

Biomonitoring Panel Report: Study Design, Interpretation & Communication

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Presented recommendations from Biomonitoring Workshop on study design, interpretation and communication. The panel was comprised of individuals with expertise in toxicology, epidemiology, statistics, medical toxicology, occupation medicine, and risk assessment. The panel's recommendations are now published in [Environmental Health Perspectives](#).

Study design –

Investigators need approval but also acceptance for human studies. There is a lengthy and sometimes involved process for IRB approval, which is necessary, but different from, acceptance from the public and stakeholders. EPA's CHEERS study had approval from IRBs, but a number of organizations objected to (i) the amount of money to be paid to participants (which appeared to be unduly coercive); and (ii) the partial sponsorship of the study by industry. Because of this, EPA has withdrawn the study.

Prioritization of chemicals – biomonitoring studies are typically limited by the volume of the sample and funding. Useful paradigm for selection of chemicals for study includes consideration of the chemical's ability to bioaccumulate, known exposures in susceptible populations, analytical capability, and suitable matrix for each chemical. New Hampshire received a biomonitoring planning grant from CDC. They selected several chemicals that they felt were of greatest concern for their population with validated methods of analysis and known links to human health concerns and the potential for biomagnification in humans.

Sample integrity – need to be concerned on collection, storage, transport, etc. for samples. Rat liver contamination by chromium from equipment used to homogenize the samples / need to evaluate breast pump chemicals for human milk biomonitoring studies.

Harmonization of study design for cross-study comparisons – would like to be able to compare across studies, cannot completely harmonize study designs, but need to at least consider for comparison. PCBs in breast milk example –if trying to compare results across breast milk studies, would need to take into consideration the number of days post-partum that the samples were collected.

Interpretation –

Risk assessment: questions have been raised regarding why are we struggling with biomonitoring data interpretation when risk assessment methods have produced acceptable levels of exposure to many environmental chemicals for many years? Risk assessment measures environmental levels, makes assumptions on how much a human is exposed to (e.g., via consumption, inhalation, dermal contact), combine concentration data with exposure to obtain a dose. Compare this dose to an EPA "acceptable" dose. For population considered, their exposure consumption is either above or below the "acceptable" dose and the appropriate action is taken. The difficulty in interpreting biomonitoring data is that it measures internal dose, but not what a person is exposed to,

which is what safe doses are based on. Need to determine the relationship between the two. This is difficult because we all handle (e.g., metabolize) chemicals differently – same exposure, different internal dose. Why can't we go from internal dose to adverse health effect? Because we measure matrices that are easily obtainable, not necessarily the target organ, not sure of the target dose. Would need the target tissue dose to determine the dose needed for an adverse health effect. Some chemicals are have sufficient data to such that we can estimate exposure based on internal dose (blood alcohol level and number of drinks consumed) and estimate health effects based on internal dose (e.g., blood alcohol level and physical/mental effects). Also blood leads have been well studied. Can move from blood leads to exposure, and from blood leads to health effects, health workers can move to action that will decrease blood lead.

3 challenges to predicting potential for adverse human health effects from environmental chemical exposure: 1) diverse properties of chemicals (risk assessors are good at 1 chemical at a time or similar chemicals, not good at many types of complex mixtures or other stressors, 2) time and dose parameters that define exposure to chemical and development of disease – linear, non-linear relationships, timing of exposure (thalidomide example) – can we extrapolate from select groups to the general public, 3) genetic and experiential diversity of human populations and surrogates for testing (rats). [Waters and Fostel]

Communication –

We need to understand our audience(s) to determine the best means of communication and the message suitable for those audiences. Pre-internet, studies were published in the scientific literature, other researchers would read and study further, data builds up. In the internet age, study is barely dry and anyone can read and interpret or misinterpret. Need to recognize who is interested in the research. Example – human milk – studies were published and data were mis-interpreted by mothers or others. Need to be able to communicate appropriately to a new mother. DDT studies have shown that high concentrations in human milk can affect the duration of lactation. Has heard the interpretation that a woman thinks that if she can't breast feed it is because she has contaminants in her milk.

The panel also noted that investigators should differentiate between statistically significant effects and clinically significant effects. Biomonitoring website – a good idea for comparing data. Panel noted that there is no established architecture for communicating population and individual based biomonitoring data (playground / arsenic example with pediatrician – they have no guidelines for testing and interpretations).

There is a rural physicians network to link rural physicians to larger medical facilities. Would be a good architecture to follow for biomonitoring data. EPA and ATSDR have funded PEHSUs many pediatricians are unaware of these units. Medical toxicologists are available as well. Resources are the limiting factor for creating a biomonitoring database for use in health effect interpretation.