Title

Evaluating the impact of an enhanced primary care diabetes service on diabetes outcomes; a pilot study.

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Abstract

Introduction

Globally, the high proportion of health care utilisation associated with diabetes exerts considerable financial pressure on health services mainly due to outpatient consultations, unplanned hospitalisation, and subsequent prolonged length of stay.

Methods

In this before and after study, eight pilot general practices providing enhanced diabetes care in Leicester UK, were compared with matched neighbouring practices with comparable benchmark demographic features providing standard care. The primary outcome at twelve months was to demonstrate equivalence in non-elective bed days. The secondary outcomes were equivalence in first outpatient appointments and hospitalisation for diabetes and its complications. The enhanced practices had general practitioners and nurses with an interest in diabetes who attended regular diabetes education meetings. The teams provided care plans for complex diabetes patients, received audit feedbacks and engaged in complex case-study discussions monthly. The control practices provided a primary-specialist care service, delivered by usual general practitioners but supported by diabetes specialist nurses, dieticians and podiatrists, working under the supervision of diabetes specialists in the secondary care units in an integrated manner.
Results

There was no statistically significant change in the difference in any of the outcomes between matched Core and Enhanced practices after the follow up. The overall mean change from baseline for the matched percentage non-elective bed days was -2.20% (95% confidence interval = -5.31%, 0.92%) per adult population. The analogous percentages for first outpatients’ attendance was -0.23% (-5.19%, 4.74%) and for diabetes and related complications admissions was -0.3% (-1.45%, 0.85%).

Conclusion

Our enhanced primary care diabetes service appears to be safe and unlikely to increase hospitalisations, first outpatients’ attendance or admissions for diabetes related complications any more than an integrated specialist –community care diabetes service. A more comprehensive evaluation of the whole service is currently being performed and is expected to further demonstrate the effectiveness.
Introduction

People with diabetes are at greater risk for cardiovascular disease, renal disease, endocrine/metabolic complications, and other chronic complications. A portion of health care use associated with these medical conditions exerts considerable pressure on health care (1). In the UK, between October and December 2014, there were 1.4 million emergency admissions to hospital; 4.3 million people attended a first outpatient appointment. Moreover, ten percent of patients admitted as emergencies stay for more than two weeks, but these patients account for 55 percent of bed days (2). In the USA in 2004, US$2.4bn was estimated to have been spent on potentially preventable hospitalisations due to uncontrolled diabetes (3).

Since diabetes can cause several acute and chronic complications which could potentially lead to hospitalisations, focusing on reducing admissions and/or the duration of episodes of admissions for people with diabetes has a huge potential for reducing hospital bed use. Emergency admissions resulting from diabetes or its complications are an unexpected health event and could represent poor outcomes or failure to initiate or augment the management of a patient with diabetes at the appropriate time (4). The resultant effect of this is not just economic loss to health care systems, but it puts a strain on patients and their families. Although some emergency admissions may be unavoidable, some may be preventable, and inability to prevent them could indicate an inefficient use of healthcare resources and negatively impacting patients’ quality of life. Reducing bed days could be a key indicator of healthcare quality and underpins appropriate allocation of resources and assessment of the impact of secondary prevention activities.

In recognition of the fragmentation of care of people with diabetes between specialist and primary care teams resulting in poor and costly outcomes, many centres have devised various models of diabetes care to suit their local populations. These models are usually multi-component interventions targeting multi-faceted health care professionals’ interaction in an integrated fashion to improve outcomes. The Chronic Care Model is an example of this integrated care and is based on
a paradigm shift of dealing with acute care issues to a system that is prevention based (5-7). The model works on the basis that quality diabetes care is not delivered independently and can be enhanced by system redesign, community resources, self-management support, decision support, clinical information systems, and organizational support working in tandem to enhance patient-provider interactions (5, 6, 8). An evaluation of this model in the US suggests that its implementation in the community is effective in improving clinical and behavioural outcomes in patients with diabetes (9, 10).

In Leicester UK, the City Clinical Commissioning Group recently reconfigured diabetes services. Working together, various stakeholders developed an innovative care model that aimed to achieve an integrated diabetes service across community, primary and acute care resulting in a more cost-effective, accessible and high quality service for all patients. General practices in the city were classified as “enhanced” or “core”. The enhanced practices used general practitioners and nurses with an interest in diabetes to provide the diabetes service in their practices. The core practices provided a primary-specialist care service, delivered by usual general practitioners but supported by diabetes specialist nurses, dieticians and podiatrists, working under the supervision of diabetes specialists in the secondary care units in an integrated manner. This evaluation focuses specifically on the impact of enhanced care package (a key part of the service redesign) on unplanned hospitalisations and length of stay for patients with diabetes (non-elective bed days). The components of the enhanced care package include supported discharges of patient from specialist care from secondary care, training, care planning, clinical engagements audits and feedback. A more detailed evaluation is currently being performed on the whole of the service redesign. Our primary objective was to demonstrate that the service provided by the enhanced practices does not lead to an increase in non-elective bed days over and above the usual care provided during the follow up period. We chose to aim for non-inferiority instead of superiority because usual care in the city of Leicester is provided by the Integrated Community Diabetes Service (ICDS) which is a multidisciplinary service that provides diabetes care closer to home for patients with poor glycaemic
control. This service has already proved to be effective in reducing hospital admissions, numbers of ambulance call-outs for treatment of hypoglycaemia, increased numbers of patients able to self-manage by 5% each year, ensures all patients have an individualised care plan, effective type 2 insulin initiation within 14 days from referral and a robust training package for all staff (11). As a result of the success of the ICDS, any alternative service redesign has got to be at least as effective. A secondary objective was to prevent an increase in first out-patient attendance for diabetes in the practices providing enhanced care. We also evaluated the impact of the enhanced care package on diabetes related comorbid bed days (admission with type 2 diabetes as primary diagnosis with selected comorbidities; non-fatal myocardial infarction, non-fatal stroke, major foot amputations and hypoglycaemia in the same spell).

**Patients and Methods**

This was a before and after study. Data from all diabetes patients older than 17 years of age registered in eight selected pilot general practices providing enhanced diabetes care in the city of Leicester were used in this evaluation. These data were compared with eight matched general practices drawn from the city of Leicester with comparable benchmarks in population demographics including age, deprivation and co-morbidities. Ethnicity data are poorly coded and not included but matched control practices were chosen only if they were within a one mile vicinity of the enhanced practice with which they were compared. In all eight enhanced practices used for the pilot, there was suitable matched practice within a mile. The east of Leicester is inhabited by a predominantly south-Asian population as opposed to the west. Therefore matched control and enhanced practices consisted of similar ethnicity composition. The evaluation was done on the care delivered between April 2013 and April 2014.
Exposure of Interest

In the practices offering the enhanced care, the lead general practitioner in each of the practices in the exposure group had to have an interest in diabetes and be studying towards or completed an MSc in Diabetes or updating their diabetes knowledge through our locally accredited programme (Effective Diabetes Education Now (EDEN)). They were supported in their practices by a practice nurse with similar or equivalent diabetes qualifications. These teams were charged with identifying patients who can be discharged from secondary care and managed effectively in primary care and target patients with an HbA1c greater than 8% (64mmol/mol) for care planning. They also focused on those diabetes patients with multi-morbidities and those who were house-bound for care-planning. The teams met up once a month for clinical discussions around complex diabetes cases selected from their practices. Monthly audits of outpatient attendances and hospital admissions were also discussed and fed back to practices. The lead general practitioners discussed stable patients still under specialist care with the specialists in charge of the patient’s care and if it was appropriated and the patients were in agreement, they were discharged back to primary care. Clinicians followed clinical care pathways for various aspects of diabetes care and referrals, and received telephone based support for complex cases, depending on the needs of the general practitioner. The enhanced practices therefore had all the resources to successfully manage the repatriation of patients from specialist care to primary care. The choice of non-elective bed days (as opposed to all bed days) as the primary outcome was to hopefully rule out admissions due to the specialist level conditions such as antenatal diabetes, diabetic foot care, renal, insulin pumps, Type 1/adolescent diabetes inpatient diabetes care (12) and complex unstable diabetes patients since the admissions from these would have been electively arranged by hospital specialists.

In the non-enhanced practices (core practices), basic diabetes care is provided as usual by general practitioners. In order to limit a two tier system of care for patients in the city and thus avoid the widening of variation in the quality of care provided, the clinicians in the core practices are
supported by diabetes specialist nurses, dieticians and podiatrists, working under the supervision of diabetes specialists in the secondary care units in an integrated manner.

Data Sources

The outcome data were drawn primarily from the Hospital Episode Statistics (HES) database. The HES database is made up of many data items relating to admitted and outpatient care delivered by NHS hospitals in England with diagnoses coded using the WHO’s International Classification of Diseases 10th revision [ICD-10].

To ensure independence, the team analysing the data did not perform the data extraction. This was dealt with by a third party who used the Mirror tool to extract the data for analysis. This tool was developed by Merck Sharp & Dohme Limited (“MSD”). The tool uses the same approach as the NHS uses in England to produce cost data based on a coding system called Healthcare Resource Group (HRG) to reimburse hospitals for the treatment they deliver. HRG is a grouping system where patient events or spells consuming a similar level of resource are allocated a cost. In order to maintain patient confidentiality, no patient’s name or unique identifier is present in this tool.

For the diabetes related non-elective admissions, we searched admissions with only type 2 diabetes as a primary diagnosis using E11 code. Similarly, for the admissions with type 2 diabetes and co-morbidities we searched E11 code and non-fatal myocardial infarction or non-fatal stroke or major foot amputations or hypoglycaemia in the same spell using I21 or I22 or I64 or E16.2 or S88 or S98 or T13.6 or T05.2-6.

The baseline data variables such as the prevalence, percentage male, percentage age over 65, deprivation and percentages achieving targets on the various cardiovascular risk factors were drawn from publicly available data on general practices in England on http://fingertips.phe.org.uk/profile/general-practice (13).
Because the data were extracted from publicly available data sources without any patient identifiers, ethical clearance for this analysis was deemed unnecessary.

**Statistical analysis**

We summarised baseline characteristics of the two groups (enhanced and core) separately using means and standard deviations. We used independent t-test analysis to compare the baseline characteristics between enhanced and core practices.

Since we were aiming for non-inferiority between the enhanced care and usual care, a lower confidence interval of not more than zero indicated a lack of increase for the outcomes. We computed the difference between the diabetes related non-elective bed days in the core and the enhanced practices before the practice accreditation was introduced (April, 2013) and 12 months later (April, 2014). A paired t-test analysis was conducted between these repeated measures to account for the practice matching. Non-elective hospitalisation (bed-days) is an undesirable outcome. If the difference between the non-elective bed days between matched core and enhanced practices is positive at any time point it means there were less of these hospitalisations in the enhanced practices at that time point. If it is negative, then the hospitalisations were more in the enhanced practices at that time point. An increase in this figure after a follow up period would suggests a relative increase in hospitalisation in the enhanced practices.

For the secondary outcomes, again, we computed the difference between the first out-patients attendance, admissions of patients with diabetes and non-fatal myocardial infarctions, major foot amputations and non-fatal strokes between the core and enhanced practices before and after the practice accreditation was introduced, before analysing the differences in these repeated measures with paired t-tests. We estimated the quality of cardiovascular risk factor control by computing mean of percentage of people achieving all four cardiovascular risk factors (HbA1c \( \leq \) 8%, blood
pressure \leq 140/80\text{mmHg},\ total\ cholesterol \leq 5\text{mmol/L}\ and\ being\ treated\ with\ renin\ angiotensin\ system\ inhibitors\ if\ a\ patient\ has\ micro-albumuria).\ Even\ though\ the\ diabetes\ related\ non-elective\ bed\ days\ refer\ to\ patients\ admitted\ with\ diabetes\ as\ a\ primary\ diagnosis,\ it\ is\ possible\ that\ some\ of\ the\ admissions\ for\ these\ diabetes\ patients\ are\ for\ other\ reasons\ unrelated\ to\ their\ diabetes\ or\ its\ complications,\ for\ example\ road\ traffic\ collisions.\ We\ carried\ out\ a\ sensitivity\ analysis\ using\ all\ admissions\ for\ diabetes\ patients\ with\ (diabetes\ as\ either\ a\ primary\ diagnosis\ or\ secondary\ diagnosis\ to\ compute\ the\ bed\ days\ and\ then\ conducted\ paired\ t-tests\ again\ to\ see\ if\ the\ results\ differed\ from\ the\ findings\ of\ the\ initial\ analysis.

Results

In total, we had access to a population of 83,435 adult patients over 17 years of age; of these 7707 have diabetes, giving a prevalence of 9.2%. Out of the total population considered, 57,943 (69.4%) were registered in enhanced practices.

The baseline characteristics were similar in both sets of populations as there were no statistically significant differences between them (Table 1). There were no significant differences between enhanced and core practices in terms of social deprivation score (p = 0.90), age (p = 0.17) or percentage of patients having at least one bed day with a diabetes co-morbidity (p = 0.71). Enhanced practices had a slightly higher percentage of male patients (p = 0.07), of patients meeting quality of care indicators (p = 0.09), and of patients having at least one non-elective bed day (p = 0.08), but these differences were not quite significant at the 5% level.

The main results are summarised in Table 2. In 2013, 1.76% more of the patients in the enhanced practices had at least one bed day than in the core practices, but in 2014 0.44% more of the patients in the core practices had at least one bed day. This change from 2013 to 2014 was not significant.
(mean = -2.20%, 95% CI = -5.31 to 0.92, p = 0.14). In the sensitivity analysis, the change from baseline was -2.90% (95% CI = -3.11%, 8.94%) per adult diabetes population over 17 years.

Similarly, differences between the first outpatient attendance per thousand adult population in matched core and enhanced practices did not increase over the 12 months of follow up. The change from baseline was -0.23 (-5.19, 4.74) per thousand population. At baseline the number of first outpatient attendances was 3.79 per thousand of the adult population less in the enhanced practices than the core practices. This figure showed a trend of even further improvement to 4.01 per thousand at the end of the follow up period.

Admissions with type 2 diabetes complication was measured as the percentage of any admission with type 2 diabetes and non-fatal myocardial Infarction or non-fatal stroke or major foot amputations in the same spell per adult population over 17 years. The difference between this in the matched core and enhanced practices did not increase over the 12 months of follow up. The change from baseline was -0.3(-1.45, 0.85). Even though at baseline the percentage of admissions with diabetes and its complications was more in the enhanced practices than the core practices by 0.15% per adult population, by the end of the follow up period, a trend towards slightly less admissions with diabetes and is complications of 0.16 per adult population was noted in these practices over the core practices.

Discussion

Our analysis demonstrates that, at the very least, this enhanced care package aspect of our service redesign is not any worse than diabetes care that is provided by the usually more expensive primary-specialist integrated care, working under the supervision of diabetes specialists in the secondary care units. The prevention of an increment in the non-elective bed days, first outpatient’s attendances and admissions with diabetes related complications has the potential to make the
practice accreditation more cost-effective as diabetes service delivery in specialist settings tend to be more expensive (14).

Also as the enhanced care package has been shown to be non-inferior to the specialist assisted integrated care provided in the core practices, we can be more confident that through the service redesign, the unintended consequence widening of variation in the quality of care for diabetes patients has not been created. In a recent study in Australia, an innovative integrated primary–secondary model of care for people with complex Type 2 diabetes demonstrated less admission for a diabetes-related complication than those receiving usual care (15). This integrated care model consisted of a multidisciplinary, community-based and integrated primary–secondary care diabetes service like the care received by our core practices. Another study evaluated this integrated primary–secondary model of care for people with complex Type 2 diabetes and showed not only positive impact on quality of the care but also did this at lower cost than usual care (16, 17). Hence this further supports the success of the non-inferiority demonstrated by our enhanced practices. In the general population, reviews and meta-analysis on secondary cardiac prevention programmes have shown improved processes of care (18) and improved patient outcomes (19). A more recent meta-analysis showed that organisational interventions led to 21% reduced all-cause mortality and a 26% cardiac-related mortality. However, not enough data were available to assess for interventions on hospital admissions (20). In these studies however, these benefits tend to diminish as time goes on thereby leading to doubts on long term clinical and economic outcomes. The use of well-trained, well-organised primary care teams, offering enhanced diabetes care as we are suggesting could potentially provide longer lasting benefits.

Repeated admissions to hospitals are increasingly being used as a measure of quality of care of patients by primary care teams in most developed countries (21, 22). In the organisation of diabetes models of care it is important to demonstrate that the service delivery is both safe and of a high
enough quality as what is already available before the analysis for any cost savings can be completed. Our enhanced care delivery seems to have achieved this.

Our secondary objective demonstrated a lack of increase in the first out patient’s attendance in the enhanced practices when compared to the core integrated practices. This means that diabetes patients get to be managed safely by well-trained primary care teams closer to their homes, possibly at a lower tariff. In addition specialist teams, both physicians and nurses, are spared to focus on more complex diabetes and endocrine conditions in the specialist settings.

**Strengths and weaknesses of the study**

The strength of this analysis is the fact that we focused mainly on clinical outcomes and admissions and outpatients attendances as opposed surrogate markers like HbA1c, blood pressure and cholesterol. Previous studies on structured integrated services redesigns have always focused on these intermediate outcomes (9, 23-27). An attempt was made to match practices in the exposed and control groups according to diabetes related characteristics and population demographics including age, co-morbidities and ethnicity. Admissions of people with diabetes could be for other reasons other than diabetes. Hence in our main analysis, we used cases in which diabetes as stated as a primary diagnosis. Furthermore, we extracted all diabetes admissions, whether diabetes was a primary or secondary diagnosis, and conducted a sensitivity analysis. The results of this further analysis were concordant with our main findings.

The main weakness of this study is that it is a population-based study but with a small sample size. Presence of real improvement in all the outcomes over and above what has been noted in this analysis is a possibility. Further more detailed evaluation involving all the practices is the city of Leicester will be adequately powered to reveal the real benefits. Also the analysis was hampered due to the lack of access to the use individual patient clinical data from practice computer systems
over the period. Our analysis was therefore handicapped by being forced to use practice level data which is relatively insensitive.

A further economic evaluation will be necessary to ascertain if there is any cost savings derived from the enhanced care package. Until then it is difficult to tell if the possible cost savings derived from the lack of increase in the non-elective bed days, first out-patient attendances and admissions with diabetes and its complications will be offset by the cost of the enhanced care package.

**Implications for practice**

Firstly, these findings are of relevance to policy makers in countries with well-established primary care services who aim to provide a safe and good quality care away from specialist centres which are associated increasing costs of delivering hospital inpatient care.

In an attempt to decrease the over dependence on the usually expensive specialist based treatments and to reduce the burden of chronic disease, models of care along the lines of the chronic care model (9) and the primary-specialist care integrated care models have been shown to improve quality outcomes for people with complex conditions (28, 29). In the UK however, services integrations can usually be very difficult to achieve due to constraints in varying sources of funding for primary and specialist teams. The use of well drained primary care teams providing service along the lines of our enhance care teams could be an alternative. This could also be welcomed by the patients who would be guaranteed continuity of care from their family physician who in addition to knowing a lot about their diabetes, also has good knowledge of the patients’ other biopsychosocial aspects of life.

**Conclusion**

Our analysis indicates that the use of structured diabetes shared care service redesign, involving enhanced diabetes-skilled primary care physicians, nurses and health care assistants in primary care
settings is unlikely to increase hospitalisations, first outpatients attendance or even admissions for diabetes related complications any more than an integrated specialist–community care core diabetes service

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We also acknowledge Merck Sharp & Dohme Limited ("MSD") for doing the data extraction as a third party.

**Declarations**

SS has received honoraria for speaking at meetings and serving on Advisory Boards for Novartis, Novo Nordisk, Janssen, MSD, Lilly and Bi.

MJD has acted as consultant, advisory board member and speaker for Novo Nordisk, Sanofi-Aventis, Lilly, Merck Sharp & Dohme, Boehringer Ingelheim, AstraZeneca and Janssen and as a speaker for Mitsubishi Tanabe Pharma Corporation. She has received grants in support of investigator and investigator initiated trials from Novo Nordisk, Sanofi-Aventis and Lilly.

KK has received funds for research, honoraria for speaking at meetings and or served on Advisory Boards for Astra Zeneca, Lilly, Novartis, Pfizer, Servier, Sanofi Aventis, MSD and Novo Nordisk.

DHB has no conflict of interest.
References


Table 1: Baseline characteristics in practices offering enhanced care and those offering core (usual) care

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Enhanced practices (N = 57,943)</th>
<th>Core practices (N=25,492)</th>
<th>p-value(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deprivation score (IMD)</td>
<td>34.04 (11.05)</td>
<td>33.33 (12.00)</td>
<td>0.903</td>
</tr>
<tr>
<td>Percentage male</td>
<td>49.40 (2.55)</td>
<td>52.55 (3.70)</td>
<td>0.067</td>
</tr>
<tr>
<td>Percentage over 65</td>
<td>14.20 (4.05)</td>
<td>11.31 (3.94)</td>
<td>0.170</td>
</tr>
<tr>
<td>Quality of care indicator(^{††})</td>
<td>78.09 (5.60)</td>
<td>70.34 (10.61)</td>
<td>0.089</td>
</tr>
<tr>
<td>NEBD 13(^◆)</td>
<td>5.62 (2.11)</td>
<td>3.82 (1.62)</td>
<td>0.077</td>
</tr>
<tr>
<td>COM13(^◆◆)</td>
<td>0.93 (0.67)</td>
<td>0.78 (0.87)</td>
<td>0.706</td>
</tr>
</tbody>
</table>

Abbreviations: COM 13, Co-morbid admissions in 2013; NEBD13, Non-elective bed days in 2013.

\(^a\) P-values compare enhanced and core practices and were estimated using independent t-tests .

\(^{††}\): Average of percentage of people achieving all four cardiovascular risk factor targets (HbA1c =/ <8% or 64 mmol/mol, blood pressure =/><140/80 mmHg, total cholesterol =/><5mmol/L, and being treated with ACE-I if there is microalbumuria)

\(^◆\): Non-elective bed days per 100 diabetes patients over 17 years between Enhanced and Core practices in 2013-

\(^◆◆\): Any admission with type 2 diabetes and non-fatal myocardial infarction or non-fatal stroke or major foot amputations in the same spell per 100 diabetes patients over 17 years in 2013.
Table 2: Effect of enhanced diabetes service on non-elective bed days, first outpatient attendance and hospitalisation with diabetes its complications.

<table>
<thead>
<tr>
<th>Difference in outcomes between matched Core and Enhanced practices. Mean (SD).</th>
<th>Change from baseline</th>
<th>95% Confidence Interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-elective bed days †.</td>
<td>0.44 (3.94)</td>
<td>-2.20</td>
<td>-5.31-0.92</td>
</tr>
<tr>
<td>Sensitivity analysis for non-elective bed days∞</td>
<td>4.50</td>
<td>-2.91</td>
<td>-3.11-8.94</td>
</tr>
<tr>
<td>First outpatient attendance ◆</td>
<td>1.59</td>
<td>-0.23</td>
<td>-5.19-4.74</td>
</tr>
<tr>
<td>Admission with type 2 diabetes complication††</td>
<td>0.16 (0.99)</td>
<td>-0.30</td>
<td>-1.45-0.85</td>
</tr>
</tbody>
</table>

†: Non-elective bed days are measured as the percentage per adult population over 17 years.

◆: First outpatient attendance is measured as the percentage per thousand population.

††: Admissions with type 2 diabetes complication is measured as the percentage of any admission with type 2 diabetes and non-fatal myocardial Infarction or non-fatal Stroke or major foot amputations in the same spell per adult population over 17 years.

∞: This analysis includes all non-elective admissions for diabetes patients (measured as the percentage per adult population over 17 years) whether diabetes is the primary diagnosis or secondary diagnosis.