National Cancer Advisory Board (NCAB)
Cancer Centers Subcommittee Meeting

Patuxent Room
Hyatt Regency Bethesda Hotel
One Bethesda Metro Center (7400 Wisconsin Avenue)
Bethesda, MD
November 30, 2009
6:30 to 8:15 p.m.

SUMMARY

Participants:

Subcommittee Members
Dr. H. Kim Lyerly (Subcommittee Chair)
Dr. Victoria Champion
Dr. Judith Kaur
Dr. Karen Meneses
Dr. Jennifer Pietenpol

Other Participants
Dr. John Niederhuber (Director, NCI)
Dr. Linda Weiss (Subcommittee Executive Secretary)
Dr. Donald Coffey (NCAB)
Ms. Kathryn Giusti (NCAB)
Dr. Diana Lopez (NCAB)
Dr. Marie Sweeney (CDC/NIOSH; alternate *ex officio* member of NCAB)
Dr. Robert Croyle (Director, Division of Cancer Control and Population Sciences, NCI)
Dr. Hasnaa Shafik (NCI)
Ms. Ann Huston (NCI)
Ms. Stacey Vandor (NCI)
Ms. Mary Fischietto (NCI)
Dr. Gail Bryant (NCI)
Dr. Rachel Ballard-Barbash (NCI)
Dr. David Maslow (NCI)
Ms. Kathleen Meister (The Scientific Consulting Group, Inc., rapporteur)

Dr. H. Kim Lyerly, Chair of the Cancer Centers Subcommittee, welcomed all attendees to the meeting and asked members of the Subcommittee and guests to introduce themselves. He explained that the evening's presentation would be on Comparative Effectiveness Research (CER), an important area of emphasis for the new Administration and an important area of stimulus package funding. CER may pose a dilemma for the directors of Cancer Centers because it is a nationally important topic but one that is not necessarily funded by the National Cancer

Institute (NCI). It can be challenging to incorporate CER into the work of Cancer Centers. Nevertheless, CER is here to stay, and it is important to understand it and to understand NCI's vision of where it is going.

Dr. Lyerly then introduced Dr. Robert Croyle, Director of NCI's Division of Cancer Control and Population Sciences and NCI's representative on NIH's committee on CER.

Comparative Effectiveness Research and NCI Designated Cancer Centers – Dr. Robert Croyle

Dr. Croyle began his presentation by noting that CER activities at Cancer Centers differ depending on whether the Cancer Center is at a university that also has a school of public health and also with the size of the Cancer Center. He noted that the definition of CER has been a contentious issue, but less so for NCI than for other National Institutes of Health (NIH) Institutes and Centers (ICs) because much NCI research falls easily within the Department of Health and Human Services' (DHHS) current definition of CER. Although DHHS has agreed on a working definition of CER, that definition can be expected to continue to evolve with time. In particular, if a healthcare reform bill passes, it can be expected to greatly affect the definition and conduct of CER.

Under the American Recovery and Reinvestment Act (ARRA), $1.1 billion were allocated for CER, with $400 million going to NIH, $300 million to the Agency for Healthcare Research and Quality (AHRQ), and $400 million to the Office of the Secretary (OS) of HHS. NIH was able to make use of its share of the funding quickly by directing it to extramural research; 85 percent of the ARRA funding received by NIH for CER was allocated in FY 2009. The other agencies, which are more oriented toward infrastructure, moved less rapidly to allocate their funds.

NCI received 21 percent of the ARRA CER funds awarded to NIH. NCI was especially effective in competing for the most ambitious types of projects because such projects could be piggybacked onto existing research, rather than starting from scratch. NCI received 28.7 percent of the funds awarded to NIH for large Grand Opportunity (GO) grants and 40.2 percent of the funds awarded for payline expansions. NCI was particularly well equipped to compete for the latter type of grants because many CER-related grant applications had already been submitted and reviewed.

Dr. Croyle presented examples of a wide variety of cancer research projects funded with ARRA CER dollars. In addition, some NCI CER projects have been supported by stimulus package funds not specifically earmarked for CER. Many projects already in NCI's portfolio meet the definition of CER.

CER was placed in the spotlight when the attention of the White House Office of Urban Affairs focused on the effect of stimulus funding on the Seattle area. The White House is interested in looking at areas of synergy between biomedical research and economic and urban development. The Seattle tour by the Office of Urban Affairs highlighted the success of the Fred Hutchinson Cancer Research Center (which received a GO grant funded by ARRA CER dollars for its

Center for Comparative Effectiveness Research in Cancer Genomics [CANCERGEN]), the University of Washington, and other area institutions in spurring scientific research efforts, including CER. Key take-away messages from this experience for Cancer Centers are as follows:

- The Obama Administration recognizes the importance of investing in CER.
- Cancer Centers should think strategically about how to engage in CER.
- Dissemination of CER information and encouraging adoption of best practices will be challenging.

ARRA called for the Institute of Medicine (IOM) to produce a report on CER. This report, entitled *Initial National Priorities for Comparative Effectiveness Research*, was released on June 30, 2009. Its content has been very important to NIH—even more so than had been anticipated. The report included 100 national priorities for CER (quite a few of which relate to cancer); meeting one of these priorities has become one of the criteria for obtaining funding. For some other ICs, matching research proposals to these priorities has been much more difficult than for NCI. As NIH Director Dr. Francis Collins has noted, concerns have been expressed that rare diseases may not be included in the priority list. It may be possible, however, for poorly funded areas to be piggybacked onto better funded ones, including NCI research areas. Institutions that have Cancer Centers do not just do cancer research; they are also involved in research on many other diseases.

FY 2010 funding under ARRA will focus on as-yet-unfunded priorities in the top quartile of those identified in the IOM report. The cancer research constituency should be able to compete effectively for such funding.

The IOM CER report's recommendations for long-term investment focused on the following:

- Ensuring meaningful consumer, patient, and caregiver participation.
- Building robust information systems and research methods.
- Development and support of a highly skilled CER workforce.
- Supporting efforts to translate CER knowledge into everyday clinical practice.

Engagement of stakeholders is a particularly important issue that has been emphasized in all reports on CER to date and is beginning to take on the flavor of a regulatory requirement. DHHS wants its agencies to develop more formalized processes for public input and engagement. The AHRQ is developing an entirely new citizens' forum to formally engage stakeholders and expand public involvement. NIH, however, is more likely to build on processes already in place unless new legislation requires a different approach. NCI has an advantage over the other ICs in terms of leveraging existing processes because it already has the Director's Consumer Liaison Group (DCLG). No other IC has anything like the DCLG.

A new HHS governing process that will oversee CER has been initiated, but it is unclear exactly how it will operate. Much depends on what happens with healthcare reform.

Collaboration with other ICs, other government agencies, and non-governmental entities will play an important role in the future of CER related to cancer. NCI is attempting to ensure that it has input into all cancer-related projects, regardless of who is conducting them or how they are funded. For example, the Centers for Disease Control and Prevention (CDC) is interested in data linkage; NCI staff members have been working with CDC to help them get up to speed on topics such as the Surveillance, Epidemiology, and End Results (SEER)-Medicare linkage and how it works. NCI also is continuing to work with other agencies, including the Centers for Medicare and Medicaid Services (CMS) in enhancing the national capacity for data linkage.

Dr. Croyle noted that with regard to data linkage, funding circumstances may differ among Cancer Centers depending on whether or not they are in SEER domains. Several Cancer Centers outside of SEER domains have built strong relationships with state cancer registries and have been negatively impacted by state funding cutbacks.

The Health Maintenance Organization (HMO) Cancer Research Network (CRN) is likely to be one of the mechanisms by which various agencies can collaborate on CER. Early in 2010, a new brochure explaining the HMO CRN and how to work with it will be published. The HMO CRN has received a great deal of CER and other stimulus package funding and is becoming an international, rather than strictly American, network.

The clinical research infrastructure of NCI, including the Cancer Centers Program, the NCI Community Cancer Centers Program (NCCCP), the Specialized Programs of Research Excellence (SPOREs), and the Clinical Trials Cooperative Groups Program, all can be leveraged for CER.

One way in which NCI has participated in CER is through physician surveys that provide provider perspectives on patterns of cancer care. Information about these surveys can be found at http://appliedresearch.cancer.gov (click on Physician Surveys). NCI also is involved in survey collaborations with other government agencies and non-governmental groups, such as the American Cancer Society. Some of these surveys track the public's sources of cancer information and cancer-related beliefs, as well as their health decision making processes. Other NCI projects that tie in with CER include the Breast Cancer Surveillance Consortium (BCSC), the Cancer Care Outcomes Research and Surveillance Consortium (CanCORS), the Genomic Applications in Practice and Prevention Network (GAPPNet), and the Trans-NCI Pharmacogenomics and Pharmacoepidemiology Working Group (Trans-NCI PPWG).

There have been questions from Cancer Centers about how to connect genomic and personalized medicine initiatives with the new focus on CER. In the long term, translational genomics initiatives will be developed. NCI already is working toward this goal. One focus will be on compiling evidence in ways that make it usable to the practitioner.

Dr. Croyle concluded his presentation by emphasizing the following practical take-home messages about CER for the Subcommittee and Cancer Center directors:

- Multidisciplinary staff expertise is essential. A lack of such expertise has hampered some Cancer Centers in competing for CER funding.
- It is important to adopt a long-term perspective. The short-term ARRA funding will not be the only source of support for CER; other funding opportunities can be expected in the future.
- Whenever possible, CER should be piggybacked onto existing work.
- Early collaboration with other ICs and other agencies is important. Some of this collaboration will involve cross-disease research, which DHHS is very interested in funding.
- The public, advocates, and patients should be engaged early.
- Investment in measurement and data standards is needed.
- Practice must inform research. This is not the traditional mindset of cancer researchers, but it is becoming an important approach.
- CER is here to stay!

Discussion

Dr. Lyerly asked Dr. Croyle how much money he expects will be spent on CER in the future. Dr. Croyle replied that if a healthcare reform bill passes and a new entity is created, hundreds of millions of dollars will be allocated to fund CER projects. It is uncertain, however, what the funding mechanism will be, and whether it will operate through an independent entity or through existing agencies.

Several Subcommittee members said that it would be helpful if NCI could categorize all of the opportunities for CER funding into one package. Dr. Croyle and Dr. Linda Weiss said that NCI could disseminate information of this type to NCAB and the Cancer Centers.

Dr. Croyle noted that various segments of industry, particularly pharmaceutical and medical device companies, are planning to scale up their research capacities around CER and that venture capital companies are interested in this field. A shift is taking place from suspicion and concern to productive engagement and efforts to shape CER research.

Dr. John Niederhuber observed that Cancer Centers need to be a major resource for training the next generation of scientists for CER. The workforce with a commitment to this kind of science is insufficient, and the Cancer Centers would be an ideal environment to jumpstart the development of qualified CER-oriented scientists.

Dr. Croyle noted that there will be a need to grapple with the implications of the fact that much of the CER funding related to cancer comes from sources other than NCI. Dr. Weiss stated that the increasing importance of non-NCI funding sources will be taken into account in the next version of the Cancer Center guidelines. It would not be appropriate to focus on NCI funding alone in the current collaborative environment; this is one of the rationales for the elimination of the benchmark ratio.

Dr. Croyle explained that one common area of interest for Cancer Centers is learning how to work collaboratively with Department of Veterans Affairs (VA) investigators. Because the VA is

now sponsoring a one million member cohort study, many Cancer Centers want to learn to understand the mechanisms for working with the VA. NCI can help Cancer Centers to navigate these collaborations.

Dr. Weiss mentioned a Cancer Center that is currently in the developmental stages of establishing a CER shared resource.

Dr. Jennifer Pietenpol asked Dr. Croyle how he views the next 5 years of CER/genomic research interaction. Dr. Croyle replied that there has been NIH-wide discussion about whether new structures need to be developed to address this domain. Some of the ARRA-funded GO projects address this issue and will provide proof-of-principle for different strategies. Much creative thinking is occurring, but currently it is heterogeneous. There are important differences between Cancer Centers that have interdisciplinary capacity and those that do not. Cancer Centers need to play to their strengths and not spread themselves too thin. It is best to start from areas of strength—whether they be genomic medicine, relationships with HMOs, or something else—and leverage them into a strategic plan for CER.

The Subcommittee meeting adjourned at 8:15 p.m.

Action Items

- DCCPS personnel will provide NCAB members with specific links to the physician surveys regarding patterns of cancer care discussed at the Subcommittee meeting.
- Dr. Croyle will make the slides from his presentation at the Subcommittee meeting available to all NCAB members.
- Dr. Croyle and Dr. Weiss will provide NCAB members and Cancer Centers with examples of potential opportunities for CER, such as those involving the VA, the HMO CEN, and the SEER network.
- NCI should begin to consider the Cancer Centers Program as a powerful tool to support CER.
- Dr. Weiss will organize a conference call with the Cancer Center directors to update them about CER and to foster ongoing dialogue about CER opportunities.

Dr. H. Kim Lyerly, Chair — 12/16/09 Date

Dr. Linda Weiss, Executive Secretary — 4/28/09 Date