Research Article ISSN 2639-9326

Diabetes & its Complications

Call to Standardize Diagnostic Practice for Type 2 Diabetes Mellitus World-Wide; A Review of Various Guidelines Used Internationally

Adri-Anna Aloia, MB BCh BAO, HBSc*

Royal College of Surgeons in Ireland Medical University of Bahrain, P.O. Box 15503, Adliya, Kingdom of Bahrain.

***Correspondence:**
Adri-Anna Aloia, MB BCh BAO, HBSc., Royal College of Surgeons in Ireland Medical University of Bahrain, P.O. Box 15503, Adliya, Kingdom of Bahrain.

Received: 11 September 2019; **Accepted:** 02 October 2019

Citation: Adri-Anna Aloia, MB BCh BAO, HBSc. Call to Standardize Diagnostic Practice for Type 2 Diabetes Mellitus World-Wide; A Review of Various Guidelines Used Internationally. Diabetes Complications. 2019; 3(3): 1-4.

ABSTRACT

Background: *As Type 2 Diabetes Mellitus has become a current epidemic, it is important to emphasize the use of one universal guideline or criteria for the diagnosis of Non-Insulin Dependent Diabetes Mellitus.*

Methods: *The study assesses the potential variability of incidence values through different, available guidelines used by organizations and countries worldwide. These guidelines include those used by WHO, NICE, UK, India, Japan, United States of America and Canada. Data recorded and used in a previous publication defining the incidence of Type 2 Diabetes Mellitus in the Bahraini population was inputted, using the listed guideline Fasting Blood Sugar cutoff values, for 1613 patients.*

Results: *The results presented a varied "diabetic" population percentage within the data set of Bahrain, ranging from 12.7% up to 38.3%, depending on the guideline used.*

Conclusion: *This study is meant to highlight potential discrepancies regarding Diabetes Mellitus prevalence internationally. The aim of this study is to theoretically highlight the importance of one standard guideline for practice and community awareness to establish a more truer value regarding the prevalence of Diabetes Mellitus worldwide to date as an implication of the importance of clinical labeling of patients for further development and adequately budgeting of preventative management services within a governed community.*

Keywords

Diabetes mellitus, Diabetes mellitus type 2, Non-insulin dependent diabetes mellitus, WHO, NICE, ADA, Canada, Japan, America, India.

Background

Type 2 or Non-Insulin Dependent Diabetes Mellitus (NIDDM), herein referred to as Type 2 diabetes, is due to a resistance to insulin or loss of responsiveness to the hormone [22]. Thus, in type 2 diabetes, insulin is being produced however the body itself cannot use it, resulting in a rise in blood glucose levels. Genetic predispositions as well as lifestyle habits, usually related to sedentary lifestyle and high caloric intake, increase the risk of developing type 2 diabetes [22].

There are many guidelines and criteria practiced worldwide, however, incongruences found within the various guidelines call to question whether there is an international consensus for such diagnostic criteria. As observed in Table 1, many of the current guidelines in circulation and use to diagnose Type 2 Diabetes Mellitus vary, especially in regarding what is considered a "normal" blood glucose measurement range. For example, the lowest lower limit of a "normal" blood glucose measurement range is for the WHO guidelines of 2.61 mmol/L, which would fall under the "hypoglycemic" range for NICE, UK, India, USA and Canadian guidelines. Likewise, values above 7.0 mmol/L, considered "Diabetic" for WHO, NICE and Japan guidelines, marks some of the prediabetic patients in UK, USA and Canadian guidelines as being inappropriately categorized, which may have implications towards health management concerns. The guidelines for India, however, would have patients who would be considered within their normal range as "Diabetic" based on all other guidelines.

	WHO guidelines	NICE guidelines	UK	India	Japan	USA guidelines	CA guidelines
Hypoglycemic	</= 2.6 mmol/L	<4.0 mmol/L**	<3.5 mmol/L**	A1C <5** (5.38 mmol/L)*	N/A	<70 mg/dL** (<3.88 mmol/L)*	<4.0 mmol/L**
Normal	2.61 – 6.09 mmol/L**	4.0-5.9 mmol/L (4.0 – 5.59 mmol/L)**	3.5-5.5 mmol/L or <6.0 mmol/L	A1C 5-8 (5.38-10.16 mmol/L)*	<6.1 mmol/L	70-130 mg/dL (3.88-7.22 mmol/L)* A1C 7%	4.0-7.0 mmol/L
Prediabetic	6.1-6.9 mmol/L	5.6-6.9 mmol/L	A1C 6.0-6.4% (7.0-7.61 mmol/L)*	10.16-10.95 mmol/L**	6.1-6.99 mmol/L**	N/A	A1C 6.0-6.4% (7.0-7.61 mmol/L)*
Diabetic	>/= 7.0 mmol/L	>7.0 mmol/L	A1C 6.5%+ (7.7 mmol/L)* Or > 7.0 mmol/L	<8.5 good (<10.96 mmol/L)* 8.5-9 fair (10.96-11.76 mmol/L)* >9.5 poor (12.55 mmol/L)* 10.96-12.55 mmol/L**	1AC >/= 6.5% (7.7mmol/L)* Or >/= 7.0 mmol/L	>130 mg/dL** (>7.22 mmol/L)*	A1C 6.5%+ (7.7 mmol/L)*
Severe diabetic	N/A	N/A	N/A	>12.55 mmol/L**	N/A	N/A	N/A
Countries/ organizations following same guideline	IDF Australia Ireland		UK NHS-UK			American Diabetes Association	
Notes	Specified values without medication use		Notes Specified values without medication use UK – did mention NICE guideline 4.0-7.0mM/L	No defined unit of measurement (assumed percentage)		Specified for individuals with diabetes Updated ADA guidelines follow prediabetic and diabetic cutoffs [25]	

Table 1: Fasting Blood Glucose measurements overview cutoffs [2-4,6-12,14,15,19,21,23]. All reference values were converted to a standard unit of mmol/L, as per the previously collected data [24].

Between 2010 and 2030, there will be a 69% increase in numbers of adults with diabetes in developing countries and a 20% increase in developed countries [20]. With a worldwide diabetes prevalence of 6.4%, affecting 285 million adults, in 2010, and will increase to 7.7%, and 439 million adults by 2030, thus monitoring and assessment of Type 2 diabetes among the public, standardization of clinical guidelines and criteria becomes fundamental in both screening and diagnosis [5,16,18,23].

Methods

In this study, the prepared data from the study: The Epidemiologic Profile of Diabetes Mellitus among Attendees of Outpatient Clinics at Bahrain Defense Force Hospital: A Cross-Sectional Study was used to compare various Fasting Blood Sugar values of the Bahraini population using different guidelines from across the globe to highlight the variability between each official guidelines and how they may represent the incidence of Type 2 Diabetes Mellitus from the data collected from the Bahraini population. Each guideline's value will be used to organize the data collected and previously reported in the above, published study [24]. The same method of analysis was used with the inferred values of clinical cutoff values described in chart 1 to assess the overall average Fasting Blood Sugar, as well as that for overall male and female values, and listed age categories. A total number of 1613 patients' Fasting Blood Sugar and demographic information were used. P value of ≤0.05 was considered significant. Age categories were organized as follows:

- Age category 1: 0-20 years of age
- Age category 2: 20-40 years of age
- Age category 3: 40-60 years of age
- Age category 4: 60-80 years of age
- Age category 5: 80+ years of age

Results

All referred values are based on Fasted Blood Sugar cut offs as per each guideline or converted appropriately as described using Figure 1, Equation 1 and Equation 2. Documented values which had noted limits but did not intersect or label further values were inferred as hyperglycemic, prediabetic and severe diabetic clinical labels.

A1C	eAG	
%	mg/dl	mmol/l
6	126	7.0
6.5	140	7.8
7	154	8.6
7.5	169	9.4
8	183	10.1
8.5	197	10.9
9	212	11.8
9.5	226	12.6
10	240	13.4

Figure 1: Conversion table between A1C percentages and eAG values [7]. (1)

(1) **Equation 1:** Conversion of A1C percentages to eAG values [7,10].
28.7 X A1C – 46.7 = mg/dL

Equation 2: Conversion of units "mg/dL" to "mmol/L".
X mmol/L = (Ymg/dL)/18

Based on the WHO, NICE and the Japanese guidelines 38.3% are

diabetic whereas only 35.3% and 29.8% are diabetic according to American and Canadian guidelines respectively. Using the UK guidelines, the percentage of diabetics was 29.8%. The Indian guidelines were the odd in the group and showed a prevalence of diabetes of 4.3% and severe diabetes of 7.9% whereas it labeled 55.2% as normal. Gender specific results were reported through all guidelines for prediabetic and diabetic as seen in tables 2-8. India's guidelines were the only ones that considered severe diabetic with a male to female difference of 1.3%. The Japanese guidelines failed to describe a hypoglycemic label group.

	FBS Cutoffs	Overall	Male	Female	Agecat1	Agecat2	Agecat3	Agecat4	Agecat5
Hypoglycemic	</=2.6	0.1%	0%	0.1%	0%	0.4%	0%	0%	0%
Normal	2.61-6.09	47.2%	45.5%	47.9%	78.7%	71.1%	42.3%	37.2%	44.1%
Prediabetic	6.1-6.9	12.8%	14.8%	12.0%	13.1%	8.6%	12.6%	15.8%	8.8%
Diabetic	>/=7.0	38.3%	38.7%	38.0%	8.2.%	18.2%	43.3%	45.4%	44.1%

Table 2: Adjusted data based on WHO guidelines. Note: no cutoff documented for severe diabetic [23].

	FBS Cutoffs	Overall	Male	Female	Agecat1	Agecat2	Agecat3	Agecat4	Agecat5
Hypoglycemic	<4.0	1.5%	1.2%	1.7%	0%	1.4%	0.4%	3.1%	8.8%
Normal	4.0-5.59	34.7%	32.5%	35.6%	68.9%	60.0%	29.8%	23.8%	26.5%
Prediabetic	5.6-6.9	23.9%	26.5%	22.7%	23.0%	18.6%	24.8%	26.1%	17.6%
Diabetic	>7.0	38.3%	38.7%	38.0%	8.2%	18.2%	43.3%	45.4%	44.1%

Table 3: Adjusted data based on NICE guidelines. Note: no cutoff documented for severe diabetic [19].

	FBS Cutoffs	Overall	Male	Female	Agecat1	Agecat2	Agecat3	Agecat4	Agecat5
Hypoglycemic	<3.5	0.9%	1.0%	0.8%	0%	0.7%	0.3%	1.8%	2.9%
Normal	3.5-5.5 (<6.0)	32.9% (45.4%)	30.3% (43.7%)	34% (46.2%)	65.6% (78.7%)	57.5% (70.7%)	27.4% (39.5%)	23.2% (35.9%)	29.4% (44.1%)
Prediabetic	(6.0-7.0) 7.0-7.61 (7.61-7.69)	(16.3%) 7.6% (0.9%)	(17.6%) 7.2% (0.8%)	(15.7%) 7.7% (1.0%)	(13.1%) 1.6% (0%)	(11.1%) 2.5% (1.1%)	(17.2%) 8.8% (1.1%)	(18.7%) 8.8% (0.8%)	(11.8%) 14.7% (0%)
Diabetic	>/=7.7	29.8%	30.7%	29.4%	6.6%	14.6%	33.7%	35.5%	29.4%

Table 4: Adjusted data based on UK guidelines. Note: no cutoff documented for severe diabetic [10].

	FBS Cutoffs	Overall	Male	Female	Agecat1	Agecat2	Agecat3	Agecat4	Agecat5
Hypoglycemic	<5.38	29.8%	27.5%	30.8%	55.7%	51.8%	23.6%	23.6%	29.4%
Normal	5.38-10.16	55.2%	57.3%	54.3%	41.0%	38.9%	59.8%	59.1%	58.8%
Prediabetic	10.16-10.95	2.8%	3.2%	2.6%	0%	0.4%	3.5%	3.3%	11.8%
Diabetic	10.96-12.55	4.3%	3.2%	4.8%	0%	2.1%	5.1%	4.9%	2.9%
Severe diabetic	>12.55	7.9%	8.8%	7.5%	3.3%	6.8%	8.1%	9.0%	2.9%

Table 5: Adjusted data based on India guidelines [16].

	FBS Cutoffs	Overall	Male	Female	Agecat1	Agecat2	Agecat3	Agecat4	Agecat5
Normal	<6.1	47.2%	45.5%	48.0%	78.7%	71.4%	42.3%	37.2%	44.1%
Prediabetic	6.1-6.99	14.4%	15.8%	13.8%	13.1%	10.4%	14.2%	17.2%	11.8%
Diabetic	>/=7.0	38.3%	38.7%	38.0%	8.2%	18.2%	43.3%	45.4%	44.1%

Table 6: Adjusted data based on Japan guidelines. Note: no cutoff documented for hypoglycemic or severe diabetic [13].

	FBS Cutoffs	Overall	Male	Female	Agecat1	Agecat2	Agecat3	Agecat4	Agecat5
Hypoglycemic	<3.88	1.4%	1.2%	1.5%	0%	1.4%	0.4%	3.1%	2.9%
Normal	3.88-7.22	63.3%	63.7%	63.1%	91.8%	81.1%	59.4%	55.9%	58.8%
Diabetic	>7.22	35.3%	35.1%	35.3%	8.2%	17.5%	40.2%	41.1%	38.2%

Table 7: Adjusted data based on USA guidelines. Note: no cutoff documented for prediabetic or severe diabetic [2].

	FBS Cutoffs	Overall	Male	Female	Agecat1	Agecat2	Agecat3	Agecat4	Agecat5
Hypoglycemic	<4.0	1.5%	1.2%	1.7%	0%	1.4%	0.4%	3.1%	8.8%
Normal	4.0-7.0	60.2%	60.1%	60.3%	91.8%	80.4%	56.3%	51.5%	47.1%
Prediabetic	7.0-7.61 (7.61-7.7)	7.6% (1.1%)	7.2% (1.0%)	7.7% (1.2%)	1.6% (0%)	2.5% (1,1%)	8.8% (1.1%)	8.8% (1.4%)	14.7% (0%)
Diabetic	>/=7.7	29.8%	30.7%	29.4%	6.6%	14.6%	33.7%	35.5%	29.4%

Table 8: Adjusted data based on Canadian guidelines. Note: no cutoff documented for severe diabetic [3].

Discussion

Average FBS readings, as a result of varying guidelines, presented a different value of diabetes prevalence for the same data collected in Bahrain. India's guidelines presented a prevalence of 12.7%, which included their values for "severe" diabetes. Guidelines for the UK and Canada presented a prevalence of 29.8%. Guidelines for the United States presented a prevalence of 35.3%. WHO, NICE and Japan's guidelines presented a prevalence of 38.3% for the given data.

All regions have "prediabetic" criteria; of note, the criteria for the United States was not included in this paper. Percentages found here varied even more, listed in ascending order: 2.8% (India), 8.7% (Canada), 12.8% (WHO), 14.4% (Japan), 23.9% (NICE) and 24.8% total (UK). Arguably, the prediabetic prevalence would be more important than the diabetic prevalence with respect to funding for community initiatives and lifestyle education as this group would be considered most manageable prior to pharmaceutical intervention.

For most of the results, males presented with a higher percentage of prediabetic and diabetic cases. Canadian guidelines showed a high percentage of female prediabetics and guidelines for India and the United States showed an increased percentage of female diabetes.

In 2014, the year in which this data was originally retrieved, IDF values retrieved for Bahrain showed a national prevalence of 17.5% [13]. It is shown in figure, prevalence of 38.3% by WHO guidelines, representing Bahrain's diabetes prevalence. Most of the trends found between the age categories were similar to that observed in the author's previous study, in that prediabetic and diabetic percentages increased with age as normal reading percentages decreased [24]. Even with the variability between the guidelines there is a strong correlation of an increase in age contributing to the onset of type 2 diabetes. With the overall data, UK, India (combining diabetic and severe diabetic percentages), USA and Canada's guidelines underrepresented the actual prevalence of Type 2 Diabetes Mellitus in Bahrain, published for that year. Utilizing these alternative FBS cutoff values, as per their respective guidelines, may have an impact on potential governmental budgeting efforts for preventative program services, meal planning and more for which these values were originally attained to describe an accurate incidence of diabetes.

References

1. Akter S, Rahman MM, Abe SK, et al. Prevalence of diabetes and prediabetes and their risk factors among Bangladeshi adults: a nationwide survey. Bulletin of the World Health Organization. 2014; 92: 204-213A.
2. http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/checking-your-blood-glucose.html
3. http://www.diabetes.ca/diabetes-and-you/healthy-living-resources/blood-glucose-insulin/managing-your-blood-glucose
4. http://www.diabetesadvocacyalliance.org/html/resources_diabetes_facts_future.html
5. http://www.diabetesaustralia.com.au
6. http://professional.diabetes.org/GlucoseCalculator.aspx
7. http://www.diabetesindia.com
8. http://www.diabetes.ie
9. http://www.diabetesincontrol.com/images/issues/2011/Feb/average_blood_glucose.pdf
10. http://www.diabetes.org.uk/Guide-to-diabetes/Monitoring/Testing/
11. http://www.idf.org/sites/default/files/IDF-Guideline-for-Type-2-Diabetes.pdf
12. http://www.idf.org
13. http://www.jds.or.jp
14. Kosaka K, Kuzuya T, Yoshinaga H, et al. A prospective study of health check examinees for the development of non-insulin-dependent diabetes mellitus: relation of the incidence of diabetes with the initial insulinogenic index and degree of obesity. Diabet Med. 1996; 13: S120-S126.
15. http://healthintelligence.drupalgardens.com/content/prevalence-diabetes-world-2013
16. http://www.medindia.net/patients/calculators/bloodsugar_chart.asp
17. http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf
18. http://www.nhs.uk/conditions/diabetes-type2/pages/diagnosis.aspx
19. https://www.nice.org.uk
20. Shaw JE, Sicree R, Zimmet PZ. Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Research and Clinical Practice. 2010; 87: 4-14.
21. Rhodes, Pflanzer. Human Physiology: 4th Edition. Thompson Learning, Brooks/Cole. 2003.
22. Wild S, Roglic G, Green A, et al. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care. 2014; 27: 1047-1053.
23. http://apps.who.int/iris/bitstream/10665/76173/1/9789241548397_eng.pdf
24. http://scientonline.org/fulltext/the-epidemiologic-profile-of-diabetes-mellitus-among-attendees-of-outpatient-clinics-at-bahrain-defense-force-hospital-a-cross-sectional-study/21456
25. American Diabetes Association. Standards of medical care in Diabetes-2016. Diabetes Care. 2016; 39: S4-S5.