



Funding research to ensure pediatric anesthesia safety

## Frequently Asked Questions for Parents & the Public

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### What are the concerns about anesthetics and children?

There is mounting evidence that laboratory animals exposed to anesthetic agents early in life demonstrate long-term changes in their brains that can affect learning. Studies in humans have been less clear, but some studies have suggested that there may also be adverse effects on behavior, learning and memory when children under 4 years of age have prolonged or repeated exposures to anesthesia and surgery. To date, there is no direct evidence that anesthetics are unsafe for children but more research is needed.

### How did doctors become aware of the problem?

For the past 15 years, researchers have conducted studies to investigate the effects of anesthetics on the nervous systems of developing animals. The results of these research studies demonstrate that exposure to some anesthetics and sedatives causes memory and learning difficulties and other harmful changes in the central nervous systems of some laboratory animals. These findings created a heightened level of concern resulting in the development of an international work group to generate additional data. Currently, inadequate data exist to prove or disprove whether similar effects occur in children. More information on study results can be found on the SmartTots website.

### If anesthetics cause problems in animals, will they cause similar problems in people?

Although research in animals is often very helpful, it may sometimes cause undue concern. Animals are not human and changes in practice based only on laboratory animal studies may have unintended consequences that are not in the best interests of children. Much more research is needed to provide parents with additional information about the safe use of anesthetic and sedative drugs in children. Until more information is available it is important that children continue to receive any necessary surgery and anesthesia. SmartTots is working diligently to fund new studies to increase the safety of anesthetic and sedative drugs.

### Why might my child need anesthesia or sedation?

The most common procedures for young children requiring sedation or anesthesia include ear tubes for chronic ear infection, tonsillectomy, hernia repair, and circumcision, all procedures that typically last less than 60 minutes.

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Many children need anesthesia or sedation for procedures requiring the child to stay still (MRI, some types of X-ray) or may be briefly painful (broken bones or sutures). Children may also need surgery or sedation for less common conditions.

### **What should I do if my child needs surgery or a procedure requiring anesthesia or sedation?**

Parents and caregivers should discuss the risks, benefits, and timing of surgery and procedures requiring anesthetics and sedative drugs with your child's health care providers. Other than delaying the exposure to anesthetics and sedatives until the child is older, there are no proven ways to mitigate the possible effects. Additionally, for most surgical procedures, there are currently no realistic alternatives to the medications used for general anesthesia. Untreated pain is known to be harmful in children and to the developing nervous system. For necessary non-surgical procedures where pain management is not an issue, it may be worthwhile to explore alternatives to anesthesia or sedation.

### **Should I consider putting off a needed procedure until my child is older?**

Children do not generally undergo surgical procedures that require anesthesia unless the surgery is essential to their health. Therefore, postponing a necessary procedure may itself cause problems and would not be an option for the majority of children. 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. Parents of children requiring surgery should consult a qualified professional for advice about their child's situation.

### **Is one anesthetic or sedative better or worse?**

No, all commonly used sedatives and anesthetics have been implicated in animal studies.

### **Where can I learn more?**

A multitude of resources can be found at [Smarttots.org](http://Smarttots.org), including information about 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](http://Smarttots.org/resources).

### **How can I help?**

SmartTots funds research necessary to make anesthesia safer for children around the world. Your generous donation will make a dramatic impact to help make this research possible. For your convenience, SmartTots has a number of giving options available – visit [Smarttots.org/donate](http://Smarttots.org/donate) for the option that best suits your needs.

### **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.