

New Study Designs for Interpretation of Chemical Exposure Data

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Either through lack of power or systematic design flaw, data collected using standard designs are often ill suited to investigate complex exposures and outcomes adequately. Methods have been developed to analyze complex chemical mixtures and attempt to account for different sources of bias and unnecessary variability from data using traditional designs. However, the effectiveness of these techniques is limited by the data collection process, where new study designs would lead to data better suited to address the challenges posed by complex chemical mixtures. More suitable designs might be able to limit more complex statistical methods in lieu of more straight-forward techniques. These types of advancements in the study design phase will improve our ability to quantify relations between mixtures of chemical exposures and outcomes under the constraints of cost and complexity.

We will develop state of the art study designs to evaluate the impact of various types of chemical exposures on human health effects. These study designs will include case-time-control, case-crossover, two-stage, and the hybrid (pooled-unpooled) designs. Our aim is to explore and maximize already stated benefits of each while broadening their use for the investigation of biochemical exposures. Our emphasis will be on limiting difficulties specific to biochemical exposures, such as high cost of sample procurement and measurement leading to reduced power, intermittent exposures leading to risk of acute events, and accounting for the effects of multiple types of measurement error, specifically limits of detection and random measurement error. Appropriate sample size calculation methods will accompany all methods developed. Upon completion of the work, we will prepare peer reviewed scientific manuscripts. These papers are expected to document the epidemiological and statistical issues, offer statistical approaches for obtaining valid parameter estimates along with confidence intervals, and empirically demonstrate the utility of the proposed methodology. The panel of pre- and post-doctoral fellows has not yet been selected.

Implications: This study will offer DESPR investigators and external consultants an opportunity to develop new and innovative design approaches that account for the difficulties of high cost of sample procurement and measurement, measurement error and correlated exposures, among others. New designs will incorporate biomonitoring when possible to improve patient safety while conducting informative and efficient investigation of exposures and potential human health risks. These new study designs will provide researchers and external consultants with tools to investigate chemical exposures and associated outcomes with increased power, efficiency, and reliability, while remaining fiscally responsible. Employing these innovative designs for complicated chemical exposures data will enable improved decision making by researchers and policy-makers.

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