic mean HbA1c were mentioned as key elements that contributed to increased awareness and sustainability of the project.
- More frequent consultations for patients with poor glycaemic control and regular team meetings were also perceived as key success factors. At the end of the project 12 of 13 clinics reported more frequent consultations as an established routine (2018).
- Increased use of CGM.

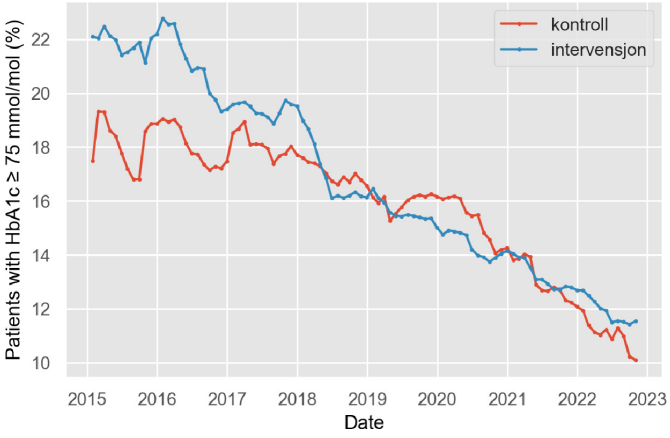

Figure 2 Statistical process control (SPC) run-chart showing the proportion of patients with HbA1c≥75 mmol/mol for intervention and control clinics in the period 31 January 2015–31 October 2022 (based on monthly updates). HbA1c, glycated haemoglobin.

DISCUSSION

Between 2016 and 2019, both the intervention clinics and the control clinics reduced the proportion of patients with poor glycaemic control (HbA1c≥75 m mmol/mol) and the mean clinic HbA1c. Overall there was a significant reduction in the proportion of patients with poor glycaemic control both at intervention clinics (19.3%–14.1%) and at control clinics (17.3%–14.4%). Overall mean HbA1c decreased by 2.8 mmol/mol at intervention clinics compared with 2.3 mmol/mol at the control clinics. At the clinic level 8 of the 13 intervention clinics vs 5 of 14 control clinics had a significant improvement in the proportion of patients with HbA1c≥75 mmol/mol and 11 of the 13 intervention clinics vs 7 of the 14 control clinics had a significant decrease in mean HbA1c. These improvements in glycaemic control over the course of 3 years across inboth intervention and control clinics are welcome findings that should reduce the risk of patients developing diabetes-related complications in the future. Can any of the improvement in glycaemic control be attributed to the QIC? The scientifically correct answer to this question is that the QIC did not contribute to the improvement in glycaemic control as there was no statistically significant differences in the improvement in glycaemic control at intervention clinics compared with control clinics after correction for baseline differences in HbA1c. This suggests that the improvements in glycaemic control were mainly driven by other factors such as more widespread use of CGM.

However, we cannot entirely exclude the possibility that the QIC contributed indirectly to the improvements in glycaemic control via a spillover effect to control clinics. Spillover effects from QICs have been reported in other quality improvement studies and may complicate designs with a control group.[12 30] Arguments in support of a spillover effect are that NDR-A has from the outset of the QIC had a plan to ensure that gains are maintained beyond the life of the collaborative and that gains are spread to all clinics in Norway. Important elements in this plan were that both intervention and control clinics were given online access to monthly updated benchmarking key performance indicator reports that display the proportion of patients with HbA1c≥75 mmol/mol, the proportion of patients with HbA1c≤53 mmol/mol and mean HbA1c at their clinic compared with other clinics and the national average. The same indicators were also included in the annual quality feedback report that the NDR-A distributes to all diabetes clinics in Norway. Furthermore, representatives from almost all clinics in Norway attend an annual NDR-A feedback meeting where the above-mentioned HbA1c quality indicators and the improvement collaborative are discussed.

Support for the argument that the QIC may have influenced glycaemic control in both groups can also be found in the SPC run chart (figure 2). At intervention clinics, a decline in proportion of patients with HbA1c≥75 mmol/mol started at the initiation of the QIC and continued to the present date. Whereas at non-participating clinics the decline started approximately 2 years later and continued to the present date.

Our study also illustrates the challenges associated with designing and analysing a QIC study in a complex and changing medical environment. We chose a controlled before and after study design. However, we invited clinics with the highest proportion of patients with HbA1c≥75 mmol/mol to participate in the intervention group as, from a quality improvement perspective, there was most room for improvement at these clinics. This introduced a bias in the study as participating clinics were identified by their 'outlier status' with respect to the proportion of patients with HbA1c≥75 mmol/mol. Additional statistical analyses were required to adjust for baseline differences in glycaemic control between intervention and control clinics. In addition, the number of patients registered at the clinics increased to a greater extent at the intervention clinics compared with control clinics and we had to perform a sensitivity analysis to assess the possibility that new patients with lower HbA1c had influenced the results.

The possibility of using a randomised controlled study (RCT) design was considered during the planning phase, but we thought that an RCT had some drawbacks as blinding is not possible in a QIC. We also reasoned that clinics might be less willing to participate in a QIC with an RCT design due to the risk that they might be allocated to a control group and that would be contrary to their wish to improve glycaemic control.

With hindsight an interrupted time series analysis may have been the best study design to evaluate the impact of this QIC. However, during the planning phase, we felt that we lacked the competency to assess the methodological considerations specific to interrupted time series analysis in this type of intervention.

Regardless of the choice of study design, it will always be difficult to evaluate the isolated effect a QIC has on a chronic condition like diabetes in a complex and changing medical environment.

The provision of monthly updated outcome data that were readily available to all healthcare workers after clicking on an icon in the diabetes EPR was probably the QIC feature that was most likely to influence provider behaviours and stimulate interest in improving glycaemic control. However, this feature was available for both intervention and control clinics and may have reduced the likelihood of finding statistically significant differences between intervention and control clinics.

Comparison with other studies

The Swedish paediatric diabetes quality registry (SWEDIABKIDS) QIC from 2014 reported a mean reduction in HbA1c of 3.7 mmol/mol in patients with T1DM.[12 31] In a meta-analysis including 120 randomised QIC, Tricco *et al* found that HbA1c was reduced by a mean difference of 0.37% (4 mmol/mol) (95% CI 0.28 to 0.45).[11] In a national QIC in Australia where 743 health services in primary care participated, the mean percentage of patients with diabetes type 1 or 2 with HbA1c≤53 mmol/mol improved from 25% at baseline to 38% after 18 months.[32] While these studies show a similar reduction in mean HbA1c during the QIC, our study also demonstrates that the patients with the poorest glycaemic control (HbA1c≥75 mmol/mol) benefited from the QIC. Helping this group of patients to improve their glycaemic control has seldom been addressed in previous studies despite that improved glycaemic control in this situation could lead to significant clinical benefit by preventing late diabetes complications and early death.[1 2 33]

Participating clinics' evaluation of important elements in the QIC

Several of the success factors described by participating clinics such as an opportunity to discuss improvement methodology and treatment strategies with colleagues at the seminars have been described in other studies.[12 34–36] However, the monthly update reports on the proportion of patients with T1DM and HbA1c≥75 mmol/mol and mean HbA1c was a novel initiative in our project. The reports were predefined at baseline and were readily available in the diabetes EPR at all the clinics. Participating centres described the reports as a key factor that contributed both to increased awareness and sustainability of the project, and that it was inspiring to follow the monthly feedback reports especially when trends started to improve.

Strengths and limitations

The study has several strengths. It was representative for the population of patients with T1DM as approximately 45% of patients with T1DM in Norway were included in the intervention or control group and reliable clinical outcome measures were available in the NDR-A. Furthermore, the study included an self-evaluation of the improvement process in each of the participating clinics—a feature that is often lacking in similar studies.[10] No clinics in the intervention group dropped out of the QIC.

We have also performed a sensitivity analysis as the number of patients included at centres increased between 2016 and 2019. The results of the sensitivity analysis confirm that the improvement in glycaemic control we find in the total population is not caused by the addition of new patients with lower HbA1c to the groups.

A limitation of the study is that we cannot rule out that increased use of CGM at all the hospitals in Norway during the project period may have been the main driver of improvement in glycaemic control in both groups.[37–41] However, when we examine national trends in the NDR-A database, we find sustained improvement in glycaemic control both in CGM users and non-users. Finally, correcting for HbA1c measurement bias was not performed and may have effected HbA1c-results.[42]

CONCLUSIONS

This registry linked QIC did not result in a significantly greater improvement in glycaemic control at intervention clinics compared with control clinics. However, there has been a sustained improvement in glycaemic control and importantly a significant reduction in the proportion of patients with poor glycaemic control at both intervention and control clinics during and after the QIC time frame. It is possible that some of this improvement may be due to a spillover effect from the QIC.

We think that our experiences with this QIC could be of interest to other countries that have national quality registries for diabetes and other chronic conditions.

Author affiliations
[1]The Norwegian Organization for Quality Improvement of Laboratory Examinations (Noklus), Haraldsplass Deaconess Hospital, Bergen, Norway
[2]Western Norway University of Applied Sciences Faculty of Health and Social Sciences, Bergen, Norway
[3]Department of Medicine, Stavanger University Hospital, Stavanger, Norway
[4]DIPS Bergen, Bergen, Norway
[5]Department of Global Public Health and Primary Care, Faculty of Medicine, University of Bergen, Bergen, Norway
[6]Department of Medical Biochemistry and Pharmacology, Haukeland University Hospital, Bergen, Norway, Bergen, Norway, Norway

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and was approved by the regional committee for medical and health research ethics in Norway (REK) assessed the project as a QIC (2018/1116/REK). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Norwegian law regulates the sharing of individual patient data and raw data from this article cannot be published in the public domain. However, data in the register are available to anyone who wishes to use the data within in the aims of the register (quality improvement, research, health analysis and statistics) provided the necessary approvals and criteria are met (for more information: https://www.noklus.no/norsk-diabetesregister-for-voksne/datatilgang/).

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Supplementary File 1. Level of progress in a Quality improvement collaborative (QIC) and description of the levels (1-5)[1].

Level of progress in a QIC	Description of the levels
1	The team has not started. Plans and ideas, but no activity
2	Activity without improvements. Meetings, mapping, review of previous results, various measurements, but no change in practice
3	Some improvements. Changes in practice compared to baseline
4	Significantly improvements obtained. Changes have resulted in measurable improvements compared with baseline
5	Significantly improvements obtained, and the improvements have attained breakthrough in the system. The changes have been standardized in the system and will be continued after the end of the project

Supplementary File 2. Questionnaire designed to map how work routines had changed when treating patients with diabetes with poor glycaemic control (defined as HbA1c ≥ 75 mmol/mol).

Questions	**Answers**
Does the department have a special focus on patients with HbA1c> 75 mmol/mol?	
Does the department use telephone consultations or e-mail correspondence as a supplement to those patients who at times need closer follow-up?	
Have patients with HbA1c ≥ 75 mmol/mol been offered more frequent consultations than before?	
Have you introduced telephone contacts with the relevant patient group as a suplement to regular consultations?	
Have you used the HbA1c reports HbA1c ≥ 75 mmol/mol at diabetes team-meetings?	
Have you used updated results on the "Dashboard" at meetings of the diabetes team?	
Did you have a start-up meeting / crowd meeting in the diabetes team at the start of the project?	
Did you make an action plan for the project?	
Did you discuss the topic of patients with HbA1c ≥ 75 mmol/mol at diabetes-team meetings at least once a month?	

Supplementary File 3

Table 1. Percentage of patients with type 1 diabetes and HbA1c ≥75 mmol/mol at each of the 14 diabetes outpatient clinics in the control group in 2016, 2018 and 2019, difference after intervention (2018) and one year after intervention (2019) from baseline (2016).

Diabetes outpatient clinic in control group	2016, % (n)	2018, % (n)	2019, % (n)	Difference in HbA1c 2018-2016 [1]				Difference in HbA1c 2019-2016 [1]			
				Difference in percentage	RR (95% CI)	*p-value*		Difference in percentage		RR (95% CI)	*p-value*
1	9.0 (178)	11.7 (196)	11.3 (213)	+2.7	1.22 (0.74-2.02)	0.443		+2.3		1.22 (0.71-2.10)	0.483
2	28.7 (87)	22.8 (127)	21.1 (142)	-5.9	0.83 (0.57-1.21)	0.326		-7.6		0.78 (0.57-1.08)	0.133
3	17.9 (884)	16.0 (1103)	12.9 (1035)	-1.9	0.87 (0.75-1.01)	0.072		-5.0		0.71 (0.60-0.84)	**<0.001**
4	17.4 (69)	14.5 (83)	11.7 (94)	-2.9	0.82 (0.53-1.29)	0.393		-5.7		0.67 (0.35-1.29)	0.231
5	23.0 (356)	17.0 (546)	15.8 (669)	-6.0	0.73 (0.59-0.92)	**0.006**		-7.2		0.68 (0.55-0.85)	**<0.001**
6	16.8 (101)	22.6 (115)	23.5 (115)	+5.8	1.27 (0.87-1.88)	0.221		+6.7		1.52 (1.01-2.28)	**0.044**
7	17.0 (53)	15.9 (63)	16.4 (67)	-1.1	0.83 (0.61-1.13)	0.241		-0.6		0.94 (0.46-1.94)	0.871
8	10.3 (985)	6.3 (1066)	7.4 (1083)	-4.0	0.61 (0.49-0.77)	**<0.001**		-2.9		0.72 (0.58-0.89)	**0.002**
9	27.3 (648)	21.2 (849)	20.9 (988)	-6.1	0.79 (0.69, 0.91)	**<0.001**		-6.4		0.77 (0.66-0.89)	**<0.001**
10	10.7 (56)	14.3 (133)	14.4 (125)	+3.6	1.30 (0.57-2.99)	0.535		+3.7		1.31 (0.60-2.84)	0.499
11	15.7 (185)	14.8 (209)	15.3 (215)	-0.9	0.91 (0.63-1.31)	0.603		-0.4		0.88 (0.59-1.31)	0.519
12	9.2 (65)	14.3 (77)	13.8 (80)	+5.1	1.47 (0.71-3.11)	0.294		+4.6		1.47 (0.67-3.23)	0.337
13	17.6 (119)	14.1 (156)	17.2 (180)	-3.5	0.75 (0.51-1.01)	0.130		-0.4		0.96 (0.66-1.40)	0.826
14	15.4 (214)	12.2 (245)	14.1 (270)	-3.2	0.83 (0.61-1.13)	0.240		-1.3		0.89 (0.65-1.23)	0.482

[1] RR and p-value calculated from binomial Generalized Estimating Equations (GEE)- model with log link and unstructured correlation structure. CI= Confidence interval

Table 2. Mean HbA1c in patients with type 1 diabetes in the 14 diabetes outpatient clinics in the control group in 2016, 2018 og 2019, difference in mean HbA1c after intervention (2018) and one year after intervention (2019) from baseline (2016).

Diabetes outpatient clinic in control group	Mean HbA1c, mmol/mol				Difference in mean HbA1c, mmol/mol			
	2016 (n)	2018 (n)	2019 (n)		Difference 2018-2016 (95% CI)	*p-value**	Difference 2019-2016 (95% CI)	*p-value**
1	58.8 (178)	59.3 (196)	57.7 (213)		0.2 (-2.0, 2.3)	0.887	-1.4 (-3.8, 1.1)	0.272
2	68.4 (87)	65.3 (127)	63.4 (142)		-3.2 (-6.2, -0.3)	**0.032**	-4.2 (-6.8, -1.6)	**0.002**
3	62.6 (884)	62.1 (1103)	60.1 (1035)		-0.8 (-1.5, -0.01)	0.050	-2.7 (3.5, -1.9)	**<0.001**
4	60.7 (69)	57.4 (83)	58.2 (94)		-3.2 (-5.8, -0.6)	**0.016**	-2.4 (-5.3, 0.6)	0.113
5	66.4 (356)	63.1 (546)	62.0 (669)		-3.0 (-4.4, -1.6)	**<0.001**	-4.1 (-5.6, -2.7)	**<0.001**
6	61.6 (101)	64.3 (115)	64.4 (115)		2.2 (-0.04, 4.5)	0.054	3.2 (0.8, 5.5)	**0.008**
7	61.6 (53)	64.0 (63)	63.5 (67)		1.8 (-1.0, 4.7)	0.213	1.7 (-1.3, 4.7)	0.272
8	61.4 (985)	58.3 (1066)	57.6 (1083)		-3.4 (-3.9, -2.8)	**<0.001**	-3.9 (-4.5, -3.3)	**<0.001**
9	67.2 (648)	65.2 (849)	65.0 (988)		-1.7 (-2.6, -0.7)	**<0.001**	-1.7 (-2.7, -0.6)	**0.002**
10	63.8 (56)	63.2 (133)	62.1 (125)		-0.9 (-3.1, 1.3)	0.412	-2.0 (-4.3, 0.3)	0.088
11	62.8 (185)	62.3 (209)	61.8 (215)		-0.7 (-2.2, 0.9)	0.409	-1.6 (-3.5, 0.3)	0.105
12	58.1 (65)	60.3 (77)	60.8 (80)		1.2 (-1.0, 3.4)	0.275	2.3 (0.1, 4.5)	**0.043**
13	61.9 (119)	62.4 (156)	61.6 (180)		0.2 (-1.9, 2.4)	0.834	0.3 (-1.9, 2.5)	0.763
14	60.9 (214)	58.2 (245)	59.6 (270)		-2.2 (-3.6, -0.8)	**0.003**	-1.0 (-2.5, 0.5)	0.203

*p-value calculated from linear Generalized Estimating Equations (GEE)- model with identity link and unstructured correlation structure. CI= Confidence interval.

Supplementary File 4

Table 1. Sensitivity analysis of overall percentage of patients with type 1 diabetes and HbA1c ≥75 mmol/mol and RR (95% CI) at the diabetes outpatient clinics in the intervention- and control group in 2016, 2018 and 2019, difference after intervention (2018) and one year after intervention (2019) from baseline (2016).

	Overall percentage of patients with type 1 diabetes and HbA1c ≥75 mmol/mol				**Difference in HbA1c 2018-2016[3]**			**Difference in HbA1c 2019-2016[3]**		
	2016, % (n) [1]	**2018, % (n) [1]**	**2016, % (n) [2]**	**2019, % (n) [2]**	**Difference in percentage**	**RR (95% CI)**	***p-value***	**Difference in percentage**	**RR (95% CI)**	***p-value***
All intervention clinics (n=13)	19.1 (807)	14.9 (630)	19.1 (787)	13.2 (546)	-4.2	0.78 (0.73-0.84)	**<0.001**	-5.9	0.69 (0.64-0.75)	**<0.001**
All control clinics (n=14)	16.5 (557)	13.0 (439)	16.3 (520)	12.4 (395)	-3.5	0.79 (0.72-0.86)	**<0.001**	-3.9	0.76 (0.69-0.83)	**<0.001**
Interaction test between groups (unadjusted for baseline HbA1c)						0.99 (0.89-1.11)	0.864		0.91 (0.81-1.03)	0.146
Interaction test between groups (adjusted for baseline HbA1c)						1.06 (0.96-1.17)	0.253		0.99 (0.89-1.11)	0.885

[1] Patients with type 1 diabetes and HbA1c measured in both 2016 and 2018. [2] Patients with type 1 diabetes and HbA1c measured in both 2016 and 2019. [3] RR (relative risk of having HbA1c ≥ 75 mmol/mol) and corresponding p-value calculated from binomial GEE model with log link and unstructured correlation structure.

Table 2. Sensitivity analysis of overall mean HbA1c of patients with type 1 diabetes at the diabetes outpatient clinics in the intervention- and control group in 2016, 2018 and 2019, difference after intervention (2018) and one year after intervention (2019) from baseline (2016).

	Overall mean HbA1c for patients with type 1 diabetes					Difference in mean HbA1c, mmol/mol			
	2016 (n) [1]	2018 (n) [1]		2016 (n) [2]	2019 (n) [2]	Difference 2018-2016 (95% CI)	*p-value*[3]	Difference 2018-2016 (95% CI)	*p*-value[3]
All clinics in the intervention group (n=13)	64.2 (4220)	62.2 (4220)		64.1 (4127)	61.5 (4127)	-2.1 (-2.4, -1.7)	**<0.001**	-2.7 (-3.0, -2.3)	**<0.001**
All clinics in the control group (n=14)	62.9 (3374)	61.1 (3374)		62.7 (3198)	60.4 (3198)	-1.8 (-2.2, -1.5)	**<0.001**	-2.3 (-2.7, -1.9)	**<0.001**
Interaction test between groups (unadjusted for baseline HbA1c)						-0.3 (-0.7, 0.2)	0.317	-0.3 (-0.9, 0.2)	0.233
Interaction test between groups (adjusted for baseline HbA1c)						0.2 (-0.2, 0.6)	0.370	0.2 (-0.2, 0.7)	0.316

[1] Patients with type 1 diabetes and HbA1c measured in both 2016 and 2018. [2] Patients with type 1 diabetes and HbA1c measured in both 2016 and 2019. [3] p-value calculated from linear GEE model with identity link and unstructured correlation structure

Supplementary File 5. Summary of key elements from the action plans made by the intervention outpatient diabetes clinics to reduce the proportion of patients with HbA1c ≥ 75 mmol/mol.

- Make a list of patients with HbA1c ≥75 mmol/mol, and each caregiver responsible for a patient should have a review of the treatment plan for their patients.
- Offer more frequent consultation for a period for the patients with T1DM and HbA1c ≥ 75 mmol/mol.
- Raise awareness for each of the patients that a high HbA1c is serious condition that require action, and map the reasons for the lack of goal attainment
- Encourage to more frequent self-monitoring for the patients that measure to rarely
- Change to the newest insulin for the patients with old regimes. For example, to slow-acting insulin analogues to reduce the risk of hypoglycemia
- Increase use of insulin pump and the clinic's competence
- Increase use of CGM and the clinic's competence
- Re-education in diet and use of insulin
- Offer courses to the patients to increase the diabetes-knowledge when needed
- Offer courses in diet and carbohydrate assessment at the clinic
- Increased use of telephone consultations in addition to ordinary consultations
- What to do with patients that do not meet for ordinary consultations
- Increase use of Diasend
- Offer individual conversations and group conversations with psychologist or other personnel with skills in behavior-change
- Weekly and/or monthly discussion of process goal and share of patients with HbA1c ≥75 mmol/mol in the diabetes team using local reports and dashboard
- Courses in the clinics regarding challenges related to patients with diabetes and HbA1c ≥75 mmol/mol