



General Anesthetic and Sedation Drugs: Drug Safety Communication – New Warnings for Young Children and Pregnant Women

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FDA 發布一則安全警訊，小於三歲孩童和妊娠第三期，在手術過程中重覆性或延長使用全身麻醉劑和鎮靜藥品可能影響孩童大腦的發展。

在幼年的動物研究中，已證明使用阻斷 NMDA(N-methyl-D-aspartate)受體或增強

GABA(gamma-aminobutyric acid)活性的麻醉劑和鎮靜藥物超過 3 小時，可能增加大腦神經元的凋亡導致長期的認知缺失。與動物研究一致，在人體嬰幼兒研究，單一劑量和相對短時間暴露於全身麻醉劑和鎮靜藥品不太可能對行為和學習產生負面的影響。然而，仍需要有更進一步的研究來充分描述造成認知行為的可能性，包括不健康的嬰幼兒暴露於全身麻醉劑和鎮靜藥品的年齡，性別的差異，特定麻醉藥品等。

因為潛在風險，FDA 要求全身麻醉劑和鎮靜藥品於仿單上新增警語，同時也會繼續監測這些藥物在兒童和孕婦中的使用情況，如果有其他研究資料會再做更新。

建議

醫療人員應該同時考量孩童和妊娠第三期適當給予麻醉劑之益處與麻醉劑對大腦發育的潛在風險，以權衡利弊，尤其是小於三歲孩童需要持續超過三個小時或多個程序的手術。

也應考量適當的手術時間安排，如果可以延遲，應以不會危及孩童健康為優先考量。

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AUDIENCE: Consumer, Surgery, Anesthesiology

ISSUE: FDA is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains.

Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

To better inform the public about this potential risk, FDA is requiring warnings to be added to the labels of general anesthetic and sedation drugs (see List of General Anesthetic and Sedation Drugs Affected by this Label Change). FDA will continue to monitor the use of these drugs in children and pregnant women and

will update the public if additional information becomes available.

See the FDA Drug Safety Communication for a data summary and listing of general anesthetic and sedation drugs affected by this label change.

BACKGROUND: Anesthetic and sedation drugs are necessary for infants, children, and pregnant women who require surgery or other painful and stressful procedures, especially when they face life-threatening conditions requiring surgery that should not be delayed. In addition, untreated pain can be harmful to children and their developing nervous systems.

FDA has been investigating the potential adverse effects of general anesthetic and sedation drugs on children's brain development since the first animal study on this topic was published in 1999. FDA held advisory committee meetings in 2007, 2011, and 2014. To coordinate and fund research in this area, FDA also formed a partnership with the International Anesthesia Research Society (IARS) called SmartTots (Strategies for Mitigating Anesthesia-Related neuroToxicity in Tots). More research is still needed to provide additional information about the safe use of these drugs in young children and pregnant women.

RECOMMENDATION: Health care professionals should balance the benefits of appropriate anesthesia in young children and pregnant women against the potential risks, especially for procedures that may last longer than 3 hours or if multiple procedures are required in children under 3 years. Discuss with parents, caregivers, and pregnant women the benefits, risks, and appropriate timing of surgery or procedures requiring anesthetic and sedation drugs.

Parents and caregivers should discuss with their child's health care professional the potential adverse effects of anesthesia on brain development, as well as the appropriate timing of procedures that can be delayed without jeopardizing their child's health. Pregnant women should have similar conversations with their health care professionals. Also talk with them about any questions or concerns.

List of General Anesthetic and Sedation Drugs Affected by this Label Change*

**This list includes anesthetic and sedation drugs that block N-methyl-D-aspartate (NMDA) receptors and/or potentiate gamma-aminobutyric acid (GABA) activity. No specific medications have been shown to be safer than any other.*

Generic Name	Brand Name
Desflurane	Suprane
Etomidate	Amidate
Halothane	Only generic is available
Isoflurane	Forane
Ketamine	Ketalar
Lorazepam injection	Ativan
Methohexital	Brevital
Midazolam injection, syrup	Only generic is available
Pentobarbital	Nembutal

Propofol	Diprivan
Sevoflurane	Ultane, Sojourn