Twelve-year follow-up of a population-based primary care diabetes program in Israel

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Abstract

Objective. To describe the effects of a long-term intervention including 72% of Israeli diabetes patients, aimed at improving diabetes care in a primary care setting.

Design. A retrospective periodic population-based cross-sectional study.

Setting. Two health maintenance organizations (HMOs) in Israel—intervention and control.

Participants. All diagnosed diabetes patients enrolled in both HMOs.

Intervention. Multifaceted interventions directed toward primary care providers, including educational strategies, registries, clinical pathways, care quality indicators, computerized reminders and feedback.

Main Outcome Measures. Performance in quality indicators, compared with an HMO that did not implement an intervention program.

Results. The prevalence of diabetes increased from 20.2/1000 in 1995 to 63.7/1000 in 2007. Annual testing of hemoglobin A1c (HbA1c) rose from 22% in 1995 to 88% in 2007. The corresponding figures for low-density lipoprotein (LDL) were 23 and 89%, respectively ($P<0.0001$ for all comparisons). The proportion of HbA1c $\leq 7\%$ increased from 10 to 53%, while HbA1c $>9\%$ decreased from 40 to 13% ($P<0.0001$). Good control of LDL $\leq 100$ mg/dl increased from 26 to 59% ($P<0.0001$). In the comparison HMO, subtle increases in the performance of HbA1c (55.8–63.4%), LDL (59.7–67.0%) and microalbumin (55.1–67.6%) were noted between 2005 and 2007, respectively. HbA1c $\leq 7\%$ and $>9\%$ remained stable (36 and 13%, respectively), while LDL $\leq 100$ mg/dl rose from 38 to 44% in the control HMO.

Conclusion. A community-oriented program for diabetes care led to improvements in performance of tests, as well as control of HbA1c and LDL among 72% of diabetes patients in Israel.

Keywords: diabetes, primary care, quality of care, multifaceted intervention, quality indicators

Introduction

Diabetes is a major chronic disease in Western society and its prevalence is on the rise worldwide [1, 2]. The progression of diabetic microvascular complications can be slowed, but probably not stopped, with interventions such as aggressive control of glycemia, laser therapy for retinopathy and angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers for nephropathy [3]. The most effective approach for prevention of complications appears to be...
multi-factorial risk factor reduction (control of glycemia, aggressive blood pressure control, treatment of dyslipidemia, smoking cessation) [4].

Many health systems have implemented disease management programs in order to improve quality of care for diabetes and other chronic conditions [5, 6]. These programs typically incorporate population-based strategies, such as disease registries, clinical guidelines, performance feedback, physician reminders, self-management support for patients and targeted case management for high-risk patients [5, 6].

In Israel, according to the National Health Insurance Law of 1995, four health maintenance organizations (HMOs) supply primary care services for all of the population, and are responsible for their members’ quality of care. Israel’s health system has recently been described as ‘integrated, equitable, efficient and sustainable’ [7]. Lessons learned from the Israeli health system can be extended to other countries, as suggested by Chenichovsky [7].

Clalit Health Services (Clalit) is the largest HMO in Israel, and provides health care for 4.0 million citizens, 53% of the Israeli population [8]. The prevalence of diabetes in the Israeli population is reported to be 4.2% as of 2007; 6.2% in the population aged 18 and over [9]. Seventy-two percent of people with diabetes in Israel are insured by Clalit [9]. Therefore, the quality of care in Clalit is a major determinant of the national quality of care for people with diabetes [9].

The Israeli population is diverse and heterogeneous, with a large proportion of immigrants. According to the Israeli Central Bureau of Statistics data, of the current population of 7.6 million, 3.1 million (40%) have immigrated to Israel since its establishment in 1948, of whom 1.2 million immigrated after 1990 (16% of the population) [10]. According to the National Insurance Institute of Israel’s report, Clalit’s members are older than the national average, have a lower-than-average income, and are more likely to be of Arab ethnicity; they include a high proportion of those receiving welfare funds [8]. Thus, Clalit insures a lower socioeconomic stratum of the Israeli society. It is well documented that poorer patients have worse outcomes with management and control of chronic diseases in general, and especially in diabetes [11].

Clalit owns and operates 1198 primary care clinics (employing 2000 general practitioners and family physicians and 2050 nurses), 14 hospitals and 150 secondary care practice guidelines for diabetes care were developed and updated in 1996 and 2000. Central and clinic diabetes registries were established. These registries were managed manually in 1996–97 and subsequently computerized in 1998. Flowcharts for diabetes care were developed. An electronic version of the flowchart was available as of 1999. Clinical pathways that defined the role of primary care in diabetes care were established, shifting diabetes patients’ case management from consultants to primary care providers with follow-up of patients conducted by primary care nurses. As of 1998, automated reminders were implemented in the electronic medical record software, addressing follow-up and control issues, e.g., alerts when blood pressure, HbA1c and LDL levels were higher than target levels or when adherence to follow-up, blood pressure monitoring, or blood tests was
suboptimal. Over the years new topics were added to the educational kit, which also became available in an online version. A set of quality indicators for diabetes care was developed and included in the central computerized dataset in 2001, facilitating retrieval of information on national, regional, clinic and physician clinical performance. These included both process indicators, such as measuring blood pressure, HbA1c and lipid level and outcome indicators, such as the proportion of patients with HbA1c <7%, LDL <100 mg/dl, blood pressure <130/80, etc. Provision of personalized performance feedback to physicians was started in 2003. Educational material for patients in Hebrew, Arabic and Russian (the main languages spoken in Israel) were produced as of 1999, including a printed self-care instruction kit, video and website, and self-care, healthy lifestyle workshops for patients were implemented. Lifestyle improving workshops were presented and cookbooks for healthy food based on traditional Arabic cooking were composed. A process of outreach visits of diabetes specialists to primary care clinics was established.

Neither positive nor negative incentives for primary care providers were established, except for displaying outcomes every 3 months in Clalit’s intranet, as of 2003. As of 2007, a compound score summarizing the performance of the clinic in 60–70 quality indicators (diabetes quality indicators comprise 17% of the score) was calculated and used to compare the performance of the clinics and reward the best districts and clinics. The reward was used for the clinic and not paid directly to employees. No additional personnel were provided in the process. For a summary of the intervention, see Table 1. All interventions were targeted at all patients with diabetes, both types 1 and 2.

**Definition of variables for clinical outcomes**

The quality of diabetes care in Clalit was evaluated using diabetes-specific indicators. These include process indicators, such as the percentage of diabetes patients with annual testing for HbA1c, LDL cholesterol and urine protein or microalbuminuria; measurement of blood pressure; as well as good compliance with angiotensin-converting enzyme inhibitors or angiotensin receptor blockers for patients with microalbuminuria. Outcome indicators for diabetes include the percentage of patients with HbA1c <7%, and those over 9%, the percentage of diabetes patients with LDL <100 mg/dl versus those with LDL >130 mg/dl, and the percentage of patients with blood pressure <130/80 mmHg versus >160/90 mmHg.

Performance was evaluated starting in 1995. Computerized quality indicators for the entire population of diabetes patients were available as of 2001. Prior to 2001, control of cholesterol levels was evaluated using total cholesterol values. Starting in 2001, it was based on LDL levels. Data on blood pressure measurement and control were available as of 2006.
Data collection and statistical analysis

Clalit has developed a comprehensive computerized database with continuous real-time input from pharmaceutical, medical and administrative computerized operating systems. The diagnoses of chronic diseases, including diabetes, are included in a national chronic diseases registry, based on data drawn from hospital and primary care physicians’ reports. The registry is validated by primary care physicians based on registered chronic diseases diagnoses. The validity of diagnoses in the register was previously estimated and found to be high for important chronic diagnoses. For diabetes, accuracy was over 90% [16] and sensitivity was estimated at 96% [17]. Quality indicators are also based on this database, for example, performance of laboratory tests (e.g. Hb A1c, LDL-cholesterol, microalbumin) and their results. Similarly, anthropometric data, blood pressure results and consultations with an ophthalmologist are automatically recorded into the database. This database was implemented in 2001, from which time results relate to the computerized database, including all diabetes patients in Clalit. Before 2001, data were manually collected, first from a representative sample of 876 physicians (in 1997) and later, directly from a sample of 2867 diabetes patients (in 1999) [13–15].

In order to evaluate changes in the follow-up and control of diabetes patients in Clalit, we compared process and outcome measures among Clalit’s members with diabetes, to diabetes patients enrolled in a different HMO (LHS). A similar registry of diabetes patients was also developed in LHS in order to facilitate reporting to the National Programme for Quality Indicators of Health in Israel. A comparison of enrollees in Clalit and LHS is given in Table 2. The indicators used for assessing diabetes care in LHS are identical to the ones in Clalit and are derived from the National Programme for Quality Indicators of Health in Israel [9], facilitating the comparison between the two HMOs. In both Clalit and LHS indicators cover all diabetes patients, both types 1 and 2. Process indicators are defined as performance of the needed test at least once annually. Outcome indicators are based on the most recent result of the test within a given year.

The study data are presented as percentages, analyzed using Stata for Windows, version 8 (Stata Corporation, College Station, TX, USA), with the chi-square test for detecting statistical significance in categorical variables.

Results

The intervention program was successfully implemented for most providers in Clalit. More than 75% of primary care physicians and nurses in Clalit participated in the continuous medical education sessions conducted annually.

The prevalence of diabetes as reported to the central registry rose from 20.2/1000 in 1995 to 42.3/1000 in 1999, 47/1000 in 2001, 49/1000 in 2003 and reached 63.7/1000 in 2007 (P < 0.0001). In 2007, 47% of diabetes patients were male, median age was 65 years, and 76% of diabetes patients were over the age of 55 years. Eight-four percent were Jewish and 16% were Arab.

The proportion of patients who had the necessary blood tests increased 4-fold over 12 years. The proportion of patients whose HbA1c was tested at least once annually increased from 22 to 88%. The performance of LDL cholesterol tests increased from 23 to 89% and that of microalbumin from 10 to 69% (P < 0.0001). An improvement in blood pressure, available as of 2006, rose from 77 to 88% over 1 year (Table 3).

An improvement in diabetes control, reflected in HbA1c levels, began to emerge as of 2000. The proportion of patients with good control of diabetes rose from 28% in 1999 to 53% in 2007. The proportion of patients with poor control decreased from 41% in 1999 to 13% in 2007 (P < 0.0001; Table 3).

LDL cholesterol control improved as well. The percentage of diabetes patients with well-controlled LDL cholesterol (≤100 mg/dl) rose from 26% in 2001 to 59% in 2007, and the proportion of patients with LDL >130 mg/dl decreased from 34 to 15% (P < 0.0001). An improvement in blood pressure control was seen from 2006 to 2007 (Table 3).

The proportion of patients with good compliance for angiotensin-converting enzyme inhibitors or angiotensin receptor blockers among patients with microalbuminuria rose from 75.9% in 2005 to 78.9% in 2007 (P < 0.0001; Table 3).

Process and outcome indicators were compared with those reported by LHS. Although quality indicators among LHS

<table>
<thead>
<tr>
<th>Variable</th>
<th>Clalit</th>
<th>LHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–14</td>
<td>26.2</td>
<td>30.7</td>
</tr>
<tr>
<td>15–34</td>
<td>30.0</td>
<td>29.9</td>
</tr>
<tr>
<td>35–64</td>
<td>30.9</td>
<td>31.4</td>
</tr>
<tr>
<td>65 and older</td>
<td>12.8</td>
<td>8.2</td>
</tr>
<tr>
<td>Male gender</td>
<td>48.8</td>
<td>49.7</td>
</tr>
<tr>
<td>Welfare recipient</td>
<td>12.8</td>
<td>8.1</td>
</tr>
<tr>
<td>Handicapped</td>
<td>7.2</td>
<td>6.2</td>
</tr>
<tr>
<td>HIred workers</td>
<td>92.0</td>
<td>90.9</td>
</tr>
</tbody>
</table>

Table 2: Demographic and socioeconomic profile of patients in Clalit Health Services vs. LHS, 2008–09

Data are modified from the National Insurance Institute report, June 2010 [3].

P < 0.0001 for all comparisons.
HbA1c, some outcome measures (the proportion of patients with microalbumin testing and blood pressure measurement) and process measures (HbA1c performance, LDL performance, results were found among Clalit’s enrollees regarding all... blood pressure control and treatment for microalbuminuria were not available from LHS."

Discussion

In the current study, trends in diabetes control over the last 12 years among Clalit’s enrollees are described—the prevalence of diabetes increased, the proportion of patients performing routine laboratory tests (HbA1c, LDL cholesterol, and urinary microalbumin) rose. The proportion of patients with adequately controlled HbA1c and LDL increased, while the proportion of patients with poorly controlled HbA1c and LDL decreased. Regarding most quality indicators, results for Clalit’s enrollees were better than those reported by the comparison of HMO, LHS. There appears to be a threshold beyond which improvements were more difficult to attain, as illustrated by the smaller decline in HbA1c >9% between 2006 and 07.

To date, evidence for effectiveness of disease management comes primarily from small efficacy trials [3, 18–20]. Such studies consistently found improved processes of diabetes care; however, improvements in outcomes were less consistent [3, 20–22]. Most studies evaluated one or two strategies, rather than multifaceted programs, in selected clinical settings. It is unclear how well findings from these smaller studies apply to ‘real life’ large patient populations.

Randomized clinical trials that evaluated the effectiveness of interventions focusing on healthcare providers compared with usual care [23–24] have identified improvements in diabetes process indicators, but not in outcome measures. Only trials of relatively small groups of patients have found improvement in diabetes control as well [4, 24].

As the described intervention was a multifaceted one, we cannot prove that one specific component of the intervention was more effective than others. However, we speculate that the most influential components were the infrastructure changes (mainly the ability for continuous monitoring of diabetes control as of 2001) and the continuous medical education (CME) sessions.

The first years of the program were focused on improving follow-up while later years focused on control of diabetes. Indeed, it could be seen in Table 3 that indicators related to

Table 3 Performance of follow-up and control, Clalit’s diabetes patients, 1995–2007

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Percent of patients fulfilling the indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1995</td>
</tr>
<tr>
<td>HbA1c performance</td>
<td>22.0</td>
</tr>
<tr>
<td>LDL performance</td>
<td>23.0</td>
</tr>
<tr>
<td>Microalbumin test</td>
<td>9.5</td>
</tr>
<tr>
<td>BP measurement</td>
<td>NA</td>
</tr>
<tr>
<td>HbA1c ≤7%</td>
<td>10.0</td>
</tr>
<tr>
<td>HbA1c &gt;9%</td>
<td>40.0</td>
</tr>
<tr>
<td>LDL ≤100 mg/dl</td>
<td>NA</td>
</tr>
<tr>
<td>LDL &gt;130 mg/dl</td>
<td>NA</td>
</tr>
<tr>
<td>BP &lt;130/80 mmHg</td>
<td>NA</td>
</tr>
<tr>
<td>BP &gt;160/90 mmHg</td>
<td>NA</td>
</tr>
<tr>
<td>ACEI/ARBs for microalbuminuria</td>
<td>NA</td>
</tr>
</tbody>
</table>

ACEI, angiotensin-converting enzyme inhibitors; ARBs, angiotensin receptor blockers; BP, blood pressure; NA, not available.

For trend <0.0001 for all comparisons.

Table 4 Performance of follow-up and control, Clalit vs. LHS diabetes patients, 2005–07

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Clalit (%)</th>
<th>LHS (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c testing</td>
<td>83.3*</td>
<td>85.9*</td>
</tr>
<tr>
<td>LDL testing</td>
<td>83.0*</td>
<td>86.2*</td>
</tr>
<tr>
<td>Microalbumin testing</td>
<td>56.9*</td>
<td>64.8**</td>
</tr>
<tr>
<td>BP measurement</td>
<td>69.3*</td>
<td>77.4*</td>
</tr>
<tr>
<td>HbA1c ≤7%</td>
<td>43.4*</td>
<td>51.0*</td>
</tr>
<tr>
<td>HbA1c &gt;9%</td>
<td>17.0*</td>
<td>13.7***</td>
</tr>
<tr>
<td>LDL ≤100 mg/dl</td>
<td>46.7*</td>
<td>52.3*</td>
</tr>
<tr>
<td>LDL &gt;130 mg/dl</td>
<td>20.7*</td>
<td>17.6*</td>
</tr>
</tbody>
</table>

*P < 0.001 (Clalit vs. LHS in the equivalent period); **P > 0.05 (Clalit vs. LHS in the equivalent period); ***P < 0.01 (Clalit vs. LHS in the equivalent period).
diabetes follow-up (performance of HbA1c, LDL and microalbuminuria) improved mainly until 1999, while indicators related to control of diabetes (control of Hb A1c and LDL) improved mainly up to 2003. Testing for microalbuminuria improved further in 2005 as a result of focused CME effort and distribution of guidelines regarding microalbuminuria and diabetic nephropathy.

The National Program for Quality Indicators for Health in Israel was established in 2004 and was largely based on quality indicators developed in Clalit. Therefore, the improvement seen from 1996 to 2004 was probably independent of the National Program. As of 2004, the participation of Clalit in the National Program probably increased the motivation for further improvement. In LHS (the comparison HMO) some improvement was also seen, mainly in recent years. The gap in the measures between the HMOs (Table 4) can probably be attributed to a gap between a relatively new program (LHS) and an older one (Clalit). Similar to trends within Clalit, the gap in process quality indicators was closed first, and only later did a trend towards closing the gap in control quality indicators begin to emerge. The relatively quick achievements seen over a short period in LHS probably relate to its participation in the National Program and to the fact that LHS has a smaller population of diabetes patients (about one-fifth of that of Clalit) and did not have to re-develop interventions, since they could adopt a ready-made model learned from other HMOs, including Clalit.

Results of the current study should also be compared with other national diabetes control programs, such as those in Sweden [25–26], the USA [27], and the UK [28]. The Swedish National Diabetes Registry was initiated in 1996. Mean HbA1c levels in Sweden decreased significantly from 1996 to 2003 (from 7.8 to 7.2%) in type 2 diabetes patients. The proportion of patients reaching the treatment target of 7.3% increased from 41% in 1996 to 58% in 2003, while rates of poor control (>9%) decreased from 10.3% in 1996 to 7.4% in 1999. Blood pressure also decreased significantly. As of 2003, control of LDL to <130 mg/dl and <100 mg/dl in Sweden reached 55 and 33%, respectively [25–26]. While some of these results (but not all) are better than in the current study, it should be noted that participation in the Swedish registry is voluntary [26]. Therefore, selection bias is probably present in the Swedish registry. Primary care centers, which are highly motivated regarding diabetes care and quality assurance, are probably more likely to register their patients. Therefore, results from Sweden probably over-estimate good clinical results [25]. In comparison, our results include all primary care physicians and clinics in Clalit, treating a national, highly heterogeneous population including minorities and low socioeconomic status populations. The Healthcare Effectiveness Data and Information Set (HEDIS) program in the USA reported a higher rate of HbA1c performance in 2005 (87–89%), but also a higher rate of poor control (22–37%) [27]. A higher rate of LDL performance (91–94%) and a similar rate of LDL <100 mg/dl (40–48%) were found in HEDIS [27]. While HEDIS results are similar to ours, HEDIS includes HMOs on a voluntary basis, and excludes low socioeconomic status groups who are insured by Medicaid and the uninsured. In contrast, Israel has universal health insurance. In the UK, a recent initiative for healthcare improvement is the pay-for-performance contract of family practitioners, with £1.8 billion ($3.2 billion) committed to this initiative as of 2004. As a result, the quality of care for type 2 diabetes (as well as asthma and coronary heart disease) improved considerably from 2003 to 2005. Performance of HbA1c increased from 87% in 1998 to 93% in 2003 and 99% in 2005. Control of HbA1c to <7.4% increased from 38 to 40% and then reached 51% in 1998, 2003 and 2005, respectively. Control of total cholesterol to <190 mg/dl increased from 22 to 52% and then 73%, while blood pressure control to <140/85 mmHg, was achieved in 22 and 35% in 1998 and 2003, and reached 49% in 2005 [28]. In contrast to the British initiative, improvements described in the current study in Clalit were achieved without any financial incentives. Primary care clinics did not recruit any additional workforce in order to carry out the intervention program.

One of the present study’s strengths is that it was not conducted in an artificially created environment for the purpose of the study, but rather in an actual, thriving primary care system. All primary care providers and diabetes patients were included in the outcome analysis, minimizing the potential for selection bias. Other strengths include the size of the intervention group, the length and consistency of the follow-up period and the mode of data collection by a central computerized system, which promotes accuracy and prevents mistakes incurred by manual data entry. While it could be claimed that the measures are unstable over time (we compared data for only three points in time between two HMOs), the rate of HMO membership mobility in Israel is minimal (1.4% in 2009 for the general population and <1% for people over 45 years [8], and probably <1% for chronically ill patients). Given the large size of each group, the estimations are statistically very robust.

The present study is an observational quasi-experimental study, not a clinical trial, and therefore has some inherent limitations. One potential limitation of this study is the absence of a control group within Clalit, due to Clalit’s policy of including all of its population in improvement programs. However, the comparison to LHS gives an indication of the possible impact of the program, as LHS has a similar patient population and only implemented an intervention program as of 2006. Since the validity of the comparison to the control group used in this study (LHS) is limited, the results can only partially be attributed to the intervention program as the major force behind the improvements shown. Clalit’s data regarding 1995–1999 have lower reliability because they were manually collected. The lack of consistency in the data systems over time may have also introduced bias into the findings. For example, computerized data systems might be better at capturing information on the quality of care. Also, they might be better in Clalit than in LHS. Nevertheless, Clalit’s data from the earlier years are consistent with Clalit’s data for the following years, 2001–2007. The effect of each intervention was not measured separately. However, due to the comprehensiveness of the program, it is artificial and
impossible to isolate the effect of each intervention component on glycemic control, lipid levels control or blood pressure control. The patient population has increased over the years, to include patients with a shorter duration of disease and therefore better Hba1c and LDL control. Possibly, over time, patients with a milder disease were more likely to be diagnosed with diabetes. Worldwide trends in improvement of knowledge on diabetes care could have influenced the results of the study. The available data did not allow a hierarchical analysis dealing with the potential nesting and cluster effects at the practice or clinician level. As most practices and healthcare providers participated in the program, we could not assess the association between the level of practice participation in various aspects of the intervention and the level of improvement of outcomes. Therefore, we cannot causally link the intervention to the improvement in diabetes follow-up and care over the years. However, some aspects of the improvement, especially blood pressure control, which show a significant improvement over 1 year, are more likely to be associated with the intervention. Because the intervention may have increased the likelihood of a patient with a milder degree of disease to be diagnosed with diabetes, some correction or control for changes in the underlying population is needed. Data regarding the duration of disease are available for Clalit only. Such an analysis is, however, beyond the scope of the present study. We hypothesize that the increase in the prevalence of diabetes is due to increased provider awareness and skills, as no policy of screening for diabetes was ever initiated in Israel.

In this study we described the outcome of a primary care-based intervention program for diabetes care. This program seems to be at least as effective as previously described more expensive interventions based on consultants specializing in endocrinology and diabetes care [4]. The intervention described in the present study is comprehensive at the population level, consistent over time, and based on the methodology of continuous quality improvement, rather than a short focused project. Such a program should be maintained over time, as the disease worsens over time for most patients.

To conclude, the quality of diabetes care of Israeli patients enrolled in Clalit has improved significantly, possibly as a result of empowering the primary care clinics with responsibility for diabetes care, together with a multifaceted intervention program that did not involve modifying financial incentives or expansion of the healthcare workforce.

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