

# Does MRI pose more than minimal risk in pediatric research?

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(Garrison, NY) Shedding light on a question that has baffled research ethics review boards, a new analysis of the use of magnetic resonance imaging (MRI) in pediatric clinical trials finds that the risks of physical and psychological harm associated with this procedure are no greater than the risks that healthy children face from everyday activities, such as playing soccer or riding in motor vehicles. However, adding an intravenous contrast dye or sedation to an MRI increases the odds of harm and makes them unacceptably high.

These findings are important because they clarify which kinds of MRI studies meet the "minimal-risk standard," which ethics review boards use to determine if a study can proceed. The report appears in [\*IRB: Ethics & Human Research\*](#), a journal of The Hastings Center.

MRI affords researchers exceptional views inside the human body, but it also poses risks, including physical injury from the strong magnetic forces and [psychological harm](#) such as anxiety. For their risk analysis of the procedure, the authors considered the risks from MRI alone, as well as the risks from contrast-enhancing agents and [sedation](#), which are sometimes used with MRI examinations. The authors also examined systematic reviews of the risks from several "everyday" activities of healthy [children](#).

They found that the risk of physical injury from MRI is 17 per 100,000 examinations and that the risk of death is 4 per 100 million examinations. In contrast, the risk of injury in children under the age of

16 from a wide variety of sports and recreation activities ranges from 4 per 100,000 hours of participation in soccer to 12,730 per 100,000 hours of playing ice hockey. Assuming that an MRI examination lasts an hour, the risk of injury associated with an MRI falls within the lower end of this range, the authors write.

The authors also compared the death rates of children undergoing MRIs versus children riding in motor vehicles, which poses the highest risk of mortality to healthy children. The motor vehicle risk ranges from 6 deaths per 100 million car trips for children ages 14 years and younger to 40 per 100 million for children ages 15 to 19. "Thus, the risk of death from an MRI examination (four per 100 million) is clearly less than the risk of death from a car trip," the authors conclude.

As for psychological harm, in studies of children ages 10 to 18 years old who had MRI scans, 12 percent said they felt disturbed by the confined space, 16 percent said they were bothered by the noise, and 1.2 percent could not complete their MRI scan due to claustrophobia. But these percentages were lower on average than the percentages of children who report fears associated with anxiety disorders – in one study of children 8 to 13 years of age, for example, 49 percent reported fears associated with subclinical anxiety and 22 percent met the full criteria of an anxiety disorder.

When an MRI examination calls for the injection of a contrast dye, there is the risk of allergic reactions, such as fever, headache, and anaphylaxis. The authors compared these risks with the risk of allergic reactions following routine vaccinations: while the risk of local and minor systemic reactions from MRI contrast dyes (4 percent to 6 percent) is comparable to the risk of minor reactions from routine vaccinations, the risk of anaphylaxis from MRI contrast dyes (7.5 per 100,000 doses) is higher than the risk of anaphylaxis from vaccinations. "MRI with contrast enhancement therefore does not meet the minimal-risk

standard," they conclude.

They also conclude that the risk from sedation in MRI protocols, which includes gastrointestinal complaints (18 percent to 37 percent) and motor imbalance (66 percent to 85 percent), does not meet the minimal-risk standard, based in the risks posed by sedating medications such as over-the-counter cold medicines.

"We urge researchers and REBs [research ethics review boards] to collaborate in the ongoing effort to minimize the risk of harm and discomfort associated with pediatric MRI research," write the authors: Matthias H. Schmidt, MD, FRCP, of Dalhousie University; Jennifer Marshall, MSc, of University of Toronto; Jocelyn Downie, LLB, LLM, SJD, of Dalhousie University, and Michael R. Hadskis, LLB, LLM, of Dalhousie University.

Provided by The Hastings Center

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