



# Research in Pregnancy and Lactation: A Participant Perspective

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# 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.

# Background

- ▶ 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.

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# Background

- ▶ 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.

# Background

- ▶ 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.



# Research

- ▶ 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.

# Research

- ▶ 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.



# Research

- ▶ 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.

