

On Dec. 14, 2016, the U.S. Food and Drug Administration (FDA) issued a safety announcement regarding anesthesia exposure and a potential undesired effect on brain development in babies and young children. To better serve our patients, we are sharing information about the FDA's announcement with pregnant women who require general anesthesia or sedation.

What does the FDA safety announcement mean?

- Prolonged (> 3 hours) or repeated use of general anesthetic and sedation drugs in pregnant women during their third trimester may affect the development of children's brains. This may also affect children under the age of 3, according to the FDA safety announcement.
- A single, relatively short exposure to general anesthesia or sedative drugs is unlikely to have undesired effects on behavior or learning.
- Pre-clinical research suggests that repeated or prolonged use of general anesthetic or sedative drugs may have undesired effects on the developing brain. These effects are subtle and may include learning, memory or behavior problems.
- No specific anesthetic or sedative medications have been proven to be safer than any other.
- More research is needed to provide definitive answers.



Who needs anesthesia during pregnancy?

While most women will not need surgery during their pregnancy, approximately one in 50 women will undergo surgery or a procedure requiring anesthesia at some point during pregnancy. When surgery or other procedures are necessary, anesthesia or sedation is necessary to prevent pain, stress and anxiety.

Pregnant women in 3 main categories may require anesthesia:

- Anesthesia for Obstetric Surgery (pregnant women undergoing surgery related to their pregnancy such as cervical cerclage or cesarean delivery)
 - These surgical procedures are performed to deliver the baby (cesarean delivery) or to prevent miscarriages. In cervical cerclage surgery, a stitch around the cervix (cerclage), is performed to allow babies to have more time to grow and develop in the womb.
 - Cesarean deliveries are most often performed under neuraxial (epidural or spinal) anesthesia. The FDA safety announcement only applies when general anesthesia is used.
 - In some instances (for example, emergency cesarean deliveries), general anesthesia may be the best choice for the safety of the mother or baby.
 - Studies have shown that children exposed to general
 anesthesia during cesarean delivery are not more likely to
 develop learning disabilities compared to children delivered
 vaginally. This suggests that brief exposure to anesthesia
 around the time of delivery does not adversely affect
 long-term developmental outcomes.
- Anesthesia for Non-Obstetric Surgery (pregnant women undergoing surgery unrelated to their pregnancy, such as appendectomy or gallbladder removal)
 - Elective surgery is not performed during pregnancy. The
 decision to perform a surgical procedure during pregnancy
 is determined by emergent conditions, or situations where
 a delay in surgery would increase risk to mom and possibly
 baby. No woman should be denied a procedure that is
 necessary simply because she is pregnant.
 - You will receive the amount of anesthesia necessary to keep you comfortable during the procedure.

- 3. Anesthesia for Fetal Surgery (women undergoing surgery for conditions related to their unborn child)
 - Fetal surgery is performed on babies with rare conditions who will benefit from surgical treatment before they are born.
 - While the exposure to anesthesia in some of these cases may be lengthy or repeated, anesthesia for fetal interventions has not been specifically determined to be associated with neurodevelopmental impairment in childhood.
 - Some disorders in the fetus that warrant fetal intervention may be associated with neurological impairment if left untreated.

Become an Informed Patient

- Ask for information about the planned surgery or procedure, including the need for anesthesia or sedation, the duration, and the need for any repeated procedures.
- Talk to your surgeon and anesthesiologist about potential adverse effects of anesthesia on the brain development of your child or unborn child. This discussion can occur at any time before the surgery.
- For obstetric or non-obstetric surgery, call the Pre-Anesthesia Testing Clinic at **832-826-3631**.
- For surgery related to a fetal condition, call **832-824-5800** to speak with a fetal anesthesiologist.

Other Useful Resources:

U.S. FDA Safety Announcement on Anesthesia: fda.gov/Drugs/DrugSafety/ucm532356.htm

American College of Obstetrics and Gynecology: acog.org

Society for Obstetric Anesthesia and Perinatology: soap.org

Society for Pediatric Anesthesia: pedsanesthesia.org

Texas Children's Hospital Pediatric Anesthesiology: texaschildrens.org/departments/anesthesiology

SmartTots: smarttots.org

Texas Children's Pavilion for Women 6651 Main St. Houston, TX 77030 832-826-3000 women.texaschildrens.org



Pavilion for Women