

Comments on research for pregnant women with tuberculosis to the PRGLAC Task Force

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I would like to thank the Task Force for giving me the opportunity to comment on research needs facing pregnant women. I am Kate O'Brien – a mother, an advocate and a TB survivor. I'll be focusing my comments to reflect the experience of having TB while pregnant, and the vital need to expand research to meet the critical treatment needs of all pregnant women that have TB.

When I became pregnant with my second baby in 2015 I was overjoyed. That wonderful feeling abruptly changed when I almost immediately started feeling terrible. After months of confusion and misdiagnosis after misdiagnosis, I landed in a hospital ICU and learned I had active tuberculosis. I was kept in isolation for 75 days in total, away from my toddler son.

While everyone around me knew how to treat tuberculosis, and I had a drug-susceptible strain that has been "cureable" for many years, my pregnancy seemed to throw a wrench into everything. Despite my correct understanding that pregnant women have been treated for TB for decades, that pregnant women were being treated for TB all over the world, I felt like an outlier, a "special case". I was given the typical first-line drugs for the illness, which pass through the liver. I woke up scratching myself at night, wondering if the negative pressure air in my isolation room made things dry. I secretly hoped my skin was stretching from the pregnancy and the baby was gaining weight despite my inability to do the same. I cheerfully reported this symptom to my doctor the next day, and was gently shown a skyrocketing liver chart. The liver is more sensitive during pregnancy, so the first-line antibiotics used to treat TB gave me hepatitis. Even though I was showing progress on fighting the illness and was eating more and coughing less - we had to wait a week without medication for my liver to "cool down". I stopped eating. I started feeling awful. Then I would start a new drug. We repeated this cycle several times. I was unable to take pyrazinamide and rifampin, two of the four drugs used to routinely treat TB.

This cycle resulted in extra weeks away from my child and unnecessary medications for my baby. Why was I taking them? Was this typically how a pregnant woman with TB reacts or was my liver extra-EXTRA sensitive? If so many women had taken and were taking the EXACT same antibiotics, why couldn't anyone tell me?

We started on second line drugs, drugs typically used to treat resistant strains, drugs that have less information and more side effects. We had no idea if they would work, if I could tolerate them. I had no idea when I would be able to leave the hospital and my family was totally upended, living week to week by my liver. Despite having a common strain of a common illness that has been around for centuries, my baby and I were an experiment.

They wondered if we would have to deliver early in order to treat me. Everyone was concerned with killing the TB, but as you can all imagine, the overriding thought for me was "What is going to happen to my baby?" My baby was the only one with me in many of those hours spent in isolation. I loved my baby, and the feeling of guilt was only outmatched by anxiety. Was it going to be alright? What was I doing to it? This drug causes hearing loss, will my baby be deaf? Should I breastfeed? If women in poor countries get this disease so much, their babies must be breastfeeding, right? I had question after question with no concrete answer. This made the anxious thoughts and fears worse, this made the guilt worse, it made everything worse. Eventually I kept asking "why isn't anyone writing down what happens to pregnant women when they take these medications? Don't TB patients get followed for months? Doesn't anyone care about their babies?" The answer I was getting by not getting an answer was 'No'. No one cared

about their babies enough to record anything, and no one was going to take note of mine, either. There wasn't a place to put the information. There wasn't anyone interested.

Earlier today a registry was mentioned, to collect this sort of data on pregnant women with tuberculosis. This would have had a profound impact on my situation in every aspect. I would have been treated better, faster, with much less insecurity and fear. The length of treatment and uncertainty was so difficult not just for me but for my toddler son, for my husband, for our parents and our finances. The information is available, but it's not being collected in a way that can help us answer these questions! These patients are under DOT and are already being monitored to some extent. The data is out there ready to help someone, and to CONTINUE helping people for years and years.

Pregnancy isn't a "complication" or a "condition" - and it certainly shouldn't be an *exclusion* criterion for studies of medicines that women may need to take *while pregnant*. Most women are able to conceive from 16-40. We are of "childbearing age" for much of our lives. A drug isn't truly safe for women unless it is safe for pregnant women, and if the goal we keep seeing of having women equally represented in medical research is ever going to be fully realized, we have to stop pretending that pregnancy isn't some sort of a discrepancy and acknowledge that living with the chance of pregnancy is half of female adulthood. This is especially true of women around the world who don't have the same agency to pick when they conceive, as perhaps many of us do. We aren't "special women". We are women.

I gave birth in April 2015 to a beautiful baby boy. Jimmy is affectionate, funny, climbs on everything and appears to be healthy but I still worry all the time. He doesn't really talk yet, and well meaning people tell me not to be concerned. In the absence of information, what else can I be? I urge you to end the neglect of pregnant women in research and their exclusion from clinical trials, especially those designed to evaluate treatments for new and frightening drug resistant strains of TB. I can tell you from first hand experience - pregnant women will be forced to take these treatments anyway. Give them the support of doing so under careful observation in the context of a supervised clinical trial, that has the potential to inform the safe treatment of pregnant women in the future. Give them the knowledge that their situation, their children are worth a few notes. This WILL make things easier for patient and doctor down the road and it's the right way to do things.

I thank you for your interest and work in maternal health from the bottom of my heart today, and on behalf of my children.

- Kate O'Brien, "We Are TB"