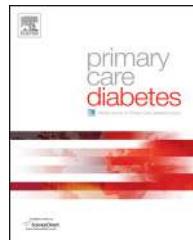




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Original research

Evaluating the impact of an enhanced primary care diabetes service on diabetes outcomes: A before–after study

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ABSTRACT

Diabetes is an ambulatory care-sensitive condition and a high quality primary care or risk factor control can lead to a decrease in the risk of non-elective hospitalisations while ensuring continuity of care with usual primary care teams.

Aims and methods: In this before and after study, eight primary care practices providing a newer enhanced diabetes model of care in Leicester UK, were compared with matched neighbouring practices with comparable demographic features providing a more expensive integrated specialist—community care diabetes service. The primary outcome at twelve months was to demonstrate equivalence in non-elective bed days. The enhanced practices had primary care physicians and nurses with an interest in diabetes who attended monthly diabetes education meetings and provided care plans and audits. The control practices provided an integrated primary-specialist care service.

Results: The difference between the mean change in the non-elective bed days from baseline and at follow up in core and enhanced practices was not statistically significant (mean = 2.20 per 100 patients, 95% CI = -0.92 to 5.31 per 100 patients, $p=0.14$). The analogous change for first outpatients' attendance were 0.23 per 100 patients (95% CI = -0.47 to 0.52 per 100 patients $p=0.92$) and for diabetes related complications admissions was 0.30 per 100 patients (95% CI = -0.85 to 1.45 per 100 patients $p=0.55$).

Conclusion: A model of enhanced primary care based diabetes care appears unlikely to increase hospitalisations, outpatients' attendance or admissions for diabetes related complications.

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1. 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]. Diabetes is a primary care-sensitive or ambulatory care-sensitive condition and a high quality primary care or risk factor control can lead to a decrease in the risk of non-elective hospitalisation due to these conditions. In the general UK population, 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% of patients admitted as emergencies stayed for more than two weeks, but these patients accounted for 55% 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 the number and/or duration 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] thus indicating an inefficient use of healthcare resources.

Many centres have now devised various models of diabetes care to suit their local populations [5]. These models are usually multi-component interventions targeting multi-faceted health care professionals' interaction in an integrated fashion to improve outcomes [6]. 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 [7-9]. 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 [10,11]. Many such models are being implemented in other countries including the UK. In Leicester UK, the City Clinical Commissioning Group (CCG) recently reconfigured diabetes services. General practices in the city were classified as "enhanced" or "core". The new enhanced practices used primary care physicians (PCPs) with an interest in diabetes, supported by multidisciplinary primary care teams to provide the service within their practices. The core practices provided usual care, an-integrated specialist-community care diabetes service, universally available to all primary care physicians and their patients.

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). 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 core service. We chose to evaluate non-inferiority instead of superiority because core care in the city of Leicester is provided by intermediate care clinics for diabetes (ICCD) [12], which is a multidisciplinary service that

provides diabetes care closer to home for patients with poor glycaemic control. The service had already been evaluated and appeared to be effective in reducing hospital admissions and numbers of ambulance call-outs for treatment of hypoglycaemia [13]. As a result of these successes, our alternative service redesign, which is cheaper, should not reduce the quality of the care. A secondary objective was to examine whether there was also equivalence in first outpatient attendance for diabetes between the practices providing enhanced and core 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 and at least one of the following comorbidities: non-fatal myocardial infarction, non-fatal stroke, major foot amputations and hypoglycaemia in the same spell).

2. 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 general practices providing enhanced diabetes care in the city of Leicester, UK 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 namely percentage of patients older than 65 years of age, mean deprivation (Index of Multiple Deprivation 2010) scores, percentage of patients with at least one co-morbidity (non-fatal myocardial infarction or non-fatal stroke or major foot amputations). For each of the eight enhanced practices, there was a suitably matched practice within one mile. If there were more than one, the practice most similar in terms of the matching characteristics was used. Ethnicity data are poorly coded and were not included in the matching process. A predominantly south-Asian population as opposed to the west, inhabits the east of Leicester. Therefore since matched core and enhanced practices were within one-mile vicinity, they were assumed to consist of similar ethnicity composition. The evaluation was done on the care delivered prior to April 2013 (before) and April 2014 (after).

2.1. Exposure of interest

In the practices offering the enhanced care, the lead PCP had to have an interest in diabetes and be studying towards or have completed an MSc in Diabetes or updating their diabetes knowledge through our locally accredited programme (Effective Diabetes Education Now (EDEN)). A practice nurse with similar or equivalent diabetes qualifications supported them. These teams were charged with identifying patients who could be discharged from secondary care and managed effectively in primary care. They targeted patients with HbA1c greater than 8% (64 mmol/mol), multi-morbidities and those who were housebound for care planning. The teams met up once a month for clinical discussions around complex diabetes cases selected from their practices. 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 PCP. The non-elective bed days (as opposed to all bed days) was chosen as the pri-

mary outcome in an attempt to rule out admissions due to the specialist level conditions.

2.2. Data sources

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

To ensure independence, a third party extracted the data using 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.

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 analysed were diabetes prevalence, percentage male, percentage of people aged over 65, deprivation and percentages achieving targets on the various cardiovascular risk factors. We estimated the quality of cardiovascular risk factor control by computing mean percentage of people achieving all four cardiovascular risk factors ($\text{HbA1c} \leq 8\%$, 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). All these baseline variables were drawn from publicly available data on general practices in England [14]. Because the data were extracted from publicly available data sources without any patient identifiers, ethical clearance for these analyses was deemed unnecessary.

2.3. Statistical analysis

Baseline characteristics of the two groups (Enhanced and Core) were summarised separately using means and standard deviations. Paired t-test analyses were used to compare the baseline characteristics between enhanced and core practices.

We computed the change in the number of diabetes related non-elective bed days between 2013 and 2014 in the enhanced and the core practices. Since we were evaluating non-inferiority between the enhanced care and core care, a lower confidence interval of not more than zero indicated a lack of increase for the outcomes. A paired t-test analysis was conducted to compare the change from baseline (2013) between the two groups. Non-elective hospitalisation (bed-days) is an undesirable outcome with a positive change from baseline implying more of these hospitalisations at follow-up and vice-versa. For the secondary outcomes, again, we computed the change in the first outpatients' attendance, admissions of patients with diabetes and non-fatal myocardial infarctions, major foot amputations and non-fatal strokes between 2013 and 2014 in the enhanced and the core. A paired t-test analysis was conducted to compare the change from baseline between the two groups. A sensitivity analysis was

conducted 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 primary analysis. All the outcome data were expressed per hundred adult patients ≥ 18 years of age due to differences in patient list size between the practices. Statistical analyses were performed using SPSS (version 22.0, Chicago, IL, US).

3. Results

Data were available for 8366 adult patients with type 2 diabetes and aged ≥ 18 years of age in the sixteen practices. Of these, 6054 (72.4%) were registered in the eight enhanced practices and 2312 (27.6%) were registered in eight matched core practices.

The baseline characteristics were similar in both types of practices (Table 1) apart from the percentage of male patients which in the enhanced practices was (mean [SD] = 49.4% [2.6%]) and in the core practices (52.6% [3.7%]; $p = 0.011$). However, when a linear regression analysis was conducted for the mean differences in the outcomes upon the difference in the percentage of male patients in the core and enhanced practices, there was no statistically significant correlation between any of them and the percentage of male patients; $p = 0.089$, 0.44, 0.63 and 0.20 for non-elective bed days, first outpatient appointment, admissions with type 2 diabetes and complications and admissions with type 2 diabetes-primary or secondary respectively.

The main results are summarised in Table 2. Whereas in the core practices the mean change in non-elective bed days was 1.29 (2.85) per 100 patients, suggesting an increase in non-elective admission after the follow up periods, in the enhanced practices the mean change in non-elective bed days was -0.91 (2.1) per 100 patients suggesting a trend towards a decrease in non-elective bed days after the follow up period. The difference between the non-elective bed days in core practices and that in enhanced practices was not significant (mean = 2.20 per 100 patients, 95% CI = -0.92 to 5.31 per 100 patients, $p = 0.14$). In the sensitivity analysis, when the analysis included all non-elective admissions for diabetes patients whether diabetes was the primary diagnosis or secondary diagnosis, the difference between the non-elective bed days in core practices and that in enhanced practices was 2.78 per 100 patients (95% CI = -2.71 to 8.27 per 100 patients, $p = 0.27$).

Similarly, differences between the mean first outpatient attendances in the adult population in matched core and enhanced practices also increased over the 12 months of follow up. The difference between the mean first outpatient attendance in the core practices and that in enhanced practices was 0.02 per 100 patients (95% CI = -0.47 to 0.52, per 100 patients $p = 0.92$), suggesting a trend towards a decrease in the first outpatients' attendance in the enhanced practices at the end of the follow up period. Admissions with type 2 diabetes complications were 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

Table 1 – Baseline characteristics in practices offering enhanced care and those offering core (usual) care Mean (SD).

| Baseline characteristics | Enhanced practices (N=57,943) | Core practices (N=25,492) | p-Value* |
|--|-------------------------------|---------------------------|----------|
| Deprivation score (IMD) | 34.04 (11.05) | 33.33 (12.00) | 0.780 |
| Percentage male patients | 49.40 (2.55) | 52.55 (3.70) | 0.011 |
| Percentage of patients aged ≥65 years | 14.20 (4.05) | 11.31 (3.94) | 0.219 |
| Quality of care indicator ^a | 78.09 (5.60) | 70.34 (10.61) | 0.073 |
| Non-elective bed days ^b | 5.62 (2.11) | 3.82 (1.62) | 0.075 |
| Co-morbid admissions ^c | 0.93 (0.67) | 0.78 (0.87) | 0.734 |

IMD: index of multiple deprivation.

* p-Values compare enhanced and core practices and were estimated using paired t-tests.

^a 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 = <5 mmol/L, and being treated with ACE-I if there is microalbumuria).^b Non-elective bed days per 100 diabetes patients ≥18 years of age.^c 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 ≥18 years in 2013.**Table 2 – Effect of enhanced diabetes services on non-elective bed days, first outpatient attendance and hospitalisation with diabetes its complications.**

| Outcome ^c | Change from 2013 to 2014 | | Mean difference | Lower confidence interval | Upper confidence interval | p-Value ^a |
|--|--------------------------|------------------------------|-----------------|---------------------------|---------------------------|----------------------|
| | Core practices mean (SD) | Enhanced practices mean (SD) | | | | |
| Non-elective bed days | | | | | | |
| Diabetes as primary diagnosis | 1.29 (2.85) | -0.91 (2.1) | 2.20 | -0.92 | 5.32 | 0.14 |
| Diabetes as primary or secondary diagnosis ^b | 3.85 (5.86) | 1.06 (4.01) | 2.78 | -2.71 | 8.27 | 0.27 |
| First outpatient attendance | -0.10 (0.38) | -0.13 (0.44) | 0.02 | -0.47 | 0.52 | 0.92 |
| Admission with type 2 diabetes complication ^d | 0.04 (1.09) | -0.26 (0.60) | 0.30 | -0.85 | 1.45 | 0.55 |

^a Comparing change from 2013 to 2014 between core and enhanced practices estimated using paired t-tests.^b This analysis includes all non-elective admissions for diabetes patients whether diabetes is the primary diagnosis or secondary diagnosis.^c All outcome data reported per hundred patient populations over 17 years.^d Admissions with type 2 diabetes complication is measured as any admission with type 2 diabetes and non-fatal myocardial Infarction or non-fatal Stroke or major foot amputations in the same spell.

not increase over the 12 months of follow ups 0.30 per 100 patients (95% CI = -0.85 to 1.45 per 100 patients p=0.55) suggesting a trend towards a decrease in the admissions in the enhanced practices at the end of the follow up period.

4. Discussion

Our analysis demonstrates that, this enhanced care package aspect of our service redesign had similar outcomes to that provided by the more expensive primary-specialist integrated care [12]. The prevention of an increment in the outcomes has the potential to make the enhanced diabetes service more cost-effective as diabetes service delivery in specialist settings tend to be more expensive [15]. The choice of the ICCD as a comparator could have blunted the benefits of our enhanced care package. This is because ICCD has already been evaluated and proved to be effective in reducing hospital admissions [13]. Probably if our comparator service was another service delivery system, such as the NHS Portsmouth CCG, we could have demonstrated superiority in the outcomes. This CCG has similar characteristics such as population density, indices of deprivation 2010 (average score) and percentage of population from black ethnic groups to NHS Leicester City CCG [16,17]. This allows for appropriate benchmarking. This CCG has had

its own service re-organisation since 2009 [5]. As of December 2013, people with diabetes in NHS Portsmouth CCG were 77.2% more likely to have a myocardial infarction, 33.1% more likely to have a stroke, 85.7% more likely to have a hospital admission related to heart failure and 42.1% more likely to die than the general population in the same area [16]. In the same period, people with diabetes in NHS Leicester City CCG were only 38.9% more likely to have a myocardial infarction, 14.8% more likely to have a stroke, 58.7% more likely to have a hospital admission related to heart failure and 24.5% more likely to die than the general population in the same area [17].

Our findings support a recent study in Australia where an innovative integrated primary-secondary model of care for people with complex type 2 diabetes demonstrated fewer admissions for a diabetes-related complication than those receiving usual care [18]. This integrated care model consisted of a multidisciplinary, community-based and integrated primary-secondary care diabetes service similar to the care received in the core practices in Leicester City. 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 [19], hence further supporting the success of the non-inferiority demonstrated by the enhanced practices.

In the general population, reviews and meta-analysis of secondary cardiac prevention programmes have shown improved processes of care [20] and improved patient outcomes [21]. A more recent meta-analysis showed that organisational interventions led to 21% reduced all-cause mortality and a 26% reduction in cardiac-related mortality [22]. 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, which was the basis of the intervention evaluated in this study, could potentially provide longer lasting benefits. The longevity of the benefits could be truncated by competing pressures from other disease conditions. However, when primary care teams collaborate with each other, they may be able to accommodate these challenges. People with diabetes can be managed safely by well-trained primary care teams closer to their homes. 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 [23]. 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. Here we demonstrate that our enhanced care delivery seem to achieve this.

4.1. 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 [10,24–28]. In these previous studies, even when improvements in metabolic outcomes were demonstrated, one could directly extrapolate that these would lead to important clinical outcomes like out-patients' attendances and admissions with diabetes related complications. Hence the use of real meaningful clinical outcomes demonstrates a strength of this analysis. 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 was 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. All the outcome data were collected independently.

The main weakness of this study is that it is an observational study with a small sample size. Also, the matching of practices could not take into account practice list sizes as the focus was matching the patient demographic characteristics.

4.2. 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 [29] away from specialist centres, which are associated with 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 [10] and the primary-specialist care integrated care models have been shown to improve quality outcomes for people with complex conditions [30,31]. In many countries 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-trained 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.

5. Conclusion

Our analyses indicated that the use of a 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, outpatients' attendance or admissions for diabetes related complications any more than an integrated specialist-community care core diabetes service.

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Author contributions

SS co-ordinated the enhanced diabetes service, led the design, analysis and writing up of the project.

KK, MJD and DHB, directly supervised the project, design, analysis and writing up of the project.

EMB helped with the writing and proof-reading of the drafts.

HD led the upskilling of the primary care teams and accreditation of their practices to provide enhanced care.

BS co-ordinated the delivery of the project for all the practices.

AF led the conception of diabetes transformation in Leices-ter and all the subsequent pathway way redesigns.

Conflict of interest

SS has received honoraria for speaking at meetings and serving on Advisory Boards for Novartis, Sanofi-Aventis, Novo Nordisk, Janssen, Merck Sharp & Dohme, AstraZeneca, Lilly and Boehringer Ingelheim.

AF has received honoraria for speaking at meetings for Novartis, Sanofi-Aventis, Novo Nordisk, Janssen, Merck Sharp & Dohme, AstraZeneca, Lilly and Boehringer Ingelheim.

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, Janssen, Servier, Sanofi Aventis, MSD and Novo Nordisk.

DHB, EMB, HD and BS have no conflict of interest.

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