Impact of an Electronic Clinical Decision Support Tool on Early Maternal Glucose Screening in Pregnancy

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ABSTRACT

Gestational diabetes mellitus (GDM), diabetes diagnosed in the second or third trimester of pregnancy that is not clearly overt diabetes, has become more common as the rates of obesity in women of childbearing age have increased. Undiagnosed, uncontrolled diabetes in pregnancy can lead to maternal and infant health comorbidities as well as have adverse long-term effects for mother or baby. Although routine screening for gestational diabetes mellitus (GDM) occurs between 24 and 28 weeks gestation, the American Congress of Obstetricians and Gynecologists (ACOG) recommends screening earlier in pregnancy for women at risk for undiagnosed type 2 diabetes. Risk factors include previous history of GDM, known impaired glucose metabolism, or obesity (BMI $\geq$ 30). The purpose of this project is to implement the clinical practice guideline for early maternal glucose screening during pregnancy in women with risk factors through the integration of a clinical decision support (CDS) tool in an electronic health record (EHR). CDS tools can be utilized as a point of care strategy to remind providers of the clinical practice guidelines and to assist providers in decision-making related to screening. Participating providers (n=18) utilized the CDS tool during the initial obstetrical visit for at risk women without a pre-pregnancy diabetes diagnosis and entering prenatal care prior to 24 weeks. The impact of implantation of the CDS tool shows that an increase in screening was statistically significant ($p<.001$).

Keywords: glucose tolerance, pregnancy, diabetes, gestational diabetes mellitus, clinical decision support tool, CDS tool

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Up to 9.2% of women who give birth in the United States each year develop diabetes during their pregnancy (DeSisto, Kim, & Sharma, 2014). The obesity and diabetes epidemics have led to an increase in type 2 diabetes in women of childbearing age, and in the number of pregnant women with undiagnosed type 2 diabetes [T2DM] (ADA, 2015). The HAPO study revealed that uncontrolled diabetes in pregnancy can lead to adverse maternal and fetal outcomes (Metzger, Lowe, Dyer, Trimble, Chaovarindr, Coustan, Hadden, McCance, Hod, McIntyre, Oats, Persson, Rogers, & Sacks [HAPO], 2008). Diabetes in pregnancy (DIP) is any form of diabetes while pregnant, including GDM, Type 2 DM (T2DM) or insulin resistant diabetes, and Type 1 DM (T1DM) or insulin-dependent diabetes (Chamberlain, McNamara, Williams, Yore, Oldensburg, Oats, & Eades, 2013) Gestational diabetes mellitus (GDM) is diabetes diagnosed in the second or third trimester of pregnancy that is not clearly overt diabetes (American Diabetes Association [ADA], 2015).When undiagnosed T2DM is recognized, it is later in pregnancy due to routine GDM screening protocol and considered to be GDM based on timing of recognition (ADA, 2015). In the meantime, because it is unrecognized prior to routine GDM screening, undiagnosed type 2 diabetes remains uncontrolled during the first trimester. The impact of uncontrolled diabetes on mother and baby can be devastating; however this can be alleviated with early maternal glucose screening. While routine screening for gestational diabetes in the United States occurs between 24 and 28 weeks gestation, multiple national organizations recommend early screening based on maternal risk factors. What constitutes risk factors varies with each expert opinion guideline (American Congress of Obstetricians & Gynecologists [ACOG], 2014; ADA, 2015; US Preventative Services Task Force [USPSTF], 2014).

Background

GDM has become more common as the rates of obesity and diabetes mellitus of women of childbearing age have increased (Centers for Disease Control & Prevention [CDC], 2014; Hillier, Vesco, Whitlock, et al., 2008). It is estimated that there are 13.4 million women diagnosed with diabetes; it is projected that one out of three people will develop diabetes in their lifetime (CDC, 2014). The increase of diabetes in women is leading to concern for maternal and fetal outcomes

Recent evidence shows that in women with risk factors such as marked obesity, personal history of GDM, or glycosuria, early screening is a predictor of gestational diabetes and may be an indicator of pre-gestational diabetes (ADA, 2015; Chamberlain, et al., 2013; Corrado, D'Anna, Cannata, Interdonato, Pintaudi, & Di Benedetto, 2012; Farah, McGoldrick, Fattah, O'Connor, Kennelly, & Turner, 2012; Harrison, et al., 2015; Syngelaki, et al., 2015; & Teede, Harrison, Teh, Paul, & Allen, 2011). Routine screening for gestational diabetes has been recommended between 24 and 28 weeks gestation., The American Congress of Obstetricians and Gynecologists (ACOG), whose guidelines are most recognized among childbearing care providers, recommends screening women at risk for undiagnosed type 2 diabetes as early as the first prenatal visit.

Clinical Significance

Diabetes in pregnancy can lead to both fetal consequences such as macrosomia, shoulder dystocia, neonatal hypoglycemia, and increased neonatal intensive care unit (NICU) admissions, as well maternal consequences such as increased risk of preeclampsia and increased risk of operative delivery, among other adverse maternal outcomes. The associated longer hospitalizations drive up healthcare costs. Additionally, in utero exposure to GDM puts the

infant at six times higher risk of later developing impaired glucose tolerance or T2DM (Holder, Giannini, Santoro, Pierpont, Shaw, Duran, Caprio, & Weiss, 2014). Mothers are at seven times higher risk of developing T2DM later in life (Kim, 2014). The increased risk for mother or baby to develop T2DM later in life also contributes to the rising economic impact of diabetes (CDC, 2014). Earlier screening, diagnosis, and treatment improve perinatal outcomes and long term economic effects of diabetes.

Internal evidence

The project site is Federally Qualified Health Care (FQHC) in the southwestern United States. The interdisciplinary team of eighteen providers includes physicians, nurse practitioners, and nurse midwives that care for women across the continuum of pregnancy. Many of the women who receive prenatal care met the risk factors for early diabetes screening in pregnancy; however, a review of one hundred charts revealed that few women with risk factors were screened early for GDM.

Patients are screened at 24-28 weeks gestation for GDM; those with elevated screenings have diagnostic testing approximately one to two weeks later. If t patients had undiagnosed T2DM prior to pregnancy, there is potential for 25-30 weeks of unmanaged diabetes in a 40-week gestational period. Some providers only order early screening for those women who had a previous pregnancy with gestational diabetes. The project site lacks a standardized practice regarding early screening for diabetes.

Clinical practice guidelines can be implemented at the point of care through the use of electronic clinical decision support (CDS) tools. CDS tools can be imbedded in electronic health records (EHR) to assist providers in decision-making related to the application of screening and management guidelines. Studies have demonstrated a positive impact of CDS tools on healthcare

provider adherence to preventative care recommendations (Jaspers, Smeulers, Vermeulen, & Peute, 2011).

While early screening does not prevent later diagnosis of gestational diabetes leads to initiation of earlier intervention, treatment, and prevention of adverse outcomes (Gabbay-Benziv & Baschat, 2015; Nilofer, Raju, Dakshayini, & Zaki, 2012). This has led to the clinically relevant PICOT question: "In women with risk factors for GDM, how does early maternal glucose screening using an electronic clinical support tool compared to current practice standards affect timely diagnoses of diabetes in pregnancy?"

Search Strategies

In order to answer this clinical question, an exhaustive search of the literature was carried out. The Cochrane Database, CINAHL, and PubMed were searched using the keywords (with Boolean connectors) *glucose tolerance* (and) *first trimester.* Additional keywords included *pregnancy, screening, diabetes, gestational diabetes mellitus, GDM,* and *CDS tool*. Searches were restricted to peer-reviewed journals written in English and published from 2011 to 2016. Abstracts were inspected to determine relevancy to the clinical question. To be considered for inclusion, studies were required to have glucose tolerance screening prior to 24 weeks gestation as the primary intervention. Exclusion criteria included glucose tolerance screening initiated after 24 weeks gestation and results that did not pertain to pregnant women with risk factors.

CINAHL yielded 16 results, with two being chosen for further appraisal. A search under the Cochrane Database yielded two reviews, with neither being chosen as appropriate. PubMed yielded 43 articles, and ten were selected for review. A total of 12 articles were critically examined for level of evidence and clinical relevancy. One randomized controlled trial, two retrospective cohort studies, one prospective observational study, and one prospective double-

blinded randomized study were chosen for inclusion in this review.

Critical Appraisal and Synthesis

Evidence shows that in women with risk factors, early screening may identify women with pre-gestational diabetes, or those who most likely progress to GDM, thus improving the timeliness of diagnosis (Kulaksizoglu, S., Kulaksizoglu, M., Kebapcilar, Torun, Ozcimen, & Turkoglu, 2013). The effects of poor glycemic control and length of disease can be devastating to both maternal and fetal outcomes (Ballas, Moore, & Ramos, 2011). Those who are diagnosed with gestational diabetes early are more likely to require medication for glycemic control, and achievement of tighter glycemic control shows a decreased poor perinatal outcomes (Alunni, Roeder, Moore, & Ramos, 2015; Reece, 2010). Early screening, diagnosis, and treatment correlate to perinatal outcomes, further demonstrating the importance of screening early (Neelakandan & Sethu, 2014; Reece, 2010).

The purpose of a CDS tool built into an EHR is to support delivery of evidence-based care and facilitate decision-making (Silvestrin, Steenrod, Coyne, Gross, Esinduy, Kodsi, Slifka, Abraham, Araiza, Bushmakin, & Luo, 2015). The use of a CDS tool has been shown to be effective in various clinical settings. Valuable areas of improvement include efficient use of laboratory services and cost containment, as well as improving early detection of disease processes (Algaze, Wood, Pageler, Sharek, Longhurst, & Shin, 2016; Allen, 2012). It has also found to decrease non-essential testing while providing high-quality care and maintaining safety (Kharbanda, Madhok, Krause, Vazquez-Benitez, Kharbanda, Mize, & Schmeling, 2016).

Purpose Statement

The purpose of this project is to improve timeliness of diagnosis of diabetes in pregnancy so that lifestyle changes and necessary treatment can be initiated. A CDS tool in an EHR,

implementing the ACOG clinical practice guideline for early maternal glucose screening during pregnancy in women with risk factors, facilitates early recognition. Early recognition and treatment plays an important role in improving outcomes, and obstetrical providers are vital in achieving progress toward the goal of short-term and long-term maternal and fetal health.

Evidence-Based Practice Model

The Stetler Model is a five-step model focused on critical thinking and the use of evidence by the practitioner (Schaffer, Sandau, & Diedrick, 2012). The first step is preparation, which was done by assessing the needs of a FQHC in relation to influential factors such as patient population and circumstances. Many of these women met the requirements for early screening, but where not being screened. The second step is validation through systematically searching databases for relevant studies, critiquing them, and summarizing the evidence found in each study. The third step, comparative evaluation and decision-making were done by comparing the studies with similar interventions and outcomes to determine which would appropriately answer the PICOT question and synthesize the data. Part of the decision-making assessed the projected process based on the fit of setting, feasibility, the substantiality of evidence, as well as current practice in the setting, and determined if it would be possible within the system. It was determined it would be more effective to focus on a provider centered project to broaden the effects of improved patient outcomes. The fourth step, translation and application, is the net process. The net process involves implementing a tool into the EHR developed around ACOG's guidelines for early diabetes in pregnancy screening and collecting data surrounding the tool usage. Once this step was completed, the fifth step, evaluation, was done to determine whether the PICOT question was appropriately answered and the goals were met. The practice itself will evaluate the process to determine if it is sustainable.

Contribution of Theory

Ferlie and Shortell developed a model for improving quality and outcomes in healthcare (Ferlie & Shortell, 2001). This is done through a multilevel approach containing four levels of change, individual healthcare practitioner, the healthcare team, the overall organization, and the cultural environment of the organization (Ferlie & Shortell, 2001). The first level is the individual practitioner. Utilization of the ACOG guideline based algorithm criteria will serve as a reminder to the provider to screen patients for diabetes early in pregnancy if they meet the criteria. Healthcare is usually delivered in groups or teams, and a well-functioning team is generally associated with higher quality care (Ferlie & Shortell, 2001). In the collaborative care clinic in which the project was implemented, involving the healthcare team improved the success rate of identifying, screening, and treating those who meet the criteria. For a sustained change, the ability of an organization to provide overall climate and cultural change is necessary (Ferlie & Shortell, 2001). By obtaining buy-in from the organization, the early screening project was possible and has increased potential of being rolled out organization-wide once it has successfully commenced. By considering multiple levels, the greatest impact can be achieved (Ferlie & Shortell, 2011).

Project Methods

After the project received expedited review and approval by the Arizona State University IRB on 10/11/2016, it was implemented at the project site. Providers (n=18) from the Women's Health clinics, including nurse practitioners, midwives, and physicians (MD, DO) were recruited at a monthly provider meeting. A recruitment/informed consent letter was given to those providers interested in participating in the project.. No member has a dual role with the study population.

Pre Intervention

The co-investigators and IT specialist worked together to add an Early Gestational Diabetes Screening CDS tool to the obstetrical template in the History of Present Illness (HPI) section of the EHR. The CDS tool is a drop down style format that integrates the ACOG recommendation for early gestational diabetes screening. Patients that qualified for early gestational diabetes screening included: BMI≥30, GDM in a previous pregnancy, or known impaired glucose. If a patient qualified for early screening, the CDS tool provided a prompt for the participating provider as a reminder to order early screening. The CDS tool is a system-wide change and therefore available for use by all providers regardless of whether they participate in the project.

The co-investigator performed a review of a convenience sample of 20 of the participating providers' records from patients seen within 6 months prior to the intervention for baseline performance data.. Eligible patient charts were determined by gestational age of pregnancy and the following codes for OB Visit in their patient assessment: Z34.01, Z34.02, Z34.81, Z34.82, O09.5, O09.521, O09.522, and Z3A.10-Z3A.23. These records were further stratified based on assignment as a "New OB Visit". Records of patients with a pre-pregnancy diagnosis of diabetes (T1DM or T2DM) were excluded. The chart audit form was developed by the co-investigator and face validity was confirmed by 10 reviewers, three ASU faculty, one being an experience women's health nurse practitioner and the other two are experienced family nurse practitioners, four peers in the women's health nurse practitioner program, and three healthcare providers, one an experienced women's health nurse practitioner, one experienced obstetrician & gynecologist, and one experienced family nurse practitioner in a federally qualified health canter.

Intervention

Participating providers received training during a 15 minute session by the co-investigator, at a women's health provider meeting or at an individual meeting, on early screening recommendations for gestational diabetes and the new electronic CDS tool in the EHR. The participants were given a hard copy of the Early Screening for GDM Algorithm for reference.

Participating providers were able to utilize the new CDS tool in the EHR system during the initial obstetrical visit for women entering prenatal care prior to 24 weeks gestation and who do not have a pre-pregnancy diagnosis of diabetes. Participating providers were sent electronic reminder messages approximately once per month encouraging use of the CDS tool.

Post Intervention

The co-investigator performed a post intervention review of 20 of the participant provider's patient charts using the same criteria as in the pre-intervention chart audit. This process determined rate of early screening for gestational diabetes in patients with risk factors, documentation of electronic CDS tool use, and referral to the registered dietician.

Cost

There was no additional cost for screening because all required GDM screening is included in the obstetrical package. There were negligible costs for IT integration, as the IT specialist is a full time employee of the site and did not require more than 15 minutes to integrate the data into the EHR system. Long term use of the CDS tool will incur no additional costs.

Outcomes

Eighteen providers were educated on the guidelines and tool usage. However, only six providers used the screening tool. A chi-squared test was performed for both providers who used

the tool and all providers combined. The outcome was measured through increase in percentage of patients with risk factors that were screened at the first prenatal visit or in the first trimester of pregnancy, both with and without tool usage, and increased percentage of patients diagnosed early with diabetes in pregnancy referred to a registered dietician for diabetic diet education and management.

All Providers

A total of 489 charts were reviewed, 244 pre-implementation charts and 245 post-implementation charts. Up to 20 charts per provider were reviewed over a six month period prior to implementation, and up to 20 charts per provider were reviewed over the three month period following implementation. Some providers had less than 20 cases during each of these time periods, with one provider not having any charts meeting criteria. Of the 244 pre-implementation charts, 110 qualified for screening, but only 13 (12%) were screened, five of which went on for diagnostic testing. Of those five, four of those were diagnosed early with GDM and two of the four diagnosed were referred to a dietician. Post-implementation, 151 qualified for screening and 46 (30%) were screened. Of those 46 screened, 15 went on for diagnostic testing. Ten of the 15 were diagnosed early with GDM, with six of the 10 being referred to a dietician. Screening increase was statistically significant ($p=<.001$). Diagnosis increase ($p=.067$) and referral rate ($p=.594$) were not statistically significant.

Providers Using CDS Tool

The results were then run to only include the six (33%) providers who used the CDS tool as guidance. A total of 224 charts were reviewed, 105 pre-implementation and 119 post-implementation charts. Of 105 cases audited, 58 qualified for screening based on ACOG criteria. Of those 58, 11(19%) were screened. Of the 11 screened, 4 went on for diagnostic testing and 3

were diagnosed early with GDM in this pregnancy. Of the three diagnosed, only one was referred to the Registered Dietician. Post-implementation, 61 qualified for screening based on ACOG criteria. Of those 61, 30 (49%) were screened, 26 (87%) of which the CDS tool was used. Of the 30 screened, 12 underwent diagnostic testing and 8 were diagnosed early with GDM in this pregnancy. Three of those diagnosed had GDM in a previous pregnancy and five met ACOG criteria for screening with obesity. Of the eight diagnosed, in seven of them, the CDS tool was used, and five were referred to a registered dietician. Screening increase was statistically significant ($p<.001$). Screening with tool usage was statistically significant ($p=.001$). Diagnosis increase ($p=.635$), diagnosis with tool usage ($p=.002$), and referral rate ($p=.424$) were not statistically significant.

Discussion

This project was implemented as a system change. Once the CDS tool was embedded in the EHR, it is fully functional and no further costs need be incurred in maintaining the tool, making it sustainable. Limitations of this project included the small number of providers willing to use the CDS tool. Additionally, there was low consistency of use for those who did use it (40.3%). Compliance improved after email reminders were sent out, but dropped off after a short time. However, there were increases in screening numbers following education and distribution of the algorithm whether the screening tool was used or not used. Recommendations for future implementation would be to start in a single clinic rather than a system of clinics or obtain buy-in by all providers for improved tool usage. An additional recommendation would be to implement a site-based project champion and organizational change champion. These two forms of champions complement each other to best implement and sustain organizational diabetes improvements (Shaw, Howard, West, Crabtree, Nease, Tutt, & Nutting, 2012).

Conclusion and Implication

Diabetes, including gestational diabetes mellitus, is a rising problem in the United States. In addition to increased diabetes in pregnancy, there are women who become pregnant unaware that they have diabetes and who are diagnosed during pregnancy. Both women with gestational diabetes and infants of those women are at increased risk of both short term and long term complications associated with diabetes. There is a large economic impact due to the cost of treating the related morbidities in addition to the morbidities themselves.

Nurse practitioners play an essential role in screening and educating patients about their health risks and management of diabetes in pregnancy. Early screening for undetected diabetes is associated with prompt diagnosis and treatment initiation. A point of care CDS tool can improve provider adherence to clinical practice guidelines for early maternal glucose screening during pregnancy. Additionally, use of a site champion team including a nurse practitioner, physician, and medical assistant may improve implementation success of a CDS tool and early screening follow through.

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