

SHANGHAI HEALTH STUDY

Overview

Purpose: To gain an accurate understanding of the relationship between benzene exposure and the risk of certain hematopoietic diseases. This study is an important element in the product stewardship programs of participating companies. It could also lead to improved, health-based regulatory (e.g., ambient air, water & occupational) standards worldwide, by providing the regulatory and scientific communities with additional information for more accurate assessment of the risks from exposure to benzene.

A unique set of circumstances exists at this point in time in Shanghai to conduct benzene research. These include a database of occupational exposures, and qualified co-investigators influential in local scientific medical, and regulatory establishments. Therefore, questions that have complicated benzene health risk assessment for decades may be addressed in Shanghai.

The Studies: The program involves three inter-related studies:

- Case-Control Study - A hospital-based case control study investigating the potential relationship between benzene exposure and both Non-Hodgkins Lymphoma (NHL) and Acute Myelogenous Leukemia (AML), including an attempt to quantify the potency of the AML response.
- Disease Progression Study - A hospital/clinic-based investigation of the potential relationship between non-cancer diseases of the bone marrow and AML to determine if effects on bone marrow progress through non-cancer stages to an ultimate leukemia. This study is also attempting to define the shape of the dose response for possible “precursor” diseases and could result in characterization of unique identifiers of benzene-induced AML.
- Molecular Epidemiology Study - Investigating if there is a quantitative relationship between benzene exposure and potential early indicators of both exposure and effect in a focused population of workers.

The investigators are leading experts in their fields, coming from such well-known institutions as the University of Colorado Health Sciences Center and Fudan University Medical Center. The combined studies apply cutting-edge, 21st century technologies in ways that will not only advance our understanding of benzene-induced disease, but may also identify potential prevention strategies for benzene-induced disease in individuals.

Benefits: Information gained from this project may have direct relevance for worldwide regulatory standards designed to protect workers and the general population from benzene-induced disease. These include air and water quality standards, as well as hazardous waste and site remediation standards. These studies will assist contributing companies in achieving the highest product stewardship goals and in oversight of their risk management programs.

Challenges: The proposed studies meet several technical, ethical, and cultural/political challenges.

- Technical - In order to stand up to scientific scrutiny, studies must be large, well-managed, and incorporate the latest technology. State-of-the-art research is absolutely necessary to make real progress in developing sound benzene risk assessments. To that end, a Scientific Review Panel made up of leading experts from a number of fields relevant to these studies has reviewed and endorsed the research protocols. Additionally, the protocols have been reviewed by Use of Human Subjects Committees (IRB) both in the US and China.

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- Ethical - To address ethical issues posed by the study, the protocols have undergone a thorough analysis to ensure that they meet international standards for research involving humans, including for example insuring that the subjects and the communities benefit from participating in the study; that confidentiality is preserved, and that participants are fully informed about the research to give their informed consent. An Ethics Panel is part of the oversight for the project. It includes bioethicists from the U.S., China and Europe.
- Cultural/Political – A key to this program's success is local partnerships. Collaborators on these studies include researchers from the Medical School at Fudan University, the Institute for Public Health Supervision, and the Shanghai Municipal Centers for Disease Control and Prevention (the latter two are governmental agencies responsible for occupational exposure monitoring and enforcement in Shanghai).

Funding: Funding for the project is being provided by a consortium of interested oil and chemical companies. It is anticipated to take five years to complete the project, and that the costs are highest in the first years of the project.

For More Information: Please contact any one of the following individuals.

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Summary of Ethics Review Panel Roles and Responsibilities

ETHICS REVIEW PANEL (ERP)

Initial membership of the ERP was determined by the Business Oversight Committee. Members are experts in bioethics. The ERP members are responsible for adding appropriate members as appropriate. It should consist, at a minimum, of members drawn from the U.S., from Europe, and from China. The ERP makes recommendations to ensure that the research meets internationally accepted ethics standards and reflects relevant cultural or other patterns in Shanghai. It reviewed the protocols, recommending changes that were incorporated to meet international guidelines. It has also reviewed the consent forms, and other aspects of the research ethics, to ensure that recommendations of the ethics review process had been incorporated. It will review any relevant changes before they are implemented. It will also periodically review the conduct and progress of the research to see that the ethics standards are being followed. ERP members are available to respond as needed to issues raised by the investigators, the Scientific Review Panel or the company sponsors.

ERP members:

Dr. Xu Zong-Liang, Dean, Faculty of Humanities and Social Sciences, Fudan University Medical Center; Director, Bioethics Research Center, Fudan University Medical Center

Dr. Juhana Idanpaan-Heikkila, World Health Organization, Geneva, Switzerland