Research in Pregnancy and Lactation: A Participant Perspective

MELISSA GORMAN MSN, RN-BC, CCRN-K
Background

- 29 years old, healthy, 9 weeks pregnant with my first child
- First time tonic-clonic seizure, unwitnessed, in my kitchen
- Found by my husband unresponsive, with a facial laceration
- Misdiagnosed in emergency department with syncopal episode
- 2 months later, diagnosed with epilepsy via EEG
- A neurologist ordered Keppra to start immediately while 17 weeks pregnant. With the exception of a multivitamin, I had not taken any medications at all at this point in pregnancy.
As a Masters prepared nurse I have always placed a strong value in evidence based practice.

I immediately looked to the research to support the safety of this medication in pregnancy.

I was shocked to see minimal research involving this drug in pregnancy and it was labeled as a category C drug.

I was not reassured by the data that was available at the time, and as a result, did not start taking the medication as ordered.

Pregnancy Risk Factor C

Animal reproduction studies have shown an adverse effect on the fetus. There are no adequate and well-controlled studies in humans and the benefits from use of the drug in pregnant women may be acceptable, despite it’s potential risks.

or

Animal reproduction studies have not been conducted.
The neurologist recognized that I was in need of a second expert opinion and referred me to a neurologist at another large teaching hospital in Boston.

The second neurologist specialized in caring for pregnant women with epilepsy and spent much of her career involved in research regarding pregnancy and epilepsy.

After discussing the risks and benefits in depth with this physician, I began taking the medication as ordered and was followed closely by this doctor for the remainder of my pregnancy.

I also enrolled in the North American AED Pregnancy Registry, which tracks effects of epilepsy medications during pregnancy.
While I put a lot of trust in the medical care I was receiving, and had a healthy pregnancy, I spent most of my pregnancy worrying about the health of my unborn child. Although ultrasounds showed no physical defects, I worried about the potential neurologic and developmental effects on my daughter.

In 2010, I gave birth to a healthy baby girl. With the support of my neurologist, I made the decision to breastfeed while taking Keppra, despite manufacturer recommendation not to breastfeed while taking the drug. Again, there was not a great deal of evidence available on the subject.
Prior to becoming pregnant with my second child, I received an invitation to participate in a research study related to conception and pregnancy in women with epilepsy.

I immediately agreed, as I was eager to contribute to any research related to pregnant women with epilepsy.

This study required study visits, telephone interviews, additional blood draws, and close tracking of symptoms in a mobile app.

My epilepsy treatment was not altered as part of the study, and study requirements were easy to follow.
During my second pregnancy, I was invited to participate in another research study that would follow me and my unborn child throughout the pregnancy, as well as follow my child’s development through early childhood.

I quickly agreed to this study, as this was exactly the type of research I was looking for when I was started on an antiepileptic with my first pregnancy three years before.

In 2013, I gave birth to another healthy baby girl.
The requirements of this study included:

- Daily entries into a mobile phone app regarding seizures and medication history
- Monthly mood and sleep questionnaires via mobile app
- Study visits with physical exam, intelligence testing, blood draws and questionnaires
- Phone interviews at regular intervals
- Cord blood sample when the baby was born
- Post partum visits to assess my health and the baby’s health and neurologic assessment, including blood draws on myself and my daughter
- Developmental testing of my child at 2, 3 and 4 years of age
Why did I agree to participate in this research?

- To contribute to the evidence regarding the impact of antiepileptic medications on pregnancy and lactation.
- To provide more information to parents who are hesitant to take seizure medications while pregnant or breastfeeding or are hesitant to become pregnant with epilepsy.
- Minimal risk – my seizure medication regimen was not altered in any way for the study. It was an observational study and it was monitoring outcomes based on a therapy I would have been on unrelated to the study.
- Minimal inconvenience – many study components were done via mobile app or telephone interview. Study appointments were planned around pre-planned doctor’s visits and took place in a location that was convenient to me.
Benefits of participating in research

**Obvious benefit:**
- I felt like I was able to contribute to an area of research I felt was lacking as a patient.

**Unexpected benefits:**
- Daily mobile app diary entries ensured I was in tune to symptoms and served as a reminder to take my medication each day.
- Frequent visits with my neurologist and close monitoring of blood levels and overall health was reassuring.
- While breastfeeding, antiepileptic drug levels were tested in my daughter, which was reassuring to see just how little of the drug was detectable in her blood.
- My daughter had full developmental assessments at age 2, 3 and 4 years, which were very thorough, reassuring and gave me insight into many of her strengths.
Summary

- I feel very fortunate to have had the opportunity to participate in this research and to be cared for by experts who are contributing to this evidence.
- As a pediatric nurse educator, I rely on research on a daily basis to make decisions to provide the best care possible.
- As a patient, the lack of research when I needed it most was troubling.
- There were many expected and unexpected benefits to participating in these studies.
- I hope the outcomes of these and similar studies will help pregnant women and their care providers to make informed, evidence-based decisions in the future.