



Consensus Statement FAQs for Health Care Professionals

Why was the Consensus Statement developed?

In December 2012, SmartTots released its first Consensus Statement on the *Use of Anesthetics and Sedatives in Children*. Its purpose was to provide guidance to health care providers and parents with regard to research findings that suggest anesthetics may be harmful to the developing brain. SmartTots has now updated the statement in light of recent research.

Who developed and reviewed the Consensus Statement?

experts in anesthesia, pediatric medicine, neuroscience, and patient safety to consider the emerging evidence and review the original 2012 statement. This newly drafted *Consensus Statement on the Use of Anesthetic and Sedative Drugs in Infants, Toddlers, and Preschool Children* is the result of many hours of deliberation by that diverse group of experts. Additional input was obtained from more than 20 stakeholder organizations. See the full statement for a list of endorsing organizations.

What research is it based on?

In humans, the formation of brain structures and rapid brain growth starts early in pregnancy and continues for up to three years. In rats and mice, the comparable period of brain development is the first two weeks of life. In the animal research studies, when administered during rapid brain growth in rodents, all of the anesthetics and sedatives commonly used in infants and children caused widespread loss of nerve cells and/or later abnormal behavior. Recent data show that a loss of nerve cells in the brain also occurs when commonly used anesthetics are administered to newborn monkeys. The results from observational studies of anesthetic exposure in children have been mixed, and more preclinical and clinical studies are required to determine whether anesthetics cause injury to humans.

Who is the audience?

The *Consensus Statement* was created as an educational tool to provide guidance to health care providers, parents and caregivers.

When will the Consensus Statement next be reviewed?

In anticipation of the completion of additional preclinical and new clinical research studies, the IARS and the FDA plan to reconvene an advisory group in 24 months. At that time the group will revisit the statement and update the content to reflect new scientific findings.

What research is ongoing?

SmartTots continues to facilitate and support studies of existing anesthetic drugs and their effects on childhood development, as well as the impact of drug type, dosage amounts and number of exposures. Information from these research studies will help to determine if particular anesthetic drugs pose hazards to young children, to design the safest anesthetic regimens (dose and duration), and potentially foster the development of new anesthetic drugs. SmartTots and

the FDA are working closely to coordinate and fund future research programs with the goal of improving the safety of surgery.

Current studies include:

- Lena Sun, MD, Columbia University Medical Center, Pediatric Anesthesia NeuroDevelopment Assessment (PANDA) Study
- Mary Ellen McCann, MD, MPH, Harvard Medical School, Boston Children's Hospital, *The GAS Study*
- Jeffrey Sall, PhD, MD, University of California San Francisco, *Recognition Memory Following Early Childhood Anesthesia*
- Caleb Ing, MD, Columbia University, *Anesthetic Exposure Duration and Effects on Cognitive and Language Ability*
- Ansgar Brambrink, MD, PhD, Oregon Health & Science University, *Long-Term Outcome of Single vs. Triple Anesthesia Exposure of Infant Monkeys*

Additionally, SmartTots is working with an international team of expert neuroscientists to develop a clinical trial. Several other studies, independent of FDA, IARS and the SmartTots Public Private Partnership, are also underway at major universities.

What should I tell parents if their child needs surgery or a procedure requiring anesthesia or sedation?

To parents, one of the most fearful aspects of surgery can be anesthesia. Taking the time to properly prepare and inform parents can help the entire family feel less anxious about anesthesia and surgery. Make it clear to parents that the recommended surgery is essential to the child's health. Help the parent or caregiver understand that postponing a necessary procedure may itself cause problems and would not be a prudent option. For example, children with chronic ear infections may have delays in the development of speech related to problems with hearing. Surgery to treat this problem may improve learning whereas a delay may result in long-term difficulties in the normal development of speech.

Where can I learn more?

A multitude of resources can be found at Smarttots.org, including the latest research studies, newsletter articles and scientific presentations. You may also sign up to receive updates on the latest research at Smarttots.org/resources.

About SmartTots

SmartTots is a Public-Private Partnership (PPP) between the US Food and Drug Administration (FDA) and the International Anesthesia Research Society (IARS). The mission of this partnership is to coordinate and fund research with the goal of ensuring safe surgery for the millions of infants and young children who undergo anesthesia and/or sedation each year. The FDA and IARS work together with multiple stakeholders to leverage their collective resources in an effort to address this important issue.