**Identifying effective pathways in a successful continuous quality improvement programme: The
GEDAPS Study**

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Abstract

Rationale, Aims and Objective: Continuous quality improvement programmes often target several aspects of care, some of which may be more effective meaning that resources could be focussed on these. The objective was to identify the effective and ineffective aspects of a successful continuous quality improvement programme for individuals with type 2 diabetes in primary care.

Methods: Data were from a series of cross-sectional studies (GEDAPS) in primary care, Catalonia, Spain in 55 centres (2239 participants) in 1993, and 92 centres (5819 participants) in 2002. A structural equation modelling approach was used.

Results: The intervention was associated with improved microvascular outcomes through microalbuminuria and funduscopy screening, which had a direct effect on microvascular outcomes, and through attending 2-4 nurse visits and having ≥ 1 blood pressure measurement which acted through reducing systolic blood pressure. The intervention was associated with improved macrovascular outcomes through blood pressure measurement and attending 2-4 nurse visits (through systolic blood pressure) and having ≥ 3 education topics, ≥ 1 HbA1c measurement and adequate medication (through HbA1c). Cholesterol measurement, weight measurement and foot examination did not contribute towards the effectiveness of the intervention.

Conclusions: The pathways through which a continuous quality improvement programme appeared to act to reduce microvascular and macrovascular complications were driven by reductions in systolic blood pressure and HbA1c, which were attained through changes in nurse and education visits, measurement and medication. This suggests these factors are potential areas on which future quality improvement programmes should focus.

Introduction

Continuous quality improvement programmes can result in better care and health for patients with type 2 diabetes mellitus (T2DM) [1-3]. These programmes employ a cyclical process of data audit and feedback to identify weaknesses and educational needs of health care practitioners, and to improve services for patients [4,5]. This service improvement often takes a multifactorial approach depending on the issues raised by the data, and may include tactics such as education and mentoring for health care professionals, improving referral pathways, and providing self-management programmes for patients. This and other factors mean that these programmes typically fit the Medical Research Council (MRC) complex intervention definition [6].

Process, intermediate and final outcome indicators are often collected and fed back in quality improvement programmes and then targeted for improvement [7]. Process or implementation indicators relate to the organisation, are markers of the quality of care received by patients, and can be an early indicator of improvements in care; for example, the percentage of patients who have had their blood pressure (BP) measured. Intermediate outcomes relate to the patient and are usually biomarkers associated with a subsequent adverse condition. For example, HbA1c is a commonly used intermediate outcome in T2DM research due its strong association with mortality and microvascular and macrovascular complications [8]. Final outcomes also relate to patients and tend to be hard outcomes, such as morbidity or mortality. The same outcomes are typically used to evaluate the programme. It is important to include both process and outcome indicators in such an evaluation to provide supporting evidence that the changes were resulted from the programme, rather than external influences, so long as the process and outcome indicators have an established relationship [7].

Structural equation modelling is recommended by the MRC [6] to characterise the resulting pathways from the programme through the process indicators to the final outcomes. We employed this approach in a novel setting to identify effective causal pathways in a primary care continuous quality improvement programme implemented in Catalonia, Spain to improve the quality of care received by patients with T2DM [1,9]. The programme has been shown to improve patient outcomes [1,9], and partly adopted by the national health service [10,11]. Understanding the pathways through which such programmes are effective is vital if they are to be generalised to and adopted in other settings.

Methods

The GEDAPS Study

The GEDAPS Group (Group of Study of Diabetes in Primary Care) implemented a continuous quality improvement programme to improve the quality of care received by patients with T2DM in primary care (Catalonia, Spain; 1993-2002). A detailed description is available elsewhere [1,9]. This was a multifactorial programme that included regular data feedback, the publishing of guidelines, and the provision of workshops and seminars to implement the St Vincent recommendations [12].

Participating centres were volunteers. Annual workshops were delivered by region with approximately 20-25 participants per session, usually comprising one general practitioner (GP) and one nurse per centre. Attendees were expected to pass on knowledge from the workshop to other professionals in their centre. Anonymous data feedback involved providing centres with their average value of key indicators and discussing these with them, in comparison with average results from their local area and Catalonia, to identify methods for improving services. There were also ad hoc activities between sessions, such as the transfer of requested articles.

At each data collection point (1993, 1995, 1998, 2000, 2002), data were collected from paper medical records for the year prior to data collection (except amputations which included all prevalent amputations). Centres provided summary information about the centre, such as the number of doctors, and individual level data for approximately 5% (n=30-50) of randomly selected patients with T2DM registered at the centre. A different random selection was conducted each time, thus a series of cross-sectional studies were performed. Patients were excluded if they had type 1 diabetes, had been diagnosed with T2DM or registered at the practice for less than 6 months, were cared for solely by other professionals or in secondary care, were terminally ill or had an extremely limited quality of life, or had not had any contact with the centre in the preceding year. If a patient was excluded then the next patient of the same gender was included. Patients were not required to give written informed consent because the study was based on retrospective, anonymous clinical records. The study was approved by the Consell Assessor de la Diabetis (Advisory Board on Diabetes) of the Health Department of the Autonomous Government in Catalunya that behaved as the Institutional Review Board.

Variables

Process indicators, agreed in advance with the professionals participating in GEDAPS, were 2-4 nursing visits per year, at least three patient educational interventions, funduscopy screening,

microalbuminuria screening, foot examination, and at least one measurement of BP, HbA1c, total cholesterol, and weight (all binary). The number of GP visits was also recorded but was excluded due to high correlation with the number of nurse visits. The desirable number of nursing visits was set as 2-4 by the investigators who believed that this reflected a sufficient level of care without overburdening patients. The number of educational interventions reflects the number of education topics that the patient discussed with their GP and/or nurse, regardless of the number of visits. The programme also focussed on tackling clinical inertia, therefore we added a further process indicator: prescription of adequate anti-hyperglycaemic medication (binary). Treatment was reported as no medication, oral anti-diabetic drug only, insulin only, or oral drug and insulin. Patients were defined to be adequately treated, except those with HbA1c >8% on no medication or oral anti-diabetic drugs only who were defined to be inadequately treated.

Intermediate outcomes were HbA1c, total cholesterol, body mass index and systolic BP (SBP; all continuous), and current smoker (binary). HDL cholesterol and diastolic BP were also measured but were not included as they were highly correlated with total cholesterol and SBP, respectively, which would affect the model fit. Final outcomes were grouped as microvascular and macrovascular complications. Microvascular complications were defined as at least one of microalbuminuria (>30mg/24-hour sample before 2000; albumin/creatinine ratio >30mg/dl from 2000), renal failure (plasma creatinine > 1.5mg/dl), or retinopathy (presence of any lesion diagnosed by an ophthalmologist, including amaurosis). Macrovascular complications were defined as at least one of coronary artery disease (acute myocardial infarction or angor pectoris recorded in primary care or hospital records), stroke or transient ischaemic attack (recorded in primary care or hospital records), foot ulcer or low limb amputation (registered in the clinical record of the foot examination). A combined outcome of any microvascular or macrovascular complication was analysed but results were very similar to those for microvascular complications and so are not shown.

Statistical analysis

The purpose of the analyses was to identify pathways through which the intervention impacted on the final outcomes via the process and intermediate indicators. Data were summarised by centre and year as mean and percentage for continuous and binary variables, respectively. These summary data were used in the analyses, so all available data were included and else, by definition, the only people with a value available would be those who had had it measured.

The same process was used to select separate structural equation models for microvascular and macrovascular complications. First, the full model was fitted, which included all plausible paths from the intervention to the final outcome. The intervention (defined as 0 in 1993, 1 in other years) could only directly affect process outcomes, nurse and education visits were hypothesised to affect all intermediate outcomes, measurement indicators to affect the outcome they were measuring, and anti-hyperglycaemic medication to affect HbA1c. All intermediate outcomes and foot examination, microalbuminuria screening and funduscopy were hypothesised to directly affect the final outcome. The full models were the same, except that microalbuminuria screening and funduscopy were only in the microvascular model, and foot examination was only in the macrovascular model.

After the full model was fitted, the following steps were taken to identify the best fitting, most parsimonious model: 1) intermediate outcomes non-significantly associated with the final outcome were removed, 2) incomplete pathways were removed, 3) non-significant effects of process on intermediate outcomes were removed, 4) incomplete pathways were removed, 5) plausible pathways and co-variances identified using modification indices were added, 6) excluded intermediate and process outcomes were added back in one at a time, 7) latent variables were added where pathways were incomplete, and 8) non-significant variables were removed. At all stages except the last, the model with the lowest Akaike's Information Criterion (AIC) was selected, and so changes were discarded if they resulted in an increase in AIC. The process was repeated until doing so no longer improved the model fit. Analyses were performed in Stata v13.0. P-values less than 0.05 were treated as statistically significant. Foot complications are not always counted as macrovascular complications, therefore sensitivity analyses were performed by re-fitting the final macrovascular model with foot complications excluded.

Results

Table 1 shows the characteristics of participating centres and their patients. The number of participating centres increased over time, and subsequently the number of individuals for whom data were available also increased. The percentage of urban centres and females decreased slightly over time, while the mean age and mean diabetes duration increased slightly. Most process indicators significantly improved over time, except for BP measurements, weight measurements and funduscopy which significantly declined, and education topics which did not change significantly. The number of smokers and average BMI increased over time, but SBP, HbA1c and total cholesterol improved as did all final outcomes.

The best fitting model for microvascular complications is shown in Figure 1. In line with the summary analyses (Table 1), the intervention was associated with a significant increase in the percentage of people who had microalbuminuria screening by 30% (95% CI: 25%, 36%), increased attendance at 2-4 nurse visits by 8% (95% CI: 4%, 12%), and a decrease in the percentage of people who had BP measurements and funduscopy screening by 2% (95% CI: 0%, 3%) and 7% (95% CI: 5%, 9%) respectively. For each 10% increase in the percentage of people who had had a BP measurement or had attended 2-4 nurse visits, the mean SBP in the centre was 0.3 (95% CI: -0.4, 1.0) mmHg or 0.5 (95% CI: 0.3, 0.8) mmHg lower on average, respectively. Higher SBP, microalbuminuria screening and funduscopy screening were associated with increased occurrence of microvascular complications in the preceding year; for example, a 1 mmHg increase in mean SBP was associated with a 0.20% (95% CI: 0.06%, 0.34%) increase in prevalence of microvascular complications.

Figure 2 shows the best fitting model for macrovascular complications. The intervention was associated with a lower percentage of people having a BP measurement, and a higher percentage of people having 2-4 nurse visits, at least three education topics, an HbA1c measurement and being on adequate medication. A higher percentage of people having 2-4 nurse visits and at least one BP measurement were associated with lower SBP. A higher percentage of people having at least three education topics and an HbA1c measurement were associated with higher HbA1c, whilst being on adequate medication was associated with lower HbA1c. Higher SBP and HbA1c were associated with more macrovascular complications. Estimates were similar, albeit weaker, when foot complications were not included in the definition of macrovascular complications (Supplementary Figure 1).

Discussion

These analyses identified causal pathways through which a successful continuous quality improvement programme may have resulted in reductions in microvascular and macrovascular complications. Both of these pathways acted through SBP and one acted through HbA1c, which could suggest that these are intermediate outcomes on which similar programmes should focus on improving.

In both models, attending 2-4 nurse visits and having at least one BP measurement were associated with lower SBP, which in turn was associated with fewer complications, in line with other studies [13]. This suggests that if resources are limited then focussing on improving these processes would potentially have a greater impact than focussing on other areas, particularly in terms of lowering SBP by a small but significant amount. That is not to say that the improvement of other processes and

intermediate outcomes should be ignored, but only that many health centres do not have the resources to improve all areas at once and so have to prioritise, but often lack guidance in how to set these priorities [14]. Conversely, three process indicators were not part of any of the identified pathways (cholesterol measurement, weight measurement and foot examination); therefore, it might be reasonable to give these processes a lower priority, though they currently form part of recommended guidelines for routine care [15], and other studies have shown that foot examinations lead to lower amputations [16]. It was expected a priori that approximately 2-4 nurse visits would reflect a high standard of care, as patients may need at least 2 visits to receive enough nurse contact time to receive a sufficient level of care, but that too many visits can also be detrimental as it places a high burden on patients, and could reflect that a lower quality of care is being delivered in each session, thus the need for more sessions. It seems plausible that the quality of each nurse session improved since GEDAPS included education programmes for nurses to help them to better manage their T2DM patients, and it has been shown that such programmes result in better care processes [17].

For macrovascular complications, there was also a significant pathway through reduced HbA1c, which accords with knowledge that higher HbA1c is associated with increased risk of macrovascular complications [8]. The processes that were associated with lower HbA1c were being on adequate medication, receiving less than three education topics, and not having HbA1c measured. It is unsurprising that being on adequate anti-hyperglycaemic medication was associated with lower HbA1c since these medications have been shown to be effective in lowering HbA1c [18]. It seems counter-intuitive however that fewer education topics and measurements would be related to lower HbA1c, and this is in direct contrast to other evidence [19]. It is plausible that this reflects the cross-sectional nature of the data and that these associations are due to reverse causality, i.e. participants with high HbA1c values had their HbA1c measured more regularly and received more education as to how to manage their diabetes. Indeed, there is evidence that patients' with poorly controlled glucose levels have more primary care visits, which would support this hypothesis [20].

The uptake of microalbuminuria screening increased greatly over the study period from 34% to 73%. Whilst it is possible that GEDAPS contributed to this increase, it is likely that this increase is due largely to the introduction of albumin:creatinine ratio to diagnosis microalbuminuria during the study period [21]. Conversely, funduscopy screening decreased slightly over the study period from 50% to 46%, in contrast with other studies which showed an increase in eye examinations over a similar period [22]. While this decline is small, it was significant and it is disappointing not to see an increase in uptake to funduscopy, as observed for microalbuminuria and foot complication

screening. It is probable that this is because funduscopy is performed by an ophthalmologist and so the referral pathway is more complicated than for other screening types, since patients need to be referred by their GP, receive an appointment from the ophthalmologist, and then attend that appointment. This highlights a need for this process to be improved in Catalonia; such improvements are already underway since the introduction of equipment that allows images to be taken by a member of the primary health care team. Despite these differences, both microalbuminuria screening and funduscopy were associated with increased microvascular complications. This is probably because those who were diagnosed with retinopathy or nephropathy must have been screened for these conditions. It is a limitation of this study that prospective data on the same individuals were not available to be able to observe the known long term benefits of screening on complication rates [23,24].

Co-variances between same-level indicators were added where they improved the fit of the model. Both models included nearly all of the possible co-variances between process indicators. This is unsurprising since centres that are good at one process are likely to be good at others [25]. This also reflects the high correlation between the process and outcome indicators that were measured, and further adds to the earlier argument that it is worth prioritising certain processes for improvement, since other processes are likely to also improve to some extent by virtue of this correlation.

The primary limitation of this study is that it comprises a series of cross-sectional studies; it would have been desirable to have prospective data on the same set of subjects for these analyses. These data were not collected because the primary aim of the data collection was as part of the continuous quality improvement programme, and for that purpose it is usual to review a sample of randomly selected records as was done in this study. Furthermore, participation in the study was voluntary, and so included centres may have been more motivated. The impact of this limitation is however likely to be small since it seems unlikely that effective pathways would differ systematically between motivated and unmotivated centres. Finally, medication data other than anti-diabetic treatment were not available, and the study data are now relatively old (1993-2002), however the aspects of diabetes care considered in this study, such as regular screening and measurement, are still advocated, therefore these results remain relevant. The study has many strengths, such as the novelty of the analysis approach, the multifactorial, pragmatic approach of the programme, the adoption of the programme into practice ensuring that the findings are clinically relevant, and the availability of long term outcomes.

In these analyses of a successful continuous quality improvement programme for the care of people with T2DM in primary care, we identified pathways through which the programme appeared to act

to reduce microvascular and macrovascular complications. These pathways were driven by reductions in SBP and HbA1c which were attained through changes in nurse and education visits, measurement and medication. This suggests these factors are potential areas on which future continuous quality improvement programmes should focus.

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Figure legends

Figure 1

Title: Final model for microvascular complications showing the significant pathways from the intervention to the outcome.

Footnotes: All process level co-variances were included except microalbuminuria screening-funduscopy screening and nurse visits-blood pressure measurements as these did not improve the fit of the model.

Numbers are beta coefficient (95% confidence interval).

Abbreviations: BP, Blood Pressure.

Figure 2

Title: Final model for macrovascular complications showing the significant pathways from the intervention to the outcome.

Footnotes: All process and intermediate outcome co-variances were included except nurse visits with BP measure, education topics and HbA1c measurement, as these did not improve the fit of the model.

Numbers are beta coefficient (95% confidence interval).

Abbreviations: BP, Blood Pressure.

Table 1. Characteristics of participating centres and their patients.

Variable	1993	1995	1998	2000	2002	P for trend
Centre characteristics						
Number of participating centres	55 (100.0)	76 (100.0)	77 (100.0)	81 (100.0)	92 (100.0)	
Urban centres	36 (65.5)	43 (56.6)	43 (55.8)	44 (54.3)	54 (58.7)	0.022
Patients characteristics						
Number of participants	2239 (100.0)	3532 (100.0)	4217 (100.0)	4564 (100.0)	5819 (100.0)	
Female	1268 (56.6)	1925 (54.5)	2230 (52.9)	2380 (52.1)	3017 (51.8)	<0.001
Age, years	65.2 [10.2]	66.3 [10.3]	67.2 [10.6]	67.1 [10.8]	67.3 [10.9]	<0.001
Diabetes duration, years	7.5 [7.1]	7.8 [7.5]	8.2 [7.1]	7.6 [6.8]	8.0 [7.0]	<0.001
Process indicators						
2-4 Nurse visits	648 (28.9)	992 (28.1)	1456 (34.5)	1734 (38.0)	2559 (44.0)	<0.001
≥3 Education topics	569 (25.4)	1545 (43.7)	1638 (38.8)	1499 (32.8)	2062 (35.4)	0.835
≥1 BP measurement	2115 (94.5)	3284 (93.0)	3963 (94.0)	4201 (92.0)	5370 (92.3)	<0.001
≥1 HbA1c measurement	1528 (68.2)	2822 (79.9)	3613 (85.7)	3884 (85.1)	5042 (86.6)	<0.001
Adequate medication ^a	560 (25.0)	964 (27.3)	1216 (28.8)	1238 (27.1)	1469 (25.2)	<0.001
≥1 Cholesterol measurement	1699 (75.9)	2842 (80.5)	3506 (83.1)	3854 (84.4)	5034 (86.5)	<0.001
≥1 Weight measurement	2039 (91.1)	3148 (89.1)	3894 (92.3)	4008 (87.8)	5011 (86.1)	<0.001
≥1 Foot examination	1094 (48.9)	2060 (58.3)	2289 (54.3)	2469 (54.1)	3294 (56.6)	0.004
≥1 Funduscopy screening	1129 (50.4)	1656 (46.9)	1995 (47.3)	2022 (44.3)	2671 (45.9)	<0.001
≥1 Microalbuminuria screening	759 (33.9)	1729 (49.0)	2636 (62.5)	3134 (68.7)	4235 (72.8)	<0.001
Intermediate outcomes						
Current smoker	273 (12.2)	436 (12.3)	572 (13.9)	589 (12.9)	812 (14.0)	0.046
Systolic BP, mmHg	143.8 [17.2]	143.1 [16.9]	141.8 [16.1]	139.5 [15.6]	137.9 [15.3]	<0.001

HbA1c, %	7.7 [1.9]	7.6 [1.6]	7.1 [1.6]	7.0 [1.7]	7.1 [1.4]	<0.001
Total cholesterol, mg/dl	227.8 [42.5]	223.8 [41.3]	221.6 [42.4]	210.4 [40.7]	206.6 [40.0]	<0.001
BMI, kg/m ²	29.1 [4.6]	29.1 [4.7]	29.5 [4.8]	29.8 [4.9]	29.9 [4.9]	<0.001
Final outcomes						
Microvascular complications	553 (24.7)	748 (21.2)	972 (23.0)	910 (19.9)	1143 (19.6)	<0.001
Macrovascular complications	520 (23.2)	733 (20.8)	814 (19.3)	785 (17.2)	1023 (17.6)	<0.001
Any complications	870 (38.9)	1234 (34.9)	1508 (35.8)	1471 (32.2)	1870 (32.1)	<0.001

Data are n (%) or mean [standard deviation].

^a Poorly controlled patients (HbA1c>8%) on no medication or only on oral anti-diabetic drugs were defined to have inadequate medication. All other patients were defined to have adequate medication.

Figure 1.

Figure 2.