INTERNATIONAL DIABETES FEDERATION

IDF GDM MODEL OF CARE

IMPLEMENTATION PROTOCOL

GUIDELINES FOR HEALTHCARE PROFESSIONALS

WINGS
WOMEN IN INDIA with GDM STRATEGY
An International Diabetes Federation Project

International Diabetes Federation

MADRAS DIABETES RESEARCH FOUNDATION

Abbott Fund

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IDF GDM Model of Care
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List of acronyms

ANC	:	Antenatal Care
BP	:	Blood Pressure
CRF	:	Case Report Form
EDD	:	Estimated Delivery Date
FFQ	:	Food Frequency Questionnaire
FPG	:	Fasting Plasma Glucose
GDM	:	Gestational Diabetes Mellitus
HAPO	:	Hyperglycaemia and Adverse Pregnancy Outcomes Study
HbA1c	:	Glycated Haemoglobin
ICU	:	Intensive Care Unit
IDF	:	International Diabetes Federation
LGA	:	Large-for-Gestational Age
LMP	:	Last Menstrual Period
MDRF	:	Madras Diabetes Research Foundation
mg/dl	:	Milligram per decilitre
MNT	:	Medical Nutrition Therapy
MoC	:	Model of Care
NICU	:	Neonatal Intensive Care Unit
NPH	:	Neutral Protamine Hagedorn Insulin
OGTT	:	Oral Glucose Tolerance Test
PAQ	:	Physical Activity Questionnaire
PG	:	Plasma Glucose
PPPG	:	Post-Prandial Plasma Glucose
RPG	:	Random Plasma Glucose
SGA	:	Small-for-Gestational Age
SMBG	:	Self-Monitoring of Blood Glucose
WINGS	:	Women In India with GDM Strategy
WHO	:	World Health Organization

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INTRODUCTION TO THE WINGS PROJECT

The WINGS Project (Women in India with GDM Strategy)

Gestational Diabetes Mellitus (GDM) is a severe and neglected threat to maternal and child health. Fifteen per cent of pregnant women globally develop GDM during pregnancy[1]. Prevalence varies around the world.

Objective

Community-based and facility-based intervention for the management of pregnant women with gestational diabetes in low-resource settings.

Project summary

The WINGS project (Women In India with GDM Strategy) was the first-ever IDF strategy to tackle the rising prevalence of GDM in low resource settings such as India. The aim of the project was to develop a context-adapted model approach to care in low-resource settings to confront the widespread challenges in GDM screening and management. The project developed a standardized approach to GDM care, seeking to improve the health outcomes of women with GDM and their new-borns, and to strengthen the capacity of selected health facilities to address GDM.

The IDF GDM Model of Care was piloted in seven (urban and rural) collaborating health centres in Tamil Nadu State (South India), from June 2012 to December 2015. The IDF GDM Model Approach to Care has been developed using best practice of care and established clinical guidelines. It has now been adapted and made available to other low and middle-income countries worldwide.

These guidelines provide practical information to health care providers from different countries on how to implement the IDF approach to care for GDM in their own clinics.

1 International Diabetes Federation, Diabetes in pregnancy – Protecting Maternal Health, Policy Briefing. Sept. 2011

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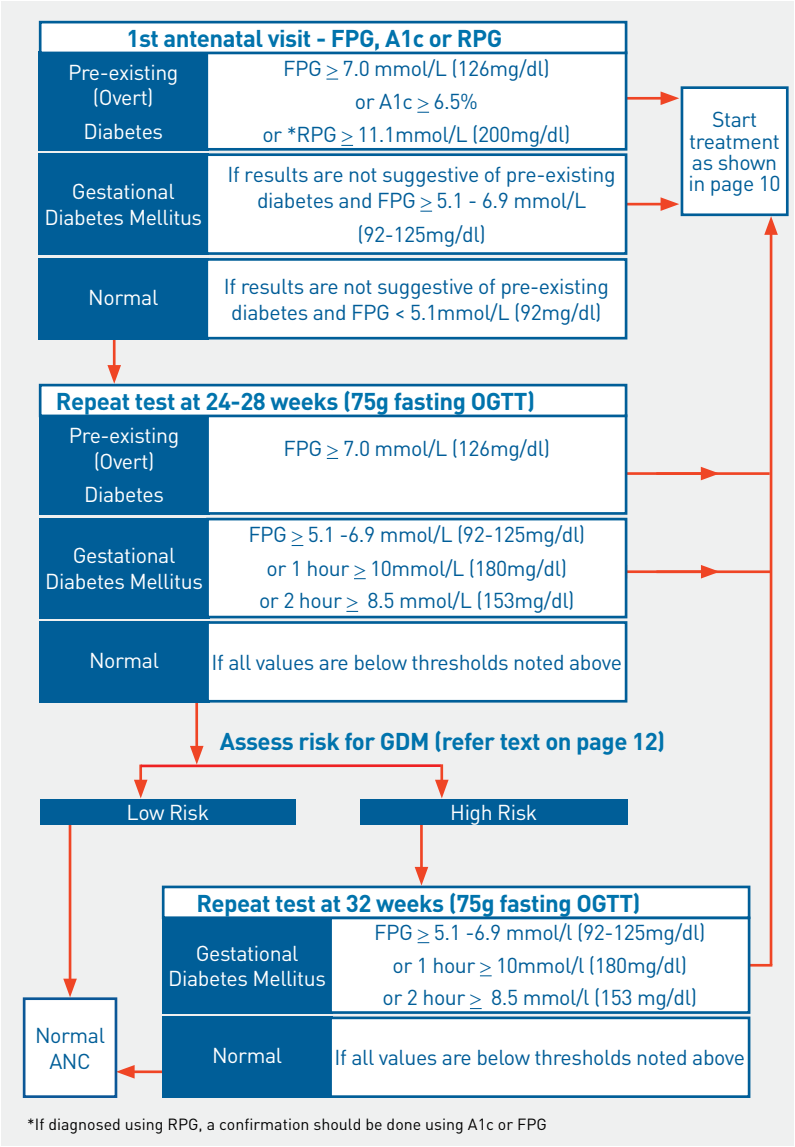
RECOMMENDED PROTOCOL FOR SCREENING, MANAGEMENT AND FOLLOW UP OF WOMEN WITH GDM

Screening for GDM

Screening Criteria

1st antenatal visit - FPG, A1c or RPG*
→ All pregnant women are screened at their first appointment (regular antenatal clinic).
→ Screening at 1st visit is done to rule out pre-existing diabetes. Overt diabetes is diagnosed if any one of the following are present: FPG value ≥ 7.0 mmol/L (126 mg/dl) or A1c ≥ 6.5%. or RPG ≥ 11.1 mmol/L (200 mg/dl)
→ A confirmation test using A1c or FPG is recommended on a subsequent visit
At 24-28 weeks; The GDM screening test:Oral Glucose Tolerance Test (OGTT)
→ Testing is to be performed by a lab technician at the health centre.
→ Patient should be fasting for at least 8 hours (overnight). The time of last meal taken the previous night should be noted.
→ Women are advised not to consume any food, drink or smoke for the duration of the test.
→ In the fasting state, 5ml venous blood is drawn into a fluoride tube
→ The woman is then administered a glucose solution consisting of 75gm glucose powder in 200 to 300ml of water to be drunk within 5 minutes.
→ Venous blood samples (5ml) are drawn at 1 and 2 hours after the glucose load
*FPG - Fasting Plasma Glucose, A1c - Glycated Hemoglobin, RPG - Random Plasma Glucose

DIAGNOSTIC ALGORITHM[2]: INTERPRETATION OF RESULTS

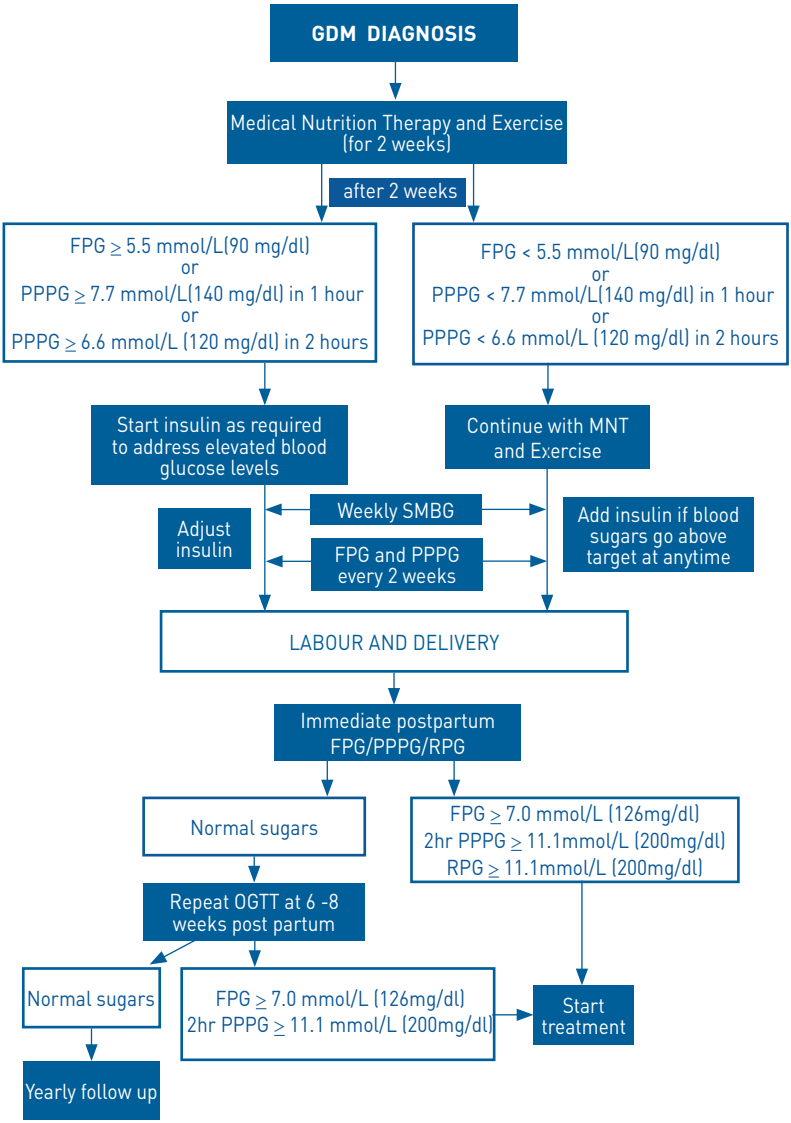


*If diagnosed using RPG, a confirmation should be done using A1c or FPG

2. International Association of Diabetes and Pregnancy Study Groups Consensus Panel, Metzger BE, Gabbe SG, Persson B, Buchanan TA, Catalano PA, Damm P, Dyer AR, Leiva Ad, Hod M, Kitzmiler JL, Lowe LP, McIntyre HD, Oats JJ, Omori Y, Schmidt MI. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classifi ation of hyperglycemia in pregnancy. Diabetes Care. 2010 Mar;33(3):676-82.

Management protocol for GDM

This algorithm will help to decide on the line of management of women screened under the Model of Care.



*PPPG - Post-Prandial Plasma Glucose

Management of women with GDM

I. Confirmed cases of gestational diabetes mellitus (GDM)

Women who are diagnosed with GDM as per the diagnostic algorithm will be managed with:

Medical Nutrition Therapy (MNT) and Exercise for the fi st two weeks to try to achieve target blood glucose levels. Refer to the Management Protocol for further details

Follow up monitoring of GDM:
→ Fasting and postprandial plasma glucose testing every 2 weeks
→ If the fasting value is less than 5.5 mmol/L (90 mg/dl) or the 1 hour postprandial plasma glucose (PPPG) is less than 7.8 mmol/L (140 mg/dl) or 2 hour PPPG is less than 6.7 mmol/L (120 mg/dl), continue the same management ◊ Advise self-monitoring blood glucose (SMBG) with a hand held meter at frequent intervals and FPG and PPPG advised every 2 weeks at the health centre.
→ If the FPG is more than or equal to 5.5 mmol/L (90 mg/dl) OR the 1 hour PPPG is more than or equal to 7.8 mmol/L (140mg/dl) OR the 2 hours PPPG is more than or equal to 6.7 mmol/L (120 mg/dl), treatment with insulin should be started. (please refer detailed management protocol for choice of insulin and dosage) ◊ Advise self-monitoring of blood glucose (SMBG)[3] with a hand held meter every week until target levels are achieved. ◊ When targets are reached check a minimum of once per month until late in the 2nd trimester ◊ Then increase to every 2 weeks

3 Metzger BE, Buchanan TA, Coustan DR, De Leiva A, Hadden DR, Hod M. Summary and recommendations of the fifth international workshop-conference on gestational diabetes mellitus, Diabetes Care. 2007; 30(suppl 2):S251-260.

II. Women with risk factors of GDM but with normal OGTT

In women with any one of risk factors for GDM[4] (obesity, family history of diabetes in parents or sibling, history of GDM in previous pregnancies, history of impaired glucose tolerance but having normal blood glucose levels in OGTT, hypertension, etc.), management includes

Medical nutrition therapy and exercise

↓

Follow up:

- → Repeat OGTT at 32 weeks
- → Further management depending on the diagnostic algorithm
- → If the repeat OGTT shows normal values, the woman will continue with normal ANC care

III. Women with normal OGTT and no known risk factors for GDM

Normal Antenatal Care

4. American Diabetes Association. Gestational diabetes mellitus. Diabetes Care. 2003 Jan;26 Suppl 1:S103-5.

DETAILED MANAGEMENT PROTOCOL

Education on diet

On diagnosis of GDM, an information booklet on gestational diabetes is provided to all women. The medical provider will explain the usage of the booklet for healthy eating, glucose monitoring and physical activity.

The patient will be educated regarding healthy eating, spacing of meals and portion control. The pregnant women diagnosed with GDM will be encouraged to increase low glycemic index foods in their diets. Taking 6 – 8 small meals and snacks spread throughout the day including more fruits and vegetables will be encouraged.

Education on physical activity[5]

Exercise at a minimum of 30 minutes every day will be advised. Strength training exercises may be performed with certain upper body exercises being safe even in late pregnancy. The booklet explains some of these exercises with diagrams. A pedometer can be suggested to the pregnant women and its usage should be explained to them. The woman is encouraged to measure and record the number of steps taken every day in the booklet. This is expected to provide self-motivation for exercise and overall improvement in physical activity.

Insulin therapy

Treatment with insulin is indicated when the target blood glucose levels are not achieved with diet and physical activity.

Human insulin is recommended in pregnancy. Rapid acting insulins (lispro and aspart) have been shown to be safe in pregnancy. They improve postprandial levels of blood glucose and lower the risk of postprandial hypoglycemia.

Long acting insulin: the usual recommendation is to use NPH or Detemir as basal insulin. Detemir has been approved for use in pregnancy. Premixed insulins are a convenient alternative but lack the flexibility of a basal bolus regimen.

Starting dose: If the fasting blood glucose levels are found high, NPH is to be started at bedtime. If the postprandial blood glucose levels are high, soluble or rapid acting insulin is to be started before the meal. A suggested starting dose is 4 units, titrating 1-2 units/every 2 days until targets are reached. The woman will be educated on how to administer the insulin, how to store the insulin and self-management of hypoglycemia.

Treatment with Oral Hypoglycemic Agents (OHAs)

There is some evidence that the use of oral hypoglycaemics such as metformin or glyburide (glibenclamide) are safe in pregnancy[6]. However, metformin and glyburide cross the placenta and long term safety data is not available. If the pregnant woman is already on metformin, it may be continued during the pregnancy. Metformin may be used if insulin is not available, not practical or refused by the woman.

5 Metzger BE, Buchanan TA, Coustan DR, De Leiva A, Hadden DR, Hod M. Summary and recommendations of the fifth international workshop-conference on gestational diabetes mellitus, Diabetes Care. 2007; 30(suppl 2):S251-260.

6 Perkins JM, Dunn JP, Jagastia SM. Perspectives in gestational diabetes mellitus: a review of screening, diagnosis and treatment, Clinical Diabetes. 2007;25(2):57-62.

Education for women diagnosed with GDM under the Model of Care

"Having a baby? Now is the time to learn about gestational diabetes" is a practical booklet to be distributed to pregnant mothers with gestational diabetes mellitus (GDM) and those at risk. It offers guidance ranging from tips on eating healthy and physical activity, to postnatal follow-up. It encourages pregnant women with GDM to log their activities including their blood glucose results throughout the pregnancy.

It is suggested the woman brings the booklet to every clinic visit so that important medical details can be filled in either by her health care providers or by herself.

The booklet is currently available in English, Hindi and Tamil, but can be translated into other languages as needed. Prior to translation, please refer to IDF Brussels Executive Office.

Monitoring and Evaluation

The woman should visit the health centre every 2 weeks for clinical and lab follow up.

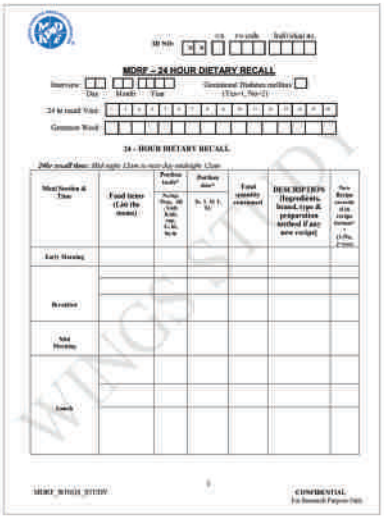
After delivery, blood glucose levels should return to the non diabetic range, that is fasting less than 6.1 mmol/L (110 mg/dl), and 2 hour less that 7.8 mmol/L (140 mg/dl) and medication should no longer be necessary. However, in some women with GDM, the diabetes may continue after the delivery.

Approximately 50% of women with gestational diabetes will develop type 2 diabetes mellitus within 5 – 10 years following their pregnancy[7]. Hence, the mother is advised to return to the clinic for follow-up testing 6 - 8 weeks after delivery and an OGTT test will be done to assess her glycaemic status. Screening for diabetes once every year is advised.

7. Kim C, Newton KM, Knopp RH. Gestational Diabetes and the Incidence of Type 2 Diabetes: A Systematic Review, Diabetes Care 25, 2002.

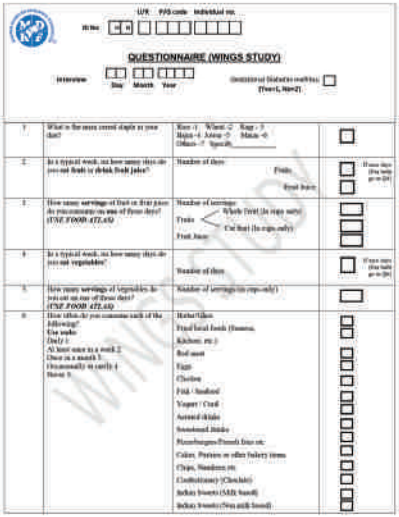
ANNEXES

We recommend to use the following 3 data collection tools available on the IDF website - www.idf.org/women-india-gdm-strategy-wings



MDRF – 24 HOUR DIETARY RECALL

24 - HOUR DIETARY RECALL



QUESTIONNAIRE (WINGS STUDY)

WINGS- PHYSICAL ACTIVITY QUESTIONNAIRE

PHYSICAL ACTIVITY

In this section, you will be asked about the time spent doing different types of physical activity in a typical day. Please answer these questions even if you do not consider yourself to be a physically active person

SECTION I – PHYSICAL ACTIVITY AT WORK: *This section applies only to those who are employed. Housewives and those who are unemployed can skip this section and go to IQ. no 6).*

1.	Does your work involve Seasonal Activity	Yes 1 / No 2	
2.	Specify Seasonal / Primary or Full Time Activity / Occupation		
3.	Specify Off-Seasonal / Part-time Activity / Occupation		
4a	Indicate your duration of occupation **per year**		
4b	Seasonal Occupation / Full Time: Months ☐☐ /Year	b.	Off- Seasonal Occupation / Part-Time: Months ☐☐ /Year
5a	Indicate your duration of occupation **per Week**		
5b	Seasonal Occupation / Full Time: Days ☐☐ /Week	b.	Off- Seasonal Occupation /Part-Time: Days ☐☐ /Week
6a	On an average, how many hours **per day** do you spend at work place?		
6b	Seasonal Occupation / Full Time: ☐☐ ☐☐ / Day — Hours : Minutes	b.	Seasonal Occupation / Full Time: ☐☐ ☐☐ /Day — Hours : Minutes
7	At the **work place**, how many hours per day do you spend on the following:		

Seasonal Activity / Full Time / Day		Duration (Hrs: mins)	Off- Seasonal Activity (Part – Time / Day		Duration (Hrs: mins)
a.	Sitting (Office Work)	☐☐ ☐☐	b.	Sitting (Office Work)	☐☐ ☐☐
b.	Standing	☐☐ ☐☐	b.	Standing	☐☐ ☐☐

CONFIDENTIAL

WOMEN IN INDIA WITH GDM STRATEGY (WINGS)

CASE REPORT FORM

Participant's Code/ID NO:

W	N	U/R	P/G	Centre Code			Id code		
W	**N**								

Name of the Centre:

Name of the Participant: Husband's Name:

Date of birth: d d m m y y y y

Participants' &Address: _____

_____

_____

_____

Email id: _____

Alternate Address (eg. Mother)

_____

_____

_____

Contact No: *(Land line / Mobile)*

Contact No:*(Land line)*

Mobile No:

Mobile No: *(Husband's)*

Date of first visit:

d d m m y y y y

Gestational age :

Weeks days

REFERENCES

1. International Diabetes Federation, Diabetes in pregnancy – Protecting Maternal Health, Policy Briefing. Sept. 2011

2. International Association of Diabetes and Pregnancy Study Groups Consensus Panel, Metzger BE, Gabbe SG, Persson B, Buchanan TA, Catalano PA, Damm P, Dyer AR, Leiva Ad, Hod M, Kitzmiler JL, Lowe LP, McIntyre HD, Oats JJ, Omori Y, Schmidt MI. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care. 2010 Mar;33(3):676-82.

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4. American Diabetes Association. Gestational diabetes mellitus. Diabetes Care. 2003 Jan;26 Suppl 1:S103-5.

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