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-----Original Message-----
From: **Clegg, Patsy M SCC-CHSE-PC**
Sent: Thursday, 29 August, 2002 23:33
To: Wood, Nick N SCHINA-EA
Cc: Sullivan, Nancy E SCC-CBAR; Colletti, Sarah J SCC-CSEA
Subject: Shanghai Benzene Health Study

Nick,

I was given your name by Sara Colletti as the appropriate person to contact to begin discussions on informing the right people involved with the Nanhai project about a large benzene health study being co-sponsored by Shell Chemicals in Shanghai China. Nancy Sullivan, VP of the Aromatics/Phenol PBU, is the business sponsor. I represent Shell on the oversight committee for the consortium sponsoring the study. We also have representatives on the technical, communications and legal committees. As a starting point, I am sending you the pre-reading and slides used at a recent presentation to US oil and chemical high level staff including Fran Keeth, EVP for Customer Fulfillment in Shell Chemicals and CEO of Shell Chemical LP in the US; Nancy Sullivan; Al Schmidt, manager of HSE Product Stewardship for the former Equiva (now Shell Oil Products) representing Judy Moorad, VP HSE; Alistair Fraser, Medical; and US Shell Chemicals Issue Management. I would like the opportunity to discuss this project with you and develop a plan to keeping the Nanhai project people updated.

<< File: Shanghai Benzene Health Study - Summary.doc >> << File: China basic intro talk 7-02.ppt (Compressed) >>
Best regards,

Patsy Clegg
Product Steward
Shell Chemical LP
One Shell Plaza, 910 Louisiana, Houston, TX 77002-4916

Tel: +1 713 241 2521 **Fax:** 3325
Email: pmclegg@shellus.com
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-----Original Message-----
From: Colletti, Sarah J SCC-CSEA
Sent: Thursday, August 29, 2002 10:06 AM
To: Clegg, Patsy M SCC-CHSE-PC
Subject: FW: benzene study

-----Original Message-----
From: Wood, Nick N SCHINA-EA
Sent: Thursday, May 23, 2002 6:43 PM

To: Colletti, Sarah SJ SCC
Cc: Wang, Yean-Sung YS SC-CXHC; Briggs, Barnaby D SC-CSEA; Freer, Jacky J SC-CSEA; Tan, EkKia EK SCHINA-CH; Vong, Tanny VK SCHINA-EAG; Ng, Nicholas WK SHELHK-CHOS
Subject: RE: benzene study

Sarah,

Indeed we have several major projects with Sinopec involving EP, OP and GP. We supported their IPO in 2000 and have a Strategic Alliance with them that includes a number of projects, the biggest of which is a 500-station retail joint venture in Jiangsu in East China.

I copy in Tanny, who can advise you further as our government affairs manager.

I am still waiting for a few more details of this multimillion dollar study in China, about which we were not informed. This would be a good starting point.

Nick

From: Colletti, Sarah SJ SCC
Sent: Thursday, May 23, 2002 11:09 PM
To: Wood, Nick N SCHINA-EA
Cc: Wang, Yean-Sung YS SC-CXHC; Briggs, Barnaby D SC-CSEA; Freer, Jacky J SC-CSEA
Subject: benzene study

Hi Nick,
Does Shell have any dealings with SINOPEC?
If so, do we (the consortium of companies working on the benzene shanghai study)need to approach them about the Shanghai Benzene study that is being planned.?
Are there sensitivities we should know about?
If we should approach, what would be the best way to do it?

This is all for the purpose of planning a communication strategy around the study....

Any advice would be most appreciated..
Thanks,
Sarah

Shanghai Health Study

Sponsored by

Benzene Health Research Consortium

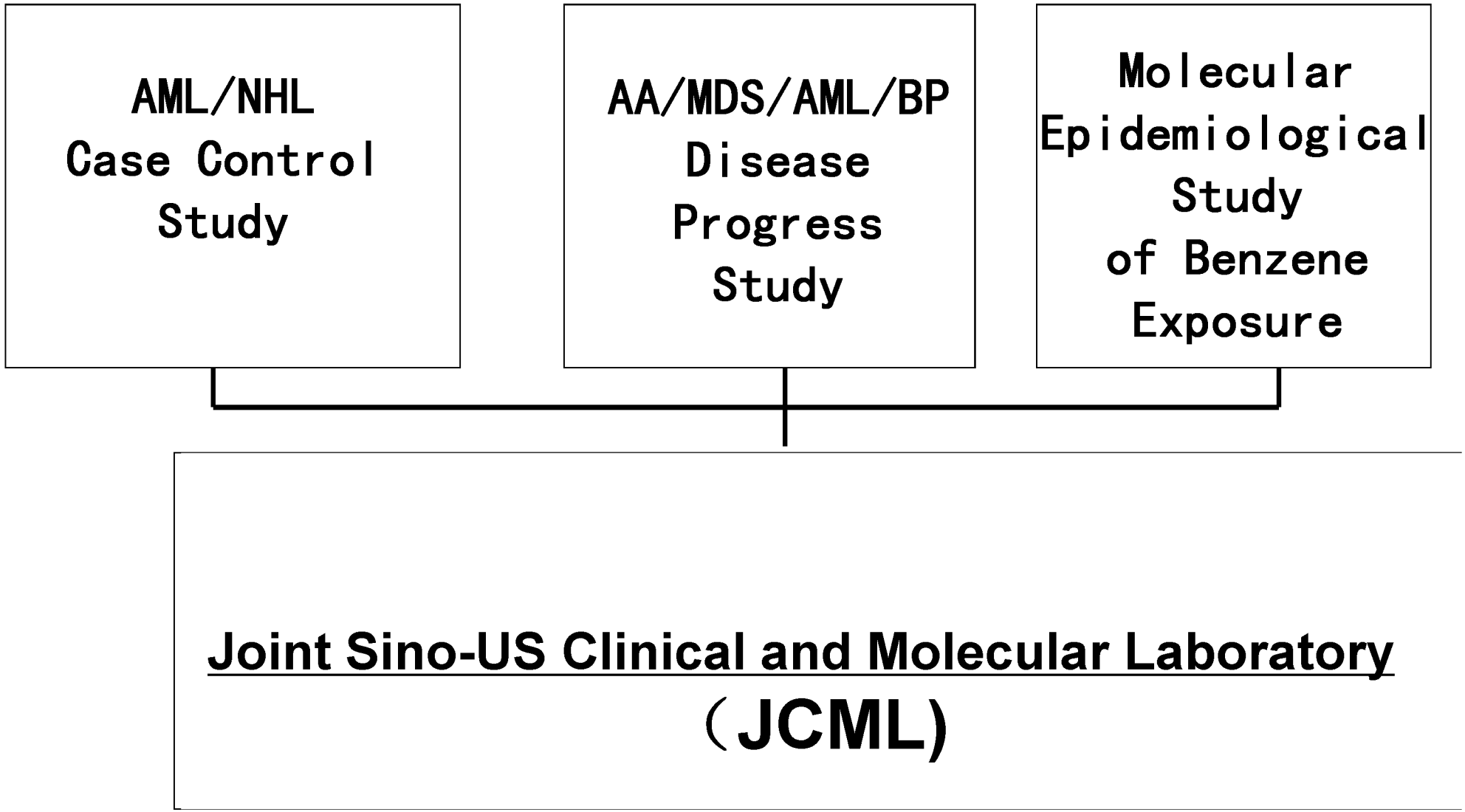
Shell Update

April 2004

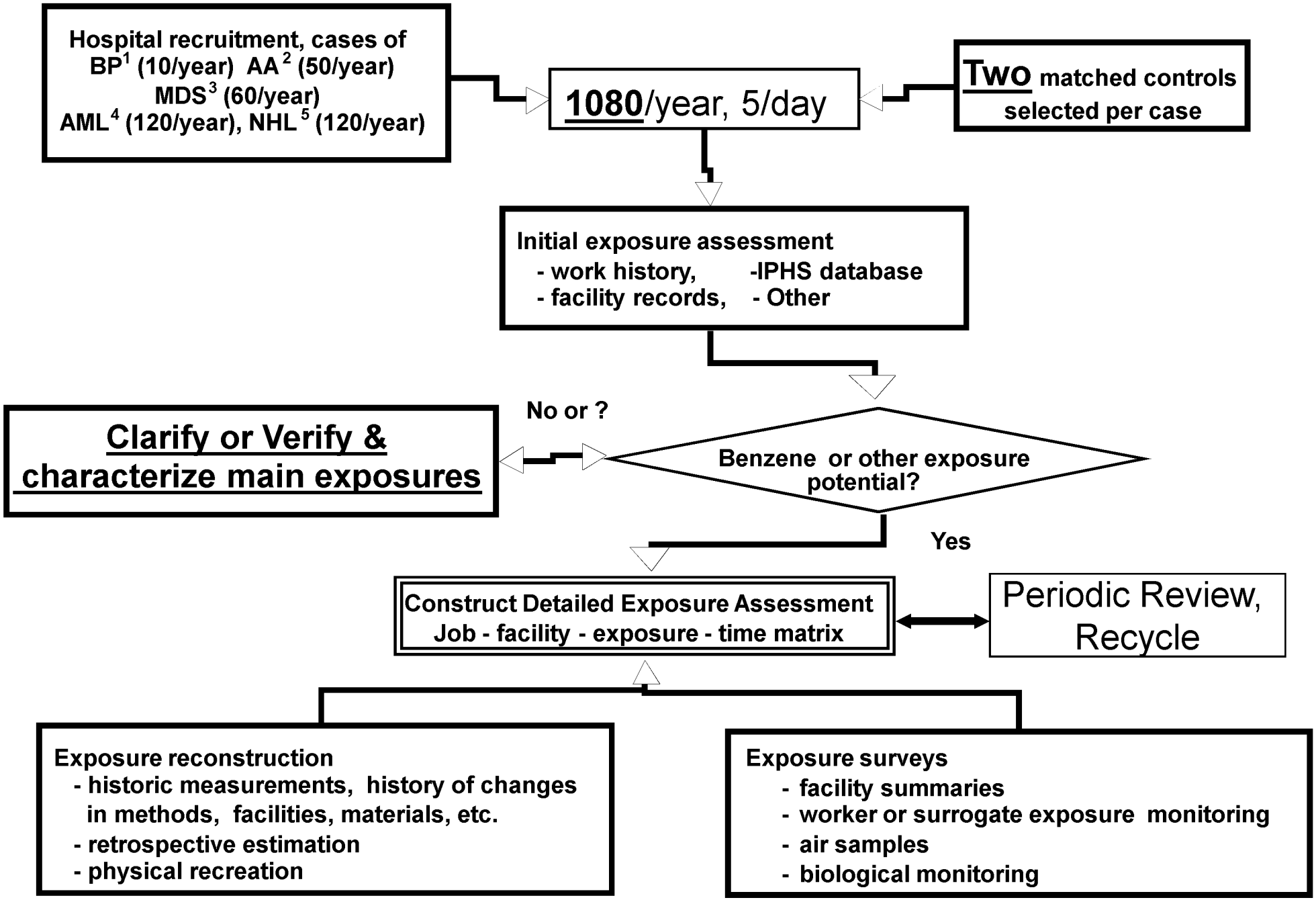
Shanghai Health Study

- Program
- Current status of studies
- Program management
- Communication and outreach
- Shell activities
- Opportunities

Health Effect Study of Benzene in Shanghai



AML/NHL & DP Exposure Assessment Overview



Shanghai Health Study
Current status of studies

- Study began accruing cases in July 2003 – meeting expected case targets: 26 hospitals participating
  - Cases versus expectations as of December 2003: BP (0 vs.10/yr), AA (17 vs. 50/yr), MDS (26 vs. 60/yr), AML (42 vs. 100/yr), NHL (66 vs. 120/yr). Diagnosis of laboratory versus secondary pathology review high, > 90 %.
- Investigators considering protocol revisions, with scientific review, both University Institutional and Consortium Science Review Panel (SRP). Exposure assessment a current focus of the SRP.
- Process underway to replace chair of Ethics Review Panel . Seeking new US member along with current members (China and EU).

Shanghai Health Study
Program Management

- Budget planning
  - Budget revised to meet new funding level, $21.08M
  - Quarterly financial report format expanded to include study milestones (cases accrued).
  - Investigators working on reporting costs and cost projections based on accrual rates for improving spending rate estimates.
  - Current budget spending projections suggest additional consortium member payments not required until 2005 or perhaps 2006 (to be clarified by 2Q04).
- Contract reviews completed
- API-BHRC contract currently being revised
- External Stakeholders Engagement
  - Consortium meeting - April 2004.

Shanghai Health Study Communication and Outreach

- First Annual Meeting was a success
- Launch event celebrating completion and start up of the laboratory – December 2003
- Stakeholder Engagement to begin
- API Engagement – Ed Murphy, Downstream, HES, Subscription Projects
- Next annual meeting – August 2004
- Annual meeting in Shanghai - Nov 2005

Shanghai Health Study Communication and outreach

- Stakeholder Engagement discussions Beginning discussions identified a broader range of intentions of consortium members than anticipated. Next meeting April 21-22 to align intentions and/or reach understanding.

Shanghai Health Study Communication and outreach

- Shell intentions to be based on:
  - Protecting reputation – in China and around the world.
  - Protect relationships/investments in China.
  - Meet commitment to transparency and ethics.
  - Protect credibility of project and participants.
  - Raise awareness and understanding of the project.
  - Secure buy-in and constructive feedback into the process.

Shanghai Health Study
Shell Activities

- Comprehensive Shell internal communication plan has been drafted, includes:
  - Global Shell engagement on regular basis
  - Quarterly updates
  - Issues management process
  - Ongoing connection to Shell China external affairs team.
  - E-news (on a quarterly basis).

Opportunities

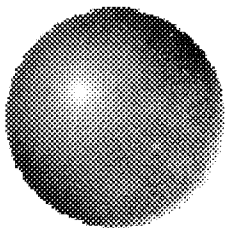
- Opportunities for enhanced outreach and communication:
  - Shell currently holding consortium leadership positions:
    - Patsy Clegg - consortium oversight committee Chair
    - Stuart Cagen - technical committee Vice-Chair and Chair of finance committee
    - Shan Tsai - adjunct professor, Fudan University
- Shanghai Benzene Study contributes to a larger global benzene industry research effort:
  - Benzene Symposium – Munich, Germany - October 2004
  - CONCAWE benzene epidemiology meta-analysis - ongoing.
    - Shell participation via Health Services

Nela Briefing Points:

- **Important Study** – This study will have implications in the following ways:
  - Efforts to engage and manage stakeholder concern about Shell's impact on community/fenceline/product health issues
  - Reputation and position in China
  - OP has benzene in its feedstocks and gasoline (consumer exposure)?
  - Identify health impacts and level of exposure at which effects are seen
  - Provide data to determine whetherprotocols and business practices need to be adjusted
  -
  - Protect reputation on Benzene
- Shell and other Consortium members have some **recommendations for improving process:**
  - API management – further document review and control to ensure consistency of message
  - Project management
    - Cost management/controls
    - Scope creep
    - Stakeholder engagement- proactive strategy
- **Next Steps aimed toward implementing recommendation above (for internal Shell discussion only)**
  - Nancy Sullivan will engage business equivalent consortium members
  - Participate in consortium/API discussion about closing the financial gap
  - Sarah and Lauren are taking proactive role in developing stakeholder engagement/public affairs strategy
  - Chemicals is lending support to help build financial control structures (Tarita's time)
  - The Benzene PBU budgeted funds in draft 'tox' budget for next year
- **Nela/OP's role for API Meeting: June 19th**
  - Talking Points:
    - Reiterate the importance and benefits of the study for the industry as a whole
    - API's financial support is important
      - (footnote: The five participants contributed significantly (16.5MM); those members pay 80% of the API dues)
    - The whole industry will benefit from the study findings

Issues: may be raised at meeting

- ***Why is Shell Oil not participating?*** Governance/timing issue – different OUs have different focuses – Shell Chemical is the biggest stakeholder in Royal Dutch; ranking #2 in Benzene market.
- **Why isn't ACC providing support?** Ten years ago, ACC and API decided to allocate responsibility for products – API got Benzene and ACC got BD.

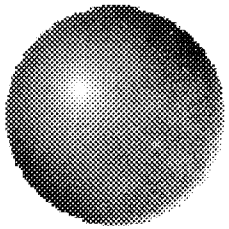


The Shanghai Health Study

Sponsored by:

Benzene Health Research Consortium

Presentation Topics



- Shanghai Health Study Overview
- Shanghai Solutions
- Current Benzene Science
- Shanghai Health Study Elements
- Shanghai Health Study Sponsors
- Shanghai Health Study Funding Structure
- Shell Steering Team
- Study Challenges

What is the Shanghai Health Study?

- A long-term clinical study to investigate the potential causes and development of lympho-hematopoietic diseases (diseases of the lymphoid organs, blood and bone marrow) as related to benzene

- A project of Fudan University Medical Center; University of Colorado Health Sciences Center; Applied Health Sciences - an independent U.S. research firm; Chinese public health agencies; and Shanghai hospitals

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

Why Shanghai?

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

Unparalleled Collaboration

- "This study is an enormous collaborative effort, unlike anything American and Chinese researchers have ever done."
  - Dr. Richard Irons, PhD, SHS principal investigator, professor and director of the University of Colorado's Molecular Toxicology and Environmental Health Sciences Program

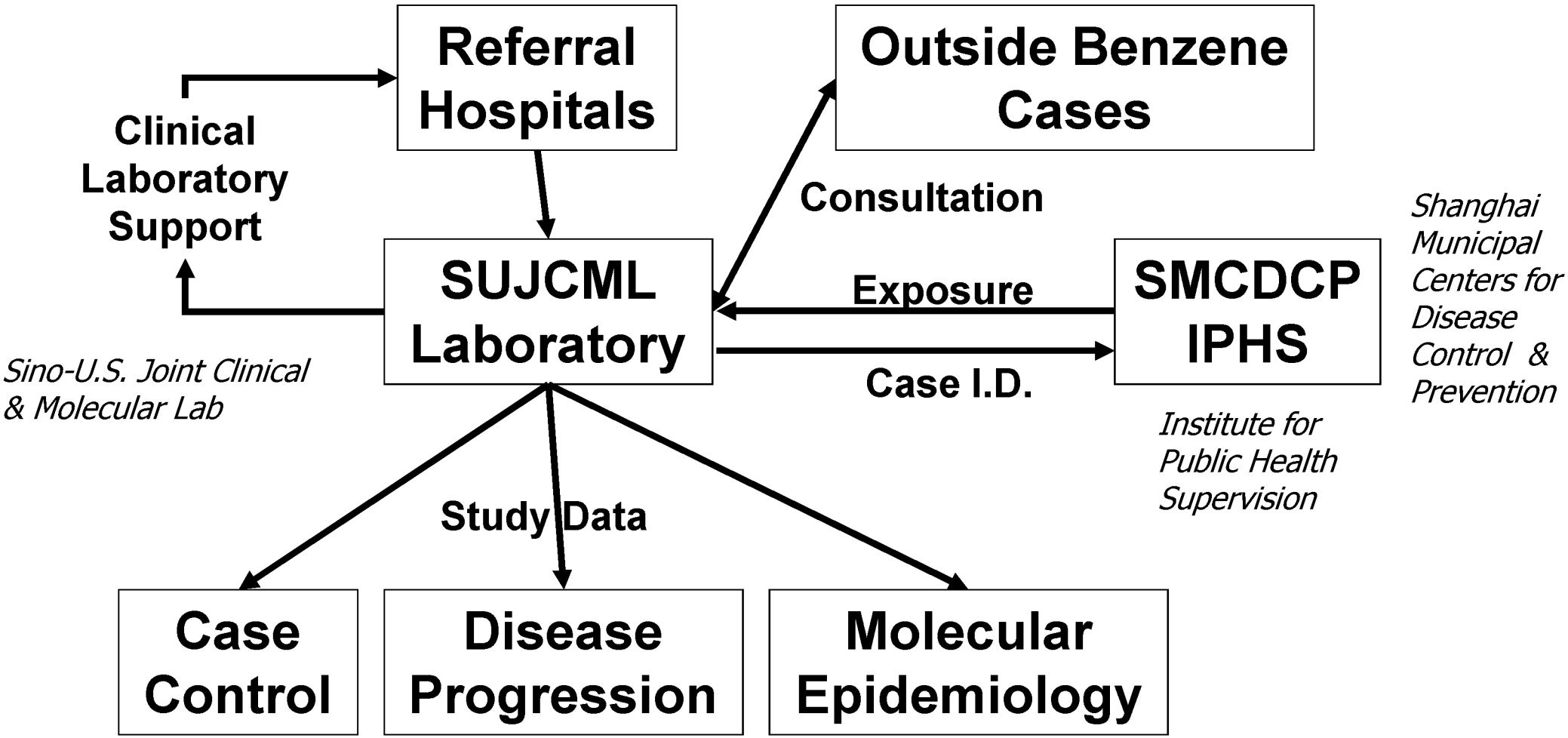
Difficulties in Past Benzene Research

- Animal models do not replicate human benzene-related diseases
- Retrospective research
  - Review case files of people who have died
  - Rely on inexact diagnoses
  - Accuracy of reconstructed exposure data
  - Guess at lifestyle and dietary habits

How is the SHS Distinct?

- Prospective research
  - Patients at participating hospitals suspected of having a lymphoid, blood or bone marrow disease will be referred to the SHS
  - Patients' diets, environmental exposures and family histories will be recorded
  - Patient disease progression followed at supporting hospitals

Shanghai Health Study



How is the SHS Distinct?

- Study will be able to examine primary diagnostic and medical data in real time
- First-hand exposure reports are more reliable than second-hand or reconstructed information
- State-owned databases document worker histories

Shanghai Solutions

- Unique Study Environment
- Unparalleled Collaboration
- Shanghai Health Study Genesis
- Rare Opportunity
- Shanghai Health Study Partners
- Shanghai Health Study Hospital Partners
- Sino-U.S. Joint Clinical & Molecular Lab

Unique Study Environment: Shanghai

- Robust data set
  - State-maintained benzene exposure and health effects databases documented from 1970s
  - Benzene related health effects are #2 in reported chronic occupational health hazards in China in 2001 (*Source: Ministry of Public Health*)
  - Large range of exposure levels from a variety of occupational sources
- Regulatory authorities interest in improving benzene exposure regulation and enforcement

Unique Study Environment: Shanghai

- China interested in scientific basis for improved worker-safety regulations
  - Chinese occupational standards based on measurable human health effects
- Chinese Occupational Diseases Protection Law *(effective May 1, 2002)*
  - Increases worker protections
  - Specifies company role regarding worker health problems resulting from occupational exposures
  - Benzene receiving additional scrutiny

Unique Study Environment: Shanghai

- High interest in collaborating on research
  - Technology transfers
  - International health standards
  - State-of-the-art lab/ equipment
  - Shanghai hematology/pathology communities support and expertise
  - Strong research program supports China's regulatory understanding and objectives

Unique Study Environment: Shanghai

- Fudan University Medical Center
  - Research partnership with a leading research university
- Community participation
  - 30 hospitals will refer patients to the SHS
  - Shanghai Municipal Center for Disease Prevention and Control
  - Shanghai Institute for Public Health and Supervision

SHS Genesis

- NCI/CAPM study in Shanghai
  - Retrospective study published 1997
  - Raised new questions on effects of low-level benzene exposure
- Assessed feasibility of building on Shanghai experience
- Three distinct, highly integrated studies designed

Rare Opportunity

- Unique data set
- Technological advances
- Early, consistent detection and diagnosis of leukemias and related diseases in Shanghai
- Identification of more sensitive benzene exposure biological markers
- Convergence of company and local Shanghai research interests

Shanghai Partners

- Fudan University Medical Center
- Institute for Public Health Supervision
  Shanghai Public Health Bureau
- Shanghai Hematology Society
- Shanghai Pathology Society
- Shanghai Municipal Centers for Disease
  Control and Prevention

Epidemiology Conclusions pre-1997

- Acute Myelogenous Leukemia (AML) associated with benzene
  - No risk at exposures < 1ppm
  - Clear risk at exposures > 20 ppm
  - Insufficient data at 1-20 ppm to assess risk
- Some steps are not dose-dependent and are governed by a threshold mechanism
- All steps required for induction of cancer have not been determined

U.S. Regulatory Interpretation

- Regulatory decisions based on no-threshold assumption
- More research needed to assess threshold assumption

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): unusual association with a non-AML cancer
  - Study design did not add to understanding of threshold (lowest exposure group was 10 ppm or less)

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

SHS Elements

- Case Control Study
- Disease Progression Study
- Molecular Epidemiology
- Quality Science
- Scientific Review Panels
- Current Status
- Scientific and Ethical Reviews
- Projected Timeline

Specific Study Goals

- Understand relationship, if any, between benzene exposure and development of specific hematopoietic diseases: AA, MDS, AML and NHL
  - Causation of specific diseases/subtypes
  - Mechanism of disease progression
  - Dose-response relationships
  - Identification of cofactors and confounders
  - Identification of biomarkers of exposure and disease progression

Study #1 - Case Control Study

- Traditional epidemiology study to determine risk of AML, and potentially NHL, among benzene exposed workers
- Data collected will allow analysis of other causal factors for NHL
- Estimate 4 to 5 years to obtain 450 AML and 450 NHL patients into study
- Improved exposure assessment based on historical and concurrent workplace monitoring and questionnaire

Study #2 - Disease Progression

- Prospective study on relationship of non-cancer bone marrow disease and benzene-induced AML
  - Is benzene-induced AML different from spontaneous AML by unique cellular markers?
  - Does AML involve a progression through one or more non-cancer states?
- Research methods: questionnaires, interviews, review work histories; examine blood, breath, urine; study/evaluate potential biomarkers

Study #3 – Molecular Epidemiology

- Prospective study to establish quantitative relationship between exposure and effect
  - Do low benzene exposures cause blood effects?
  - Is there an association of blood effects and genetic susceptibility?
  - Do biomarkers of exposure accurately reflect workplace exposures?
- Healthy workers at sites with varying levels of benzene exposure will participate; extensive lab work, including genetic tests, will be conducted

Quality Science

- 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 Ethics Expert Panel
  - International Scientific Expert Panel
    - 12 members
    - 6 scientific disciplines
  - Involved during entire project

Current SHS Status

- State-of-the-art laboratory constructed on Fudan University campus
  - Sustainable technology transfer an important project design component
  - Built according to international standards
  - Lab will support the project, Shanghai medical community and remain at Fudan
- Technology transfers
  - Chinese staff receiving training at University of Colorado
  - U.S. researchers worked with Chinese colleagues and government officials to finalize methodologies, questionnaires, etc.

SHS Projected Timeline

- Questionnaire development, pilot testing, 2002
- Key laboratory personnel trained, 2002
- Laboratory completed, early 2003
- Case recruitment began – 3rd quarter, 2003
  - 1600 benzene exposed workers, 400 controls
  - Time necessary to identify qualified patients
  - Length of study may be extended if required
- Opening Ceremony – Dec, 2003
- Research, analysis expected 2003-2007
- Results published upon project completion

Who is Sponsoring the SHS?

- A consortium of petroleum and chemical companies concerned about understanding the human health effects of benzene
  - British Petroleum, ChevronTexaco, ConocoPhillips, ExxonMobil, Shell
    - Marathon/Ashland providing additional support
  - American Petroleum Institute, project administrator

Why Industry Sponsors?

- SHS goal to provide an accurate understanding of how benzene works on a molecular level in humans
  - Product stewardship and corporate responsibility programs
  - Advanced understanding of benzene-induced disease could lead to development of effective disease prevention strategies
  - Would allow a more finely calibrated assessment of potential health effects
  - Provide best protection for workers and public

Why Industry Sponsors?

- Worldwide, benzene occupational exposure regulatory standards vary widely
  - 0.5ppm in Malaysia; 1.0ppm in U.S.; 10ppm in Japan
  - American Conference of Governmental Industrial Hygienists recommends 0.5ppm
- Industry has long sponsored benzene research

SHS Funding Structure

- $20.8 million program total for all costs over 5 years
  - Sponsor allocation originally based on refinery production capacity in Oct 2000.
  - Additional funding committed in 2003 based on % of original commitment
  - $16.5 paid by sponsors thus far

Conclusions

- Study will advance benzene science
- Sponsors funding study
  - Product stewardship
  - Corporate social responsibility goals
- Anticipate results published 2007/8
- Results will add to accepted body of scientific research on benzene
  - Referenced by government, industry decision-makers

Shell Team

- Steering Team: Business sponsor, HSE, EA, legal, finance, OP
- Shell Reps to consortium
  - Patsy Clegg, Oversight Committee
  - Stuart Cagen, Technical & Budget Committees
  - Shan Tsai, Technical
  - Sarah Colletti, Communications
- Shell Financial Commitment: $4.1MM

Shell Strategy

- Issue Management: On CEC, CMD Issue list
- Quarterly communication to a broad distribution
- Active participation in consortium

Stduy Challenges

- Exposure Assessment
- Sustainability of lab when study is concluded
- Budget