



**Advisory Committee to the Director
Centers for Disease Control and Prevention (CDC)
1825 Century Boulevard,
Atlanta, Georgia**

**MEETING SUMMARY
March 3, 2005**



**Department of Health and Human Services
Public Health Service**

Acronyms used in this report

ACIP	Advisory Committee on Immunization Practices
APHA	American Public Health Association
ASTHO	Association of State and Territorial Health Officers
CDC	Centers for Disease Control and Prevention
C/O	Centers, Institutes, and Offices
CMS	Centers for Medicare and Medicaid Services
CCHIS	Coordinating Center for Health Information and Services
CCTPER	Coordinating Center for Terrorism Preparedness and Emergency Response
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DoD	Department of Defense
EPA	Environmental Protection Agency
FTE	Full Time Employee
HRSA	Health Resources and Services Administration
IRB	Institutional Review Board
LRN	Laboratory Response Network
MSM	Men Who Have Sex with Men
NCHSTP	National Center for HIV, STD and TB Prevention
NVAC	National Vaccine Advisory Committee
NIH	National Institutes of Health
NACCHO	National Association of County and City Health Officers
NICHD	National Institute of Child Health and Human Development
NHIS	National Health Interview Survey
OPHR	Office of Public Health Research
OMB	Office of Management and the Budget
OSH	Office of Smoking and Health
OTPER	Office of Terrorism Preparedness and Emergency Response
RCT	Randomized Controlled Trial
SAMHSA	Substance Abuse Treatment and Mental Health Services Administration
SEER	Surveillance, Epidemiology and End Results
VAERS	Vaccine Adverse Events Reporting System
VTEU	Vaccine Treatment Evaluation Unit
YBRFSS	Youth Behavioral Risk Factor Surveillance Survey

Table of Contents

Summary Minutes of the March 3, 2005 Meeting

AGENDA

Welcome and Introductions	2
State of CDC	2
Goals Development Workgroup Report	5
CDC Research Update	6
Research Agenda Development Workgroup Report.....	7
Ethics Workgroup Report	8
Participatory Goals Development & Execution: Role of CDC's Federal Advisory Committees	9
HIV/AIDS Update	9
Preparedness Grants.....	11
Vaccine Safety	12
Tobacco Issues	13
ATTACHMENT: Attendance.....	15

Advisory Committee to the Director

Summary Minutes of the March 3, 2005 Meeting

A meeting of the Advisory Committee to the Director (ACD) of the Centers for Disease Control and Prevention (CDC) was held on March 3, 2005, in Atlanta, Georgia. The meeting was convened by Executive Secretary Mr. Robert Delaney. Committee Chairman, Dr. John O. Agwunobi, welcomed the members and other attendees, who are listed on the Attachment.

AGENDA

Welcome and Introductions

The formal meeting was preceded by a tour of the NCEH Environmental Health Laboratory. Following introductions of the committee and other attendees, Mr. Delaney updated the members on the process of inter-meeting committee communication. Ms. Donna Garland, Chief, Office of Enterprise Communication, CDC, asked members to participate in a small workgroup to develop and test timely electronic communication methods.

State of CDC

An update on the State of the CDC was provided by CDC Director, Dr. Julie Gerberding. She also reported on the CDC budget for Chief Operating Officer, Mr. Bill Gimson. The draft State of CDC Report distributed to the committee members listed goals and priorities under discussion.

CDC's work proceeds in three directions, to *people across* the life stages (infancy, childhood, adolescence, adult and senior health); *preparedness* (intramural and state grants), and *places* (specified goals that go beyond workplace occupational health, such as in schools and homes where CDC has responsibility for other environmental health activities). The draft State of CDC Report distributed to the committee members listed goals and priorities under discussion. Dr. Gerberding used a chart visualizing what the agency is changing from and to and outlined its priorities:

- *Achieving the greatest possible impact* on people's health and safety by aligning CDC's strategies, goals, and performance.
- *Being customer-centric*: Move from a disease orientation to a more holistic health protection focused on people rather than "body parts" or diseases.
- *Being accountable*: Move from primarily allocating resources to effectively leveraging those (\$7.5 billion, >\$5 billion of which goes to state and local health departments). To better account for those expenditures and achieve efficiencies, a uniform system is being piloted (the "Portfolio Management Project") in eight states. Resulting savings found will be redirected to the states for the categorical areas from which the funding came and, as possible, they will be able to use broad indirect cost categories (e.g., for grant/financial management/oversight) for their other priorities. Congress can also be petitioned for that flexibility.

- *Leading*, by leveraging CDC's unique capabilities, partnerships, and networks to improve the health system, by:
 - Development of the public health workforce: Congress has approved assignment of CDC preparedness staff to states and exempted them from its FTE ceiling. (The committee welcomed this.) That is hoped to be expanded to other categories of health personnel to serve in the states. Further, public health leadership needs credentialing and accreditation. With NACCHO and ASTHO support, CDC's Office of Workforce and Career Development addresses broad issues of recruitment, retention and succession planning, and assessment of future skill needs. A National Academy of Public Administrators team will report March 31 on its assessment of CDC's needs relative to comprehensive workforce diversity, and satisfaction with jobs, work environment and career development. Recent surveys revealed staff satisfaction with pay and job, but for exceptions in the visible minorities (specifically, disabled employees). Response initiatives are likely.
 - Maximizing cross-DHHS agency relationships and developing a collaborative research agenda paralleling CDC's goals. To aid this, CDC adopted the NIH Impact 2 Grants Management System. Specific work includes recent collaborative diabetes research to translate prevention and control science to individual-level application, as well as other work in genomics. Current staff-level systems of collaboration will be expanded to system-wide approaches. To institutionalize CDC's interventions, a CMS/CDC "Virtual Center" will leverage CMS' regulatory, reimbursement and quality improvement powers to speed intervention research into CMS-supported practices (e.g., currently, initiatives for influenza immunization and prevention of surgical site infections). The incorporation of further prevention services (e.g., HIV testing, adult immunizations) in the new HRSA medical clinics being established in poor areas also is being discussed.
- *Conducting public health research*: Create and disseminate the knowledge and innovations that people need to protect their health now and in the future, as a science-based organization conducting independent research. New extramural research funding this year will focus on health marketing, translating known-effective interventions for use in the population. R-01 and Centers for Excellence funding (≤\$8 million) will support the launch of this focus.
- *Maximizing global health impact* by extending CDC's knowledge and tools around the world. CDC has a key role in supporting in-country results of the President's emergency plan for AIDS relief, as well as in the global polio elimination program.

Budget. The President's proposed fiscal year 2006 (FY06) budget will be heard by the Appropriations Committee in April. CDC's proposed \$7.5 billion FY06 budget has increases in three areas: the Strategic National Stockpile (including countermeasures and expanded hospital surge capacity through mobile hospitals), influenza preparedness and global disease detection. Reductions totaling \$500 million were programmatic rather than across the board. About half was for buildings and facilities – an area reduced before, but often restored by Congress. Seven facilities will be opened at CDC this year, four of them major ones, and FY06 funding will complete the Ft. Collins Infectious Disease Lab. One more major infectious disease lab is needed, and the CDC staff scattered around 40 sites in Atlanta still need to be consolidated in one place. Other reductions included:

- Elimination of the successful VERB health marketing exercise campaign aimed at youth, when its five-year authorization ended. This program is a proof in principle supporting development of the National Center for Health Marketing.
- \$130 million of CDC's support to states preparedness, some offset by the Stockpile increase. The rationale, from the lessons of information technology and risk communication, is that some things can be done at the federal level once, and more efficiently, rather than 50 times over.
- Reduced block grants for noncategorical state priority programs. However, ~65% of that total is covered by CDC programs not in place when the block grant program was begun. CDC is working with ASTHO and the state health officers to determine how to offset any problems caused by that reduction.

Discussion included a request to send the committee more of the meeting material in advance. Other comments were:

- Regret was expressed by several committee members that the VERB campaign was ended. However, marketing campaigns also have a natural life span, particularly those to youth, and CDC hopes to build on VERB to continue reaching that important demographic. All the future grants will include specific and measurable performance indicators.
- The noncategorical funding (~\$30 million in addition to HIV and other categorical funding allows infrastructure building and enhanced capacity in critical areas (e.g., in countries important to influenza surveillance but without those systems). But the challenge to CDC remains to develop the science to support its work; it is still not perceived as a research agency despite the research it does.
- The \$30 million reduction of funding previously used to build state infrastructure and response was of concern, although CDC still funds \$900 million to preparedness. The original preparedness grants championed by Senators Kennedy and Frist focused on rebuilding the neglected public health infrastructure, activity that continued with the bioterrorism response funding. CDC has been documenting the resulting successes (e.g., capability for mass vaccinations in an Illinois meningitis outbreak) to illustrate the value of those investments. However, Congressional interests and definition of "preparedness" can change, and realistic expectations must be created.
- Vivid examples were found in public health research during CDC's development of the *Guide to Community Preventive Services*. "Insufficient evidence" found missing for intervention after intervention was not a euphemism for ineffective work. There simply is not enough rigorous study to support the effectiveness of commonly used interventions, and particularly lacking are ethnic-specific analyses. Another gap, seen in this season's influenza vaccine shortage, was the lack of a mechanism to determine if a lower antigen dose would still be effective. No agency has the lead in such work. Such a gap is particularly acute in such emergencies as the anthrax attacks, when testing is critical to response.
- Dr. Benjamin noted that the nation's health care expenditures could be slashed if the interventions known to work were simply implemented, and CDC plays an important role in getting that information out. CDC's \$7.5 billion budget is about half of what it would need to do the research needed.

- CDC has had very good support from the OMB and Congress, particularly since its movement to modern management methods.
- CDC and NIAID have liaisons to coordinate the agencies' research. In fact, Dr. Zerhouni had been scheduled at CDC the next day for a Grand Rounds on the influenza dose-response question. This is an area in which the advisory committees can help to identify potential collaborative work.
- The DHHS Secretary is very open to agency networking and connectivity.
- Dr. desVignes-Kendrick appreciated the emphasis on more practice-based research for local level use. She also reported community concern at an increasing "spin" on CDC work, which may be contrary to what the objective research actually demonstrates. Dr. Gerberding responded that CDC's enhanced, 3-5 year rotating peer review process will ensure the objective evaluation of the data and strengthen CDC's ability to stand behind it. Peer review of extramural research will also be done, in cooperation with the NIH, through joint study sessions. She asked for specific examples of where CDC's reputation for strong scientific objectivity has been jeopardized. She also requested the committee's comment if any indication is detected of bias in what is not studied or noted in the peer review.
- In CDC discussions with CMS, Dr. Bender suggested a fresh look at incentives and reimbursement strategies that CDC could influence. For example, a GM workforce diabetes pilot program partnered labor, GM physicians and community physicians to improve even out-of-control diabetes cases by 95% in 3-6 months. Dr. Gerberding thought that perhaps a special workgroup could be formed to identify such opportunities and help craft a discussion with Mark McClellan and the Secretary to examine those ideas.

Goals Development Workgroup Report

A Goals Development report was provided by Dr. Debra Lappin, Chairperson of the Goals Development Workgroup. The group discussed the definition of "health" in a holistic framework of life stages with measurable objectives. Substantive engagement of the stakeholders is involved, in response to raised public expectations of its relationship with CDC – which includes an infusion of values into public health's primarily science-focused process. Ten key sector stakeholders of the organized process in this process were identified, as were the "unorganized" public, and a model was applied to involve them in achieving CDC's goals (e.g., 95% of children will have a healthy weight; 75% of adolescents will be smoke free).

The Workgroup concluded that the goals are good, but need to be reduced from ~60 goals to ~20. CDC was asked to develop for the Workgroup by March 31 the completion of the goals. The overarching business plan for public engagement with the inputs provided by the Workgroup on the previous day, and to develop related measurable draft objectives deadline was not determined. Serious engagement of the stakeholders in CDC's planning process, including feedback on what is done with that input, will enhance trust. The committee will discuss this goal architecture in the next teleconference to determine what sectors should be involved to introduce the value equation into the direction of the scientific research, based on the evidence, impact, resources, feasibility, and health disparities.

Discussion included:

- Document the work of how the goals were developed to further substantiate them (e.g., in a Power Point presentation that includes the background of the process).
- Better ways to communicate how the science serves the public are needed. The "informed public" understands, but new partnerships require higher levels of trust and willingness to risk by both sides.
- As with the public engagement for the broader 2010 goals, make clear to people what this next stage could mean and its relevance to CDC.
- The process of input may have to be tiered (e.g., by those interested in grants/resources, access to affordable healthcare, etc.) and the lessons learned might prompt re-prioritization.
- The business plan will identify some areas of expertise that could help in this new process.

Dr. Lappin moved that the committee endorse the CDC's draft goals as presented, to be finalized by March 31; that the members request a business plan to be developed for the committee's input/review on the goals and objectives; and that a structured program for tiered, substantive sector input/engagement be crafted to suggest priorities for those objectives. Dr. Galli seconded the motion.

Vote: All were in favor and there were no abstentions. **The vote passed.**

CDC Research Update

An update on CDC Research was provided by Dr. Dixie Snider, Chief Science Officer, CDC. A new Science Vision and Alliances Team will develop future strategies for relationships with other agencies. This will be discussed with the top management of other agencies in the next week. The Office of the Chief Science Officer houses three offices: the Office of Technology Transfer, the Office of Public Health Research (OPHR), and Scientific Regulatory Affairs Services (advises on human subjects, OMB clearance, privacy, etc. for the researchers).

OPHR's organizational chart and website were shown and its four key functions were outlined: 1) develop and maintain a CDC-wide research agenda and enhance/leverage research resources; 2) evaluate/monitor progress by the overall research portfolio toward the CDC research agenda and health impact goals; 3) enhance CDC extramural research by developing, supporting and training in standardized best practices across CDC, including implementation of CDC's peer review policy; and 4) develop and support new research initiatives and peer review and grants management for cross-cutting research on public health priorities/goals. In FY04, CDC released for the first time \$22 million in R01, K01, T01 and P01 awards, in its Health Protection Research Initiative. The FY05 initiative will help provide a science base for the new CCHIS, as well as the development of methods with which to estimate preventable health burdens for risk factors of concern. The Woodruff Foundation also has provided \$2M through the CDC Foundation for collaborative research with Emory University.

Dr. Robert Spengler presented the committee with two research concepts. Those will be posted on the CDC website in order to notify the field of CDC's consideration of related funding. Dr. Robert Galli **moved**, and Dr. Antronette Yancey seconded, a motion to approve the research concept development document for Centers for Excellence in Health Marketing and Health Communication, and a Centers of Excellence in Public Health Informatics. **The motion passed unanimously.**

Dr. Spengler then diagrammed how CDC will integrate its goals, research and programs. The research agenda is to fill knowledge gaps in order to achieve the agency's health protection goals; provide evidence for new or improved interventions; identify broad research themes/focus areas to guide the CCs and CIOs; help plan, communicate and market CDC research; and assist in agenda evaluation/updates. Among the development steps is the formation of workgroups, whose structure, composition and charges were outlined. The workgroups have worked on the existing emphasis areas of goals management (adolescent and adult health, and preparedness), with four priority setting criteria: public health need/importance, relevance to reducing health disparities, potential for broad impact, and relevance to CDC mission/goals. The planned time line for this work began in January and will end August 15. It includes four public input meetings and the issuance of a draft agenda in the Federal Register for public comment. The website address is www.cdc.gov/od/ophr/.

Research Agenda Steering Workgroup Report

Dr. Robert Galli (co-Chair with Dr. Sandra Mahkorn) **reported** on the discussions of the Research Agenda Steering Workgroup. The members met in person on January 10 and have had monthly conference calls. They **planned** to hold a conference call the following week to review the draft "starter list" of research focus areas which will be used to help develop the health protection research agenda. Dr. Robert Spengler, Director of the CDC Office of Public Health Research, presented an overview of the research agenda development process.

The involvement of other CDC advisory committees in providing expert advice on the developing research agenda was urged. For example, the NIOSH BSC is involved in the NORA development, but has never forwarded advice to Dr. Gerberding. The timing of that involvement may be problematic, as their meetings are infrequent (1-2 a year). Dr. Agwunobi urged the Chairs to add 5 minutes to their agendas to discuss this process. Dr. Spengler pledged to provide the relevant materials as soon as possible and to attend (or send a delegate) their meetings if requested. Dr. Jean McGuire suggested that a flow chart be developed to show the intersection of the advisory committees with the research development agenda.

Given this interest, Dr. Gerberding asked if the agenda development process should be slowed. The current timetable was prompted by a pressing need for input to the federal budget cycle process. So as to have something to present, Dr. Benjamin suggested that CDC develop long- and short-term research agendas that are integrated into other agendas such as NORA's. The recalibration of the NORA process will begin soon and will be an important part of "a" CDC research agenda. Discussion is needed with OPHR about the cross-BSCs integration needed to ensure the desired specificity and granularity.

Dr. Agwunobi summarized the committee's consensus to give more time to development of the research agenda, to allow more coordination with the Goals Workgroup and more input/discussion from the other advisory workgroups.

Ethics Workgroup Report

Dr. Snider outlined the activity of the ACD Ethics Workgroup which held its first meeting on February 28. It is chaired by Dr. Ruth Macklin, of the Albert Einstein College of Medicine. Committee member Dr. Marilyn Maxwell represents the ACD on the Workgroup. Its charge is to: 1) counsel CDC on a broad range of public health ethics questions and issues arising from programs, scientists and practitioners, and 2) support the development of internal CDC capacity to identify, analyze and resolve ethical issues. That second component distinguishes this workgroup from its predecessor. Three Workgroup members have already met with the Influenza Workgroup to participate in its discussions of vaccine prioritization during periods of vaccine shortage.

The Workgroup's potential topics include the ethics related to surveillance, public health research versus practice, and data collection; the response to terrorism (informed consent, diagnostic tools), public health ethics capacity building; advice to ACIP and NVAC; and response to queries by CDC entities. Its next steps include consulting with ACIP and NVAC (e.g. in prioritization of vaccine and antiviral drugs during an influenza pandemic), establishing a ListServe, collecting and distributing relevant information, and meeting quarterly in person and further by teleconference.

Discussion included:

- The Workgroup collaboration with similar entities (e.g., at NIH) was urged.
- Discussions have already taken place about conflict of interest and bias. The committee members chose to become Special Government Employees, with full disclosure. Mr. Shepherd Smith suggested contact with Chris Bachrach and Susan Newcomer at NICHD, who have addressed bias and conflicts, which can arise in the social or behavioral sciences.
- A separate IRB is housed in the scientific and regulatory component of the Office of the Chief Science Officer.

Data sharing. Dr. Lappin recommended that the committee read and comment on the Vaccine Research Data Sharing and Public Trust report. It is relevant to the development of new databases, access issues, etc., especially if they are to be the basis of any public health policy decision. CDC's data sharing policy assumes that the data collected belongs to the taxpayers of the country. Data can be shared, but selectively, according to privacy, proprietary and national security interests. Such issues are important, more in terms of ability to link data and identify people than regarding the stand-alone database. Agencies have different approaches to program data collection (e.g., CDC/SAMHSA), such as are applied to service delivery versus research. Discussion with OPHR was suggested to clarify the difference between surveillance and research data. The Executive Secretaries of CDC's committees know that advice is available on those issues, and contact persons in the CIOs conduct relevant scans internally. A session on data sharing and security was requested. The advisory committee should review the policies to ensure that CDC is following the best practices and intent of the law. CDC was cautioned that the pursuit of its large research portfolio could be impeded by related debate with strong opinions; Dr. Georges Benjamin of

APHA, offered the group's help in such events. Dr. Agwunobi also suggested asking the Ethics Workgroup about examining the CDC goals and research agenda to try and answer questions before they arise.

Participatory Goals Development & Execution: Role of CDC's Federal Advisory Committees

A presentation on Participatory Goals Development and Execution was provided by Dr. Lonnie King, Director, Office of Strategy and Innovation, CDC. CDC's categorical centers are critical to its success, housing as they do the world-renowned expertise in specific areas. But a pilot is being done as the first step in integrating CDC's work internally. This change is not superficial to CDC's legacy operations, but a fundamental change to a new work process. This is expected to accelerate the health impact when the tipping point of cultural change is passed. A "trailblazer initiative" was begun that focuses on four critical areas: influenza, adolescent health, obesity and chronic disease.

CDC is rethinking how the groups already involved with it may participate in the development of its goals and implementation of its strategies (i.e., the best use of expertise and alignment of systems and strategies). Whether this should be accomplished through new committees, workgroups, or the existing structures' use in new ways, was discussed. The intent is to create networks around the trailblazing areas of focus. Dr. Lappin's group was asked to help design an approach for the trailblazer initiatives, preferably in concert with the other advisory committees, to be brought back to the committee for comment. Suggestions included:

- An ad hoc advisory committee with its membership drawn from CDC's advisory committees was deemed the best vehicle to oversee these trailblazer initiatives and avoid redundancy of action.
- The EPA advisory committee process was offered as a model. An EPA program creates and disseminates a charge with questions, and the advisory committee responds with a report built upon the questions. This process could involve other constituencies and interested parties (who also may be able to fund the process).
- A different strategy of participation for each cross-cutting issue mix could be used.
- Mixed-and-matched, or refocused, existing advisory groups

CDC preparedness activities may be guided by a Secretarial-level committee, and its global health work could be guided with new methods (e.g., the CDC Foundation's Global Health Roundtable).

Dr. King's expertise in animal health and zoonotic vectors was welcomed. He hoped to facilitate convergence of human and animal health, as done in European zoonotic disease centers, through multi-disciplinary approaches involving veterinarians, human physicians, communications experts, etc. The proactive participation of the world's animal health organization, the OIE, particularly in surveillance, would also be an asset.

HIV/AIDS Update

An update on HIV/AIDS was provided by Dr. Ron Valdiserri, Deputy Director, NCHSTP, CDC. He described the case in New York City of a man diagnosed with rapidly progressing and multi-drug-resistant AIDS. CDC is stressing to its partners that this individual engaged in a large number

of unsafe sex acts while under influence of crystal methamphetamine (meth). Since the late 1990s, an epidemic of methamphetamine use among men-who-have-sex-with-men (MSM) has been associated with outbreaks of syphilis, and unsafe sex. The report of a CDC-convened panel of experts on the state of knowledge about crystal meth, focusing on unsafe sex in gay men, will be issued soon and relevant policy recommendations are in development. A CDC randomized control trial (RCT) under development will study behavioral interventions to reduce unsafe sexual behavior among MSM using crystal meth. The HIV advisory committee urged the DHHS Secretary in late 2004 to develop an action plan in response to this public health problem.

NHANES data on HIV seroprevalence 1988-94 and 1999-2002 showed no change in seroprevalence overall, but a significant increase in HIV seroprevalence among non-Hispanic blacks. Seventeen out of 23 HIV infected persons failed to respond to repeated contacts from study staff to notify them of their infection. Further, internal models develop by HIV/AIDS epidemiologists suggest that most new infections originate from such people. CDC will intensify efforts to promote early diagnosis of HIV as well as prevention. The former includes negotiation with OraQuick for a bulk purchase of rapid tests to be used in social networking and partner notification efforts. CDC, HRSA, NIH and FDA also recently released guidelines for post-exposure prophylaxis in non-occupational settings. It was emphasized that the use of post exposure prophylaxis is not a substitute for consistently safe behaviors and is intended for limited use in high risk circumstances.

CDC has been on record since 1994-95 that routine HIV testing should be done in areas with HIV seroprevalence of $\geq 1\%$, and more recently has encouraged routine HIV testing in healthcare settings. The normalization of HIV testing is seen as an important element in stopping the spread of HIV transmission—especially from persons who are infected and do not know it. Only ~10-20% of HIV testing done in the U.S. is paid for by CDC or public funds. Implementation by state and local health departments is critical, as is the participation of ERs and other out-patient health care facilities, especially in areas of high HIV prevalence. Demonstration projects have been done in the latter settings to learn what is needed to scale-up routine testing nationally. The committee should invite the program back in the future to advise further on progress made toward promoting early diagnosis of HIV infection. Dr. Valdiserri specifically acknowledged Dr. McGuire's research in Massachusetts, which demonstrated increased early diagnosis through ER screening funded by health departments. This is a key area where CDC collaborates with HRSA and is exploring strategies that will encourage CMS to support routine HIV testing.

Racial and ethnic health disparities are reinforced in the numbers just shared and the undue share of the burden in certain communities needs to be removed. In New York City, ~20% of the excess mortality in poor/ethnic communities is attributed to HIV, and in 32 states with stable, long-term, named HIV reporting, ~50% of the HIV diagnoses from 2000 to 2003 were among African-Americans, who do not constitute half the population in those states or in the U.S. This pertains to discussions by the Ethics Workgroup of how population based problems are viewed and how resources are prioritized and allocated. It was also noted that greater routine access to voluntary testing and engagement with the public has been successful in accomplishing early diagnosis.

Preparedness Grants

Public Health Emergency Preparedness and Response grants were presented by Ms. Donna Knutson, Senior Advisor to the COTPER Director. Within COTPER, the Division of State and Local Readiness manages the annual ~\$1 billion in preparedness grant funding to states, cities, and territories. The grant requirements were outlined. The funding began in 1999 at \$40.7 million, grew to \$49.9 million by 2001 and then leapt to \$949.7 in 2002. It exceeded \$1 billion in 2003 then dropped to \$849.5 million in 2004 and \$857.3 million this year. This funding builds the capacity to prepare for and respond to public health emergencies, those naturally occurring and those intentionally caused by terrorists. The characteristics of the 64 grantees were outlined. Most state agencies claim they have increased their ability to respond to an attack of smallpox, fewer grantees have indicated they are fully prepared for pandemic influenza response; and most are not prepared for incidents involving nerve, blood and blister agents. Most (70%) state response exercises have been done for an anthrax or smallpox attack.

As far as laboratory capacity, protocols have been developed for sample transport to labs, information exchange, and surge response agreements. The LRN testing capacity to address Category A and B threat agents was charted (all confirmatory labs for various agents); it is now conducting proficiency testing for a second tier of labs. In the BioWatch Program, EPA-produced air monitors are tested daily in 31 cities and supported by 23 LRN/BioWatch facilities. This will be expanded.

A chart of CDC's ten preparedness goals was shared, which are still being vetted by other DHHS agencies and state/local health departments. Two of the goals pertain to performance that would occur before an event, five pertain to performance that we would want to occur during an event, and three goals associated with performance after an event. Additional processes that informed the preparedness goal development include work with the Department of Homeland Security. DHS has developed 36 target capabilities, of which public health has a primary or secondary role in nearly 1/3. NACCHO and ASTHO have been working on the DHS' 36 target capabilities, and CDC is part of the DHHS team providing comments to DHS.

A new 5-year preparedness cooperative agreement period will begin July 1 (or August 31) that will focus on state, territorial and "priority local public health agencies," with increased emphasis on urban areas. The guidance will be framed by CDC's preparedness goals and measured by the progress in times/frequencies to respond faster and better. Data will be collected regarding performance goals and process objectives of grantees throughout the year.

Discussion included advice that CDC review the response plans developed by eight academic centers, which have developed emergency response plans as part of regional efforts. The developers of the plans feel the products have been largely ignored by NIH and DHS. The network of people who developed the plans could be very helpful to state and local public health agencies. Ms. Knutson will refer the projects to the staff member responsible for CDC's Centers for Public Health Preparedness program to Dr. Lemon to explore. The new cooperative agreements for the Centers for Public Health Preparedness require that the academic centers build tools expressly needed by state/local health departments, and they are integrated into the community response. All tools are made available through a network of all other state/local U.S. health departments.

The absence of a CDC trauma response was questioned, but the presentation covered only ~\$900 million of CDC's funding. The other work done, such as with trauma centers, ERs, and with the media and community (educating on appropriate comment to avoid panic, for example) was quickly sketched out as additional investments in CDC that meet the goals of injury and trauma centers. An example of such work is demonstrated through a cooperative agreement, which produced a website by the Red Cross and CDC that had just "gone live" this week.

Preparedness goals will result in performance measures (e.g., time from exposure, from report to response, etc.) and will include opportunities to measure performance during outbreaks and naturally occurring events, as well as events caused by terrorist. Dr. Gerberding also stated CDC's recognition that the food supply is an ongoing area of focus relative to terrorist threats, both that domestically produced and imported.

Vaccine Safety

Vaccine Safety activity was outlined by Dr. Snider. Young parents have never seen the diseases prevented by current vaccines, and so they now are more concerned with possible adverse vaccine effects. Since many vaccines are mandated by state law for school entry, employment, etc., CDC's relationship with the public around vaccines differs from its other work. The success of immunization depends on the public's confidence in vaccine benefits and safety, and in CDC's recommendations.

To maintain that confidence, and in view of the growing number and combinations of recommended immunizations (particularly for children aged <2 years), CDC will formally notify Congress of four initial steps to be taken, to: 1) increase resources for immunization safety research and safety activities; 2) work with sister DHHS agencies to prioritize and set an agenda for vaccine safety research and monitoring; 3) separate vaccine safety activities from other CDC immunization activities (particularly vaccine purchasing and promotion); and 4) emphasize the transparency of CDC's science and research on immunization safety issues. Advice has already been gathered from a 2004 blue ribbon panel on immunization safety activities, from public forums held around the nation, and from CDC's own scientists and health experts.

A Vaccine Safety Office will be established in the Office of the Chief Science Officer. Among its initial activities will be review of the recent IOM Report on the Vaccine Safety Datalink which recommends the establishment of an internal/external oversight board. With this independent reporting structure and oversight, CDC hopes to reassure those with concerns about CDC's objectivity and commitment to protecting our children's health and safety.

Discussion included note of the jointly conducted CDC-FDA VAERS system; the opportunity to maximize vaccine safety research in NIH's VTEUs, and the support of the NVPO and NVAC's Vaccine Safety Subcommittee. The NVPO's recent focus has been on seasonal influenza and pandemic influenza, but they agree that a national vaccine safety plan is needed. NVAC, whose membership includes vaccine manufacturers and all the federal agencies involved with vaccines, is responsible for advising the Secretary on vaccine issues. Dr. Snider added another consideration for CDC, of whether those promoting interventions should be housed separately from those

assessing the interventions and determining if the risks have been appropriately considered and effectively communicated to the public. The relationship between CDC and the ACIP is another area that needs re-examination.

Dr. Melissa McDiarmid applauded this last conversation as the richest of the day. This kind of self-examination and discussion of unintentional biases is very helpful and should continue between the advisory committees and their colleagues in Atlanta. Safety issues are very serious and should involve the FDA more. FDA participation could benefit CDC in terms of responsibility (and perhaps funding), particularly since drug safety is not CDC mission and the agency should not have to pay for it. Among the issues of concern is that many vaccines are vetted very differently than for other drugs.

Tobacco Issues

The quantitative and qualitative issues and CDC activities related to Tobacco Control were outlined by Dr. Corinne Husten, Acting Director, Office on Smoking and Health, CDC. The individual, social, cultural and economic environments of the U.S. are reflected in the racial disparities evident in the burden of tobacco use and related health effects. Tobacco use still kills 440,000 people annually in the U.S., and sickens 20 more for each death. The related annual cost is \$157 billion in health care and lost productivity.

Tobacco's impact is great since its toxins follow the blood and affect every organ. A rise in youth smoking incidence in the early 1990s has lowered, making achievement of the 2010 goal of 16% prevalence in that group possible, but that trend may be plateauing among high school seniors. Decreases in state funding for tobacco prevention and control and increases in tobacco advertising may jeopardize the progress that has been made.

The NHIS data of cigarette smoking trends among adults from 1965-2003 were charted. Since 2002, for the first time, more people quit than were still smoking. Robust evidence exists on what works to prevent initiation, promote cessation, and reduce exposure to second-hand smoke. The estimated annual change in cancers of the lung and bronchus were charted, comparing data from the California and SEER registries. Those showed improved health outcomes even in terms of cancer after 10 years of a comprehensive tobacco prevention and control program.

The three interventions above, which were researched and documented in the *Guide to Community Preventive Services*, were outlined. A good evidence base also exists for comprehensive tobacco control programs, demonstrating that investment equates to impact: in states with comprehensive programs, consumption dropped twice as fast as in states with low levels of spending. That was paralleled for youth smoking in more recent studies, where modeling estimated a 3%-13% lower smoking prevalence among youth if CDC's recommended level of spending was followed (8% of the MSA and tobacco taxes).

The effects of funding cuts in several states were also outlined. Within just a few months of the reduction, data indicated a 15 percentage point increase (from 43% to 58%) in youth at risk (measured by youth not expressing a firm commitment not to smoke) in Minnesota; Massachusetts measured an increase in illegal sales to minors, in the absence of funds for monitoring; and

Florida's "Truth Campaign," which had lowered youth smoking by 40% over two years, was virtually eliminated by a 98% reduction – with insufficient funding left to even determine the impact of the cuts. And, alongside government budget cuts, foundations also had less money to contribute. The OSH is working with states to see how they can keep such important programs running with less and be able to ramp up activity again upon funding.

A chart was shared of the components of comprehensive tobacco control programs, given available resources. The low- and moderate- resources (for interventions) were charted with minimum- and optimum best practices for five program components: community interventions, counter marketing, cessation programs, youth programs, and surveillance/evaluation.

Discussion included Mr. Smith's note of the hypocrisy of the trial lawyers who argued for anti-smoking settlements but are not now arguing for the cessation programs. Dr. Husten described the results of MSA funding. Flat prevalence rates of adult tobacco use in the 1990s began to decline in 1997 and provisional 2004 data indicate a continuing decline. With every 10% price increase, another 4% reduction in consumption is seen; some people do not quit, but they cut back. There are no data to indicate what single intervention will sustain a decrease; all the components of a comprehensive program have synergistic independent effects.

Dr. Benjamin stressed that the importance of the doubled tobacco advertising cannot be understated, and noted that children are more price-sensitive than adults. New smokers are generally among the youth groups; little initiation is seen after age 25. The NHIS data soon to be published will show a drop in prevalence among the young adult (18-24 years) population that is not statistically significant, but still a reversal of recent patterns. One public health challenge to come, with the release of new tobacco products to be released (e.g., Philip Morris' "Ultra-Smooth"), is the "seduction of harm reduction." Population risk may not be lowered if people use alternate products instead of quitting. For example, people who smoked the low-tar cigarettes inhaled more deeply and/or blocked the vent holes to get more smoke in their lungs; and those switching to cigars still inhaled the smoke, and their risks were not significantly reduced.

Public comment was solicited, to no response. With thanks to the members and participants, Dr. Agwunobi adjourned the meeting.

ATTACHMENT: ATTENDANCE, Advisory Committee to the Director (ACD) Meeting

Julie L. Gerberding, MD, Director, CDC

Robert Delaney, Chief of Staff, CDC, Executive Secretary, ACD

Committee members present:

- *John O. Agwunobi, MD, MBA, MPH, Committee Chair. Secretary of Health and State Health Officer, Florida Department of Health, Tallahassee, FL*
- *Joel Reed Bender, MD, PhD, MSPH, Corporate Medical Director, General Motors Corporation, Detroit, MI*
- *Georges Benjamin, MD, FACP, Executive Director, American Public Health Association (APHA)*
- *Mary desVignes-Kendrick, MD, MPH, FAACP, Professor-Management, Policy and Community Health, Deputy Director-Center for Biosecurity and Public Health Preparedness UT Health Science Center at Houston, School of Public Health, Houston, TX*
- *Thomas R. Frieden, M.D., M.P.H., Commissioner, New York City Department of Health and Mental Hygiene, New York, NY*
- *Robert L. Galli, M.D., Professor and Chair, Emergency Medicine, University of Mississippi Medical Center, Jackson, MS*
- *Joseph Hogan, President and CEO, General Electric Medical Systems, Waukesha, WI*
- *Debra Lappin, J.D., Director's Council of Public Representatives, National Institutes of Health, Englewood, CO*
- *Sandra K. Mahkorn, M.D., M.P.H., M.S., Chief Medical Office for Health Information, Division of Health Care Financing, Department of Health and Family Services, Madison, WI*
- *Joe S. McIlhaney, M.D., M.P.H., M.S., Founder/President, Medical Institute for Sexual Health, Austin, TX*
- *Shepherd Smith, Founder/President, Institute for Youth Development, Sterling, VA*
- *Antronette K. Yancey, MD, MPH, FACPM, Adjunct Associate Professor, University of Southern California School of Public Health, Los Angeles, CA*

Member absent: *Marilyn M. Maxwell, M.D., Associate Professor of Internal Medicine, St. Louis University, St. Louis, MO*

CDC FACA Committee Chairs present:

- Stanley Lemon, NCID Board of Scientific Counselors (BSC)
- Jean McGuire, HRSA, HIV/STD advisory Committee
- Kowetha Davidson, ORRHES
- Philip Harber, Safety and Occupational Health Study Section
- Henry Anderson, MD, NIOSH BSC
- Melissa McDiarmid, NCEH/ATSDR BSC

CDC staff present:

Mitch Cohen
Blake Caldwell
Thayes Carswell
Bridget Cleveland
Jeffrey Cook
Donna Garland
Heather Horton
Lonnie King
Donna Knutson

Jo McDonald
Brad Perkins
Molly Rodriguez
Tom Sinks
Dixie Snider
Bob Spengler
Stephen Thacker
Ed Thompson
Charles Schable

Donald Schriber
Anant C. Shah
Tom Smith
Ed Sondik
Jill Surrency
Michelle Wilson

Others present:

Patrick Kelly, NAESM, Inc., Atlanta, GA
Marie Murray, Recorder, Atlanta, GA
Susan Sanders, Atlanta, GA

I hereby certify that the foregoing summary of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC) meeting held on Thursday March 3, 2005 is accurate and complete to the best of my knowledge.



John O. Agwunobi, M.D., M.B.A., M.P.H., Chairman

08/08/05
Date



Robert Delaney, Executive Secretary

08/18/05
Date