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ORIGINAL RESEARCH

Comparison of National/Regional Diabetes Guidelines for the Management of Blood Glucose Control in non-Western Countries

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ABSTRACT

Introduction: Development of higher standards for diabetes care is a core element of coping with the global diabetes epidemic. Diabetes guidelines are part of the approach to raising standards. The epidemic is greatest in countries with recent rises in income from a low base. The objective of the current study was to investigate the availability and nature of locally produced diabetes guidelines in such countries.

Methods: Searches were conducted using Medline, Google, and health ministry and diabetes association websites.

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Results: Guidelines were identified in 33 of 75 countries outside North America, western Europe, and Australasia. In 25 of these 33 countries, management strategies for type 1 diabetes were included. National guidelines relied heavily on pre-existing national and international guidelines, with reference to American Diabetes Association standards of medical care and/or other consensus statements by 55%, International Diabetes Federation by 36%, European Association for the Study of Diabetes by 12%, and American Association of Clinical Endocrinologists by 9%. The identified guidelines were generally evidence-based, though there was some use of secondary evidence reviews, including other guidelines, rather than original literature reviews and evidence synthesis. In type 1 diabetes guidelines, the option of different insulin regimens (mostly meal-time + basal or premix regimens) was recommended depending on patient need. Type 2 diabetes guidelines either recommended a glycosylated hemoglobin target of <7.0% (<53 mmol/mol) (70% of guidelines) or <6.5% (<47 mmol/mol) (30% of guidelines) as the ideal glycemic target. Most guidelines recommended a target fasting plasma glucose that fell within the range of 3.8–7.2 mmol/L. Most guidelines also set a 2-h post-prandial glucose target value within the range of 4.0–8.3 mmol/L.

Conclusion: While only a first step in achieving a high quality of disease management, national guidelines of quality and with fair consistency of recommendations are becoming prevalent globally. A further challenge is implementation of guidelines, by integration into local care processes.

Keywords: Diabetes; Fasting plasma glucose; Guidelines; Non-western countries; Local care; Post-prandial glucose; Type 1 diabetes; Type 2 diabetes

INTRODUCTION

The worldwide prevalence of diabetes was estimated as 366 millions in 2011 (8.3% of the population), and is predicted to rise to 552 millions (9.9%) by 2030 [1]. The total number of excess deaths due to diabetes in 2011 in the 20–79 age group was estimated to be nearly 4.6 million (6.8% of global deaths) [2]. According to forecasts, diabetes will have an increasing impact on years of life lost due to premature death and disability, shifting from the eleventh to seventh most common cause of death by 2030 [3]. In addition, diabetes has an important economic burden; globally, 12% of health expenditure was expected to be spent on diabetes in 2010 [4]. The greatest increases in diabetes prevalence have occurred in countries in economic transition, in particular in the Middle East, sub-Saharan Africa, China, and the Indian subcontinent [5]. This has the potential to put severe strain on healthcare systems in these countries [6–8].

There are a number of internationally recognized guidelines, algorithms, and position statements for the diagnosis, control, and management of diabetes [9–13], covering a range of different components of diabetes care, often with an emphasis on glucose-lowering therapies. These factors together with updates make use and implementation of the latest versions of the guidelines desirable but challenging [14–18]. However, implementation of guidelines for the management of diabetes has beneficial effects for the individual with diabetes, including a significant reduction in complications associated with diabetes, such as hospitalizations [19].

Despite the increasing burden of disease, measures of the use of guidelines repeatedly show poor implementation of, and adherence to, current recommendations [20, 21]. The quality of disease management is reduced because there is a gap between guideline recommendations and clinical practice [21]. Amongst reasons for non-implementation of guidelines may include poor access to the guidelines for clinicians, and the reduced access to healthcare resources of the target population [22].

Development and implementation of local standards of care quality to ensure 'local ownership' are considered important in securing a basis for guideline implementation [23]. Indeed, implementation of diabetes clinical practice guidelines have resulted in increases in the percentage of patients reaching glycosylated hemoglobin (HbA_{1c}) and low-density lipoprotein (LDL) targets [23, 24]. Compliance with national standards of care has been shown to make a substantial difference in the control of chronic diseases, such as diabetes [21, 25].

The purpose of the current study was to identify the establishment of national guidelines for the management of diabetes for a range of countries where income is changing from a low base, to investigate the coverage of these local guidelines, and to discuss the differences between different local guidelines and between local and international guidelines.

METHODS

Search Strategy and Terms

Searches were conducted using Medline, Google, and health ministry and diabetes association websites. Medline searches used the term 'diabetes' combined with 'guideline' or 'recommendations' or 'consensus', and the country names of non-western countries (outside North America, western Europe, and Australasia) available from International Diabetes Federation (IDF) member associations list. Countries included Albania, Algeria, Argentina, Azerbaijan, Bangladesh, Belarus, Bolivia, Brazil, Cameroon, Central African Republic, Chad, Chile, China, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Gambia, Guatemala, Honduras, Hong Kong, India, Indonesia, Iran, Iraq, Israel, Ivory Coast, Jordan, Kazakhstan, Kenya, Kuwait, Lebanon, Libya, Lithuania, Malaysia, Maldives, Mauritius, Mexico, Morocco, Nepal, Nicaragua, Nigeria, Pakistan, Panama, Paraguay, Peru, Philippines, Puerto Rico, Qatar, Russia, Rwanda, Saudi Arabia, Senegal, Seychelles, Singapore, Slovakia, Slovenia, South Africa, South Korea, Syria, Taiwan, Tanzania, Thailand, Tunisia, Turkey, United Arab Emirates, Uganda, Ukraine, Uruguay, and Venezuela, or their regions (e.g., South America). Countries with guidelines were grouped into four regions: North Africa and Middle East, East and South Asia, Central and South America, and 'Other' (Table 1). Google searches were made using similar terms and combinations of terms to those listed above. Google searches were also run for ministry of health and diabetes association websites in the individual countries listed above, and those websites searched for guidelines.

Inclusion Criteria and Translation

Identified guidelines were retained for further analysis if they made recommendations for use or titration of glucose-control therapies in type 1 or type 2 diabetes; or if they contained

Table 1 Breakdown of non-western countries with identifiable national guidelines by region

North Africa and Middle East ($n = 11$)	East and South Asia ($n = 9$)	Central and South America ($n = 5$)	Other ($n = 8$)
Algeria	Bangladesh	Argentina	Belarus
Egypt	China	Brazil	Kazakhstan
Iraq	India	Chile	Israel
Jordan	Indonesia	Mexico	Kenya
Lebanon	Malaysia	Venezuela	Russia
Libya	Singapore		Turkey
Morocco	South Korea		Ukraine
Saudi Arabia	Taipei		South Africa
Syria	Thailand		
Tunisia			
United Arab Emirates			

guidelines specific for control of post-prandial glucose (PPG) levels or hypoglycemia; or special groups, such as children, the elderly, or those with complications. Guidelines were not included if they only dealt with lifestyle management, patient education, or psychological care; or were only concerned with screening and diagnosis; only concerned with non-glucose cardiovascular risk factors; or were specific to monitoring of glucose control, or specific to management of specific complications, including preventative foot care. If more than one guideline was available from any country, the authors relied on the knowledge of a local Novo Nordisk clinical advisor to advise on the main guideline in clinical use.

Guidelines that were not in English were translated using Google translate, including translations from Spanish, Portuguese, French, Indonesian, Hebrew, and Thai. Some guidelines could not be translated using the Google translate program and in these instances the guidelines were translated and tabulated by a local clinical advisor who was a native speaker, kindly provided by the local Novo Nordisk affiliate.

Analysis

The following parameters were assessed in the national guidelines: the source of the guidelines, e.g., whether from a national society or from the ministry of health; year of most recent guideline; year of previous guidelines; whether national guidelines were specifically based on international guidelines or consensus documents; whether specific recommendations for pediatric populations, the elderly, and gestational diabetes were present; post-prandial control; management of hypoglycemia; recommended first-, second-, and third-line insulin treatment for type 1 diabetes (if any); and recommended first-, second-, and third-line therapies for type 2 diabetes (if any).

This article does not contain any studies with human beings or other animals performed by any of the authors.

RESULTS

National guidelines for the management of glucose control were not identified for 42 (56%) of the 75 countries; one or more guidelines were available for 33 countries (Table 1). The year of the latest national guideline (2003–2010) was available for 31 (94%) of the 33 countries. Twenty-one (68%) of 31 countries in this group had developed or updated national guidelines since 2008. The identified guidelines were generally evidence-based, though there was some use of secondary evidence reviews, including other guidelines, rather than original literature reviews and evidence synthesis.

Origin of National Guidelines

National guidelines were developed or supported by national ministries of health in 36 % of countries, national diabetes societies/associations in 58 % of countries, and both the ministry of health and national diabetic association in 6 % of countries.

Specific mention was made to source other national or international guidelines in the recommendations from 26 of 33 (79%) countries. The World Health Organization (WHO) definition of diabetes was mentioned by ten (30%) countries, reference to the American Diabetes Association (ADA) standards of medical care and/or other consensus statements was made by 18 (55%) countries, IDF guidelines by 12 (36%) countries, European Association for the Study of Diabetes (EASD) consensus statement by four (12%) countries, Association Latin America de Diabetes (ALAD) guidelines by 1 (3%) country, and American Association of Clinical Endocrinologists (AACE) guidelines by three (9%) countries.

Type 1 Diabetes

National guidelines for type 1 diabetes, or provision for type 1 diabetes in broader guidelines, were available for 25 of 33 (76%) countries (Table 2). Sixteen of the 25 countries (64%) that provided recommendations for first-line insulin therapy suggested the option of more than one type of regimen according to individual requirements. Meal-time + basal insulin regimens and premixed insulin were recommended in 60% of guidelines as first-line treatment options. Insulin analogs, such as the rapid-acting insulins (aspart, lispro), the long-acting insulins (glargine, detemir), and premixed insulin analogs, were specifically mentioned as available options in 18 of 25 (72%) national guidelines.

Nine of the 25 (36%) country guidelines specified a second-line insulin regimen. Intensification with a meal-time + basal regimen was specified by four countries, use of insulin pump therapy was specified by two countries, and three countries suggested more than one option for intensification. Two countries mentioned a third-line management option of intensification of meal-time + basal insulin therapy.

Targets for Glycemic Control

Targets for glycemic control varied between guidelines. However, all guidelines either recommended an HbA_{1c} target of <7.0% (<53 mmol/mol) (70% of guidelines) or <6.5% (<47 mmol/mol) (30% of guidelines) as the ideal glycemic target (Table 3). Most (89%) guidelines recommended a target fasting plasma glucose (FPG) that fell within the range of 3.8–7.2 mmol/L, and the remaining guidelines set a FPG target of <8.0 mmol/L. Most (68%) guidelines also set a 2-h PPG target

Table 2 Non-western countries with national guidelines for type 1 diabetes or provision for type 1 diabetes within broader diabetes guidelines, and those with guidelines for type 2 diabetes

	North Africa and Middle East	East and South Asia	Central and South America	Other
Type 1 diabetes (*n*)	7	9	4	5
	Algeria	Bangladesh	Argentina	Kazakhstan
	Egypt	China	Brazil	Kenya
	Iraq	India	Chile	Russia
	Lebanon	Indonesia	Venezuela	Turkey
	Syria	Malaysia		Ukraine
	Tunisia	Singapore		
	United Arab Emirates	South Korea		
		Taipei		
		Thailand		
Type 2 diabetes (*n*)	11	9	5	8
	Algeria	Bangladesh	Argentina	Belarus
	Egypt	China	Brazil	Kazakhstan
	Iraq	India	Chile	Israel
	Jordan	Indonesia	Mexico	Kenya
	Lebanon	Malaysia	Venezuela	Russia
	Libya	Singapore		Turkey
	Morocco	South Korea		Ukraine
	Saudi Arabia	Taipei		South Africa
	Syria	Thailand		
	Tunisia			
	United Arab Emirates			

value somewhere within the range of 4.0–8.3 mmol/L and the remaining guidelines set a PPG target of either <8.8 mmol/L or <10.0 mmol/L.

First-line Medication Therapy for Glucose-Lowering in Type 2 Diabetes

Overall, 33 countries had national guideline recommendations for type 2 diabetes (Table 2). Most countries (67%) recommended lifestyle changes either before or in conjunction with beginning therapy with oral glucose-lowering drugs (OGLDs).

In only one country (Mexico) metformin was not formally endorsed as first-line therapy, but this guideline made provision for use of any oral agent. In South Korea, first-line options included metformin, a glucagon-like peptide-1 (GLP-1) receptor agonist, a dipeptidyl peptidase-

Table 3 Type 2 diabetes glycemic control targets across regions

Region	Glycemic target			
	HbA1c <6.5% (<48 mmol/mol) (%)	HbA1c <7.0% (<53 mmol/mol) (%)	FPG (mmol/L)	PPG (mmol/L)
North Africa and Middle East	30	70	4.4 to <7.8	5.5 to <10.0
East and South Asia	43	57	4.4 to 8.0	4.4 to <10.0
Central and South America	20	80	3.8 to 7.2	7.7 to <10.0
Others	0	100	3.9 to <7.0	4.0 to 8.0

HbA1c glycosylated hemoglobin, *FPG* fasting plasma glucose, *PPG* post-prandial glucose

4 (DPP-4) inhibitor, an alpha-glucosidase inhibitor, or a sulfonylurea. In Russia, first-line options included metformin, a GLP-1 receptor agonist, or a DPP-4 inhibitor, especially if metformin is poorly tolerated. In all other countries (94%), metformin was recommended as the first-line treatment. However, in 48% of countries who recommended beginning OGLD therapy with metformin, provision was also made for metformin to be used in combination with either another oral agent therapy if HbA_{1c} was >8.0% (>64 mmol/mol), or with insulin if HbA_{1c} was >9.0% (>75 mmol/mol).

Specific recommendations for non-obese, weight-unspecified, or metformin-intolerant people were available in guidelines from 26 (79%) countries. Alternatives included sulfonylureas (77% of countries), thiazolidinediones (35%), glinides (19%), alpha–glucosidase inhibitors (27%), GLP-1 receptor agonists (19%), or DPP-4 inhibitors (35%).

Second- and Third-line Medications for Glucose-lowering in Type 2 Diabetes

In most instances, second-line therapy was recommended when blood glucose control was not maintained at a target HbA_{1c} level of <53 mmol/mol (<7.0%), but some guidelines suggested up-titration if above 47 mmol/mol (6.5%) or >42 mmol/mol (>6.0%). In many guidelines, an interval of 3–6 months was suggested after starting metformin or other medication before a further medication was added. Most recommendations were for a second oral agent rather than an injectable; usually (in 66% of guidelines) addition of a sulfonylurea to metformin. Some guidelines also suggested alternatives to sulfonylurea for use as a second drug in combination therapy, including thiazolidinediones, DPP-4 inhibitors, or alpha-glucosidase inhibitors. GLP-1 receptor agonists were suggested as a second-line combination option by only 2 of 32 (6%) guidelines. In some countries (46%) when HbA_{1c} was >9.0% (>75 mmol/mol), starting with basal insulin plus one OGLD was recommended as an option.

Twelve of 32 (38%) guidelines suggested that insulin therapy could be considered second-line in conjunction with metformin or another oral agent. The type of insulin was unspecified in 42% of guidelines, but in 42% basal insulin as a single insulin was an option, and in 25% premixed insulin was an option.

Third-line therapy was specifically mentioned in 30 guidelines, with an additional oral agent suggested as an option in 40% of these. Insulin therapy was suggested as an option by 25 of 30 (83%) guidelines. Of these

guidelines, the type of insulin was not specified in 44% of guidelines (e.g., insulin initiated according to the patients' needs), beginning with basal insulin was recommended in 44%, with premixed insulin in 32%, long-acting in 12%, and 20% of guidelines allowed initiation with more than one specified insulin regimen (e.g., initiate with long-acting or long-acting plus rapid-acting or premixed).

Guidelines from 22 of 33 (67%) countries made specific provision for post-prandial blood glucose control within their diabetes guidelines. There was little regional variation in these recommendations, with eight of 11 North African and Middle Eastern countries, six of nine South and East Asian countries, three of five Central and South American countries, and five of eight other countries suggesting this measure should receive attention. Four of these countries suggested the use of alpha-glucosidase inhibitors to improve post-prandial blood glucose control (Lebanon, Libya, Mexico, Tunisia), while eight suggested rapid-acting (meal-time) insulin analogs (Saudi Arabia, Malaysia, Singapore, South Korea, Brazil, Mexico, Belarus, Kazakhstan).

Hypoglycemia Treatment Guidelines

Guidelines from 23 of 33 (70%) countries included recommendations for the management of hypoglycemia. While this was mainly for the use of oral carbohydrate for symptomatic hypoglycemia, the use of intramuscular or subcutaneous glucagon was the most widely recommended intervention for severe hypoglycemia.

Special Groups

Information was available for special groups of people with diabetes in guidelines from 31 of the 33 countries. Of these, 23 countries (74%) had recommendations for the management of gestational diabetes, 16 of 31 (52%) for the elderly, and 21 of 31 (68%) for pediatric patients.

DISCUSSION

The development of insulin analogs and GLP-1 receptor agonists, and the increase in the number of available OGLDs have increased the number of glucose-lowering therapy options for people with type 1 or type 2 diabetes [26–28], while management of other conditions (elevated lipids and blood pressure, or complications) has also evolved [26–28]. Some clinicians find authoritative guidelines useful in giving direction to the appropriate management pathways, while others use them to endorse and review their own practice in the diverse areas of diabetes care [12]. While national and international guidelines, algorithms, and position statements on the management of diabetes, and more specifically on glucose-lowering medication, published by ADA, IDF, EASD, and ALAD, together with some high-quality national guidelines, seek to address the clear medical need for guidance in the management of diabetes, these may not meet the needs of local populations at the national or provincial level in non-western countries.

Not surprisingly, the national guidelines identified in this review relied heavily on pre-existing international guidelines. In most countries, the latest version of national guidelines was published before 2012 and consequently could not contain reference to the latest position statement from ADA/EASD [17]. This may be problematic as there was significant change between 2009 and 2013 in glucose-lowering treatment options. Also endorsed in the new statement from ADA/

EASD was the approach to individualization of medical decision-making [17]. Ideas on individualizing management, and an approach to variation in provision of care according to available resources, were espoused by the 2005 IDF type 2 diabetes guideline, but changes were needed for the 2012 revision in light of new therapy options [16]. Also, the ADA standards in medical care is updated annually to include the latest available information on managing diabetes [18] while national guidelines are updated less frequently and may not reflect all new therapy options as they become available.

As this study focussed on adults, the authors have not included international pediatric type 1 diabetes guidelines, such as those from the International Society for Pediatric and Adolescents Diabetes (ISPAD), in the present analysis [29]. However, most national guidelines for type 1 diabetes in adults emphasized the importance of meeting the needs of individual patients when beginning and modifying insulin therapy, with meal-time + basal insulin regimens most commonly cited as being likely to meet individual requirements, especially for post-prandial blood glucose control and for reducing the risk of hypoglycemia. Insulin analogs, such as the rapid-acting insulins (aspart, lispro), biphasic insulins based on these, and the long-acting insulins (glargine, detemir), were specifically mentioned as available options in 18 of 25 (72%) national guidelines for type 1 diabetes.

In the management of hyperglycemia in type 2 diabetes, most national guidelines were in agreement with international guidelines in their recommendation of metformin as the treatment of choice for first-line therapy, especially in obese patients, though the option of combination with another OGLD or insulin was addressed in 48% of countries. Likewise, most national guidelines acknowledged sulfonylureas as a first-line treatment option in people who were not obese and for those who could not tolerate metformin. This was in general agreement with recommendations in IDF guidelines and ADA statements on the use of sulfonylureas if and when metformin is insufficient, is not tolerated, or in people who are not overweight [16–18].

Differences do, however, appear in both national and international recommendations as to the use of second-line therapies if glucose-control targets are not attained within 3–6 months or if subsequent deterioration of glucose control occurs. While the cost-effective sulfonylureas are most commonly recommended, some guidelines also made provision for the addition of other OGLDs drugs, including thiazolidinediones, DPP-4 inhibitors, and alpha-glucosidase inhibitors. Many guidelines (12 of 33) also suggest the option of injectables, GLP-1 receptor agonists, and insulin as a second-line therapy options, as does the recent position statement from the ADA/EASD group [17].

A problem with international guidelines is that they can give so many alternative treatment options that the less specialist practitioner may fail to make the optimum treatment recommendations for each type of patient. In addition, complex regimens may lead to payors agreeing to reimburse the cheapest available option(s). National guidelines that allow multiple treatment options but discuss the benefits and weaknesses of individual classes of glucose-lowering therapies may then be closer to assisting health-care professionals in meeting the medical needs of people with type 2 diabetes.

Another consideration is whether provision is made in national guidelines for specific clinical situations, post-prandial blood glucose control, and hypoglycemia. Guidelines from 67% of countries in the study made some provision for PPG control, with use of a rapid-

acting insulin as part of a meal-time + basal insulin regimen the most common recommendation, and an alpha-glucosidase inhibitor was recommended in some guidelines. Guidelines from 70% of countries made provision for hypoglycemia.

A limitation of the current study is that it has not been comprehensive in the inclusion of all available national guidelines for all the countries, but has specifically focussed on treatment guidelines, which may have introduced bias into the final analysis. A further limitation was that some national guidelines may have been inadvertently missed because they were not freely available on the internet or were restricted to a non-English website. Some countries may also have one or more national guidelines that they refer to. Furthermore, the study had to rely on translation of guidelines from the original language into English for many countries, and this may have led to the inclusion of inaccuracy or inconsistencies in the analysis. For guidelines that could not be translated using Google translation, the accuracy of the data depended on the interpretation of a local clinical advisor provided by Novo Nordisk who translated the guidelines from the native language. Also, the study did not include guidelines for special groups, such as recommendations for the management of diabetes during Ramadan [30–32]. However, the authors note that guidelines on the management of diabetes during Ramadan stress the importance of individualizing treatment to meet the patient's needs [30–32].

CONCLUSION

In conclusion, national guidelines were identified for 33 out of 75 (44%) lower income countries, of which 76% also had guidelines for type 1 diabetes. Two-thirds of countries with national guidelines for type 2 diabetes had made the latest version of their guidelines available after 2008, enabling the latest treatment options to be included. Given that, the consensus algorithms developed by ADA/EASD have been criticized because they were based mostly on expert opinion rather than on an evidence-based process [26, 30]. Therefore, it is notable that many national guidelines seem now to have adopted a more evidence-based approach. Furthermore, with regular updating to reflect the rapid pace of change in the management of type 2 diabetes, this suggests that quality national guidelines may benefit a wider international population of people with diabetes.

However, establishment of national guidelines is only the first step in achieving a high quality of disease management and more efforts need to be made for clinicians and patients to adhere to the recommendations of national guidelines, since glycemic control is still poor in the countries where this study was conducted.

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Conflict of interest. PH or institutions with which he is associated receives funding from most manufacturers of glucose-lowering medications for his research, advisory and educational activities. JH has acted as a speaker for Novo Nordisk, Novartis, MSD, Merck Serono, and AstraZeneca, and an advisory board member for Novo Nordisk and Merck Serono. ZAL is an advisory board member and has been a principal investigator for Novo Nordisk. PS is an advisory board member for Novo Nordisk, Sanofi-Aventis, and Novartis. YB has participated in advisory boards and as a consultant for Novo-Nordisk. LL is a speaker and member of the Latin American Board of Eli Lilly, and the Argentinian Boards of Novo Nordisk, Novartis, Sanofi, BMS, and AstraZeneca. He is also a principal investigator of clinical trials run by Eli Lilly, Novo Nordisk, and AstraZeneca. SG has participated in international clinical trials sponsored by Novo Nordisk. J-WC is an employee of Novo Nordisk A/S. AZ has participated as a speaker for Abbott, AstraZeneca/BMS, Bayer, Berlin-Hemi, Novartis, Novo Nordisk, and Sanofi and has also participated in clinical trials sponsored by Lilly, Novartis, Novo Nordisk, and Sanofi.

Ethical Standard. This article does not contain any studies with human beings or other animals performed by any of the authors.

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