Covid-19 Vaccination Toolkit for Pregnancy: A Quality Improvement Project

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Abstract

Nature and scope of the project: Education and guidance regarding the covid vaccination during pregnancy is limited. The purpose of this project is to create a toolkit that can be given to healthcare providers who are looking to educate and facilitate conversation with pregnant patients regarding the covid-19 vaccine.

Synthesis and analysis of supporting literature: Toolkits have proven to be effective for other pregnancy-related health issues (zika virus, stillbirth) as they guide healthcare providers and increase their knowledge in regards to the topic of interest.

Project implementation: Covid-19 vaccination toolkits were dispersed to five obstetric healthcare providers in central Minnesota. The toolkit and a follow up survey were sent to health care providers via email to review the information. The survey assessed if the toolkit was beneficial, if it would be useful in practice, and provided an opportunity for recommendations.

Evaluation criteria: After receiving all anonymous survey results, modifications were made to the covid-19 toolkit. Questionnaires were not linked to individual providers and feedback looked at aggregate rather than individual responses.

Outcomes: When asked 'How likely is it that you will use this toolkit in your current practice?' 60% of providers answered 'likely' while 40% answered 'very likely'. When asked 'how beneficial would you say the content within this toolkit is in your current practice?' 20% of providers answered 'a great deal' while 80% providers answered 'a lot.' When asked 'How likely is it that you would recommend this toolkit to other health care providers in the same specialty?' 40% of providers answered 'very likely' while 60% of providers answered 'likely'.

Recommendations: It is important that a toolkit be created to help guide obstetric providers and their patients in making vital decisions regarding the covid-19 vaccination during pregnancy.

A COVID-19 Vaccination Toolkit for Pregnancy: A Quality Improvement Project

As of April 18th, 2022, more than 199,484 pregnant women have been infected with the coronavirus (covid-19) (Center for Disease Control and Prevention [CDC], 2022a) The covid-19 pandemic, caused by the acute respiratory syndrome coronavirus 2 (SARS-COV-2) was spreading rapidly across the United States and continued to threaten vulnerable populations. According to the Center for Disease Control and Prevention (CDC), pregnant women with covid-19 have an increased risk of severe illness (ICU admission, mechanical ventilation, and death) and adverse birth outcomes (preterm birth) when compared with non-pregnant women of reproductive age (Guan et al., 2020). Fortunately, covid-19 vaccines are now being offered to pregnant women. Mass distribution of these vaccines have had a significant impact on the ongoing global pandemic. However, more information, education, and guidance was needed regarding these covid-19 vaccinations during pregnancy.

Limited data was available on the safety of mRNA vaccines administered during pregnancy as no clinical trial had been done on this specific population (Horton et al., 2020). Lack of credible, consistent, and reliable information raised concern among pregnant women as they decide whether or not to receive the vaccination. This quality improvement project examined the current covid-19 vaccine recommendations and provided an informative toolkit to guide healthcare providers caring for their pregnant patients. Toolkits in the healthcare settings have proven to be beneficial and cost effective for both patients and healthcare professionals (Walker et al, 2018). Thus, a consistent, reliable, and up-to-date toolkit would facilitate an important conversation during a vulnerable time in a patient's life.

The Problem Identification/Available Knowledge

According to the CDC, only 1 in 4 pregnant women report having received the covid-19 vaccine, indicating a need for education and guidance regarding vaccination during pregnancy (Center for Disease Control and Prevention, 2021b). The main purpose of this quality improvement project was to create a toolkit that could be reviewed by healthcare providers who were looking to educate and facilitate conversation with pregnant patients regarding the covid-19 vaccine.

PICO Question

How do healthcare providers feel about implementing a covid-19 vaccine toolkit to educate their patients in comparison to current obstetric covid-19 vaccination education?

Problem Background

Vaccination in pregnancy provides two main benefits: maternal protection against infection, thus protecting the fetus from maternal disease, and secondary fetal protection through maternal-fetal antibody transfer (Goldfarb et al., 2021). The Moderna and Pfizer vaccines are inactivated mRNA vaccines, meaning they are not created from a live virus. Instead, mRNA vaccines stimulate the cells in the body to create protein - or a piece of protein - that triggers an immune response. Once injected, the immune system mounts a response to that protein, creating antibodies and protection from the virus without being infected (CDC, 2022b). The Johnson & Johnson vaccine functions similarly to Moderna and Pfizer, the main difference being a disabled adenovirus delivers instructions to mount the immune response rather than mRNA. Currently, two other vaccines; influenza and tetanus, diphtheria, and acellular pertussis (Tdap); are strongly recommended during pregnancy, as evidence suggests the benefits outweigh the risks (Kang et al., 2014). Currently, the documented benefits and risks of the covid-19 vaccine in pregnant women count more than the theoretical risks (Bosson et al., 2017. Major health benefits of

vaccination include: reduction of infectious disease morbidity and mortality, prevention of disease transmission, herd immunity, and reduction in secondary infections (Plotkin & Rodrigues, 2020). The risk of non-vaccination in pregnancy can result in contracting covid-19. As mentioned above, pregnant women are at an increased risk of pregnancy complications when infected with covid-19 (thromboembolic disease, preterm birth, preeclampsia, and cesarean delivery) (Aranu, et al.).

Problem Scope

Covid-19 vaccines are now being offered to all Minnesotans five years of age and older. Both Pfizer and Moderna have manufactured and distributed mRNA-based vaccines with 94.1 % and 95% efficacy against symptomatic covid-19 infections after two doses (Branswell, 2021. Johnson & Johnson has also manufactured a vaccine with 66.3% efficacy at preventing laboratory confirmed covid-19 infection after one dose (CDC, 2021a). Vaccinations can contribute significantly to the sustainability of healthcare systems through reduced and efficient healthcare spending as vaccines have the ability to reduce medical visits, treatments, and hospitalizations (Bresse et al, 2015).

Problem Consequences

Pregnant women are more susceptible to certain infections due to mechanical and physiological alterations that occur during pregnancy. The Center for Disease Control indicate individuals with covid-19 who are pregnant are at an increased risk of intensive care unit (ICU) admissions (10.5 vs. 3.9 per 1000 cases), mechanical ventilation (2.9 vs. 1.1 per 1000 cases), and death (1.5 vs. 1.2 per 1000 cases) when compared with infected non-pregnant women after adjusting for race, age, ethnicity, and comorbidities (Parchem, Sibai, & Stafford, 2021). Panagiotakopoulos et al. (2020) reiterated this information as they found that of 43 hospitalized

covid-19 pregnant patients, 30% were admitted to the intensive care unit and 14% needed mechanical ventilation. Further, pregnant women infected with covid-19 are at a higher risk of thromboembolic disease, preterm birth, hypertensive disorders, and cesarean delivery (Aranu, et al.). Thus, the CDC has indicated pregnancy as a risk factor for severe covid-19 infection, information that has been reiterated by the American College of Obstetricians and Gynecologists (ACOG), Society for Maternal-Fetal Medicine (SMFM), and other women's health organizations.

Knowledge Gaps

Pregnant women were excluded from covid-19 vaccine trials, like almost all clinical trials, due to historical restrictions and ethical concerns regarding potential harm to the fetus. This lack of clinical data causes hesitation for many pregnant individuals as they ponder whether or not to receive the vaccine. With evidence mounting that pregnant women are at greater risk for covid-19 complications, it is essential that health care providers are educating patients about the vaccine. Information regarding covid-19 vaccination is ever-changing as research and data becomes more readily available. Thus, a covid-19 vaccination toolkit will allow for providers to easily find the most up-to-date information on the safety of the vaccine and current recommendations.

Proposed Solution/Health Program

The proposed solution in response to lack of concise and clear covid-19 vaccination information is to create a toolkit for providers to use as they look to educate patients on the most up-to-date recommendations regarding covid-19 vaccinations during pregnancy. The goal of this toolkit was to facilitate both patient-provider and provider-provider communication. As previously mentioned, the covid-19 vaccine was relatively new and limited information was

available regarding the safety of the covid-19 vaccination during pregnancy. On October 23rd 2021, the CDC released the first covid-19 toolkit for pregnant, recently pregnant, and new parents. However, this toolkit can be overwhelming as it provides an abundance of information and resources for the obstetric population and their families. The quality improvement project developed a toolkit that focused specifically on covid-19 vaccination during pregnancy and serve as a "one stop shop" for healthcare providers looking for up to date recommendations. This toolkit will mirror other toolkits that have been established for pregnancy related concerns including the Zika virus and stillbirth.

Project Setting, Sponsor, Stakeholders, and Participants

Project Setting

At the time of implementation, a specific agency site was not established. Rather, this quality improvement (QI) project focused on obstetric healthcare providers in the Central Minnesota area. Those providers who agreed to participate in this quality improvement project reviewed the toolkit. The goal for the toolkit was to eventually provide it to patients in the surrounding obstetric clinics. However, for this QI project, the obstetricians, nurse midwives, and family practice providers reviewed the tool kit and provided necessary feedback rather than implementing it directly to their patients in a clinic setting.

Population

The information included in the toolkit was geared towards women who were currently pregnant, women who planned to become pregnant, and their families. Health care providers who reviewed the toolkit included obstetricians, nurse midwives, and family practice providers as they were the main point-of-contact for obstetric patients.

Inclusion and Exclusion Criteria

Providers that care for pregnant patients and individuals of child-bearing age were included in this project. The toolkit provided specific information and recommendations for patients currently pregnant or planning to become pregnant. The toolkit was not intended to be used for patients currently hospitalized or postpartum. The information provided in the toolkit was not intended for the general population as the goal was to educate a specific population.

Interprofessional Team

Collaboration between interprofessional team members was essential to ensure successful implementation of this quality-improvement project. Key members of the team included the Doctor of Nursing Practice students who were the project leads, health care providers who specialize in obstetrics, and obstetric clinic Registered Nurses (RNs). The members of this team worked together to make adjustments to the toolkit as needed while maintaining the patient's best interest. It was the responsibility of all team members to educate themselves on current covid-19 vaccine recommendations, know how and where to access the toolkit, and be able to assist patients when further information was requested. The interprofessional team was able to discuss the toolkit with patients, provide handouts, coordinate vaccine administration to those who wish to receive it, and request updates and changes to the toolkit as new information became available.

Stakeholders

Stakeholders for this project included health care organizations, medical doctors (MD), certified nurse midwives (CNM), certified nurse practitioners (CNP), physician assistants (PA), patients, family members, insurance companies, pharmacies, and pharmaceutical companies. Physicians, other providers, and nurses worked together to positively advocate this QI project to ensure patients were receiving accurate and up-to-date information regarding vaccination during

pregnancy. Organizational leaders and health care providers were vital stakeholders as they have the capability to support the project needs and allow implementation of the toolkit at their facilities. Insurance companies were also key stakeholders as vaccinated patients were less likely to become hospitalized. Pharmacies and pharmaceutical companies were also crucial stakeholders as they provided and stored covid-19 vaccinations. The MDs, CNMs, CNPs, and PAs could use the toolkit information to facilitate conversation, educate patients, and address common questions and concerns in regard to the vaccine. The patient and their family members were the recipients of this toolkit, helping guide their decision on whether or not to receive the covid-19 vaccine. It was essential that all stakeholders fundamentally agreed and supported the project's requirement to ensure successful implementation.

Organizational Needs Assessment

There was not a specific site established for this project. However, most health care providers who reviewed this toolkit were employed through a hospital in Central Minnesota. This healthcare system focused on implementing therapeutic approaches that encompass the whole person to achieve optimal health and well-being for all individuals. They focus on developing a comprehensive and preventative treatment plan for all patients, grounded in innovation and factual information (Nurse Manager, Personal Communication, 2021). Thus, it was imperative as a health system to provide obstetric patients with trusted and accurate information regarding the safety of the covid-19 vaccine during pregnancy. However, limited information was readily available for patients seeking support on this important decision. The organization provided a brief paragraph on their website which discusses the administration of the covid-19 vaccine during pregnancy. In summary, limited information and guidance is given as the clinical trials conducted by Pfizer, Moderna, and Johnson & Johnson exclude pregnant

individuals. However, the Society for Maternal-Fetal Medicine (MFM), American College of Obstetricians and Gynecologists (ACOG), and the CFC's Advisory Committee on Immunization Practices (ACIP) currently recommend that pregnant and lactating women be offered the vaccine.

Strength, Weaknesses, Opportunities, and Threats Analysis

This organization had many strengths that proved beneficial during the project implementation. First, this was a teaching organization, making it more accessible when finding providers willing to teach and provide feedback. In addition, this organization served a large number of patients in the metropolitan area. The size could be beneficial in the future as more patients would have access to the toolkit if it were implemented into the organization's setting. In opposition, the size of the organization could be a weakness as providers may be rushed to see numerous patients, limiting their time to review the toolkit. One opportunity of this project was the potential to increase the number of toolkits created and utilized in the organization's setting. Lastly, one threat of this project was the skeptisms around covid-19 vaccine and the resistance of patients and providers to review the toolkit.

Literature Search Process

Scholar was the primary database used to identify articles related to the covid-19 vaccine during pregnancy and benefits of using toolkits in a healthcare setting. Key terms that were utilized in the search bar include "covid-19 vaccine", "pregnancy", "safety", and "toolkits". During each step of the search, relevant and reliable articles were gathered to support the clinical project. The search was limited to articles published within the last 10 years and in the English language. Articles published more than 10 years ago were excluded.

Literature Matrix Table

A review of literature was conducted to locate the most up-to-date information and recommendations in regard to vaccinating pregnant women against covid-19. In addition, benefits of previous toolkits were reviewed and summarized in the literature matrix table (See Appendix A).

Literature Synthesis

Covid-19 was a relatively new virus and the information available to healthcare providers is continually changing. At the time, toolkits available for healthcare providers intending to educate their patients about the covid-19 vaccine during pregnancy were limited. According to Bosson et al. (2017), "patient information leaflets" or educational toolkits were helpful resources for patients, specifically when the patient was susceptible to poor recollection or recall of what was discussed with the physician. Well-written educational pamphlets used at an appropriate time could improve patient knowledge and understanding and induce better adherence to treatment and to lifestyle advice, specifically in the short term (Bosson et al., 2017). Thus, educational pamphlets should be considered as a clinical tool to improve patient's knowledge and satisfaction when contemplating their vaccination status.

Literature Related to Previous Toolkits

Toolkits have proven to be effective for other pregnancy-related health issues including stillbirth and the Zika virus. For example, a toolkit was created to help healthcare providers understand stillbirth and how to determine a patient's risk for having a stillbirth. This toolkit was emailed to healthcare providers caring for pregnant women. The email included a link to the toolkit and a pre-test for the provider to complete through "Survey Monkey". This pre-test gave the evaluator an understanding of the providers baseline knowledge (Ford et al., 2017). There was also a post-test which the provider was to complete after reading through the information

provided in the toolkit. There was a significant increase in the level of knowledge reported between the pre-test and the post-test. It was noted that this toolkit needed to be refined to include home instructions for patients who are at an increased risk of stillbirth (Ford et al., 2017). Overall, this toolkit increased provider's knowledge of stillbirth and many reported that they would continue to implement this toolkit in their practice (Ford et al., 2017).

The Office of Population Affairs (OPA) also developed a toolkit for pregnant patients seeking information and resources related to the Zika virus. This toolkit was established to help healthcare providers communicate the concerns of the Zika virus with pregnant and non-pregnant patients. This virus is known to cause harm to the fetus so having open communication about the Zika virus with patients of reproductive age is important. Information within this toolkit is updated on a regular basis as new information becomes available (Dehlendorf et al., 2017. This toolkit is available to all healthcare providers on their website. In addition, other toolkits have been developed to help guide healthcare providers with conditions unrelated to pregnancy. Overall, these toolkits have been found to be helpful in guiding healthcare professionals when caring for patients across the lifespan. One toolkit was developed to improve the primary care for autistic adults. This toolkit included worksheets, checklists, and resources for both patients and primary healthcare providers (Nicolaidis et al., 2016). This toolkit allowed patients to create a personalized accommodation report which they could give to their primary healthcare providers and helped establish each patient's needs. Many of the healthcare providers who gave feedback on this toolkit found it to be moderately or very useful and stated that they would recommend it to other healthcare providers and patients (Nicolaidis et al., 2016).

Literature Related to the Measures and Outcomes of the Project

In the United States, six million pregnancies occur annually, making vaccination during pregnancy a critical part of an effective public health response. The current covid-19 pandemic gave healthcare providers an opportunity to educate their patients regarding vaccination during pregnancy. The goal of this clinical project was to give healthcare providers an educational toolkit to educate patients to ease their vaccine decision. Vaccinations play a significant role in controlling and maintaining the spread of covid-19. Thus, effective communication was imperative to address concerns and provide factual information to build public confidence regarding the decision of whether or not to vaccinate. Successful vaccination endeavors promise an alternative future: a return to a sense of normalcy, innovation in vaccine research specifically in pregnant populations, and the investment of United States society as a whole in viewing vaccines as a public health benefit (Borio et al., 2020). Further, this clinical project highlights the need for more randomized controlled trials that include pregnant women as the FDA now encourages developers of covid-19 vaccines to consider pregnant subjects in their clinical trials (Bornstein et al., 2021).

Theoretical Framework and Change Theory

Theoretical Framework

To better understand why pregnant women were hesitant and skeptical to receive the covid-19 vaccine, it was useful to look at the Uncertainty in Illness Theory, developed by Merle Mishel, PhD, RN, FAAN. Although Mishel based most of her research on individuals coping with cancer; this research can be applied to people confronting their uncertainty of receiving the covid-19 vaccine. Mishel's Uncertainty in Illness Theory provides a conceptual framework to explain how patients and caregivers address uncertainty related to disease diagnosis, outcomes, and treatments. Key components of this theory include: antecedents generating uncertainty

(stimuli frame, cognitive capacity, structure providers), appraisal of uncertainty, coping with uncertainty, and formation of new perspective related to illness (Zhang, 2017). According to Mishel (1988), a patient's understanding of illness related stimuli (symptom pattern, event familiarity, event congruency) is strongly influenced by their cognitive capacity. A stronger cognitive capacity facilitated a better understanding of the stimuli, reducing his or her uncertainty. Further, this theory suggested that providers also influence how individuals interpret and respond to illness related stimuli. Patients would better understand their experiences when appropriate education, social support, and support from healthcare providers was provided; resulting in reduced uncertainty. Another main concept of this theory was appraisal of uncertainty; placing value on the uncertainty of a situation. Patients either view a stressor as a "danger" or "opportunity" and evaluate the availability of coping resources to respond to this stressor (Zhang, 2017). Mishel suggests that patient's use different coping strategies based upon their appraisal of uncertainty. Lastly, adaptation to illness and formation of new perspectives is a major component of this theory. Adaption is achieved when patients find a balance between adjusting to the new illness related experience that generated uncertainty (Mishel, 1988).

Theoretical Framework/Clinical Fit

After examining Mishel's Theory, it is clear that pregnant women may feel an increased amount of uncertainty related to the unknown effects of the covid-19 vaccine. In order to address this uncertainty, health care professionals must provide up-to-date information regarding the covid-19 vaccine and provide patients with the resources to improve vaccination knowledge. Further, strategies to promote patient-provider communication must be utilized to reduce uncertainty and increase patient's cognitive capacity through education and support. A toolkit can help facilitate a conversation regarding the benefits, risks, and effects of the covid-19

vaccine. In order to target appraisal, health care professionals can encourage reframing of uncertainty in a positive light. Healthcare professionals can provide information that may help patients view the vaccine as an “opportunity” rather than a “threat”. Educating patients on the importance of mass distribution of vaccines may help prevent the spread of covid-19 and may ease their decision of whether or not to get vaccinated.

Change Theory

This project followed the Plan-Do-Study-Act cycle. The PDSA cycle is one that is often used in healthcare as it allows changes to be made in small increments and can be repeated several times in order to achieve the intended outcome. Plan includes deciding how, when, and where the project will be implemented. Do is the act of implementing the project and allowing it to run its course. Study includes taking the data that was collected and identifying what changes could be made and if they would be beneficial. Act is making the necessary changes in hopes of improving project outcomes (Christoff, 2018). The PDSA cycle fits this quality improvement project as it allowed changes to be made after reviewing results. This cycle will allow for additonal changes to be made as new information about the covid-19 vaccination in pregnancy becomes available.

Aim, Project Goal, and Objectives

The overall goal of this project was to develop a covid-19 vaccine during pregnancy toolkit for obstetric healthcare providers to review and provide feedback. The obstetricians, nurse midwives, and family practice providers reviewed the covid-19 toolkit sent via Microsoft Word documents. Feedback and advice about the tool kit was obtained anonymously via Survey Monkey. The Survey Monkey link was provided via email. (See appendix C for an example of the tentative survey that will be provided).

The main aim of this toolkit was to educate patients, facilitate conversation, and provide resources about the covid-19 vaccine during pregnancy. This toolkit gave patients the information they needed to make an important and educated healthcare decision during their pregnancy. The overall goal of this project, like many quality-improvement projects, was to improve patient outcomes. Located in Appendix B Table 1 is the logic model that this project will follow.

Objective 1

Create a toolkit with evidence-based information, which can be utilized by healthcare providers in obstetric clinics to increase communication, about the covid-19 vaccination by week four of the project timeline.

Implementation

The toolkit contained the most up-to-date information available regarding the covid-19 vaccination and the safety of the vaccine during pregnancy. In order to fulfill objective one, information was collected about each of the covid-19 vaccinations (Johnson & Johnson's Janssen Moderna, and Pfizer-BioNTech). This toolkit included current covid-19 vaccine recommendations, information to help patients understand how to limit their exposure, and contact information in case further questions arise.

Outcome Measure and Evaluation

This step was completed by week four of the project timeline to ensure the intended outcome was met. The toolkit was ready to be sent to healthcare providers and content experts by week four.

Objective 2

Disperse the covid vaccination toolkit to 10 obstetric healthcare providers in Central Minnesota for review by week five.

Implementation

After the covid-19 vaccination toolkit was developed it was dispersed to healthcare providers and content experts for review. The toolkit was in word document format and was sent via email.

Outcome Measure and Evaluation

The evaluation was met or not met depending on the disbursement of the covid-19 vaccination toolkit by week five.

Objective 3

The surveys were created and scheduled to be seen on week seven through “Survey Monkey" to those providers who agreed to review the toolkit by week nine.

Implementation

Surveys were sent via email to healthcare providers using “Survey Monkey”. The survey was anonymous and allowed room for feedback and recommendations. This survey was used to collect qualitative data without taking up too much of the provider’s time. Questions included in the survey were intended to look at the whole toolkit and not necessarily pinpoint specific pieces in the toolkit. The goal was to have limited questions that provided enough feedback for the team to make appropriate changes to the toolkit.

Outcome Measure and Evaluation

The success of this objective was measured by the percentage of providers who completed the survey after reviewing the toolkit.

Objective 4

By week 12, changes to the toolkit based on the feedback received from healthcare providers were completed.

Implementation

After receiving all anonymous survey results, modifications were made to the covid-19 toolkit. Questionnaires were not linked to individual providers and feedback looked at aggregate rather than individual responses. The updated toolkit will be available for review upon provider request. This toolkit will be stored in a locked computer file for up to six months from the project completion date.

Outcome Measure and Evaluation

The covid-19 toolkit was updated based on provider feedback and recommendations.

Work Plan

This QI project required direct assistance from project leads, the project chair, and obstetric health care providers. The project leads were the driving force behind the project, making sure goals, objectives, and outcomes were met. Obstetrics health care providers offered their expertise by providing feedback and critique of the toolkit. Collaboration between all members of the team was essential for a successful QI project.

The critical events and milestones of this QI project are displayed in the gantt chart (see Appendix B, Table 2). These events included creating the toolkit, sending the toolkit to healthcare providers for review, allowing time for review, sending a survey for healthcare providers to review, and making revisions based on feedback. The project was allotted to take 12 weeks from start to finish. This quality improvement project was not funded and did not have a budget.

Communication Matrix

Due to the covid-19 pandemic and the distance between project team members and the project chair, communication occurred through the use of Zoom, conference calls, and emails. Dispersing of the toolkit and surveys to healthcare providers and content experts was completed through email. It was expected that response emails between team members would be completed within 24-48 hours from the time of the initial email. Documents, tables, and templates were completed using Google docs and Google sheets. This was done to ensure that all team members had equal access to these components of the project. A visual communication matrix is available in Appendix B Table 3.

Methodology and Influencing Factors

Pre-implementation: Protection of Human Subjects

Pre-implementation of this project included the creation of the covid-19 vaccination toolkit that was reviewed by obstetric providers. The toolkit was created based upon information currently available about the safety of the covid-19 vaccination during pregnancy. This toolkit was used for educational and informational purposes only, and was not intended to sway a patient's decision on whether or not to receive the vaccination. For the purpose of this project, the toolkit was reviewed by current healthcare providers and was used with patients. Human subjects were not used in this project as this toolkit was only reviewed at this time. However, the safety of human subjects was taken into consideration in the event that this toolkit be implemented for use in future clinic practice.

Implementation

The implementation phase of this project included dispersing the covid-19 vaccination toolkit to five obstetric healthcare providers. The toolkit was provided through Microsoft Word documents sent via email. Providers also received an anonymous survey to complete via Survey

Monkey. A period of 3 weeks was given to these providers to respond to the survey. See Appendix C for survey questions.

Post-Implementation/Monitoring

The post-implementation phase of this project included reviewing the survey results and making necessary changes. Common themes from the survey were taken into consideration when revising the toolkit. The anonymous survey results will be kept in a locked computer file and destroyed upon completion of the project. The final toolkit may be emailed to healthcare providers upon request, but was not automatically dispersed after revisions were made. This covid-19 vaccination toolkit is stored on a locked computer. In the event that a healthcare provider, content expert, or healthcare organization would like to review this toolkit for potential implementation in practice they can contact the project lead.

Ethical Considerations

The risks of this quality improvement project were minimal. In order to adjust for risks related to social discomfort the survey was anonymous to avoid judgment or bias. To protect participants' privacy, questionnaires were not linked to individual providers and feedback looked at group responses rather than individuals. Further, the tool kit and survey was easily accessible to minimize the risk of participant frustration related to time constraints and technical difficulties.

American Nurses Association code of ethics was followed during the creation and implementation of this project to ensure beneficence, justice, and non-maleficence (American Nurses Association, 2015). Vulnerable populations (pregnant population) were not directly impacted by this project as the toolkit was not implemented into an obstetric setting. This project is in compliance with the Health Insurance Portability and Accountability (HIPAA) as patient

information was not used during any stage of this project. The IRB application for this project was submitted through the college's IRB committee and accepted December 2021.

Implementation

The implementation of this project began shortly after the IRB application was accepted. The timeline of the implementation and evaluation of the project's goals and objectives closely followed the timeline noted in the Gantt chart, with slight modifications due to schedule changes. The first four weeks of the implementation process included developing the toolkit and updating information based on new data and research that aligned with major health organizations (AGOG, CDC, WHO). Once established, the toolkit was sent to five obstetric healthcare providers that work in Central Minnesota to review and offer recommendations. The Survey Monkey link was also sent with the toolkit – a slight change in the original Gantt chart. This change in timeline occurred in hopes to make it easier on participants that agreed to review the toolkit as all the information was sent in one email opposed to separate emails. This allowed participants to review the toolkit and provide feedback on their own schedule, further adjusting for time constraints. The Microsoft Word document of the toolkit and the Survey Monkey link were sent via email to healthcare providers by week nine. Of all five participants, 100% agreed to review the toolkit and provide feedback, meeting the goal of 75% participation. Lastly, changes to the toolkit were made based on feedback and recommendations given by obstetric healthcare providers.

Results from Data Collection

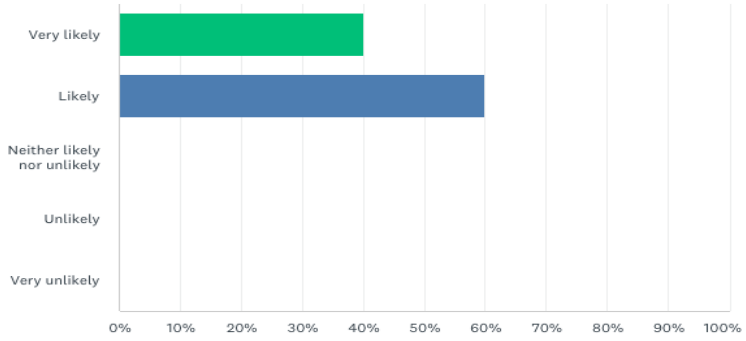
Data was collected and represented using Survey Monkey. Five questions were included in the survey: 3 multiple choice questions and 2 short answers. All five participants completed questions 1-3 while three participants completed the last two questions. All answers were

recorded and no data was missing from the results. Descriptive statistics were used to summarize and analyze the data. Data analysis and interpretation of results were listed below. The questions and answers of each survey question were represented and illustrated below.

Participant Survey Question One

How likely is it that you will continue to use this toolkit in your current practice?

Answered: 5 Skipped: 0

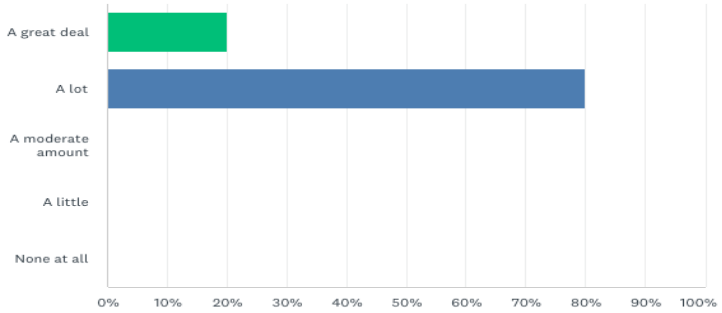


ANSWER CHOICES	RESPONSES	
Very likely	40.00%	2
Likely	60.00%	3
Neither likely nor unlikely	0.00%	0
Unlikely	0.00%	0
Very unlikely	0.00%	0
TOTAL		5

Participant Survey Question Two

How beneficial would you say the content within this toolkit is in your current practice?

Answered: 5 Skipped: 0

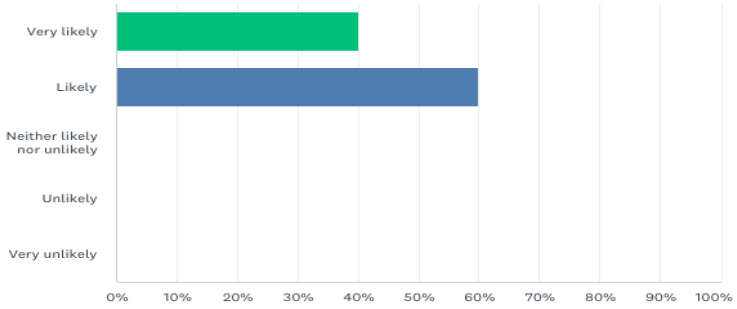


ANSWER CHOICES	RESPONSES	
A great deal	20.00%	1
A lot	80.00%	4
A moderate amount	0.00%	0
A little	0.00%	0
None at all	0.00%	0
TOTAL		5

Participant Survey Question Three

How likely is it that you would recommend this toolkit to other health care providers in the same specialty?

Answered: 5 Skipped: 0



ANSWER CHOICES	RESPONSES	
Very likely	40.00%	2
Likely	60.00%	3
Neither likely nor unlikely	0.00%	0
Unlikely	0.00%	0
Very unlikely	0.00%	0
TOTAL		5

Discussion of Data/Outcomes Interpretation

Descriptive statistical analysis was used to bring meaning to the data as it describes the likelihood of usage and recommendation of the toolkit in future practice. The results are as follows: When asked 'How likely is it that you will use this toolkit in your current practice?' two providers answered 'very likely' (40%) while three providers answered 'likely' (60%). The second question measured 'how beneficial would you say the content within this toolkit is in your current practice?'. One provider answered 'a great deal' (20%) while four providers answered 'a lot'(80%). Next question asked 'How likely is it that you would recommend this toolkit to other health care providers in the same specialty'? Two providers were 'very likely' (40%) to recommend the toolkit to fellow colleagues while three providers were 'likely' (60%). The following two open ended questions results are as follows: When asked 'What other content related to the covid-19 vaccination would you like to see included in this toolkit?' one provider felt 'information about vaccination around **active** covid-19 is missing;' while another provider felt the toolkit should 'include what patients should do if they get covid-19 between their first and second dose.' Finally, the last question asked 'Do you have any other recommended changes that you wish to see in this toolkit?'. One provider recommended 'combining all the documents into one' while another provider offered the suggestion to 'condense the toolkit into a pamphlet so it is more appealing to patients'. Intellectus was utilized to analyze the results below.

Summary Statistics Table for Interval and Ratio Survey Question One

How likely is it that you will use this toolkit in your current practice?	*M*	*SD*	*n*	SE_M	Min	Max	Skewness	Kurtosis
Very_likely	2.00	-	2	-	2.00	2.00	-	-
Likely	3.00	-	3	-	3.00	3.00	-	-
Neither_likely_nor_unlikely	0.00	-	0	-	0.00	0.00	-	-
Unlikely	0.00	-	0	-	0.00	0.00	-	-

Very_unlikely	0.00	-	0	-	0.00	0.00	-	-

Note. '-' indicates the statistic is undefined due to constant data or an insufficient sample size.

Summary Statistics Table for Interval and Ratio Survey Question Two

How beneficial would you say the content within this toolkit is in your current practice?	*M*	*SD*	*N*	SE_M	Min	Max	Skewness	Kurtosis
A_great_deal	1.00	-	1	-	1.00	1.00	-	-
A_lot	4.00	-	4	-	4.00	4.00	-	-
A_moderate_amount	0.00	-	0	-	0.00	0.00	-	-
A_little	0.00	-	0	-	0.00	0.00	-	-
None_at_all	0.00	-	0	-	0.00	0.00	-	-

Note. '-' indicates the statistic is undefined due to constant data or an insufficient sample size.

Summary Statistics Table for Interval and Ratio Survey Question Three

How likely is it that you would recommend this toolkit to other health care providers in the same speciality?	*M*	*SD*	*n*	SE_M	Min	Max	Skewness	Kurtosis
Very_likely	2.00	-	2	-	2.00	2.00	-	-
Likely	3.00	-	3	-	3.00	3.00	-	-
Neither_likely_nor_unlikely	0.00	-	0	-	0.00	0.00	-	-
Unlikely	0.00	-	0	-	0.00	0.00	-	-
Very_unlikely	0.00	-	0	-	0.00	0.00	-	-

Note. '-' indicates the statistic is undefined due to constant data or an insufficient sample size.

The interpretation of the outcome results supports the previous findings that a covid-19 toolkit for pregnant patients could prove beneficial in a healthcare setting and improve patient outcomes. However, one limitation of this project was the small sample size (N=5) as this reduces the reliability of the survey results. Further, covid-19 vaccination was a prevalent and considerably controversial topic during the project implementation, making it difficult to adjust

for research bias. Future research should focus on conducting randomized controlled trials with the goal of measuring patient education post toolkit implementation vs. standard education. This would strengthen the consensus that a covid-19 toolkit is useful in an obstetric healthcare setting.

Dissemination

The goal of this project in the future would be to implement a covid-19 toolkit into practice across obstetric clinics in Central Minnesota. Reaching this goal would involve gaining approval from stakeholders, including system Medical Directors. In addition, this project would need to align with vaccine education that is already being implemented in these settings. Research on covid-19 vaccines during pregnancy would be reviewed and the toolkit would remain up to date in hopes this toolkit can serve patients and providers in the future.

Conclusion

It is important that all pregnant women are prioritized in the public health response against covid-19 to ensure fair and equal access to effective and safe vaccination - especially with recent data suggesting that covid-19 is more severe during pregnancy. Thus, health care providers play a crucial role in educating pregnant women about the covid-19 vaccine. Using a toolkit can facilitate an important conversation about vaccination and can help patients make informed decisions. Toolkits are easy to access, easy to follow, require minimal training, and are cost-effective. It is important that a toolkit be created to help guide patients and their healthcare providers in making important decisions regarding the covid-19 vaccination during their pregnancy. Toolkits related to pregnancy have proven to be beneficial in the past, and have the potential to be beneficial during the current covid-19 pandemic.

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Appendix A

Reference	Purpose/Question	Design	Sample	Intervention	Results	Notes
Aranu, S., De Mucio, B., Macias, D., & et al. (2020). Adverse events associated with the use of recommended vaccines during pregnancy: an overview of systematic review. *Vaccines*. doi: https://doi.org/10.1016/j.vaccine.2020.07.048	Examines the maternal-fetal outcome associated with vaccines during pregnancy	Systematic Review	Seventeen systematic reviews were identified.	The systematic review examined abortion, stillbirth, chorioamnionitis, congenital anomalies, microcephaly, neonatal death, neonatal infection, preterm birth, low birth weigh, maternal death, and small for gestational age.	Stillbirth and preterm birth were the most frequently reported outcomes, followed by abortion, congenital anomalies, neonatal death, low birth weight, chorioamnionitis, and maternal death.	Limitations: Data are strongly based on observational data. More randomized control trials are needed with larger high quality observational studies.

Dehlendorf, C., Gavin, L., & Moskosky, S. (2017). Providing family planning care in the context of Zika: a toolkit for providers from the US office of population affairs. *Contraception, 95,* 1-4. https://dx.doi.org/10.1016/j.contraception.2016.08.013	The purpose is to understand how a toolkit can be beneficial for both patients and health care providers. This toolkit was specifically for guiding patients with pregnancy and family planning during the Zika virus.	n/a	n/a	Establishing a toolkit to guide health care providers with family planning in the context of the Zika virus.	This toolkit consisted of information about Zika virus, counseling considerations, job aids for providers to use when counseling patients, handouts, community outreach materials, and research and clinical guidance	Implementation/Intervention
Dolce, M.C., Parker, J.L., & Werrlein, D.T. (2017). Innovations in oral health: A toolkit for interprofessional education. *Journal of Interprofessional Care, 31*(3), 413-416. https://dx.doi.org/10.1080/13561820.2016.1258394	The purpose of this toolkit was to help educate health professionals on oral health. The main concern was tooth decay.	Qualitative Study	Pilot-study was completed with students and faculty from 13 different professions.	Establishing a toolkit to help health care professionals in guiding patients with their dental health.	Feedback from students and faculty noted that the toolkit was well organized, easy to implement, and adaptable for different learning levels.	Implementation/Intervention

Ford, A.L., Cramer, M.E., & Struwe, L. (2018). Identification of populations at risk: Stillbirth toolkit for health care providers. *Applied Nursing Research, 39,* 249-251. https://doi.org/10.1016/j.apnr.2017.11.005	This toolkit was established to help providers identify those patients at an increased risk for stillbirth	Qualitative Study	Healthcare providers treating pregnant women.	Establishing a toolkit to help providers identify and educate those patients who are at an increased risk of stillbirth.	The toolkit increased the healthcare providers knowledge on stillbirth. 43.8% of the healthcare providers who used the toolkit found it to be helpful and another 34.8% said they would continue to utilize it with their patients.	Implementation/Intervention Measures/Outcomes

Gray, K.J., Bordt, E.A., Atyeo, C., Deriso, E., Akinwunmi, B., Young, N., Baez, A.M., Shook, L.L., Cvrk, D., James, K., De Guzman, R.M., Brigida, S., Diouf, K., Goldbarb, I., Bebell, L.M., Yonker, L.M., Fasano, A., Rabi, S.A., Elovitz, M.A., Alter, G., & Edlow, A.G. (n.d.). COVID-19 vaccine response in pregnant and lactating women: a cohort study. *American Journal of Obstetrics and Gynecology.*	The purpose of this study was to determine the safety of the covid-19 vaccine for pregnant and lactating women.	Cohort Study	131 enrolled participants, 84 pregnant, 31 lactating, and 16 non-pregnant of reproductive age.	Administering the covid-19 vaccine to pregnant, lactating, and non-pregnant women of reproductive age.	This study found that the vaccine does cross the placenta and transfers antibodies to the fetus. They collected cord blood. The cord with the lowest amount of IgG was matched to a mother who had delivered between her first and second doses of the vaccine. This tells us that 2 doses may provide the best protection to the neonate.	Measures and Outcomes of the Project

Guan W, Ni Z, Hu Y, et al. (2020). Clinical characteristics of coronavirus disease 2019 in China. The New England Journal of Medicine. doi: 10.1056/NEJMoa2002032	Examines clinical data of individuals infected with covid-19 in regards to intensive care unit admission, use of mechanical ventilation, or death.	Retrospective Review	7736 patients were admitted at 552 sites during the study period. Data was obtained on 1099 of these patients.	Electronic health records were used to obtain clinical data including signs and symptoms, exposure risk, laboratory findings, and radiologic findings. Based on the American Thoracic Society guidelines for community acquired pneumonia patients were grouped into severe or nonsevere categories. Admission to the intensive care unit (ICU), use of mechanical ventilation, or death were primary composite endpoints.	Of the 1099 patients, 67 patients (6.1%) experience ICU admission, mechanical ventilation or death, leading to a cumulative risk of 3.6%.	Limitations must be considered: This study included only a small "portion of the overall sample size of confirmed covid-19 patients".

Guoqiang, S., Qing, L., Yao, C., & Yizhi Z. (2020). Blood test results of pregnant covid-19 patients: An updated case-control study. Frontiers in Cellular & Infection Microbiology, 19. doi: 10.3389/fcimb.2020.560899	Examines blood and liver function of pregnant individuals with chronic conditions diagnosed with covid-19.	Case Control Study	Pregnant women with covid-19, pregnant women with covid 19 and diabetes, and pregnant women with covid-19 and hypertension were included. Data from clinical blood tests were gathered to determine effects of covid-19 on patients with chronic conditions.	The tests used to compare blood and liver functions between the groups include: Chi square tests, Wilcoxon signed-rank tests, and Kruskai Wallis.	Blood and liver function tests show that chronic complications could increase the risk inflammation and liver injury in pregnant women infected with covid-19.	

Horton J., Jamieson J., Kelley C., & Rasmussen S. (2020). Coronavirus disease 2019 (Covid-19) vaccines and pregnancy: what obstetricians need to know. *Obstetrics & Gynecology.* *doi:*10.1097/AOG.0000000000004290	Provides a summary of data that is available to guide obstetricians regarding benefits and risks of covid vaccination	Systematic Review	Information gathered from Obstetric and Gynecologic and Vaccination Journals		Obstetricians need to work with pregnant patients to weigh the benefits and risks of the covid vaccine, as data are limited.	Limitations: Randomized controlled studies are needed to strengthen the evidence

Kang G, Keller-Stanislawski B, Englund J. A., et al. (2014). Safety of immunization duringpregnancy: a review of the evidence of selected inactivated and live attenuated vaccines. *Vaccine, 32*(52), 7057–7064. doi: https://doi.org/10.1016/j.vaccine.2014.09.052	Examines available evidence on vaccination safety in pregnant women from published literature and surveillance programs.	Literature Review	989 articles were identified Randomized controlled trials, case, series, and signal detection reports were considered.	Data was reviewed for vaccines against diseases, which increase the risk of morbidity and mortality of pregnant women. These vaccines include: "inactivated seasonal and pandemic influenza, mono- and combined meningococcal polysaccharide and conjugated vaccines, tetanus toxoid and acellular pertussis combination vaccines, rubella, oral poliomyelitis virus and yellow fever".	There is no evidence of adverse outcomes in pregnancy for the inactivated vaccines reviewed. Live vaccines may pose a risk as they can pass the placental barrier to the fetus.	Randomized controlled studies are needed to strengthen the evidence.

Nicolaidis, C., Raymaker, D., McDonald, K., Kapp, S., Weiner, M., Ashkenazy, E., Gerrity, M., Kripke, C., Platt, L., & Baggs, A. (2016). The development and evaluation of an online healthcare toolkit for autistic adults and their primary care providers. *Journal of General Internal Medicine,* 1180-1189. doi:10.1007/s11606-016-3763-6	A toolkit was developed to help facilitate the care of autistic patients.	Qualitative Study	259 autistic adults and 51 primary care providers.	This toolkit was established to help primary care providers guide the care of autistic adults.	Feedback showed that this toolkit was a reliable healthcare accommodation tool and was accessible.	

Walker, L.O., Sterling, B.S., Becker, H., Hendrickson, S., & Xie, B. (2018). Development and evaluation of a mother-centered toolkit for postpartum behavioral and psychosocial health. *Journal of Behavioral Medicine 41,* 591-599. https://doi.org/10.1007/s10865-018-9928-5	This toolkit was established to help mothers during the postpartum period with their behavior and psychosocial health.	Qualitative Study	Participants were between the ages of 18-44. They were all mothers of infants or children under the age of 3. There were a total of 24 participants.	This toolkit was created to help mothers and healthcare providers with behavioral and psychosocial health during the postpartum period.	Both patients and healthcare providers liked the implementation of this toolkit. They found that it was easy to use, required little training, and was cost effective.	Implementation/Intervention Measures/Outcomes

Appendix B

Table 1
Logic Model

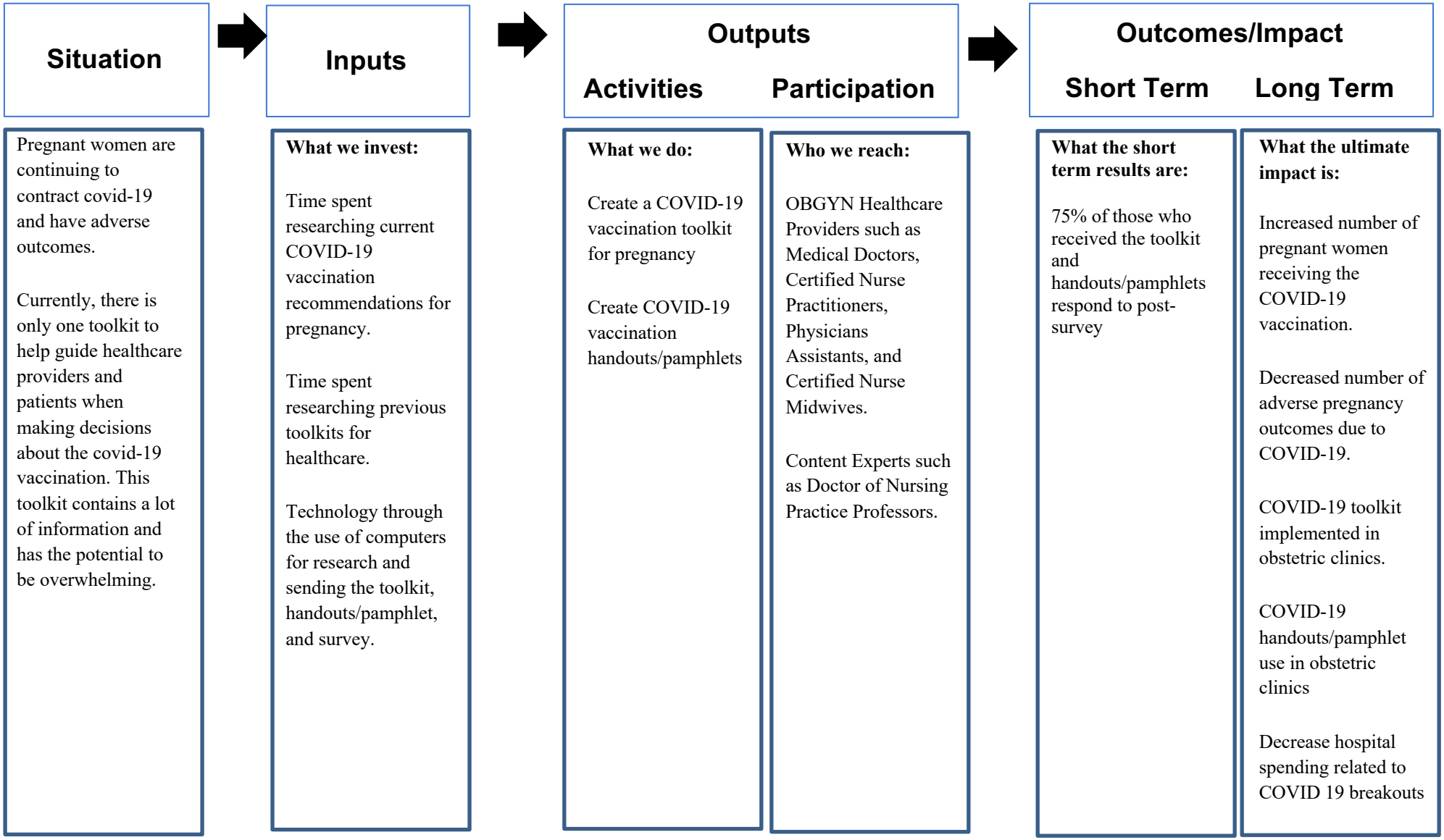

Table 2
Ghantt Chart

Objective	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Establish toolkit making sure all information is up to date.												
Send toolkit to healthcare providers and content experts for review												
Allow healthcare providers and content experts time to review the toolkit.												
Send survey to healthcare providers and content experts who agreed to review the toolkit. Hope to have 75% respond by week 9.												
Make changes to the toolkit based on survey results.												

Table 3
Communication Matrix

Communication	Purpose	Medium	Frequency	Audience
Initial Meeting	Discuss project and plan	Zoom or Conference Call	Once	Project Team and Project Chair
Project Team Meetings	Go over updates to the project and project status. Discuss and resolve any new issues.	Email, Zoom or Conference Call	Monthly	Project Team
Check-in with Project Chair	Discuss current status of the project. Ask questions if any arise.	Zoom or Conference Call	Bi-Monthly	Project Team and Project Chair

Appendix C

COVID-19 Vaccination Guidelines for Pregnancy

Post Survey for Health Care Providers and Content Experts

1. How likely is it that you will continue to use this toolkit in your current practice?

NOT AT ALL LIKELY EXTREMELY LIKELY

1 2 3 4 5 6 7 8 9 10

2. How beneficial would you say the content within this toolkit is in your current practice?

NOT BENEFICIAL EXTREMELY BENEFICIAL

1 2 3 4 5 6 7 8 9 10

3. How likely is it that you would recommend this toolkit to other health care providers in the same specialty?

NOT AT ALL LIKELY VERY LIKELY

1 2 3 4 5 6 7 8 9 10

4. What other content related to the COVID-19 vaccination would you like to see included in this toolkit?

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5. Do you have any other recommended changes that you wish to see in this toolkit?
