2

Review of Literature

The review of literature pertaining to the study entitled, **"Development and Optimisation of a Sustainable Standard Operating Protocol for Medical Nutrition Therapy to Improve Maternal Foetal Outcomes among GDM Women"** is discussed under the following headings:

2.1 Gestational Diabetes Mellitus – A Compendium of Literature
2.2 Medical Nutrition Therapy for Sustainable Strategies in Management of GDM
2.3 Standard Operating Protocol Enhanced Management of GDM

2.1. Gestational Diabetes Mellitus – A Compendium of Literature

2.1.1 Definition

Gestational Diabetes Mellitus or GDM in simple terms is the glucose intolerance that is usually seen only during pregnancy which reverts to normal for most women after their delivery.

Gestational diabetes mellitus (GDM) was defined as "any degree of glucose intolerance with onset or first recognition during pregnancy" (Metzger and Coustan, 1998). Several definitions for GDM have been given by various organizations. WHO in 1999 described GDM as "carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy." This does not rule out the chance of existence of glucose intolerance prior to pregnancy but has been previously left undiagnosed.

In 2013, WHO proposed that "hyperglycaemia first detected at any time during pregnancy should be classified as either diabetes mellitus in pregnancy or gestational diabetes mellitus as follows.

Diabetes in pregnancy should be diagnosed if one or more of the following criteria are met: fasting plasma glucose ≥ 126 mg/dl, 2 hour plasma glucose ≥ 200 mg/dl following a 75g oral glucose load, random plasma glucose ≥ 200mg/dl in the presence of diabetes symptoms.

Gestational diabetes mellitus should be diagnosed if one or more of the following criteria are met: fasting plasma glucose 92-125 mg/dl, 1 hour plasma glucose ≥180mg/dl following a 75g oral glucose load, 2 hour plasma glucose 153-199 mg/dl following a 75g oral glucose load."

The ambiguities in the definition were further clarified by ADA in 2017 which defined gestational diabetes mellitus as "diabetes diagnosed in the second and third trimester of pregnancy that was not clearly overt diabetes prior to gestation."

Quintanilla Rodriguez and Mahdy, 2023 describe GDM as a "disease developed during the second and third trimester of pregnancy, characterized by a marked insulin resistance secondary to placental hormonal release" and further classifies it into two types denoted as A1GDM and A2GDM. Diet-controlled GDM, also known as A1GDM, is defined as gestational diabetes treated without medication and responsive to dietary therapy while GDM managed with the use of medicines for effective control of blood glucose is classified as A2GDM. The medical condition known as gestational diabetes mellitus, or GDM, is characterized by reduced glucose tolerance that first manifests during pregnancy

2.1.2 Prevalence of GDM – Global Scenario

GDM is the leading health disease among pregnant women (Choudhury and Rajeshwari, 2021) and it can globally affect 15 to 25 percent of pregnant women (Hu et al., 2021; Tarry-Adkins et al., 2020).

IDF region	Age-adjusted prevalence	Raw prevalence	Number of live births affected in millions
World	**15.2%**	**16.7%**	**21.1**
SEA	28.0%	25.9%	6.8
NAC	20.7%	17.2%	1.3
SACA	13.7%	15.8%	1.0
WP	12.4%	14.0%	3.9
EUR	12.2%	15.0%	1.6
AFR	11.4%	13.0%	4.1
MENA	8.6%	14.1%	2.4

DF: International Diabetes Federation; AFR: Africa; EUR: Europe; MENA: Middle East and North Africa; NAC: North America and Caribbean; SACA: South and Central America; SEA: South-East Asia; WP: Western Pacific

Figure: 1
Hyperglycaemia in Pregnancy (20-49 years) ranked by age-adjusted comparative prevalence estimates (Figure generated from IDF Atlas, 2021)

The International Diabetes Federation (IDF) Atlas 2021 estimated that globally 21.1 million (16.7%) of live births to women had some form of hyperglycaemia in pregnancy with 80.3 per cent being due to GDM, 10.6 per cent as a result of diabetes detected prior to pregnancy and 9.1 per cent due to Type 1 and Type 2 DM first detected during pregnancy. The age-adjusted prevalence of hyperglycaemia in pregnancy was highest in South East Asian regions (Figure 1) compared to all other regions.

The prevalence of hyperglycaemia in pregnancy has also been reported to have increased vastly with 87.5 percent of cases in low and middle income countries (IDF, 2015) and is found to be progressing with age with a prevalence of 42.3 per cent among women in the age group of 45-49 years. Also, reports describe nearly half (46.3 %) of all cases of hyperglycaemia in pregnancy to occur in women under the age of 30 years due to higher fertility rates in younger women (IDF Atlas, 2021). Studies have also reported the prevalence rate of GDM to have increased two to eleven fold, attributed to the use of the International Association of Diabetes and Pregnancy Study Group (IADPSG) as the diagnostic criteria for GDM (Brown et al., 2017; Jiwani et al., 2012).

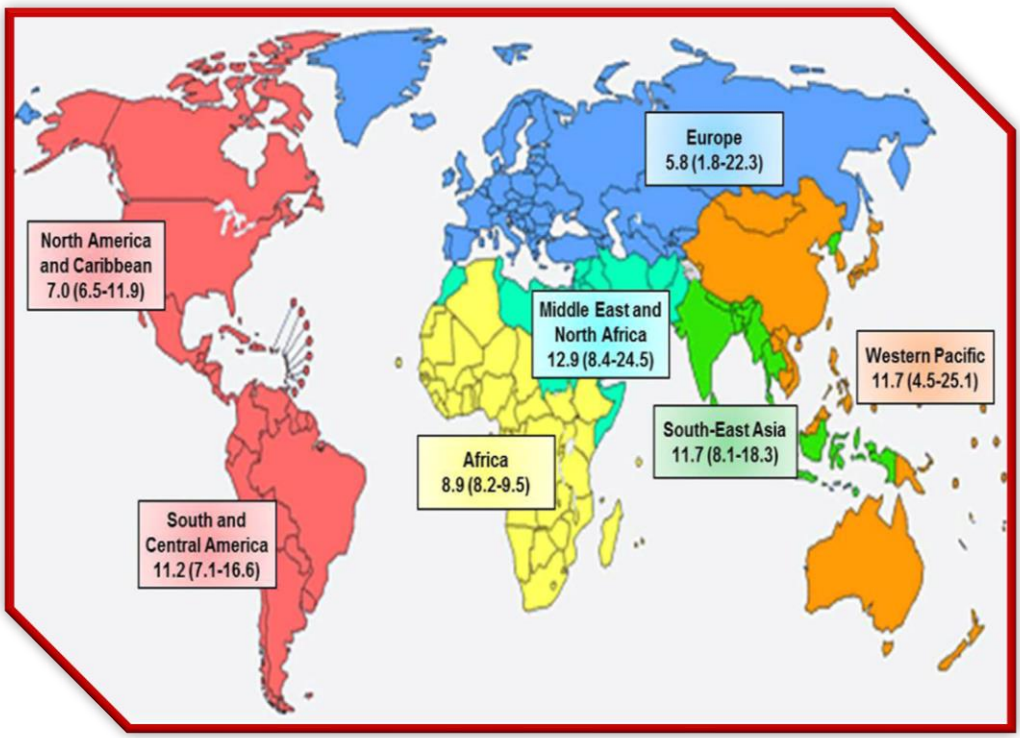

Figure 2

Median (interquartile range) prevalence (%) of GDM by WHO region, 2005–2015 (Map generated from WHO website at http://www.who.int/ about/regions/en/)

Zhu and Zhang, (2016) in a countries-specific prevalence estimate study showed that the highest prevalence of GDM with a median estimate of 12.9 per cent was seen in Middle East and North Africa compared to other regions and the lowest median estimate of 5.8 per cent in Europe (Figure 2).

Approximately 7 per cent of pregnancies are complicated by GDM, resulting in over 200,000 worldwide cases annually. However, the prevalence may vary from 1 per cent to 14 per cent of all pregnancies depending on the population studied and the diagnostic tests used (Sue Kirkman and Schaffner, 2012).

The prevalence rates of GDM have been reported to vary from one percent to 28 percent which is largely dependent on various factors such as maternal age, socioeconomic status, race and ethnicity, body mass index, screening methods and the diagnostic criteria used in detecting GDM (Hedderson et al., 2012; Nguyen et al., 2018; Zhu and Zhang, 2016; Ovesen et al., 2018).

2.1.3 Prevalence of GDM in India

GDM has become a significant health issue in India, impacting a sizable number of births every year. The reliability of the prevalence estimate is, however, hindered by variations in screening and diagnostic criteria. The first multicenter studies were carried out in the 1990s that used WHO criteria for documenting India's high prevalence of GDM. A random GDM prevalence study in Chennai resulted in 18.9 per cent GDM cases. A prevalence study on GDM from 2002-2003 in various cities in India using the two-hr 75 gm post glucose value of ≥ 140mg/dl as diagnostic criteria for GDM showed an overall GDM prevalence rate of 16.55 per cent (Seshiah et al., 2004). In one of the largest community-based GDM screening studies conducted in Tamil Nadu, GDM prevalence of 17.8 per cent in urban, 13.8 per cent in semi-urban and 9.9 per cent in rural areas was observed (Seshiah et al., 2008).

More recent research has revealed varying but rising incidences across India, which is connected to rising obesity and diabetes rates. According to suggestions made by the ICMR expert group, most centres diagnose GDM using either the WHO 1999 criteria or modified variants (Seshiah et al., 2016). Using several criteria, a meta-analysis done from 2009 to 2015 discovered that the national prevalence of GDM was 10.2 per cent and the prevalence was higher (13.4 %) in urban areas than in (7 %) rural areas (Bhavadharini et al.,

2017). This rise in GDM is concomitant with the increase in the rates of obesity among women of reproductive age, advancement of maternal age for conception, sedentary lifestyle and urbanization (Sweeting et al., 2022; Gyasi-Antwi et al, 2020; Seshiah et al., 2009).

In India, four million women suffer from GDM. When compared to other Asian nations, GDM is more common in the Indian population. According to Anjana et al. (2017), the prevalence of GDM varies over time between six per cent and nine per cent in rural areas and 12 per cent to 21 per cent in urban areas. It is projected that 62 million individuals in India currently suffer from Type 2 DM and by 2025; this figure is expected to rise to 79.4 million. Since managing diabetes and its complications costs a great deal of money to the society, effective control measures are desperately needed to stop this epidemic. Unsurprisingly, there appears to be a rising prevalence of GDM, or diabetes diagnosed during pregnancy, concurrent with the rise in the prevalence of diabetes. There have been reports of varying prevalence rates of gestational diabetes in India: 3.8 per cent in Kashmir, 6.2 per cent in Mysore, 9.5 per cent in Western India, and 17.9 per cent in Tamil Nadu. Prevalence rates as high as 35 per cent from Punjab and 41 per cent from Lucknow have been reported in more recent studies using different criteria. Pregnant women in these areas vary in age and/or socioeconomic status, which have been linked to regional variations in prevalence. According to estimates (Mithal et al., 2015), 4 million Indian women are thought to be impacted by GDM at any given time.

Using both the updated Indian Council of Medical Research (ICMR) and World Health Organisation (WHO) criteria, the prevalence of GDM among pregnant women screened in Haryana between 2015 and 2016 was estimated to be 14 per cent (Gambhir et al., 2018). According to a hospital-based study conducted in Maharashtra using the modified ADA criteria, 18.9 per cent pregnant women in urban area were reported to have GDM (Agarwal et al., 2010). As per the modeled projections based on region-specific statistics, there were over 3.5 million cases of GDM annually, or a national prevalence of about 10 per cent (Jain et al., 2018).

Compared to rural areas, GDM is more common in cities (Seshiah et al., 2009). According to Manju and Abin (2015) and Paulose (2008), the prevalence of GDM was found to be 15.9 per cent in northern Kerala and 11.2 per cent in southern Kerala.

A recent systematic review and meta-analysis of national and regional prevalence of gestational diabetes mellitus by Mantri et al. (2024) showed that the pooled prevalence of GDM varied across the five zones (north, south central, east and west) of India. Highest prevalence of GDM of 16.1 per cent was found in north region followed by 12.6 per cent in south region. Whereas lower prevalence rates of GDM were reported with 12 per cent in central, 11.5 per cent in east and 7 per cent in west regions of India (Figure 3).

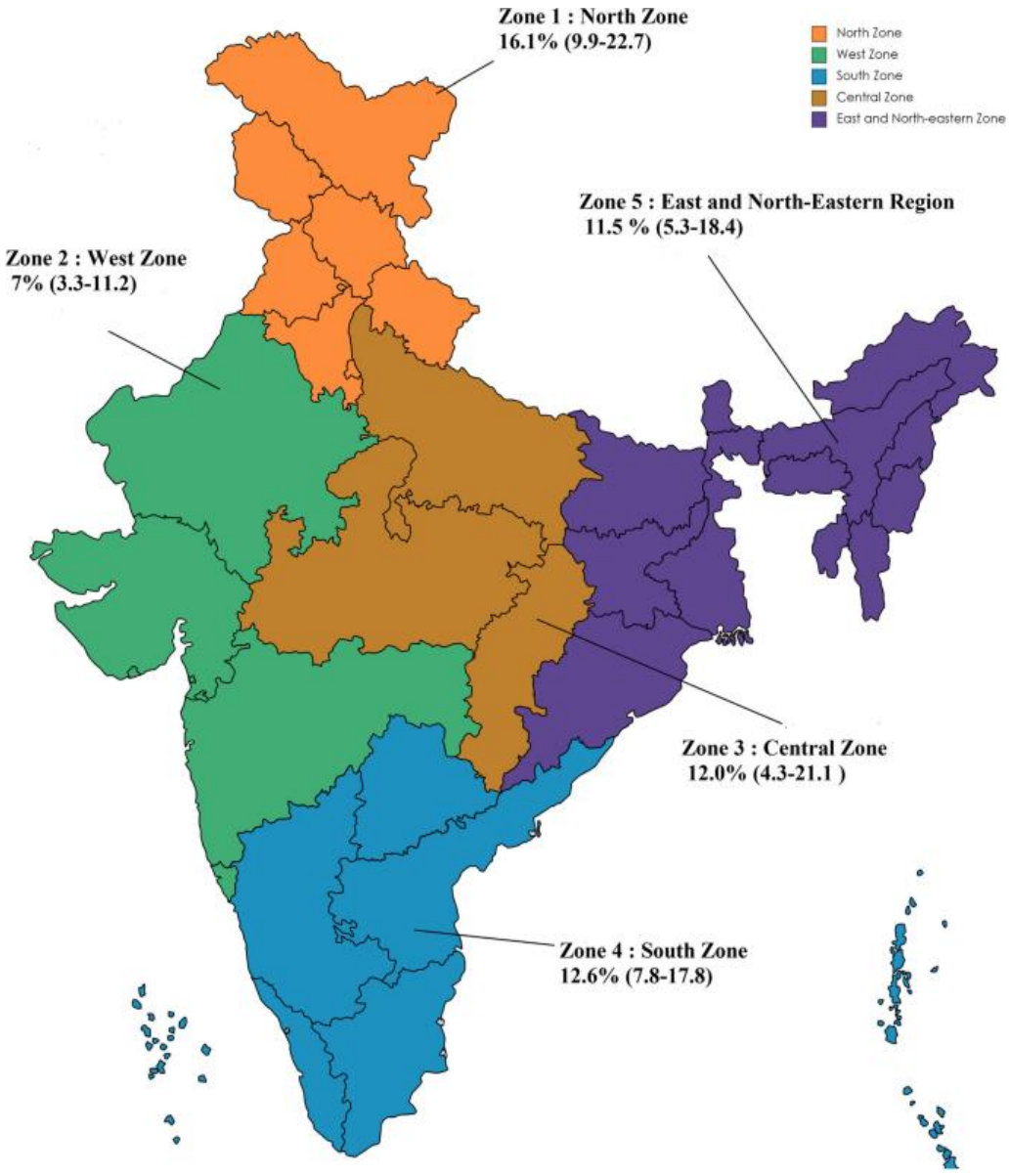

Figure 3

Prevalence of GDM in five different zones in India

(Map generated from Mantri et.al, 2024.National and regional prevalence of gestational diabetes mellitus in India: A systematic review and Meta-analysis. *BMC Public Health, 24* (1), 527. https://doi.org/10.1186/s12889-024-18024-9)

2.1.4 GDM – A forerunner of Type 2 Diabetes Mellitus (Type 2 DM)

In GDM there is insulin resistance and impaired secretion of insulin thus sharing the same risk factors as that of Type 2 DM. The prevalence of GDM also has been reported to closely resemble that of Type 2 DM in a population (Ben-Haroush et al., 2004). There are evidences that show GDM as a forerunner of Type 2 DM in predisposed women who are faced with metabolic challenges of pregnancy (Bentley-Lewis, 2009). GDM seems to be a significant factor with susceptibility to increase the epidemic of Type 2 DM among women and future generations in Asia. It is estimated that 10 per cent to 31 per cent cases of diabetes in parous women are associated with previous GDM (Cheung and Byth, 2005). A multiethnic long-term study reported offspring of mothers who were detected with GDM in their pregnancy had a five-fold greater risk of developing impaired glucose tolerance than those who were not exposed to GDM (Holder et al., 2014).

Bellamy et al., (2009) in a systematic review and meta-analysis on Type 2 DM after GDM reported that women who previously had GDM have a seven-fold increased risk for developing Type 2 DM in future compared with women who were not diagnosed with GDM. Current data reveals that women with a history of GDM have eight to ten-fold higher risk for developing Type 2 DM than those without it and the highest chances for occurrence of Type 2 DM is between three to six years after a GDM pregnancy (Song et al., 2018; Vounzoulaki et al., 2020; Li et al., 2020).

2.1.5 Risk factors for GDM

The risk factors for GDM as reported by Lee et al., (2018) in a meta-analysis in Asia were history of previous GDM, macrosomia, congenital anomalies, pregnancy-induced hypertension, history of still birth or abortion or preterm delivery in previous pregnancy, BMI $\geq$25kg/m^2, family history of Type 2 DM, history of polycystic ovary syndrome, age $\geq$ 25yrs and multiparity. The study highlights the need for giving special attention for those with previous history of GDM, congenital anomalies or macrosomia as high-risk cases for GDM in pregnancy.

Numerous risk factors contribute to gestational diabetes mellitus such as advanced maternal age, higher pre-pregnancy body mass index, obesity, overweight, family history of diabetes mellitus, previous history of GDM, higher socioeconomic status, previous history of hypothyroidism and polycystic ovarian syndrome (Kurian et al., 2020; Lewandowska

et al., 2020; Swaminathan et al., 2020; Kouhkan et al., 2021; Uchamprina et al., 2022, Qiu et al., 2022) are the main etiological factors.

Seshiah et al., (2009) in a community-based study involving pregnant women from urban, semi-urban and rural areas found family history of Type 2 DM, maternal age greater than or equal to 25 years and body mass index greater than or equal to 25 to have significant positive association with GDM.

The major risk factors associated with GDM diagnosis were higher maternal age, obesity, family history of Type 2 DM, previous history of GDM, and previous history of macrosomia in a cohort study conducted among Iranian pregnant women (Kouhkan et al., 2021).

The risk factors of GDM are also found to be influenced by race and ethnicity. In a retrospective study on the relationship of race/ethnicity and age of pregnant women on risk of gestational diabetes mellitus, higher risk was seen among Asians, Hispanics and Arab Americans and lower risk among African Americans compared to whites. Higher maternal age (≥23 years) was also seen to be significantly associated with increased risk for GDM (Liu et al., 2020).

Another meta-analysis study on the factors associated with GDM indicated pre-pregnancy overeweight and obesity, family history of Type 2 DM, previous history of GDM, macrosomia, still birth, premature delivery, pre-gestational smoking and primigravida as independent risk factors of GDM. It is thus imperative that all pregnant women be screened early for GDM so that identification of high risk pregnant women can be done and early diagnosis and intervention done (Zhang et al., 2021).

2.1.6 Management of GDM - Screening, Diagnosis, Treatment, Monitoring and Evaluation of GDM

2.1.6.1 Screening and Diagnosis of GDM

Asians have greater susceptibility to Type 2 DM and metabolic syndrome due to their genetic makeup and Indian women in particular have greater predisposition to develop GDM and its complications (Rani et al., 2016). There is thus the dire need for early screening and diagnosis of GDM for effective management of GDM. Sahu et al., (2021) recommends timely screening and adequate treatment of GDM to minimize the impact on adverse outcomes. GDM diagnosed early with subsequent evidence-based lifestyle

interventions can reduce the risk of developing Type 2 DM in both mother and her offspring (Herath et al., 2017).

There is still no consensus on the best screening and diagnostic approach to GDM (Minschart et al., 2021). Universal screening or selective screening based on high risk factors, one step or two step approach is to be used is still a matter of debate as the screening approaches vary among countries, region and year (Zhu and Zhang, 2016).

Early screening approaches to identify pregnant women at high and low risk of GDM as well as to detect undiagnosed DM cases, have been demonstrated in several studies but with conflicting results, not affirming if early screening would improve maternal and foetal outcomes. For example, a study by Ryan et al. (2018) reported that early screening improved the primary composite outcomes such as emergency caesarean surgery, macrosomia and neonatal hypoglcaemia in GDM high risk women. However, another study by Bianchi et al., (2018) demonstrated that early versus standard screening and treatment of GDM in high risk women showed similar short-term maternal-foetal outcomes although women with an early diagnosis were treated with insulin therapy. Thus, GDM screening done at 24-28 weeks of gestation is still the widely accepted screening approach and close monitoring of women with a high-risk profile or past history of GDM is suggested (Raets et al., 2021).

GDM screening is mostly performed between 24-28 weeks of pregnancy because insulin resistance increases at the second trimester and there is a concurrent rise in glucose levels in women who are unable to produce enough insulin to counteract this resistance (Rani et al., 2016). Prediction models for GDM involving identification of risk factors, would be helpful not only in improving the diagnostic accuracy of selective screening strategies but also initiate lifestyle interventions in early pregnancy to prevent of GDM and adverse pregnancy outcomes (Minschart et al., 2021).

Table I – shows the existing screening and diagnostic criteria for GDM developed by various health organizations

Table 1 Current Guidelines for Screening and Diagnosis of GDM

Guideline, Year	Range	One-Step	Two-Step	OGTT Criteria	OGTT Time	Risk Factors List	Screening in Early Pregnancy
DIPSI, 2006	India	√		≥140mg/dl (2h)	First antenatal visit and at 24-28 weeks	-	First antenatal visit and at 24-28 weeks
IADPSG, 2010	Global	√		≥92mg/dl (fasting), ≥180mg/dl (1h) and/or ≥153mg/dl (2h)	24–28 weeks	√	FPG ≥92mg/dl in early pregnancy is diagnosed as GDM
WHO, 2013	Global	√		IADPSG	Any time	-	Criteria apply for the diagnosis of GDM at any time during pregnancy
FIGO, 2015	Global	√		IADPSG	24–28 weeks or any other time	√	Not applicable due to lack of clear evidence
NICE, 2015	UK	√		≥126mg/dl(fasting) or ≥140mg/dl (2h)	24–28 weeks	√	75g 2h OGTT in women with previous GDM as soon as possible after booking
ACOG, 2018	US		√	CC/NDDG	24–28 weeks	√	Consider testing in all women with BMI >25 kg/m^2 (or >23 kg/m^2 in Asian Americans) and with ≥1 additional risk factors
ADA, 2021	US	√	√	IADPSG/CC	24–28 weeks	√	OGTT for high-risk women at the first antenatal visit and classified as T1DM or T2DM

Notes: The OGTT threshold value of IADPSG criteria is 92mg/dl, 180mg/dl and 153mg/dl for a 2h 75g OGTT. One or more of these threshold values must be equaled or exceeded for the diagnosis of GDM. The OGTT threshold value of CC criteria is 95mg/dl, 180mg/dl, 155md/dl and 140mg/dl for a 3h 100g OGTT. The OGTT threshold value of NDDG criteria is 105mg/dl, 190mg/dl, 165mg/dl and 145mg/dl for a 4h 100g OGTT. For CC and NDDG criteria, a diagnosis generally requires that two or more thresholds be met or exceeded, although some clinicians choose to use just one elevated value.

Abbreviations: GDM, Gestational Diabetes Mellitus; OGTT, Oral Glucose Tolerance Test; IADPSG, International Association of Diabetic Pregnancy Study Group; FPG, fasting plasma glucose; WHO, World Health Organization; FIGO, International Federation of Gynecology and Obstetrics; NICE, National Institute for Health and Care Excellence; ACOG, American Congress of Obstetricians and Gynecologists; CC, Carpenter and Coustan; NDDG, National Diabetes Data Group; BMI, body mass index; ADA, American Diabetes Association; T1DM, Type 1 Diabetes Mellitus; T2DM, Type 2 Diabetes Mellitus.

2.1.6.2 Treatment of GDM

Owing to the dearth of randomized clinical trials, it is very challenging to suggest a clear-cut and consistent management model for GDM patients that would result in obstetric outcomes comparable to those of healthy women. Expert opinion and consensus are the foundations for the treatment of GDM. Cochrane Database Reviews analyses revealed a dearth of clear information regarding the relationship between obstetric outcomes and the degree of glycaemic control (Martis et al., 2016). According to a meta-analysis conducted between 2014 and 2019 by Mitanchez et al., (2020) found that combining dietary therapy with exercise has the biggest effect on lowering the number of obstetric complications.

2.1.6.3 Diet Therapy

Dietary guidelines assist women in achieving normoglycemia, ideal weight gain, and healthy foetal development; the initiation of a pharmaceutical treatment does not absolve the mother of her responsibility to adhere to the diet. A personalized diet plan must be created for each patient with GDM, taking into consideration work, rest, exercise, and the mother's nutritional preferences in addition to glycaemic self-control, optimal weight gain based on pre-pregnancy BMI, energy requirements, and macronutrient proportions (American Diabetes Association, 2018).

In comparison to general recommendations, Chao et al. (2019) found that individualised diet control along with nutrition guidance for GDM women produced better results than the GDM women who followed conventional dietary guidance. In order to guard against nocturnal hypoglycaemia and morning ketosis, it is advised to eat three main meals and two to three snacks each day, usually with a snack around 9:30 pm. More frequent meals were associated with improved glycaemic control in a prospective observational study employing the 24-hour online diet and glycaemic tool ("Myfood24 GDM") (Morris et al., 2020). Carbohydrates are the primary macronutrient in women with

GDM, and consuming too many of them can result in hyperglycaemia. However, glucose is essential to the placenta and foetus's healthy growth and metabolism because it serves as their primary energy substrate (Hay, 2006).

According to the ADA, starchy foods with a low glycaemic index (GI) should make up the majority of the diet's carbohydrates, which should account for 40–50 per cent of total energy required, or at least 180 g per day. The recommended daily intake of dietary fibre is 25–28g, which equates to a serving of roughly 600g of fruit and vegetables, including at least 300 g of vegetables, whole grain bread, pasta, and rice. With a minimum recommended daily intake of 71 g, protein should make up approximately 30 per cent of the caloric value, or about 1.3 g/kg of body weight/d (ADA, 2018).

Reducing consumption of red and processed meats and increasing consumption of plant protein, lean meat, and fish can help manage GDM and potentially enhance insulin sensitivity (Jamilian and Asemi, 2015). According to Rasmussen et al., (2020) a diet high in fat is not recommended as it can cause placental dysfunction, infant obesity, increased inflammation and oxidative stress, and impaired maternal muscle glucose uptake. A diet low in fat should comprise no more than 20–30 per cent of the recommended daily caloric value, including less than 10 per cent saturated fat. Since polyunsaturated fatty acids (PUFA) like n-3 linolenic acid and n-6 linoleic acid are the most important fatty acids for foetal growth and development, consumption of saturated fat should be limited in favour of these PUFAs.

2.1.6.4 Exercise in GDM

Regarding enhancing glycaemic control in women with GDM, the quantitative and qualitative exercise recommendations are unclear (Brown et al., 2017). It is important to adhere to obstetric indications and contraindications. The observational studies that are currently available show that physical activity is safe to engage in during pregnancy, provided there are no contraindications (ACOG, 2015). Low-intensity fitness exercises, walking, cycling, swimming, and some types of Pilates can all be started and continued safely. After speaking with your obstetrician, it is safe to resume (but not start) yoga, running, tennis, badminton, and strength training. Contact activities such as sports, horseback riding, surfing, skiing, and diving are not recommended for expectant mothers.

The results of Aune et al., (2016) analysis indicated that women who were physically active had a 38 per cent lower risk of GDM (RR 0.62, 95% CI 0.41–0.94).

In an intervention study conducted by Nasiri-Amiri et al., (2019), on overweight patients found that women who exercised no more than three times a week had a 24 per cent lower risk of GDM. Ming et al., (2018) found that among women with normal body weight, increased physical activity led to a 42 per cent reduction in the risk of GDM (RR 0.58, 95% CI 0.37−0.90, p = 0.01) and a lower weight gain during pregnancy without affecting the child's weight or the frequency of Caesarean sections. Harrison et al., (2016) conducted a meta-analysis of eight randomized trials and found that women who engaged in 20–30 minutes of activity three–four times a week had significantly lower levels of postprandial glucose and fasting.

2.1.6.5 Pharmacological Treatment

Pharmacological treatment should be administered to patients who are unable to meet their glycaemic targets despite following a well-balanced diet and correcting any dietary errors (Landon et al., 2009). According to the majority of research, insulin therapy is the safest kind of care; OAD (orally administered drugs) should only be used if the patient refuses insulin therapy or it is not available (Nguyen et al., 2018). Subcutaneous injections are used to administer insulin therapy in the functional intensive insulin therapy (FIIT) paradigm. It has been shown that using human insulin during pregnancy is safe (Blum, 2016). Randomized trials verified the safety of using Aspart and Detemir analogs, while observational studies demonstrated the safety of Lispro and Glargine analogs. However, none of the studies demonstrated the passage of insulin analogs across the placenta (Pantalone et al., 2011).

Glibenclamide and Metformin are currently taken orally. Although they pass through the placenta, Metformin and Glibenclamide (glyburide) are not likely to cause birth defects (Lee et al., 2014). One of the biggest randomized controlled trials, the Metformin in Gestational Diabetes (MiG) trial involving 751 women with GDM, prospectively assessed a composite of neonatal complications as the primary outcome and secondary outcome of neonatal anthropometry at birth. The trial was a landmark investigation. It was determined that there was no correlation between increased perinatal complications and metformin, either by itself or in combination with additional insulin. Several other studies evaluating the safety and effectiveness of Metformin use in GDM were based on this trial

(Rowan et al., 2008). According to certain research, taking Metformin while pregnant is linked to increased body weight, visceral and subcutaneous tissue, and blood glucose levels in the 9-year-old offspring (Rowan et al., 2018). Despite Glibenclamide's great efficacy, there is a chance that using it will increase the risk of intrauterine deaths and neonatal problems like macrosomia, hypoglycaemia, and foetal growth restriction (FGR) (Zeng et al., 2014).

The ADA and ACOG continue to recommend insulin as the primary medical treatment if the glycaemic treatment goals are not achieved with lifestyle intervention, despite the growing body of evidence supporting the use of Metformin or Glyburide for GDM. This recommendation stems from the lack of evidence regarding the long-term safety of these alternative medications. Sodium-glucose cotransporter-2 (SGLT2) inhibitors decrease blood glucose levels by increasing renal glucose excretion by blocking the transporter in the kidney's proximal tubule that facilitates renal tubular reabsorption of glucose (Yu et al., 2021).

Pregnancy-related UTIs in women with diabetes may increase the risk of pyelonephritis, sepsis, and long-term consequences for the foetus (Mukerji et al., 2017). Although there is no available data from humans, animal reproductive studies have reported some adverse events, including negative effects on renal development when SGLT2 inhibitors were used in the second and third trimesters. It is not advised to use SGLT2 inhibitors while pregnant. GLP-1 agents have recently been used in GDM, according to certain studies. GLP-1 agents, such as glucagon-like peptide-1 receptor agonist (GLP-1 Ra) and dipeptidyl peptidase-4 (DPP-4) inhibitor, have been shown to improve insulin secretion in pancreatic b-cells and have numerous benefits in the treatment of Type 2 DM, although they are not frequently prescribed for GDM (Marso et al., 2016).

2.1.6.6 Role of Probiotics in GDM treatment

Recent studies indicate that probiotics influence host metabolism favorably in a variety of diseases via modifying the gut microbiota and inflammatory response. In a consensus statement, the International Scientific Association for Probiotic and Prebiotic has defined probiotics as “living microorganisms that, when administered in adequate amounts, impart a health benefit on the host.” Probiotics can be consumed during pregnancy and after delivery because they are generally safe, well-tolerated, and they have a high compliance

rate. Probiotic supplementation has been proven to be beneficial for controlling fasting blood glucose (FBG), fasting serum insulin (FSI), and HOMA-IR levels. Moreover, high-sensitivity C-reactive protein (hs-CRP), interleukin-6 (IL-6), and tumor necrosis-α (TNF-α) levels have all been shown to be reduced with probiotic administration. Similar positive effects of probiotics have been found in adults with prediabetes and Type 2 DM (Chen et al., 2020).

The gut microbiota (GM) is a vast collection of microorganisms composed of bacteria, fungi, archaea, and viruses inhabiting the gastrointestinal tract. They form a complex ecosystem involved in, for example, harvesting energy, metabolizing nutrients and drugs, synthesizing vitamins, defending against inflammation, and protecting against pathogens. The action of the GM is not limited to the gastrointestinal tract. Currently, the gut–brain, gut–liver, gut–skin, and gut–heart axes are the subjects of many studies. Pregnancy, both normal and complicated with diseases, also changes the composition and activity of the GM because of fat mass gain, hormonal changes, and increased release of pro-inflammatory cytokines. Compared to the state before conception, in pregnancy, the GM is characterized by an increase in bacteria belonging to the phyla Proteobacteria and Actinobacteria, with a simultaneous depletion of the beneficial *Roseburia intestinalis* and *Faecalibacterium prausnitzii* (Obuchowska et al., 2022).

Preventing GDM, rather than treating it, can have a number of benefits, both health and economic. Homayouni et al. (2020) suggests that probiotics are a relatively new intervention that can lower glucose levels, prevent GDM, and reduce maternal and fetal complications resulting from it. Several studies have shown that the gut microflora is significantly altered in women with GDM and is similar to that of adults with Type 2 DM (Kuang et al., 2017). An increased number of gram-negative bacteria, such as *Parabacteroides*, *Prevotella*, *Haemophilus*, and *Desulfovibrio*, have been found in the intestines of GDM patients. However, a study by Mokkala et al. (2021) showed that the presence or absence of a specific bacterial species or function did not predict the onset of GDM, nor did it differ depending on the severity of GDM, although in the group of women with GDM, a higher number of *Ruminococcus obeum* was found in late pregnancy. Bouter et al. (2017) studied the intriguing how gut microbiota affects the onset of GDM. GDM was linked to altered intestinal microflora in women who were in the third trimester of

pregnancy. Nevertheless, the results of research on the potential benefits of probiotics for the prevention or treatment of GDM remain equivocal (Pan et al., 2017).

The roles of probiotics in modulating the composition of the intestinal microbiota and reducing the adherence of pathobionts, regulating the permeability of the intestinal epithelium and reducing the inflammatory process have been observed (Hasain et al., 2020). A randomized study of probiotics (*Lactobacillus rhamnosus GG* and *Bifidobacterium lactis*) showed a reduction of more than 60 percent in GDM, with an incidence of 13 percent in the probiotic group compared with 34 percent in the control group. However, some studies found no significant differences between the probiotic and placebo groups in terms of glycaemia control and antioxidant capability. Nevertheless, the study by Sahhaf Ebrahimi et al. (2019) found that the use of probiotic yogurt improved blood glucose levels as well as glycosylated hemoglobin (HbA1c) levels.

2.1.6.7 Monitoring and Evaluation of GDM

The monitoring and evaluation goals described by various organisations are represented in Table II.

Table II Monitoring and Evaluation Goals from Various Organisations

ACOG (2013)	ADA (2003; 2015)	CDA (2013)	IDF (2015)	NICE (2015)
Insufficient evidence on optimal frequency of testing Generally recommend testing four times daily (fasting, after each meal) Postprandial glucose goals (mg/dL): • 1-hour <120	Monitor glucose daily Plasma glucose goals (mg/dL): • Fasting ≤105 • 1-hour PP ≤155 • 2-hour PP ≤130. Whole blood glucose goals (mg/dL): • Fasting ≤95 • 1-hour PP ≤140 • 2-hour PP ≤120. Limited evidence that postprandial monitoring is superior in patients on insulin	Monitor fasting and postprandial glucose daily Goals (mg/dL): • Fasting <95 • 1 hour PP <140 • 2 hour PP <120	Monitor fasting and postprandial glucose daily, preferably 1 hour after eating Capillary glucose goals (mg/dL): • Fasting 90–99 • 1-hour PP<140 • 2 hour PP <120-127 Target as low as possible ensuring patient comfort and safety	Multiple insulin injections daily: monitor fasting, pre-meal, 1-hour postprandial, and bedtime All others: monitor fasting and 1-hour postprandial Capillary glucose goals (mg/dL): • Fasting <95 • 1-hour PP<140 • 2 hour PP <115

ACOG, American College of Obstetricians and Gynecologists; ADA, American Diabetes Association; CDA, Canadian Diabetes Association; GDM, gestational diabetes mellitus; IDF, International Diabetes Federation; NICE, National Institute for Health and Care Excellence; PP, postprandial.

2.1.6.8 Blood Glucose Monitoring

Self-monitoring of blood glucose (SMBG) should be performed by women four times a day, one or two hours after meals (after the first bite of a meal), and fasting glucose upon waking. Since the risk of macrosomia rises with elevated maternal glucose levels after meals, monitoring blood glucose after meals is preferred in GDM over pre-meal testing (Jovanovic-Peterson et al., 1991). In a randomized clinical trial (de Veciana et al., 1995), this was demonstrated by comparing pre-prandial glucose monitoring to one-hour post-prandial (PP) testing. The results showed that women who monitored their glucose after meals had a significantly lower incidence of macrosomia, caesarean deliveries, and neonatal hypoglycaemia. It is unknown; nevertheless, if a one- or two-hour PP test is the best course of action for reducing foetal risks. As a result, patients can check their blood sugar at any convenient time after eating, such as one or two hours afterward, or whenever they believe their blood sugar will peak after a meal. For instance, they can choose the time when their blood sugar was elevated during an OGTT (Blumer et al., 2013).

Pregnant women typically have lower average blood glucose concentrations than non-pregnant women, which explains why their glycosylated hemoglobin (HbA1C) values tend to be lower. A lower HbA1C is also influenced by the increase in red cell mass and red blood cell turnover that occurs during pregnancy. When evaluating glycaemia control during pregnancy in women with GDM, routinely measuring HbA1C may not be helpful for those whose initial HbA1C level was low. Nonetheless, individuals with overt diabetes who have an HbA1C >6.5% may find its measurement useful (Jovanovič et al., 2011).

Continuous glucose monitoring (CGM) involves a disposable subcutaneous electrochemical sensor measuring interstitial glucose based on its reaction to glucose oxidase. The sensor is connected to a receiver to measure and store interstitial glucose data automatically (Cappon et al., 2019). Average values can be displayed on a monitor at ~5-minute intervals, yielding ~288 measurements daily for the Medtronic iPro2 and Dexcom G5, or every 15 minutes for the FreeStyle Libre Pro. Resulting data is accessible as an Excel list of measurements or a continuous curve, mapping magnitude, frequency, and duration of glucose excursions (Di Filippo et al., 2022)

CGM has been used in gestational diabetic women primarily as a management tool allowing a more acceptable and reliable glucose reading and control than self-monitoring of blood glucose (SMBG), as reported in a recent systematic review (Yu et al., 2019).

2.1.6.9 Complications of GDM – Maternal Outcomes and Foetal Outcomes

i. Short-term Risk

GDM patients are more likely to experience obstetric interventions such as induction of labour, caesarean sections, and delivery-related complications like uterine rupture and perineal lacerations, which are mostly related to foetal macrosomia and polyhydramnios. Preeclampsia and gestational hypertension are also more common in women with GDM, as evidenced by HAPO study and other studies. Circumstantial evidence linking diabetes to microvascular disease suggests that disruptions in glucose metabolism impact trophoblast invasion, resulting in compromised placentation and an increased risk of preeclampsia. According to in vitro research, high glucose concentrations inhibit trophoblast invasiveness by preventing uterine plasminogen activator activity, suggesting that the mechanism is likely related to insulin resistance and the activation of inflammatory pathways (Vounzoulaki et al., 2020).

ii. Long-term Risk

According to Kim et al., (2007), women who were diagnosed with GDM using the pre-IADPSG diagnostic criteria have a higher chance of developing GDM again in subsequent pregnancies, with recurrence rates ranging from 30 per cent to 84 per cent. According to Vounzoulaki et al. (2020), having a diagnosis of GDM can also increase the lifetime risk of Type 2 DM by up to 20 times. According to a recent comprehensive review and large meta-analysis encompassing 20 studies (n = 1 332 373, including 67 956 women with GDM), women with a history of GDM are at a ten-fold higher risk of developing Type 2 DM, primarily in the first five years after GDM. After 14 years of HAPO, Hyperglycaemia and Adverse Pregnancy Outcomes- Follow Up Study (HAPO-FUS) showed that more than 50 per cent of women whose OGTT thresholds satisfied the IADPSG diagnostic criteria for GDM (untreated) had impaired glucose tolerance (Lowe et al., 2019). These findings emphasize the need of managing GDM for early prevention of Type 2 DM. For instance, according to Murphy's (2020) update to the NICE guidelines, diabetes prevention is now advised for all women who have previously had GDM.

Cardiovascular risk factors like obesity, hypertension, and dyslipidemia are also linked to prior GDM. According to Retnakaran (2009), women with Type 2 DM have a nearly three-fold increased lifetime risk of cardiovascular disease after GDM, and this risk is even 1.5 times higher in women without Type 2 DM. Additionally, studies show that

women with a history of GDM had a 43 per cent increased risk of a myocardial infarction or stroke and a 26 per cent increased risk of hypertension (Tobias et al., 2017). International organizations, such as the American Heart Association, have recently acknowledged the significance of GDM as a risk factor for Type 2 DM and cardiovascular disease (Brown et al., 2018).

Table III Maternal and Neonatal Complications of Gestational Diabetes Mellitus

Complications	Maternal	Neonatal
Short term	Preeclampsia, Gestational hypertension, Polyhydramnios, Urinary tract/Vaginal infections, Instrumental delivery, Caesarean delivery, Traumatic labour/Perineal tears, Postpartum hemorrhage Difficulty initiating and / or maintaining breastfeeding	Stillbirth, Neonatal death, Preterm birth, Congenital malformations, Macrosomia, Cardiomyopathy, Birth trauma: Shoulder dystocia, Bone fracture, Brachial plexus injury, Hypoglycemia, Hyperbilirubinemia, Respiratory distress syndrome
Long term	Recurrence of GDM, Type 2 DM, Hypertension, Ischemic heart disease, Non-alcoholic fatty liver disease, Dyslipidemia, Chronic kidney disease	Metabolic syndrome, Hyperinsulinemia, Childhood obesity, Excess abdominal adiposity, Higher blood pressure, Possible early onset cardiovascular disease, Possible attention-deficit hyperactivity disorder, autism, spectrum disorder

Sources: Scholtens et al., (2019) and Saravanan (2020).

Abbreviation : GDM, Gestational Diabetes Mellitus.

Larger babies with higher birth weights are more common in mothers with GDM. To lower the risk of harm to the mother and child, this increases the number of deliveries by cesarean section as opposed to vaginal delivery. But once more, women who have good glycaemic control are less likely to experience these complications. The children born to these women represent another facet of the consequences of a GDM pregnancy. While not all of these women's offspring will be born with birth defects, the likelihood of birth defects is increased if the pregnancy's blood glucose levels were not controlled. The perinatal mortality rate of babies born to mothers with gestational diabetes mellitus is comparable to

that of the control group, but the rate of macrosomia and morbidity—including respiratory distress, hypoglycemia, hypocalcaemia, hypoglycemia, and birth trauma—is higher (King, 1998).

Pregnant women with poorly managed diabetes have a six to ten per cent chance of giving birth to a child with birth defects; this is double the risk in cases where the mother has well-controlled diabetes. Birth defects that are linked to this condition include spinal cord defects (spina bifida), heart defects, skeletal defects, and digestive, reproductive, and urinary system defects. Additionally, babies born to diabetic mothers are more likely to be born with jaundice, or yellowish skin, low blood sugar (hypoglycemia), and breathing difficulties (Al-Hakeem, 2006).

While GDM has been linked with a higher offspring body mass index (BMI), several studies have suggested that this association is confounded by higher BMI in the mother. In HAPO-FUS, children aged 10–14 years, no association was found between GDM and overweight/obesity defined by BMI after adjusting for maternal BMI during pregnancy (Lowe et al., 2018). However, a recent population based retrospective study of 33,157 children aged 1–6 years in China showed that offispring of GDM women and those born as large for gestational age had a higher BMI z-score and increased risk for overweight from one to six years and the association became more significant after adjusting the maternal pre-pregnancy BMI. The study highlights the need to focus on pre-pregnancy weight to reduce the prevalence of childhood overweight and obesity (Chen et al., 2020).

Higher maternal BMI could be associated with higher childhood adiposity through genetic transmission, shared postnatal lifestyle/environment, and intrauterine environment (Godfrey et al., 2017). Positive associations between GDM and skinfold thickness have been observed in children at birth and later childhood (aged 5–10 years), with limited evidence in children aged 2–5 years (Shafaeizadeh et al., 2020).

Children born to GDM women may be at risk of immune dysregulation. A recent US study of 97,554 children (median age: 7.6 years) reported that the rate of childhood asthma might be influenced by severe GDM requiring medication use (Martinez et al.,

2020). Compared with non-GDM women, an increased risk of childhood asthma was reported only in offspring of GDM cases requiring antidiabetic medications (HR: 1.12, 95% CI: 1.01–1.25) but not in those without requiring medications. These findings were independent of maternal asthma.

2.1.6.10 Epigenetic Programming and GDM

Even after a pregnancy ends, GDM can still have an impact on the health of the offspring. Neural and mental injury, respiratory distress syndrome, macrosomia, hypoglycemia, cardiovascular disease, and other conditions are among the consequences of GDM on the offspring.

The multi-differentiation proficiency of intracorporal stem cells may be altered by an intrauterine high-glucose environment, resulting in decreased proliferation and osteogenic capacity, increased adipogenic ability, accelerated apoptosis, and the occurrence of premature failure. Additionally, in this milieu, medullary cell mobilization increases while bone marrow stem cell mobilization decreases. This raises the risk of obesity, cardiovascular and neurological diseases, and metabolic abnormalities by causing pro-inflammatory circumstances and persistent inflammation in the body (Zhuang, 2020).

The "foetal origin of adult disease" hypothesis proposes that gestational programming may critically influence adult health and disease (Barker, 1995). Even a brief exposure to maternal diabetes during early development can cause long lasting changes in the expression of genes controlling insulin secretion and DNA methylation, suggesting an epigenetic mechanism mediated by methylation for the intergenerational glucose intolerance caused by GDM (Zhu et al., 2019).

The rising trend in diabetes and related Non Communicable Diseases (NCDs) is also linked to hyperglycemia in pregnancy (HIP). Maternal hyperglycemia causes abnormal in-utero stimulations to the developing foetus making the offspring prone to develop NCDs in adulthood. Resistance to the hormones insulin and leptin in the offspring affects the metabolic milieu predisposing the individual to obesity and diabetes. The adverse intra-uterine programming that occurs during HIP leads to a vicious cycle (Figure 4) of transgenerational transmission of obesity, insulin resistance, diabetes and other related NCDs to future generation. (Bronson & Seshiah, 2021).

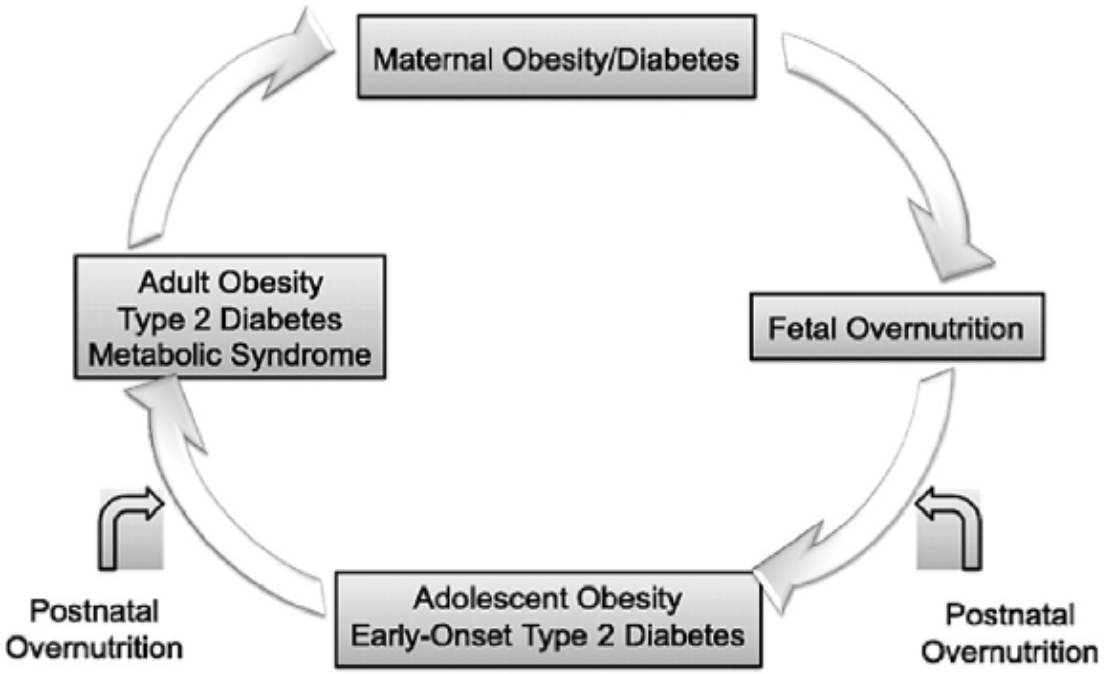

Figure 4

Transgenerational Transmission of Diabetes – The Vicious Cycle
(Adapted from Dabelea and Crume, 2011. Maternal environment and the transgenerational cycle of obesity and diabetes. Diabetes.60:1849–1855

2.1.6.11 Barriers to Medical Management of GDM

Pre-gestational diabetes and GDM increase the risk of macrosomia, obstructed labour, spontaneous abortion, stillbirth, and maternal and perinatal deaths. GDM may have especially detrimental effects on the health and well-being of the mother and child in nations where there is a dearth of access to adequate care for obstetrical emergencies. Accordingly, GDM poses an underappreciated and unacknowledged barrier to the best possible mother and newborn health in low- and middle-income countries (LMIC) (World Diabetes Foundation, Global Alliance for Women's Health, 2009).

Previous research has outlined the obstacles and enablers to postpartum care for GDM patients. Among Missouri women receiving care in Federally Qualified Health Centers (FQHCs), access to public transportation and prenatal diabetes education were significantly linked to the recommended postpartum screening. Fragmented care, inadequate information, difficulties adjusting to a new role as a mother, lack of support during the postpartum period, and erroneous perception of future Type 2 DM risk were common barriers identified in qualitative studies (Bennett et al., 2011 Van Ryswyk et al.,

2015). The provision of childcare, relationships with clinical staff, and social support were found to be facilitators of care-seeking (Dennison et al., 2019).

Participants in the majority of these studies had private insurance. Patients talked about poor experiences with healthcare providers, losing healthcare coverage after giving birth, and a lack of culturally sensitive practices in a study of low-income women with GDM (Oza-Frank et al., 2018). There is only one study that took into account the perspectives of both patients and healthcare providers in an urban safety-net setting. It found that providers typically prioritize the health of the newborn after delivery and that poor coordination and inconsistent communication can obstruct care. The healthcare system, interpersonal relationships, and individual-level factors that affected the uptake of screening were identified through a systematic review of qualitative studies investigating women's perspectives on postpartum Type 2 DM screening following a diagnosis of GDM (McCloskey et al., 2019).

An observational study by Nwose et al., (2019) included lack of screening for blood glucose as part of routine antenatal protocol and the lack of registers for recording GDM detection and post partum follow up. The study emphasised the need to train healthcare professionals involved in antenatal care and the maintenance of proper registers for GDM management.

The approach to GDM in India in the early 1990s, as in many parts of the world, was affected by the following problems: (1) there was no standard method for screening; (2) there was no consensus on whom, when, and how often to screening; (3) the paramedical staff were often poorly educated about GDM; and (4) there was poor awareness of the impact and long-term consequences of GDM. Later, when treatment for GDM progressed globally, India too worked towards developing national guidelines for GDM in India which was made on 2014 under the auspices of Ministry of Health and Family Welfare, Government of India and revised in 2018. (Thanawala, 2021).

Poor socioeconomic status, lack of family, peer and community support, effects of pregnancy, complicated therapeutic regimen, pathophysiology of diabetes, cultural and religious beliefs, and poor health care system were the identified barriers of adherence to treatment of GDM women in a study conducted in Zimbabwe. (Mukona et al., 2017)

2.2 Medical Nutrition Therapy (MNT) for Sustainable Management of GDM

2.2.1 Definition of MNT and Purpose of MNT in GDM

The first step in treating GDM and lowering maternal and fetal complications over the short and long term is MNT, in conjunction with regular self-monitoring and physical exercise. While MNT adheres to certain well-defined guidelines, each pregnant woman's cultural traits, level of learning and decision-making ability, and support from her family must all be taken into consideration (National Diabetes Services Scheme, 2019).

The American Diabetes Association (ADA) (2021) guidelines state that changing one's lifestyle and behavior is crucial to managing GDM. MNT is recommended as the first line of treatment for GDM in all national and international guidelines, along with weight control and physical activity (PA) (Kim, 2010). According to a summary of Cochrane systematic reviews, the only interventions that demonstrated improved health outcomes for women and their children were lifestyle modifications (MNT, PA), and self-management training (SMBG) (Martis et al., 2018).

Once GDM diagnosis is confirmed, MNT must be started with counseling by a licensed dietitian experienced in GDM management. 30 minutes of PA per day is advised. Research indicates that in 70-85% of women with GDM diagnoses, lifestyle modification alone is adequate to control blood glucose. Insulin or medication must be added if glycaemic goals are not met with appropriate MNT and PA (Anjana et al., 2019).

In order to delay or prevent complications from diabetes, MNT aims to: (1) achieve individualized goals for blood pressure, lipids, glycaemic control, and body weight; (2) address each person's nutritional needs based on health literacy and numeracy, cultural and personal preferences, availability of healthy food options, willingness and ability to make behavioral changes, and obstacles to change; (3) maintain the enjoyment of eating by promoting positive food choices while restricting food options only when supported by scientific evidence; and (4) give diabetic patients useful tools for daily meal planning instead of focusing on specific macronutrients, micronutrients, or single foods (Evert et al., 2019).

MNT has been demonstrated to enhance glycaemic control (Reader et al., 2006) and is the cornerstone of treatment for GDM (Metzger et al., 2007). Achieving normal blood glucose levels while encouraging sufficient weight gain and nutritional status without going into ketosis is the main objective of MNT. Additionally, MNT for GDM may serve as a springboard for dietary adjustments toward a healthful diet that may continue beyond childbirth, potentially offering long-term benefits such as mitigating the risk of Type 2 diabetes.

2.2.2 Nutrition Care Process for GDM Management

The optimal diet for women with GDM which includes carbohydrate restriction, energy content, and the kind and amount of macronutrients—remains uncertain despite a number of recent studies (Kim, 2010). According to Evert et al., (2013), it is sufficient to tailor dietary advice based on the American Diabetes Association guidelines for all individuals with diabetes, regardless of pregnancy. However, the most recent clinical guideline from the Academy of Nutrition and Dietetics indicates that not all women with GDM should follow the same type of nutrition plan (Duarte-Gardea et al., 2018).

ADA's NCP is a standardized process for dietetics professionals and not a means to provide standardized care. A standardized process refers to a consistent structure and framework used to provide nutrition care, whereas standardized care infers that all patients/clients receive the same care. This process supports and promotes individualized care, not standardized care. As represented in the model (Figure 5), the relationship between the patient/client/group and dietetics professional is at the core of the nutrition care process. Therefore, nutrition care provided by qualified dietetics professionals should always reflect both the state of the science and the state of the art of dietetics practice to meet the individualized needs of each patient/client/group (Splett, 1999).

2.2.3 Using the NCP

Even though ADA's NCP will primarily be used to provide nutrition care to individuals in health care settings (inpatient, ambulatory, and extended care), the process also has applicability in a wide variety of community settings. It will be used by dietetics professionals to provide nutrition care to both individuals and groups in community-based agencies and programs for the purpose of health promotion and disease prevention (Endres, 1999 & Splett, 1990 as cited in Lacey, 2003).

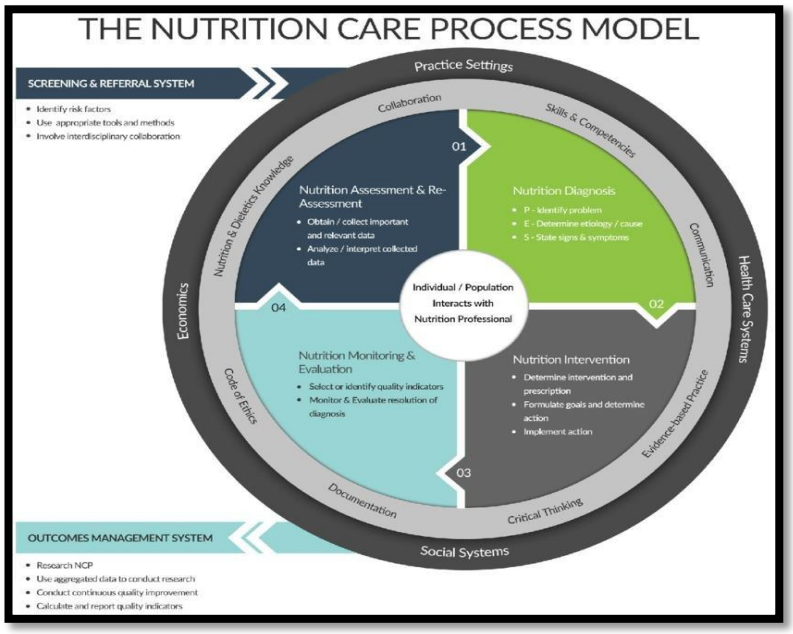

Figure 5

Nutrition Care Process Model

(Adapted from the website of the Academy of Nutrition and Dietetics, https://www.eatrightpro.org/practice/nutrition-care-process/ncp-overview)

2.2.4 MNT and Maternal Foetal Outcomes

According to Jiménez-Moleón et al., (2002), GDM affects two to five percent of pregnancies and is linked to unfavorable outcomes for both the mother and the foetus. In addition to being linked to the mother's future development of Type 2 DM (Damm, 2009), GDM is associated with a number of unfavorable foetal outcomes, including congenital defects, stillbirths, macrosomia, shoulder dystocia, and other birth injuries, as well as neonatal hypoglycemia (Xiong et al., 2001).

Even at glucose levels below those thought to be indicative of GDM, the HAPO study demonstrated a persistent correlation between maternal glucose and rising birth weight and cord blood C-peptide levels. Treatment for GDM lowers perinatal complications and enhances health quality of life, according to the Australian Carbohydrate Intolerance Study (ACHOIS), a randomized trial of GDM treatment for women (Crowther et al., 2005). Treatment of GDM was found to be effective in lowering the rates of macrosomia, preeclampsia, and shoulder dystocia, according to a systematic review by Falavigna et al., (2012).

Together with an increase in diabetes prevalence in the general population, there is a worrying rise in the prevalence of diabetes during pregnancy. Pregnancy-related hyperglycemia affects approximately 1 in 6 live births; of these patients, approximately 85% have GDM, with pre-gestational diabetes accounting for the remaining cases (Murphy et al., 2021).

Pregnancy-related hyperglycemia increases the risk of poor outcomes for both the mother and the fetus (Yang et al., 2002). Reducing the risk of perinatal outcomes like macrosomia, birth trauma, neonatal metabolic abnormalities, and cesarean section is the goal of treating diabetes during pregnancy (Langer et al., 2005). The first line of treatment is lifestyle modification, which includes glucose monitoring, exercise, and medical nutrition therapy (MNT). Depending on the presence and severity of hyperglycemia, agents such as insulin, glyburide, or metformin may be used in addition to MNT as part of pharmacological therapy. If modifying one's lifestyle is not enough to achieve euglycemia, then insulin is the recommended pharmacological treatment for managing diabetes during pregnancy (American Diabetes Association, 2018).

2.2.5 Dietetic Interventions in GDM

Randomized controlled trials are used in nutritional research in three main ways: as an intervention, with dietary advice; as a comparison with food items or supplements; or as a means of implementing "whole-diet" strategies, which aim to change the overall composition or quality of the diet (Weaver et al., 2021).

Research on the whole-diet provision that is well-designed can yield new information about the genesis and treatment of disease. The DiRECT trial, which involved giving non-pregnant adults with Type 2 DM a reduced-energy diet (825–853 kcal/d) for 12–20 weeks, is an example of a successful whole-diet intervention. The trial's outcomes included improvements in glycaemia, induced diabetes remission, and decreased cardiovascular risk (Lean et al., 2018). Although they are less common, whole-diet approaches have been utilized during pregnancy. For instance, Hodson and associates enlisted women with GDM who were given a 1200 kcal/d diet for four weeks. The program was well-received and led to a notable weekly weight loss of 0·4 kg (Hodson et al., 2017). These findings demonstrate the potential value of these kinds of energy-restricted whole-diet interventions in enhancing clinical outcomes.

In a systematic review and meta-analysis of randomized controlled trials examining the impact of modified dietary interventions on maternal glucose control and neonatal birth weight by Yamamato et al., (2018) showed decrease in fasting and post prandial glucose among those who followed modified dietary interventions compared to controls. The modified dietary interventions were also found to be associated with lower infant birth weight and lesser cases of macrosomia. Previous research has shown that it is safe for pregnant women with GDM to restrict their caloric intake (Feng et al., 2021 and Tsirou et al., 2021).

2.2.6 MNT Guidelines for GDM Management

In the management of GDM, MNT is acknowledged as the first-line therapy. Clinical outcomes in diabetes have been demonstrated to be improved by evidence-based MNT (Franz et al., 1995). In the United States, evidence-based nutrition practice guidelines (NPG) for GDM were initially released by the Academy of Nutrition and Dietetics (AND) in 2008. When these guidelines were applied in non-diabetes specific clinics, glycosylated hemoglobin follow-up was significantly lower and insulin use was reduced when compared to usual MNT. As far as we are aware, the USA guidelines are the only published evidence-based guidelines for GDM that are specific to nutrition and have been informed by a systematic review of scientific literature. According to Duarte-Gardea et al., (2018), there are guidelines for the nutrition assessment procedure, the frequency and length of MNT visits, the prescription of calories, the requirements for macronutrients, the supplementation of vitamins and minerals, the frequency of meals and snacks, the use of sweeteners and alcohol, and the monitoring and evaluation of nutrition.

The guideline advises that all women with GDM are referred to a dietitian for individualised MNT that includes initial education (group or individual for 60–90 min) followed by at least two individual review visits (30–45 min duration). Guideline recommendations also include provision of individualised calorie prescriptions (based on the Institute of Medicine maternal weight gain guidelines) and adequate macronutrients to support pregnancy (minimum of 175 g carbohydrate, 71 or 1.1 g protein kg–1 body weight) (Duarte-Gardea et al., 2018).

2.2.7 Barriers to Medical Nutrition Therapy in GDM

According to a recent systematic review, "lack of time" continues to be a major obstacle for GDM women seeking to modify and maintain their lifestyle (Dennison et al.,

2019). The current study's results confirm earlier findings by demonstrating that childcare and work obligations are still the biggest obstacles to implementing a healthy lifestyle program, followed by "lack of time." These results could help to partially explain why women who had two or more children had a significantly lower likelihood of meeting the recommendations for aerobic exercise. In addition, those who expressed interest in taking part in a lifestyle program indicated that they preferred online formats over home visits or outdoor settings for program delivery, which could potentially lower the childcare barrier. Even so, poor adherence (<20%) was reported in a recent ten-week live online webinar program that involved group education and exercise for women who had given birth within a year (Christie et al., 2022). For the sake of future program success, more flexibility in timing (asynchronous) and/or format, as well as the inclusion of one-on-one coaching, may be more advantageous.

It's interesting to note that reporting meeting the current strengthening exercise recommendations and being more willing to participate in a lifestyle intervention were both correlated with having tertiary level education or higher. In the future, interventions that more clearly illustrate the benefits of strengthening exercises and lifestyle modifications for health could be developed to address this disparity. It is commonly known that low recruitment and high attrition rates in studies involving this population make it challenging to determine the efficacy of novel lifestyle interventions for GDM (Gray et al., 2021).

The most frequent obstacles faced by expectant mothers include a lack of drive, acting like inpatients, having little faith in medical professionals, adhering to medical advice improperly, having a propensity to downplay their own role in the educational process, and not wanting to help carry out instructions and prescriptions. Health care providers may also face obstacles like the use of a non-motivation approach, inadequate communication skills, a lack of special training, or a lack of time. According to Rhee et al. (2005), additional obstacles that could arise during the educational process include socioeconomic, geographic, cultural, and health literacy issues as well as patient education levels and lack of access to educational resources.

2.3. Standard Operating Protocol Enhanced Management of GDM

2.3.1 Definition of SOP

A standard operating procedure is a set of written instructions that describes the step-by-step process that must be taken to properly perform a routine activity.

A standard operating procedure (SOP) is a set of step-by-step instructions compiled by an organization to help workers carry out routine operations.

The standards and indicators found within the SOP and SOPP reflect the minimum competent level of nutrition and dietetics practice and professional performance for RDNs. The SOP in Nutrition Care is composed of four standards that apply the Nutrition Care Process and Terminology in the care of patients/clients/populations (Swan et al., 2017).

2.3.2 Purpose of SOP in Quality Enhancement

Standard operating procedures provide the policies, processes, and standards needed for the organization to succeed. They can benefit a business by reducing errors, increasing efficiencies and profitability, creating a safe work environment, and producing guidelines for how to resolve issues and overcome obstacles (Brush, 2021).

The standards promote:

- safe, effective, quality, and efficient food, nutrition, and related services, and dietetics practice;
- evidence-based practice and best practices;
- improved nutrition and health related outcomes and cost reduction methods;
- efficient management of time, finances, facilities, supplies, technology, and natural and human resources;
- quality assurance, performance improvement, and outcomes reporting;
- ethical and transparent business, billing, and financial management practices
- verification of practitioner qualifications and competence because state and federal regulatory agencies, such as health departments and the Centers for Medicare and Medicaid Services (CMS), look to professional organizations to create and maintain standards of practice
- consistency in practice and performance;
- nutrition and dietetics research, innovation, and practice development; and
- individual professional advancement. The standards provide:
- minimum competent levels of practice and performance;
- common measurable indicators for self-evaluation;
- a foundation for public and professional accountability in nutrition and dietetics care and services;

- a description of the role of nutrition and dietetics and the unique services that RDNs offer within the health care team and in practice settings outside of health care;
- guidance for policies and procedures, job descriptions, competence assessment tools; and
- academic and supervised practice objectives for education programs (USDHHS, 2017).

SOP Process

A standard operating procedure (SOP) is a step-by-step, repeatable process for any routine task. It's a kind of documentation that prevents stress, mistakes, and miscommunication. SOPs ensure reliability, efficiency, and consistently hitting quality standards in regular work activities.

SOP Format

An SOP format is a template your organization uses to document standard operating procedures. Giving your team a template (or many SOP examples) to follow helps ensure yours is high-quality and clear.

Types of SOP Format

Simple SOP Format

Best for standard operating procedures that are straightforward and low-complexity

A simple format shares key steps in an easy-to-digest overview. With a simple SOP format, you'll want to keep the document length to three to five sections and include:

- a statement of purpose
- a short summary
- bulleted step-by-step instructions or a short table
- the responsible person for each step

Hierarchical SOP Format

Best for large, *complex, or technical SOPs*

Also called a complex SOP format, this is a more formal format that includes a table of contents and headings to help organize the information into bite-sized pieces.

When using a hierarchical format, you'll want to include a table of contents and organize the procedure into several sections that include:

- a statement of purpose
- a summary or overview
- step-by-step instructions with details on how each task should be completed and links to any standards to its related checklists or action plan(s)
- responsible teams or stakeholders for each step

Flowchart SOP

Best for standard operating procedures that have a flexible scope

Using a flowchart SOP format can be useful to outline both simple and complex procedures. SOPs with a flowchart can vary in length. They need a few essential components that include:

- a statement of purpose or introduction
- an easy-to-follow flowchart or diagram outlining what happens in various scenarios
- the responsible people for each step

How to Write a Standard Operating Procedure (SOP) Document

According to (Brush, 2021), the steps for writing a SOP is as follows:

1. **Step 1: Identify how things work now.** If you are not the owner of the process day-to-day, interview the stakeholders who are and determine exactly how the process works. A great SOP starts with a clear picture of what *actually* happens, even if it's not working well.
2. **Step 2: Determine where to document.** Look for a tool that supports sharing with your team, or one like Guru where you can easily and intuitively share all kinds of documentation with stakeholders you work with even if they're not already using it.
3. **Step 3: Identify your audience.** Will the procedures be used by a wider team to ensure continuity of delivery? If so, you'll want to craft a detailed, step-by-step process that meets them at their level of skill and familiarity with the tools and technologies used.
4. **Step 4: Write up the SOP.** Now that you know what you're writing and for whom, you can draft an SOP that covers each step and who owns each.

5. **Step 5: Improve your process.** Finding ways to level up a process is simpler when you get it out of your head. Easy ways to streamline SOPs include minimizing unnecessary back and forth, streamlining your workflows with automation, and improving the hand-off between parties by creating templates that share the right information in the best way possible.

6. **Step 6: Update your SOP.** Quickly update your SOP when a process changes, show its current order by verifying it, and even alert colleagues to the change by sending an announcement.

7. **Step 7: Continue to refine and update.** SOPs are never "done." Aim for finding the way that works best by refining yours over time.

2.3.3 SOP for GDM Management

The Women in India with Gestational Diabetes Mellitus Strategy-4 (WINGS 4) study by Kayal et al. (2016) on the methodology and development of model of care for gestational diabetes mellitus (WINGS 4) focused on diagnosis, management, and follow-up of women with GDM was one of the first studies to give a comprehensive package at every level of care for women with GDM.

2.3.4 SOP and Maternal Foetal Outcomes

The Women in India with Gestational Diabetes Mellitus Strategy Study -10 (WINGS-10) by Uma et al. (2017) applied the structured model of care from WINGS-4 study on GDM women and showed that a larger percentage of 84.4 percent women were able to manage GDM with MNT and physical activity itself. The implementation of the structured model of care among GDM women resulted in pregnancy outcomes that were similar to the outcomes seen among non-GDM women.

2.4 Mobile Apps for Gestational Diabetes Mellitus

There are various apps available for pregnancy, offering various features such as estimating stress scale, due date, tracking baby's growth and development, providing health information, monitoring blood glucose, offering food choice and meal plans and giving health tips. A few of the highly rated Apps with a rating of 4.7 and more, taken by running a search in Google Play store are described below.

Gestational Diabetes Stress Scale (Rating 4.7)

The main feature of this app is to find out the stress associated with diabetes in pregnant women and to also evaluate the awareness about gestational diabetes in women with GDM.

Gestational Age (baby's age) (Rating 4.8)

This is an App features a gestational BMI calculation and also estimates the foetal weight for the given gestational age.

Pregnancy App (Rating 4.7)

This App is one of the top pregnancy apps which tracts pregnancy, calculate current week of gestation, track pregnancy weigh and tract baby kicks and contractions

Doctor Gestation Calculator (4.7)

This App is developed for use by doctors. It provides various types of gestation calculations such as expected due date from last monthly period and expected due date from period of gestation, body mass index, estimated foetal weight and iron calculator.