NCID/CDC/BSC Meetings Minutes Analysis – 2002-2006

These are excerpts from the Centers for Disease Control (CDC)/National Center for Infectious Diseases (NCID)/Board of Scientific Counselors (BSC) minutes from meetings that took place from December 2002 until the reorganization in March 2007. The NCID has announced that their materials, presumably including these minutes, will be removed from the Internet.

Only excerpts of meetings relevant to Lyme disease or the Infectious Diseases Society of America (IDSA) are included. References to Walter Stamm are also included. Stamm was the president of IDSA in 2005, the time of the meeting where promoting IDSA Lyme disease guidelines and disparaging alternative Lyme disease guidelines was discussed.

In doing this review, two things leave an impression.

One is that the CDC repeatedly states how they are viewed as the ultimate and most trustworthy source of health information in the world. They refer to this as brand name recognition. Their clout in the medical community and the endorsement of the IDSA Lyme disease guidelines as a sole source is a major factor in the publicity and spread of the IDSA Lyme guidelines and acceptance by the medical profession. This despite the fact that there were only 14 authors of the IDSA Lyme disease guidelines, these authors had serious and significant conflicts of interest, and most medical studies relating to Lyme disease seem to have been purposely ignored. The eager endorsement and publication of these guidelines by the CDC should be questioned.

Second, existing guidelines by doctors and medical associations for various conditions and diseases were not questioned in any of these meetings. In no instance was there any mention of the need to disparage or squash any guidelines for the diagnosis and treatment of health conditions or to promote certain guidelines. The sole exception was Lyme disease.

A major CDC/IDSA affiliation was mentioned in the December 2004 meeting; the Emerging Infections Network (EIN). What is remarkable is IDSA's statement that only 60% of their 7,000 members (in 2004) were clinicians and that one-fifth of these were consultants. This is at odds with IDSA's implied claim that their Lyme disease guidelines are followed by 8,000 (in 2008) members. Also, there are IDSA members who do not agree with the IDSA Lyme disease guidelines. This meeting mentioned funding in the amount of $3.6 million for "new research on Lyme disease" to 10 institutions.

The May 2005 meeting discussed Lyme disease and the need to discourage guidelines that deal with the recognition and long-term treatment of chronic Lyme disease. The meeting also brought up the need to update IDSA Lyme disease guidelines. The revised IDSA guidelines were issued in late 2006, about 16 months after this meeting. This was the only meeting in which Lyme disease was extensively discussed.

The November 2005 meeting has an intriguing reference to CDC "control." This aspect was brought up by Stamm, president of IDSA. He "wonders how the balance will be struck in managing regional, international, and CDC control of activities; which agency will serve as the primary decision-making entity?" This would appear to be a ploy by IDSA to be able to use their influence with the CDC to promote other guidelines or otherwise "control" medical diagnoses and treatment.

Apparently, affiliations between IDSA and various US Government health agencies have been going on for some time. This has proven to be a detriment to Lyme disease patients. The abandonment of these patients resulting from IDSA Lyme disease guidelines has delegated

many chronic Lyme disease patients without financial resources to expensive government assistance through such programs as Medicare and Medicaid.

The most relevant segments relating to IDSA and Lyme disease are highlighted.

December 12-13, 2002 Minutes

No mention of Lyme, IDSA, or Stamm.

Focus of the meeting was on bioterrorism and vaccines.

May 2, 2003 Minutes

No mention of Lyme, IDSA, or Stamm.

Focus of the meeting was the CDC budget and SARS.

December 11-12, 2003 Minutes

No mention of Lyme or IDSA. Stamm listed on Board of Scientific Counselors. This is the first instance in which Board of Scientific Counselors are listed.

Focus of the meeting was on the CDC budget, bioterror labs (BSL 2, 3, 4), and emerging diseases which did not include Lyme disease.

May 3-4, 2004 NCID Minutes

Focus of the meeting was on the CDC budget, bioterror, hepatitis, pneumococcal vaccines, and influenza. First mention of IDSA in the NCID/CDC/BSC minutes.

Dr. Lemon commented on the paucity of new classes of antimicrobial agents and incentives for pharmaceutical companies and Dr. Heilman informed the Board of NIAID's second collaborative summit in August with Infectious Diseases Society of America (IDSA) and ASM collaboration in which these issues will be discussed. NIAID is currently engaged in internal discussions regarding the encouragement of drug companies to develop new pharmaceuticals to meet these needs. In regards to Dr. Lemon's inquiry regarding economic incentives to drug companies, Dr. Heilman stated that would be brought to the community by ASM and IDSA, not NIAID.

December 9-10, 2004 Minutes

Focus of the meeting was antibiotic resistance, vaccine development, the Emerging Infectious Diseases (EIN) network, and IDSA. Lyme funding was mentioned.

EXTRAMURAL RESEARCH PRIORITIES

Dr. Brian Mahy

Dr. Mahy provided BSC and other meeting attendees with background information regarding the Office of Extramural Research (OER) within NCID. The office was established in August 2002 and is headed by Dr. Mahy (Acting Director). This office is responsible for announcing and peer reviewing NCID extramural research, developing programs, monitoring and administering extramural research grants, and providing stewardship of NCID funds for extramural research.

The following activities were conducted in FY '04:
- funded $3.6 million to 10 institutions for new research on Lyme disease.

Other Items for Discussion

Dr. Gerberding is strongly in favor of peer reviewing CDC programs. A policy was instituted 6 years ago that called for each CDC intramural program to be peer reviewed by an external group of subject matter experts once every 5 years; however, because of other public health priorities that have emerged over the past several years, not all programs have had such a review. Peer-review activities within divisions should take place in the near future, and reports from the reviews will be presented to the BSC. The BSC also should be represented on the peer-review team; board members will be called upon to serve in this capacity, and members should notify division directors if they are interested in being involved.

Dr. Hughes called attention to the Infectious Diseases Society of America publication *Bad Bugs, No Drugs*. The publication focuses on issues related to the antibiotic development pipeline. This subject is a priority for IDSA, and the antibiotic issue should be examined in depth by CDC; the Board of Scientific Counselors also should focus on the antibiotic crisis that faces the nation.

Dr. Hughes also reminded the Board that the current issue of the *Emerging Infectious Diseases Journal* is now available. This issue focuses on zoonotic disease and would be informative to BSC members.

Infectious Diseases Society of America (IDSA) Emerging Infections Network

Dr. Larry Strausbaugh

The rationale for forming the IDSA network was based on the excellent communication and rapport that infectious disease (ID) specialists have with the larger medical community (e.g., microbiologists and pharmacists); infectious disease specialists usually have a finger on the pulse of what is occurring out in the community. Therefore, obtaining information from ID specialists can be reliable and representative. The IDSA Emerging Infections Network (EIN) is a CDC-sponsored, provider-based sentinel network that was formed in 1995. More than 890 infectious-disease consultants currently participate in the network, most of whom practice adult infectious-disease medicine. The IDSA EIN operates with several objectives, including

- the detection and reporting of new or unusual clinical events;

- case identification to assist with outbreak investigations;

- acquisition of knowledge about emerging infections; and

- communication and education.

EIN members are engaged in several activities aimed at obtaining information from patients, primarily completion of both periodic and urgent surveys. Periodic surveys are one-page requests for information on a specific topic that take participants approximately 2 minutes to complete. These surveys are distributed to EIN members approximately every 6-8 weeks via e-mail and fax. About 50 periodic surveys have been issued since January 1997 on a variety of topics, including *Kingella kingae* infection, SARS, CA-MRSA infections, and *Clostridium difficile*.

EIN participants also are expected to complete urgent surveys, which are issued with the goal of obtaining assistance in outbreak investigations. These surveys are one page long and are distributed by e-mail and fax. EIN members are expected to complete these surveys within 24-72 hours of receipt. Since January 1997, eight urgent surveys have been distributed on various topics (e.g., cyclosporiasis, West Nile-like viral encephalitis, smallpox vaccination, and severe influenza A).

Beyond completing surveys, EIN members participate in an electronic mail conference, which is a listserv for more than 800 members including 133 staff members from CDC and state/local health departments. The mail conference allows for the two-way exchange of information. During 2001-2003, more than 800 discussions took place on the electronic mail conference regarding a wide variety of topics. This conference has allowed for the dissemination of materials from CDC's COCA and DHQP.

Future plans for IDSA's EIN include development of a web collaboration portal system to replace the electronic mail conference, expansion of on-line survey activities, improvement of linkage and collaboration with state and local health departments, the introduction of PDA technology for surveillance activity, and further involvement of international members.

Discussion

- Dr. McDonald inquired about how members of EIN were recruited and about whether IDSA attempts to increase membership. Dr. Strausbaugh informed her that the creation of the network and request for participants was communicated through the internet, specifically over the IDSA website. Once a year, IDSA sends state ID society presidents a letter asking them to provide names of potential additional members. In addition, if EIN participants fall behind and don't complete surveys, they are sent a warning letter regarding their EIN status; if these participants still do not actively participate despite receipt of the letter, they are placed in EIN's inactive category, and they stop receiving surveys.

- Dr. Strausbaugh was asked about IDSA's capacity to conduct surveys. He noted that more surveys could be done and that the society has a willingness to drop all other

activities to respond to urgent health issues. On the other hand, the society tries to avoid burn-out of their network participants.

- One meeting attendee asked about the percentage of clinical consultants that are members. According to Dr. Strausbaugh, 60% of the 7,000 IDSA members are practicing clinical medicine, and one-fifth of these clinicians are consultants.

May 12-13, 2005 Minutes

Focus of the meeting was the CDC budget, waterborne illnesses, influenza, Hemorrhagic Fever, antimicrobial resistance, emerging diseases, and "intense focus on" Lyme disease.

Division of Vector-Borne Infectious Diseases (DVBID)
Dr. Mary Jane Ferraro served as group facilitator for the Division of Vector-Borne Infectious Diseases breakout group and presented to the Board. The group tackled issues identified by Dr. Petersen (the division's director) as being worthy of intense focus by the group: construction and Lyme disease activities.

Substantial construction of new facilities is occurring on DVBID's Ft. Collins campus. Although CDC's objective in adding a new building was to increase laboratory space at the campus, budgetary restrictions have made construction problematic. The original plan for the new lab building called for 9 floors and 270,000 square feet of usable space; however, after building activities were initiated, CDC budget constraints required this plan to be scaled back to include only 5 floors comprised of 85,000 square feet. This smaller "revised" facility provides each full-time technologist with only 160 square feet of space, whereas the standard amount of space for these employees in other NCID facilities is 270 feet; space for office staff is also insufficient at the new building, providing only 80 square feet of space per full-time employee versus 150 feet for Atlanta-based NCID staff.

DVBID's facility inadequacies prompted the breakout group to focus on solutions. The group examined the current budget and discussed needed funding. Completion of phase 1A and 1B of building (i.e., total completion of one laboratory facility) requires $102 million, representing a shortfall of $22 million. Of this total amount, $80 million has been allocated and spent. In examining the FY '06 budget for DVBID, the breakout group determined that approximately $30 million has been allocated; however, concern exists that this money will be tapped to be used as a "payback" for money once borrowed by DVBID.
In light of the problematic funding situation at the Ft. Collins campus, the breakout group provided the following recommendations.

- Plans for phase 1A and 1B should be completed; the $30 million included in the FY '06 budget should be used to finish the facility to that level. Any outstanding loan should be forgiven.

- Because a "phase 2" building likely will never be built, older buildings should be renovated and used as office or conference space.

- The new Ft. Collins facility should be used as a back-up laboratory for the entire agency.

Completing the Ft. Collins facility currently under construction has many advantages. Although $22 million is required to complete phase I, this amount will triple if construction activities must be halted and then begun during a different fiscal year. Providing the Ft. Collins campus with more adequate space ensures that this group can remain in Colorado, which is an appropriate placement for a division focusing on vectorborne disease.

The second topic of discussion among members of the breakout group is Lyme disease --- particularly the challenges presented by this disease that extend beyond science. Recently, highly organized groups of people have been expressing concern for CDC's current case definition and laboratory criteria. Much of this effort has been triggered by unpaid insurance claims from patients with symptoms that are not included in CDC's case definition for Lyme disease. In addition to these vocal organized groups, laboratories across the country are conducting inappropriate, or questionable, testing for Lyme. The tests are being sent to physicians who have not been appropriately trained to interpret them.

The breakout group issued the following recommendations for DVBID regarding these Lyme-disease-associated issues.

- The IDSA guidelines should be updated; a consensus document should be made available to physicians who need guidance.

- The CDC guidelines for interpreting laboratory tests should be updated in collaboration with industry and government experts.

- As updated guidance becomes available, an effort should be made to notify physicians and other practitioners regarding availability of clinical and laboratory documents.

- CDC researchers should focus on science and not on the concerns of patient groups; other groups may need to step in and assist DVBID with public interface.

Discussion:

- Dr. Lemon reiterated that the building should be completed sooner rather than later. He asked Dr. Petersen to provide the Board with a business plan to be used to develop recommendations. Dr. Petersen informed him that a business plan is being developed but is not yet available.

- Dr. Neill expressed the need for more detailed information regarding build-out of the phase I "shell" facility before the Board can support the completion of the laboratory building. Dr. Schuchat noted that NCID believes the build out of the facility is important; however, funding is lacking. The agency is not pushing HHS for additional funding at this time.

- Dr. Eberhart stated that inappropriate laboratory testing and treatment are occurring in many states. Commonalities throughout the states should be identified. Dr. Quinlisk

concurred; she receives e-mails from constituents asking why the state health department does not agree with their private doctors. Many of these constituents can not be convinced by science; therefore, accurate information should be distributed to clinicians.

- Dr. Stamm commented that rogue guidelines are legitimizing long-term treatment for chronic Lyme disease; as long as these guidelines can be accessed, this type of treatment can be legitimized.

- The breakout group also discussed the concept of "breaking down the walls" between different CDC organizations. The group members would like CCID and NCID leadership to review the proposed organization for viral and rickettsial diseases and consider aligning these subject areas with vectorborne infectious diseases. Doing so may reduce redundancy. Dr. LeDuc commented that aligning programs can present logistical problems, as some activities are better placed at the Ft. Collins campus, whereas others function better in Atlanta.

- The issue of emerging vectorborne diseases was raised. These diseases should be recognized in the bioterrorism arena, along with other natural agents that could become a substantial public health threat within the United States. Resources should be appropriately allocated.

- Dr. LeDuc added that NCID recognizes the need for new policy guidelines regarding transplantation. Recently, rabies has been transmitted from organ donors to their recipients. A policy for tracking this type of transmission must be defined.

- Dr. Granger expressed appreciation to the Board for including USDA in its discussions. USDA is interested in tickborne diseases, particularly because these diseases cause disease in cattle. The agency is examining tick collections and is trying to isolate agents at a Ft. Collins facility. This presents an excellent opportunity for synergy between USDA and CDC's DVRD. USDA and CDC have a different focus on achieving the same mission; collaboration could be beneficial to both agencies. Dr. Lemon concurred that the agencies should work

Office of Antimircobial Resistance

Dr. J. Todd Weber

Dr. Weber provided meeting attendees with information regarding NCID's Office of Antimicrobial Resistance (OAR). The office was created in 1996; it began as an office of one staff member, but has been gradually expanded in the past few years.
OAR has been given several unique responsibilities. It is in charge of prioritizing and distributing all AR program funds; representing CDC on all AR issues; and coordinating activities among other organizations, including NCID divisions and other CDC centers (through the Antimicrobial Resistance Working Group). The Office also coordinates activities between CDC and other federal agencies (e.g., FDA, NIH, and EPA). For example, OAR co-chaired the Interagency Task Force on Antimicrobial Resistance in 1999, works with FDA to deal with antimicrobial-drug-related issues, worked with NIH on the Best

Pharmaceuticals for Children Act, and consulted with EPA on the issue of antimicrobial pesticide registration. Finally, OAR coordinates activities between CDC and foreign governments, global organizations, NGOs, and medical societies, including WHO, PAHO, EU, APUA, ACP, and IDSA.
The funding for the office was originally obtained through the Emerging Infections Program; funds were then formally appropriated by Congress in 2001. Since the creation of the office in 1998, approximately 100 projects and programs have been funded.

OAR has had many accomplishments in the few years since its inception. First, it has spearheaded the "Get Smart: Know When Antibiotics Work" campaign. Through participation from more than 95 organizations, this national Get Smart campaign has involved evidence-based reviews, state-based campaigns, advertising campaigns, the establishment of a medical school curriculum, the development of health plan employer data and information set measures, and campaign evaluation.

- BSC members were updated regarding IDSA's Bad Bugs, No Drugs campaign. The IDSA has hired lobbyists to support the two antimicrobial-associated bills that are currently under consideration.

- Dr. Stamm asked about whether more attention should be given to the topic of rapid diagnostics for antimicrobial resistance. The availability of rapid diagnostics could substantially limit drug resistance through the avoidance of inappropriately prescribed broad-spectrum antibiotics. Dr. Weber noted that CDC has not focused enough on this issue because the agency has not had the funding to support the technology required to investigate diagnostic tools. The issue of rapid diagnostics is, however, part of the CDC-wide agenda for the Futures Initiative.

November 29-30, 2005 Minutes

No mention of Lyme disease.

CDC CHIEF SCIENCE OFFICER UPDATE

Dr. Dixie Snider

CDC's Chief Science Officer, Dr. Dixie Snider, updated BSC and other meeting attendees regarding recent activities that have occurred within CDC's new Office of the Chief Science Officer (OCSO) and within CDC's advisory committees.

Discussion:

- Dr. Walter Stamm inquired about the increasingly important issue of ensuring that CDC guidelines are appropriately updated. Dr. Snider agreed that this issue deserves attention from the agency. In recent discussions with ACIP, options for updating guidelines have been proposed, including enabling the Committee to "lift" certain sections from previous guidelines to be updated; these updated sections would then be rewritten and published without having to redo the entire document.

GLOBAL DISEASE DETECTION
Drs. Scott Dowell and Ray Arthur

BSC members were updated regarding CDC's new global disease detection strategy. Dr. Scott Dowell first discussed background information for CDC's Global Disease Program. CDC began funding the program in 2004. Funding for the program was quickly and easily obtained from Congress, and as a result, the activities that were first conducted within the program were not methodically identified or justified. As the program evolves, however, CDC is working to focus and prioritize its global health activities through the development of a global health strategy.

- Dr. Walter Stamm commented that the proposal for GDD is an "exciting agenda." However, he wonders how the balance will be struck in managing regional, international, and CDC control of activities; which agency will serve as the primary decision-making entity? In addition, Dr. Stamm asked for clarification regarding whether the Control Centers will be examining a) animal disease in addition to disease in humans and b) disease investigation in addition to surveillance. Dr. Dowell agreed that central control is needed to enable the Control Centers to function as a network. Currently, WHO's global network of voluntary partners is very loosely controlled. CDC's proposed GDD Control Centers provide the opportunity to have centrally funded, tightly controlled global disease activities. To answer other questions, Dr. Dowell noted that CDC has planned to focus on human disease surveillance, although recently the need to better address disease in animals has been discussed.

May 11-12, 2006 Minutes

Focus on the CDC budget and restructuring of NCID.

No mention of Lyme, IDSA, or Stamm.

March 15, 2006 Minutes

Focus of meeting was on the upcoming reorganization and staff.

This was the final meeting before reorganization.

No mention of Lyme, IDSA, or Stamm.