

Centers for Disease Control and Prevention

**National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry**

Board of Scientific Counselors

Records of the First Meeting

May 20-21, 2004

RECORDS

**Meeting held at the
NCEH/ATSDR Headquarters
Atlanta, GA**

Table of Contents

Acronyms used in this report.....	1
Summary of the Meeting.....	1
MINUTES OF THE MEETING	1
MAY 20, 2004	1
REVIEW OF THE MINUTES	1
PUBLIC COMMENT	1
PRESENTATIONS	2
<i>Proposed Ongoing Formal Program Peer Review</i>	2
<i>Peer Review of the National Human Exposure Registry (NHER)</i>	2
<i>CDC Futures Initiative</i>	3
<i>Function of the CCEIO</i>	4
REVIEW OF THE PREVIOUS BSC SUBCOMMITTEES AND WORKGROUPS	6
<i>Reports of the Three Previous Subcommittees'</i>	7
VOTE TO RE-ESTABLISH SUBCOMMITTEES AND WORKGROUPS	8
MAY 22, 2004	12
PRESENTATIONS	12
SECOND NATIONAL REPORT ON HUMAN EXPOSURE (NHER) TO ENVIRONMENTAL CHEMICALS	12
NCEH/ATSDR TECHNOLOGY TRANSFER	14
SETTING PRIORITIES FOR PHA ACTIVITIES AT SUPERFUND AND PETITION SITES	16
USE OF ENVIRONMENTAL BURDEN OF DISEASE IN WORK PRIORITIZATION	18
<i>Summary of the Subcommittees/Workgroup</i>	21
COMMITTEE RESPONSE TO CDC'S FUTURES INITIATIVE	21
Certification	22
Attachments	23
Attachment # 1: Meeting Attendance	24
Attachment # 2: Public Comment	27
Attachment # 3: Proposed Programs for Peer Review	30
Attachment # 4: Program Responses to NHER Peer Review	31
Attachment # 5: CDC Futures Initiative	34
Attachment # 6: Proposed BSC Subcommittee/Workgroup Charges	35
Attachment # 7: Setting Priorities for PHAs at Superfund and Petition Sites	36
Attachment # 8: Use of Environmental Burden of Disease in Priority-Setting	41
Attachment # 9: Motions passed	44
Attachment #10: Initial List of (ACTION) Items	45

Acronyms used in this report

APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officers
ATSDR	Agency for Toxic Substances and Disease Registry
BLL	Blood Lead Level
BSC	Board of Scientific Counselors
CCEIO	Coordinating Committee for Environmental Health, Injury Prevention and Occupational Health
CCHIS	Coordinating Committee for Health Information and Services
CCHP	Coordinating Committee for Health Promotion
CCIP	Coordinating Committee for Infectious Diseases
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CSTE	Council of State and Territorial Epidemiologists (CSTE)
DHAC	Division of Health Assessment and Consultation (ATSDR)
DHS	Division of Health Studies (ATSDR)
EBD	Environmental Burden of Disease
ECOS	Environmental Council of States
FACA	Federal Advisory Committee Act
NACCHO	National Association of County and City Health Officers
NAS	National Academy of Science
NCEH	National Center for Environmental Health
NCIPC	National Center for Injury Control and Prevention
NCHS	National Center for Health Statistics
NCHSTP	National Center for HIV, STD and TB Prevention
NCBDDD	National Center for Birth Defects and Developmental Disabilities
NCID	National Center for Infectious Disease
NEHA	National Environmental Health Association
NHANES	National Health and Nutritional Examination Survey
NIEHS	National Institute of Environmental and Health Sciences
NHER	National Human Exposure Report
NIOSH	National Institute for Occupational Safety and Health
NIP	National Immunization Program
NPL	National Priority List
OS	Office of Science
PHA	Public Health Assessment
PHC	Public Health Consultation
RCRA	Resource Conservation and Recovery Act
SARA	Superfund Amendments and Reauthorization Act of 1986
TCE	Trichloroethylene

**Summary of the Meeting
NCEH/ATSDR Board of Scientific Counselors
May 20-21, 2004**

The first meeting of the Board of Scientific Counselors to the newly consolidated National Center for Environmental Health (NCEH) and Agency for Toxic Substances and Disease Registry (ATSDR) was held in Atlanta, Georgia, on May 20-21, 2004. The meeting focused on the reconstitution of the subcommittees of ATSDR's Board of Scientific Counselors (BSC), a proposal to formally establish peer review of NCEH/ATSDR's programs as an ongoing process, and on the effect of CDC's Futures Initiative on the agency as a whole.

Presentations were provided relevant to each of the above, and specifics on the second National Human Exposure Report (NHER) and the peer review done of that program; on the organization of this committee and its sub-entities under the Federal Advisory Committee Act; on the process of setting priorities for public health assessments at Superfund and Petition sites; and on the use of disease burden as a method of setting priorities for agency work.

Reconstituted formal subcommittees were the Community and Tribal Subcommittee and the Program Peer Review Subcommittee. The previous Health Department Subcommittee was reconstituted as a workgroup. The Workgroup's status will be reviewed in a year.

Public comment supported development of the public workforce, the reinstatement of the Community and Tribal Subcommittee (CTS), and raised the issues of "brownhouses" and agency communication and work in the communities.

In **action items**, NCEH/ATSDR agreed to shorten the minutes format and to provide the committee with an NCEH/ATSDR budget breakdown and the names of the toxicological experts who recommended on the exposure prioritizations for the NHER. Committee members offered to provide the EPA Advisory Committee's consensus recommendations which involve ATSDR. Members offered to help the agency in listing standard batteries of tests across sites, to achieve more uniform data for analysis, and to develop a model of a document of collected site-specific data. The latter's purpose would be to help congressional representatives explain the agency's priorities to their own constituents.

BSC responses to presentations included the following:

- X *PHA priority setting*: pursue a more definitive way of setting and conveying priorities; seek partners to address lower priorities and non-agency mission tasks assignable to others; more efficiently identify and respond to target audiences by using an iterative process between sites that could accomplish some closure at all sites.
- X *Use of environmental burden of disease (EBD)*: This approach might miss prevention opportunities and important issues of sub-population disparities, miss

opportunities to explore high-impact smaller-dimension environmental interventions, and fail to identify data gaps. Attention is needed to how public or political attention to certain diseases affects agency funding. Approaches of interest discussed, other than EBD, included prevention and intervention strategies related to environmental disease, and looking at the interactions between the social environment, behaviors, cultures, and the genetic makeup of populations, and their contribution to environmental disease.

The **fall meeting** will be held on November 18-19, 2004. Future meeting announcements will include that there may be a closed executive session. Agenda items suggested for the next meeting included:

- X Reports of the two subcommittees and the workgroup.
- X Division of Health Studies presentation on how congressional inquiries, petition process, etc., all contribute to prioritization of the PHAs/PHCs.
- X Presentation on the NCEH/ATSDR budget.
- X Overview/briefing on the ATSDR toxicological profiles (past, present, future).
- X An overview of 2-3 programs, other than those peer-reviewed (every meeting).
- X Overview of how NCEH/ATSDR uses the social/behavioral sciences, with people with that expertise present.
- X Discussion of a matrix of the programs' position in the organization (understanding that this is evolving).

Actions related to BSC response to the Futures Initiative included:

- X Request for a presentation, in the fall or next spring, on the priority activities and how they were enhanced in value by the reorganization (i.e., increased effectiveness/efficiency across the previously independent elements), with performance measures for both CDC as a whole and the operating units. For example, outline how five initiatives advanced as a result of the reorganization (e.g., asthma response as maximized by NIOSH bench research extended to occupational and environmental associations).
- X Request for clarification of the CCHIS in terms of goals, function, and placement. Some of its functions are pure research and some are not. Reassurance was desired that this will not further separate the science from the programs. "Even soft boundaries can still mean nothing gets over them," it was commented. How does work cross between the Coordinating Centers (e.g., the CCEIO and the CCID)?
- X Request for a presentation on how the increased overhead to the lab, to support the reorganization's expanded administrative costs, affects NCEH/ATSDR.
- X Advice that the agency consider using terms reflective of partnerships with communities/groups, rather than "marketing" and "customers."
- X Request to know how the organization chart will reflect a high priority of addressing health disparities (e.g., restoring the Offices of Minority Health, Women's Health, etc.)

**Centers for Disease Control and Prevention
National Center for Environmental Health/Agency for Toxic Substances and
Disease Registry
Board of Scientific Counselors**

**MINUTES OF THE MEETING
May 20-21, 2004**

MAY 20, 2004

One May 20-21, 2004, the first meeting was held in Atlanta, Georgia, of the Advisory Committee to two, newly merged federal entities: the National Center for Environmental Health (NCEH), a part of the Centers for Disease Control and Prevention (CDC), and its sister agency, the Agency for Toxic Substances and Disease Registry (ATSDR). Those attending are listed in Attachment #1. One of the committee's two Co-Chairs, Dr. Melissa McDiarmid, was ill and unable to attend. The meeting was convened at 9:08 a.m. by Co-Chair Dr. Patricia Nolan

OPENING COMMENTS - Dr. Henry Falk, Director of the combined NCEH/ATSDR, welcomed the new advisors to this consolidated agency. Its Chamblee campus headquarters are hoped to be completed in 2-3 years. He described the "rolling roll-out" of CDC's Futures Initiative, which is changing the agency's organization and manner of working. The Initiative will remain an ongoing process.

REVIEW OF THE MINUTES - Dr. Nolan commented on the helpfulness of the detailed minutes of the last, joint meeting of the NCEH advisory committee and the ATSDR Board of Scientific Counselors (BSC). This committee will continue the BSC's role of program review, which will be an ongoing agency process. *A motion was unanimously approved* to accept the December 1-2, 2003, meeting minutes with two corrections: replace "environmental contaminants" with "environmental chemicals" (page 5, ¶1) and to delete the word "never" before "served in the military" (page 36). In discussion, the minutes' uses were outlined (Website posting, input to the agency's annual report). It was agreed to adopt a shorter format of summary minutes, executive summary, and list of action items. **(ACTION)** Tracking the latter is the responsibility of the committee's designated federal official (DFO), Dr. Thomas Sinks.

PUBLIC COMMENT was solicited four times in the course of the meeting and is detailed in Attachment #2. These comments addressed development of the public workforce, supported the reinstatement of the former BSC Community and Tribal Subcommittee (CTS), and raised the issue of "brownhouses" as a new health issue in Superfund communities. They called for greater communication with the communities in which the agencies work. A reassessment of the public health assessment and consultation processes was also suggested, such that the consultation would be more like the present health assessment, and the latter would be more like ATSDR's current rapid response process.

PRESENTATIONS were provided, beginning with the ***Proposed Ongoing Formal Program Peer Review***. CDC/ATSDR policy requires peer review of intramural research programs once every five years. To do so, an ad-hoc process began in 2002, with two board members and consulting experts. This provided valuable feedback. Dr. Robert Spengler, Acting Associate Director for Science, NCEH/ATSDR, described the proposed expansion of this peer review beyond intramural research, to include non-research program areas, public health services and extramural research programs. A formal Program Peer Review Subcommittee would establish workgroups to conduct the program reviews, with the support of the NCEH/ATSDR Office of Science (OS). The OS would select the reviewers with the approval of the agency Director and BSC Chair. The Subcommittee would meet between the semi-annual Board meetings, review the workgroups' reports, and recommend back to the BSC, which in turn would advise the agency. The Subcommittee requires one Board member to Chair it and a varying number of expert members to appropriately conduct the review. The program peer review process, which takes about eight months, was reviewed, and a list of 18 programs to be reviewed was provided (Attachment #3).

Dr. Harris, who had served on the last peer review, estimated a 2.5 to 3-week time investment per program, and urged the BSC members' involvement. Three options of review were discussed: 1) an official subcommittee; 2) workgroups reporting directly to the BSC (requiring more member time); or 3) independent special emphasis panels for each review, which would report back to the BSC. In *discussion*, the BSC members:

- X Agreed that such a group was needed to be a facilitator for workgroups and to ensure continuity between all of them.
- X Agreed that, since this is a critical function to the agency and likely to continue, the formal construct of a FACA subcommittee was advisable. Its transparency and ability to provide consensus advice outweighed the downside of its more cumbersome functionality (e.g., the FACA requirements of public meetings announced well in advance and, more importantly, that a majority [50% plus one person] of the Subcommittee membership must be BSC members).
- X Agreed that the subcommittee will read/review the workgroup reports but not vet (i.e., filter) them in any way. That is the BSC's function.

The ***Peer Review of the National Human Exposure Registry (NHER)*** was presented by Dr. David Williamson, Director of ATSDR's Division of Health Studies. The NHER was established by the 1980 CERCLA legislation (the Superfund authorization) to establish a registry of toxic substances in the environment. The NHER's collection, banking, and analysis of data on specific persons in targeted sub-populations help in assessing the long-term health consequences of exposures to hazardous substances. The charge of the 2003 NHER peer review panel was provided, as were the NHER's accomplishments, future plans (short- and long-range). Also provided were exposures and disease rates reported in excess (including for minority populations). (Attachment #4). The peer review panel recommended:

1. The analysis and dissemination of the 1989-2000 data. A large portion of the analysis has been done and draft journal articles are in hand.
2. A re-examination of the NHER design to allow better characterization of individual

- exposure and maximal use of the deep NCEH laboratory resources.
3. Collection of external input (e.g., an NHER science advisory committee, peer review, professional meeting presentations).
 4. A forward-thinking and opportunistic approach to program growth/direction: input from and collaboration with nontraditional areas/partners; maintaining cutting-edge technology/methods; maximizing database linkages; researching with NHER data and marketing the use of NHER data.

Committee discussion included compliments for Dr. Williamson's staff on what it had accomplished.

- X It was clarified that the 18 programs were selected based on their size (e.g., small ones could perhaps be reviewed with other areas). They include the congressionally funded programs and some narrow interest issues not well funded. No major activity was excluded. The maximum possible programs to review per year is probably four. Review of NCEH/ATSDR work in surveillance of hazardous substances and response to emergency events will be first.
- X A comparison of BSC and staff prioritization would be interesting. Other possible prioritization approaches included:
 - Program budget and its potential impact.
 - Particular populations/issues that might span across currently-defined programs (e.g., disparities).
 - Program impact as a get topic
- X The program review is not directed at specific studies, but the Program Review Subcommittee could comment on additional work needed. For example, there is no *program* on health effects among agricultural migrant workers, although other programs such as biomonitoring could include that. Over decades, a registry of such workers would involve thousands and be a natural program of itself. The Futures Initiative and the new linkage of NCEH, ATSDR, NIOSH and the NCIPC will pursue such holistic research approaches.
- X The BSC needs to advise, short-term, on the next programs to evaluate, and longer term, on a reproducible methodology to peer review so many programs. The methodology used for the NHER peer review should be examined as a model. A matrix of all programs (e.g., congressionally mandated or not) would be very helpful to understand the overall considerations. **(ACTION)**
- X Dr. Williamson reported that the data to 2000, now being finalized, will be reviewed with internal and external consultants to see how the registries could best serve the community. In the next couple of days, he expected to provide the reports generated to the peer review panel members, to ensure that their recommendations' intent was reflected.
- X Dr. McClellan hoped to hear about the consultants' response to the peer review. And, since such major efforts as better characterization of exposure will take considerable time to accomplish, he asked for a progress report in a year or so. **(ACTION)** He also advised agency care to avoid over-expectations by the study populations.

An overview of the **CDC Futures Initiative** was presented by Dr. Steven Solomon, of

the CDC Office of the Director. CDC is among the most trusted, credible and respected agencies in the U.S. and the world, but its last functional change was 25 years ago. The demands of a globalized world pose very different public expectations and economic and social milieus. It became clear that the public, decision makers, and even CDC's partners did not understand that CDC's work extended beyond addressing infectious disease. To rectify that and to gather greater support for its full mission, the ability to demonstrate the profound impact of its work on U.S. health was needed.

A strategic planning process began about a year ago in an outside-in process called the Futures Initiative. External consultants were interviewed on what was expected of CDC. To achieve a CDC that is interactive, bidirectional, data driven, and focused on its customers, the strategic direction was the first focus. That is complete; now the implementation stage of altering its structure and process is underway.

Dr. Solomon described the strategic imperatives in this initiative, the agency's specific health protection and preparedness goals, and the design principles that led to the new organizational chart (Attachment #5). The latter reflects the agency's intent to work with the partners, alliances, and stakeholders, through channels that encompass the public health system, communities, business, education, healthcare delivery and federal agencies. This will be done through a primary vehicle, the Coordinating Center for Health Information and Services (CCHIS), whose Director is Dr. James Marks. The CCHIS combines the established National Center for Health Statistics with two new Centers: National Center for Health Marketing (the outreach component, to understand the nation's health needs and to develop strategies to optimally deliver needed services) and the National Center for Public Health Informatics.

Feeding into the CCHIS are three Coordinating Centers and two Offices.

- X Most relevant to this committee is the Coordinating Center for Environmental, Injury, and Occupational Health (CCEIO), which combines NCEH/ATSDR, NIOSH, and NCIPC. Director: Dr. Falk.
- X The Coordinating Center for Infectious Disease (CCID, combining NCID, NCHSTP, NIP). Director: Dr. Mitchell Cohen
- X The Coordinating Center for Health Promotion (CCHP, combining NCCDPHP, NCBDDD, Genomics). Director: Dr. Donna Stroup.
- X The Office of Global Health. Director: Dr. Stephen Blount.
- X The Office of Terrorism Preparedness and Emergency Response. Director: Dr. Charles Schable.

All of these report to the CDC Management Council, Executive Leadership Team and Executive Board. These in turn receive input from another four CDC Offices: Strategy and Innovation, Human Capital and Professional Development, Science, and Public Health Improvement. Finally, the CDC leadership interacts with each of the above: the Director, the Chief of Staff and the Chief Operating Officer, and the Washington D.C. office.

Dr. Falk outlined the **Function of the CCEIO**. It is aimed to address the interactions of violence, workplace safety, and injury, and their connection to environmental health (e.g.,

emergency response and bioterrorism issues) to more effectively address non-infectious threats. The strong laboratories of NCEH and NIOSH will be better coordinated with each other and with the NCIPC's work with Poison Control Centers. The aim is for the CCEIO to be "small, nimble and agile," optimizing rather than diminishing all three Centers' work. Dr. Falk is assembling the transition team. Only Dr. Marks and he still direct Centers as well as Coordinating Centers. The Centers' advisory committees will not be combined, but a meeting of their Chairs could be helpful.

CDC's broader mission is more clearly conveyed, now that its organizational chart clearly shows infectious disease as only 25% of its mission. The Coordinating Centers will coordinate not just internally but between each other. The congressional mandates of both ATSDR and NIOSH remain undiminished.

Discussion included:

- X The CCEIO budget and staffing decisions are not finalized, but the addition of NIOSH's large budget roughly doubled that of NCEH/ATSDR, to a level of ~\$600-\$700 million. Staff is similarly doubled, to ~2,400. One challenge to the new CC, however, is NIOSH's distance from Atlanta, being housed primarily in Ohio and West Virginia.
- X The reorganization is designed to maximize efficiency, effectiveness and output. This, in turn, is hoped to optimize CDC's share of the federal budget. While the restructuring has been vetted through the DHHS, much must be finalized before the final structure can be submitted for an "official" determination.
- X The development of the Centers' and Coordinating Centers' collaborations is an active process. The relationship between the Management Council, Leadership Team and Executive Board with the rest of the organization is evolving, but it is meant to be more externally focused. This allows the CDC Director, her staff and their Offices to better focus on the institution internally.
- X Dr. McClellan called for ongoing evaluation of CDC's effectiveness and efficiency as the reorganization progresses (**ACTION**). He advised attention to the realism of the "marketing" desired, noting the necessarily wide variety of approaches involved, and caution to avoid neglecting the broad population's needs in an over-focus on special interest groups (e.g., industry, minority groups). Dr. Bowler commented that appropriate response to "special interests" vary, noting the greater needs of disproportionately affected minority and poor communities. ATSDR's original mission focuses on that inequality and must not be lost.
- X Dr. Nolan and others voiced concern that the charted CCHIS looked like a barrier. Dr. Solomon hoped not; it is designed to facilitate and amplify CDC's communication and interaction with the external world. It would act as a "sluice to speed things up" in disseminating products, and would centralize the information assembly for use and presentation in a life stages framework of health. Dr. Falk noted that new Centers and Offices were created to conduct work formerly done in part by previous CDC entities (e.g., NCEH's global health work). This will be important to discussions of funding and staff. However, the organizational chart is only "how" things will be done; the "what" will be addressed in the agency's setting

of explicit goals and priorities.

- X Dr. Wartenberg suggested the term “users of services,” rather than “customers.” He also noted that, while the unity of a single dissemination source such as CCHIS reflects one principle of good information, it also can depersonalize the process, which is contrary to good communication. He suggested consideration of a new healthcare model of scale (e.g., in which smaller groups allow patients to always see the same practitioner).

A **REVIEW OF THE PREVIOUS BSC SUBCOMMITTEES AND WORKGROUPS'** process issues and status was presented by Dr. Thomas Sinks, Acting Deputy Director for Program, and Ms. Renee Ross, of CDC's Management Analysis and Services Office.

Ms. Ross distinguished between the roles of subcommittees and workgroups in detail, and the process by which committee recommendations are advanced. FACA-charted groups, such as this committee and its subcommittees, require a quorum to conduct business (i.e., one more than half the membership). Electronic participation can contribute to a quorum. This committee's current quorum is 14 members, half the present membership of 26, plus one. The goal is to reduce that to 16 members within two years, however, and then the quorum will be nine. Non-voting federal experts and liaison representatives do not count toward a quorum. The consensus reached may not be ideal, but would be a final decision acceptable to all. Considerations are raised until all have had opportunity to speak.

FACA Subcommittees are designed for long-term work relevant to the agency, and report to a parent committee. Like the latter, the meetings must be open to the public and be announced in the Federal Register within 15 days of the meeting. The subcommittee must be defined in an established memorandum with a membership roster and the anticipated number of meetings. The DFO must be present at FACA meetings, but need not be at workgroup meetings. Workgroups are not subject to FACA. They generally are formed to address short term projects (normally less than a year) to research and analyze issues. They can be independent (i.e., not part of a subcommittee) and can be renewed annually. Their members need not be on the Board, and their consultants need not meet FACA's financial disclosure considerations.

Central to these presentations and the ensuing discussion was a newly received reinterpretation of FACA from the DHHS Secretary's office. Rather than the previous understanding that a subcommittee need have only one Board member, at least 51% of membership now must be Board members.

Discussion included:

- X Informal phone conversations with board members need not be announced, unless a quorum of members participate. That constitutes an open meeting, which must be announced in the Federal Register.
- X A “subcommittee of one” is not possible if any consultants are involved (i.e., one consultant would require two Board members). Subcommittee consensus decisions also require a quorum (e.g., of 5 subcommittee Board member, at least

3 must attend). Subcommittee rules do not apply to special consultants, only those who continuously attend or are members. Consultants do not contribute to a quorum or vote.

- X The workgroup's composition and function is decided by the Board. It was agreed that it should include at least one Board member, to report back.

Reports of the Three Previous Subcommittees' activities were provided. Dr. Gayle Windham, Chair, presented the history, activities, and accomplishments of the *Health Department Subcommittee*. Its members advised ATSDR's BSC on state and local health department issues. They drafted a Resolution on Bioterrorism and Environmental Health Tracking for submission to the BSC that was also incorporated in part into the CSTE position statement, assisted with the development of the Interstate Chemical Terrorism concepts (including a conference), and helped conduct a state survey on funds for chemical terrorism in BT projects. They also discussed, made presentations to the BSC, and proposed workgroups on vapor intrusion and arsenic in well water. Other activities included participation in the revision process for the PHAGM (chapters 8 & 9 in particular), and collaboration with the CTS on various issues. Reinstatement of this Subcommittee was proposed, with suggested membership by representatives of the CSTE, ASTHO, NACCHO, ECOS or NEHA, the APHL, state/local health departments, and a state that leads or carries out ATSDR activities.

Dr. Rosemarie Bowler reported for the *Social Behavioral Science Workgroup*. This group was charged to recommend initiatives and strategies to enhance development and support of the social/behavioral sciences in agency research and public health practice. They inventoried ATSDR's social/behavioral science activities and charted two areas of focus, chemical/bioterrorism events and hazardous waste sites. In remaining work, these would be examined for the components of prevention and health education, applied research, design of interventions and follow-up on the latter's effectiveness. Consultations were held with relevant CDC workgroups. Research questions were developed and framed through cluster analysis and a draft document for BSC input was submitted at the last meeting. Along with reinstatement of this workgroup, a one-day conference was proposed with external experts on methods and measurements of health surveillance, environmental research questions, etc.

Discussion included the Workgroup's ability to supplement ATSDR's unique role of response to chemical terrorism events. The after effects of such an attack are far ranging, since to the neuropsychological aspects of toxins involve both organic and behavioral manifestations. However, confusion lingered between the Workgroup's role to provide advice as opposed to conducting a program, and greater clarity on its products was requested. Dr. Bowler cited as one, development of a guidance document on what methods and measures should be incorporated into ATSDR's work on specific chemical effects. Of particular interest was developing a uniform standard of core data collection methods to enable data sharing, analysis, and research interventions across hazardous waste sites. Another was to add a behavioral component to the Office of Terrorism. The Workgroup would advise the Board of its recommendations, work with staff and perhaps other experts (e.g., in methods and measures). A term of one year

would be sufficient to complete what it had begun.

Dr. Elizabeth Howze, of ATSDR's Division of Health Education and Promotion, related public health's use of the social and behavioral sciences in responding to the stress after 9/11 among New York communities. More work is needed in these sciences to answer such community needs and to improve agency communication.

Awards to the CTS' special consultants, for the important contributions of their four-year terms, were presented by Dr. Falk to Ms. Cynthia Babich, of the Delamo Action Committee of Torrence, CA, and Ms. LeVonne Stone, of the Fort Ord Environmental Justice Center of Marina, CA.

Dr. Cynthia Harris reported on the *Community/Tribal Subcommittee (CTS)*. This group provided first-hand perspectives on ATSDR's community and tribal involvement. It held four face-face meetings (two concurrent with BSC) and 12 conference calls annually. They addressed issues and improvements to the toll-free ATSDR number; jointly participated in EPA's discussion on cumulative risk with the National Environmental Justice Advisory Committee; and participated in the revision of ATSDR's Public Health Assessor Guidance Manual. The latter included development of a community check list. Reinstatement of the subcommittee to ensure sustained involvement of the communities was proposed.

Committee discussion included:

- X It was unlikely that these subcommittees/workgroups would act as science advisors, as the agency already has plentiful peer review (e.g., from the CERCLA process, journal publications' peer review, program peer review panels, etc.).
- X In the past, ad hoc workgroups had provided helpful, non-consensus advice with community input, and the Board could be regularly updated on how such panels could be useful. An active dialogue with these groups and other formal advisory groups (e.g., the NCEH Lead Poisoning Prevention Advisory Committee, CDC's Advisory Committee on Immunization Practices), was urged.
- X To assist prioritization of the BSC's work, Ms. Dunlop requested information to enable a cost-benefit analysis of funding and staff resources. Dr. Falk agreed to provide a budget analysis for NCEH/ATSDR (e.g, grants, state cooperative agreements, etc.) by the next meeting. **(ACTION)**

A **VOTE TO RE-ESTABLISH SUBCOMMITTEES AND WORKGROUPS** was taken. The charges of each are listed in Attachment #6.

A **Program Review Subcommittee**, with a BSC member participating, could help to manage the evaluation of about four programs a year, up to the BSC's review/approval. It could ensure continuity of the process over time and allow transparency of the priorities that determine the programs to be reviewed. The Office of Science (OS) will facilitate, manage, and monitor the process. The Workgroup's reports likely would provide a range of opinions rather than a single statement. The Subcommittee would act as a review vehicle for the entire BSC in preparation for its consensus recommendation

to the agency. The Subcommittee and Workgroup would work with the OS to plan a prioritization scheme that would be brought back to the BSC for review and modification or agreement.

Dr. McClellan *moved that the Board establish an NCEH/ATSDR Program Peer Review Subcommittee to serve the function of organizing, facilitating, and providing a long-term perspective to the conduct of peer review of significant elements of the NCEH/ATSDR program, anticipating that 3-4 reviews would be initiated/completed each year. The total program would be reviewed over a period of ~5 years. The Subcommittee would serve a role of facilitation and continuity. The program would be carried out by workgroups with specific expertise related to the topics. The Subcommittee would act as a review or vetting committee to the entire Board of reports generated by the workgroup.*

Vote:

In favor: All
Opposed: None
Abstained: None

The motion passed to establish the Program Peer Review Subcommittee.

Health Department Subcommittee. While the subcommittee advantage is to provide consistency of approach over long period of time, Dr. Sinks felt that this link between the BSC and health departments could be done well through a workgroup(s) to address policies or specific projects.

Dr. Laessig moved to ask the Board to constitute a workgroup with the charge as given in the meeting book (Attachment #6), substituting the word "Workgroup" for "Subcommittee" in all locations; and that the agency be advised by the Board that the membership on this workgroup should include CSTE, ASTHO, NACCHO, and APHL, as well as ECOS or NEHA. Dr. Wartenberg seconded the motion. Amendments were:

- X Dr. McManus: *The workgroup's first task is to define the top 3-5 critical issues needing to be addressed at the next BSC meeting. Accepted by Dr. Laessig.*
- X Dr. McClellan: *With substantial agency funding to the health departments and the high degree of coordination needed, this should be a standing subcommittee. If this is initially a workgroup, re-evaluate the function of this workgroup and its potential transformation to a subcommittee after one year.*
- X Dr. Windham: *Have at least one workgroup member be from a state with a CDC cooperative agreement.*

Dr. Laessig agreed to these amendments and Dr. Wartenberg seconded them. There was considerable discussion of whether this should be a workgroup or a subcommittee.

- X Subcommittee advantages cited included its ability to hold the agency and itself accountable and to maintain long-term relations and interactions. Since health commissioners often serve only ~18 months, a stable entity to oversee the significantly changing dynamics is very important for both states and the federal government.

- X Workgroup advantages listed were that with all the suggested representation, the subcommittee could become larger than the BSC and prevent compliance with the FACA membership rules. To be practical, it seemed advisable to begin as a workgroup with a less complex structure. This would be reconsidered in a year, when the BSC would be more knowledgeable of the agency and its work. The currently critical component was to get the broadest possible field support for this agency. The 3-5 issues listed could be discussed at next meeting, and could indicate whether this should be a subcommittee or a workgroup.
- X To enlist the representation desired (perhaps aided by one or more multi-representatives), the group should be assembled to meet and conduct the exercise within six months. A BSC workgroup to pull this together was suggested.

A **vote** was taken to establish a subcommittee of four Board members, three standing members, and a dozen special consultants. With the Chair abstaining, six were in favor and nine opposed. The **motion failed**. The discussion returned to the concept of a workgroup and later consideration of a subcommittee, since the group's function was clearly important enough to support such.

Subsequently, *Dr. Wartenberg moved that the BSC establish a Health Department Workgroup to propose a more long-term process for addressing health department issues with respect to ATSDR and NCEH.* Dr. Laessig seconded the motion. Dr. Sinks cited the reality of the difficulty of achieving a subcommittee's quorum, one reason the CTS had not met for a year. Functionally, a workgroup better aided agency work. That was a deciding factor for Dr. Gold, who urged a pragmatic approach to move on. Dr. Laessig agreed, raising the importance that health departments be involved from the beginning.

Mr. Derouin offered a *substitute motion that the BSC create a workgroup to prepare recommendations to it that: 1) identify up to five of the most significant issues relevant to the relationship between NCEH, ATSDR and local/state and territorial departments of health, and 2) recommend whether the charge should be carried out by a workgroup or a subcommittee. The Workgroup would report back to the BSC at its next meeting and would make an effort to include organizations such as CSTE, ASTHO, NACCHO, APHL ECOS, NEHA, and others.*"

Vote on the substitute motion:

In favor: 7
 Opposed: 5
 Abstained: 4

The motion passed.

Community/Tribal Subcommittee. Since all the NCEH/ATSDR programs most directly affect the communities and their participation needs to be sustained over time, "*Dr. Harris moved that the Community Tribal Subcommittee (CTS) be reinstated as a subcommittee according to the charge in the meeting book (Attachment #6), but adding to the end, after 'and programs,' "... and with authority to recommend to the BSC the*

establishment of workgroups.” Dr. McManus seconded the motion.

Dr. Falk approved, noting that this could provide a method of forming other workgroups to address the needs of communities beyond ATSDR’s traditional constituency, but with specific public health interests (e.g., Mothers Against Asthma and Allergy). Dr. Nolan reported her conversation with Dr. McDiarmid about the importance that workgroup recommendations come back to the BSC for ratification. It must be clear that the workgroups are integral to the BSC, not just to their Subcommittee. Dr. McManus offered a *substitute motion, amending Dr. Harris’ motion to add that “Any Workgroup established by the Subcommittee would be reviewed and ratified by the BSC.”*

So, the substitute motion was to reinstate the CTS with the charge in the meeting book and including the authority to recommend to BSC the establishment of workgroups. A subcommittee, rather than a workgroup, was desirable for its openness, to reassure communities and tribal individuals that decisions are not made without their input. The CTS process was also set and ongoing, unlike the planned expansion of the Health Department Workgroup.

Vote on the substitute motion:

In favor: 16
Opposed: None
Abstained: One

The **motion passed**.

Social/Behavioral Science Workgroup. Dr. Bowler *moved to reinstate the Social Behavioral Science Workgroup in the form presented in the charge document (Attachment #6) for a period of one year.* Dr. Wartenberg seconded the motion. With a friendly amendment from Dr. McManus, she added clarification that the SBSWG “. . . a) will undertake the same type of activity as performed for ATSDR and apply it to NCEH; change b) to “identify social and behavioral science data gaps,” and delete item c) of the charge.

Discussion included:

- X The work described did not address the big issue of helping to lower the public’s stress level related to the science of risk assessment, and its fear over daily exposures and resulting chemical levels in the body. Perhaps “risk communication” should be added to its charge.
- X The proposal would involve more work for ATSDR staff, as opposed to independently providing input to the agency.
- X The charge should be more crisp (e.g., paralleling the Health Department’s Workgroup’s five action recommendations, but relevant to the social/behavioral sciences) and should be more realistic. In particular, part (a) of its charge was thought to be an impossible mandate.
- X A CDC-wide group is addressing the social/behavioral sciences. The contribution of this workgroup to the BSC’s work remained unclear.

Vote:

In favor: 3
Opposed: 13
Abstained: None
The **motion failed**.

Dr. Falk thanked the committee for their work and regretted that his daughter's wedding on the following day prevented his attendance. Dr. Nolan asked the members to tell her of their interest in working on the workgroups/ subcommittees formed, and the meeting adjourned at 5:55 p.m.

MAY 22, 2004

PRESENTATIONS continued on the following morning. A presentation on the CDC **SECOND NATIONAL REPORT ON HUMAN EXPOSURE (NHER) TO ENVIRONMENTAL CHEMICALS** was provide by Dr. James Pirkle. A summary of the report and a listing of the chemicals measured was distributed. Dr. Pirkle outlined the exposures and health effects pathways for external and internal dose. *Biomonitoring* measures the amount of persistent (present for an extended period) or non-persistent chemicals in the body, either as a toxicant or as its metabolites or adducts. With biomonitoring, exposures or disease can be detected, health risk can be assessed (using animal or human data), and interventions can be developed, applied, and assessed for effectiveness.

Prioritizing the toxicants for which exposures would be measured involves the number of people affected and the human dose, relative to a health threshold. Priority is given to: 1) the U.S. population and major U.S. demographic subgroups; 2) special population groups with known or suspected elevated exposures; and special populations with disease either known or suspected to result from chemical exposures. The nomination process of the chemicals to be measured and reported is detailed on the NHER Website (www.CDC.gov/exposurereport).

The proposed criteria, weighting process and selected criteria (Attachment #4) were announced for public comment in iterative Federal Registers. Addressing 116 chemicals, the NHER is the most extensive assessment ever done of U.S. population exposures to environmental chemicals. Samples collected in the National Health and Nutritional Examination Survey (NHANES) in 1999-2000 were used to measure these exposures. Report's communication stresses that a chemical's measurement does not equate to its harm. It reports the central tendency for a particular population group, the geometric mean (95% confidence interval), and high measurements for populations grouped by age in years (1-5, 6-11, 12-19, and 20+), gender, and race/ethnicity (Mexican American, non-Hispanic blacks, non-Hispanic whites).

Details were provided on blood lead level (BLL) measurements. These spurred Congress to accelerate the removal of lead from gasoline, rather than to allow its reintroduction (which was proposed). Subsequently, the risk of lead poisoning from dust was measured and reported. Present BLLs overall are <2 micrograms per deciliter (Φ g/dL). Among U.S. children, they dropped from 88.2% with levels of $\geq 10 \Phi$ g/dl in the

period 1976-1980, down to 2.2% from 1999-2000. The NHANES III data (1988-1991) measurement of cotinine exposure from tobacco smoke demonstrated that, rather than the tobacco industry's estimate of 23% of population so exposed, 99% were. This supported efforts to restrict smoking in public places. Levels in children were higher than in adolescents, who in turn were higher than in adults. Levels in non-Hispanic blacks were about twice higher than non-Hispanic whites, who in turn were higher than Mexican-Americans. CDC discovered that ~85% of non-Hispanic blacks smoke menthol cigarettes, whose anesthetic effects may have allowed smoke to be taken deeper into their lungs. NHANES showed a drop from 1988-1991 in median cotinine levels among children of 58%, 55% among adolescents, and 75% among adults. Nonetheless, children's levels are still more than twice the levels of adults, and non-Hispanic blacks' levels are more than twice those of whites or Mexican-Americans.

Practical examples of the usage of these data were provided. They related to the creation of smoke-free zones in airports; reassurance to firefighters at the World Trade Center about their chemical exposures; and elevations found of blood mercury levels in women of childbearing ages. New reports will be issued every two years, and more chemicals will be added for measurement. The upcoming (January 2005) report's chemicals to be measured are listed on the Website.

Discussion included:

- X To address questions about mercury in vaccines, the lab is developing a method to separate organic from inorganic mercury; that is, methyl- (from food), ethyl- (from thimerosal in vaccines) and phenyl-mercury. These data can then be linked to prospective pre- and post-vaccination epidemiological vaccination studies.
- X The American College of Toxicology recommended the experts who reviewed the list and aided prioritization of NHER chemicals' selection. Their names would be e-mailed by the DFO to the committee. **(ACTION)** Dr. McClellan wished for discussion of the experts' selection. Dr. Pirkle added that CDC used the weighted criteria in a numerical process from both those experts and from other sources of advice (e.g., An FDA request to include a chemical).
- X Arsenic is only now measured, thanks to a method developed to speciate the forms of arsenic exposures (i.e., from water versus from food). Previously, only the total arsenic could be reported. The 2003-04 NHANES is measuring those two different types.
- X *How reliable are the reference ranges of these limited samples?* NHANES' selection of the populations, methodology, etc., is described on their Website. They work with the Census Bureau to sample at about 30 U.S. county sites, based on major demographic factors (age, race urban/rural, etc). Sub-populations might be pooled under the "Other" category. Adequate sample size for small populations cannot be achieved. CDC ensures that there are no outlier results. Sites can be compared, but they are blinded to ensure privacy. If higher rates are seen at a site, EPA is notified so that this can be addressed without violating the confidentiality of the survey. With a mass spectrometry isotope dilution, work can be done on very small NHANES samples. One or two milliliters are retained for possible future work.

- X Manganese, which may go into gas in Canada, is now being measured for 2003-04; anything put into gasoline will be measured.
- X Another section of the Division does a rapid toxic screen, including all the nerve agents such as sarin. While it has a short half-life, sarin forms adducts that lasts a couple of months.
- X The success story for lead BLL reduction cannot be replicated for mercury, since it was not measured until 1999. Future reports will now be able to track levels.
- X Dr. Gold asked about the criteria for inclusion of substances in the National Report on Human Exposure to Environmental Chemicals. She had nominated trans-fatty acids for inclusion. She urged that CDC take a closer look at chemicals that occur naturally in the U.S. diet. The vast proportion of chemicals measured in the National Report are synthetic industrial chemicals, which are included primarily because of positive results in high-dose animal cancer tests. Every chemical, however, is toxic at some dose, and the proportion of naturally occurring chemicals in the US diet that are positive in those same tests (50%) is the same as the proportion for synthetic chemicals. The enormous background of naturally occurring chemicals casts doubt on the likely importance for human cancers of the low-level exposures to synthetic chemicals that are environmental pollutants. The focus on blood measurements of synthetic pollutants in the National Report ignores the "control group" of rodent carcinogens that are natural chemicals in the diet. An assessment of potential hazard requires a comparison of blood measurements for naturally-occurring chemicals in the diet. Dr. Gold also inquired whether the children with high cotinine measurements lived with smokers. Dr. Pirkle responded that trans-fatty acids were in the Priority #1 group. The lab is developing a test for trans-fatty acids, both conjugated and unconjugated, that they hope will be added to NHANES next January. The Report is not restricted to substances that do not occur naturally and NHANES has included other naturally occurring substances.
- X Ms. Cynthia Babich lauded the report as important information for the communities. She raised the issue of a predominantly Latino community nearby one of the country's largest mercury emitters, a DDT production plant. The biomonitoring done by ATSDR could not be compared to NHANES data, and the NHER reports Latino populations' DDT levels to be three times higher. She asked that the lab follow up with her to help her get the relevant agencies to address her community's problems. Dr. Pirkle agreed to consult with her. (ACTION) Ms. Babich also requested more meeting time for discussion.

NCEH/ATSDR TECHNOLOGY TRANSFER TO STATES was described by Laboratory Division Director Dr. Eric Sampson. Intramural funding for 24 Phase I planning grants sent a total of \$5 million grants to 33 states, to see how they could incorporate biomonitoring to their work. This was the first direct funding to state labs. For the Phase 2 implementation grants, 19 applications (\$18.5 million) arrived from 40 states, two territories, and the District of Columbia. However, with the doubling of the lab's internally-assessed overhead charges, they could award only ~\$2 million of the original \$5 million planned. With the lab overhead still rising, even less funding is probable (~\$700,000 to \$800,000 in FY04). Examples of the work planned by the grantees were

outlined:

- X New York: VOCs in children exposed to urban air pollution; cotinine levels to evaluate new smoking prevention programs.
- X New Hampshire: Mercury speciation in fish eaters (New Hampshire lakes have the nation's highest mercury levels); arsenic speciation in people drinking water from private wells.
- X New Mexico Consortium: Pesticide exposures in farm workers working in cotton, green chilies and peanut fields; arsenic speciation in the population.
- X New York City: NHANES-type sampling in four clinics (2000 adults aged 20 years and over, to determine health status and exposures to cotinine, mercury, and pesticides. Collaboration with New York state and CDC. Status: Underway.
- X States of Washington, Wisconsin, California, and the Western Consortium (NM, AZ, CO, MT, UT, and WY): Again, NHANES-type sampling, in the early planning stage. The biggest obstacle is funding, both state and federal. The potential NCEH issue to be addressed is public health training and service. Consortium states have the nation's highest arsenic levels in drinking water.

Discussion included:

- X Since all the of the laboratory's funding is internal, not external (one of the few for which that is so), the change in the overhead formula assessment hit them harder than many.
- X *Does the lab have measurement methods for amniotic fluid, cord blood, or breast milk?* The lab is working with universities to study the use of meconium as a possible measure of accumulated exposure, but that would be investigator-initiated work. Blood and urine are the best media for epidemiologic purposes; the number of tissue samples is limited. Dr. Pirkle said that measurement of breast milk has been suggested frequently (he asked the BSC's opinion), but the lab's sensitive methods can extrapolate from blood samples what is in breast milk; and the samples come from everyone, not just lactating mothers. Some work has been done on cord blood and amniotic fluid, but not in a major push. NHANES does not supply that. A large number of vitamins and nutrients are already measured in NHANES. That information is decoupled in the NHER report, but NHANES will provide those data on a CD.
- X More information on how to couple such data into the NHER was desired. **(ACTION)** National sampling does not allow identification and follow-up on cases that likely need attention. The lab does the quality control for the nation's newborn blood spot screening, but another issue is that many more conditions can be identified than can be addressed.
- X The current congressional allocation for the lab is \$37 million, but that is tied to many different studies. Delineating the cost of the NHER is difficult; it could be the cost of the test, or the cost of the infrastructure (~\$8 million for the ongoing exposure report). The other studies conducted, not part of report but aiding its interpretation, cost another ~\$8 million.
- X Dr. McClellan asked that this very important program have continued close review, which would also help to strengthen it. Dr. Laessig, as a state lab director, defined this as CDC's most valuable program to him. Its data is whetting the

interest of the state epidemiologists, and the lab's development of methods, which involves an expense beyond the states' capacity, is invaluable.

- X Dr. Nriagu asked what focus was in place to address the rising concerns of the elderly population. Dr. Pirkle reported that NHANES data analyses can be done for persons aged 60 years and over, and those analyses are issued in different reports.

The process of **SETTING PRIORITIES FOR PHA ACTIVITIES AT SUPERFUND AND PETITION SITES** was described by Dr. William Cibulas, Acting Director of ATSDR's Division of Health Assessment and Consultation (DHAC). Since 1992, ATSDR has attempted to implement formal approaches to the selection of sites and exit strategies for public health assessment, but these were consistently defeated by competing priorities. A new draft prioritization scheme was developed in 2001.

The committee's input was requested as to how to prioritize the sites and how to streamline the public health assessment process to be more efficient and timely. One of most important partners in addressing sites is the regional EPA operations staff, who work closely with communities on their region's site-specific concerns.

Dr. Cibulas outlined the authorities conveyed to ATSDR under the CERCLA legislation, to conduct public health assessment assessments for the ~1,250 sites on EPA's National Priority List. That constitutes about 66% of the agency's work. The balance is done under the Resource Conservation and Recovery Act's (RCRA) mandate to response to community petitions.

Also outlined were ATSDR's primary response activities, the definition of a public health assessment and public health consultations; the steps of the public health assessment process, what triggers it and what reports results; as well as examples of ATSDR's exposure investigations and technical assistance (Attachment #7). When an imminent hazard to public health is found, the ATSDR administrator alerts the EPA with a Public Health Advisory, but this is a rare occurrence.

Mr. Rick Gillig outlined the issues and criteria considered in setting priorities for site selection. Based on the Superfund Amendments and Reauthorization Act of 1986 (SARA) legislation, these are: potential health impact, community health concerns, site managers' needs, political interest (the wild card, but generally the citizens have already contacted ATSDR previously) and relation to CDC future goals. Clients and partners in ATSDR's work were outlined. Client feedback to date include appreciation of ATSDR's Rapid Strike Force and the detail of the health assessment, but also inconsistent timeliness of response and that documents are too long and hard to read. Three examples of rationales that prioritized of site work were provided (Attachment #7).

The committee members were asked how they would resolve competing priorities at selected sites, and how ATSDR could simplify the PHA process, provide more timely responses, and bring site activities to closure more efficiently. *Discussion* included:

- X Site evaluations have only been done after the PHA process, but the first site visit

could perhaps indicate the prioritization's appropriateness. About 25% of sites have been clear public health hazards; another 30-40% have been indeterminate, due to lack of clear data (revisits are done upon more information); the rest have no apparent, or no, public health hazard. Superfund work involves a multi-year process (e.g., the Tar Creek site has been worked by CDC/ATSDR and EPA for the last 21 years). Some sites' work results in a single document; others produce multiple documents over time.

- X Site-specific community concerns generally are on what site contaminants the community was exposed to, and if their health is impacted.
- X A small team was suggested, including some Board members and ATSDR staff, to analyze the key aspects of the work done and data collected to date (i.e., the site chemistry involved, potential routes of exposure to a population, etc.) to set up a prioritization scheme. Mr. McManus offered to help.
- X Site work is iterative to some degree (i.e., what is learned at one site is reapplied to others), but more could be done. One approach might be to select the top ten substances found at sites and assess whether the approaches to them were consistent, given that sites differ.
- X There are multiple audiences for the public health assessments, among them EPA, for remediation; the community, for health status; and the scientific field, for new knowledge. Greater flexibility would be good in the type of document developed, but CERCLA's PHA requirements are inflexible. A new monitoring approach developed by ATSDR for a non-Superfund Western New York accidental release site was described and appreciated. Such assistance to states, and greater interagency cooperation/collaboration, are to be desired.
- X The number of petitions received by ATSDR is variable. The peaks seen in the early- to mid-1990s might have been due to the Federal Register notice about the ATSDR petition process. To date, 30 have been received in 2004 and the frequency of petitions has risen for no apparent reason. Dr. Harris suggested exploring whether the average 2.4-year study length has discouraged communities from petitioning. Ms. Leslie Campbell reported that a new petition process is being prepared and offered to share it with the Board. Dr. Harris also wished to review the petitions as well. **(ACTION)**.
- X Dr. Bowler offered to work with staff on behavioral social tests to include in site work in order to produce more useful data (e.g., for health studies, the use of normative data as well as control/exposed methods). She urged the BSC to form a workgroup or other method to help the larger PHAs use control groups as well as special populations. This could maximize the use of the very rare and valuable data on special populations.
- X Mr. Derouin offered to provide some of the EPA advisory committee's consensus recommendations which involve ATSDR, and volunteered to participate in a peer review or workgroup. He advised greater clarity to communities of what the ATSDR work product would be and making it more user friendly.
- X *What is the relationship of NCEH/ATSDR and the NIEHS?* Communication is underway to incorporate ATSDR's needs into NIEHS work (e.g., NIEHS methodologic studies of arsenic speciation). Prioritization of data needs has been successfully coordinated since 1992 between the agencies, and the last NIEHS

basic science grant announcement has a strong component of development of more robust techniques to document exposures in real time. ATSDR is also researching with NIEHS on how the community understands the PHA process, what it expects, and how they respond to the PHA regarding their own individual behavior change.

- X *How are health effects prioritized for ATSDR assessment?* The health studies are done as a result of public health assessments and consultations, congressional inquiries, the petition process, etc. Perhaps this can be discussed by the Division of Health Studies at the next meeting. **(ACTION)**
- X Ms. Dunlop stated that how an exposure impacts public health is the number one issue, and that the best presentation of information is in a transparent, uncomplicated way. Prioritization will always be necessary due to finite resources. She urged ATSDR to develop and regularly release (e.g., monthly, bimonthly, etc.) such a simple site-specific document, to give information to officials and the public so they can make decisions. Education also is essential to ensure that the communities understand that environmental impacts will differ between sites. She offered to help ATSDR with its work as she could.
- X *Is ATSDR trying to align its prioritization criteria with those of other agencies also addressing sites?* No, but ATSDR has sought input on the two prioritization schemes developed to date.

Dr. Nolan summarized the excellent presentation and session. It raised side issues not part of DHAC work that could be addressed by the DHS at the next meeting. Points made included the need for a more concrete way of evaluating priorities and the effect of past prioritizations; the need to find partners to address low priority work and/or work not part of ATSDR's mission; and the contribution that an iterative process could make, for example, to open or close work at other places.

The background and methods used in an ***NCEH/ATSDR ASSESSMENT OF THE USE OF ENVIRONMENTAL BURDEN OF DISEASE IN WORK PRIORITIZATION*** was presented by Dr. Josh Mott, of the NCEH Air Pollution and Respiratory Health Branch. This exercise was done very quickly (~3 weeks) upon the request of CDC's Director. It compared budget expenditures and the burden of disease or risk factors for disease, and assessed the attributable and preventive fractions of the leading causes of death and disability. A more thorough and systematic study will be done. That will include complete review of cohort studies and expansion the quantitative component of the current analysis, creation of summary tables, recalculation to allow comparisons, and development of summary statistics (medians, range). The report will then be summarized and published.

The uses of an EBD assessment were outlined, as were three different EBD studies by the Dutch, the WHO, and one American study. Each defined "environment" differently and assessed different contributors to disease. After review of such existing work, NCEH and ATSDR staff identified major ICD-10 disease categories. They assessed them as related to a broad view of "environment," including chemical events, war, and the built environment. Other than morbidity and mortality, EBD indicators such as economics, qualitative environmental associations, and estimated environmentally-

attributable risk were used, as well as other quantitative risk measures.

Attachment #8 provides the details of this presentation regarding the EBD associations for asthma, COPD, CVD, all cancers, birth defects, infectious diseases, nervous system disorders, obesity, diabetes, and mental health.

Discussion included:

- X Diet was included in the chain of EBD examined (e.g. the built environment, access to food, opportunity to exercise, etc.)
- X Health disparities between populations and demographic subgroups are anticipated to follow EBD.
- X This work is a research priority that could find potentially important causes of disease and will identify data gaps. Consistency of the outcomes studied across categories was advised, as was developing QALYs and a sensitivity analysis.
- X Given CDC's mission (and name), use of disease burden for setting priorities (rather than, for example, exposure), was suggested by a member, as was the inclusion of diet as an important component. Multivariate analysis probably will be needed to address multiple causes of death.
- X Dr. Koenig advised emphasis that associations are not proof of a cause and effect. He noted that U.S. air is cleaner today; four of six major pollution components have decreased in the last 30 years and the other two remained stable. Rather than the quality of outdoor air, increased asthma may have more to do with increased use of antibiotics and children staying indoors in protective environments, leading to a weaker immune system. The ozone level of outdoor air also may have less to do with disease than airborne particulate matter.
- X Dr. McClellan urged an understanding of the base statistics for the U.S. in comparison with the current measures, as well as the regional, SES, ethnic, etc. variables involved. He cautioned that much of the literature was developed for regulatory use (e.g., the standard cancer risk coefficient is the upper 95th percentile, which is not a true risk estimate).
- X The three studies cited demonstrated the difficulty of deciding the appropriate definition of "environment." There is also an internal environment, involving micronutrients and the effects of genetics. NCEH/ATSDR will have to agree internally how it will proceed.
- X There was some thought of limiting the analysis to the stronger data of cohort studies. But Dr. Nolan discouraged any over-limitation, since discoveries often come from "side routes." Dr. Gold agreed. A restriction to only cohort studies would miss a lot of environmental research. She suggested, instead, developing a strength of evidence matrix for the result cited; urged the inclusion of diet; and suggested formation of an intra-agency committee to focus on this issue of evidence.
- X Dr. Wartenberg encouraged going beyond mortality to disease incidence, QALYs, years of life lost, etc. Death occurring earlier due to some factor is important to examine, and will be fundamental to understanding the burden of disease. This will be harder to tease out of the literature. That is particularly true with the narrowness of the literature on sub-populations, which may merit a higher priority

- for intervention than the broader population.
- X Dr. Okun recalled a recent publication on EBD by an Emory professor and offered to provide the reference.
 - X Assurance of clear criteria/methodology was urged to facilitate reproducible research. Also recommended was clearly marking report data “DRAFT” to prevent its citation as final work, and including a study limitations statement. It should be stated from the beginning that there are no really good measures of health, but there are of disease. CDC should start thinking of how to measure health and try not to lose sight of things that impact that.
 - X Dr. Nriagu advised caution in defining “disease burden,” noting that the U.S. has poor populations that still have third world diseases. The burden depends on the population examined. Some way to link these different worlds in the analysis is needed.
 - X Comparison of budget expenditures to disease burden and risk factors misses the disease prevented (e.g., by providing clean drinking water, or lowering blood lead levels). Such things, which admittedly are much harder to measure, also should be in the analysis.
 - X This EBD analysis was conducted CDC-wide, but NCEH went a little farther in providing attributable risk information.

Dr. Nolan summarized that an EBD analysis might miss prevention opportunities as well as subpopulation disparities (which could miss smaller intervention opportunities of potentially great impact) as well as data gaps. Not mentioned in this discussion was the need to attend to how things like EBD get involved in funding decisions. Such diseases lack the cache of the “disease of the month” or of a congressman’s family. Several other approaches were suggested: environmental disease as related to prevention and intervention strategies, interactions between the social environment, behaviors and cultures; and the genetic makeup of populations.

CLOSING DISCUSSION. The *fall meeting* was scheduled for November 18-19, a Thursday/Friday. Future public notice of the meetings should include that there could be an executive session called. **(ACTION)** Agenda topics suggested were:

- X Reports of the two subcommittees and the workgroup.
- X More time for discussion
- X Division of Health Studies presentation on how congressional inquiries, petition process, etc., all contribute to prioritization of the PHAs/PHCs.
- X Presentation on the operational NCEH/ATSDR budget.
- X Overview/briefing on the toxicological profiles, past, present, future.
- X Every meeting, overview of 2-3 programs, other than those peer-reviewed.
- X Overview of how NCEH/ATSDR is using social/behavioral science, with people with that expertise present.
- X Presentation of a matrix of the programs, to position them within the organization.

This committee can suggest expansion of programs, but should also suggest how to expand and fund them.

A Summary of the Subcommittees/Workgroups was provided:

Program Peer Review Subcommittee: Chair: Terry McManus

- X Fast track development. Interested members: Roger McClellan, Becky Norton, Dan Wartenberg. Dr. Nolan will set up a conference call with Drs. Sinks and McDiarmid the first week in June and will ask Dr. Bowler of her interest in this group. Two others not at this meeting could provide a good distribution of membership.
- X First step: decide how to select the programs to be reviewed. Dr. James Melius' input will be welcome. Dr. Cynthia Harris also is willing to work on this.

Community and Tribal Subcommittee: Chair: Dr. Cynthia Harris.

- X Suggested membership: seven; four BSC members and three consultants. Interested members: Jerome Nriagu, Miguel Fernandez; one more person is needed.
- X A way to figure out how to downsize this committee is needed, such as good use of special consultants on both subcommittees.
- X Clarity about how recommendations are accepted and followed up is needed. If the latter will not be done, suggest ensuing routes for the subcommittee or workgroup to pursue. Ensure that linkages and dialogue are related to specific work activities and actionable products, since their report lets people know that they have been heard.
- X The Board is to identify how it can be most effective in terms of its role with the CTS (e.g., linking to priority issues with consultant input, how best to engage and charge the CTS; use of the tracking system and of feedback loops). **(ACTION)**
- X Further public comments are desirable other than from special consultants (i.e., general public).

Health Department Workgroup Chair: Dr. Gayle Windham.

- X Members should be appointed by the second week in June. This will be discussed with the co-Chairs in the teleconference the first week in June. The Office of Science will support the workgroup; the process can grow/shift over time.
- X First step: identify the five most significant issues to health departments and discuss whether this should be done by a subcommittee or workgroup. This will be decided by the BSC in November. Examination is needed of the group's representation, both institutional and of broader involvement by groups not now so involved. When the subcommittees and workgroups are formed, the OS will be asked for support. The subcommittees need a DFO. The agency will assign the Executive Secretary (the primary DFO) and then assign a co-DFO if needed.

COMMITTEE RESPONSE TO CDC'S FUTURES INITIATIVE WAS AS FOLLOWS:

- X The Initiative and the "rolling reorganization" offer opportunities for both improved effectiveness and efficiency. However, concern was also expressed about its apparent increase in bureaucracy and the remaining lack of clarity of what exactly all the new components were to accomplish. A presentation in a year on the priority activities and how they were enhanced in value (i.e., increased

effectiveness/efficiency across the previously independent elements) was requested, with performance measures for CDC as a whole and the operating units.

- X There was concern that the science and the programs would be further divorced by this reorganization. In the presentation a year from now, show how five initiatives advanced as a result of the reorganization (e.g., asthma response maximized by Morgantown bench research extended to occupational and environmental associations).
- X The CCHIS in particular puzzled members, with its placement looking more like a counterproductive barrier and depersonalization of communication.
- X Concern was expressed about the radical rise in the laboratory's overhead charges, which seem to support the expanded administrative costs. An explanation was requested of how that escalation happens and how it affects NCEH/ATSDR.
- X The use of terms reflective of partnership, rather than "marketing," was advised.
- X If health disparities are a high priority, that should be reflected in the organizational chart (e.g., Offices of Minority Health, Women's Health, etc.) Dr. Falk said that the placement of such Offices is not yet finalized; they may be in CCHIS to relate directly to the public.

With no further comment, Dr. Laessig moved to adjourn and Dr. Gold seconded the motion. The meeting adjourned at 3:20 p.m.

Certification.

I hereby certify that these minutes are complete and accurate, to the best of my knowledge.

Patricia A. Nolan, MD, MPH, Co-Chair

Date_____

Attachments

Attachment # 1: Meeting Attendance

Dr. Patricia Nolan, Co-Chair
Dr. Thomas Sinks, NCEH/ATSDR, Designated Federal Official

Committee members:

Dr. Rosemarie Bowler
Mr. James Derouin
Ms. Becky Norton Dunlop
Dr. Miguel C. Fernandez
Dr. Joxel Garcia (5/20)
Dr. David W. Gaylor
Dr. Lois Swirsky Gold
Dr. Cynthia M. Harris
Dr. Nancy K. Kim
Dr. Harold M. Koenig (5/21)
Dr. Ronald H. Laessig
Dr. Roger O. McClellan
Mr. Terrence J. McManus
Dr. Jerome O. Nriagu
Dr. Geary W. Olsen
Dr. Daniel Wartenberg
Dr. Gayle C. Windham

Members absent:

Dr. Melissa A. McDiarmid, Co-Chair
Mr. Scott Holmes
Dr. Ngozi T. Oleru
Dr. Dennis Paustenbach
Dr. Donald Statuto
Dr. Raymond S.H. Yang

Ex-Officio liaisons present:

Dr. Andrea Okun, National Institute for Occupational Safety and Health
Dr. Buck Grissom (for Dr. Allen Dearry), National Institute of Environmental and Health Sciences

Ex-Officio liaisons absent:

Ms. Barbara Brooks, Department of Energy
Dr. Bonnie Richter, Department of Energy
Dr. Hal Zenick, Environmental Protection Agency

ATSDR/CDC staff present:

Dr. Henry Falk, Director, NCEH/ATSDR

Carol Aloisio

Grant Baldwin
Mark Basher
Sherri Berger
Kim Blindauer
Martha Boisseau
Valeria Brown
Leslie Campbell
William Cibulas
Debbie Combs
Alan Crawford
Carolyn Cusak
Scott Deeter
Chris DeRosa
Michael Donnelly
Michael Fay
Miguel Fernandez
Diane Flagler
Sharon Williams Fleetwood
Richard Gillig
Ginger Gist
Carolyn Harper
Cynthia Harris
Janet Heitgerd
Dan Holcomb
Libby Howze
Helen Kuykendall
Penny Lampe
Sandra Malcom
Susan Metcalf
Moiz Mumtaz
L. Laszlo Pallos
Cathie Ramadie
Renee Ross
Eric Sampson
Jay Sapp
Steven Solomon
Robert Spengler
James Tulus
Pamela Tucker
Preston Wang
Megan Weil
Mildred Williams-Johnson
Ronnie Wilson

Members of the public:

Tim Aldrich

Cynthia Babich
Shirley W. Baker
J. Kyle Bryant
Robert Duff
Lawrence Hanrahan
Earl Hatley
Marie Josette Murray
LeVonne Stone
Ross Vincent

Attachment # 2: Public Comment

Dr. Tim Aldrich, a former Special Consultant to the previous Health Department Subcommittee, asked about CDC's attention to health department employee development, thinking the organizational chart identified human development only as internal to CDC. Dr. Solomon explained that this is also external, through the Office of the Chief of Public Health Improvement. That Office will help to improve state and local capacity as regards public health resources, organization, infrastructure, new ways of doing business, etc. CDC's education on what the public health system delivers also will include healthcare delivery system professionals, to get them more engaged in the entire process (e.g., by rotating people from healthcare delivery into the public health system).

Dr. Aldrich asked if the agency's response time varied according to whether a state has a cooperative agreement. Mr. Gillig was unsure that such information had ever been analyzed. Dr. Aldrich also was part of the exposure registry review which was done last fall. He noted that the definitions were 20 years old and should be updated. He suggested that a health assessment should be more like a health consultation and the consultation should be more like the rapid response, to better serve the agency's clients. The workgroups might be able to help in such a reassessment of the process.

Mr. Ross Vincent, a former Special Consultant to the previous CTS, disliked the use of the term "customer," pointing out that taxpayers are "employers" of government. He preferred, if necessary, the term "beneficiary." He also asked the difference between informatics and information and statistics. Dr. Solomon defined informatics, as he understood it, as the whole model of how information moves. For example, the Informatics staff had national and international linkages set up within 24 hours of the recognition of SARS' threat. This new areas of expertise (and terminology) supplements the well-defined portfolio of NCHS' information-gathering activities. Mr. Vincent supported work to "shorten the distance between people with information and those with services and products needed by the public."

Ms. LeVonne Stone, a former Special Consultant to the previous CTS, spoke three times. First, she noted that communities were under health systems on the organizational chart, separate from the agencies and stakeholders. She asked where federal facilities fit in, since these include their involved communities. Dr. Solomon responded that the reorganization and chart were not yet official, but the content and meaning would remain. He was sensitive to the different connotations/denotations of "community." That is one challenge to communicating how this organizational structure would maintain CDC's credibility and commitment to those served.

Later, Ms. Stone wished the agencies to more quickly involve community residents in the work done at hazardous waste sites, and inform them of the work and findings on exposure health effects. She cited four years of bringing concerns to a point where there seemed some action might result; of asking the agencies' standing regarding environmental justice and communities of color in the U.S.; and of traveling to the agency to express her wish to participate and be heard. She cited work to get a

community stress program, which turned into a two-year process that resulted in nothing. She said she felt short-changed, and particularly mentioned her disappointment at not attending CDC's partners' meeting. She asked what had happened to the protocols developed.

She read, as an example of the materials the people are receiving, from a portion of a health risk assessment. It cited the use of a conservative assumption that a person would breathe in the contaminant/chemical for "30 years or 6 years," and she asked "what on earth that [meant]?". The PHA explained that PCE was used for years at federal facilities to wash uniforms, equipment, etc., which went into groundwater. She then commented on community residents "getting nose bleeds for no reason," and that "some seem to think the people are not smart enough to know the difference between exposure health effects and allergies." She stated that the communities will fight to be heard, since they are forced to stay and suffer with what is in their environment.

Finally, Ms. Stone charged that the PHAs do not provide good results for the communities, that the less affluent African-American community rarely gets to comment on the process, and that they must participate in creating the resulting documents. The agencies must advise when they send someone into the community, not after the fact. She stated that she had not had a response to her petition, and called for the entire process to be more transparent.

Mr. Earl Hatley, of the Cherokee and Delaware Nations, was part of the work that resulted in "Inconclusive by Design." This document discussed how public health assessments never concluded anything for the communities. He also helped draft the checklist for the community and tribal protocols. Listing his own personal contributions, he outlined the help that special consultants can provide in working with the CTS and BSC, and looked forward to continuing this input. He encouraged the Board to reinstate the CTS and the continuation of its Public Health Assessment Workgroup, which contributed to the PHA guidance manual and the community checklist. His opinion was that PHA requests had dropped because the public has no confidence in them. They wonder what will happen if they do not get a "good result," since 40% are determined to be inconclusive. His community petitioned ATSDR to return to Tar Creek, where only the groundwater path was studied, but not the mountains of chat piles (mining debris). Scattered among residential areas of the county, these were used for driveway and other construction. EPA studied children's blood lead levels in Region 7, but not in Region 6, and left Tar Creek for ten years. They only returned because one doctoral candidate doing a study for the IHS raised other environmental concerns. Reconstituting the Workgroup could reassure the public about the value of PHAs by linking community representatives into the process.

Ms. Cynthia Babich related her activism to the discovery that DDT in her backyard was contaminating her chickens and organic vegetables. She has worked with agency staff for ten years. Not renewing the CTS would be an error, in her opinion, particularly after ATSDR spent ~\$50,000 on the "painful, but productive" evaluation of the CTS. She also expressed her insult if cost-benefit was to be a major consideration regarding agency

work, since angry people are waiting for a response. She urged against not renewing the CTS as a potential cost-cutting measure. Providing copies of the comments generated by her committee on the guidance manual, she also urged that the agency provide a timely response to such comments, particularly when recommendations are not implemented. Similarly, she called for a speedier release of the studies done, but not if that requires sacrificing their quality. Finally, she called for agency attention to combined exposures.

Ms. Shirley Baker, a former Special Consultant to the previous CTS, is with the group Community Against Pollution, of Anniston, AL, whose main focus was PCBs from a Monsanto plant. She asked the Board to remember that their work will affect the community. Collaborative projects by ATSDR have formed partnerships that produced good results. Her community's final report was well received due to community involvement throughout the process, and the community always provides a different perspective than the scientific community.

Mr. Robert Duff, a former Special Consultant to the Health Department Subcommittee, hoped that the questions raised by Dr. Cibulas and Mr. Gillig at this meeting would be addressed by the Health Department Workgroup. He also suggested that the Workgroup have a member who has done these public health assessments and consultations, to provide that expertise.

Mr. Kyle Bryant referenced "brownhouses," homes with defined contamination levels, as a new health issue in Superfund communities. Such houses, if below EPA threshold levels, will not be tested for free and yet cannot be sold. Addressing this issue is a major gap between the missions of EPA, HUD, and NCEH/ATSDR. That is important, since many people spend more time in their homes than elsewhere. Community based participatory research should be paralleled by agency participatory research, including with local health departments. Such "cross-pollination" can ensure maximum data usage.

Attachment # 3: Proposed Programs for Peer Review

Biomonitoring
Chemical mixtures and computational toxicology
Community health investigations
Emergency response/terrorism preparedness
Environmental health services
Environmental health tracking
Exposure and health registries
Great Lakes Human Health Effects Research
Hazardous Substances Emergency Events Surveillance
Health studies
Laboratory and medical testing services
Lead poisoning
Pediatric Environmental Health Specialty Units
Public Health Assessments
Radiation studies
Refugee health
Respiratory health studies
Toxicological Profiles

Attachment # 4: Program Responses to NHER Peer Review

Charge of the 2003 NHER Peer Review:

- X Review program accomplishments, quality of science, impact, direction
- X Recommend on continuation, improvements, modifications

Peer Review Recommendations

- Conduct analysis and dissemination of the 1989-2000 data
- Re-examine study design
- Seek external input
- Be forward-thinking and opportunistic in program development/direction.

Recent NHER Accomplishments

Analysis and Dissemination of the 1989-2000 Data

- Data Analysis: Descriptive and statistical analysis done, information prepared for release.
- X Community reports on all four subregistries
- X Report on longitudinal data on volatile organic compounds (VOCs)
- X Report on minority/ethnicity factors data (see below)
- X Draft journal articles are in compilation and will be will submitted to journals in the next few months.

Future NHER Plans

Study Design

- Develop better characterization of individual levels of exposure in terms of length and the entire gradient of exposure (i.e., beyond just low exposure levels); tie in to the deep resources of the NCEH laboratory.
- Ensure sufficient sample size. Answers to the important questions about exposures and adverse health outcomes require at least a minimum number in the registries.
- Pursue verification of health outcome information. Be ready to gather information from other than traditional sources, such as cancer registries.
- Pursue identification of appropriate comparison populations, beyond use of the National Center for Health Statistics' National Health Interview Survey data.
- Develop control for confounders.
- Revisit criteria for registry inclusion and termination. Evaluate them for effect (e.g., from attrition); evaluate the validity of the scientific data and conclusions about impacts.
- Ensure flexibility of design to enable customization (e.g., longitudinally, or to set up a field registry immediately after an event to record exposure levels, biological plausibility of effects, number of people exposed, etc.).

Seek external input from a) an NHER science advisory committee, to include 1-2 BSC members; b) attend professional meetings to gather input and c) get peer review input (e.g, from advisory board, journal articles' publication peer review, etc.)

Be forward-thinking, be opportunistic in program redirection. Science and technology

has changed since the NHER was formed.

- Identify targeted populations (e.g., have an environmental justice workgroup to suggest future registry focus areas).
- Stay on the cutting edge to employ state-of-art technology and analytic methods (e.g., Geographic Information Systems, with disclosure limitation methods critical to maintenance of data confidentiality).
- In an ongoing manner, use existing and develop new database linkages (e.g., with the NCEH environmental tracking program).
- Expand collaborations internally at CDC, with the NCCDPHP, NIOSH, etc.; and with non-traditional partners: academia, industry, minority caucuses, unions, communities.
- Conduct a registry conference to explore facets of recruitment, data collection, etc.
- Develop a research program within the registry process.
- Develop a marketing program to disseminate NHER data.

Immediate Next Steps

- Issue the full review report, with responses to the peer review recommendations.
- Pursue publications and data releases.
- Form a Science Advisory Committee.
- Pursue collaborations with other agencies and groups.

NHER In the Future

- Explore a method through which to determine a relationship between exposure to hazardous substances and adverse health outcomes.
- Assist individuals and communities exposed to those hazardous substances.

NHER Findings of Exposure/Disease Rates Reported in Excess

- Benzene: Anemia, arthritis, cancer, diabetes, kidney disease, liver disease, respiratory allergies, skin rashes, stroke, urinary tract disorders
- Dioxin (Arkansas): Anemia, arthritis, asthma, cancer, diabetes, hypertension, kidney, liver, respiratory allergies, skin rashes, stroke, ulcers, urinary tract disorders
- Dioxin (Missouri): Anemia, cancer, liver, skin rashes, stroke, ulcers, urinary tract disorders
- TCA: Anemia, cancer, diabetes, stroke, urinary tract disorders
- TCE: Anemia, arthritis, cancer, diabetes, hearing impairment*, hypertension, kidney disease, liver disease, respiratory allergies, skin rashes, speech impairment*, stroke, ulcers, urinary tract disorders * (0-9 years of age only)

NHER MINORITY ANALYSIS

- Dioxin
 - *Non-white*: Anemia, arthritis, asthma, cancer, kidney disease, respiratory allergies, skin rashes, ulcers, urinary tract disorders
 - *Hispanic*: Respiratory allergies, skin rashes, ulcers, urinary tract disorders
- VOCs (non-white): Cancer, skin rashes, urinary tract disorders

NHER Criteria Weighting Factors:

1. Population exposures to chemical is persisting, increasing, or decreasing—25%
2. Seriousness of known/suspected health effects—25%;
3. Proportion of population exposed to levels of known or potential health significance—25%
4. Need to assess effectiveness of public health action to reduce exposures in the U.S. population—10%
5. Existence of analytical methods for measurement of the chemical—10%
6. Incremental analytical costs (dollars and personnel) to measure the chemical—5%.

Chemicals measured/reported:

- X Lead, mercury, cadmium, uranium, thallium, other heavy metals.
- X Cotinine (tobacco smoke exposure).
- X Dioxin, furans, and coplanar polychlorinated biphenyls (PCBs).
- X Non-coplanar PCBs and polyaromatic hydrocarbons (PAHs).
- X Organochlorine pesticides.
- X Organophosphate and carbamate insecticides.
- X Herbicides.
- X Phytoestrogens.
- X Phthalates.
- X Pest repellants and disinfectants.

Public health uses of the report

- X Measure what chemicals actually get into Americans.
- X Determine how many Americans have elevated levels.
- X Assess the effectiveness of exposure reduction efforts.
- X Establish references ranges, identifying unusual exposures.
- X Identify levels in susceptible groups, like women of childbearing age and children.
- X Establish priorities for health research.

Future directions of the NHER:

- X More chemicals: VOCs (benzene, MTBE, toluene, styrene, others); perfluorinated compounds; polybrominated diphenyl ethers (PBDEs)
- X Speciated arsenic
- X Separate measurements for methyl mercury and ethyl mercury
- X Perchlorate
- X Acrylamide
- X PAHs with 5 and 6 rings (the more carcinogenic PAHs)

Attachment # 5: CDC Futures Initiative

Achieving Health Protection for the 21st Century: Future's Initiative

Process: *Input – Ideas – Implementation – Impact*

Strategic Imperatives

- X Achieve health impact and reduce health disparities for customers (people whose health CDC protects)
 - Alignment of strategy, goals, and action.
 - Performance: measurement and improvement
 - Integration across organizational units
 - Marketing
- X Lead the nation's public health system.
- X Expand public health research as the foundation for all CDC work.
- X Expand global health impact.
- X Support the world's best workforce and maximize CDC's effectiveness and accountability.

Goals:

Health Protection

- X Prevention of disease, injury, and disability: All people will achieve their optimal lifespan with the best possible quality of health in every stage of life. By 2015:
 - At least 90% of adults have a healthy weight (NHANES baseline).
 - Mortality is reduced 20%, saving an additional 800 lives per year (NCHS) baseline
 - At least 95% of adolescents practice behaviors which protect them from illness and injury now.
 - The United States is one of five countries with the highest rates of infant survival (baseline, 1999)
 - The average lifespan of older americans is increased by two years.
-

Preparedness: People in all communities will be protected from infectious, environmental, and terrorist threats.

Organizational Design Principles

- X Strategy and goals derive from population health assessments ("customers' health") to achieve health impact.
- X Strategy and goals drive agency's priorities and allocations.
- X Emphasis on research and innovation.
- X Health protection "marketing."
- X Consolidation of business and other cross-cutting services.

"Customers:" Safer Healthier People (organizational chart).

Attachment # 6: Proposed BSC Subcommittee/Workgroup Charges

Community/Tribal Subcommittee

Under the charge of the Board of Scientific Counselors, the “Community/Tribal Subcommittee” (CTS) is established to provide the BSC with a forum for community and tribal first-hand perspectives on the interactions and impacts of the National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry’s (NCEH/ATSDR) national and regional policies, practices, and programs.

Health Department Subcommittee

Under the charge of the Board of Scientific Counselors, the “Health Department Subcommittee” (HDS) is established to provide the BSC with a forum for state and local health departments and health associations’ representation and input on the activities of the National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry (NCEH/ATSDR). The Health Department Subcommittee will formulate recommendations and offer advice on topics relevant to interactions between NCEH/ATSDR and local, state, and territorial departments of health.

Social Behavioral Science Workgroup

Under the charge of the Board of Scientific Counselors, the “Social Behavioral Science Workgroup” (SBSW) is established to provide the BSC with a forum to discuss methods of enhancing the development and support of social and behavioral sciences at NCEH/ATSDR in research and public health practice. The Workgroup will continue its actions and activities cited in its previous charge to include, but not limited to, the following:

- a. Provide an assurance that social and behavioral science and public health concerns of a consolidated agency are accurately addressed, in part by strengthening social science contributions to solving environmental health problems. The Workgroup will incorporate new concepts as updates to the SBS Initiative draft document submitted for Advisory Board review in December 2003.
- b. Consider and develop strategies of input to the working group process to assure that the resultant initiatives accurately address social behavioral science data gaps in public health practices experienced by agency staff in its delivery of site-specific evaluations and services.
- c. Strategize and plan a session or opportunity for experts in social behavioral sciences to appear before the workgroup to offer science based insights relevant to the charge of SBS.

Attachment # 7: Setting Priorities for PHAs at Superfund and Petition Sites

Dr. William Cibulas; Mr. Richard Gillig

Questions for the Committee

- X What advice would the committee offer to resolve competing priorities at selected sites?
- X How can ATSDR simplify the PHA process, provide more timely responses, and bring site activities to closure more efficiently?

Background:

Under what authorities does ATSDR conduct Public Health Assessments?

- X Comprehensive Environmental Response, Compensation, and Liability Act
- X Resource Conservation and Recovery Act

What are the primary response actions at sites?

- X Public Health Assessments
- X Public Health Consultations
- X Public Health Advisories
- X Exposure Investigations
- X Technical Assists

What is a Public Health Assessment?

The evaluation of data and information on the release of hazardous substances into the environment in order to assess any [past], current, or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects.

What is a Health Consultation?

An assessment focusing on one particular public health question, e.g., a specific exposure pathway, substance, health condition, or technical interpretation.

What is the PHA process?

STEPS

Initial site visit
Ranking of site
Gather/review data
Prepare the PHA
Initial release for data validation
Public Comment period
Final Release

SOURCES OF INFORMATION

Environmental data
Exposure data
Community health concerns

Health effects data (toxicological and epidemiological)

What triggers a Public Health Assessment?

- X National Priorities Listing
- X Other Agency Requests
- X Citizen Petitions

Public Health Assessments, FY 1999-2003:

- X 150-200 PHAs conducted annually
- X NPL sites average 2.7 years
- X Federal sites usually take longer (the longest has been 14 years)
- X Petition sites average 4.8 years to do, partly due to the time to get them into the work queue of the mandated workload. Another reason is that the data for these generally must be developed “from scratch.”

Public Health Consultations, FY 1999-2003

- X 150-200 done.
- X 200 - 400 PHCs conducted annually
- X Time to complete PHCs ranges from 1 – 24 months; ave. 6 months
- X Petitioned PHCs average 3 years to completion

What does the workload look like for other DHAC products?

- X 15-20 EIs are conducted annually
- X 25-50 Strike Team Rapid Response (within 24 hours; staff rotate to work on these) documents completed annually
- X 1500 - 2000 Technical Assists conducted annually

Agreement Cooperative Partners Role (map)

New Sites Reports vs Total Reports (chart) (by Fiscal Year)

Number of New Sites (FY1994 to Q2 FY2004) with One Report, Two Reports, etc

What are the resource implications?

- X FY 2004 work plans identify 320 partner sites, 135 DHAC sites (which seem to be a little more complicated). Concurrently, health assessor FTEs are decreasing; DHAC – 50 today vs. 64 in 2000; Partners – 65 today vs. 70 in 2000.
- X Positions have been eliminated, reassigned and/or vacant.

What are the issues that should be considered in setting priorities?

- X SECTION 104 (i) of SARA “...the Administrator of ATSDR, in consultation with the Administrator of EPA, shall give priority to those facilities at which there is documented evidence of the release of hazardous substances, at which the potential risk to human health appears highest . . . In determining the priorities for conducting health assessments the Administrator of ATSDR shall consider the National Priorities List schedules and the needs of the Environmental Protection

Agency and other Federal agencies pursuant to schedules for remedial investigation and feasibility studies.”

Criteria for Prioritization

- X Health impact of exposures
- X Community health concerns
- X Need of site managers
- X Political interest
- X Relation to CDC goals

Primary Clients and Communities

- X Federal and State Site Managers
- X Federal, State and Local Health Departments
- X Department of Defense
- X Department of Energy
- X Tribes
- X Congress

Client Feedback on ATSDR Work

- X Inconsistent Timeliness
- X At Times Too Much Information
- X Purpose Is Not Always Clear

Site Work Examples

Dow Chemical & Tittabawassee River Sites

- X Midland/Tittabawassee River
- X Background Information
- X ATSDR Petitioned Site and RCRA Facility and State Lead Site
- X Chemical Manufacturing since 1897
- X Waste Water and Airborne Dioxin Releases
- X Contaminated Soils, Sediments, and Biota
- X Complex Scientific Issues
- X Health Impact of Low Level Dioxin Exposures
- X Challenges in Stakeholder Coordination
- X Community Concerns and Mistrust
- X Confounding Exposure Factors
- X Dioxin Exposure from Soil and Dietary Sources

Deemed an ATSDR Priority Because of:

- X Past/Current/Future Exposure to Dioxin
- X ATSDR Petitioned Site
- X Community Health Concerns

Bear Creek, Butler & Armstrong County, Pennsylvania

Bear Creek Background Information

- X State Environmental Agency Lead Site
- X 26 Waste Disposal Areas (2 NPL Sites)
- X 1930s – 1970s Waste Disposed: Areas Previously Strip or Deep-Mined for Coal
- X Private and Small Public Drinking Water Wells Contaminated
- X Bottled Water Provided to Over 900 Homes Since 2001
- X Currently Contaminated Water Used for Showering Bathing and Other Household Uses
- X Community Drinking Water System Being Planned
- X Unusual Chemicals: Resorcinol, Meta-Benzene Disulfonic Acid, Benzene Sulfonic Acid, Para-Phenol Sulfonic Acid, Calcium Petronates
- X Complex Hydrogeology – Fractured Rock
- X PA Department of Health Requested ATSDR Assistance;

Bear Creek Deemed an ATSDR Priority Because of:

- X Past/Current/Future Exposure to Hazardous Materials with Very Limited Toxicological Information
- X Includes 2 NPL Sites
- X Limited Previous ATSDR Site Activities
- X Very High Level of Community Concern

Tar Creek, Ottawa County, Oklahoma

Background Information

- X 40 square mile site
- X Tribal Governments, 5 communities
- X Mining for lead and zinc
- X 75 million tons of mining waste
- X Mine shafts, sink holes, and subsidence fishing of Tar Creek
- X Children aged 1 - 5 years with blood lead levels of 10 µg/dL and greater:
- X In 1995, 35% of tribal children, in 1996, 31% of site area children; In 2003, 2.8% of site area children
- X Clean-up of over 2,200 properties, 1995 through 2003. Residential yards, parks, and playgrounds

Chat Piles in Picher and Cardin Area (Photo)

Soil Lead Levels in Tar Creek (Chart)

Tar Creek Priority Because of:

- X Past, present and future exposure of children to lead
- X Community Health Concerns
- X Request from former OSDH Commissioner Beitsch
- X Congressional request in ATSDR appropriations

Discussion Questions

Prioritization:

- X Should ATSDR adopt a transparent and consistent approach to site prioritization?
- X Should public health considerations be the primary driver for all site work?
- X Should ATSDR assign weighting factors for competing priorities at selected sites?

Simplifying the PHA Process

- X Should health consultations be the norm for site work, and full public health assessments be the exception?

Providing more timely responses

- X Should shortening the time frame for public health assessments and health consultations be one of the highest priorities for the agency?

Bringing site activities to closure more efficiently

- X Should the agency adopt a transparent and consistent approach for bringing site activities to closure?

Attachment # 8: Use of Environmental Burden of Disease in Priority-Setting

Background of this initial assessment

- X This work was done in response to a request from the CDC Futures Initiative for information on budget and disease burden.
- X This presentation is only of background and methods used for response.
- X This is a work in progress and should not be considered a definitive assessment.
- X The team will conduct a more thorough and systematic assessment over the coming year.

Asthma

- In the U.S., 14,600,000 people have asthma. Each year 478,000 persons are hospitalized and 4,600 persons die from asthma.
- Eliminating exposures to indoor allergens could prevent over 2 million (44.4%) of the 4.6 million cases of doctor-diagnosed asthma among persons 6 to 16 years old in the United States.
- During a 22.5% reduction in peak traffic flow associated with the summer Olympics, the number of acute asthma care events in Atlanta decreased by 41.6%.
- The percentage of worldwide asthma that is attributable to indoor air allergens was estimated to be 20%. Outdoor air pollution was estimated to contribute an additional 5-15%.

COPD

- In the U.S. in 2000 there were:
 - 10,515,000 persons with self-reported COPD.
 - 726,000 hospitalizations for COPD.
 - 199,054 deaths from COPD.
 - In the U.S., 80-90 percent of COPD has been attributed to cigarette smoking.
 - The population attributable risk for occupational factors related to COPD in the U.S. has been estimated at 15%.
 - An analysis of NHANES III data produced an estimated attributable fraction of COPD related to work of 19.2% overall and 31.1% among never smokers.

Cardiovascular diseases

- Over 930,000 Americans die of cardiovascular disease each year.
- About 61 million Americans have some form of cardiovascular disease.
- Almost 6 million hospitalizations each year are due to cardiovascular disease.
- Environmental fraction of the burden of ischemic heart disease and cerebrovascular disease in high-income nations is from 1% to 5 %.
- Attributable risks for cardiovascular diseases associated with being overweight and having low levels of leisure-time physical activity were estimated to be 3% to

- 6%; and 22% to 39% respectively.
- The risk of selected cardiovascular causes of death associated with an increase of 10 mg/m³ PM₁₀ is estimated to be between 5% to 10%.
- Attributable risks for ischemic heart disease associated with and residential noise is estimated to be 1% to 5%.

All Cancers

- An estimated 1,368,000 new cancer cases will be diagnosed in 2004.
- An estimated 564,000 people will die from cancer in 2004.

Cancers: associations observed

- Infections
- Alcohol
- Sunlight/UV radiation
- Obesity
- Ionizing radiation
- Indoor radon
- Occupational exposures
- Indoor and outdoor air pollution
- Environmental tobacco smoke

Birth defects

- Approximately 120,000 children in the U.S. are born with a serious birth defect each year.
- In children under 15 years old there are about 143,000 hospitalizations for congenital abnormalities.
- In 2001, there were 5,513 deaths, due to congenital malformations, deformations, and chromosomal abnormalities.
- Environmental risk factors for preterm birth include occupational exposures, air pollutants, persistent organic pollutants, PCBs, metals, and water disinfection byproducts.
- About 7-11 percent of birth defects have been associated with a known agent (e.g., radiation, drugs, chemicals, infection, maternal metabolic imbalance).

Infectious diseases

- In the U.S., food borne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year.
- The fraction of intestinal illness attributable to water, sanitation and hygiene is about 60%.

Nervous system disorders

- Parkinson's disease
- Multiple Sclerosis
- Amyotrophic Lateral Sclerosis
- Lead Poisoning and Cognitive Impairment in children

Obesity and Diabetes

- Genetic contribution to obesity ranges from 5% to 25%.
- Urban residents have been found to have diabetes rates higher than rural dwellers.
- Over 75% of the risk of Type II diabetes is attributable to obesity.

Mental Health

- 45% to 55% of a population exposed to a disaster can be expected to show psychiatric symptoms.
- Environmental exposures from toxicological disasters, natural disasters, terrorism, war, and the built environment have been associated with adverse mental health outcomes.
- Environmental fraction of the burden of depression in high-income nations is from 1-5 %.

Attachment # 9: Motions passed by the NCEH/ATSDR BSC, May 20, 2004

Program Peer Review Subcommittee

Dr. McClellan moved that the Board establish an NCEH/ATSDR Program Peer Review Subcommittee to serve the function of organizing, facilitating, and providing a long-term perspective to the conduct of peer review of significant elements of the NCEH/ATSDR program, anticipating that 3-4 reviews would be initiated and completed each year, and that the total program would be reviewed over a period of about 5 years. The program would be carried out by workgroups with specific expertise related to the topics. The Subcommittee would act as a review or vetting committee, to the entire Board, of the reports generated by the workgroup.

Health Department Workgroup

Mr. Derouin moved that the BSC create a workgroup to prepare recommendations to it that: 1) identifies up to the five most significant issues relevant to the relationship between NCEH, ATSDR, local, state and territorial departments of health, and 2) recommends whether the charge should be carried out by a workgroup or a subcommittee. The workgroup would report back to the BSC at its next meeting. The workgroup would make an effort to include the representation of such organizations as CSTE, ASTHO, NACCHO, APHL, ECOS, NEHA, and others.

Community and Tribal Subcommittee

Dr. Harris moved that the Community Tribal Subcommittee be reinstated as a subcommittee to provide the BSC with a forum for community and tribal first-hand perspectives on the interactions and impacts of the National Center for Environmental health and the Agency for Toxic Substances and Disease Registry's (NCEH/ATSDR) national and regional policies, practices and programs, and be invested with the authority to recommend to the BSC on the establishment of workgroups.

Attachment #10: Initial List of (ACTION) Items, NCEH/ATSDR BSC Meeting, May 2004

Information to be provided by NCEH/ATSDR:

- X Use a summary minutes format with an executive summary and action item list.
- X By the next meeting NCEH/ATSDR budget breakdown (grants, cooperative agreements to states).
- X Names of the American College of Toxicology experts who were recommended on the national environmental exposures' prioritization.
- X To Dr. Cynthia Harris: lab to follow up with her to separate out the measurements needed to address her community's problems (e.g., community rates of hypospadias).

Information to be provided by the BSC members, consultants:

- X Mr. Derouin offered to provide the EPA Advisory Committee's consensus recommendations which involved ATSDR, and advised the input of the EPA peer review subcommittee.
- X Dr. Bowler commented that even the most minimal batteries of tests were not used in standard fashion across sites. She offered to work with staff to suggest proper tests to include and to ensure useful data (e.g., health studies could use normative data as well as control-exposed methods). She urged that a workgroup or other method be used in developing agency site work to help the larger PHAs to use control groups as well as special site groups to make maximal use of these very rare and valuable data from special site populations.
- X Ms. Dunlop offered to help in the development of a document of collected data to provide information to officials and the public to aid their decision making, on a site-specific basis. This would help congressional representatives explain the priorities to their own constituents.

Summary of BSC responses to presentations:

- X PHA priority setting: pursue a more definitive way of setting and conveying priorities; seek partners to address lower priorities and non-agency mission tasks assignable to others; more efficiently identify and respond to target audiences by using an iterative process between sites that could accomplish some closure at all sites.
- X Environmental burden of disease: This approach might miss prevention opportunities and important issues of sub-population disparities, miss opportunities to explore high-impact smaller-dimension environmental interventions, and identification of data gaps. Attention is needed to how things like EBD affects funding, aside from the "disease of the month" or of the congressman's family. EBD does not have that kind of cache. Other approaches of interest include prevention and intervention strategies related to environmental disease: looking at the interactions between the social environment, behaviors/cultures, and the genetic makeup of populations, and their contribution to environmental disease.

Fall meeting: November 18-19, 2004. In future public meeting notices, include that there could be a closed executive session.

Suggestions for the fall agenda:

- X Reports of the two subcommittees and the workgroup.
- X More time for discussion.
- X Division of Health Studies presentation on how congressional inquiries, petition process, etc., all contribute to prioritization of the PHAs/PHCs.
- X Presentation on the NCEH/ATSDR budget.
- X Overview/briefing on the tox profiles: past, present, future.
- X Every meeting, overview of 2-3 programs, other than those peer-reviewed.
- X Overview of how NCEH/ATSDR is using social/behavioral science, with people with that expertise present.
- X Provide a matrix of the programs to position them within the organization, with the understanding that this may change by November.

Actions related to BSC response to the Futures Initiative

- X In November, or next May, have a presentation on the priority activities and how they were enhanced in value (i.e., increased effectiveness/efficiency across the previously independent elements), as well as demonstrated performance measures for CDC as a whole and the operating units, to assess their effectiveness.
- X Clarify, as able, the utility of the CCHIS in terms of goals, function, and placement. Clarify the Informatics Center's goals; some are pure research and some are not.
- X The Coordinating Centers' placement looks more like a counterproductive barrier and depersonalization of communication
- X Show clearly how the increased overhead to the lab to will support the reorganization's expanded administrative costs. Clearly show how that affects NCEH/ATSDR.
- X Consider using terms reflective of partnerships with communities/groups rather than "marketing" and "customers."
- X It was strongly suggested that, if addressing health disparities are a high priority, this be reflected on the organization chart (e.g., restoring the Offices of Minority Health, Women's Health, etc.).
- X Concern was expressed that linking infomatics and marketing may isolate the science from the programs even more than previously. And, even "soft boundaries can still mean nothing gets over them." How does work cross between the Coordinating Centers, e.g., for CCEIO and the Center for Infectious Diseases?
- X In November or a year from now, present how five initiatives are advancing as a result of the reorganization (e.g., asthma response maximized by Morgantown bench research extended to occupational and environmental associations).