
 *The Shanghai Health Study*


Benzene Health Research Consortium

February 1, 2003 4

 *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

February 1, 2003 2

 *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)

February 5, 2003 3

1

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

February 6, 2002

2

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

February 6, 2002

3

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

February 6, 2002

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

February 3, 2003

Scientific Review Panels

General Toxicology and Biochemistry	Dr. Jerry R. Rice, [Chair], IARC; Dr. Helmut Grotz, Technical U. of Munich
Epidemiology	Dr. Nancy Mueller (Vice Chair), Harvard U., Public Health; Dr. Harvey Ostrachow, WA U.
Statistics	Dr. Howard Rockwell, U. of Pittsburgh
Industrial Hygiene	Dr. John Cherni, Aberdeen U., Inst. Of Occ. Medicine; Dr. Robert F. Herwick, Harvard U., Public Health
Hematology	Dr. Richard Larson, U. of Chicago Medical School; Dr. Mark Hensler, U. of Wisconsin
Genetic Toxicology	Dr. G. S. Sullivan, Chinese Academy of Preventive Medicine; Dr. Richard Albertine, U. of VT, College of Medicine
Ethics Review Panel	Dr. Sarah Brody (Chair), Baylor College of Medicine; Dr. Jinhua Ma, Fudan University

February 3, 2003

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

February 3, 2003

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

February 3, 2003 10

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

February 3, 2003 11

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

February 3, 2003 12

 *Who is Sponsoring the SHS?*


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

February 3, 2003 13

 *Why Participate*

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

February 3, 2003 14


 *Shanghai Health Study*

Summary

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

February 3, 2003 15

2/3/2003


For More Information

- Bill Frick, API
 - 202.682.8240
 - Frick@api.org
- Myron Harrison, ExxonMobil
 - 972.444.1673
 - Myron.c.harrison@exxonmobil.com
- Lorraine Twerdok, BHRC Administrator
 - 202.682.8344
 - Twerdok@api.org

February 3, 2003 14
