A controlled before–after trial of structured diabetes care in primary health centres in a newly developed country

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Abstract

Objective. To evaluate the long-term impact of a structured approach to improving the quality of diabetes care in general practice in the United Arab Emirates.

Design. Controlled before–after trial within a health district with three primary health centres (PHCs) in the intervention group and the six remaining serving as controls. Outcomes and adherence to guidelines were measured over the year before the intervention began and for a second 1-year period at the end of the intervention period. Data were collected by chart abstraction.

Setting. The study was performed in PHCs in the United Arab Emirates, a newly developed country on the Arabian peninsula.

Study participants. Subjects continuously followed in nine PHCs for diabetes care for the period of the study (N = 738) were included in the study.

Intervention. Structured diabetes care, including the development of general practice diabetes clinics, a patient education program, a health care professional education program, and improved recording of clinical information, was provided for the 33-month time period.

Results. There was a statistically significant improvement in three of the process of care variables (ordering HbA1c, cholesterol, and documenting foot examinations) whereas the four remaining variables did not improve. There was limited impact on outcome variables.

Conclusions. The intervention described in this study demonstrated an improvement in some process of care measures suggesting an impact of this type of delivery model in this environment.

Keywords: diabetes mellitus, physician practice pattern, practice guidelines, primary health care, therapy, treatment outcome

Management of diabetes mellitus is a major challenge to primary care systems worldwide. Diabetes mellitus is an especially common and serious medical condition in the United Arab Emirates (UAE). A prevalence survey, performed in 1989–90 on adults in the UAE, and two nearby rural communities [1], in which diagnosis was made using a single fasting glucometer reading of >11.1 mmol/liter, found an overall prevalence of diabetes mellitus of 6%. A more recent survey suggests a much higher prevalence of over 20% of the urban adult population over 30 years of age in Al Ain, UAE (Earl Dunn, personal communication).

Evidence from the United Kingdom Prospective Diabetes Study strongly suggests that improved control of glucose and blood pressure [2] results in a significant reduction in complications of Type 2 diabetes. Moreover, abnormal lipid levels appear to be an independent predictor of the development of diabetes complications [3] and therefore should be aggressively treated if they remain abnormal once glycemic control has been achieved. Despite advances in our knowledge of the optimal management of diabetes mellitus, studies using standardized measures from the United States [4] and other countries to assess diabetes quality, indicate that care for patients with diabetes usually falls short of that advocated by current guidelines worldwide. For example, in one large study in the USA, annual ordering of hemoglobin A1c (HbA1c) was not documented in 50% of patients, foot examinations were not documented in 94% of patients, and urine protein measurements were not taken in 52% of patients [5].

As the site of care for the majority of patients with diabetes is in primary health care, interventions to improve diabetes care...
management in this sector are of great importance. In the United States, ∼71% of the total diabetes care is delivered by primary care physicians [5]. In the UAE, diabetes mellitus is the fourth most common disease group seen in primary care and accounts for 5.3% of all visits [6]. Many studies have been carried out to improve the management of diabetes mellitus in the primary care sector [7,8]. Multi-component structured programs, particularly those that include a modification of the clinical care system such as the use of generalist diabetes clinics within primary care show the greatest promise [9]. These clinics, which are referred to as chronic care clinics in the United States [10] and mini-clinics in Europe [11–12] and Australia [13], provide care through the use of teams of primary care physicians, nurses, and other primary care providers. These proviers use a common set of structured diabetes protocols. These clinics also frequently include patient education and empowerment interventions, which also increase the likelihood of improvement in clinical outcome [9]. Experience with structured primary care for diabetes is limited in Western countries but appears in formal evaluations to be at least as successful as unstructured specialty care for diabetes [7].

In a previous preliminary study carried out by the authors of this paper [14], an intervention was developed and implemented which centered on the development of chronic care/mini-clinics at three primary health care centres (PHCs) in Al Ain. These clinics used structured care protocols, patient education, and a common paper-based system for recording of critical clinical data. Six other PHCs were used as controls. A controlled before–after study design was used. Before the initiation of the study, a set of clinical guidelines was developed, which was distributed to all primary health care providers [15]. Adherence to these guidelines using a common data collection form adapted from the Diabetes Quality Improvement Project (DQIP) measurement set was used as the primary quality measure. Short-term outcomes were measured in 219 subjects. Significant improvements in adherence to nearly all guidelines were documented; however, the short-term period of the study was felt to reflect on the beginning of a comprehensive quality improvement program and the changes in the process measures did not have sufficient time to have an impact on outcome measures such as lipid levels or blood pressure.

Due to promising findings in adherence to guidelines in the preliminary study, this second evaluation was carried out using a larger sample size and allowing a longer time period for the intervention to have an impact as we hypothesized that the intervention would grow more potent with time as well as determining whether the changes noted were sustained.

**Methods**

**Study design**

This study is a controlled before–after design comparing outcomes and adherence to guidelines in the control and intervention clinics. This study protocol was approved by the UAE University Ethics Review Committee.

### Study site and population

Health care in the UAE has developed rapidly over the past 40 years when the first hospital was established in the region. The federal government provides primary care to a mixed population of patients, both UAE citizens and expatriate workers (primarily male) from some neighbouring countries in the Middle East (Jordan, Syria, and Lebanon), Africa (Egypt and Sudan), and the Indian subcontinent (Pakistan, Afghanistan, Bangladesh, and India). Expatriate general practitioners and nurses, also from the same regions, provide most clinical care. General practitioners in the UAE usually do not have formal training or certification in primary care. The Al Ain federal health district provides primary care through 10 urban PHCs, to a city with a population of approximately 400 000 people. Three clinics were chosen as the sites for the intervention based primarily on whether they had enough clinical exam rooms to provide a supplementary clinical program. Six other clinics served as control clinics for comparison. A 10th clinic was excluded from the study as it had been used as a pilot site for some of the components of the clinical trial.

Before the initiation of the study intervention, a set of clinical guidelines was developed based in part on evidence-based guidelines from the American Diabetes Association as well as supplemental material from the World Health Organization. These guidelines were adapted to local circumstances by a committee of interested clinicians as previous literature supports the need for local adaptation of guidelines to ensure their acceptance [15]. These guidelines were subsequently adopted nationwide by the Federal Ministry of Health [16]. These guidelines included a recommendation that at every visit to the clinic, diabetic patients have their blood pressure measured, their urine checked for albumin, and their blood glucose measured by glucometer. On an annual basis patients were to be referred to an ophthalmologist for a diabetic eye examination and to have their total cholesterol and HbA1c measured.

### Physician participants

All physicians providing care in both control and intervention clinics were included in this study and were the primary target of the intervention. Due to a high degree of shared care among the physicians, the clinic was chosen as the unit of analysis, which was measured by review of medical records of diabetic patients attending the clinic.

### Patient participants

Subjects in both the intervention and control clinics who were continuously using the PHCs for diabetes care were recruited to participate in the study by trained nurses in the PHCs after being identified through the use of chronic disease registers maintained in all the PHC clinics. Continuous care was defined as seeing a PHC physician for diabetes care, one or more times during both time periods. Informed consent was obtained from study participants for a brief interview and review of patient records.
Intervention

The intervention that this study sought to evaluate included multiple modalities to provide structured diabetic care for intervention clinic sites including:

Establishing diabetes chronic care clinics. A major change in diabetes care was the development and implementation of diabetes chronic care clinics with medical care provided by general practitioners with a special interest in diabetes care. These clinics were initiated at the beginning of the study period. These clinics identified diabetic patients using a diabetic registry previously established and operating in all the clinics being studied. Care was provided at a dedicated half-day clinical session devoted to the care of diabetic patients.

Patient education program. A program for patient education was developed and provided by nurse–physician teams based in the clinics. Its goal was to enhance motivation and provide support for patients. Two nutritionists provided nutritional patient education at the three intervention clinic sites. A clinic nurse at each site was also designated to provide diabetic education unrelated to diet. These providers were available for consultations at other times in addition to being available in the generalist diabetes clinics.

Health care professional education program. Although all PHC providers participated in the educational sessions on diabetic patient education, diabetic nutrition, and motivational interviewing, physicians in the intervention clinics were given additional interactive sessions on oral hypoglycemic agents, insulin use, and detection of diabetic retinopathy with the ophthalmoscope. Within each intervention clinic, one or more physicians were identified to serve in the role as local expert on diabetes management. There were asked to lead clinic-based diabetes quality improvement initiatives within their clinic to facilitate adherence to guidelines. In addition, closer links with hospital-based consultants were established to increase access to specialists for complex cases.

Improved recording of clinical information. Flow-charts were included in the records of patients with diabetes in the interventions which were developed and provided in the guidelines. In addition, patients were given a card containing relevant data about their care, which they were asked to carry with them to each primary care and specialist visit. This card allowed patients to carry relevant data between specialists and PHC-based providers.

Outcome measures and statistical analysis

Many investigators in this field have recommended the use of a common set of measures of quality of diabetes care that are both easy to obtain and are clinically meaningful. The DQIP [4] was sponsored by several US health care organizations to develop a common data set to determine the success of health care plans, physicians, clinics, and other health care providers in managing diabetes mellitus. This data set was adapted and modified for use in this study to include three additional measures of diabetes control more commonly used in the UAE (fasting blood glucose, total cholesterol, and urine testing for proteinuria). Medical records were reviewed using trained nurse data abstractors for the 12 months before the intervention and the last 12 months of the 33-month intervention period to determine diabetes outcomes and adherence to diabetes guidelines. The data used in this study included the following measures.

Provider adherence to care process measures

Provider adherence to international accepted and locally modified care process measures was evaluated by identifying the percentage of diabetic patients enrolled in the study in the control and intervention groups who have the following measurements recorded in the medical record:

(i) One or more HbA1c test per year;
(ii) Blood pressure recorded and noted to be below 140/90;
(iii) One or more total cholesterol determination recorded in the medical record in the past year;
(iv) An eye examination in the past year;
(v) A documented foot examination in the past year;
(vi) One or more tests for proteinuria as an assessment of diabetic nephropathy in the past year.
(vii) One or more fasting blood glucose determinations.

Clinical outcomes

Although not the primary emphasis of the study, patient clinical outcomes were measured to develop a clinic level change score. Four measurements of diabetes outcome were abstracted from the medical records of the patients.

Glycohemoglobin (HbA1c) and fasting blood glucose (FBG) determinations. The last HbA1c level dated within the relevant time period in the PHC medical records was recorded. As ordering of HbA1c was generally low, the last FBG in the relevant time period was also recorded as this was recommended in the guidelines for routine monitoring of diabetic control.

Lipid levels. Total cholesterol levels are commonly used as a less expensive mechanism of screening for elevated lipids in the UAE and is the only lipid test other than a triglycerides test that can be ordered directly by primary care physicians without consultant approval. Therefore, frequency of ordering and levels of total cholesterol were used as the primary measurement of blood lipids assessment as this was the test recommended in the guidelines.

Blood pressure. The last systolic and diastolic blood pressure in each of the two time periods were recorded.

Data analysis

Statistical analysis was performed on the SPSS statistical package version 12. Comparisons between control and intervention
clinics were made using a nested mixed-model ANOVA. Clinics were tested as random factors and used as the replicates for testing the effect of the intervention.

**Results**

The study sample was composed of 738 subjects (378 males, 360 females). The subjects were distributed between the three intervention clinics \((n = 354)\) and six control clinics \((n = 384)\). Over 80% of the subjects who were contacted consented to participate in the study and an attempt to contact all subjects on the diabetes register was made at each site. The characteristics of the physicians in the two samples are listed in Table 1. The population of patients enrolled in the study is listed in Table 2.

Three of the seven process of care measures showed a pattern of statistical improvement in the intervention clinics including increased use of HbA1c, documented foot examination, and use of cholesterol examinations (Table 3).

**Table 1** Baseline characteristics of physicians in intervention and control clinics

<table>
<thead>
<tr>
<th></th>
<th>Intervention clinics ((n = 25)), (n \ (%))</th>
<th>Control clinics ((n = 38)), (n \ (%))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender</td>
<td>13 (52)</td>
<td>18 (47)</td>
</tr>
<tr>
<td>Expatriate nationality</td>
<td>25 (100)</td>
<td>38 (100)</td>
</tr>
<tr>
<td>First language</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arabic</td>
<td>13 (52)</td>
<td>18 (47)</td>
</tr>
<tr>
<td>General Duty</td>
<td>25 (100)</td>
<td>38 (100)</td>
</tr>
<tr>
<td>Medical Officer</td>
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</table>

**Table 2** Baseline characteristics of patient subjects in intervention and control clinics

<table>
<thead>
<tr>
<th></th>
<th>Intervention clinics ((N = 354))</th>
<th>Control clinics ((N = 384))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (±SD) age in years</td>
<td>53.3 ± 10.9</td>
<td>54.1 ± 10.4</td>
</tr>
<tr>
<td>Mean (±SD) duration of diabetes in years</td>
<td>9.8 ± 4.9</td>
<td>9.3 ± 4.9</td>
</tr>
<tr>
<td>Male gender, (n \ (%))</td>
<td>163 (46)</td>
<td>215 (56)</td>
</tr>
<tr>
<td>Married, (n \ (%))</td>
<td>305 (86)</td>
<td>337 (88)</td>
</tr>
<tr>
<td>No formal education, (n \ (%))</td>
<td>197 (56)</td>
<td>193 (50)</td>
</tr>
<tr>
<td>UAE nationality, (n \ (%))</td>
<td>311 (88)</td>
<td>261 (68)</td>
</tr>
<tr>
<td>Using pharmacological treatment, (n \ (%))</td>
<td>332 (94)</td>
<td>365 (95)</td>
</tr>
</tbody>
</table>

Three outcome variables were also compared. There was a statistically significant change in total cholesterol measurements in the intervention clinics \((-12.0 \text{ mg/dl})\) compared with the control clinics \((+8.3 \text{ mg/dl})\). The rate of measuring HbA1c was too low to determine whether any changes were made in this parameter. Fasting glucose did improve in the intervention clinics \((-0.7 \text{ mg/dl})\) when compared with the control clinics \((+4.8 \text{ mg/dl})\) although this was not statistically significant. Mean blood pressure worsened in the intervention clinics \((+2.7 \text{ mm Hg})\) when compared with the intervention clinics \((-1.4 \text{ mm Hg})\) and this difference was statistically significant.

**Discussion**

The intervention developed for this study shows a net positive effect on improvement of adherence to three of seven process measures. This included two measures of test ordering (cholesterol and HbA1c) and one measure of clinical care (recording of the foot examination). The failure to demonstrate an increase in blood pressure measurement is likely due to a ceiling effect as nearly every clinic visit has recorded blood pressure. The falling rates of glucose determination in both the intervention and control clinic reflects a temporary shortage of supplies of glucometer strips for several months that occurred during the after time period and may have obscured a real improvement in their use. The remaining two process measures of urine protein determination and annual ophthalmology referrals both demonstrated movement in the expected direction but the changes were modest.

The lack of statistically significant improvement in the outcome measures is not unexpected as this was not the primary emphasis of the intervention. It is very difficult in a study such as this one to link improvements of process measures to outcome measures as the outcomes have multiple determinants and it is difficult to know what proportion of a given health outcome is determined by processes of care and what is due to patient-related risk factors. We were unable to analyze changes in HbA1c as the low levels of use before and after precluded this analysis. The finding that blood pressure worsened in the intervention group was unexpected. The changes noted in blood pressure although statistically significant were small. Although a statistically significant improvement in total cholesterol levels was noted, there was a relatively small proportion of the population who had these determinations made even after the intervention occurred.

A significant limitation to this study is that the clinics were not randomly selected. The intervention clinics were chosen because they had space to accommodate the diabetes clinics and therefore tended to be larger and newer. It is not possible to determine what impact (if any) the difference in facilities may have had on the outcome. However, it is important to note that the distribution of the physicians in the clinics who were the primary target of the intervention were similar with regard to gender and those whose primary language was Arabic.

We also identified barriers to the implementation of this study. During the course of the study, the number of patients...
being seen in primary care increased while the number of available physicians remained stable. This increased pressure to see large numbers of patients very quickly and may have diluted the impact of the intervention. Near the end of the study period, when there were patients who did not show for the diabetes chronic disease clinics, regular patients were seen to deal with the increased volume. This may have diluted the impact of the clinic for those patients with diabetes.

In conclusion, this model of care demonstrated a statistically significant improvement in three process measures while two others showed changes consistent with improvement but did not reach statistical significance. A lack of change in two other measures is easily explained. Although these process changes were not reflected in improvements in outcomes, this is not unexpected given the multiple determinants of outcome measures.

Acknowledgements

The UAE University Faculty of Medicine and Health Sciences Intramural Research Grants Program funded this study.

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Accepted for publication 6 March 2005