Quality of diabetes care in India, China, Brazil, Mexico and Russia

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ABSTRACT

Employing US national standards, baseline data for type 2 diabetes were collected in India, China, Brazil, Mexico and Russia prior to Staged Diabetes Management implementation.

In all, 5507 patients (India 2778, China 489, Brazil 1106, Mexico 925, and Russia 209) were evaluated. No site sample met the US standard for HbA_{1c} or blood pressure. China, India and Mexico achieved criteria for LDL ≥130mg/dL. Post-programme data from Russian sites showed significant improvement in HbA_{1c} ($p<0.00001$). In Brazil a trend toward improvement in blood pressure and blood glucose was also noted.

Assessing current diabetes care employing US national criteria can serve as a benchmark for interventions to improve diabetes care. Collecting follow-up data measures programme impact and identifies areas requiring further intervention. Copyright © 2009 John Wiley & Sons.

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KEY WORDS

staged diabetes management; diabetes care; quality improvement

Introduction

An estimated 246 million people worldwide have diabetes, half of whom remain undetected.[1] This prevalence is projected to increase, reaching approximately 366 million by 2030.[2] This rising prevalence is especially found among urbanised populations in developing countries and therefore presents a significant public health dilemma. Randomised clinical trials have uniformly demonstrated that improvements in blood glucose (BG) and blood pressure (BP) control contribute to a reduced risk of diabetes-related microvascular and macrovascular disease.[3–5] Long-term follow up has shown that these improvements have a protective benefit well after the trial is completed.[6–8] What is needed are evidence-based interventions that fundamentally alter diabetes management and thereby improve diabetes outcomes.

For 20 years the International Diabetes Center (IDC), a World Health Organization Collaborating Center devoted to the translation of research findings into clinical practice, has approached improvement in diabetes care from a unique systems-based perspective. Recognising that most countries rely on primary care to manage diabetes, IDC developed Staged Diabetes Management (SDM).[9,10] A systematic, evidence-based approach utilising customised clinical pathways to prevent, detect, and treat diabetes, metabolic syndrome and associated disorders, SDM is organised around national standards of care that reflect the changing responsibilities of primary care. SDM has been evaluated in the United States, Russia, France, Germany, Brazil, Mexico, Korea, Japan, Poland, Vietnam, Malaysia, Singapore, Bangladesh and Pakistan.[11–16] While the approach is continually being refined, its original principles and processes remain unchanged: (1) assess community diabetes care needs, (2) identify groups interested in improving care, (3) develop the scientific rationale for diabetes treatment, (4) customise SDM to reflect local needs, and (5) evaluate SDM implementation and care outcomes.

In 2003, the opportunity arose to expand SDM implementation in Brazil, Mexico and (in 2007) Russia and to initiate new programmes in China and India. Together these countries constitute more than one-third of the worldwide prevalence of diabetes (Table 1).[1,17] To support implementation, IDC worked with clinicians in these countries to collect a uniform set of baseline data related to clinical processes and outcomes. This report describes the baseline findings and examines post-programme implementation in selected pilot sites.

Methods

Participant recruitment

IDC collaborated with academic, government, and private organisations to coordinate this international project. SDM-based intervention models for the management of type 2 diabetes were customised with representatives from each country. A train-the-trainer model was modified to fit the unique aspects of the health care system. In Brazil, public and private centres were targeted. Multidisciplinary teams at facilities in three states participated in the training programme. In China, five hospitals – in Beijing (two), Harbin (one) and Nanjing (two) – participated, based on their unique role in health professional training; while, in Russia, five major regional academic medical

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centres networked with the Center for Advanced Medical Studies in Moscow to implement SDM. Unique to Russia, was the participation of representatives from the regional ministries of health. Due to both size and diversity, the model in India optimised medical school faculties by initiating training programmes aimed at undergraduate and postgraduate education. Mexico benefited from an ongoing collaboration with the state secretary of health in one region enabling the development of a centralised training programme (Pachuca) with satellite programmes throughout the country.

The project protocol was approved by the Park Nicollet Institutional Review Board and was shared with each country champion who, in turn, followed the local requirements for collection of patient-related quality improvement data.

SDM intervention

Two months prior to SDM training, participating doctors in each country collected baseline data on 20 patients with type 2 diabetes selected from their practices using a standardised abstraction form. Patient selection varied from choosing consecutive patients seen within a specific time frame to selecting charts at random. Data were blinded and entered into an Excel template and forwarded to IDC for final compilation and analysis.

Next, professionals from IDC and local champions conducted intensive SDM training in all countries except Russia. Participating endocrinologists and health ministry representatives from Russia attended a training programme in the US at the IDC. SDM training consisted of 16 hours focusing on: (1) epidemiology, natural history and pathophysiology, (2) clinical pathways, (3) foot examination, glucose monitoring and insulin injection techniques, (4) principles of patient education, and (5) complications surveillance. The SDM Master DecisionPath for type 2 diabetes (Figure 1) was customised for each country to fit local guidelines and optimise therapies using a treat-to-target approach. Baseline data organised by site were used to provide background, identify areas of

Table 1. Estimated diabetes prevalence by country, 2007 (ages 20–79)

Country	Population (000s)	Prevalence (%)	People with diabetes (000s)
India	659 570	6.2	40 850.8
China	929 432	4.3	39 809.6
Russia	106 481	9.0	9631.6
Brazil	119 519	5.8	6913.3
Mexico	64 939	9.4	6115.7

Source: *Diabetes Atlas,* 3rd edn. Brussels: International Diabetes Federation, 2006.

Figure 1. Staged Diabetes Management Master DecisionPath for type 2 diabetes

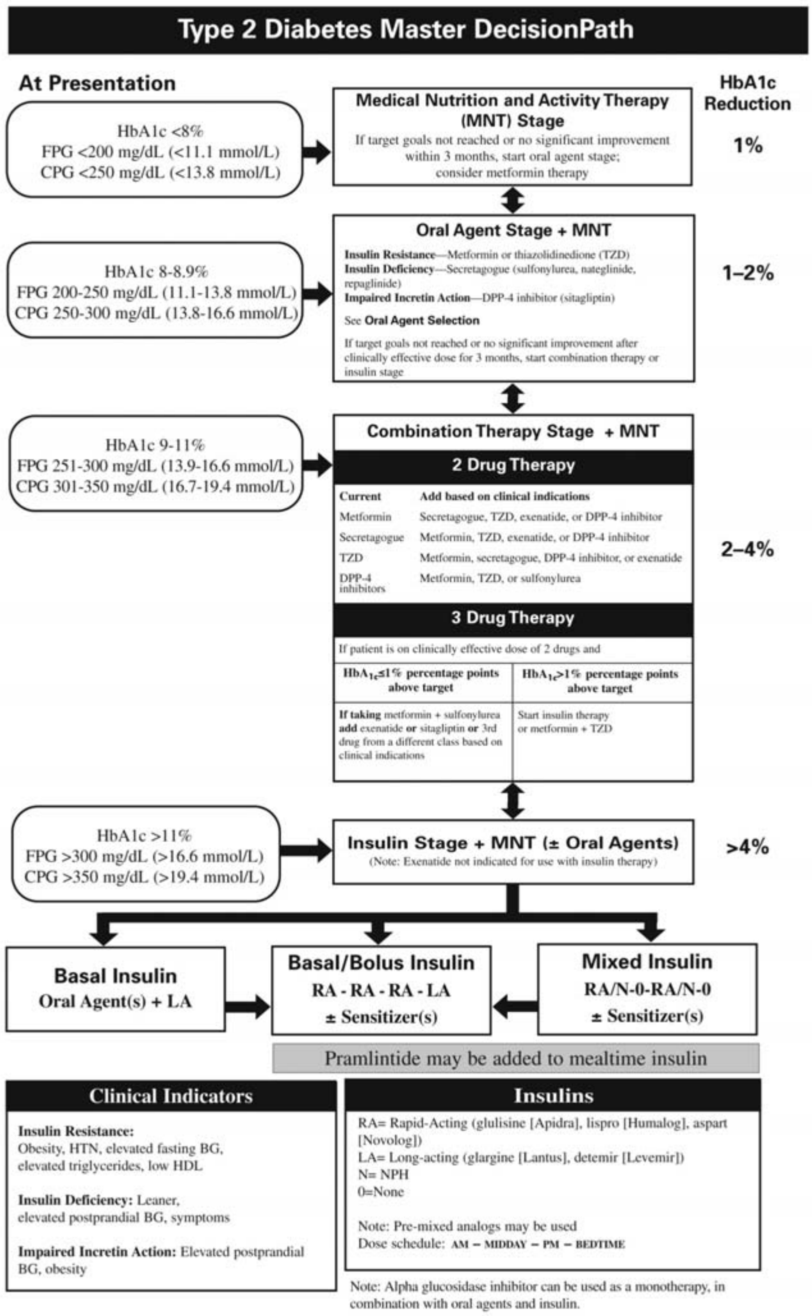


Table 2. Baseline characteristics from each country

	Pooled	SD	Russia		China		India		Mexico		Brazil	
Number	5507		209		489		2778		925		1106	
% female	50	10	40		50		60		40		40	
			Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age (yrs)	55.2	19.4	55.9	9.0	59.1	14.5	48.5	15.6	58.1	13.1	54.3	21.3
Duration of diabetes (yrs)	9.7	2.1	8.8	6.9	8.8	7.1	7.9	7.1	13.3	9.5	9.6	7.4
HbA_{1c} (%)	8.3	3.0	8.9	1.5	8.6	2.3	7.8	1.4	7.9	1.8	8.1	2.0
Systolic BP (mmHg)	132.1	50.3	137.8	16.4	129.4	17.9	130.1	18.3	130.1	19.6	133.1	23.9
Diastolic BP (mmHg)	80.3	31.7	84.7	10.5	76.9	10.2	82.1	10.1	77.8	9.8	80.2	12.3
Total cholesterol (mg/dL)	199.8	68.3	221.3	47.5	189.0	50.1	190.7	41.5	199.8	50.2	198.4	53.2
LDL (mg/dL)	116.0	33.4	134.1	54.9	109.1	37.5	113.9	34.1	105.7	45.1	117.2	40.8
HDL (mg/dL)	50.0	10.8	55.4	27.9	48.1	15.9	44.7	20.5	52.9	28	49.2	21.9
Triglycerides (mg/dL)	187.5	37.7	215.9	115.2	188.2	172.2	167.3	69	200	118.5	165.9	116.8

deficiency and establish emphasis during the instruction. Case studies based on patients in active treatment were prepared by participating physicians and employed to demonstrate application of country-specific clinical pathways (copies of these are available from the authors). Lastly, strategies for SDM implementation specific to each site and for later re-customisation and dissemination in the country were developed.

Measures

Baseline variables were defined using the Diabetes Physician Recognition Program (DPRP) published by the American Diabetes Association (ADA) and the National Committee for Quality Assurance (NCQA).[18] The DPRP is a voluntary programme used in the US to assist physicians to encourage application of evidence-based measures to improve care for their patients with diabetes. DPRP includes process measures (annual eye, foot and kidney examinations, and tobacco cessation) and outcome measures (HbA_{1c}, BP and lipid profile). DPRP variables are linked to a series of criteria (considered sentinel events) which serve as a benchmark. Because US measures are generally considered among the most stringent by diabetes experts and because similar international criteria did not exist, we used these criteria in our examination of the international data set.

Additional parameters relating to treatment, complications, monitoring and education were included to provide a broader base from which to evaluate current care.

Data editing

Since the focus of this SDM initiative was type 2 diabetes, data were included for analysis only if diabetes was documented or if treated without insulin (a proxy for type 2 diagnosis). Only those tests and medical examinations occurring within the past 12 months were included. Patients <16 or >100 years of age were excluded from analyses. When it appeared that laboratory values recorded were not biologically feasible, they were excluded (e.g. HbA_{1c} <4% or LDL ≤50mg/dL). For DPRP process measures, instances where the test or examination was documented as not completed were combined with those with missing data and categorised as not meeting DPRP criteria. The same data editing was used for non-DPRP measures. Of the 6467 cases audited, 85% (5507) of the charts met the inclusion criteria: 1106 Brazil, 489 China, 2778 India, 209 Russia and 925 Mexico.

Analysis plan

Due to differences in laboratory assay methods, each site specified their normal ranges. Prior to analysis, all laboratory data were converted to mg/dL using a standard equation. A data quality evaluation was performed and revisions were made to ensure that formats used for dates and laboratory values were consistent. These data sets were then exported to SPSS Graduate Pack™ 15.0 for Windows® and combined into a single database for analysis. Data for selected variables were recoded in accordance with DPRP criteria. Analyses consisted of descriptive statistics in which all sites were pooled according to country.

Results

The combined database represents the practices of 323 physicians (Brazil 71, China 25, India 157, Mexico 59 and Russia 11). Table 2 summarises the demographic and physiological data for the 5507 evaluable cases. Overall, the combined sample was equally divided by gender with a mean age of 55±19 years and diabetes duration 9.7±2.1 years (range 7.9–13.3). It was noted that while the data from each country differed, the differences were not statistically significant due to the wide variance between participating sites within each country. Russia consistently recorded the highest mean values for all physiological measures. Mexico had the oldest patients with a longest duration of diabetes; and India had the youngest patients with the shortest duration of diabetes and the lowest HbA_{1c}.

Outcomes and process criteria

Data are summarised in Table 3. At baseline, none of the country samples met the DPRP standards for patients with HbA_{1c} <7% (≥40% of patients). More than 35% of the patients sampled in Brazil and Mexico had HbA_{1c} values <7%. The Indian sample attained the DPRP standard for HbA_{1c} >9% (≤15% of patients). No country sample met the standard for BP <130/80mmHg. China, India and Mexico samples

Table 3. Comparison by country with Diabetes Physician Recognition Program (DPRP) criteria*

	DPRP criteria* (%)	Russia (%)	Brazil (%)	China (%)	India (%)	Mexico (%)
Glucose control						
HbA_{1c} <7%	≥40.0	5.7	35.1	23.0	20.7	38.5
HbA_{1c} >9%	≤15.0	40.6	20.9	34.6	13.9**	24.4
Blood glucose >125mg/dL	NA	NA	65.4	64.0	71.4	53.2
Blood pressure control						
≥140/90mmHg	≤35.0	49.8	51.2	31.2**	44.6	38.5
<130/80mmHg	>35.0	24.9	14.8	31.2	15.5	26.5
Cholesterol control						
Complete lipid profile in last year	NA	97.0	44.7	80.2	39.3	45.0
Total cholesterol <200mg/dL	NA	34.5	56.5	62.7	57.5	58.2
Total cholesterol 200–240mg/dL	NA	32.3	29.0	25.4	30.9	25.7
Total cholesterol >240mg/dL	NA	34.0	14.5	11.9	11.6	16.0
LDL ≥130mg/dL	≤37.0	54.5	38.7	15.5**	27.9**	20.4**
LDL <100mg/dL	>36.0	25.0	33.9	40.2**	33.2	48.2**
HDL <40mg/dL	NA	19.6	25.5	34.4	33.7	19.0
HDL 40–49mg/dL	NA	38.5	35.8	28.1	45.6	25.6
HDL 50–59mg/dL	NA	22.2	24.3	20.0	15.6	23.9
HDL ≥60mg/dL	NA	19.6	14.4	17.5	5.2	31.5
Trigycerides <150mg/dL	NA	29.3	55.4	56.4	39.4	34.8
Trigycerides 150–199mg/dL	NA	18.6	21.4	19.9	40.1	22.8
Trigycerides 200–399mg/dL	NA	47.6	21.8	17.1	19.7	35.5
Trigycerides ≥400mg/dL	NA	4.6	1.4	6.6	0.8	6.9
Process measures						
Eye exam	>60.0	90.0**	35.6	33.1	44.1	40.0
Foot exam	>80.0	91.5**	49.6	29.2	42.4	46.0
Self-management education	NA	97.6	56.0	46.0	72.3	69.3
Tobacco cessation counselling	>80.0	19.0	11.5	23.6	62.4	31.3
Nephropathy assessment	>80.0	69.8	37.4	48.1	40.0	41.1
Self-monitoring blood glucose	NA	98.1	22.4	50.5	39.3	41.3

* Based on 2006 criteria. ** Measure which met DPRP established criteria.

reached the DPRP standard for LDL ≥130mg/dL (≤37.0% of patients) and Brazil almost achieved the standard (38.7%). Only Russia reached the DPRP process criteria for eye exam and foot exam.

Non-DPRP variables were inconsistent between sample sets. While at Russian sites approximately 98% of the patients had participated in a diabetes education programme, Chinese sites reported that less than half participated. Self-monitoring was reported in almost all patients in the Russian sample, while in the Brazilian sample less than one-quarter of the patients used self-monitoring. We could find no relationship between these self-care focused variables and the principal clinical outcome, HbA_{1c}.

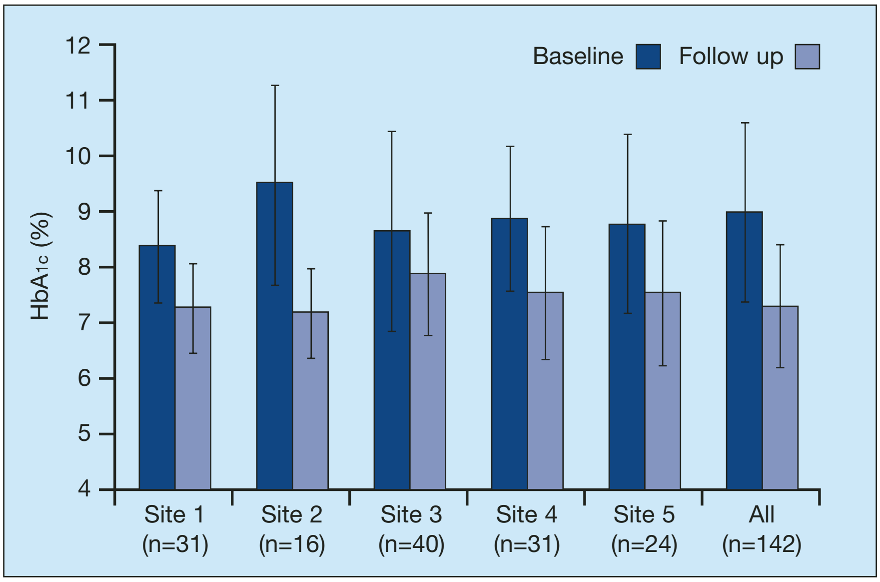
Post-SDM implementation results from Russia and Brazil

Sites in Russia and Brazil conducted a follow-up evaluation in a sample of patients for whom pre- and post-programme data would be available. In Russia, each endocrinologist followed 20 patients for three months using a treat-to-target approach based on their customised SDM clinical pathways. In order to make the study comparable, adjusted HbA_{1c} was used to correct for different assays. Of the 220 subjects who participated, 142 had both baseline and follow-up HbA_{1c}. There were no significant differences in demographic or physiologic baseline measures between sites or among patients who completed the study and those who did not return to the clinic for follow up. After three months of intervention individually and collectively the sites showed significant ($p<0.00001$) improvement in HbA_{1c} (Figure 2).

The study design in Bahia, Brazil, utilised a different approach. Over the past decade the Brazilian Ministry of Health has focused on the link between cardiovascular disease and diabetes/hypertension management. Consequently, both BG and BP were tracked at public health clinics in two cities as the outcome measures over eight months following implementation. While BP measurements were completed at each visit, BG and/or HbA_{1c} were sporadically performed. Random sampling at baseline and at eight months was used to determine the effectiveness of SDM across each site's patient population.

The participating physicians and their staff were trained by local faculty (originally trained by IDC staff in 2002 and 2003) from Centro de Diabetes e Endocrinologia da Bahia (CEDEBA). The SDM Master DecisionPaths for type 2 diabetes along with clinical pathways for management of hypertension were customised at the sites in 2007 with baseline data collected from a sample of 227 patients. Changes in BP and BG (measured by both HbA_{1c} and random BG) varied between sites. At site A (n=103) BG remained unchanged (177±75mg/dL *vs* 176±79mg/dL) while systolic and diastolic BP were reduced (144±33mmHg to 134±20mmHg and 85±12mmHg to 83±12mmHg [NS]), respectively. In contrast, at site B (n=124) BP remained unchanged at approximately 137±26mmHg/81±4mmHg, while BG reduced from 181±85mg/dL to 169±66mg/dL (NS).

Figure 2. Change in HbA_{1c} pre- and 3 months post-SDM implementation in Russia (p<0.00001 each individual site and all sites)



Discussion

The increasing prevalence of type 2 diabetes, especially among urbanised and 'Westernised' populations in developing countries presents a significant public health dilemma. Our primary objective was to understand the scope of this dilemma in preparation for implementation of Staged Diabetes Management in China, India, Brazil, Mexico and Russia. To accomplish this we measured the quality of care currently provided in diverse health care settings. Baseline data for individuals with type 2 diabetes were collected at selected clinical sites using criteria established by the ADA and NCQA as well as additional parameters related to treatment, self-care and education. Our secondary objective was to determine the feasibility, in pilot sites, of assessing the impact of SDM.

Of 6467 cases examined at baseline, we were able to obtain sufficient data from 5507 to characterise both the metabolic state and quality of care delivered to these individuals in such diverse clinical settings: (1) public and private facilities in Brazil, (2) polyclinics in Russia, (3) university-based facilities in India, (4) specialty hospital-based centres in China, and (5) rural health stations in Mexico. These baseline data helped provide guidance for interventional emphasis and strategies. Using DPRP standards, we found that the current level of glycaemic control as reflected in HbA_{1c} was better than might have been expected in light of the limited availability of antidiabetic medications. With respect to patient self-care, although the Russian sample appeared to include virtually all patients in education and self-monitoring practices, this was not reflected in the ability to achieve tight glycaemic control in this sample. Their HbA_{1c} was the poorest of all countries.

Our findings concerning the current quality of care and clinical practices in these countries, as represented by samples from selected sites, to some extent differ from other recently published data. A study in urban India found that the proportion of patients with HbA_{1c} >8% was approximately 42% which was similar to our own findings; while they reported 40% of patients with LDL ≥130mg/dL, we found only 28%.[19] Similarly, while 63.2% of their sample had BP >140/90mmHg only 44.6% of our Indian sample were in this range. In Brazil, one study reported that 46% of patients met the HbA_{1c} goal of 1% above the upper limit of normal, whereas 35.1% of our sample met this goal.[20] They also found that 21% had LDL <100mg/dL compared to 33.9% in our sample. Measured against a population-based survey in Mexico, our sample was slightly older (58.1 *vs* 55.2 years) and of greater diabetes duration (13.3 *vs* 8.8 years); nevertheless, hypertension was present in 38.5% of our Mexican sample compared to 50.3%.[21] A report from Russia, concerning 68 subjects with type 2 diabetes and hypertension, showed average BP in treatment was 172±26/98±16mmHg *vs* 135±16/85±10mmHg for our sample.[22]

It is also instructive to compare our findings with data from the US. One study reported that 20.6% of adult participants had HbA_{1c} >9%.[23] Interestingly, our samples from five countries ranged from 13.9% (India) to 40.6% (Russia). With respect to LDL <130mg/dL the US was 64.2% compared to a range of 45.5–84.5% in the five-country sample.[23] A closer US comparison would be with 2253 cases from eight medical centres measured at baseline prior to SDM interventions in 2002/2003. We found that 44% of the subjects in the US sample had HbA_{1c} <7% compared to 25% in the current study; systolic BP <130mmHg was 38% in the US and 39% in the multi-country study and LDL <100mg/dL was 49% *vs* 36%.[24]

Our data are based on sampling only those patients who were being followed in health centres for which we were preparing an intervention. Since population-based samples may include people with little or no care, we could expect to find better results in our samples. Additionally, 15% of of the international study charts could not be used due to missing values or incomplete records. For example, HbA1c data were omitted in one-third of the cases and LDL values were missing for almost half of the cases in three of the five countries.

Conversely, while BP data were available for nearly all patients in China, Brazil and Mexico, one-sixth of the India sample did not have a current BP. Since diabetes care is highly data-driven, these findings indicate a need to improve testing, measurement and documentation in these clinical settings. Did the missing data skew our results? Perhaps, although missing data do not always bias survey results.[25] Inconsistent data collection methods may mean the samples were not actually representative of each provider's patient population. There was wide variability in the format for medical records between and within the study countries. These differences could have resulted in less accurate records that may lead to under-estimation or over-estimation of the performance of process measures. Consequently, from a purely epidemiologic perspective, we are not prepared to generalise to larger populations within these countries. Since the initial focus is to determine local needs and design interventions to address these needs, we believe the data, even with these limitations, served this purpose. Overall, the lack of a common database presents both a challenge and an opportunity. The challenge is to produce a uniform set of data and the opportunity is to convert this into a common international database for assessment of diabetes care.

SDM provides a framework for changing diabetes care. We found in the current study that close surveillance of patients in Russia by doctors trained in SDM improved outcomes in the five selected clinics. In Brazil, evaluation of two public health facilities revealed that one site was able to show a moderate, albeit not statistically significant, improvement in glucose control while another was able to improve BP control.

It is clear that the baseline data and subsequent follow up were a first step in understanding the scope of the public health dilemma that will face these five countries over the next several decades as type 2 diabetes increases in prevalence. Although limited in scope, the data provide a unique vantage point from which to view the nature of diabetes care in developing countries. For the first time, we were able to collect the same data in five countries that constitute more than one-third of the prevalence of type 2 diabetes worldwide. As the prevalence of diabetes is reaching pandemic proportions, the search for intervention models is, consequently, a necessity. Staged Diabetes Management has shown in the current study, albeit in a small subsample, that – even with limited resources – improved care can occur. Taken on a larger scale, is it possible to intervene to promote prevention and management strategies that reflect the current medical system, but optimise its limited resources and still provide improved services? We believe the answer is a definitive, yes. Is it necessary to monitor these interventions more closely to measure their processes and outcomes? Again we believe the answer is a definitive, yes.

> **Key points**
>
> - Assessing diabetes care using US national standards for diabetes care across multiple countries can serve as a benchmark for quality improvement interventions
> - Collecting follow-up data can determine the effectiveness of the intervention as well as identify areas for further interventions

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Conflict of interest statement

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