



Honors College

Honors Thesis

An Honors Thesis Titled

Maternal Medication Use while Pregnant and/or Breastfeeding

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Nursing

by

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Print

Maternal medication use while pregnant and/or breastfeeding

Introduction

During pregnancy and while breastfeeding, many women are required to take medications for pre-existing conditions such as high blood pressure, diabetes, or mental illnesses. However, some of these medications are considered unsafe for fetuses or infants and these medications are collectively called category X medications. Category X medications are those that have demonstrated causing fetal abnormalities or evidence of human risk based on adverse reactions; examples include blindness and Down syndrome. Other medications, including the cholesterol management drug atorvastatin and the blood thinner Warfarin, are classified as category X because there is not much information or research on their effects. Certain category X medications are necessary to maintain the optimal quality of life for the women taking them; in some cases, the discontinuation of these medications can have life-threatening effects on mothers. Many mothers choose to stop taking category X medications during pregnancy to avoid risk to their fetuses; often, these mothers choose to breastfeed and continue to not use these drugs because they can be passed through that breastmilk to the child. The discontinuation of these drugs can have life-threatening effects on mothers.

Drugs vary in their critical period of susceptibility, adverse effects, and teratogenic (defect-creating) effects. All of these factors play important roles in deciding whether or not a mother should continue or discontinue the drugs that she began taking prior to pregnancy. Pregnant and breastfeeding women, as well as women trying to conceive, need to be well informed and professionally advised about the risks of category X medications. However, existing research suggests that women often receive limited or conflicting advice from their

healthcare providers. By examining maternal medication use during pregnancy and while breastfeeding, I have found that women are being provided with differing information on medication use if they are being provided any information at all. This is important because the health and safety of both mother and baby is in jeopardy if medications are not utilized at their peak efficacy.

Looking at the growth and development of a fetus is an important step in analyzing the costs and benefits of using medication while pregnant and/or breastfeeding. Development of an embryo or fetus can be interrupted or delayed at any point during the pregnancy. Starting in weeks four and five of pregnancy, the brain, spinal cord, heart, and arm and leg buds begin to form (HHS, 2017). By week eight, all of the major organs and external body structures have been formed (HHS, 2017). This begins the point where damage from chemicals or drugs is more likely to cause functional damage rather than structural damage. Many women do not even discover that they are pregnant until they are upwards of eight weeks pregnant. This leaves almost two months of time for potential harm that women who did not plan their pregnancy or use assistive reproductive technologies do not know that they are pregnant and that their actions may potential harm the embryo that is growing inside of them.

Preconceptual counseling is an option for many women or couples who desire to have an increased knowledge about their bodies and potential barriers to a healthy pregnancy prior to actually conceiving a baby. According to the American College of Obstetricians and Gynecologists (2017), preconception counseling is used to “identify factors that could affect a pregnancy and take the steps that can increases the chances of having a healthy pregnancy and a healthy baby.” This may include going over the mother’s health history, family medical

histories, diet, and medications that she is taking (ACOG, 2017). While looking at the medications that a woman is taking, her provider may be able to share information about those medications with her and potentially switch her to medications that are safer during pregnancy if needed. By going through preconceptual counseling, women are able to prepare themselves physically and mentally prior to conception.

There are many different factors that play into the toxicity or teratogenicity of medications. Some of these include time of medication administration, dose, frequency of medication use, infant metabolism, and lipid solubility of the medication (Al-Sawalha, Tahineh, Sawalha, & Almomani, 2016). Davanzo et al. (2016) added that the infant's age and condition along with the "evidence of toxic effects in breastfed infants" should be considered (p. 16). On the use of medications during the breastfeeding period, Genung (2013) states that "low-dosed monotherapy [use of a single medication] is recommended whenever possible" (p. 214). The lowest dose of a single medication decreases the risk of side effects or drug-drug interactions happening within the mother's body or the milk that is being transferred to the infant.

There are countless drugs that a mother could be taking while pregnant or breastfeeding and some are much more toxic to a fetus or infant than others. For example, atorvastatin, a statin used for cholesterol management, is classified as category X because there is not much information on the effects of atorvastatin on fetuses during pregnancy; because of that lack of information, there is a potential for harm. Warfarin is another one of these drugs. It is classified as category X because it can cross the placental border and reach the fetus. Substitutions for another drug during the first trimester and during the prenatal period can improve fetal outcomes, but it increases morbidity and mortality for the mother.

(Schaefer et al., 2015). A mother taking warfarin would have to choose between continuing the regimen and decreasing the health of her baby; alternatively, she could discontinue the warfarin or switch medications, which would negatively affect her own health.

It is up to physicians to weigh the pros and cons of each individual drug for each individual patient before prescribing. It is also imperative that the mother's wishes surrounding medication use during pregnancy or breastfeeding are clearly expressed to the prescribing physician prior to any medication use. In making decisions about what drugs are appropriate to pregnant or breastfeeding mothers, doctors and patients in the United States rely on advice from the Food and Drug Administration, the governing body that "regulates medications to ensure their general safety and effectiveness" (Centers for Disease Control and Prevention, 2016). All medications are tested prior to their release to the public to check safety and efficacy (Centers for Disease Control and Prevention, 2016, para. 2). Most often, pregnant women are not included in these research studies and clinical trials because they are considered a vulnerable population. A vulnerable population is defined as "disadvantaged sub-segment of the community requiring utmost care, specific ancillary considerations and augmented protections in research" (Shivayogi, 2013, p. 53). Despite the need for special research considerations for pregnant women, there is still a minimal number of clinical trials on medications that involve pregnant women. This lack of research on medication use in pregnant women has created a massive gap in the available evidence-based data on the safety and effectiveness of medications, both prescription and over-the-counter, in pregnant women. Medications can also pass through breastmilk and get into the body of an infant that is being breastfed. Casey (2012) has described what the "ideal drug for breastfeeding mothers" is like (p. 24). Some of the characteristics of this drug are low oral bioavailability (amount of

medication that enters circulation), a milk-to-plasma ratio (movement of drugs into breastmilk) of less than 1, a short half-life, low pH, low toxicity, and high protein binding (Casey, 2012). These are all important characteristics of a medication that the Food and Drug Administration should be using to monitor the efficacy of a medication. The National Institutes of Health (NIH) has created a database called LactMed® that contains “information on drugs and other chemicals to which breastfeeding mothers may be exposed” (Centers for Disease Control and Prevention, 2017). Though these resources and many others are available to mothers, they may not be utilized to their peak efficiency, if at all. Mothers may not be made aware of these resources through their health care providers which leaves these women making pivotal decisions about their and their infant’s health and safety without adequate information.

Literature Review

There have been few studies analyzing the lived experiences of pregnant and breastfeeding mothers in the United States of America who have had to decide whether or not to continue taking certain medications that could potentially transfer to the fetus or infant. This is due in part to pregnant women being considered a vulnerable population. Vulnerable populations are not allowed to have research regarding medications be done on them unless extensive review is done and many protections are put in place to protect this population. The available literature regarding medication use tends to only focus on women during the breastfeeding period. To supplement the shortage of studies in the United States, we can turn to research from Norway, Jordan, and the United Kingdom for insights into women’s attitudes and knowledge regarding medication use.

There are many different types of medication that women may be recommended to use during pregnancy and/or while breastfeeding including prescription, over-the-counter, and herbal medications. A national study in Jordan looked at maternal use of over-the-counter (OTC) and prescribed medications as well as the avenues of gaining product information surrounding those medications. This cross-sectional study also used a questionnaire along with semi-structured interviews. Though this process, the researchers found that 17% of breastfeeding women reported taking OTC medications and that 7% of participants reported taking OTC and prescribed medications while breastfeeding (Al-Sawalha, Tahaineh, Sawalha, & Almomani, 2016, p. 388. These findings support the need for medication education as almost one-fourth of the women in this study were taking some kind of medication while breastfeeding. Along the same line, less than 40% of women reported that their physician or pharmacist informed them of the details regarding the medication that was prescribed (Al-Sawalha et al., 2016, p. 389). This is a major issue as missed or confused information can lead medication administration errors which could harm either the mother and or/the infant. Because the number of women taking medication(s) while pregnant and/or breastfeeding, it is necessary to conduct further research to find out when these women are making that decision.

Despite being prescribed medication from their providers, women are often unsure of pertinent information about those medications including side effects, dosages, and timing of administration. A cross-sectional study of the use of antimigraine medication and the informational need of Norwegian women found that the majority of women in their study wished for closer care from their physician and more “available and consistent information about medicines” (Amundsen, Øvrebø, Amble, Poole, & Nordeng, 2016, p. 1531). Though

this study, which used an online questionnaire format, looked solely at the use of antimigraine medications during breastfeeding, the lack of information easily accessible and the barriers to communication between patient and physician can be found regardless of the type of medication being used. This study calls for clearer guidelines regarding the various optimal treatment pathways during pregnancy and breastfeeding; something that would be beneficial for all mothers who have to make a decision to continue or discontinue a certain medication (Amundsen et al., 2016, p. 1532). This study further confirms the notion that women are concerned about the various safety issues surrounding prescribed medications for migraines, a chronic and often controllable medical condition. Further studies must be performed to discover the most desirable ways of communicating between patients and physicians based on the past experiences of pregnant and breastfeeding women.

The concerns that women have surrounding medication use manifest themselves in many different attitudes regarding medication use. Colaceci et al. (2016) did a mixed-methods study in Italy that discovered three main attitudes that women most often have regarding medication use while breastfeeding. One is to continue breastfeeding and not use the drug for treatment at all; another is to continue breastfeeding and switch to a natural product; the third category is to completely discontinue breastfeeding and continue using the drug (Colaceci et al., 2016, p. 329). Though these categories do capture the decisions of the majority of women, there are still other women that do not fall into these categories including ones that choose to continue breastfeed and decrease drug dosage or change drug type. When it comes to making this important decision, Colaceci et al. (2016) discovered that there are many different providers who play a role in providing critical information to patient including pediatricians, obstetricians, general practitioners, midwives, and herbalists (p. 329).

The opinions of those prescribers can vary greatly as many of them have different areas of specialty or patients for whom they are primarily responsible. Colaceci et al. (2016) suggest that the way to provide the best care to mothers and babies is to provide “accessible and validated data” while simultaneously “tailor[ing] to the single mother-baby case” (p. 331). This study does not provide any suggestions on how to individualize a plan of care for each mother-baby case. Also lacking are any suggestions on how to unify health care providers in their ways of treatment and/or how to ensure that the data available to practitioners is the same across all fields of practice and is evidence-based.

There are many different factors that play a role in how women make decisions regarding medication use while pregnant and breastfeeding. Casey (2012) suggested four main principles in the form of “if-then” statements to guide decisions regarding medication use and breastfeeding. According to Casey (2012), if the drug does not enter milk, then continue breastfeeding as normal (p. 22). If the dose received by the infant is low and the drug is unlikely to affect the baby, then the mother should continue breastfeeding while observing the infant for adverse effects (Casey, 2012, p. 22). If the dose received by the infant is “moderate and/or there may be an adverse effect on the infant,” then continue breastfeeding with closer observation for adverse effects (Casey, 2012, p. 22). Along with this suggestion is that if the medication is a single dose or short term, the considering an alternative way of feeding the infant for the duration of treatment and “expressing and discarding” breast milk (Casey, 2012, p. 22). Finally, if the dose received by the infant is high and/or the drug is of a high potential toxicity, then discontinue breastfeeding along with following the same recommendations about short term or single dose treatment (Casey, 2012, p. 22). These recommendations provide a standardized treatment plan for most women to

follow. Though each and every case should be looked at and decisions should be made on an individual basis, it is convenient to have a standardized template for women and physicians to use to decide what the best decision is for them. Also, this template does not take into account the mother's feelings regarding this very personal decision.

One factor that plays a role in whether or not women use medications during pregnancy and while breastfeeding is the safety of the medication. Grant and Golightly (2010) looked at the safe use of medications in mothers during solely the breastfeeding period in the United Kingdom. There has not been as much data compiled on medication use during the breastfeeding period as there has been on medication use during pregnancy. According to this study, the keys to a safe medication-breastfeeding relationship include reviewing the drug regimen before delivery and timing feedings around drug administration (Grant & Golightly, 2010, p. 72). This would require knowledge on drug peak and trough levels that is accurately taught to the breastfeeding mother as well. This study concludes by saying "breastfeeding rarely needs to be discouraged or discontinued (exceptions are cytotoxic agents and radiopharmaceuticals)," but does not thoroughly explain the best ways for clinicians to encourage the continuation of medications while breastfeeding (Grant & Golightly, 2010, p. 73). There is a need to further examine how patients have been educated by physicians in the past and the most effective ways for continuing that education to achieve the best outcomes for patients and their breastfed babies.

There are many avenues through which more knowledge could be shared with women regarding medication use. In an Italian policy statement, Davanzo et al. (2016) recommended a common knowledge base and shared methodology between health professionals other than pediatricians. These other health professionals include primary care physicians, midwives,

and pharmacists. By providing this unified foundation amongst health professionals that care for pre- and post-natal women, there is less room for confusion and contradictory information to be presented to patients. Davanzo et al. also give suggestions on ways to improve the information given to patients along with possible improvements to how that information is delivered. Davanzo et al. (2016) suggest that health professionals “do not simply refer to the patient information leaflets” to provide quality information to their patients (p.16). To avoid doing this, it is necessary for physicians to know the evidence that is available regarding the medications that are prescribing so that they can give a patient “definitive advice within 24 hours” (Davanzo, 2016, p. 16). This relatively short turnaround time for information provides prescribers with ample time to do the necessary research of the medication and its interactions, but also requires that the prescriber is clear and concise when they do finally give a recommendation based on that research.

One other recommendation given by Davanzo et al. (2016) is that health professionals should “follow a methodologically correct assessment” when asked to provide guidance and care for a patient who is contemplating the safety of a medication during pregnancy and breastfeeding (p. 18). Oftentimes, health professionals will cut corners on assessments or while taking health histories so that they can see patients as quickly as possible, but that also leads to potentially missed diagnoses and a less developed patient-physician relationship which can hinder proper medication education from taking place. This policy addresses some areas of much needed improvement in communication and care standards for patients and physicians. Additional information should be gathered to discover how realistically the standards proposed in this policy are being followed.

Purpose

The purpose of this study was to gather information on the lived experiences of women who used medications while pregnant and/or breastfeeding in order to better understand women's decision-making processes.

Ethical considerations

This research study C Confidentiality was ensured through anonymity of participants and their responses. Participants were informed that they did not have to complete any questions that made them uncomfortable and that they may stop the questionnaire at any time. Research findings will be gathered and disseminated once research is complete.

Methods

This study was conducted in Salisbury, Maryland in October of 2017. Research was conducted using a purposive (hand selected) sampling method. This involved hand-selecting participants based on inclusion criteria. Inclusion criteria included being female, a member of the faculty, staff, or student body at Salisbury University, have given birth to a live full-term baby within the past five years, and attempted to breastfeed their baby. Once a pool of potential participants was selected, nine participants were emailed and asked to answer an eight response questionnaire. The link to the questionnaire was provided within the email. The survey was hosted on Survey Monkey. Completion of any portion of the survey indicated consent and that was stated within the initial email provided.

Variables

The independent variable is knowledge about and attitudes towards medication use. The dependent variable is medication use. The timeframe of this study is during pregnancy and while breastfeeding.

Confidentiality statement

Participants' confidentiality was protected through anonymity on the questionnaire via Survey Monkey. The information was gathered without any identifying information. The length of time that the data will be kept is one year. The data will be deleted after completion/dissemination of the study through shredding of paper materials. Data was stored in a binder in a locked cabinet. Those who have access to the data include the primary investigator, co-investigator, and the three additional undergraduate thesis committee members.

Disclosure statement and consent form

The researcher has completed the appropriate research training models (NIH Office of Extramural Research- Protecting Human Research Participants). Subjects were notified of the purpose of the study and the expected involvement. Completion of the questionnaire will imply consent.

Risks and benefits

1. Some of the questions asked of participants may bring about a minimal level of anxiety within the participants. The participants will be instructed that they do not need to answer any questions that they are uncomfortable answering.
2. A potential benefit for this research includes the gathering and dissemination of information relating to women's health. This includes educating providers on the importance of using evidence-based practice and sharing information with women on the resources available to them regarding medication use while pregnant and breastfeeding.

Results

Advisement of medication use

Of the nine people surveyed, 100% of the participants were advised to take medications while pregnant and/or while breastfeeding. Fifty-six percent (5/9) of participants reported being advised to take prescription medications while sixty-seven (6/9) percent report being advised to take over-the-counter (OTC) medications. Twenty-two percent (2/9) of participants reported being recommended to take both OTC and prescription medications.

Information regarding medication use

Seventy-eight percent (7/9) of participants reported referring to their obstetricians for information regarding the safety and use of medications or natural products while pregnant and/or breastfeeding. Twenty-two percent (2/9) of women reported consulting their lactation consultant for medication information. Eleven percent (1/9) of participants stated that they consulted their nurses. Consultation with a midwife was done by eleven percent (1/9) of

participants as well. Eleven percent (1/9) of participants stated that they consulted with their midwife. A certified nurse practitioner was referred to by eleven percent (1/9) of participants. Another eleven percent (1/9) of participants reported using La Leche League as a source of information regarding medication use while breastfeeding.

Differing provider opinions

Eleven percent (1/9) of women reported getting differing opinions from their providers regarding medications during pregnancy and/or while breastfeeding.

Listening to provider opinions

Sixty-seven percent (6/9) of participants decided to heed the advice of their obstetrician. Eleven percent (1/9) based their decisions regarding medication use off of information provided by their certified nurse practitioner. Eleven percent (1/9) of women listened to the opinion of their midwife. Lactation consultants provided the information that twenty-two percent (2/9) of women listened to. Eleven percent (1/9) of participants reported consulting their pediatrician and taking their advice as well. Eleven percent (1/9) of women reporting consulting healthcare providers, but not taking any of their opinions into account while making decisions regarding medication management while pregnant or breastfeeding. Twenty-two percent (2/9) of participants reported “following [my] instincts” was part of how they came to their decisions about medication use during pregnancy and while breastfeeding.

Knowledge of medications

Twenty-two percent (2/9) of participants reported that they felt “very” knowledgeable about medication use while pregnant and/or breastfeeding. One participant reported feeling “somewhat” knowledgeable while another reported feeling “pretty informed.” One participant reported that she felt she had “adequate” knowledge of the medications she was recommended to take. Having little knowledge was reported by one participant. A participant reported that she felt “not very [informed], but [I] followed my own health beliefs.” Another participant reported feeling comfortable once I talked to the doctor.” One participant reported feeling of an “average” comfort level describing that was “not an expert, but comfortable enough.”

Consideration of the risk-benefit ratio

Seventy-eight percent (7/9) of women responded that they did consider the risk-benefit ratio when making a decision to use medications during pregnancy and while breastfeeding. Twenty-two percent (2/9) reported that they did not consider the risk-benefit ratio. One participant reports that they did not consider the risks and benefits of medication use because “there is always a risk to taking medication at any time.”

Decision-making process regarding medication use

The decision-making process surrounding deciding whether or not to use medications during pregnancy and/or breastfeeding varied greatly. One participant reported only taking medications that there was no known risk for fetal or infant harm. Another participant reported taking into account her child’s age, other foods they were eating, and feeding schedule before taking any medication. This participant also noted that she learned that

medications that have “talk to a doctor before using if breastfeeding” does not necessarily mean that the medication is unsafe. Taking the smallest dose possible and discontinuing medication use when the symptoms of illness were relieved was another aspect of this participant’s decision-making process.

A participant was prescribed Percocet after a Cesarean section. She listened to the advice of her doctor, nurse, and midwife, which was offered immediately post-operatively; due to these circumstances, the participant believed that her “ability to make the decision on her own was compromised.” After doing more research on her own about the nature of Percocet and its inability to cross into breastmilk, the participant made the decision to continue taking the medication for the allotted time.

Twenty-two percent (2/9) of participants reported doing independent research on the medications that they were advised to take. One participant reported checking medication bottles/boxes for expiration dates prior to taking as well. Thirty-three percent (3/9) of participants also stated that they consulted a healthcare professional and used the information that they provided to make a decision. Thirty-three percent of women (3/9) reported trying not to take any medication, “despite being given a list of “safe” medications” and being advised to take two medications by her healthcare provider.

Changes regarding medication use

Seventy-eight percent (7/9) of participants reported that they would not have changed anything regarding medication use while pregnant and/or breastfeeding. One participant reports desiring to be able to go through breastfeeding without any medications, including those for pain relief. Another woman reports that it would have been beneficial for

obstetricians to provide patients with a list of medications that are safe to take while pregnant and/or breastfeeding. This woman also stated that she only received contact information for the lactation consultant who works at the hospital in which she delivered, but having information for a lactation consultant to consult that was in her local area would have been beneficial.

Discussion

In this study, the decision-making processes of women who take medications while pregnant and/or breastfeeding was examined. Previous research has been focused primarily on the effects of medication use and the need for knowledge regarding medication use during pregnancy and while breastfeeding.

One hundred percent of the women in this study were recommended to take either prescription or over-the-counter medications during their pregnancy or while breastfeeding. These recommendations led to the majority of women using a variety of sources to find information upon which they could make an informed decision regarding medication use. Fifty percent (4/8) of participants reported using information from multiple sources including different providers and internet resources to make their decision. That being said, women who are advised to take medication during pregnancy or while breastfeeding should be provided with information from their practitioner(s) about that medication and how it may affect their baby. This would allow for women to have a basic level of knowledge regarding that medication before even leaving the doctor's office. If the medication is something that should be started as soon as possible, this information via pamphlet, handout, or verbal instructions could make a difference to increase earlier adherence to the medication.

Al-Sawalha et al. (2016) found that less than 40% of women reported that their physician or pharmacist informed them of the details regarding the medication that was prescribed (p. 389). In this study, 88% of women reported getting medication information from a physician and 0% of women reported talking to a pharmacist regarding their medication use. It is beneficial that a greater percentage of women stated that they got information from their healthcare providers. This allows for more open communication between patients and prescribers as well as facilitating better health outcomes due to increased necessary medication use. It is of note that not one mother reported talking to a pharmacist about their medication choices. This may be due to a lack of interactions with pharmacists, not picking up their own prescriptions, or recall bias due to the nature of the study.

Davanzo et al. (2016) pointed out the need for a common knowledge base of all providers so that the information provided to patients is both consistent and prompt. The information received by participants in this study from their providers was consistent across providers and other sources of information (i.e. the internet) in 88% of cases. Ideally, 100% of women would receive consistent information from all providers. To reach this goal, setting up professional standards throughout institutions regarding providing information to patients may be helpful. It may also be beneficial to use a common electronic medication information database such as Micromedex or Lexicomp. Doing this would provide consistent information to patients that may enhance learning over time.

Eighty-eight percent (7/8) of participants in this study reported having two or more different steps in their decision-making process while decision whether or not to use medications during pregnancy and while breastfeeding. That being said, women should be

provided with information about each medication they are being recommended to take from each and every healthcare professional that they encounter. Doing this not only reiterates the information, but it also allows for the women to make the most informed decision possible. Providing her with information may include, but is not limited to, the use of pamphlets, handouts, internet resources, and further referrals to specialists. Virtually every woman will have to make a decision regarding medication use while pregnant and/or breastfeeding and providing her with an adequate amount of unified and consistent information regarding the medications she has been recommended will aide her in making that decision.

Limitations

One limitation of this study is generalizability. The participants were selected through purposive sampling which limits the generalizability to the larger population. Further study using a larger sample size and a broader population including women from different geographical areas, educational backgrounds, and socioeconomic classes is needed. Recall bias is also a potential factor in this study. The use of a questionnaire requires participants to think back to their previous experiences during pregnancy and while breastfeeding to respond to the questions which threatens the internal validity of the research. The potential for self-report bias is also present as this questionnaire was taken independently by participants. There may have been variability in situational condition as the questionnaire used was online and therefore was able to be taken wherever the participant was at the time of completion.

Recommendations

Providing expectant and breastfeeding mothers with as much information as possible regarding their pregnancy, fetal and infant development, and potential effects of both taking and not taking medications will help them to make the most informed decision possible. This may include information from the Centers for Disease Control and Prevention, Organization of Teratology Information Specialists (OTIS), or the American College of Obstetricians and Gynecologists. Having multiple resources available to mothers that are both in physical form and online will allow them to have references to help make their decision throughout their pregnancy and breastfeeding journey. Similarly, providers should be available to their patients. This includes having a phone line that patients can call and ask questions and have appointments available for women to come in and voice concerns they may be having. This allows them to know that there are people available to them as resources to ask any questions they may not be able to find answers to online. Also, giving patients opportunities to ask questions may either prevent them from taking a medication that is not recommended during pregnancy or allows them to take a medication that they previously thought would be contraindicated during pregnancy.

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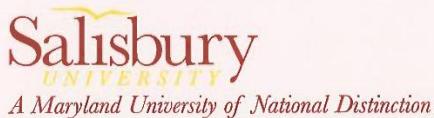
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Appendix I

Questionnaire

1. Were you advised to take any medications during your pregnancy and/or while breastfeeding? If so, was it a prescription or an over-the-counter medication?
2. To whom would/did you refer to get information about the use and safety of drugs or natural products and breastfeeding management?
3. Do you have any experience getting differing opinions from providers regarding medications during pregnancy and/or breastfeeding?
4. Which provider did you choose to listen to, if any? Why?
5. How knowledgeable did you feel about medication use while pregnant and/or breastfeeding?
6. Did you consider the risk-benefit ratio when making a decision to use medications while pregnant and/or breastfeeding?
7. Tell me about your decision-making process in deciding to use a medication during pregnancy and/or while breastfeeding.
8. Given your experience, is there anything you would have changed regarding medication use during your pregnancy and/or while breastfeeding?

Appendix II



Salisbury University
Institutional Review Board
Committee on Human Research
Phone: (410) 548-3549
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Email: humanresearch@salisbury.edu

IRB Research Protocol Approval Notification

Date: 10/12/17

To: K. Freda
RE: Protocol #28
Type of Submission: Exempt
Type of IRB Review: Exempt
Protocol is scheduled to begin 9/17 and end 5/18.

Approval for this project is valid from 10/12/17 to 5/31/18.

CONGRATULATIONS.

This letter serves to notify Kaynabess Freda that the Salisbury University (SU) Institutional Review Board (IRB) approved the above referenced protocol entitled, The lived experience of women who used medications while pregnant and/or breastfeeding on 10/12/17.

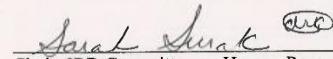
Pursuant to Federal regulations 21 CFR 56.109, the IRB has determined that this protocol qualifies for EXEMPT review.

Federal regulation 45 CFR 46.103 (b)(4)(iii) requires Primary Investigators (PI), except when a subject is in immediate danger, to assure any change to an approved protocol is not initiated prior to IRB review and approval. Additionally, the PI must also inform the IRB of unanticipated problems involving risks to participants.

These same federal regulations require continuing review of research be conducted by the IRB at intervals appropriate to the degree of risk. Your research is scheduled to begin 10/17 and end 5/18. When necessary, the PI will receive a continuing review reminder notice prior to the date protocol approval ends; however, it is the PI's responsibility to submit continuing review reports in a timely manner (at least 3 weeks prior to scheduled end date on the protocol approval).

The SU IRB is organized and operated according to guidelines of the United States Office for Human Research Protections and the United States Code of Federal Regulations and under Federal Wide Assurance No. FWA00020237.

If you have any questions about this review or questions, concerns, and/or suggestions regarding this process, please do not hesitate to contact the Office of Graduate Studies and Research at 410-548-3549 or humanresearch@salisbury.edu.


Sarah Shuck, ^{BSN}
Chair, IRB Committee on Human Research