

Original Article

Women in India with Gestational Diabetes Mellitus Stratey (WINGS): Methodology and development of model of care for gestational diabetes mellitus (WINGS 4)

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ABSTRACT

Aim: The Women In India with GDM Strategy (WINGS) project was conducted with the aim of developing a model of care (MOC) suitable for women with gestational diabetes mellitus (GDM) in low- and middle-income countries. **Methodology:** The WINGS project was carried out in Chennai, Southern India, in two phases. In Phase I, a situational analysis was conducted to understand the practice patterns of health-care professionals and to determine the best screening criteria through a pilot screening study. **Results:** Phase II involved developing a MOC-based on findings from the situational analysis and evaluating its effectiveness. The model focused on diagnosis, management, and follow-up of women with GDM who were followed prospectively throughout their pregnancy. An educational booklet was provided to all women with GDM, offering guidance on self-management of GDM including sample meal plans and physical activity tips. A pedometer was provided to all women to monitor step count. Medical nutrition therapy (MNT) was the first line of treatment given to women with GDM. Women were advised to undergo fasting blood glucose and postprandial blood glucose testing every fortnight. Insulin was indicated when the target blood glucose levels were not achieved with MNT. Women were evaluated for pregnancy outcomes and postpartum glucose tolerance status. **Conclusions:** The WINGS MOC offers a comprehensive package at every level of care for women with GDM. If successful, this MOC will be scaled up to other resource-constrained settings with the hope of improving lives of women with GDM.

Key words: Asian Indians, gestational diabetes mellitus, management, model of care, pregnancy outcomes, screening and diagnosis, South Asians, WINGS

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INTRODUCTION

Gestational diabetes mellitus (GDM) defined as any degree of carbohydrate intolerance with onset or first recognition during pregnancy^[1] contributes to about 90% of diabetes

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complicating pregnancy.^[2] GDM imposes risks for both mother and fetus, some of which continues throughout the life of mother and child. Immediate maternal complications include preeclampsia, need for cesarean sections, and poly/oligohydramnios.^[3] Complications in the baby include hyperinsulinemia, macrosomia, shoulder dystocia, neonatal hypoglycemia, and respiratory distress syndrome. Women with GDM are at an increased risk of GDM in future pregnancies and also at a higher risk of developing type 2 diabetes in the future.^[4] GDM also increases the risk of obesity and glucose intolerance in the offspring.^[5] GDM is therefore an important public health issue that has major repercussions for both mother and offspring. Detection of GDM thus provides a window of opportunity to intervene and reduce adverse perinatal outcomes.^[6]

Prevalence of GDM has dramatically increased by 16–127% in the past 20 years among various ethnic groups.^[7–11] The International Diabetes Federation (IDF) estimates that as of 2015, 16.2% of women with live births had some form of hyperglycemia in pregnancy, 85% of which were due to gestational diabetes.^[12] There is a notable difference in the prevalence of GDM, with the South East Asia Region having the highest prevalence (87.6%) of all the low- and middle-income countries (LMICs), where access to care is often limited. Asian women are more prone to develop GDM than European women and Indian women have 11-fold increased risk of developing glucose intolerance in pregnancy compared to Caucasian women.^[13] Studies done in the 1980's have shown that the prevalence of GDM in India was 2%,^[14] which subsequently increased to 16.55% in 2000.^[15]

Notwithstanding several decades of research, there are several constraints to GDM care, from screening to postpartum follow-up. Awareness and knowledge about GDM is poor even among health-care professionals (HCPs).^[16] There is an insufficient focus on prevention.^[16] Furthermore, lack of standardized protocols in screening and management and lack of coordination among HCPs involved in providing care for GDM often result in less than optimal care and poor follow-up during pregnancy and after delivery.^[16] The postpartum period provides an opportunity for lifestyle intervention to prevent future diabetes; however, this is often hindered by poor postpartum follow-up rates.^[17] Though there are several management protocols available for GDM,^[18,19] providing evidence-based care in resource-constrained settings is still a major challenge.^[20]

To address these challenges and critical gaps in effective care for GDM, the Women in India with GDM Strategy

(WINGS) project was developed in Chennai, India, offering a multidisciplinary approach to GDM care which could later be adopted in other resource constrained settings.

METHODOLOGY

The WINGS project is a flagship project of the IDF which aimed to tackle the growing problem of GDM in low-resource settings. The project was developed and supported through a partnership between the IDF, the Madras Diabetes Research Foundation (MDRF), Chennai, India, and the Abbott Fund, the philanthropic foundation of the global healthcare company Abbott. The aim of the project was to develop a standardized approach to GDM care that is feasible and effective for implementation in resource constrained settings. The project was carried out in two phases as outlined in Figure 1.

- Phase 1: Situational analysis of GDM in India. The aim of this phase was to establish a comprehensive baseline overview of GDM screening and management protocols and to understand and describe the burden of gestational diabetes in India. This would help to build a stronger evidence-base to advocate for prioritizing and improving care, and to facilitate the development of the GDM Model of Care (MOC)
- Phase 2: Development and implementation of MOC for GDM: In Phase 2, the project aimed to develop a standardized approach to GDM care that was evidence-based (based on the situational analysis), feasible, and acceptable in resource-constrained settings. The project also aimed to evaluate the effectiveness of this MOC.

Ethical clearance

The study was approved by the Institutional Ethics Committee of the MDRF. Permission was also obtained from the Directorate of Public Health and the Ministry of Health, Government of Tamil Nadu, to conduct the study in the primary health centers.

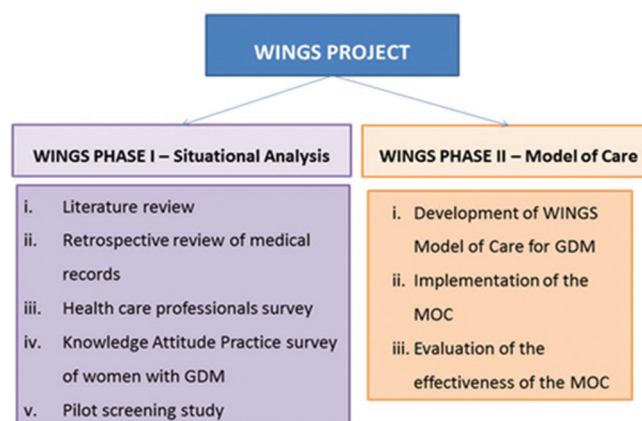


Figure 1: Overview of WINGS project

RESULTS

Phase 1: Situational analysis of GDM in India

The aim of this phase was to understand and describe the burden of gestational diabetes in India.

This comprehensive phase had five components which included the following:

1. An extensive literature review of existing research and policies on GDM
2. Retrospective review of clinical records
3. A knowledge, attitude, and practice survey among pregnant women
4. A survey among HCPs to understand the current practices in diagnosis and management of GDM in India and
5. A pilot screening study to determine the best screening criteria for GDM that the project should implement.

Literature review

More than 90 scientific sources were reviewed covering a wide range of screening and diagnostic guidelines, background information on risk factors, management of GDM, and also current on-going projects related to GDM from around the world. This review provided an overview of the available data on screening, diagnosis and management of GDM and helped to guide the development of other components of the situational analysis.

Retrospective review of clinical records

The aim of this component was to examine the progress and outcomes of GDM pregnancies and to assess how GDM pregnancies differ from non-GDM pregnancies. Clinical records of 4081 pregnant women booked between January 2011 and December 2012 at three urban hospitals in Chennai City were collected and reviewed. The study showed that there were higher rates of macrosomia, preeclampsia, and increased caesarean sections among GDM women compared to those without GDM.

Survey among health-care professionals (current practices in the diagnosis and management of gestational diabetes mellitus)

The aim of this component was to gauge which methods were widely employed for the diagnosis and management of GDM in India and to highlight areas for improvement. The survey addressed different screening techniques employed, management choices, etc. The survey was conducted between February and March 2015 among 3841 HCPs covering 24 states of India, comprising both physician/diabetologists and obstetrician/gynecologists (OB/GYNs). The results from this survey showed that more than half of the physicians/diabetologists/endocrinologists and OB/GYNs

in India do not follow any of the recommended guidelines for the diagnosis of GDM. This emphasizes the need for increased awareness about screening and diagnosis of GDM among HCPs in India.^[21]

Knowledge, attitude, and practice survey among pregnant women and health workers

This component aimed at studying a pregnant woman's understanding of GDM and barriers to care as well as to understand the constraints and the practices of rural health workers in delivering GDM care and identifying key support mechanisms, which could be utilized to develop the MOC. One hundred pregnant women visiting urban and rural health centers in Chennai and neighboring districts were interviewed and the responses from the survey showed that more than half of the pregnant women were unaware of what GDM meant, over 50% of them did not know the short and long term consequences of GDM to themselves or their babies.

Pilot screening study

The aim of this component was to determine which screening criteria for GDM was the most suitable to use for the project based on feasibility, acceptability, and scientific evidence. The study was conducted to evaluate the existing single step 75 g nonfasting oral glucose tolerance test (OGTT) as a diagnostic test for diagnosis of GDM.^[22] Pregnant women visiting rural and urban health centers in Chennai and neighboring district were screened for GDM between January 2013 and November 2013. Detailed methodology of the study procedure has already been explained in a previous publication.^[23] At first visit, the women underwent an OGTT in the nonfasting state and were requested to return 2 or 3 days later to repeat a 75 g OGTT this time after an overnight fast of at least 8 h. Venous samples were drawn at fasting and at 1 h and 2 h after the glucose load. Simultaneously, during both the nonfasting and fasting visits, capillary blood glucose (CBG) was also measured. The data from the pilot screening study were then evaluated using different GDM diagnostic criteria. Results from the pilot screening study showed that the nonfasting OGTT criteria cannot be recommended for the diagnosis of GDM due to its low sensitivity and venous plasma glucose still remains the gold standard for diagnosis. However, in resource limited settings, CBG can be used as an initial screening test.^[24]

The results from these five components considered as a situational analysis gave a baseline review of the current status of GDM care in India and this helped to develop the protocol for screening and diagnosis of GDM, its management and postpartum follow-up of women with GDM, under the WINGS MOC.

Phase 2: Development of the model of care

The WINGS MOC was developed by a panel of global experts using the data from the situational analysis and focusing on diagnosis and management. Women with GDM recruited under the MOC were followed prospectively throughout their pregnancy and were analyzed for their pregnancy outcomes. Postpartum glucose tolerance status was also evaluated within a year after delivery. The framework for the MOC is presented in Figure 2.

The framework of the model of care

The WINGS MOC was developed targeting the individual (pregnant women) their families, the health facility, community, and the global scientific audience.

- At the individual and family level, it aimed to build the awareness and education on GDM through one-on-one counseling, educational programs, and various educational materials. It also aimed to improve pregnancy outcomes
- At the health facility level, capacity building was done by training HCPs in identifying, treating, and managing GDM. A training curriculum was developed for this purpose (details below)
- At the larger community level, especially the remote and the rural regions which have limited access and availability to GDM care, community health workers (CHW) were trained with basic awareness and information about GDM. A separate training module was used for this purpose (details below)
- Global audience: The implementation of the model in India will help to provide insights and recommendations for improved care of women diagnosed with GDM in other low-resource settings. Through scientific publications, the model will be disseminated and made available to the global community.

Stages in the implementation of the model of care involved

- Development of the WINGS MOC tool kits and materials
- Identifying study sites and creating a network of collaborating centers in and around Chennai city
- Training programs for selected HCPs from the collaborating centers
- Implementation of the MOC in the collaborating health centers.

Development of the women in India with gestational diabetes mellitus strategy model of care tools and materials

Training and educational materials were developed for use by HCPs, CHWs and pregnant women. The tools included:

- An implementation protocol: A hand held standard operating procedure guide was developed for the HCPs who provide antenatal care in health clinics. The guide included a screening and diagnostic algorithm and a management algorithm with choice of drugs and guidelines for monitoring and follow-up care
- Training manual for HCPs: This set of slides, complete with teaching notes covered 8 topics-screening and diagnosis of GDM, nutrition, exercise in pregnancy, pharmacological management, monitoring, maternal and neonatal complications, labor and delivery, and postpartum follow-up. The HCPs who were trained were expected to use the manual for training the other health staff in the facility (training the trainers)
- Training manual for CHW: This guide was developed to assist rural health workers who follow-up pregnant women in remote villages where there is a limited access to specialized health services. This manual guided the CHWs in motivating and preparing the pregnant mothers for GDM screening and diagnostic tests. It provided information on medical nutrition therapy (MNT) and physical activity in pregnancy complicated by gestational diabetes. The manual also educated CHWs in the early identification and management of hypoglycemia
- Educational booklet for pregnant mothers and outreach activity for pregnant women: An educational booklet on GDM entitled "Having a baby?" was developed targeting the pregnant mothers. The booklet uses simple and easy to understand language to educate the women on what GDM is, who is at risk, how they were diagnosed with GDM, how self-monitoring of blood sugar can be done, etc. It also lists alerts about hypoglycemia and provides exercise and dietary tips during pregnancy. The booklet contains general guidelines for eating healthy. The "plate model" depicted in the booklet helps focus on making healthy eating choices. There are also pictorial representations of exercises which are safe in pregnancy and columns for noting down daily dietary patterns and

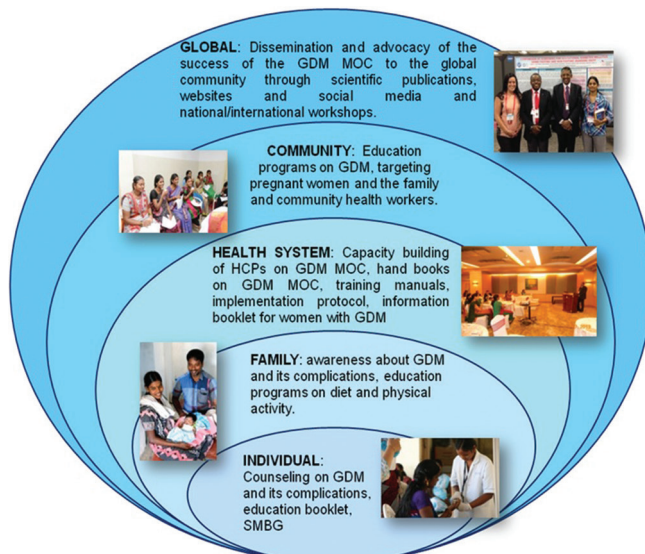


Figure 2: Framework for development of WINGS GDM model of care

daily steps taken which could be discussed with the HCP

- Snakes and ladders game: An educational game on GDM—a snakes and ladders game which gives simple messages on testing, diet advice, and exercise related to GDM care during pregnancy was developed and was disseminated to pregnant women during various educational and outreach programs.

The above resources are made available on a dedicated page on the IDF website and they may be downloaded and used free of cost with due acknowledgement given to IDF and WINGS. <http://www.idf.org/women-and-diabetes/resource-centre>.^[25]

Study sites: Identifying study sites and creating a network of collaborating centers in and around Chennai city

Six maternity clinics in Chennai offering antenatal care for pregnant women were identified as collaborating centers. A team of HCPs including physician/diabetologists, OB/GYNs, dietitians, and nurses from each collaborating center were then invited to attend the training program on the WINGS MOC.

Training program for selected health care professionals from the collaborating centers

A rigorous training program was conducted for the HCPs from the various collaborating centers, prior to the implementation of the WINGS MOC. The HCPs from various collaborating centers were trained by the WINGS Expert Committee members on several aspects of the MOC screening and diagnosis, management, follow-up, delivery, and postpartum care. A total of 67 HCPs underwent training.

A similar training program for CHWs was conducted in July 2015 and included a brief introduction to GDM, dietary management/physical activity during pregnancy, delivery, and follow-up. About 200 CHWs from all the districts in Tamil Nadu state were trained in the WINGS MOC.

Implementation of the model of care in the selected collaborating health centers

Implementation period

The WINGS MOC was implemented in the six collaborating maternity centers between November 2013 and December 2015.

Study subjects

Consecutive pregnant women with gestational age <28 weeks visiting the collaborating centers were included in the project.

Inclusion criteria

- Pregnant woman who consented for testing
- More than or equal to 18 years of age

- Gestational age <28 weeks
- Singleton pregnancies.

Exclusion criteria

- Women with known diabetes
- Multiple pregnancies/assisted pregnancies.

Study procedure

All pregnant women were screened at their first antenatal appointment. Every woman was given complete information about gestational diabetes including the risk for the baby and the future risk of diabetes for the mother. A written informed consent was obtained from every woman who underwent the screening.

Data collection

Each collaborating center implemented the MOC with a dedicated team who were specially trained for the project. These teams were provided regular support by WINGS team. The WINGS team assisted the collaborating centers in screening, data collection in the prescribed forms, follow-up of the women, and motivating them for postpartum testing. They also performed quality checks and assured quality of the data collected.

Tools for data collection

The following tools were used for data collection:

- Structured case report form to collect clinical details including obstetric history, family history of diabetes as well as current and past medications
- Physical activity and food frequency questionnaires: Physical activity and diet patterns were recorded using pretested questionnaires. The MDRF physical activity questionnaire (MPAQ) (pregnancy version) and an open-ended diet assessment questionnaire and 24 h dietary recalls. The open-ended diet assessment questionnaire was used to collect data pertaining to main staple food consumption, frequency of consumption of fresh fruits and vegetables, fat intake, junk foods, milk and milk products, special foods consumed during pregnancy, etc.

Anthropometric measurements

Anthropometric measurements were done using standard techniques. Height was measured using a stadiometer (SECA Model 213, Seca GmbH Co, Hamburg, Germany) to the nearest 0.1 cm. Weight was measured with an electronic weighing machine (SECA Model 803, Seca GmbH Co) to the nearest 0.1 kg. Body mass index was calculated using the formula weight (in kg) divided by height in meters (squared).

Screening and diagnosis of gestational diabetes mellitus

In the first trimester, pregnant women were screened to rule out overt diabetes. Women with fasting plasma glucose

≥ 7.0 mmol/l (≥ 126 mg/dl) or glycated hemoglobin (HbA1c) of over 6.5% were diagnosed with overt diabetes mellitus. Women who had fasting blood glucose (FBG) between 5.1 mmol/L (≥ 92 mg/dl) and 6.9 mmol/l (< 125 mg/dl) were considered to be GDM. Those who were normal were asked to come for an OGTT at 24–28 weeks.

At 24–28 weeks, women were screened for GDM using an OGTT with a 82.5 g oral glucose load (equivalent to 75 g of anhydrous glucose) after an overnight fast of at least 8 h. Venous samples were drawn at fasting, 1 h and 2 h after the glucose load. Overt diabetes was diagnosed in women with FBG ≥ 7.0 mmol/l (≥ 126 mg/dl). Diagnosis of GDM was made if fasting plasma glucose was between 5.1 mmol/L (≥ 92 mg/dl) and 6.9 mmol/l (125 mg/dl) or the 1 h or 2 h blood glucose values met or exceeded 10.0 mmol/L (≥ 180 mg/dl) and 8.5 mmol/L (≥ 153 mg/dl), respectively^[26] [Figure 3].

If all the blood glucose values were within normal limits at both visits, the women were referred for normal antenatal care. In the presence of any of the risk factors (family history of diabetes, obesity, previous GDM), the OGTT was repeated again at 32 weeks of gestation.

Follow-up under the model of care

Women diagnosed with GDM were recruited into the WINGS MOC and were provided counseling and support. Women with GDM were followed up throughout their pregnancy as per the management protocol laid down under the WINGS MOC.

Medical nutrition therapy

MNT was the first line of treatment given to women with GDM. MNT was followed for 2 weeks, following which women were subjected to FBG and postprandial blood glucose (PPBG) testing.

If FBG was < 5.5 mmol/l (< 90 mg/dl) or 1 h PPBG < 7.7 mmol/l (< 140 mg/dl) or 2 h PPBG < 6.6 mmol/l (< 120 mg/dl) in the subsequent follow-up visits, then MNT was continued.

Pharmacological management

At the end of the first 2 weeks following GDM diagnosis, if FBG was ≥ 5.5 mmol/l (≥ 90 mg/dl) or 1 h PPBG ≥ 7.7 mmol/l (≥ 140 mg/dl) or 2 h PPBG ≥ 6.6 mmol/l (≥ 120 mg/dl) then insulin was indicated. Insulin doses were adjusted by measuring FBG and PPBG every 2 weeks or through weekly self-monitoring of blood glucose.

Follow-up visits during pregnancy

Under the MOC, pregnant women with GDM were educated about the consequences of GDM and complications that may arise due to poor blood glucose control. Women were counseled face to face by trained nutritionists and HCPs about the benefits of healthy diet and physical activity. The education booklet “Having a baby?” developed under the MOC, explained above, was provided to them and they were encouraged and motivated to chart their daily physical activity and meal patterns. A pedometer was provided to all women in order to track their daily step counts. Pedometer readings were recorded by women in their GDM booklet. The importance of good control of blood glucose levels was reinforced at every antenatal visit.

Community-based activities were conducted as part of the WINGS outreach program with the help of experts in the field of nutrition. Pregnant women were invited to attend the program and were educated about proper nutrition and physical activity through cooking demonstrations and lively interactive sessions. These outreach programs were conducted in the collaborating centers and in rural areas.

Pregnancy outcomes and postpartum follow-up

All women under the MOC were evaluated for pregnancy outcomes. Immediately after delivery [Figure 4], if

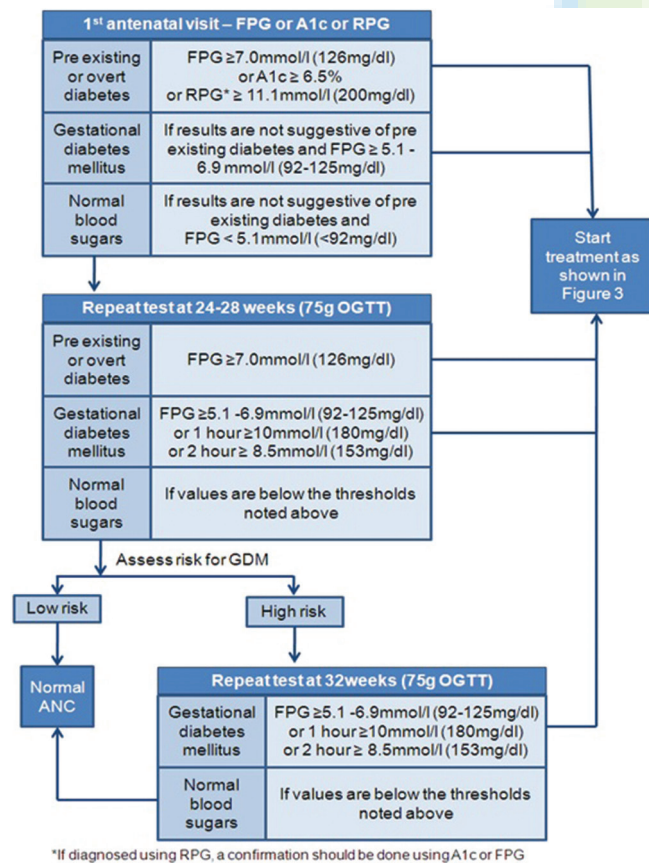


Figure 3: Diagnostic algorithm for gestational diabetes mellitus under the Women in India with Gestational Diabetes Mellitus Strategy (WINGS) model of care

FBG was <7.0 mmol/l (<126 mg/dl) or 2 h PPBG was <11.1 mmol/l (<200 mg/dl), then they were advised to return for follow-up testing at 6–12 weeks and an OGTT was done to reassess their glycemic status. Immediately after delivery or at 6–12 weeks postpartum, if FBG and PPBG levels were suggestive of diabetes (FBG >7.0 mmol/l [≥ 126 mg/dl] and/or 2 h >11.1 mmol/l [≥ 200 mg/dl]), then they were started on treatment. If the OGTT was normal at 6–12 weeks, women were advised to check their blood glucose levels annually.

Sample processing and laboratory methods

All blood samples were collected in sodium fluoride/ Na_2 EDTA vacutainer tubes to prevent glycolysis. Samples were transported to the central lab within 1 h in cool boxes, which had gel packs to maintain the temperature between 2 and 8°C. Plasma glucose was measured using an autoanalyzer AU2700, (Beckman, Fullerton, CA, USA) and HbA1c was measured by high performance liquid chromatography using variant machine (Biorad, Hercules, CA, USA). The HbA1c method is National Glycohemoglobin Standardization Program certified. The intra- and inter-assay coefficients of variation for the glucose and HbA1c were 0.78% and 1.68% and 0.59% and 1.97%, respectively. All samples

were processed in the central laboratory which is certified by the College of American Pathologists and by the National Accreditation Board for Testing and Calibration Laboratories, Government of India.

DISCUSSION

GDM is considered to be at the intersection of two major areas of health maternal and child health and noncommunicable diseases. The potential for successful treatment therefore will determine the pregnancy outcome. The WINGS project aimed to produce a comprehensive package of care for women affected by GDM, given the rising prevalence of GDM and the accompanying opportunity of preventing type 2 diabetes.

At present, there are no universal validated guidelines which are applicable to low-resource settings. In LMICs, where maternal and child mortality are highest, GDM is likely to go undetected and undiagnosed because of poor screening standards and resources.^[16] There are several reasons for poor care and follow-up of GDM in low-resource settings, some of which could be the lack of trained HCPs,^[27] lack of diagnostic facilities and standardized laboratories to carry out testing, unavailability of insulin, and inability to treat complicated cases leading to women being referred to higher centers.^[27] In addition, the presence of multiple guidelines, different cut off values and methods of testing^[2,11] for diagnosis of GDM, cause confusion among the HCPs, leading to suboptimal level of care. This emphasized the importance of educating HCPs involved in GDM care, highlighting the need for proper training on screening, diagnosing and management which will help in timely patient care. From the patient point of view, lack of awareness about GDM and its complications, late contact with the health-care provider, costs involved in treatment, and the myths surrounding insulin use are some challenges that pose a serious threat to GDM care. This brings into focus, the need to educate pregnant women on several issues related to GDM, the importance of regular monitoring, follow-up, etc.

The GDM MOC developed by WINGS aimed to respond to some of these critical gaps in GDM care prevalent in low-resource settings. The GDM MOC was developed using best practice and established clinical guidelines and was piloted in Chennai to ensure that the approach is culturally appropriate and feasible. The project focused on the importance of close follow-up and interaction between health-care workers and patients. The results from the MOC could have far reaching implications and if successful could provide improved quality of care to women with GDM in low-resource setting.

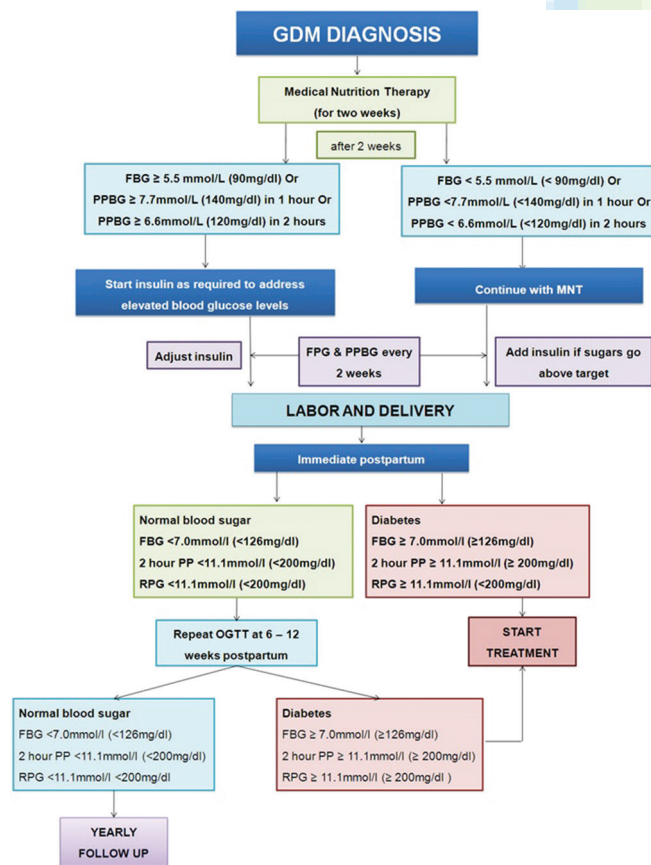


Figure 4: Women in India with Gestational Diabetes Mellitus Strategy (WINGS) management protocol for gestational diabetes mellitus

One of the limitations of our study was that the results from the MOC represent only a section of the pregnant population as it could only be tested in the urban health centers (mostly private clinics) and the rural centers were not included. Long-term impact of the project could not be measured as this was not planned as part of the project. However, the multi-level strategy helps to approach GDM at not only at the individual level but also at the family and community levels proving a holistic approach and trying to overcome barriers to care.

CONCLUSIONS

GDM poses a formidable threat to both mother and the child. Therefore, its relevance as a public health priority cannot be stressed enough. Pregnancy offers an opportunity to promote healthy lifestyle that can improve the long-term health outcomes in both mother and the baby. The WINGS MOC for GDM offers a comprehensive package of tools for every level of care. If successful, this MOC will be scaled up to other resource constrained settings with the hope of improving the lives of women with GDM.

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Conflicts of interest

There are no conflicts of interest.

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