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**New York City Department of Health and Mental Hygiene  
Agency for Toxic Substances and Disease Registry  
*World Trade Center Health Registry***



**Proceedings: Expert Panel on  
Public Health Registries**

*May 13, 2004*

<b>Table of Contents</b> .....	<b>Page</b>
<b>Executive Summary</b> .....	4
<b>Introductions</b> .....	8
Thomas Frieden, M.D., M.P.H. New York City Department of Health and Mental Hygiene <b>Importance of this expert panel to the WTCHR</b> .....	8
Henry Falk, M.D., M.P.H. Agency for Toxic Substances and Disease Registry <b>History of environmental registries at ATSDR</b> .....	9
Robert Brackbill, Ph.D., M.P.H. New York City Department of Health and Mental Hygiene <b>Overview of the WTCHR</b> .....	10
<b>Presentations on Domestic Environmental Exposure Registries</b> .....	11
G. David Williamson, Ph.D. Agency for Toxic Substances and Disease Registry <b>The National Exposure Registry (NER)</b> .....	11
Sharon Campolucci, R.N., M.S.N. Agency for Toxic Substances and Disease Registry <b>The Tremolite Asbestos Registry (TAR) and The Rapid Response Registry</b> .....	13
<i>Discussion</i> .....	14
<b>Post-Disaster Domestic Registries</b> .....	15
Krishnan Ramaswamy, M.Sc., M.S. Pennsylvania Department of Health <b>Three Mile Island Registry</b> .....	15
Sheryll Brown, M.P.H. Oklahoma State Health Department <b>Registry of Persons Exposed to the Oklahoma City Bombing</b> .....	17
<i>Discussion</i> .....	19
<b>International Registry Experience</b> .....	19
V. Ramana Dhara, M.D., Sc.D., M.P.H. Rollins School of Public Health and Morehouse School of Medicine <b>Bhopal Disaster and Aftermath</b> .....	19

C. Joris Yzermans, Ph.D. Netherlands Institute for Health Services Research <b>The Netherlands: Health Impact Assessment of Disaster</b> .....	21
— <b>Airplane crash in Amsterdam, 1992</b>	
— <b>Fireworks depot explosion</b>	
<i>Discussion</i> .....	24
<b>Longitudinal Health Study</b> .....	24
Francine Grodstein, Sc.D. <b>Brigham and Women's Hospital Nurses' Health Study</b> .....	24
<i>Discussion</i> .....	25
<b>Group Discussion — Applying what has been learned to the WTCHR</b> .....	26
Recruitment	
Follow-up and Retention Methods	
Outreach and Risk Communication	
Analysis	
<b>Final Comments</b> .....	31
<b>Summary of Final Recommendations</b> .....	37
<b>List of Attendees</b> .....	38

## Executive Summary

Immediately following the World Trade Center terrorist attacks of September 11, 2001, the New York City Department of Health and Mental Hygiene (DOHMH) and other environmental health experts became concerned about several health issues of the exposed populations. First, it was not immediately known what environmental toxins were released from the building collapse and ensuing fires, and how such toxins or irritants would affect the health of residents and office workers in the vicinity, and emergency responders. Second, there was equal concern about the mental health needs of the population attacked as well as those responding. Additionally, there were concerns about the injuries suffered by survivors and responders. After deliberations between NYC DOHMH, the Environmental Protection Agency (EPA), the Agency for Toxic Substances and Disease Registry (ATSDR), and the Federal Emergency Management Agency (FEMA), it was decided that a registry of persons exposed to the dust, airborne particulates, and fumes from the fires and the events of 9/11 was necessary to document baseline health and mental health status; and would be an investment in the City's ability to understand any long term health effects.

Registries have been used for over 30 years to study the extent of health problems from exposures to environmental contamination and disasters. A registry, unlike most epidemiological studies, allows participation of all exposed persons willing to enroll. Registries can enable long-term evaluation of health effects, since subjects for more structured studies can be selected from the registry cohort.

Funding for the World Trade Center Health Registry (WTCHR) was granted by FEMA to ATSDR in July 2002 to assist the NYC DOHMH set up a Registry. After extensive careful planning and expert consultation on the development of the scientific approach the WTCHR began data collection on September 5, 2003. Data collection continued through November 20, 2004. Over 70,000 persons were registered.

Half way through the registration period, Registry staff from DOHMH and ATSDR convened a panel of experts to examine the experience of other environmental and post-disaster registries and to advise the WTCHR on its final recruitment, retention of participants, follow-up studies, and analysis. This report contains the proceedings of that meeting, held May 13, 2004 in New York City.

### Charge to the Expert Panel

Experts who had implemented or managed registries were invited to present their experience and to answer questions posed by the Commissioner of NYC DOHMH, Dr. Thomas Frieden:

- What key issues had they faced in the development and maintenance of their respective registries?
- How were these issues dealt with?
- What worked? What didn't work?
- What would the experts recommend on recruitment issues, analyzing a potentially skewed sample, keeping registrants informed and involved, and reducing attrition rates.

### Summary of Presentations and Discussion

Experts presented information on a range of well-characterized environmental and post-disaster registries including ATSDR's National Exposure Registry (NER) and Tremolite Asbestos Registry (TAR); the injury registry set up following the Oklahoma City Bombing of 1996; and the Three Mile Island Registry (TMI) established following a nuclear reactor leak. An epidemiologist who studied health effects of the Bhopal pesticide factory disaster of 1984 and a Dutch researcher who has studied two disasters in the Netherlands, one following a plane crash and another following the explosion of a fireworks factory, presented issues they faced in looking at population- wide health effects. Finally, an

investigator from the Harvard Nurses' Health Study presented aspects of that project related to retention and follow-up of subjects.

Also invited to the meeting were members of the WTCHR Scientific Advisory Committee, a group of researchers familiar with environmental, injury, and mental health epidemiology, most of whom were engaged in studies of various aspects of the health of persons exposed to lower Manhattan on 9/11. Additional experts were invited from NYC DOHMH, the National Institute for Occupational Safety and Health (NIOSH), EPA, The Centers for Disease Control (CDC), New Jersey Medical School, and the Health Departments of New York State, New Jersey, Nassau County and Westchester County. WTCHR staff from DOHMH, ATSDR, and RTI International also participated.

The registries that were presented at the meeting differed in size, scope, and purpose. ATSDR's environmental exposure registries (NER and TAR) collected base line data and conducted long-term follow-up; however, baseline data collection occurred years following exposure. The TAR has a direct medical evaluation component. The TMI Registry was the most successful at enrolling a significant portion of the targeted population (approximately 95% of all who were within a 5 mile radius of the nuclear reactor). The only registry with mandated reporting by providers of persons injured or otherwise affected was the Oklahoma City Bombing Registry. The Oklahoma State Health Commissioner issued a mandate for health care providers to report persons injured or otherwise affected.

The Bhopal disaster affected the largest number of people, but systematic enrollment did not occur. Bhopal public health officials faced obstruction from both industry and government. Of note, epidemiologists who interviewed affected persons a decade later, report that recall of the night's events remained quite accurate (comparing each individual's self reported history with recorded facts about contamination and observations from the area where the individual was on the night of the disaster).

The Dutch experience with assessing health following two large disasters, one a plane crash, the other a huge explosion at a fireworks factory, provides lessons for future post-disaster registries, how to set up a registry quickly, how best to insure cooperation of the affected population, and the importance of having a plan and approvals in place for a post disaster population health assessment.

Finally, the Nurses' Health Study is a long-term cohort study that has successfully followed over 120,000 women since 1976. This project has sound methods in place for motivating participants, ensuring retention, and for design of follow-up questionnaires that include recommendations from participants as well as from a large group of expert advisors.

Following the presentations, the entire group discussed how to apply information from the experiences of the other registries to the WTCHR in regard to recruitment methods, follow-up and retention, outreach and risk communication, and analysis of baseline data from the brief questionnaire administered at the time of registration.

Experts advised the WTCHR to be more focused in its final months of recruitment. They pointed out that there is a danger the WTCHR could have a large number of enrollees, but insufficient numbers in many important groups. They suggested focusing on important groups that were insufficiently represented as of the date of the meeting (May 2004); but for which good recruitment would be expected given enough outreach effort to the group. For example, one or two apartment buildings could be targeted for intense enrollment effort.

For retention and follow-up data collection, TMI and the Nurses' Health Study had the strongest advice: contact all registrants about 6 months following enrollment, have a schedule for timing of follow-up projects and stick to it. Plan follow-up questionnaires well ahead to allow consultation with all advisors (both scientific and community advisors, as well as representation from registrants themselves).

Regarding outreach and risk communication, ongoing community involvement was strongly recommended. Findings from analysis of registry data must be published in peer review journals and made available to the public.

For analysis, the WTCHR might be considered as a group of registries, as the exposures differed by population group, and enrollment success would differ by group. It was advised that the WTCHR be used to put the findings of smaller but more detailed or precise studies in perspective. For example, the Mt. Sinai and the NYC Fire Department clinical studies have shown pulmonary damage in a relatively small group of highly exposed emergency responders. The WTCHR has registrants from these highly exposed groups but also from less exposed and minimally exposed rescue/recovery/cleanup workers. A dose-response to exposure could be calculated, so those with less exposure could understand how to interpret the Mt. Sinai and NYC Fire Department findings in light of their lesser exposure.

It will be very important to regularly match WTCHR registrants with cancer, death, and hospitalization registries.

Finally, it was acknowledged that the Registry baseline survey contains standard health and mental health questions that will be used to compare registrants to other populations. However, these questions are limited in scope; therefore sub-studies validating findings with medical record review or even direct testing (e.g. pulmonary function testing) of registrants would be worthwhile.

#### Final Comments and recommendations

Grouped here by topic, include:

##### Completing recruitment

- Recruit more non-response worker cohorts to have enough sample of people who were exposed to dust and burning plastics
- Target groups with low participation to-date, who are in a single location that is accessible to field recruiters (e.g., residents of an apartment building)

##### Analysis

- Focus on strategic narrow subpopulations
- Make a list of major hypotheses and don't waste time on under-powered hypotheses
- Do not spend time on establishing control groups
- Focus on one population that could be used to understand others
- Be aware of self-selection bias in large cohort
- Listen to the enrollees and the affected community members because they may report symptoms or illness that merit exploratory analysis
- Assure that results are disseminated to scientific community in a timely fashion.

##### Follow-up, retention

- People hardest to find (i.e. during the follow-up) may be those with most serious problems
- Participants will remain interested if they are regularly provided with feedback. Publish as quickly as possible

### Scientific and community guidance

- Science changes but so will social and political milieus — meet repeatedly with experts and advisors to reassess research questions
- The community, including registry participants, affected community members, and worker groups, should take an active participatory role in design implementation. Social scientists must also play a critical role.

### Policy / ensuring funding

- Some recommendations should spill into policy.
- Need a mandate from government to add weight to the initiative
- All agencies must coordinate with each other
- Sustainability: history shows that the funding will run out so must capitalize with time available.
- Carry out early analysis and early reporting to reduce risk of losing funding
- Cultivate funding mechanisms to enable more in-depth studies and to invite more investigators to apply for funding

### Use of the data

- Communicate public health lessons and answers to questions such as: how long should evacuation training efforts continue? How to get access to medical care? How best to distribute masks and ventilators and maximize their use?
- Write up guidelines that doctors can use to evaluate exposure

The group was enthusiastic about the potential value of the WTCHR, and all acknowledged the large amount of ongoing work and attention that the project demands.

## Introductions

This expert panel was convened to provide advice to the World Trade Center Health Registry (WTCHR), specifically to provide an opportunity for scientific advisors to the WTCHR to learn about other health registries, and for all to gain knowledge about what has worked or not worked in the past, in the areas of enrollment, retention, analysis and use of data.

Seven speakers discussed their experience and how their experience might inform the efforts of the WTCHR. Open discussion followed every two presentations, and then a summary discussion concluded the program.

### **Thomas Frieden, M.D., M.P.H.**

*Commissioner, New York City Department of Health and Mental Hygiene*

Welcome/Introduction: Importance of this expert panel to the WTCHR

Dr. Frieden expressed the need for expert views and discussion with other registries. He called the concept of a registry a challenging one. Unlike research studies where researchers conceive of the questions they're asking before collecting any data, the registry works in the opposite way. The registry could also aim to establish a universe for public health surveillance.

The World Trade Center Health Registry (WTCHR) has about 40,000 registrants so far, with only four months left in the registration period. The WTCHR will monitor the health impact of physical exposure, or exposure to dust, fumes, debris, and emotional trauma. So far researchers know that:

- Respiratory and mental health problems are the dominant health outcomes.
- Mental health problems increased significantly post-9/11, in a variety of forms: depression, anxiety, and substance abuse, including drug, alcohol, and tobacco use
- Fires burned for about three months after 9/11 so there is a need to evaluate short- and long-term effects from exposures to fumes and particulates.

We must also keep in mind that, years from now, a new unexpected syndrome could emerge. Having a large registry to evaluate the significance of such a syndrome will be invaluable.

We are still enrolling people in the WTCHR. Efforts are underway to reach out to:

- Mandarin and Cantonese speakers who are under-represented so far.
- School children who are also under-represented.

Baseline data evaluation has begun. The City has been releasing quarterly information on who is registered.

Dr. Frieden then put the following questions to the panel:

- What are the issues that you faced?
- How have you dealt with them?
- What worked? What didn't work?
- What would you avoid doing (especially on recruitment issues, getting a non-skewed sample, keeping registrants informed and involved, and reducing attrition rates).

Dr. Frieden also mentioned that it is ethically important for the health department to disperse health information to people as part of the registry experience.



**Henry Falk, M.D., M.P.H.***Director, Agency for Toxic Substances and Disease Registry*History of environmental registries at ATSDR

Dr. Falk opened with a review of the purpose and value of health registries, which he called a roster of people who were at a particular time and place. A registry can be a valuable source for building a cohort to study research questions that may arise in the future. In order to maintain a useful registry, he said, researchers should:

- Remember that every registry is unique
- Maintain contact with all registrants.

One obstacle to environmental registries has been trying to set up an epidemiological study on exposure when the exposure occurred decades in the past. It's difficult to recreate who was there at the time. Falk used some real-life examples to illustrate his point:

- In the 1950s, soldiers in Nevada participated in exercises on how to operate in an atomic battlefield. Small nuclear weapons were detonated and soldiers were sent in several hours later. Decades later several of those soldiers developed leukemia. Recreating the group was extraordinarily difficult and took several years even though the Army had detailed records.
- In the 1940s, people from Hanford, Washington may have been exposed to radiation from the building of the earliest nuclear weapons. Some 1990 reports suggested they may have had elevated exposure to radioactive iodine. Going back 45 years to figure out who was there and follow that group forward was very difficult. The Hanford thyroid study took almost ten years to complete.

Falk then outlined similar examples he had himself experienced:

- In the 1970s, the flame-retardant polybrominated biphenols were used as animal feed, instead of regular animal feed, and several thousand Michigan farmers were exposed to PBBs. The PBB Registry was created to allow for future studies.
- Three Mile Island Registry. Researchers were concerned that whatever the radiation doses were, there could be cancer clusters, or potentially, groups of children with leukemia somewhere in Harrisburg. It would be impossible to answer questions down the road without assembling a group of people who were there in Harrisburg at that time
- The ATSDR established a registry that would monitor groups of people exposed to various chemicals at Superfund sites: one group exposed to trichloroethylene and another to dioxin. A challenge has been that many of the sites have multiple chemicals. Also, the chemical exposures are oftentimes at low levels. It takes a lot of effort to assemble a large group of people exposed to a single substance at multiple Superfund hazardous waste sites.
- In Libby, Montana, many people were exposed to a very specific form of asbestos — tremolite asbestos. Creating the tremolite asbestos registry is enabling researchers to learn more about tremolite asbestos and its long-term health effects.

A second obstacle to creating a better mechanism for doing registries in a hurry is peer reviews and IRB reviews. Alternatively, advanced peer review of proposed registries and IRB involvement should be pursued ahead of time if possible so that registries are available in emergency situations.

Falk welcomed panel participants to offer advice on:

- Technical aspects of the WTCHR and how to improve it
- How best to use the WTCHR in the future.

**Robert Brackbill, Ph.D.**

*Principal Investigator of the World Trade Center Health Registry (WTCHR), New York City  
Department of Health and Mental Hygiene and Agency for Toxic Substances and Disease Registry  
Overview of the WTCHR*

Dr. Brackbill spoke about the origin of the registry, its goals and purpose. He also gave an overview of methodology, a summary of enrollment to date and what can be expected based on pending and current response rates.

DOHMH developed the preliminary protocol for the registry in November - December 2001. The registry was conceived to:

- Document and evaluate the physical and mental health impact of 9/11 on large and diverse populations for exposures of varying content, duration, and intensity.
- Investigate rare effects, such as cancer, with more in-depth studies.
- Be a source of information for supporting the design and implementation of health screening programs and treatment plans.

People who are eligible to be in the registry include:

- People who were south of Chambers Street on September 11<sup>th</sup> including people who evacuated from buildings that were damaged or destroyed.
- People whose primary residence on September 11<sup>th</sup> was south of Canal Street.
- School children and staff enrolled in schools south of Canal.
- People involved in the rescue, recovery, clean-up, and other activities at the World Trade Center site, or the World Trade Center recovery operation on Staten Island.

Altogether about 400,000 people are likely eligible for the registry. The most intense recruitment is taking place for about 100,000 who had the potential for the highest exposures.

Registrants are being identified and enrolled through *list building* (obtaining lists of names of potential registrants from companies, agencies, and volunteer organizations that may have had constituencies who were exposed) and *tracing*. There is also ongoing outreach to the public to encourage enrollment. Examples of outreach include presentations at apartment buildings, company locations, advertising with posters on subways and buses, on the radio, and through newspaper articles. People who think they are eligible can enroll on the web or by calling a toll-free number.

The baseline survey obtains basic information, including:

- Demographics
- Specific exposure levels by group
- Self-reported physical symptoms
- Mental health screening questions
- Information for contacting registrants in the future

The 30-minute interviews are conducted using a computer-assisted telephone personal interview. Parents or guardians do proxy interviews for children younger than eighteen years of age.

There are already three data reports available on the web site that convey initial demographic information and some broad exposure summary data ([www.wtcregistry.org](http://www.wtcregistry.org)).

Steps in the analysis of data from the WTCHR baseline interview will include:

- Evaluating completeness of enrollment by population group, adjusting for recruitment, and non-response biases.
- Formulating exposure indices that can be linked to external exposure data.
- A prevalence analysis with selected health conditions and especially respiratory symptoms and conditions, airway reactive disease, asthma, PTSD, depression, mental health effects.
- Comparing the baseline survey data to other population survey data, such as National Health Interview Survey, the Behavioral Risk Factor Surveillance Survey and New York City Community Surveys, which assessed 10,000 respondents in each of the past two years.

Follow-up plans will include:

- Maintaining contact with registrants for the follow-up analysis.
- Re-contacting registrants every two years
- Linking the registry with other registries — cancer, death, and hospitalizations — for morbidity and mortality analysis, and also conducting in-depth studies.
- Making the data available to external researchers who can also use the data for future studies.

Recruitment has been increasingly successful over the first eight months:

- Site workers — almost 5,500 registered
- Residents south of Chambers St. who did not evacuate or returned the first month — 4,600 registered.
- Children less than eighteen years of age — 1,100 registered, and about 2,000 projected.
- Pregnant women — 300 registered
- Elderly (over 64 years) registering at high rate.

Questions that need to be addressed:

- How to minimize attrition rates of registrants.
- How to account for biases (such as self-identification) in the analysis.
- What are appropriate designs for follow-up studies
- How often to link to other registries such as cancer registries, death, hospitalization discharge data

## **Presentations on Domestic Environmental Exposure Registries**

### **David Williamson, Ph.D.**

*Director, Division of Health Studies, Agency for Toxic Substances and Disease Registry  
National Exposure Registry (NER)*

Dr. Williamson gave an overview of the National Exposure Registry (NER).

Congress mandated the NER through the Comprehensive Environmental Response, Compensation, and Liability Act of 1980. It was reiterated with the Superfund Amendments and Reauthorization Act of 1986. NER's main purpose is to aid in assessing long-term health consequences of exposure to low level hazardous substances, both environmental and occupational.

NER methods:

- Monitoring 275 primary contaminants found at Superfund sites
- Using various “toxicological profiles,” the ATSDR can look at where there are data gaps, and whether establishing a registry for a particular contaminant might fill some of those gaps.

- The selection process for the registry includes three types of sites: sites listed on the EPA's National Priority List sites, dump and landfill sites, and locations where emergency releases have occurred.

Other criteria to monitor may include:

- Individual exposure data
- The susceptibility of populations.

There are several phases to NER data collection. First, during the baseline survey, face-to-face and computer-assisted personal interviews are conducted. Second, six months after baseline data are collected, the researchers go back and confirm address data. Finally, one year after the baseline, and on a defined schedule thereafter, ATSDR conducts follow-up computer-assisted telephone interviews.

Categories of data include demographics, lifestyle, residential history, and health status.

To avoid too much self-reporting bias, the NER focuses on standardized questions for self-reporting. (For example, has a physician or other medical provider told you had, or treated you for, a specific condition?)

There are four sub-registries under the NER.

- Trichloroethylene registry, established in 1989: roughly 4500 registrants from 15 sites in 5 US states (people contaminated by well and municipal water)
- Dioxin registry, established in 1989: roughly 3100 registrants (contaminated soil)
- Benzene registry, established in 1991: roughly 1100 registrants (contaminated soil)
- Trichloroethane registry, established in 1992: over 3600 registrants (contaminated soil)

Overall coverage (enrollment of eligible exposed persons) is estimated at 82%.

Last year, the CDC and ATSDR implemented a new peer review process. NER was the first program to go through the new system. A peer review panel of seven experts is reviewing the program accomplishments, the quality of science, and providing guidance and recommendations on the future directions and modifications of the NER.

The panel's recommendations for the NER, which may also be applicable to the WTCHR, included:

- Design:
  - a. Flexibility of registry design is critical
  - b. Better characterization of exposure is needed. Important to understand what the exposures are, and collect data that accounts for the complete length and gradient of exposures from low level to acute high-level
  - c. Verification of health outcome information and comparing it to other data sets such as the cancer registries and birth defect registries
  - d. Identification of appropriate comparison populations
- Analysis:
  - a. Timely preparation and data release is critical. Appropriate analysis important whether looking at complex statistical analyses, such as longitudinal data analyses, complex sample survey analyses, geographic information systems, or multiple chemical exposures.
  - b. Should carry out analysis from a scientific value standpoint, as well as giving feedback to the registrants.

- Collaboration: establishing an ongoing panel of expertise and relying more on peer-reviewed literature to find external ideas.
- Opportunity:
  - a. Ensuring the use of state-of-the-art analytic methods, the Internet and other technology.
  - b. Targeting populations more closely.
  - c. Expanding collaborations such as with the chemical safety board. To be collaborative rather than duplicative.
  - d. Building a research program that uses cohort data.

**Sharon Campolucci, R.N., M.S.N.**

*Agency for Toxic Substances and Disease Registry*

The Tremolite Asbestos Registry (TAR) and The Rapid Response Registry (RRR)

The Tremolite Asbestos Registry (TAR)

Ms. Campolucci spoke about the ATSDR's Tremolite Asbestos Registry, based in Libby, a small community in northwest Montana. A vermiculite mine, later owned by W.R. Grace Company, started operation in 1923. The company blasted vermiculite — used for insulation or as a carrier for animal feed — out of the side of the mountain. There were no known health effects previously associated with vermiculite, but the vermiculite in Libby contained a harmful transitional fiber known as tremolite asbestos.

The mine was about six miles from the community, with about 5,000 people in Libby and about 9,000 people in Lincoln County. There were also exfoliation or processing sites where this vermiculite was brought into town and heated, or “popped”. The contaminated vermiculite processed in Libby was shipped all around the United States. As a result, the Tremolite Asbestos Registry is intended to ultimately include people from other sites where exposures are likely to have occurred.

In 1999, the *Seattle Post-Intelligencer* published a series of articles about increased numbers of deaths from asbestos-related disease in Libby.

In the summer of 2000 and 2001, ATSDR screened over 7,300 people. Subjects had an in-person interview, a three-view chest X ray, and a pulmonary function test. Out of 7,300 people, about 18% had pleural abnormalities, while 51% of the former workers had pleural abnormalities. Being a former worker or being a household contact of a former worker were major risk factors for pleural abnormalities and, potentially, the development of asbestos-related disease.

The vermiculite was used widely for a variety of purposes in Libby, Montana, exposing many people who were not miners or household contacts of miners. The concern is, over the next twenty, forty, or fifty years, what's going to happen to people who lived there, or worked there, or their children. For that reason, ATSDR established the TAR.

People included in the TAR:

- Former workers. About 350 workers participated in the initial medical testing.
- Household contacts of the workers
- People who lived or worked in Libby for six months or more before December 31st, 1990

TAR was set up by tracing and locating through company lists. W.R. Grace shared records on their employees and some health records on family members. People who were previously tested in the ongoing medical testing can have their data shared with the TAR and not go through the same questionnaire twice. A toll-free number was established for people to call for a telephone interview. ATSDR is looking at mortality data using death certificates in the National Death Index.

Clinical data on chest X rays or spirometry is being collected, but only if that data was collected as a part of the initial medical testing or the ongoing medical testing in Libby.

The TAR has permission from 854 people to collect their data via the ongoing medical testing program. 1,400 additional interviews have also been carried out. Estimates from the company records, over the period of 1963 to 1990, included 1,866 workers in the small mine, and approximately 3,200 family or household contacts. There were about 5,000 people in the community based on estimates from census.

Currently ATSDR estimates that just over 10,000 individuals are eligible for a long-term registry. 3,557 are signed up so far and enrollment is ongoing.

Future TAR plans include re-screening and re-interviewing on a regular and periodic basis, based on exposure category. That information will help in the design of a smaller, more specific study. One study that has been carried out is on the use of CT scans versus the use of chest X rays in the screening program. This summer ATSDR and its partners will start another study on disease progression, examining sequential annual X-rays from the 1970s of company workers.

The main goal now is to set up long-term follow-up. Montana's Senator Baucus is very interested in creating a clinical research program, and the people are very willing to be part of the research.

### Rapid Response Registry (RRR)

The Rapid Response Registry (RRR) will be developed and maintained by ATSDR in order that a central registry of individuals exposed to terrorist and other emergency events is available. The RRR will identify and enroll exposed and potentially exposed individuals within hours of an incident, in collaboration with state and local government agencies and private response organizations. RRR activities are intended to help document an individual's presence at or near a specific terrorist or other emergency event. This information will be used primarily to provide health officials with essential information necessary for both short- and long-term follow-up with exposed/ injured individuals and their survivors (if deceased). Contact information will be used to provide information to the affected individuals regarding possible exposures, potential health impacts, updates, and available educational materials. Follow-up contacts by health officials are anticipated to be for the purposes of assessing current and future medical needs and providing appropriate and timely medical interventions where possible. Subsequent health studies (not part of this activity) may be useful to identify potential long-term health outcomes in the exposed population; the contact information will enable these studies in the future.

### **Brief discussion of ATSDR's registries:**

*DR. FALK: As we go forward on this rapid response registry we should try to get pre-approval so that in some kind of acute setting we could actually create the registry quickly. Pre-approved modules might include for example a respiratory module with pulmonary function testing.*

*DR. GALEA: Clearly the issue of selection and selection bias sort of bedevils all these registries. Fundamentally, you are sampling really a very small slice of people who might have been exposed. And, I guess the broader question is what are your thoughts about the impact of litigation on the people who eventually do end up in registries?*

*MS. CAMPOLUCCI: There has been a lot of litigation in the Libby case, but mostly a lot of personal litigation. For a long time, those cases were stonewalled by the company, and only recently have the cases come to trial and people have actually been able to have their day in court.*

*DR. GALEA: But how does that affect who ends up in registries? In my read of the literature litigants are more likely to be in registries, because they see the potential gain for their lawsuits. How is that affecting the findings you're seeing?*

*DR. FALK: As soon as lawyers enter the scene, and people feel that there is enough environmental data to make a case, they don't want any more medical testing, because they fear what if there are negative findings. But what happened in Libby is that the number of people who have pleural abnormalities on chest X ray is 18% and parenchymal abnormalities was almost 1%. As people saw these numbers they began to think that the TAR could help them, in a sense, by highlighting the problem. So people began to come forward. And, these are just the people who are well. So, it had an opposite effect than what we usually see.*

*DR. PREZANT: Your main outcome is pleural-based radiographic abnormalities, which is an outstanding marker for exposure, but not necessarily an outstanding marker for disease. Since this is a small town, an isolated community, have you looked at the medical records and the death records going as far back as possible to see if cancers have been increased, specifically mesothelioma or just generally any cancers?*

*MS. CAMPOLUCCI: The asbestosis rate is about sixty to eighty times higher than expected, and that's mostly in the workers. The lung cancer mortality is up about thirty, forty percent, compared to what would be expected. There are anecdotal reports of about two dozen cases of mesothelioma.*

*DR. PREZANT: Getting into the hospital before they destroy paper records from the Forties and Fifties, and trying to focus on the people that live there, rather than the transient workers, may give you a great wealth of information.*

## **Post-disaster Domestic Registries**

### **Krishnan Ramaswamy, M.Sc., M.S**

*Pennsylvania Department of Health,  
Three Mile Island Registry (TMI)*

Mr. Ramaswamy spoke about the Three Mile Island Nuclear Power Plant accident and the TMI Population Registry, and gave an update on the registry and related follow-up studies.

The TMI accident was 25 years ago, on March 29th, 1979. The TMI Population Registry attempted to enroll all persons who were living within a five-mile radius of the TMI Nuclear Power Plant at the time of the accident. All within this 5-mile radius were somewhat exposed. There were 134 census enumerators, with 3 counties involved.

The registry comprised almost 36,000 people and 13,221 households. This was 93- 95% of the total eligible persons living in the 5-mile radius.

Information collected from these individuals included:

- Essential demographic and identifying information
- A brief history of cancer diagnoses, thyroid disorders, radiation treatment or therapy

- Prior exposure to ionizing radiation at the job
- Pregnancies at the time of the accident
- Smoking history
- Daily travel in and out of the five-mile area during the first ten days after the accident.

To maintain current address and telephone information, the backbone item for follow-up studies, the researchers used a series of steps that included:

- *Annual post office updates*
- *Annual Pennsylvania Death Certificate file match*: also matching every three years with the National Death Index files
- *Links to the Pennsylvania Cancer Registry*: The TMI registrants were matched against the Pennsylvania Cancer Registry, and for confirmed matches, we collected relevant cancer incidence information, diagnosis, and added it on to the TMI Registry.
- *Links to the marriage files*
- *Ongoing lost to follow-up (LTF) retrieval*: LTF is a term we used to describe people (TMI registrants) sixteen years or older for whom we did not have the correct address information. We mailed inquiries to all their addresses on file. We also collected information on LTFs from the two references on file who might know the current address of LTF; through other household members of LTF who happened to have a current address; and from college alumni associations or nursing or retirement homes depending on their age.
- For people still without a current address on file we approached the *Pennsylvania Department of Transportation and Motor Vehicles Bureau*, and gave them the names, birth dates, and address information.
- Other sources included records from the TMI Mother-Child Registry.
- Every three years we approached the Social Security Administration, local voter registration office, directories, and including newspaper obituary columns.

After ten years of follow-up, in 1989, 85% of registrants were still living at a known address, 7.7 % were deceased and 7.3% were still living, but without a current address. Among registrants who had moved out of the five-mile area, 18.3% moved to an area within the state, and 6% moved outside the state. Among living registrants with a known address, 44.1 % were still at their original address after ten years. 19.7 % of registrants moved out, but were still within the five-mile radius. 16.2 % were outside of the original area, but still in Pennsylvania, and 5 % were out-of-state.

A follow-up morbidity study of the cohort was undertaken in 1985. Due to limited resources, the Pennsylvania State health department opted for a telephone interview survey of a ten percent sample. 1,250 households were selected at random for the telephone interview survey.

The follow-up morbidity survey covered five areas:

- Demographic characteristics
- General health indicators: This focused on six measures including:
  1. The number of physician visits and reasons for the visits during the last twelve months
  2. The number of hospitalizations and medical diagnoses during the same period.
  3. Prescription drugs, medical advice, or tests results received over the phone and the reasons for them during the last two weeks of this period.
  4. The number of bed-disability days due to acute illness or injury during the last two weeks.
  5. The number of work-loss days and the school-loss days for children, during the last two weeks.
  6. Accidental injuries that required a medical visit.



- Maternal reproductive problems
- Selected specific diseases and psychological stress: Under the psychological stress category, selected symptoms included in the Hopkins Symptom Checklist.
- Attitudes and behavior.

A control area was selected fifty miles away from any nuclear power plant, in the Chester County area of Pennsylvania. We went through the same questions for 1,250 households. Data collection and validations were completed in 1991.

**Sheryll Brown, M.P.H.**

*Oklahoma State Department of Health*

Registry of Persons Exposed to the Oklahoma City Bombing

On April 19, 1995, a 4,800 pound TNT equivalent ammonium nitrate and fuel oil bomb was detonated in front of the Murrah Federal building in downtown Oklahoma City. The bomb caused the collapse of 10 buildings in the downtown area including significant building collapse of the Murrah Federal building. It also caused major structural damage to 21 other buildings. There was glass breakage up to two miles away from the blast.

167 people died. About 363 occupants were thought to have been in the building although upwards of 700-800 people were employed there. The biggest concern was penetrating injuries from glass and debris and blunt trauma from structural collapse.

On April 21st, the State Health Commissioner issued a mandate that required physical injuries and other health conditions incurred in the bombing to be reportable to the State Health Department. This authority can be exercised under Oklahoma State Health Rules. This allows health department staff to get out in the field and collect data on special types of health events.

Health Department staff identified people who had been treated in a hospital or by a physician for direct injuries, persons who had been injured but not treated, and uninjured persons.

Multiple data collection methods were needed to identify all those affected and to obtain all pertinent data including:

- *Hospital records*
- *Medical examiner's records*
- *Physician mail survey*
- *Building maps and occupant survey*
- *Survivor's survey*
- *Newspaper survey*
- *A follow-up study also provided additions to the base line data*

The Health Commissioner's mandate allowed researchers to collect hospital medical records data on injuries. We asked hospitals to hold all medical records and had access to all medical examiner reports on the deceased persons. Physicians were asked to report patients that they treated for bombing injuries. Patients reported where they were when the bombing happened, and also reported some of the medical problems they were having.

Registry staff also estimated where the employees were in the buildings by contacting all employers in the area. They created 3D maps using AutoCAD.

It is not known how many individuals were within the area where injuries occurred. However, the registry staff members feel that the 841 injured people enrolled represent nearly 100% of those injured.

Four to six months after the bombing, a survivors' self-report survey was sent out. *The Daily Oklahoman* also ran a classified ad called "searching for survivors." It asked people to give their name, where they were, where they were treated.

From 1996-98 the health department did a follow up study of Oklahoma City Bombing Survivors. The study aimed to assess:

- Health status
- Emotional and physical outcomes
- Services utilized and needed
- Obtain additional info about injuries

The study measured the number, types, and severity of injuries, the causes of injuries and deaths and the locations where people were. Information was also gathered on blast effects, such as smoke and dust inhalation, auditory trauma and glass injuries. The researchers obtained Institutional Review Board approval and then established a network of service agencies and a referral protocol.

Through telephone surveys the follow-up study collected information on:

- Long-term health conditions
- Functional status changes
- Quality of life changes
- Health care services utilization
- Medical costs and payment
- Symptoms of PTSD
- Hearing and balance disorders
- Chronic pain
- HSQ 12 (Health Status Questionnaire 12).

A telephone survey instrument and face-to-face interviews were carried out. The survey included eight symptoms of PTSD, as well as questions on hearing and balance disorders, and chronic pain. The HSQ was included in the follow-up questionnaire. It is a twelve-question instrument that assesses self-perceived health status.

A total of 914 people were considered eligible for the follow-up study, 494 (54%) were interviewed. Of these, 92 % had been injured. That indicates that the results of our survey were biased toward injured persons.

The most frequently reported new types of problems were hearing problems, anxiety and depression. Almost everyone reported PTSD symptoms. However, that didn't necessarily indicate they had PTSD. The most frequently reported symptoms were: being jumpy and easily startled, having recurring distressful thoughts, and having difficulty concentrating. Counseling and audiological services were the services most frequently utilized.

Lessons learned that may be important for the WTCHR include:

- Understand that you will have incomplete data in a disaster event.
- Need to be cognizant of comparing these types of events with other ones, so important to factor in data collection.

- Some people delay in seeking treatment. This information can be obtained at follow-up.
- Obtain consent as early as possible.
- Methods used may have value for other studies e.g. the Oklahoma bombing registry methods have been applied to the Khobar Towers bombing, and the Oklahoma City tornadoes.
- Collaborating with other disciplines is very important, especially if not really sure about the outcomes.
- Offer referrals at follow-up such as counseling, financial, and medical.

### **Brief discussion of the two domestic post-disaster registries, TMI and Oklahoma:**

*DR. DOHRENWEND: You mentioned that you had a public health mandate. If that was essential, how did you get it? Is there any chance that the New York City registry could get such a thing?*

*MR. RAMASWAMY: Yes, we felt that a public health mandate was essential. We did a door-to-door survey of all the households and persons (Census) with informed consent in the TMI five-mile area. Initially, people did not question our activities, but, after a few weeks, when we went on our follow-up and non-response enumeration processes, some people said “no” to their participation. We in the Health Department did not have enough resources and it was hard to find the money without a public health mandate. So, we had to go to the Governor’s Office and State Legislature who agreed that there was an important long-term public health outcome to be concerned and also agreed to fund the TMI Registry, its maintenance and related follow-up studies efforts for a minimum of ten years.*

*MS. BROWN: We had the statute in place, and we also have a long-established history of working with the hospitals and collecting data. If you get technical about it, the mandate only extends to the health reporting entities, but we went a long way on it.*

## **International Registry Experience**

### **V. Ramana Dhara, M.D., Sc.D., M.P.H.**

*Rollins School of Public Health and Morehouse School of Medicine  
Bhopal Disaster and Aftermath*

Dr. Dhara is a member of the International Medical Commission on the Bhopal Disaster. This is a group of physicians and statisticians from around the world, brought in by the gas victims. A registry was formed by the Bhopal Research Center two years after the disaster. Currently, the Bhopal registry is backed by the local government, but government support was not initially available. Dr. Dhara notes that he does not have day-to-day knowledge of how the registry is run, but he will discuss what he has learned from talking to people working on it. First, Dr. Dhara described what happened in Bhopal and talked about the difficulties of monitoring long-term health outcomes in the absence of government support and resources.

In Bhopal, India, on December 2<sup>nd</sup> 1984, at midnight, 27 tons of methyl isocyanate leaked from two tanks owned by Union Carbide, which had set up its plant to manufacture the pesticide Sevin. The plant was located very close to highly-populated areas. Over half a million people were exposed. India had no experience in dealing with environmental disasters. There was a great deal of secrecy and a lot of medical information was suppressed both by Union Carbide, as well as by the Government of India later on.

After the gas leak, people were dying from respiratory and neurological problems. There were about 2,000 deaths within the first few weeks of the disaster. By 1992, the death toll had gone up to about 4,000. Some non-governmental organizations estimate, however, that between 15,000 and 20,000 people were killed.

The isocyanate chemical also affected the surface tissues of the eyes. The number of people with severe eye injury is not known.

Two large groups could not be accurately accounted for: migrant people living in the slum community, and people who were on trains passing through Bhopal City at the time of the gas leak.

Health effects from the Bhopal disaster included:

1. *Acute irritation of the cornea and conjunctiva*

- Early findings: intense lacrimation, redness, photophobia, corneal ulcers
- Later findings: persistent watering, corneal opacities, chronic conjunctivitis, tear secretion deficiency, cataracts
- Chronic inflammatory damage: Bhopal Eye Syndrome

2. *Respiratory Health Effects: acute irritation of upper and lower respiratory tract*

- Early findings: dyspnea, chest pain, pneumonitis, respiratory distress, pulmonary edema
- Later findings: pulmonary fibrosis, persistent cough and dyspnea, chronic bronchitis

Similarities between the Bhopal and the World Trade Center disasters include:

- Single event resulting in a large number of rapid deaths
- Terror and panic cause mass evacuation
- Large number of people exposed to air contaminants
- Agent of death: toxin versus trauma

Dr. Dhara went on to discuss epidemiological studies of people affected by the Bhopal disaster:

Established in 1985, the Bhopal Gas Disaster Research Center carried out a 6-month morbidity prevalence study, following 80,000 exposed individuals and 16,000 unexposed people. As about 500,000 people were exposed, the coverage rate was about 20%.

In January 1985, the center undertook a house-listing operation. It carried out a door-to-door survey affixing numbered tin plates on every house. Lists of family members with specific IDs for each member were prepared.

The objectives of the cohort study were to study:

- Socio-economic and demographic changes,
- Vital events such as births and deaths
- Point and period prevalence morbidity
- Follow-up on chronically ill patients

Surveys were to be done every 6 months. The center closed in early 1994 due to lack of funds. It had initiated 27 clinical studies but no data has been published in 20 years.

The responsibility for the cohort has now gone to the local Bhopal Government. They are following-up about 96,000 people. However, aside from internal reports, no data has been published since the cohort was formed.

Because a slum population is very mobile, it was very difficult to register these people, without a sampling frame available. The researchers used a cluster sample approach. They took the death rates in the exposed areas and categorized the areas as severe, moderate, and mildly affected, based on death rate. Average death rate in areas categorized as severe was 2.2%; in areas categorized as moderate, 0.13%; and in areas categorized as mild, 0.03%. Proportions included in the cohort were: 75 % of those in severe areas, 45% of those who were in moderately affected areas; and 4.2% of those from mildly affected areas. The severity rating (severe, moderate, mild) was based on death rates rather than any actual measure of true exposure.

Problems the researchers encountered included:

- Selection based on effect rather than exposure
- Non-random selection: cluster of deaths (and knowledge of exposure) may influence interviewers
- Population: cohort sample size ratio skewed toward severely affected
- Political/social considerations in selection introduce bias
- Persons migrating out were excluded rather than treated as lost to follow-up
- Non-availability of toxicologic and accident-related information
- Lack of expertise and funds

Other operational problems were:

- Only 50 staff members were trying to monitor 90,000 people
- Only 20 research assistants visited each household for data collection: daily ~1 Research Assistant / 40 families
- There was initially only one computer

Factors of this disaster that interfered with an effective registry of exposed persons included:

- Urgent health care needs
- Non-availability of toxicologic and accident related information
- Extreme sensitivity of local and national government to all aspects of the disaster
- Lack of expertise and funds

A later study was done to characterize personal exposure. Researchers went back ten years after the disaster, and took personal exposure data from the gas victims. They collected information on whether victims were inside the house, outside the house, what was their activity during the exposure, whether they were sitting inside and whether they were running outside. A lot of people remembered the night very clearly. The researchers developed a personal exposure index and correlated with lung function. Many lung symptoms did correlate to the exposure index.

### **Joris Yzermans, Ph.D.**

*Netherlands Institute of Health Services Research (NIVEL), Utrecht Center for Health Impact Assessment of Disasters (CGOR/RIVM), Bilthoven, the Netherlands*  
The Netherlands: Health Impact Assessment of Disaster

Dr. Yzermans spoke about public health efforts after two Dutch disasters.

Airplane crash in Amsterdam, 1992

In 1992, an El Al Boeing 747 cargo jet crashed into two apartment buildings in southeast Amsterdam. There were 43 casualties and dozens injured. 1,500 people saw the crash happen. 500 rescue workers were involved.

There were two distinct periods after the disaster:

- From 1992 to 1994 was the initial disaster relief period, and focused on post-traumatic effects
- Between 1995-1999 there was deepening distrust, pressure from groups centering on unexplained physical symptoms. It was known that depleted uranium was in the tail of the plane, as counter-weight, and three of the four components of the nerve gas Sarin were on board.

Five years after the incident, the Minister of Health decided to conduct an investigation into the health problems. At the same moment, the Dutch Parliament organized a Parliamentary Inquiry to determine causes and consequences of the crash.

An epidemiological study began six years after the disaster. Methods of the study included:

- Interviewing 52 family practitioners in the region
- Setting up a call center (June and July 1998)
- Comparing self reported cases with practitioners' medical records.
- Sending a symptom checklist, SCL-90, to those who consented.

The call center had 10 lines open 14 hours a day with 25 multilingual interviewers who took the histories of approximately 900 people.

The respondents presented, on average, five health problems per person, which they attributed to the crash. All these problems were symptoms of illness with no disease.

4,000 people were re-screened 10 years after the crash:

- Post-Traumatic Stress Disorder (PTSD) and Medically Unexplained Physical Symptoms (MUPS) were more prevalent than in the control population
- The number of victims who attributed their symptoms to the crash increased under the influence of our study, of the Parliamentary Inquiry, and of the full media attention, and then decreased afterwards.
- There were a lot of efforts to communicate: via website, leaflets, brochures, newspaper articles, local television and radio, and training family practitioners.

Dr. Yzermans had the following recommendations for the WTCHR and other post-disaster efforts to assess health:

- Inform victims about all services available for aftercare
- Provide one center for all information and advice
- Establish long-term monitoring of survivors' health
- Provide specific mental health care provision
- Promote peer support
- Establish emergency funds

### Fireworks Depot Explosion

Four years ago (May 13<sup>th</sup>, 2000), disaster struck again. A fireworks depot exploded in a residential area in Enschede, a city with 141,000 residents. This was the first opportunity to put the above-mentioned recommendations in effect.

There were 22 casualties, 1,000 people were injured and 1,500 lost their homes. 11,000 people registered as a victim/survivor.

The Minister of Health ordered the development of three cornerstones of care:

*A. Information and Advice Centre:* One counter for all questions and problems, established in two days under municipal responsibility (close by the disaster site, coordinates and facilitates integrated aftercare). Registrants comprised all persons from the destroyed area (through municipal identity register and zip-codes); all rescue workers (as stated by the management of their organizations) and all persons who reported to the Information and Advice Center as a victim/survivor.

Problems encountered in the registration of survivors included:

- Chaos right after incident: number of casualties, tracing relatives/friends, denominators
- Spelling of names
- Wrong address (tax-dodging/students)
- Family name of birth for women
- Bread-winner (who gives only his own name)
- Living elsewhere
- Privacy

*B. Coordination of the psychosocial aftercare. (This cornerstone was not realized).*

*C. Health Impact Assessment:*

— *Surveys.* The Health Impact Assessment was carried out three weeks after the disaster. All people involved were asked to give blood and urine and fill out a questionnaire. 45% responded. There was a follow-up without blood and urine, eighteen months later. The response rate was lower (30% of all survivors).

— *Monitoring, using existing registries and linking between registries.* In this case, the response rate was not important, because in the Netherlands, every citizen is obliged to be registered with one Family Practitioner, and the Family Practitioner acts as a gatekeeper to secondary care. There were two databases. The first database was the Information and Advice Center, and the second database was the insurance database of all Family Practitioners.

Monitoring and feedback to the Family Practitioners is continuing every three months.

Lessons learned:

- Registration of survivors based on zip codes and/or just one database not reliable
- Databases are often not compatible
- Registration is often manual work
- Many mistakes in spelling, name of birth and date of birth

Early in 2003 the Dutch Government established a Center for Health Impact Assessment of Disasters (CGOR), based at the National Institute for Public Health and the Environment (RIVM, Bilthoven). CGOR was founded to improve the national preparedness for Health Impact Assessment (in all forms) after future crises, major incidents and disasters.

Two main objectives are:

- Set up conditions to rapidly and decisively design and initiate a health impact assessment of future disasters.

- Contribute to clear and transparent decision making about the purpose, necessity and form of health impact assessments of future disasters.

To meet these objectives, CGOR develops infrastructure and knowledge, and identifies and brings together a network of experts. One important mechanism to support these objectives is to strengthen the capabilities of local public health authorities in all required fields, such as registration, organisation, logistics, questionnaire and database design, disaster exposure assessment, etc.

When disaster strikes again in Holland, the Red Cross will implement a rapid response registry within hours, in order to enable victims to re-establish contact with family members, to provide information for emergency services, and to provide names for surveys and monitoring. After a few days, the registry will be transferred to the Information and Advice Center, where any one can call and ask questions. The registration will be a web application, which makes it possible to share databases. The use of PDAs makes it possible to register from anywhere, even if no telephone is available.

### **Brief discussion of the presentations on Bhopal and the Netherlands:**

***DR. MORSE:** Centralized registries have limited life spans. Computer data management should also facilitate work so that we can produce more reports and get more information out there and do more follow-up and, thereby, have data used to lobby for ongoing funding.*

***DR. DHARA:** After major environmental disasters, sometimes symptom reporting seems to be far greater than what the objective level of ill health might actually be. We found that this is a reflection of the fact that people are still anxious. Maybe they're frustrated with the local government. And so, they feel they're expecting money to come in. For example, in Bhopal, in the severely affected areas, 97% of the people were reporting shortness of breath. That's not believable and reports seemed to decrease over time. So, we have to factor in that there is a certain amount of social dissatisfaction, which is causing people to increase reporting.*

***DR. GALEA:** Which changes in morbidity were found and do you see any specific pattern after disasters?*

***DR. YZERMANS:** Compared to the period pre-disaster (16 months before the disaster) we saw post-disaster (24 months after the disaster) 25% more MUPS, 24% more musculoskeletal symptoms, 47% more psychological problems and 41% and 28 % more gastrointestinal and skin symptoms as presented to the family practitioner. In my opinion, in the first month only anxiety and acute stress disorder is visible (apart from disaster-related wounds and fractures). After 3 months, PTSD turns up. After 1.5 - 2 years when stress-reactions become chronic, depression and MUPS turn up for some 5-15 % of the survivors and 1 % of the rescue workers.*

## **Longitudinal Health Study**

### **Fran Grodstein, Sc.D.**

*Associate Professor of Medicine, Brigham and Women's Hospital, Harvard Medical School  
The Nurses' Health Study*

The Nurses' Health Study is not a registry, and the overall goals are fairly different from the WTCHR. But certain methods in the Nurses' Health study could be applied to current and future aspects of the WTCHR.

The Nurses' Health Study has enrolled 121,701 female registered nurses since 1976. At the time of enrollment, subjects were married and lived in the largest 11 U.S. States. At outset all registrants were



aged between 30-55 years, and are now 58-83. The researchers have followed the exact same group of women throughout the study.

The initial recruitment was carried out by mailing questionnaires:

- The initial response was 70% and then grew
- The study still has 90% response over more than 25 years

The questionnaires:

- Ask about a lot of lifestyle factors such as weight, smoking habits, exercise habits and diet.
- Ask if there has been a physician diagnosis of any of a series of diseases. The advantage in this study is that all the registrants are health professionals so there is a higher chance that they will respond.
- The nurses have also sent blood samples after asking a friend to draw their blood. They have also sent urine, tap water and toenail samples. Now collecting saliva to look at DNA.

One strategy to increase response was to add questions of interest to the participants such as questions on job stress and quality of life. By responding to their interests, participation increases.

The questionnaire is sent every 2 years. To ensure response it is sent in 5 waves of mailing, with the question length decreasing with every mailing. After 3<sup>rd</sup> mail the questionnaires arrive by certified mail, which is unpopular but effective.

Other strategies to ensure participation include:

- Hand addressed mail
- Rigorously testing every question through internal pilot reviews
- Consistently keeping the questionnaire at 6 pages
- Designing the questionnaire with care:
  1. Almost no write-in responses
  2. Limited categories of responses
  3. Never include 'don't know' as response option
  4. Fill-in bubble responses
  5. Pilot testing every new question

To ensure high follow-up rates, the Nurses Study does the following:

- Identifies deaths through National Death Index
- Sends a yearly newsletter (involves family and participants)
- Mails birthday cards to older women
- Provides immediate response to subjects, questions and concerns
- Responds quickly to comments and concerns

Self-reported information should be validated by blinded physicians who confirm that the disease diagnoses met standard criteria.

### **Brief discussion of the Nurses' Health Study:**

**DR. MOSTASHARI:** *I was curious what you thought about the Commissioner's suggestion that we do as much as we can to prevent illness in the cohort and to educate people.*

**DR. GRODSTEIN:** *Since we are collecting new information from women all the time, simply participating in a research study tends to make people improve their health habits. You know, it makes*

*them more aware of what they're doing, what they're eating, and how often they're getting check-ups. So, there's certainly personal health value just from participating, you know, an awareness you have of your health. Obviously, your mandate is pretty different than ours. We're not in a position to provide personal health information. But we do things in our newsletters like, CDC recommendations on blood pressure screenings, cholesterol screenings, and so on.*

## **Group Discussion — Applying What Has Been Learned to the WTCHR in Regard to:**

- Recruitment
- Follow-up and retention methods
- Outreach and risk communication
- Analysis (what we can deliver after 5 years)

### **Recruitment**

**MR. MADDELONI:** *From an environmental perspective, how well are you going to be able to link this huge database to some exposure reconstruction?*

**DR. THOMAS:** *We are mapping people by residence, by where they were on the morning of 9/11, and by where they worked after 9/11, or went to school. We'll be doing geo-coding, and looking for analyses between what the environment showed, and the mapping of where people were.*

**MR. MADDELONI:** *Unfortunately, when things were at their worst, environmental data was at its least.*

**DR. THOMAS:** *We will have anecdotal descriptions of where the dust cloud was thickest. That will help. The WTCHR has three and a half more months of recruitment. We will definitely have some self-selection among our registrants but it's unavoidable. The more people we register, the more we will dilute out the self-selection bias.*

**DR. DOHRENWEND:** *I would prefer to see that you focus on groups where a denominator is possible. Where a denominator isn't possible, you can't even check self-selection, by most procedures.*

**DR. THOMAS:** *Most of our recruitment focuses on group one: residents south of Chambers, school children, people who were in the thirty-five damaged and destroyed buildings, and people who worked at the rescue/recovery/clean-up operations. And, we do have some denominators for those.*

**DR. DOHRENWEND:** *The next question would be how do you recruit from those groups?*

**DR. THOMAS:** *We are trying to recruit as many people as we can, from whatever source we have. A small number of businesses and government agencies have given us lists. The data collection contractor, RTI International, traces the people on the lists, and then calls those people. We are also doing outreach and marketing to let people in the community know how to register.*

**DR. ENRIGHT:** *Is there any information being passed between the registry and other medical surveillance projects such as the Mount Sinai study of firefighters? Are there any plans for it?*

**DR. THOMAS:** *There's a lot of communication — as they have findings, they share them with us. They helped us design our questionnaire, so we have used the same time periods in asking about entrance to the World Trade Center site and the time spent there. We used some of the same questions, with identical wording, so that we'll be able to evaluate answers from people that appear to have the same days of exposure.*

**DR. ENRIGHT:** *Is either the registry, or any of the other studies like, the medical surveillance group of workers, asking if that individual who's enrolled with them is also enrolled in the other?*

**DR. THOMAS:** *Not at this time.*

**DR. ENRIGHT:** *So you believe that the dose, or the exposure matrix, or calculation, or estimate is going to be identical for those two large groups? Or only similar, because there was some overlapping of intellectual input?*

**DR. THOMAS:** *Deliberately made similar. Not identical.*

**DR. GALEA:** *What's unique about this registry is that you actually have five different registries, or five pretty distinct exposure groups — people who lived there, people who worked there, people who were in the buildings, rescue workers, and children in school. What's remarkable is that your response rate, given that your denominator is an estimate, actually varies tremendously among the five groups from 5 to 35 %. So, given finite resources, is there any merit to thinking about these five groups and shifting resources to them? If you sort of focus a little bit, it's not implausible that the 5% goes up to 25%, given your relative response rate.*

*Given your current numbers, you're going to end up with 55-60,000 people. You already have the largest registry this country has. So, my question is, is it better to keep going and try to get as many people as you can? Or would it be better to end up with 40,000 and devote more effort to try to get people who are harder to get, which will require more human resources, more financial resources? I would argue that people who have not responded to the ads, are not going to come. But, if you actually prepared a new ad, for example, calling only for pregnant women, you might actually get those harder groups. But, those will require resource shift and energy. I would say it makes more sense not to get to 55,000. Get to 40,000, but go to the hard groups, while understanding that, of course, it requires compromise.*

**DR. BRACKBILL:** *If you're relying on people to self-identify, self-select, then you have the issue of bias. There would then be some difficulty in interpreting the data.*

**DR. DOHRENWEND:** *If you identify the target group, in terms of high likelihood of exposure, and also the availability of a denominator, then how you recruit from that group becomes the issue. I would re-examine how you get lists. And, if you can't get it from all that are within that group, I would focus on those from whom you might be able to get lists.*

**MS. BROWN:** *Right. It decreases the self-selection. However, you might get lists only of middle-aged people who are actively working, and you miss the elderly and the children and the residents.*

**DR. DOHRENWEND:** *I would rather do that, so that I could say something sound about the middle.*

**MS. BROWN:** *We really don't even know anything about your demographics. Could you maybe focus in on one geographical area, and define it as a group of exposure. Then, you could say something about the population. It seems like to me that a registry is like you're joining something. If you know an employer knows an employee was there, you could include them as part of your denominator, even though they may not be enrolled in your registry. Just such a simple inquiry could strengthen your denominators.*

**DR. THOMAS:** *That would require a new data collection method for us. Maybe just, you know, change that a little bit, and say 'we'd like to know if you were there', or something to that effect. There are 400,000 people who are eligible to join, though we only have 83,000 people on the lists. 15-20,000 have signed up on the Internet and we have names for 20% of those eligible. There are around 100,000 in group one. 52,000 of those people were from various lists, so that's pretty good.*

**DR. GEYH:** *You want to focus some targeted recruitment and then because funding doesn't go on forever, you want to get data or results out the door as quickly as possible. Groups you've differentiated not just by category but also by quality of the information you have about them, might drive some of the decisions about which groups to focus on, in terms of bumping up recruitment. The data analysis is going to be driven by the differentiation of populations to begin with which goes back to the question that was originally asked about how we're going to link all these different studies that weren't necessarily designed in a coherent way. I think that you're going to pull stuff out that is matchable because there was some commonality to the exposure metrics, and to the health outcome metrics.*

*So, we're going to be parsing these data sets every six ways, and you might as well start doing it now, when you start thinking about, you know, which parts of your registry are going to give you the most value in the shortest period of time.*

**DR. STELLMAN:** *Have you thought about doing any formal but very limited data collection with consent on the refusers? And, you could ask why they're refusing, and get some preliminary demographics. Because, you're going to want to know, in well-defined populations. It would be very nice, five years from now, to go back and say for example, that Hispanics were more or less likely to participate.*

**DR. YZERMANS:** *We did a non-response study of the people who didn't report to the Information and Advice Center. There was under-representation of men, of adolescent children, and of young adults, and an over-representation of firefighters and policemen, because they were obliged by their company to respond, and over-representation of people born abroad.*

**MS. DIGRANDE:** *Actually, we do have a mapping effort going on right now, in which we have census block data by age group and race/ethnicity. We're in the process of looking at enrollees who are residents and getting an idea, by census block, what proportion we have that are kids, and we'll compare those so that it becomes a target for us to focus on those particular areas.*

**MR. MADDELONI:** *We recently completed an indoor clean-up program, and offered a complete top-to-bottom asbestos remediation for anyone living below Canal Street. And, we were only able to recruit four thousand, out of an estimated thirty thousand residential units. We offered a full asbestos abatement. So, you talk about dangling a carrot, and that's all we got.*

**MR. EVANGELISTA:** *What about undocumented people? Like cleaners and hot dog men, and just people visiting others at work?*

**DR. GEYH:** *We don't have any real understanding of how many people were present. There were a substantial number of undocumented workers involved, especially cleaning out the tunnels. Finding them, pulling them in, and overcoming some of their concerns is really a struggle.*

### **Follow-up and Retention Methods**

**DR. THOMAS:** *When we enroll someone, they do a thirty-minute interview. Within the next four weeks, they get a thank you letter, a copy of the consent language that they agreed to, and a resource guide that includes phone numbers for 9/11-related services and other health services in the Tri-State area. We have also sent two email messages to 60% of registrants who gave us an email address. But, when should we do our first check for address and should we do more than just check on address? Should we have some sort of limited interview?*

**MR. RAMASWAMY:** *We did our first check for current addresses via the Post Offices within a year. We learned from our experience that a six months' check would have been a lot better for current address verifications. We had checks on the telephone numbers too. But, for telephone number verifications, we had good luck with a one-year period.*

**DR. THOMAS:** *We should do some sort of combination of e-mail and other methods. If we get the answer back, great. If not send mail, and then telephone, as a last resort.*

**DR. ENRIGHT:** *What are your plans for monitoring medical outcomes, be they symptoms or something from medical records, or are you just going to start counting bodies over the next 10 to 20 years? If you're interested in the acute effects, like the chronic cough, you would need to ask that earlier, or otherwise you'll have a recall bias problem. But, if you're just going to count bodies and cancer rates and all, then I guess you never have to ask them about medical symptoms.*

**DR. BRACKBILL:** *I think there might be two basic questions. One is, keeping contact with people so you can update their address information. The second thing is, increasing your response rate in follow-up. There are probably different techniques for both.*

**DR. GALEA:** *One of the advantages that you have is that because this registry is, by and large, self-reported, there is some sort of motivation, so you can presume they will actually want to stay with you.*

*Different things work for different demographics. What works for older Asians are different than what works for younger African Americans, in terms of actually keeping them in cohorts. So, I think we can share some of that information, which might help you be a little more cost effective, in terms of your targeting for the cohort. You have to make it as easy as possible for people to participate.*

**DR. BRACKBILL:** *We should use different methods for different populations. So for a group that self-identified through the web, we might apply a web questionnaire. We should really be prepared to be flexible in the kinds of ways we go about collecting the data.*

**DR. CONE:** *I think there's literature that shows highly sensitive questions are answered differently depending on the medium. The medium really does determine the percentage of people who will answer a section, especially if you're asking on a sensitive subject.*

**DR. GRODSTEIN:** *But, it's only introducing bias if it's different. If you think people who had high exposure to "X" answered that question differently than people who had low exposure. If diabetes is more accurate on a telephone than it is on the Internet, then that only matters if that's also related to their exposure to whatever. That seems a lot less likely.*

**DR. THOMAS:** *Should have multiple methods so you will maximize your response.*

**DR. STELLMAN:** *In the case of hospital-based case control studies in the American Health Foundation, we found that the main difference between face-to-face interviews, versus self-administered questionnaire, was mainly the completion of the questionnaire. If you leave people to their own devices, they can skip things or be incomplete or be careless. You can impose on a face-to-face interview the same structure that you would on a web-based interview, or anything that has automatic structuring to it, so that you can at least be assured that the subject is presented with the full spectrum of questions, and there is less opportunity to skip large chunks of the questionnaire.*

### Analysis

The panel talked about the set of analytical tasks for the first five years:

Questions addressed:

- What analysis can we do
- How can we do sample calculations before we do the analysis, to see whether or not we have enough of a sample?
- What are other things that we must do within the first couple of years?
- How can we deal with our list-based group, or our self-selection group? Are analytic approaches different for those two populations?

**DR. THOMAS:** *By the end of data collection we will have 50 to 60,000 interviews. The interview covers demographic information, basic exposure data. So, residents have a slightly different set of questions than do site workers, for example. And, if you were a resident and a site worker, and you worked in one of the buildings that was destroyed, you get three sets of exposure questions. And then, we have some basic health and mental health questions. We took questions from the Sinai survey, from the Fire Department, from the New York City community survey, or from national surveys, so that we'll have some sort of a comparison population.*

**DR. MORSE:** *You should create a timeline that dictates what to analyze first. And then depending on feedback, move forward. Could also follow existing literature to make comparisons.*

**MS. BROWN:** *I'm curious about what your outcomes are going to be in your analysis.*

**DR. BRACKBILL:** *We have two mental health scales. One is a psychological distress index, which is a set of six questions with a scaled answer for each. Then, we have a seventeen-question screening scale for post-traumatic stress syndrome. For physical health, we have a series of health symptoms, people report whether they experienced a symptom, and there's a free-text write-in response that they can give. There is also a series of questions about physician-diagnosed conditions.*

**MR. MADDELONI:** Most of the most highly exposed people were part of occupational cohorts of one sort or another — firefighters, the iron workers, the heavy laborers. And so, they're being tracked pretty well. My question is one other group that was very highly exposed, certainly acutely, were the people that got dusted that morning. And, how well are you trying to focus on that group and comb out acute symptoms and respiratory sequelae, which we may or may not be seeing at this point?

**DR. THOMAS:** We've got several thousand people who reported being in the dust cloud. We need to break them up into groups, based on where they were. When they were in the dust cloud, they might have had a more or less dense exposure.

**MR. MADDELONI:** Yeah. The dust cloud traveled out and then dispersed and then, it went back south. So, if you were south of the Trade Center, you got more total dust than if you were north of the Trade Center.

**DR. THOMAS:** So now our first priority is to map where people were.

**DR. BRACKBILL:** We have about 13,000 people who report being in the dust cloud.

**DR. THOMAS:** In addition, we're going to map people against the plume data and modeled data. We can measure symptoms at the time versus persistent symptoms. We also intend to re-interview a certain proportion the people. Should also do medical testing of some sample.

**DR. MORSE:** I just want to follow-up a little bit about the comparison and control group, because obviously it seems like that's a limitation. You mentioned community surveys, but they don't interview the same people over time. That uses a random digit dial method, that's different people, so you're not following a cohort of people for symptoms over the time. Is there sufficient money to try to identify comparison and control groups? Otherwise, I guess your control groups are by exposure, so you have, you know, heavy exposure, moderate, and mild.

**DR. THOMAS:** We have a fair number of people who didn't stay in the dust cloud and didn't return.

**DR. BRACKBILL:** The problem with the registry is that we have so many different exposure populations, it would be difficult to have a control group for each. For example, with the pregnant women, you have to collect the information on nutrition, and past pregnancies, to actually do a study on pregnant women. And, we weren't asking those kinds of questions. Somebody else would have to do a more in-depth study to get that information.

**DR. MOSTASHARI:** In terms of your analysis time line, because you have to give feedback to the people, to just retain them, you may want to give some thought in terms of what things you analyze first. As you sort of get some short, quick results, you can give feedback. You know, if somebody is looking at the literature and keeping a list of findings found elsewhere, you can immediately look at your cohort and focus on those analyses where they show the same thing, as a second priority, I guess.

**DR. THOMAS:** That's a good idea.

**DR. LANGLOIS:** I wonder if releasing information about the numbers that you have enrolled in certain groups, and compare it to the target would encourage people to want to respond, sort of like the NPR fund-raising campaign

**DR. THOMAS:** That's a good idea.

**DR. DOHRENWEND:** For the data analysis, there are least two general strategies that I can think of. One is looking for clear dose response set-ups, where you have well-measured contrast on the exposure variables. If you got a dose response relationship — trying to locate what you could with reference to your various health outcomes, so that a particular [exposure] is somehow appropriate to the particular health outcome. And, if that could be supplemented with the location of very small sub-populations within each of your major categories, the small sub-populations being something like two different apartment houses where you actually enrolled and interviewed everybody — just two of them and other such strategic contrasts. And, mine for those that are just not done.

**DR. THOMAS:** Good idea, do more deliberate mining during our last three months of data collection.

**MR. RAMASWAMY:** With the TMI accident, our exposure was with low-level radiation. We needed to know the level or the extent of radiation the individuals were exposed to. We had the University of

*Pittsburgh, Department of Radiation Physics estimate the likely and maximum possible whole body gamma, thyroid and total skin doses for all the registrants based on the individual's residence location, distance and direction from the TMI plant, meteorological data, the whereabouts of all registrants who went in and out of the 5-mile area during the 10-day period after the accident. So, ultimately, these individuals' radiation exposure effects on the public health outcome (short- and long-term), if any, can be studied in the future.*

*For the WTCHR, (1) We should keep the registrants informed continuously and get them involved in the process right from the beginning via follow-up tracking, short-term morbidity or special sample surveys. Needless to mention, the value of this will be immense. The participation rate and the quality of our future studies will substantially improve and the current drop out rate will be minimized. (2) In addition to our goals and purposes of the registry, we may be able to develop new ones in time based on the ongoing feedback from the registrants on the new symptoms or health effects that may be unique to the particular event or accident. This will improve the utility, value and usefulness of the registry. (3) Also, we should have a well-defined registry data-sharing and data-release policies that will minimize the conflict of interests and the number of future critics. (4) In addition, the long-term follow-up studies should be well-defined in the beginning and the required financial commitments secured in advance. Otherwise, the long-term purpose and usefulness of the registry will be lost.*

**DR. BARON:** *On the issue of control populations, I think once you get into longitudinal follow-up, the time course will be more important. So, the issue of the control group probably isn't the most important question. What we want to know is, amongst those people who got dusted, as you said, and it's no surprise they had respiratory problems, was that a temporary thing? If you had underlying asthma, did that mean your course was worse?*

**DR. THOMAS:** *We'll be able to select controls from within our own database. Now to go back to the issue of comparing data...*

**DR. ENRIGHT:** *Well, Social Security number is the obvious one. Also during one of your surveys, ask them if they are also participating in that medical survey.*

**DR. THOMAS:** *You don't think there is any parallel analysis that would be worth doing?*

**DR. ENRIGHT:** *Well, I think with calculation for dose estimates, you can have two different ways to estimate, and compare and see how it changes the classification of dose.*

**DR. BRACKBILL:** *So, if we were to find that 20 % of the people, the workers, you know, also went through the medical screening program, what would that do? How would that help us?*

**DR. ENRIGHT:** *Well, I think just even knowing that proportion is worthwhile, because you can then report it. In other words, if it's less than 5 %, then that's very useful information to know. You say we've got two totally different cohorts that we're following.*

**DR. MORSE:** *Part of the spiel on the National Exposure Registry is to avoid duplication and to have, integration of data but there seems to be some duplication of some cohorts that are being followed.*

**DR. THOMAS:** *The NIOSH group is following-up on an incredibly detailed medical evaluation, fifteen hundred bucks per case, a battery of medical evaluations and follow-up. But we are doing a population-based health assessment. It would be a mistake for us not to have some of those people in the Registry, so that we can compare medical findings.*

## Final Comments

**In summary, everyone was asked to give final recommendations or comments.**

**MS. CAMPOLUCCI:** *For the follow-up, we may want to get back with some of you at a later date, and get more input from you, more ideas from you, as we move forward and look at analyses, and look*

*at what kind of data we have, what we actually end up with in our baseline group, so we can make determinations on what sort of studies should we be doing.*

*Hearing that other people have had the same sorts of issues about attrition rates, and follow-up, admiring what you have in the Netherlands, where you have all these records, electronic, on everybody which we don't have and probably never will in the States.*

**DR. WILLIAMSON:** *I would agree. Let's sift through the comments and see what we can do, if there's anything that we can do to tweak things in one direction or another, in order to get to where the scientific advisory committee, and New York City, and ATSDR, and other partners think that the registry could go.*

**MS. BROWN:** *If I can, skip down to the lessons learned? I did have a comment about the activities of this group, and the activities of other groups that have been involved in disasters. I just think that we shouldn't lose sight of the mechanism of public health in assessing things and then somehow seeing that services and needs are met and also to fold that back into policy. Somebody made the comment about the evacuation of the buildings. I hope that somehow through all this great effort that some recommendations can spill out into policy. I think of the article I saw in USA Today about how the floors were evacuated, and the safety things that had gone into place after the '93 attempt. And, I just think that's oh, so important, and it creates a purpose, I think, of the registry.*

**DR. DOHRENWEND:** *You had many good suggestions about follow-up and retention, which is further along the line than we've gotten. I think that there were some good valuable suggestions about how to screen for subsequent studies, I think, in terms of new — you had an in-house screening for duplication and appropriateness and then, what was it, a three-step procedure that you used? I'm talking about — I think it was the Nurses' Health Study.*

**DR. GRODSTEIN:** *The pilot testing, for some questions — on a hundred people, by mail, from among our sample.*

**DR. DOHRENWEND:** *Some of the lessons learned were learned too late, I think. For me, I would underline the importance of having a mandate. And, I think that the studies that have gotten near complete censuses and strong enrollment have had Congressional mandates, and legal mechanisms supporting them. And, I think it shows how important that is, and it's under, though, of lessons too late or obstacles too — too high, in this particular case. And finally, for me, I think it would suggest that given where you're likely to be or where you are now, that a very narrow focus, on very strategic comparisons, would be invaluable. I don't think there's time or rationale for anything else.*

**DR. BRACKBILL:** *I would just emphasize that I think that the commuters and other people who were in the dust cloud, people who were not part of emergency response and clean up, that this is the only real opportunity for them to have their health effects tracked. I think you need to do everything you can to recruit more of those people in this last three and a half months, and then to analyze the data and put them at the top of the priority list, as far as, you know, what we're getting out of this registry.*

**DR. THOMAS:** *That group, that's all the people who came back to live or work in lower Manhattan in the smoke, people are interested not just in the dust cloud on that first day, but the effects of the smoke and the burning plastics after that.*

**MR. MADDELONI:** *Absolutely.*

**UNIDENTIFIED SPEAKER:** *I think further realization of, you know, communication and the need to coordinate amongst the various agencies and players needs to be kept in mind.*

**DR. MORSE:** *I'd first want to take the opportunity to thank you for pulling this together. Actually, this is a great — whoever did this — collected people and pulled this together- a great panel of presenters, and the presentations of these — some of the most traumatic events of our time. I hope somebody's compiled this, almost like even a symposium of the talks and lessons learned. There are two things that I thought about which were mentioned. I think Henry Falk mentioned developing these protocols for acute compiling of registries of events like this, and that made me think of one issue that maybe you've already covered: they did this for bioterrorism, having — I forget what they call it — legal — CDC pulled together their legal group to sort of, you know, develop model legislation.*



**MS. CAMPOLUCCI:** *Actually, there is model legislation that's been published. But, it's up to the states to pass it. Unfortunately, not a lot of the states picked up on that and have passed it. I think, maybe, twelve have passed it?*

**DR. MORSE:** *But, this is the bioterrorism public health preparedness —*

**MS. CAMPOLUCCI:** *Right, it includes a component for data collection in an emergency situation, where you don't have to go and get all the clearances, and if that legislation is passed in that state, then it basically gives you the capability to do that, and it's within a specific time frame. If I remember correctly, its seven days hence — you have to begin within seven days of the event.*

**DR. MORSE:** *I guess the second point is there's still the question about sustainability, and I believe there were some — several people mentioned, you know, lessons learned on how to try to keep retention going. But, it looks like you have a time — a limited time frame that you're going to be able to follow these. Looking at past experiences, the funding is going to end, and you might have ten years. And so, you've got to, you know, capitalize and try to get as much information out of that time.*

**UNIDENTIFIED SPEAKER:** *One of the comments I thought that was really important if you could have some population that was captured at a fairly knowable percentage and, therefore, could be used to say some things about what happened in the community at large. And then, I guess, one other point that I think would be important is communicating some of the public health lessons. We were involved with a number of the workers working in buildings that were near the site who had to come back to work. And, it was a huge issue that they felt that they were forced to come back to work too soon, and it caused a lot of conflicts. And, I think having meaningful information about what happened, in terms of people coming back to the site that early on would be useful for future situations, in informing decisions about how long to keep an evacuation going would be quite important.*

**UNIDENTIFIED SPEAKER:** *I would echo that, and just add that one of the things I'm particularly interested in is whether the community had access to medical care and other services that they need. And, if there were particular pockets of populations that had it or didn't have it, and how, as a public health issue, the City and State can address those in the future.*

**DR. THOMAS:** *One of the things we've been talking about with Jim Cone, at a couple of our scientific advisory meetings, is to update the guidelines. NIOSH and Sinai did guidelines for doctors to use to evaluate someone, and we need to update those. People are still telling us that they have insurance, they have a doctor, but their doctor doesn't have the knowledge to evaluate them. Maybe NIOSH or Mt. Sinai could tell us what we could do to help, to just write some simple guidelines. What would you do, if you saw someone walking into your office? And then, that could be promulgated to — to primary care and pulmonary doctors.*

**DR. STELLMAN:** *Most of the really important things have been said already. And, I want to endorse what Dr. Dohrenwend said. Many of his comments are really right on the mark. I think some of our experience in following a cohort of Viet Nam veterans on mental health is at that the stage of the second follow-up, many years after the first one, people who are hardest to find and the people who are most likely to be missing from the second follow-up are precisely those people with the most serious mental health problems in the first round, because that's part of the effect. If you think of post-traumatic stress disorder, one of the characteristic components is distancing from social situations, and an interview of enrolling in a study qualifies as a social situation. So, that's really a serious aspect of planning future follow-ups. What I didn't hear was a list of your favorite hypotheses that you want to test. Bearing in mind that even though this is being constructed as a cohort, until you do that very first follow-up, this is still a cross-sectional study, you can only do a cross-sectional analysis. You might want to look through your favorite potential hypotheses, and look at statistical power, and don't waste a lot of time on under-powered hypotheses because, among other things, it could be a serious public relations problem and, you know, not because it's bad data, but just because you can't. And the last gratuitous piece of advice is that searching for control groups in the general population is a very problematic activity, and I would not devote a lot of time to it.*

**DR. SMITH:** *I want to also echo the — the nature of the discussion today. I think it's been right on target, and the presentations were very helpful. And, I come away feeling that you've got a good project and many of your problems have been seen before and partially solved. I have only three things to add — to emphasize, really. They've been discussed earlier. We know that there's going to be selection bias, self-selection bias. And, we know that you're going to have a fairly large cohort. So, my concern, in terms of recruitment, is not so much on trying to get the numbers up, but trying to take one group, and it may be an occupational setting group, where you have everybody itemized and you know who's in that group, and really try to do some data collection on that group, to do an initial interview to find out who's participating, who's not, why they're not, what the demographics are of those who participate and who don't, so that at least you have some — some information about that. Because we know you're going to have a lot of bias, and it will help you answer that question. The second thing is that, in terms of retention, I don't have any other ideas on how to increase retention. But, I'll just tell you an anecdote. I was actually talking with Dr. Grodstein during one of the breaks, about the fact that I'm in the Physician Health Study, which is very similar to the Nurses' Health Study, except that we all take vitamins, and pills, and placebos, and I don't know what I'm taking. I sense like in the Nurses' Study, there is a real esprit among the participants. There's an interest in what's going on. And, part of the reason, I think, is that they communicate with us fairly frequently, as they do in the Nurses' Study. So, my — my take-home message on that is that the more frequent, rather than less frequent, communication. Provide feedback and information about the study, what you're finding. Which brings me to my third point, and that is something that's already been said. Early analysis and early reporting out of results will not only serve the purpose of getting information back to participants and, hopefully, encouraging participation, but it may also answer the potential risk of your losing funding down the road. If you can show that you've really been productive and come up with good results early on, it's something that bolsters your argument for continuing long-term follow-up.*

**DR. ENRIGHT:** *I'm known for saying things off the wall, so I'm not going to disappoint. For your final recruitment push this summer, I think you ought to target low participation groups who, this summer, are in a single location. I don't know whether that would be a school, or working at a — that their whole company moved to some other place in the City. And, send out a lunch wagon, or a nice green truck with cost-subsidized, twenty-five cent Atkins-friendly treats, and then you can put a good recruiter there, with a pad, to sign up people if they were down here on that date.*

**UNIDENTIFIED SPEAKER:** *It's kind of hard to follow-up on that lunch wagon idea, but one of the things I've been thinking about through this whole day is what is the difference in the planning for what's going to be done as part of the registry, for say, in registry maintenance and analysis of data, from the veneer of data that you're going to collect, and what are the plans to do more in-depth analyses, and more particularly, how to define those ancillary studies. In the Nurses' Health Study, it's not unlike other large NIH-funded studies that invite other funding sources to contribute to what turn out to be very, very profitable studies, because they build on that initial data collection effort with some more detailed analyses, and maybe more detailed follow-up over time. So, I don't know if my colleagues at ATSDR have any plans for the future, to invite investigators to apply for funding for more in-depth studies that will be drawn from the cohort. And, I think that those often take a long time to get established, to get support for that, to actually get the funding for it. And, if you were thinking about that now, the funding mechanisms for ancillary studies.*

**DR. ALCABES:** *Just to state — sort of state the obvious. I'm not sure that we knew that it's always hard to do this when we started planning it. So, that's a little bit reassuring. There are two — I see two lessons, two real lessons, not to state the obvious. One is that the reason it's hard is — I think the reason it's both hard and complicated is that the registry, in a sense, is study-like, but has to try hard not to be a study. That is, in the way that a study, if it's good — at least this is what I tell my students — has to be focused on a single research question or a single set of related research questions. And, the registry's value is increased to the extent that it is not focused, and we try hard to be flexible in the sorts of research questions we'll be able to answer, now and down the line. What that means, I think, is*

*that this conversation we've started having now, about the analysis of the data, is one that's always going to be conducted on shifting sands, and we have to have this conversation again six months from now, and a year from now, not just because the science changes, what people know changes and, therefore, the research question will change, but also because the social and political arena is going to change and, therefore, the values will. The other one is that I think Dr. Morse's suggestion about legal matters, to me, was that it's one of the lessons we'll learn here is that this is a valuable thing to do. There are going to be other disasters for one reason or another, and it makes sense to have some policy in place about that would allow this kind of thing to start sooner. And, one of the things we're always battling against with this registry is how late a start we got. And maybe it doesn't have to be a law, we have agencies here that make policy, make internal policy that has the effect of setting a precedent that state and local health departments can follow. And so that, even short of laws, over which we don't have a lot of control, it may be that those policies can get developed at the federal level, the federal agency level — and I'm looking at the ATSDR people — in ways that would make it easier for local and state health departments to follow, you know, the next time a disaster strikes.*

**DR. METZGER:** *One thing that I've come away with is the variety of methods of follow-up later on. I think to maintain internal validity of the cohort, once you get them, it will be important to take advantage of all the possible ways of following-up people. And especially if there are certain methods that work better for certain sub-populations, that — to really take advantage of what other registries and other cohorts have learned, to maintain that follow-up.*

**UNIDENTIFIED SPEAKER:** *I really can't add much more than what's been said. I guess I'd just like to echo, I think, the importance of publishing what you can as soon as you can, and keep the registry participants vested in this — in the registry and feel that they have ownership, and that communication is ongoing. Because, as issues and questions come up down the road, you still want to have a population here that's going to be willing and wanting to work with you. I think that that's going to be critical for your long-term goals in the registry.*

**DR. PREZANT:** *I guess I was most struck by the statement that this is, really, five registries and maybe we should look at which of the groups we're weakest in and try to build that group.*

**DR. RAMASWAMY:** *I didn't have a chance to bring forth a lesson we learned, and that is our initial data collection efforts were more oriented towards hypotheses like what are the effects of low-level radiation and psychological stress. Our data collection efforts were based on these hypotheses. We didn't think of other hypotheses or collecting any information on them. But then, at the time we were collecting the data, there were some registrants in certain areas telling or complaining about some sort of metallic taste. Our staff took notice of it and put it under the comments section of the survey and we never had a chance to look at that data. We were waiting to look at that data until after the survey data collection was completed. Please don't do that mistake. Had we looked at the comments from the other people on metallic taste, we could have re-contacted these persons and collected objective data right then to develop new hypotheses to test. Afterwards, we learned that the metallic taste might possibly be from the vapor emanating from melting uranium core that might be going around for a few miles and local residents might have reported it. We, including our advisors and scientists, didn't think about it at that time. My advice is to make your registry, through data collection, a dynamic registry. Listen to people, not only to your advisors, to laymen, to registrants. Registrants might have to report some things that can be symptoms or conditions, which you will find are related to one of the hypotheses. Don't wait to analyze the data until every data piece has come in. Put somebody in to do some continuous exploratory analysis of incoming data, every batch, every week and get clues. A real epidemiologist can figure it out.*

**DR. DHARA:** *Following up on that idea, I just want to quote a sentence that the International Medical Commission on Bhopal has used, in terms of doing our own study in Bhopal. It says that the approach to communicate epidemiology needs to be one in which the community takes an active participatory role in the design, coordination, and implementation of the registry. The reason we really put this in was because environmental disasters are really social disasters, though there are*

*strong technical components. These are really social disasters in which social scientists need to be playing a very prominent role. We technical scientists can sit and talk to each other all day, but if we are not following up on what the community is really thinking, we're losing a lot. One of the examples I wanted to give you was that when we had the community advisors in our meeting, in our technical meetings, they were actually communicating the principles of epidemiology back to the cohort. They were telling the public this is exactly what we're doing. For example, one of the opposition — the question is why is everybody from the public not being included in the study? And, we were stumped for an answer. And finally, one of our community advisors told us that the way to communicate this back to the public is that we take the example of a pot of rice that is cooking. To find out if the pot of rice is actually completely cooked, you only examine one grain in this whole pot of rice. And, that is enough to tell you that this pot of rice is cooked. This is the way that epidemiology was explained to the public. And, believe me, when this happened, the participation in our studies actually increased. You know, right now, the problem is it's an adverse kind of situation. The Bhopal victims are saying what are we getting out of these surveys? They are getting nothing out of this. You're just coming and gaining information from us, and you're not giving anything back to us. But then we started involving these people in the survey. This is when we got this feedback and we actually began learning things from them, exactly like you said about the metallic taste. We started getting, you know, anecdotal information about what else to add in our research. So, this is my advice.*

**DR. YZERMANS:** *One final warning. I do my literature search every two weeks, and there's a lot written about this disaster, and as far as I'm concerned, there's a lot of rubbish, and it has influences on the survivors, and that's a real problem. So, I think this — the aftermath of this disaster is not coordinated in that sense, and there's a disconnect. So, the warning to you is don't feel the need to publish everything, for everyone. You don't have to.*

### **Final comments from ATSDR:**

**DR. WILLIAMSON:** *We've heard if before, whether it's lessons from the National Exposure Registry or from the WTCHR, I agree with a couple of other people who have brought this forward. We've got to be better prepared for these types of disasters. Although ATSDR and New York City partnered very well on this, still it was a matter of getting the money, getting contractors on board, a matter of two years before we were able to get back out into the field and start helping this community. And, that's too long. I think there are several things that we can do in advance, to help the public health community get prepared for these types of events. That's too late to help the WTC Health Registry right now. It's too late to help the National Exposure Registry.*

*But, I think we're all here with the World Trade Center Health Registry in mind, but also a bigger picture of the public health needs. I think of things that we're trying to work on at ATSDR, the Rapid Response Registry, for one, that will help position us to do that better.*

*In listening to all of the people talk about their registries today, I do think that we need to be a little bit more concerned with the scientific community and dissemination of results to the scientific community through whatever mechanisms are most effective. Yes, the Internet. Yes, maybe Government reports. But, certainly yes, peer-reviewed publications, because I think there was a paucity of peer-reviewed publications from our registries, and I think that we could all learn from whatever we put out in the peer-reviewed literature.*

*I think that those are the broader strokes. You all have hit on a lot of very detailed suggestions that I think are extremely important for the World Trade Center Health Registry. And, I would join in thanking you for all of your efforts to get here to talk about the registries, and to help provide guidance and assistance to the World Trade Center Health Registry, to help strengthen it. And, obviously, the results of the registry will be going on for years and years, so we'll continue to need your support and guidance.*

## Summary of Final Recommendations

### Completing recruitment

- Need to recruit more non-response worker cohorts to have enough sample of people who were exposed to dust and burning plastics
- Target groups with low participation to date, who are in a single location that is accessible to field recruiters (e.g., residents of an apartment building)

### Analysis

- Should focus on strategic narrow comparisons
- Make a reasonable list of favorite hypotheses and don't waste time on under-power hypotheses
- Do not spend time on establishing control groups
- Focus on one population that could be used to understand others
- Watch out for self-selection bias in large cohort
- Listen to the laymen because they may report symptoms or illness that merits exploratory analysis
- Should be concerned with dissemination of results to scientific community in a timely fashion.

### Follow-up, retention

- People hardest to find may be those with most serious problems i.e. during second follow-up
- Participants will be interested if they are regularly provided with feedback. Publish as quickly as possible

### Scientific and community guidance

- Science changes but so will social and political milieus — meet repeatedly with experts and advisors to reassess research questions
- The community including the lay community and representatives of the registrants should take an active participatory role in design implementation, social scientists must also play critical role
- Carry out early analysis and early reporting to reduce risk of losing funding

### Policy / insuring funding

- Some recommendations should spill into policy.
- Need a mandate from government to add weight to the initiative
- All agencies must coordinate with each other
- Sustainability: history shows that the funding will run out so must capitalize with time available.
- Carry out early analysis and early reporting to reduce risk of losing funding
- Cultivate funding mechanisms to enable more in-depth studies and to invite more investigators to apply for funding

### Use of the data

- Communicate public health lessons and answers to questions such as: how long should evacuation efforts continue? How to get access to medical care? How best to distribute masks and ventilators and maximize their use?
- Write up guidelines that doctors can use to evaluate exposure

The group was enthusiastic about the potential value of the WTCHR, and all acknowledged the large amount of ongoing work and attention that the project demands.

## Expert Panel Meeting on Public Health Registries, May 13, 2004: List of Attendees

<u>NAME</u>	<u>ORGANIZATION</u>
Ackman, David, MD	Nassau County Health Department
Alcabes, Philip, PhD	Hunter College, City University of NY
Baron, Sherry, MD, MPH	National Institute for Occupational Safety & Health (NIOSH)
Basu, Paroma	NYC Department of Health & Mental Hygiene
Bennett, Jo Anne, PhD, RN	NYC Department of Health & Mental Hygiene
Cone, Jim, MD, MPH	NYC Department of Health & Mental Hygiene
Digrande, Laura	NYC Department of Health & Mental Hygiene
Dohrenwend, Bruce, PhD	Columbia School of Public Health
Enright, Paul, PhD	National Institute for Occupational Safety & Health (NIOSH)
Evangelista, Pat	Environmental Protection Agency
Galea, Sandro, MD, MPH	New York Academy of Medicine
Geyh, Alison, PhD	Johns Hopkins University
Halperin, Bill, MD	Dept. of Preventive Medicine & Community Health/ NJ Medical School
Henning, Kelly, MD	NYC Department of Health & Mental Hygiene
Klitzman, Susan, PhD	Hunter College, City University of NY
Lalak, Chris	Westchester Public Health
Langlois, Jean, ScD, MPH	National Center for Injury Prevention & Control (NCIPC)/ Centers for Disease Control (CDC)
Lefkowitz, Dan, PhD	New Jersey Department of Health
Leiberman, Brian	New York City Law Dept.
Leighton, Jessica, PhD	NYC Department of Health & Mental Hygiene
Lin, Shao, PhD, MD	New York State Department of Health
McDonald, Jennifer	Agency for Toxic Substances and Disease Registry (ATSDR)
Maddeloni, Mark	Environmental Protection Agency
Metzger, Kristine, PhD	NYC Department of Health & Mental Hygiene
Morse, Dale, MD, MPH	New York State Department of Health
Mostashari, Farzad, MD, MSPH	NYC Department of Health & Mental Hygiene
Oglensky, Bonnie, PhD	Project Liberty
Peters, Eleanor	NYC Department of Health & Mental Hygiene
Prezant, David, MD	Fire Department of New York City
Pulliam, Paul	Research Triangle Institute (RTI)
Rutland-Brown, Wes	National Center for Injury Prevention & Control (NCIPC)/Centers for Disease Control (CDC)
Smith, Perry, MD	New York State Department of Health
Stein, Diane	Mt. Sinai Medical Center
Stellman, Steven, PhD	Columbia University
Stevenson, Lori	Mt. Sinai Medical Center
Thalji, Lisa	Research Triangle Institute (RTI)
Thomas, Polly, MD	NYC Department of Health & Mental Hygiene
Thompson, Claudia	National Institutes of Health (NIH)/ National Institute of Environmental Health Sciences (NIEHS)
Walker, Deborah, PhD	NYC Department of Health & Mental Hygiene

Wilt, Susan, D.Ph, MS	NYC Department of Health & Mental Hygiene
Wong, Frances, CSW-R	St. Vincent's Catholic Medical Center
Wu, David	NYC Department of Health & Mental Hygiene
Wunsch-Hitzig, Robin, PhD	NYC Department of Health & Mental Hygiene
Zimmerman, Regina PhD, MPH	NYC Department of Health & Mental Hygiene

**SPEAKERS**

Brackbill, Robert, PhD, MPH	NYC Department of Health & Mental Hygiene; ATSDR (WTC HR)
Brown, Sheryll, MPH	Oklahoma State Health Department
Campolucci, Sharon, RN, MSN	Agency for Toxic Substances and Disease Registry (ATSDR) (Libby)
Dhara, V. Ramana, MD, ScD, MPH	Rollins School of Public Health and Morehouse School of Medicine
Falk, Henry, MD, MPH	Agency for Toxic Substances and Disease Registry (ATSDR) (NER, Rapid Response)
Frieden, Thomas, MD, MPH	NYC Department of Health & Mental Hygiene
Grodstein, Fran, ScD	Brigham and Women's Hospital, Harvard Medical School
Ramaswamy, Krishnan, MSc, MS, MAdmin	Pennsylvania Department of Health, Bureau of Epidemiology
Williamson, G. David, PhD	Agency for Toxic Substances and Disease Registry (ATSDR) (NER)
Yzermans, C. Joris, PhD	Netherlands Institute for Health Services Research (NIVEL)