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Preconception Care for Women with Pregestational Diabetes:
Information for the Family Nurse Practitioner

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ABSTRACT

Preconception Care for Women with Pregestational Diabetes: Information for the Family Nurse Practitioner

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Purpose: The purpose of this article is to evaluate present literature and guidelines regarding preconception care for women with type I diabetes mellitus (T1DM) or type II diabetes mellitus (T2DM) and familiarize the family nurse practitioner (FNP) with current clinical recommendations.

Data Sources: The guidelines reviewed include the Clinical Practice Recommendations from the American Diabetes Association 2013, the American College of Obstetricians and Gynecologists pregestational diabetes mellitus guideline reaffirmed in 2010, and the National Institute for Health and Clinical Excellence on how to manage diabetes and its complications from preconception to the postnatal period 2008.

Conclusions: Guidelines were established based on clear and compelling evidence from randomized control studies, expert consensus, and clinical experience. Grading systems were used to clarify evidence and gave basis for support of recommendations. A review and analysis of each guideline is reported for the FNP.

Implications for Practice: FNPs have the ability to promote optimal health through their role in primary care. Lack of FNP knowledge regarding recommended guidelines for preconception counseling is a barrier to providing optimal preconception care to women with pregestational diabetes. Understanding these recommendations, the FNP can play a vital role in these women obtaining a positive birth outcome.

Key words: Pregestational diabetes, preconception care, type I diabetes mellitus, type II diabetes mellitus, FNP

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Preconception Care for Women with Pregestational Diabetes:
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An estimated 371 million people worldwide are affected by diabetes, and 181 million of those are women (International Diabetes Federation [IDF], 2014). The worldwide incidence of diabetes is increasing, and in the United States, the Centers for Disease Control and Prevention (CDC) projects by 2050, 33% of U.S adults could have some form of diabetes mellitus, more than half of whom will be women (Centers for Disease Control and Prevention [CDC], 2012). The increase in rates of both type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) among women is of particular importance for women of childbearing age. Estimates suggest 1% of live births are affected by some form of diabetes (T1DM, T2DM, or gestational diabetes), and of those, between 10% and 14% are complicated by pregestational diabetes (Lawrence, Chen, Contreras, & Sacks, 2008). Current trends in diabetes prevalence also suggest this number is likely to increase (Lipscombe, McLaughlin, Wu, & Feig, 2010).

Glycemic control prior to conception reduces the risk of many pregnancy and birth related complications (Ray, O'Brien, & Chan, 2001). Women with pregestational diabetes and poor blood glucose control at the time of conception and organogenesis have a 3.8% higher risk of having a child with birth defects; every 1% in HbA1c over 6.3% is associated with a 30% increase in risk ("Diabetes birth defect risk," 2012). The risk of having a child with a major birth defect is directly proportional to the blood glucose levels of mothers during the first 12 weeks of pregnancy when major organs are developing (Mironiuk, Kietlinska, Jezierska-Kasprzyk, & Piekosz-Orzechowska, 1997). Macintosh et al. (2006) found high rates of perinatal mortality and congenital anomalies the same for women with either T1DM or T2DM

(2006). Additional complications, including spontaneous abortion, major congenital malformations of the neural tube and heart, premature birth, macrosomia, and stillbirth are also associated with the grade of glucose control prior to and during pregnancy (Lipscombe, McLaughlin, Wu, & Feig, 2010; Correa et al., 2012; Macintosh et al., 2006).

In particular, the offspring of women with pregestational diabetes mellitus are at risk for neural tube defects and congenital heart defects. Macintosh et al. (2006) found a 3.4 times higher risk for congenital heart disease and a 2.7 times higher risk with anomalies of the nervous system. The risk of neural tube defects was three to four times higher than originally expected (Macintosh, 2006).

In addition to fetal complications, pregnant women can have progression of diabetic complications secondary to pregnancy (Leguizamo, Igarzabal, & Reece, 2007). Pregnancy has been associated with increased retinopathy and nephropathy related to diabetes, as well as hypertension and a significant increase in myocardial infarction in women with pregestational diabetes mellitus (Macintosh et al., 2006; Ray et al., 2001; Leguizamo et al., 2007).

The rate of major congenital malformations among offspring of women with pregestational diabetes becomes similar to that of offspring of nondiabetic women when tight glycemic control is achieved prior to conception (Klinke & Toth, 2003). Tight glycemic control is defined as blood glucose levels between 70 and 130 mg/dl before meals and less than 180 two hours after starting a meal, with a glycated hemoglobin (A1C) level less than 7%(CDC, 2013). In addition, preconception counseling, care, and education can considerably reduce pregnancy complications with a significant positive impact on both mother and child (Leguizamo, Igarzabal, & Reece, 2007). Preconception care is defined as interventions designed to identify and modify risks to a woman's health and potential pregnancy through

prevention and management (Johnson et al., 2006). Basic steps can be taken before conception to ensure maximal benefits on pregnancy health and fetal outcomes (Johnson et al., 2006). Achieving a positive pregnancy outcome can be directly related to a woman's health prior to becoming pregnant and is particularly evident in women with T1DM or T2DM, who have a two-to four-fold increased risk in conceiving a child with birth defects than women without diabetes (Correa et al., 2012).

Evidence exists supporting the importance of preconception counseling and planned pregnancy; however, it is estimated nearly half of all pregnancies are unplanned (Mosher, Jones, & Abma, 2012). In fact, more than 60% of women with pregestational diabetes have unplanned pregnancies, lack access to preconception care, or feel challenged to comply with glycemic control regimens (Correa et al., 2012). As a result, 18% of these women do not seek early prenatal care and fewer have any form of preconception counseling (Korenbrodt, Steinberg, Bender, & Newberry, 2002).

In order to improve birth outcomes among T1DM and T2DM women, the family nurse practitioner (FNP) can play a significant role in preconception counseling and care. Given the nature of primary care and family practice, FNPs could have more frequent and early contact with women of childbearing age than other providers (Klinke & Toth, 2003). Although many women might not seek preconception counseling prior to pregnancy, over 70% of women of childbearing age were reported to seek regular preventative care from a primary care provider (PCP) (Korenbrodt et al., 2002). FNPs in primary care typically provide more information to patients, utilize better communication skills, and spend more time with patients than other providers (Horrocks, Anderson, & Salisbury, 2002). Because of this, the FNP has the unique opportunity to provide necessary education and counseling during routine preventive care

office visits. The purpose of this article is to evaluate present literature and guidelines regarding preconception care for women with T1DM or T2DM and familiarize FNPs with these clinical recommendations.

Method

Relevant research-based articles were identified using the following databases: MEDLINE, CINHAL, National Guideline Clearinghouse, and the Cochrane Library. Search terms included: *pregestational diabetes mellitus*, preexisting diabetes, type 1 or type 2 diabetes mellitus. Additionally, the terms preconception, prepregnancy, pregestational and care, education or counseling were searched. Articles published prior to 1990 were not included. Limiters were also placed for English only and peer reviewed articles. Additional searches were performed using the ancestry approach to identify primary sources and previously published literature reviews on the same subject. Several guidelines were identified, with three main guidelines selected for review. These three guidelines were selected based on international and national acceptance, most recent publication or review, and strong evidence based research criteria. They include the Clinical Practice Recommendations from the American Diabetes Association 2013, the American College of Obstetricians and Gynecologists pregestational diabetes mellitus guideline reaffirmed in 2010, and the National Institute for Health and Clinical Excellence on how to manage diabetes and its complications from preconception to the postnatal period published in 2008. Additional statistics were gathered from the Centers for Disease Control and Prevention, as well as the International Diabetes Federation, regarding diabetes prevalence and anticipated incidence in the future.

Results

Clinical guideline recommendations for preconception care have been developed to better manage diabetes mellitus in women of childbearing age (Muhmud, 2010). Because of the importance of maintaining glycemic control prior to conception, it is essential a multidisciplinary approach be taken to achieve optimal birth outcomes. The FNP, along with an obstetrician, nurse midwife, endocrinologist, or other diabetes specialist, should be aware of clinical guidelines and the emphasis placed on education for women with diabetes. The American Diabetes Association, American College of Obstetricians and Gynecologists, and National Institute for Health and Clinical Excellence have established guidelines and standards for preconception care. These guidelines will be presented and summarized to provide an up-to-date resource for the FNP.

American Diabetes Association

Each year in January, the American Diabetic Association (ADA) reports and publishes the Standards of Medical Care in Diabetes in the *Diabetes Care* journal. Part of the guideline focuses on recommendations of care for women with pregestational diabetes mellitus (ADA, 2013) and, along with the entire document, is revised annually for incorporation of new evidence based research. The recommendations are standards of care intended to provide clinicians, including FNPs, with the components of diabetes care, general treatment goals, and targets desirable for most patients with diabetes. Along with the recommendations, the ADA also provides their own grading system to explain the level of evidence for the recommendations (ADA, 2013).

In 2013 the ADA based its recommendations on current research and preconception care programs that were “multidisciplinary and designed to train patients in diabetes self-

management with diet, intensified insulin therapy, and self-monitored blood glucose” (s11–s66). Findings indicate women who achieved normal A1C levels and participated in a preconception care program prior to conception had a significantly lower incidence of major congenital malformations (ADA, 2013). Based on these results, the ADA considers the goals of preconception care to involve and empower the woman in her diabetes, achieve the lowest A1C results possible without excessive hypoglycemia (< 7%), assure contraception until acceptable glucose levels are achieved, and treat long term diabetes complications (such as retinopathy, nephropathy, neuropathy, hypertension, and coronary heart disease [CHD]) (ADA, 2013).

The ADA also addressed the problems associated with high numbers of unplanned pregnancies among women with preexisting diabetes and attributed the increased congenital malformation rate to this statistic. Recommendations for minimizing this risk include education for all women, starting at puberty or at time of diagnosis, regarding risk of malformations with uncontrolled blood glucose levels. Also imperative is to teach the use of effective contraception at all times unless actively trying to conceive when maintaining good metabolic control (ADA, 2013).

Further emphasizing the need for effective contraception, the guideline identified a number of commonly used drugs that are contraindicated or not recommended during pregnancy and should be discontinued prior to conceiving. The ADA advised against use of statins, ACE inhibitors, and ARBs during pregnancy, as well as careful evaluation of the risk to benefits ratio with use of oral antidiabetic agents (safety data is inconclusive for use in pregnancy) (ADA, 2013).

Utilization of a multidisciplinary team of experienced providers in the management of diabetes before and during pregnancy is recommended. The FNP might include an ophthalmologist, nephrologist, gynecologist, and other specialists as necessary as part of the health care team. For example, the ADA suggests that prior to pregnancy women with preexisting diabetes should have a comprehensive eye examination. The FNP's role is to educate the patient regarding the potential for development or progression of diabetic retinopathy and coordinate referral to an ophthalmologist. Finally, the ADA guideline emphasizes the importance of frequent evaluation, education, and management of diabetes in any woman of child-bearing age contemplating pregnancy (ADA, 2013).

American College of Obstetricians and Gynecologists

In March of 2005 (reaffirmed in 2012) the American College of Obstetricians and Gynecologists (ACOG) developed a suggested management guideline for pregestational diabetes mellitus. The information was designed to aid practitioners in making decisions on the most appropriate care for women with T1DM or T2DM prior to and during pregnancy (ACOG, 2005). Several clinical considerations and recommendations are applicable to FNP's.

Less than one-third of women with diabetes mellitus seek preconception counseling (ACOG, 2005). Because of this, ACOG recommended any visit to a health care provider should be used to discuss future plans of pregnancy. The discussion should focus on euglycemia before pregnancy along with the adverse maternal and fetal outcomes that can be caused from poorly controlled blood glucose levels (ACOG, 2005). No specific A1C or target blood glucose for euglycemia was given by ACOG; however, "Near physiologic levels" before conception and throughout pregnancy was advised (ACOG, 2005, p. 681).

ACOG suggested women formulate a reproductive health plan. The PCP should start by asking women at each appointment about her plan for birth control, spacing and timing of children, and future plans for conception. An open dialogue can help assess readiness for pregnancy, and when pregnancy is not desired, contraception should be discussed (ACOG Committee on Gynecologic Practice, 2012).

In an effort to decrease the incidence of neural tube defects, ACOG stated all women contemplating pregnancy should take a multivitamin containing at least 400 mcg of folic acid daily. Women with pregestational diabetes might benefit from higher doses of folic acid if other risk factors for neural tube defects are present (2005).

The ACOG guideline emphasized that poorly controlled diabetes causes severe end organ damage, and pregnancy exacerbates these complications, resulting in life threatening consequences (2005). Of these complications, the potential for diabetic retinopathy among women with pregestational diabetes is also increased. ACOG recommends these women have a comprehensive eye exam in the first trimester. Additionally, prior to pregnancy a baseline renal function should be assessed by a serum creatinine and urine protein excretion. ACOG also stated “Chronic hypertension is observed in 5–10% of pregnant women with pregestational diabetes” (ACOG, 2005, p. 677); ideally, hypertension should be controlled before conception.

As a final point, ACOG specified these guidelines are not intended to dictate practice, and variations to treatment course should be based on individual patients’ needs and type of practice. “Preconception and interpregnancy care are components of a larger health care goal—optimizing the health of every woman” (ACOG Committee on Gynecologic Practice, 2005, p. 666).

National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence (NICE) collaborated with the National Collaborating Centre for Women's and Children's Health to develop the guideline for management of diabetes from preconception to the postnatal period (2008). NICE based their recommendation on systematic reviews of the best available evidence, and provided evidence levels throughout the guideline (NICE, 2008).

The NICE guidelines stated their aims were to empower women with diabetes and their families to encourage a positive experience through pregnancy and childbirth. Preconception care was advised with every contact with the health care team, and benefits of good preconception glycemic control were stressed (NICE, 2008). Starting in adolescence, health care recommendations and counseling should focus on the importance of avoiding unplanned pregnancy.

The NICE guidelines also emphasize involvement of supportive family. Education for the patient and her partner or family member should include how diabetes affects pregnancy and how pregnancy affects diabetes—particularly the role of diet, weight, and exercise (NICE, 2008). NICE recommendations included folic acid supplementation of 500 mcg daily, up to 12 weeks gestation (2008).

Recommendations for glycemic control before and during pregnancy were also outlined. NICE advised women with preexisting diabetes who are planning to become pregnant maintain an A1C below 6.1% (2008), emphasizing any reduction in A1C towards that target is likely to reduce the risk of congenital malformation. Advising women regarding hypoglycemia was also of great importance, given the recommended A1C levels. Women with an A1C above 10% should be advised to avoid pregnancy (NICE, 2008).

NICE guidelines indicated need to discontinue ACE inhibitors, ARBs, and statins for women planning pregnancy, or as soon as pregnancy is confirmed. Metformin for preexisting diabetes is allowed under the NICE guidelines, but discontinuance of all other oral hypoglycemic medications was advised (NICE, 2008).

Along with education, tighter glycemetic controls, and thorough medication reconciliation, a retinal and renal assessment was also recommended in NICE guidelines. Ideally, because diabetic retinopathy can worsen during pregnancy, women seeking preconception care should be offered a retinal assessment upon initiation of care and yearly thereafter if no retinopathy is detected. Nephropathy associated with adverse pregnancy outcomes should also be assessed prior to discontinuance of birth control (NICE, 2008).

Discussion

Guidelines were established and updated based on clear and compelling evidence from randomized control studies, expert consensus, and clinical experience. Grading systems were used to clarify evidence and gave basis for support of recommendations. All three guidelines stated their method of grading evidence for the recommendations found in the guidelines. The grading system for the ADA guideline was developed by the American Diabetes Association and modeled after already existing methods. It was used to clarify evidence that forms the basis for the recommendations. The level of evidence that supports each recommendation is listed after each recommendation using the letters A, B, C, or E, and range from A being the highest level of evidence to E being expert consensus. The ADA standards of care are revised annually by the ADA's multidisciplinary Professional Practice Committee, incorporating new evidence (ADA, 2013).

ACOGs grading system is similar to the ADA's with the use of grading levels for both evidence and recommendations. Recommendations were given a grade from A to C. Recommendations based on good and consistent scientific evidence were given a level A rating. Level B ratings were given for recommendations based on limited or inconsistent scientific evidence, and level C recommendations were based on consensus and expert opinion. The majority of recommendations given by ACOG are level B recommendations. Each ACOG practice bulletin is reviewed every 18–24 months by a practice committee. Based on the most recent literature and consensus of the committee the guideline is either reaffirmed or withdrawn. The guideline was reaffirmed in 2012.

The NICE guideline stated their recommendations were based on reviews of best available evidence, and recommendations of the development group's opinion of good practice. No specific grading tool is given; however, each recommendation is followed by the type of evidence that supported the statement. For example, the recommendation to avoid pregnancy if A1C is greater than 10% was followed by "high quality evidence from a small non-randomized controlled trial" (NICE, 2008, p.1/6).

In reviewing the three guidelines, a few differences were noted. The NICE recommendation for folic acid supplementation was 500 mcg daily until 12 weeks gestation. This recommendation differs from other guidelines reviewed, which indicated 400 mcg daily at least one month prior to pregnancy, with higher doses if there is an increased risk of neural tube defects (ACOG, 2005). The ADA preconception guideline did not specify folic acid requirements.

Another difference in clinical guidance advised by NICE was the tighter control of blood glucose levels prior to pregnancy. NICE advised women with preexisting diabetes

planning to become pregnant maintain an A1C below 6.1% (2008). ACOG did not dictate specific A1C levels due to lack of evidence that indicated what A1C level would prevent congenital malformation. A recommendation was given for adequate glucose control to be maintained near physiologic levels. The ADA recommended levels should be < 7%, or as close to normal as possible.

All three guidelines agreed regarding discontinuance of contraindicated medications often used in pregestational diabetes, including ACE inhibitors, ARBs, and statins. The use of metformin was noted to be acceptable as adjunct or alternative to insulin in the NICE guideline. However, ACOG recommended use of metformin on an individual basis, and the ADA recommends weighing the risk and benefits of its use in the preconception period.

Implications for Practice

Current research and guidelines established by the American Diabetes Association, American College of Obstetricians and Gynecologists, and the National Institute for Health and Clinical Excellence provide vital resources for the FNP treating women with T1DM and T2DM. Preconception care recommendations based on review of the guidelines are summarized as follows:

1. Incorporate preconception counseling into all routine clinic visits for all women of child-bearing age and formulate a reproductive health plan.
2. Discuss importance of maintaining A1C < 7.0.
If A1C > 8, pregnancy is not recommended.
If A1C > 10, pregnancy is contraindicated.
3. Emphasize avoidance of unplanned pregnancy.

Encourage effective contraception until pregnancy is desired and appropriate A1C levels are achieved.

4. Refer to high risk obstetrician upon becoming pregnant.
5. Provide folic acid supplementation of at least 400mcg daily, with higher doses for women with increased risk of neural tube defects.
6. Perform medication reconciliation and education regarding medications contraindicated in pregnancy.

Discontinue use of ACE, ARBs and statins.

Discontinue all oral anti-diabetic medications.

Discuss that the long term use of metformin in utero has unknown effects and its use must be decided on an individual basis.

7. Evaluate for diabetic retinopathy and nephropathy yearly, with comprehensive eye exam and renal function baseline.

Conclusion

FNPs have the ability to promote optimal health through their role in the primary care setting. Lack of FNP knowledge regarding recommended guidelines for preconception counseling is a barrier to providing optimal preconception care to women with pregestational diabetes. By understanding these recommendations, the FNP can play a vital role in helping women with pregestational diabetes mellitus obtain a positive birth outcome.

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