

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Prevalence and predictors of Gestational Diabetes Mellitus in rural Assam: A cross-sectional study using mobile medical units
AUTHORS	Chanda, Subrata; Dogra, Vishal; Hazarika, Najeeb; Bambrah, Hardeep; Sudke, Ajit; Vig, Anupa; Hegde, Shailendra

VERSION 1 – REVIEW

REVIEWER	Nouhjah Diabetes Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
REVIEW RETURNED	25-Mar-2020

GENERAL COMMENTS	<p>-What criteria used for GDM definition? -Why Muslims were different? please insert in discussion part. -How you concluded this in conclusion of abstract part after that results. [The mobile medical units may play a significant role in the implementation of GDM screening, diagnosis, treatment to ensure better maternal and foetal health outcomes in rural Assam]</p> <p>-In introduction: Why you wrote these words with capital letter: Gestational Diabetes Mellitus</p> <p>-English editing is needed [The GDM associated maternal complications include preeclampsia, the need for caesarean]</p>
-------------------------	---

REVIEWER	Xin Sun The First Affiliated Hospital of Soochow University, China.
REVIEW RETURNED	28-Apr-2020

GENERAL COMMENTS	<p>GDM diagnostic criteria in the article was the blood sugar level of 140 mg/dL (7.8 mmol/L) or higher at 2 hours after ingestion of 75gm glucose indicates GDM (Page 7). While, it may improper. The International Association of Diabetes and Pregnancy Study Groups (IADPSG) proposed GDM diagnostic criteria in 2010: boundary blood glucose levels for fasting, 1 and 2 h after oral glucose of 5.1, 10.0 and 8.5 mmol/L, respectively, by 75-g OGTT. If any one of these three values reaches or exceeds the boundary level, the patient should be diagnosed with GDM. IADPSG criteria was recommended by ADA, WHO, and International Federation of Gynecology and Obstetrics.</p> <p>Metzger BE, Gabbe SG, Persson B, et al. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care 2010; 33: 676–682. World Health Organization. Diagnostic criteria and classification of</p>
-------------------------	--

	<p>hyperglycaemia first detected in pregnancy. <i>Diabetes Res Clin Pract</i> 2013; 103: 341–363.</p> <p>Hod M, Kapur A, Sacks DA, et al. The international federation of gynecology and obstetrics (FIGO) initiative on gestational diabetes mellitus: a pragmatic guide for diagnosis, management, and care. <i>Int J Gynaecol Obstet</i> 2015; 131: S173–S211.</p>
--	---

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name
Nouhjah

Institution and Country
Diabetes Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Please state any competing interests or state 'None declared':
None

Please leave your comments for the authors below

-What criteria used for GDM definition?

We have followed the GDM diagnostic criteria that is more relevant to Indian population and as recommended by the Ministry of Health and Family Welfare (MoHFW), Government of India. This guideline took into consideration the recommendations of the subject experts and the available national/international evidence [1-4].

Besides, MoHFW guidelines are based on Diabetes in Pregnancy Study Group in India (DIPSI) and WHO (1999) GDM diagnostic recommendations. According to government's guidelines, a woman in 24-28 weeks of pregnancy, irrespective of fasting status, ingests 75 grams of glucose orally. A pregnant woman is a confirmed GDM case if her 2-hour blood glucose value is ≥ 140 mg/dl.

Please refer to the following methodology, as mentioned in the MoHFW guidelines for GDM testing and confirmation.

- "Single-step testing using 75 gm oral glucose & measuring blood sugar 2 hours after ingestion.
- 75 gm glucose is to be given orally after dissolving in approximately 300 ml water whether the pregnant women comes in fasting or non-fasting state, irrespective of the last meal.
- The intake of the solution has to be completed within 5-10 minutes.
- A plasma standardized glucometer should be used to evaluate blood sugar 2 hours after the oral glucose load.
- If vomiting occurs within 30 minutes of oral glucose intake, the test has to be repeated the next day, or else refer to a facility. If vomiting occurs after 30 minutes, the test continues.
- The threshold blood sugar level of ≥ 140 mg/dL (more than or equal to 140) is taken as cut off for diagnosis of GDM"

References

[1] Ministry of Health and Family welfare. *Diagnosis & Management of Gestational Diabetes Mellitus. Technical and Operational Guidelines.* Government of India. Delhi:2018.
https://nhm.gov.in/New_Updates_2018/NHM_Components/RMNCH_MH_Guidelines/Gestational-Diabetes-Mellitus.pdf

[2] Polur H, Prasad K, Bandela P, et al. Diabetes in Pregnancy Study Group in India (DIPSI) – A Novel Criterion to Diagnose GDM. *Int J Biochem Res Rev* 2016;10:1–6.

[3] WHO. Definition, diagnosis and classification of Diabetes mellitus and its complications. Part I: Diagnosis and classification of Diabetes mellitus WHO/MCD/MCS/99.2 ed Geneva WHO 1999. pp. 1-59.

[4] Rani PR, Begum J. Screening and Diagnosis of Gestational Diabetes Mellitus, Where Do We Stand. *J Clin Diagn Res.* 2016;10(4):QE01-QE4. doi:10.7860/JCDR/2016/17588.7689

-Why Muslims were different? please insert in discussion part.

Thank you for your observation. We have included the same in discussion part.

-How you concluded this in conclusion of abstract part after that results.

[The mobile medical units may play a significant role in the implementation of GDM screening, diagnosis, treatment to ensure better maternal and foetal health outcomes in rural Assam]

Thank you for this valuable feedback. The study utilized a wide network of mobile medical units in rural Assam to reach the pregnant women at their nearest health facility. Since mobile medical units has deep penetration in reaching people in the far-flung areas, it is therefore easy to top-up any health program service on such a platform. Hence, we wrote that these mobile medical units may be useful for GDM screening and diagnosis. We have mentioned the same in our conclusion and first paragraph of the discussion section.

-In introduction: Why you wrote these words with capital letter: Gestational Diabetes Mellitus

Thank you for pointing this out. We wrote them in small letters.

-English editing is needed [The GDM associated maternal complications include preeclampsia, the need for caesarean]

Thank you. We have modified it appropriately for better comprehension.

Reviewer: 2

Reviewer Name

Xin Sun

Institution and Country

The First Affiliated Hospital of Soochow University, China.

Please state any competing interests or state 'None declared':

None declared.

Please leave your comments for the authors below

GDM diagnostic criteria in the article was the blood sugar level of 140 mg/dL (7.8 mmol/L) or higher at 2 hours after ingestion of 75gm glucose indicates GDM (Page 7). While, it may improper. The International Association of Diabetes and Pregnancy Study Groups (IADPSG) proposed GDM diagnostic criteria in 2010: boundary blood glucose levels for fasting, 1 and 2 h after oral glucose of 5.1, 10.0 and 8.5 mmol/L, respectively, by 75-g OGTT. If any one of these three values reaches or exceeds the boundary level, the patient should be diagnosed with GDM. IADPSG criteria was recommended by ADA, WHO, and International Federation of Gynecology and Obstetrics.

Metzger BE, Gabbe SG, Persson B, et al. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. *Diabetes Care* 2010; 33: 676–682.

World Health Organization. Diagnostic criteria and classification of hyperglycaemia first detected in pregnancy. *Diabetes Res Clin Pract* 2013; 103: 341–363.

Hod M, Kapur A, Sacks DA, et al. The international federation of gynecology and obstetrics (FIGO) initiative on gestational diabetes mellitus: a pragmatic guide for

diagnosis, management, and care. *Int J Gynaecol Obstet* 2015; 131: S173–S211.

We thank reviewer for wonderful feedback and appreciate the time to review and suggest GDM cut off values and also sharing with us the references.

We have followed the GDM diagnostic criteria that is more relevant to Indian population and as recommended by the Ministry of Health and Family Welfare (MoHFW), Government of India. These guidelines take into consideration the recommendations of the subject experts and the available national/international evidence [1-4].

These MoHFW guidelines are based on Diabetes in Pregnancy Study Group in India (DIPSI) and WHO (1999) GDM diagnostic recommendations. According to government's guidelines, a woman in 24-28 weeks of pregnancy, irrespective of fasting status, ingests 75 grams of glucose orally. A pregnant woman is a confirmed GDM case if her 2-hour blood glucose value is ≥ 140 mg/dl.

Please refer to following methodology, as mentioned in the MoHFW guidelines for GDM testing and confirmation.

- Single-step testing using 75 gm oral glucose & measuring blood sugar 2 hours after ingestion.
- 75 gm glucose is to be given orally after dissolving in approximately 300 ml water whether the pregnant women comes in fasting or non-fasting state, irrespective of the last meal.
- The intake of the solution has to be completed within 5-10 minutes.
- A plasma standardized glucometer should be used to evaluate blood sugar 2 hours after the oral glucose load.
- If vomiting occurs within 30 minutes of oral glucose intake, the test has to be repeated the next day, or else refer to a facility. If vomiting occurs after 30 minutes, the test continues.
- The threshold blood sugar level of ≥ 140 mg/dL (more than or equal to 140) is taken as cut off for diagnosis of GDM”

Moreover, multiple visits for the same beneficiaries are not possible because of difficult terrain and limited transport facilities in rural Assam. DIPSI method (on which MoHFW guidelines are based) therefore is more feasible and suited to overcome such operational challenges [5] apart from having high specificity and sensitivity [6].

References:

- [1] Ministry of Health and Family welfare. Diagnosis & Management of Gestational Diabetes Mellitus. Technical and Operational Guidelines. Government of India. Delhi:2018. https://nhm.gov.in/New_Updates_2018/NHM_Components/RMNCH_MH_Guidelines/Gestational-Diabetes-Mellitus.pdf
- [2] Polur H, Prasad K, Bandela P, et al. Diabetes in Pregnancy Study Group in India (DIPSI) – A Novel Criterion to Diagnose GDM. *Int J Biochem Res Rev* 2016;10:1–6.
- [3] WHO. Definition, diagnosis and classification of Diabetes mellitus and its complications. Part I: Diagnosis and classification of Diabetes mellitus WHO/MCD/MCS/99.2 ed Geneva WHO 1999. pp. 1-59.
- [4] Rani PR, Begum J. Screening and Diagnosis of Gestational Diabetes Mellitus, Where Do We Stand. *J Clin Diagn Res.* 2016;10(4):QE01-QE4. doi:10.7860/JCDR/2016/17588.7689
- [5] Mohan V, Usha S, Uma R. Screening for gestational diabetes in India: Where do we stand?. *J Postgrad Med.* 2015;61(3):151-154. doi:10.4103/0022-3859.159302.
- [6] Anjalakshi C, Balaji V, Balaji MS, Ashalata S, Suganthi S, Arthi T, et al. A single test procedure to diagnose gestational diabetes mellitus. *Acta Diabetol.* 2009;46:51–4.

Kindly note we have revised the manuscript based on received comments and feedback. Therefore,

we are taking an opportunity to submit two versions--“Main Document” marked copy and Main document-clean copy as suggested.

VERSION 2 – REVIEW

REVIEWER	Sedigheh Nouhjah Diabetes Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
REVIEW RETURNED	15-Aug-2020
GENERAL COMMENTS	Corrections are acceptable with connivance.