

For immediate release

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SmartTots Urges Continued Research on Possible Effects of Anesthesia on Young Children; Issues Supplement to Recent Consensus Statement

Supplement issued following recent study showing no difference in developing brain between children given general and regional anesthesia in one scenario

San Francisco, CA – November 6, 2015 – SmartTots today issued a [supplement](#) to its recent [consensus statement](#) in response to a clinical trial’s preliminary outcome that found no difference in the developing brain between two-year-olds who had undergone general anesthesia and those who had received regional anesthesia as infants.

Last month, SmartTots, a public-private partnership of the International Anesthesia Research Society and the U.S. Food and Drug Administration, released a revised consensus statement that cited growing evidence of potential risk of general anesthesia and sedatives for children under the age of 4. The statement urged continued research to determine whether these medications are safe and to seek alternative medications. The statement was developed and reviewed by more than 30 experts in anesthesia, pediatric medicine and neuroscience.

Shortly after the release of last month’s consensus statement, [preliminary results](#) of the first-ever prospective clinical trial were announced that showed no difference in cognitive function at age 2 between children who, as infants, had been given general anesthesia for under one hour and those given regional anesthesia during hernia repair surgery. The international trial, *General Anesthesia Compared to Spinal Anesthesia (GAS)*, is ongoing; the primary outcome will measure performance on a test of intelligence at age 5. At that point, changes may be evident that were not detectable at age 2. The preliminary results were announced at the American Society of Anesthesiologists’ annual conference in San Diego and reported in the November issue of *The Lancet*.

Subsequently, SmartTots convened a panel of anesthesia experts – including many who had developed the recent consensus statement as well as several investigators from the clinical trial – to discuss the trial’s early findings and consider their significance. The experts agreed that the published outcomes are consistent with most animal data and epidemiological studies, which suggest that a single short-duration exposure to anesthesia may not be harmful. Although this news is encouraging for parents whose children require a brief surgical procedure early in life, many more questions remain.

Supplement identifies unanswered questions

SmartTots developed the supplement to the recent consensus statement to recognize the recent study findings and identify many of the outstanding questions, which include:

- Brain function is very complex and cannot be fully measured with a single cognitive test. How does exposure to anesthetics affect the development of other important functions such as memory, language, motor skills, and emotional development?
- Sevoflurane is only one of the drugs used in general anesthesia. Do other commonly used drugs produce similar results?
- Many procedures require a combination of two or more anesthetics. Do the effects change when drugs are combined?
- Different medical procedures may combine with anesthetics to produce other outcomes. Are the results the same for procedures other than hernia repair?
- Much brain development occurs throughout childhood. What are the effects of exposure to anesthetics in subsequent months or years?
- Animal and epidemiological data suggest that the risk of anesthetics to the developing brain increases with longer duration exposure or multiple exposures. Is this true for children?

“Studies of the brain are extremely complex,” said Alex S. Evers, MD, co-chair of the SmartTots’ Scientific Advisory Board and head of the Department of Anesthesiology at Washington University in St. Louis. “Although these early trial results offer some positive news, much more animal and clinical research is needed – particularly additional prospective clinical trials for procedures that require different and combined medications, and longer durations of exposures. Until we know more, we continue to urge parents and health care providers to consider the risks, benefits, and timing of any treatment on very young children, and to explore alternatives to anesthesia or sedatives when pain management is not an issue.”

In conjunction with the recent consensus statement, SmartTots created FAQ sheets for [healthcare providers](#) and for [parents and caregivers](#) that offer guidance when considering anesthesia or sedative drugs for infants and toddlers.

Pilot clinical trial underway; funding sought for additional trials

Another prospective international clinical trial is in progress, looking at potential alternatives to commonly used inhalational anesthetics for children under the age of 4. In addition, SmartTots has plans for prospective clinical trials and is currently seeking funding.

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[SmartTots](#) is a Public-Private Partnership between the U.S. Food and Drug Administration (FDA) and the International Anesthesia Research Society (IARS) designed to close research gaps related to the effects of anesthetics on the developing brain, and ensure the safety of infants and young children undergoing anesthetics in medical procedures. Findings from SmartTots research studies will determine the safety of commonly used anesthetics, establish new practice guidelines, and potentially foster the development of new, safer anesthetics and sedatives.