

THE NECESSITY OF OBSERVING CHILDREN'S EXPOSURE TO CONTAMINANTS IN THEIR REAL-WORLD ENVIRONMENTAL SETTINGS

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Infants and children are exposed to a large number of environmental contaminants through various media, raising serious questions about whether such exposures are likely to cause adverse health effects. These questions can only be answered if we understand what doses cause effects and what doses children receive. At present, we have a fair amount of information on the types of health effects, but we know very little about actual exposures to environmental toxicants, except to say that often children have greater contact and intake of chemicals than adults.

Although the current regulatory structure has strenuously sought to protect children, scientists and decisions-makers from all sectors recognize the deficit in knowledge of children's contact with environmental toxicants and their subsequent exposures. This poses three main questions: Are such exposures creating adverse health effects, at what level of exposure, and what actions are needed to prevent or mitigate those exposures? We should not attempt to protect our children with guesswork and assumptions when we have the ability to protect them with improved knowledge of their exposures. We think that current knowledge about exposure is not adequate to protect infants and children within many regulations, requiring exposure research to ensure accurate information is provided to focus and strengthen regulations.

The most appropriate scientific method of determining exposures and associated health hazards is to perform observational studies of children in their daily environment. Observational studies are defined as the collection of personal environmental samples, data, and information from participating volunteers in their everyday environments as they go about their normal activities. No purposeful or intentional exposures to toxic contaminants are involved. Scientists simply observe the exposures that would happen anyway in the course of the children's normal activities. Furthermore, observational studies are subject to extensive rules and regulations (e.g., under the "Common Rule"), requiring very strict adherence to ethical standards, including expert review and approval of all human research studies. Such observational studies of children's exposure are supported by many of the National Academies of Sciences (National Research Council and Institute of Medicine) documents on environmental contaminants and risks in children. Observational studies have a history over a past century in enabling continuous improvements in health protection.

Unfortunately, there has been a lack of clear communication about the nature of such studies, specifically concerning the appropriate scientific observational approaches used to obtain the necessary knowledge ethically. These studies do not increase risk. This misunderstanding has resulted in the underfunding and cancellation of observational studies, with the unintended consequence of decreasing our ability to protect children. For example, observational studies of pesticide exposure among children of farm workers have shown that these children are exposed, despite their parents' honest assertions that they avoid exposing their children. How many other unrecognized risk scenarios exist, even when well-intentioned regulations are being met? Without exposure science, our nation's children will continue to be at an un-quantified level of risk to hundreds of compounds known or suspected to have the ability to cause harm. We need to know, and to put it more strongly, not knowing is likely to be itself unethical. Thus, we are requesting that all those concerned about children's environmental health to actively support the efforts of conscientious scientists, acting ethically under the "Common Rule", to perform observational studies of children as they go about their daily lives. The resulting analysis of exposure data will go far in increasing the accuracy of risk assessments for children as well as improving approaches to prevent or reduce those risks.

ISEE response, next page...

**ISEE Statement on the White Paper titled:
*The Necessity of Observing Children's Exposure to Contaminants in Their Real-World
Environmental Settings***

The International Society for Environmental Epidemiology (ISEE) endorses the core recommendation stated in the White Paper entitled “**The Necessity of Observing Children’s Exposure to Contaminants in Their Real-World Environmental Settings**” that those who are concerned about children’s environmental health should actively support efforts of conscientious scientists, acting ethically under the “Common Rule,” to perform observational studies of children as they go about their daily lives. This White Paper was co-authored by an *ad hoc* group of senior scientists and has been endorsed by other professional environmental health societies. The White Paper has importance and relevance for advancing research in environmental epidemiology and related fields among the especially vulnerable, namely children. There are two additional points that the ISEE would like to be considered that are not explicitly addressed in the White Paper.

The Precautionary Principle states that if a proposed action or policy could cause severe or irreversible harm, in the absence of a scientific consensus that harm would not ensue, the burden of proof falls on those who would advocate the action or policy to first demonstrate its safety. The Principle implies that there is a responsibility to intervene and protect the public from exposure to harm where scientific investigation discovers a plausible risk in the course of having reviewed the evidence for other potentially more likely causes. The application of this Principle suggests that preventive measures should not be delayed for scientifically recognized hazards, while waiting for additional evidence from new observational studies.

Furthermore, consistent with the “Common Rule” for ethical conduct of research, scientists who conduct observational studies should modify or cease an observational study if the well-being of the study participants is found to be at risk during the conduct of the study. It is therefore not necessary or appropriate for legal jurisdictions to issue general statements in the form of legislation or regulation that would restrict legitimate observational studies from being carried out on children. We refer to our society’s ethics guidelines <http://www.iseepi.org/about/ethics.html> for additional background and emphasize the need to make special assessment and stringent criteria when research involves children in less developed countries.

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