



The Shanghai Health Study

Benzene Health Research Consortium

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Why is Understanding Benzene Important?

- Benzene exposure is universal
- Advancing current scientific understanding of benzene exposure would be a significant contribution to health and worker safety
- Understanding health effects of low-level benzene exposures would improve benzene risk assessments

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Recent Epidemiological Studies

- National Cancer Institute Shanghai Study (NCI) – case-control study published in 1997
 - Benzene associated with AML and Non Hodgkin's Lymphoma (NHL): association with a non-AML cancer
 - Study design did not add to understanding of threshold (lowest exposure group was 10 ppm or less)

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Recent Epidemiological Studies

- Australian Institute of Petroleum's (AIP) Health Watch Study – case-control study released in 2001
 - ≡ Association with all leukemias, including chronic lymphocytic leukemia
 - ≡ No association with NHL or multiple myeloma

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Observations on Current Science

- No definitive epidemiological evidence to define a threshold
- NCI and AIP studies conflict with earlier studies by associating benzene exposure with non-AML cancers (NHL and CLL)
- SHS designed to quantitatively address these issues

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Shanghai Health Study Purpose

- To gain a quantifiable understanding of the relationship between benzene exposure and potential associated cancer risks
 - ≡ Researchers will use cutting-edge technologies to advance the understanding of benzene-induced disease

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Quality Science, Sound Ethics

- All protocols reviewed and approved by external Institutional Review Boards (IRB's)
 - Govern use of human subjects
 - U.S. and China independently
- Shanghai Health Study panels
 - International Independent Ethics Expert Panel
 - International Independent Scientific Expert Panel
 - 12 members
 - 6 scientific disciplines
- Expert panels will participate during entire course of studies

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Scientific Review Panels

General Toxicology and Biochemistry	Dr. Jerry R. Rice, [Chair], IARC; Dr. Nadine Grzes, Technical U. of Munich
Epidemiology	Dr. Nancy Mueller (Vice Chair), Harvard U., Public Health; Dr. Harvey Checkoway, WA U.
Statistics	Dr. Howard Rockswold, U. of Pittsburgh
Industrial Hygiene	Dr. John Cherni, Aberdeen U., Inst. Of Occ. Medicine; Dr. Robert F. Harnick, Harvard U., Public Health
Hematology	Dr. Richard Larson, U. of Chicago Medical School; Dr. Mark Henden, U. of Toronto
Genetic Toxicology	Dr. Li Sullen, Chinese Academy of Preventive Medicine; Dr. Richard Albertini, U. of VA, College of Medicine
Ethics Review Panel	Dr. Samuel Brody (Chair), Baylor College of Medicine; Dr. Sakuma Masayoshi-epidemiology, WHO; Dr. Bo Zeng-Liang, Peking University

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What is the Shanghai Health Study?

- A long-term clinical study to investigate the potential cause and development of lympho-hematopoietic diseases (diseases of the lymphoid organs, blood and bone marrow)
- A project of Fudan University Medical Center; Colorado Health Sciences Center, University of Colorado; Applied Health Sciences - an independent U.S. research firm; Chinese public health agencies; and Shanghai hospitals

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Why Shanghai?

- Unique Study Environment
 - Databases documenting exposure
 - Exposure across industries
 - Range of exposure levels
- Committed Collaboration
 - Chinese government
 - University and hospital based researchers
 - Community hospitals
 - Shanghai Municipal Center for Disease Control and Prevention
 - Institute for Public Health Supervision

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Current SHS Status

- State-of-the-art laboratory constructed on Fudan University campus; complete early 2003
 - Sustainable technology transfer an important project design component
 - Chinese staff receiving training at University of Colorado
- Questionnaire development, pilot testing in progress
- Case recruitment begins -- 1st quarter, 2003
- Research and analysis -- 2003-2007
- Results published upon project completion

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SHS Funding

- \$22.8 million program total for all costs over 5 years
- Initial budget lower
- Increased to \$22.8M in response to ethics and science recommendations of independent panels

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Who is Sponsoring the SHS?

- A consortium of petroleum and chemical companies concerned about understanding the human health effects of benzene
 - ≡ British Petroleum, Chevron/Teraco, ConocoPhillips, ExxonMobil, Shell
 - ≡ Other members being recruited
 - ≡ American Petroleum Institute, project administrator
- Individual company product stewardship and corporate responsibility programs

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Why Participate

- Study will advance benzene health science; results will be referenced by government and industry policy makers
- Responsible product stewardship and workplace stewardship
- Organizational knowledge gained from collaboration in high quality international health research
- Visibility with Chinese government and communities; international health agencies
- Participation includes regular updates, Technical Committee membership, interactions with sponsors and investigators

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Shanghai Health Study

Summary

- Opportunity to obtain a better understanding of the mechanism of benzene induced disease in humans.
- Significant impact on benzene risk assessment.
- Highest Quality of Science:
 - ≡ employ state-of-the-art biological and epidemiological science
 - ≡ represent sound product stewardship
 - ≡ exemplify best practices in research ethics
 - ≡ depend upon partnership of industry, governments, academia and public

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