DYK: Pregnant women are excluded from clinical drug trials – huh?

When you think medication or vaccine safety, you think clinical drug trials. Right?! Clinical drug trials are research studies designed to gather information to determine whether a new medication or vaccine is safe and effective in people.

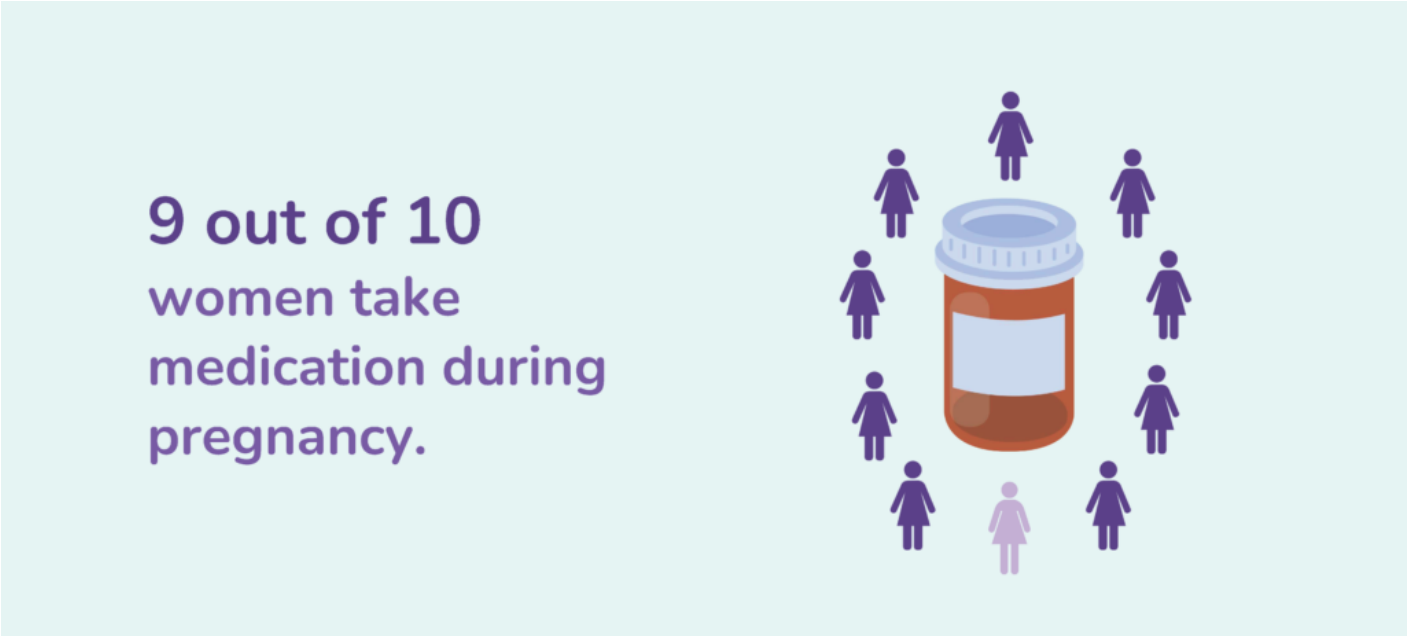
However, what most people don't know is that pregnant women are excluded from these studies when a new drug is being developed. Essentially, this means that once a medication is approved by the US Food & Drug Administration (FDA), it's prescribed to patients (including those who are or could become pregnant) with little to no information on the safety of the drug if used during pregnancy. Currently, less than 10% of medications approved by the FDA have enough information to determine their risk when used in pregnancy! To address this gap, the FDA may require observational studies, called pregnancy exposure registries, to be conducted on newly approved medications or vaccines to determine safety in pregnancy.

What are pregnancy exposure registries?

Pregnancy exposure registries are observational studies that collect health information on exposure to medical products such as drugs and vaccines during pregnancy. "Observational" means that study participants are **never** asked to take a new medication or to change any existing medications. After enrolling in the study they are simply followed by researchers through the remainder of their pregnancy, often by completing interviews or surveys or by allowing the researchers to access their medical records.

Why are pregnancy exposure registries important?

Pregnant women represent an important segment of the population, with over 6 million pregnancies occurring per year the U.S. alone. Additionally, studies have shown that 9 out of 10 women take medication during pregnancy – these women deserve to know if the medications they are taking will have any effect on their pregnancy, and pregnancy exposure registries are how we gather this information.



This information is used by pharmaceutical companies when listing safety information on drug labels. It is also helpful for healthcare providers to determine treatment plans for their pregnant patients. In many cases, pregnancy exposure registries have provided reassurance – and in some cases have raised red flags – on whether a medication is safe to take during pregnancy.

Why not just stop taking medications before you become pregnant?

It's a common misconception that quitting a medication during pregnancy will be safer for the mom and her baby. In fact, for many chronic health conditions (such as asthma or seizure disorders), it's safer for both mom and baby if the condition is well-managed. Some pregnant women may also experience acute conditions (like an infection) or develop complications during pregnancy that require medication. Physicians and pregnant women have the difficult task of balancing the risks and effects of an unmanaged condition during pregnancy versus the potential risks and benefits of starting or continuing to take a medication during pregnancy. Having enough information about the safety of the medication when used in pregnancy would make this task a whole lot easier.



And let's not forget: nearly half of all pregnancies in the U.S. may be unintended, which means that women may be exposing their pregnancy to a medication without realizing it because they weren't planning the pregnancy and won't know they are pregnant until they miss their first menstrual period.

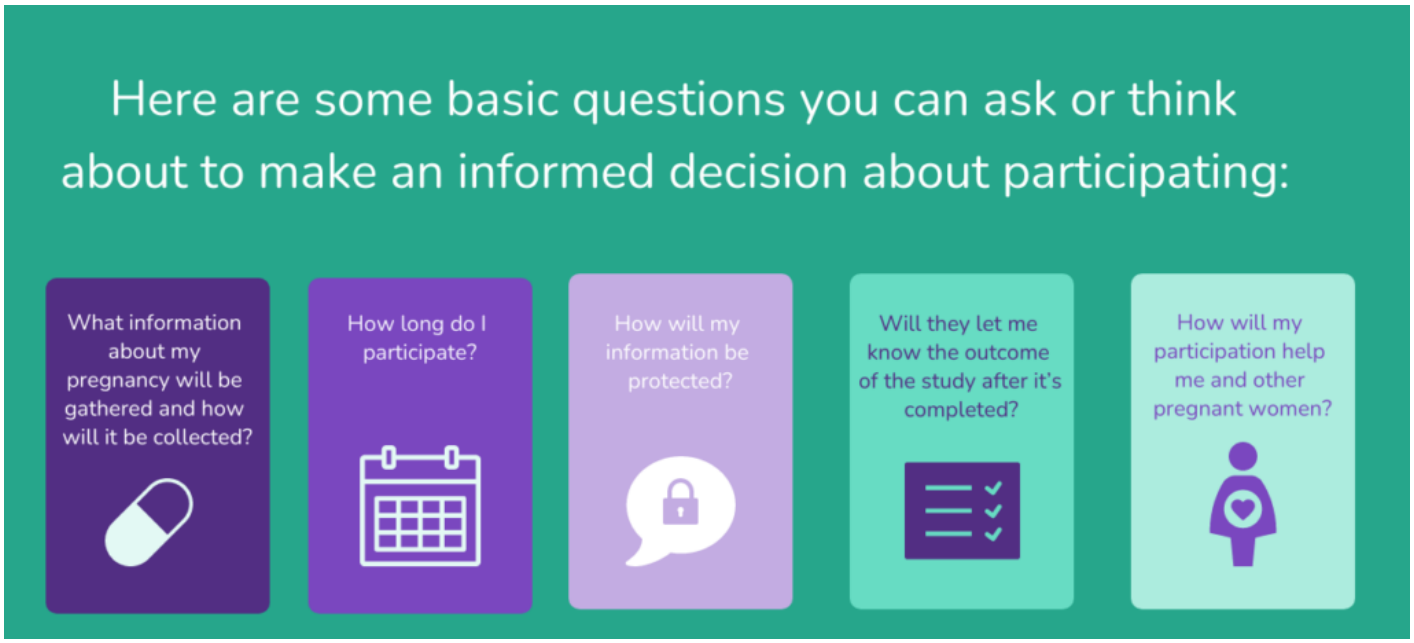
How are registries organized/structured?

It's worth repeating: Pregnancy registries are **strictly observational**. Researchers will follow participants throughout their pregnancy and sometimes after the child has been born regardless of the woman's healthcare routine.

Researchers collect data about the pregnancy from the woman and/or (with the woman's permission) from her medical records. The type of data collected, communications and length of participation vary from one registry to another, so it's important you find out all the details about the study before you join.

Here are some basic questions you can ask or think about to make an informed decision about participating:

- What information about my pregnancy will be gathered and how will it be collected?
- How long do I participate?
- How will my information be protected?
- Will they let me know the outcome of the study after it's completed?
- How will my participation help me and other pregnant women?



Who participates?

Pregnancy registries are generally designed to compare pregnant women who have been exposed to the medication/vaccine of interest to those who have not been exposed. Depending on the registry, participants can include women who:

- Have taken a specific medication or vaccine during a current or recent pregnancy.
- Are pregnant and have not taken the medication being studied, but have the same health condition being treated by the medication being studied.
- Are pregnant, have not taken the medication being studied, and do not have the same health condition being studied.

Where can I find a registry to join?

There are a variety of organizations that run pregnancy registries. A great place to start is by asking your healthcare provider. You can also look on the US FDA Pregnancy Registry site.

What makes MotherToBaby pregnancy registries different?

Here at MotherToBaby, we run several pregnancy exposure registries, called MotherToBaby Pregnancy Studies. Our studies are unique in a few different ways:

- Participants have access to our trained experts to answer questions on any exposures during pregnancy and breastfeeding – all at no cost to you.
- Some of our studies offer a free in-home examination of your infant and a consultation with an expert pediatric specialist who can answer any questions you might have about your child's growth and development.
- When you enroll in a study that includes free developmental follow-up for your child, you'll receive reports after each screening, which will provide you with information about how your child is developing relative to other children his/her age.

Interested in learning more about what it's like to participate in our studies? Meet Mariah, a study participant and maternal health advocate mom of 4. She shares her experience here.

If you or someone you know is interested in joining one of our pregnancy studies, we'd be happy to talk you through the process and answer any questions you may have.

- **Call 877.311.8972 or email MotherToBaby@health.ucsd.edu**

You can also browse through our ongoing studies here.

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Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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