DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE

MINUTES OF THE 56ᵗʰ DIRECTOR'S CONSUMER LIAISON GROUP MEETING
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Members Present

Ms. Gwen Darien, Chair	Ms. Cheryl Jernigan	Ms. Wendy Selig
Mr. Everett Dodson, Vice Chair	Dr. Michelle McMurry-Heath	Mr. Josh Sommer Ms. Arlene Wahwasuck
Dr. Jeff Allen	Dr. Deborah Morosini	Mr. Max Wallace
Ms. Joyce Wilcox Graff	Mr. Jon Retzlaff	

Speakers
Dr. Douglas Lowy, Deputy Director, National Cancer Institute (NCI)
Dr. Ken Buetow, Director, Center for Bioinformatics and Information Technology, NCI
Dr. Becky Kush, CEO, Clinical Data Interchange Standards Consortium
Dr. Adam Clark, Director of Scientific and Federal Affairs, FasterCures
Mr. Jason Bobe, Director of Community, Personal Genome Project
Dr. John Frenzel, Associate Professor, The University of Texas M.D. Anderson Cancer Center
Mr. Robert Shelton, CEO, Private Access
Dr. Meg Mooney, Chief of the Clinical Investigations Branch, NCI
Mr. Rick Borchelt, Special Assistant for Public Affairs, NCI

National Cancer Institute Staff
Ms. Shannon K. Bell, Director, Office of Advocacy Relations (OAR)
Ms. Amy Bulman, Deputy Director, OAR
Mr. Benjamin Carollo, Advocacy Relations Manager
Ms. Anne Lubenow, Special Assistant to the Director of NCI

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Opening Remarks

Rules governing potential conflicts of interest were reviewed, and a quorum was determined to be present.

NCI Leadership Update

Dr. Douglas Lowy

Dr. Douglas Lowy, Deputy Director of NCI, observed that this meeting was very timely because the National Institutes of Health (NIH) is now taking up issues of privacy and consent as they pertain to The Cancer Genome Atlas (TCGA). Dr. Lowy spoke about his background, research priorities at NCI, budgetary issues, and the Director's Provocative Questions (PQ) project (in which several DCLG members are involved).

Current Priorities at NCI

TCGA, one of NCI's top priorities, is a joint project of NCI and the National Human Genome Research Institute. Initiated with demonstration projects in three different cancers, it has now been expanded to 20 types.

Mouse models have become extremely important for studying tumors and experimental treatments. An NCI subcommittee is advising TCGA staff about the prioritizing of mouse models for analyzing mouse tumors and their potential relevance to human disease.

Much cancer research, especially the screening of experimental drugs, involves cell lines, and thus NCI is expanding TCGA to include cell lines.

NCI is endeavoring to leverage and coordinate with other entities, both here and abroad. For example, it just signed an agreement with China, where work similar to TCGA will be undertaken.

Another priority is maintaining a vigorous portfolio of investigator-initiated research, in part because some important discoveries have been made by individual investigators or interdisciplinary groups of investigators. According to a recent article in *New England Journal of Medicine,* for close to 20% of approved drugs, initial development occurred in the nonprofit sector. The single largest contributor to this research was NIH.

A third priority entails restructuring the clinical trials groups.

Budgetary Matters

NCI's current budget is about $5 billion, but a substantial proportion of the budget is already committed to ongoing activities (e.g., grants, contracts, initiatives) that were vetted by stringent peer review. Despite the doubling of the budget some years ago, NIH's current purchasing power is the same as it was in 2001, and this is a challenge because of inflation. Funds received through the American Recovery and Reinvestment Act (ARRA) were essentially incorporated as part of the operating budgets of the institutes, but the funding was for only 2 years.

At the current level of funding, obligations from noncompeting grants would permit funding of only 800 new grants. Dr. Harold Varmus, Director of NCI, is combing the budget to try to reprogram some monies into the competing pool of new proposals in an effort to fund 1,200 grants (1,253 new grants were funded in FY2010).

Provocative Questions Project

Dr. Lowy described the genesis of the PQ project, which relates to Dr. Varmus' vision of a series of important, but not obvious, questions that could stimulate the research community to use laboratory, clinical, and population sciences in effective and imaginative ways (http://provocativequestions.nci.nih.gov/). Workshops are being convened to discuss the PQs from three perspectives: clinical and translational sciences; behavior, population, epidemiology, and prevention; and basic sciences. Several DCLG members are participating in the workshops.

It is not yet clear what will happen with the PQs, but possibilities includes requests for proposals (RFPs), program announcements (PAs), and grant applications. The preference is for PAs because they are more dependent on the quality of proposals that come in. RFPs do not always garner enough high-quality proposals. Because PAs entail a review process, the PQ workshop participants could serve on study sections to evaluate applications.

After listing several of the PQs, Dr. Lowy suggested that advocacy groups that fund research could assemble small groups that parallel the PQ workshop topics.

Dialogue with the DCLG

- What is the ultimate plan to engage the Food and Drug Administration (FDA) in the PQ project? According to Dr. Lowy, NCI has frequent and positive interactions with FDA.
- The DCLG members asked Dr. Lowy to arm them with the information they will need to (1) engage their communities around NCI funding, and (2) make presentations to their Congressional representatives about the PQ project.
- NCI should continue to promote collaboration to improve efficiency.
- It will be difficult to achieve goals if one-third fewer grants are funded than are presently supported. Dr. Lowy explained efforts to free up some parts of NCI's budget to help sustain research. In FY11, if NCI ends up with the current funding level or something slightly higher, the effects will not be momentous. However, if funding levels are rolled back to FY08 levels, the consequences for NCI will be dire because a great deal of the budget is already committed.
- The NCI–FDA guidance was cited as an example of a successful joint effort of these two organizations. Some research directions that have already been taken   merit careful investigation, such as the use of response rates as trial end points (that approach has some problems).
- Dr. Lowy touched on the problems of using retrospective samples. For example, although enormous numbers of paraffin-embedded tissues exist, oftentimes the patients did not give consent for their tissues to be used in research.
- According to Dr. Lowy, the idea behind the PQ project is to ask a different class of questions than those being addressed in the current application pool. Currently, some

outstanding proposals go unfunded. Funding 20% of proposals would allow most of the outstanding grants to get funded, but NCI is nowhere near that.

NCI's Cancer E-Life Initiative

Dr. Ken Buetow

According to Dr. Ken Buetow, Director of the Center for Bioinformatics and Information Technology, NCI, the cancer field is now in a period of tremendous change. Molecularly driven research, unified discovery, clinical research, and clinical care (bench to bedside and then back to bench) are being transformed from separate phenomena into a seamless continuum. The overarching goal is to create a "learning health system."

NCI is partnering with the American Society of Clinical Oncology (ASCO) and the cancer community to create oncology-extended electronic health records (EHRs) that will enable the tracking of cancer diagnostic and staging information, treatment plans, and patient outcomes. The federal government plans to spend $44 billion on standards for developing EHRs for primary care, and NCI wants to ensure that cancer health records will be interoperative with the system under development.

The Cancer e-Life system is being developed in partnership with SAIC (McLean, Virginia) and Microsoft (Redmond, Washington). Cancer e-Life is using Microsoft's HealthVault (trademark) infrastructure. Core components allow data to be captured on diagnosis, staging, molecular or other tumor markers, pathologic information, treatment history, performance status, interventions, and outcomes. The data can be aggregated systematically. A prototype is available to explore from caBIG's Website: http://cabig.cancer.gov/perspectives/consumerengagement/models/elife/m. Cancer e-Life is supported by 19 vendors, both big and small, including SAIC as well as many small companies.

Physicians will not be the drivers for this technology, patients will. Advocates can ensure that this information is collected and generated and made available for research. In addition, patients can enter their own outcomes, and they can search for clinical trials in a directed way. It would also be possible for patients to view aggregated data on similar people and provide consent to share de-identified data with researchers.

Dialogue with the DCLG
- More back-end work (e.g., interfaces, standards) is needed to ensure that the result of the efforts described above is an interoperable biomedical infrastructure.
- It would be important with any cancer-focused EHR to be able to look at the antecedents to cancer. NCI is working with the Love/Avon Army of Women, which has signed up 400,000 women, of whom only 10% have cancer. In essence, this group is a prospective cohort. The e-Life system could be "repurposed" for any prospective cohort. It is all Web-based and can be accessed at a reasonable cost through the 19 support contractors. When cohort members develop cancer, they can be easily enrolled in a study or transferred to Cancer e-Life.
- The push for standards needs to happen now, but having 19 different vendors for e-Life could lead to divergence. Businesses tend to emphasize their own differentiators rather

than their commonalities. Visible leadership outside of NCI is needed to catalyze this activity.

- The patient/consumer group will be the true unifying force for EHRs; consumers are at the center. They are the ones who can carry their records and imaging studies from provider to provider.
- What about sharing of tissues and samples? For biologic materials, there is an additional layer of complexity because there is a physical entity that needs to be moved. "Data sharing is an easier nut to crack."
- Advocates have a large responsibility if they are going to ask their constituents to participate, because similar but competing platforms are available. What reassurance is there that Cancer e-Life will prevail over other platforms? Cancer e-Life is based on international standards and is open-source, open code. Systems based on proprietary infrastructure would present a greater risk if the proprietor goes out of business. But with 19 vendors to support this infrastructure, the risk is probably small.
- Cancer e-Life could be considered a federated model in that the primary information— local health records—remains local unless specific requests or queries bring the records together.
- The system is sufficiently flexible to set up modules for different groups, such as those persons who are at increased risk of cancer. For the Love/Avon Army of Women, modules have been created to collect epidemiologic data. Those modules could easily be repurposed for other groups.
- Cancer e-Life will be available for use by the National Community Cancer Centers.
- The present system does not interact with data from TCGA because it is not part of the care continuum; the TCGA group was selected based on the availability of biospecimens. Future TCGA activities could use Cancer e-Life to collect clinical information.

Data Sharing, Data Standards, and Integrated Data Collection

Dr. Becky Kush and Dr. Adam Clark

Data Sharing

Reentering data several times is very burdensome. To make it easier for researchers to participate in research, data should be entered only one time and be available for both patient care and research. One barrier to data sharing is privacy concerns; in the current research paradigm, researchers are reluctant to share information, and thus patients will have to push for sharing. If patients "populated" their own data in a system, researchers could access it at little or no cost. Then, recruitment would be easier, and researchers' time would be freed up for analyzing the data. It is a matter of shifting the concept of data ownership. Currently, researchers are reluctant to share because not sharing gives them an advantage with their grant applications.

If data are collected during the "pre-competitive" stage, i.e., prior to clinical trial testing, companies sometimes are willing to share data, but sponsors often consider all their data to be proprietary.

Interoperability between Clinical and Research Systems

In clinical research, most data are collected as part of clinical care. By adding a few elements specific to an investigator's protocol, data can be collected to answer the research question.

A great deal of clinical research is being carried out in different countries where EHRs are well established. When the United States began to move toward EHRs, one goal was to ensure that clinical care and research records would converge.

The term "meaningful use" refers to language in ARRA, which provided up to $44,000 reimbursement to individual physicians or groups to adopt EHRs for meaningful use. To meet this requirement, the EHR must contain several core fields (e.g., demographic information, smoking status, vital signs, lab tests). Research should be deemed a meaningful use.

According to Dr. Kush, CDISC is using the interchange of e-source data, which provides an audit trail for FDA. Data are entered only once and in electronic format. The European Medicines Agency (EMEA) has adopted e-source, which is based on good clinical practice. FDA has produced e-source guidance.

A pilot study was proposed by CDISC that would entail a commitment by the FDA to accepting data from EHRs. CDISC asked for a safe haven to do the study. Sponsors are reluctant to rely on EHRs for regulated trials, as the data could be rejected by FDA. Dr. Clark suggested that NIH could take the risk of doing a trial with EHR data to demonstrate its feasibility and acceptability to FDA. This action would break down a key barrier.

Unfortunately, the United States is being left behind as the rest of the world is adopting EHR systems to improve research and care.

Dialogue with the DCLG

- Patients want to share what happened to them to help others. Including clinically validated patient-reported outcomes in EHRs will be very important to ensure that the data are accepted by FDA.
- Sponsors could be greatly helped with recruitment if they could scan EHRs to identify potential trial participants.
- Patients can understand EHRs if this technology is properly explained. Also, advocacy groups have experts in information technology and data sharing. To make real progress with EHRs, the broader public will have to be engaged.
- Back-end data entry and mapping is difficult and expensive. Standards need to be in place at the outset. Researchers rankle about adhering to standards and say they encroach on their creativity, but if their data do not adhere to standards, FDA is hampered in its assessment of drugs or technologies. For example, data on the sex of participants might be entered as "male/female" or "M/F" or men/women. As a result of having different methods of entering sex, FDA might not even be able to figure out how many men and women are on studies, which would be a big problem!
- Building in requirements for collecting patient-reported outcomes and for using EHRs could be built in research RFPs and PAs to drive behavior.

- An effort should be made to sell the benefits of EHRs to doctors. In the long run, these records will help doctors' offices run more smoothly.

DCLG Discussion

Mr. Mittman asked the participants about critical concepts gleaned from the presentations that have influenced their thinking about the role of the patient in data collection and sharing.

- Is there a mechanism in the information technology world that could accept "dirty" data and then clean it up?
- Studies have shown that patients are not the barrier to data collection and sharing. Advocates can help to address the other barriers, but where? One possibility would be to educate the general public about data collection and sharing in order to facilitate prospective research, such as that being carried out in the Love/Avon Army of Women. Even in areas with underserved populations, there is interest in participating in research.
- Should the consumer be placed at the center of the model, or is the consumer the driver of the model?
- It feels as if we are trying to superimpose a top-down structure; we need to think about how to harvest from the bottom up.
- The consumer model is based on desire, but data sharing needs to be driven by a perception of risk or need. Altruism will not be sufficient to drive these efforts. People who perceive a need congregate around that need.
- Secondary use of data will be mainly the generating of hypotheses and is not likely to change clinical guidelines. It was recommended that goals be articulated about what researchers want to learn from the data and that researchers recognize the limitations of comparative effectiveness research.
- Regarding Cancer e-Life, small patient advocacies are likely to be reluctant about setting up their own systems within e-Life because of cost.
- As long as patients are controlling transmission of their data, the Health Insurance Portability and Accountability Act (HIPAA) does not pertain. HIPAA covers only provider-to-provider transmission of patient information.
- If information is deemed a resource, and it becomes more readily available and saves time, an incentive is brought into play, which can change supply-and-demand factors, thereby driving behavior.
- NIH needs to explore ways to modify grant requirements to implement data sharing, adherence to standards, and so forth. This would be the most straightforward way to transform research. If the work of NIH-funded investigators does not contribute to the research cycle and cannot be used by other researchers, it is a travesty. Are we making the best investment if we continue to fund this system? Some accountability needs to be integrated into funding grants.

The Personal Genome Project—Challenges and Opportunities in Engaging Research Participants in Full Personal Disclosure

Mr. Jason Bobe

Mr. Jason Bobe, the Director of Community for the Personal Genome Project, said that in 1997 the project started using open consent documents, which means that no attempt is made to keep the data of participants confidential. The underlying premise is that researchers cannot promise anonymity or confidentiality because nothing is foolproof; one cannot assume that de-identified data will never intersect with identified data. A lack of privacy does not equate with publicity, however.

The Personal Genome Project started with 10 fully identified participants who were highly informed about genetics. The first IRB approval was obtained in 2004 or 2005. Now, about 1,200 participants are fully enrolled, and the ultimate plan is to enroll 100,000 people. The investigators are collecting tissues, performing biological analyses, and collecting information on traits such as disease history and facial appearance (the latter through three-dimensional photos).

Individual genomes are the ultimate "Social Security number." It would be disingenuous to promise participants confidentiality, and it would be impractical to de-identify genotypic and phenotypic data, underscoring the logic of open consent. Unfortunately, overpromising privacy and confidentiality is putting the entire research enterprise at risk.

The project could also be a vehicle for testing the effectiveness of privacy technologies.

Dialogue with the DCLG

- The United States is going to be leapfrogged by other countries that are already collecting and aggregating patient data. Government support will be required to make meaningful progress.
- How does the Personal Genome Project differ from other cohort studies? One difference is that little effort has been made to recruit participants. Accrual has been mainly through self-selection.
- The Personal Genome Project is drawing from a very narrow population base. Will it be possible to generalize the findings to a broader population? There are ongoing efforts to broaden the inclusion criteria. Initially, participants had to have master's level training in genetics, but now a quiz has been implemented instead. To further broaden eligibility, an educational component is being added.
- Data from the Personal Genome Project could be used for hypothesis generation, but there is a move to use the data for clinical research (e.g., for dynamic phenotyping). But the project is large enough that some pools of data can be used for real-time clinical analysis while others could be used for hypothesis generation.
- Some researchers lack the computing power to download huge databases and analyze the data; clearly, it is not good enough to create terabytes of data that are unusable. Cloud computing would be one way to offer computational power when the data is being used.
- The Personal Genome Project likely would not be feasible without an open consent model.

- The Project could be a valuable resource for studying rare variants, which are the key to studying disease causation in families. Such studies can be done with small numbers of participants.
- African Americans and certain other racial/ethnic groups are underrepresented in the Personal Genome Project cohort. Efforts are under way to set up a partnership with a university in the South to set up a study site there. There is a moral imperative to ensure that all parts of society have access to this opportunity.

*my*MD Anderson Patient Portal

John Frenzel

Dr. Frenzel, a professor at the University of Texas M.D. Anderson Cancer Center, said that the portal offers patients secure e-mail, appointment scheduling, lab results, and nearly complete access to their medical records. About 850,000 patients are registered on the system. Referring physicians can log on and check their patients' records. Approximately 13,000 to 15,000 patients log on each week.

Clicking on the description of a test (e.g., colonoscopy) directs the user to an educational component about that procedure. A glossary of medications is included. The portal is available in Spanish as well as English.

On the secure messaging page, patients can communicate about billing or scheduling, or they can escalate a message if a timely response is not forthcoming. When patients send an e-mail through the portal it becomes part of their medical records.

The majority of records are available to patients through the portal in near-real time. Some documents that are not in the final state (e.g., pending pathology reports) are embargoed for 7 days. Bandwidth limitations prevent the staff from putting imaging studies on the portal, but the patient can get the written reports of these studies. No notes from the psychiatry service or a chaplain are posted on the portal. Real-time vital signs can be obtained through the portal.

Data sharing by patients seems to occur within ecosystems, but who are the people with whom patients are sharing their data? Are there family "interpreters" of such data? How does sharing occur? Are access credentials shared between interested persons, or are data cut and pasted? What resources are needed to help patients understand and interpret what they are reading?

One poignant concern was expressed during a patient focus group: "The entire medical record is all about me, but not anywhere from me." In response, a project was initiated to include validated instruments to collect patient-reported outcomes. The ultimate measure of care is how the patient is doing, beyond cure or remission. Physicians can prescribe the surveys for their patients.

The degree of openness offered by *my*MD Anderson is likely to become the standard. Methods are needed to help patients understand and share their data, and the voice of the patients must be included in their records.

Dialogue with the DCLG

- Could patients suppress information in their record? Some patients will send e-mails to correct what they see as errors: "I quit smoking 20 years ago, not 10." Also, on a few occasions, some patients write paragraphs disagreeing with things. Even more interesting, some patients read the care plan, think about it a while, and ask good questions that do not come up in the exam room. That is a uniquely powerful aspect of this patient portal.
- An effort will soon begin to explore whether participation in *my*MD Anderson reflects the diversity of the patient population. Most likely, there will be significant geographic differences. It would be interesting to see if physicians in remote areas access their patients' information. To date, we have not pushed *my*MD Anderson up to the front page of the M.D. Anderson web site.
- M.D. Anderson has 65,000 new patients each year; about 25% have logged onto *my*MD Anderson.
- Patients may want to use their data for research, to give to another physician, or to add to a personal health record. M.D. Anderson itself is building EHRs, and so interoperability and portability are important. The detailed federal standards for health data interchange are not yet in place, and thus the data in the portal have not been assembled in a vendor-blind way. Both the Google Health and Microsoft platforms have been investigated. Data are not portable, but patients can copy, paste, and print information; the same is true for the physician portal. Patients' personal physicians cannot download the entire file.
- Uptake is growing more rapidly among community physicians than among patients. A system is being rolled out to allow users to create an account online with no paperwork. Reports could be delivered electronically to community physicians.

Private Access—A Model for Consumer Control of Data Sharing

Mr. Robert Shelton

Mr. Shelton, the CEO of Private Access, said that it took 5 years and $8.5 million to develop that organization. He stated that privacy is an infrastructure project; if the infrastructure is right, privacy issues can be in the background. Patients do not want to give up privacy in order to share their data.

Mr. Shelton spoke about a 2009 study at Case Western in Cleveland, Ohio, that examined people's willingness to share DNA from their children's blood spots. Without permission, 73% of the parents were somewhat or very unwilling to share these blood spots. With permission, however, 76% of parents were very willing to share their blood spots. "When you ask, you get."

Mr. Shelton demonstrated how Private Access works. The demonstration "patient" entered the site because he was referred from a page where he had indicated interest in a clinical trial. Once the patient set up his Private Access account, he could choose privacy settings based upon the types of information about him that might be sought by investigators and others. Privacy alerts let him know when there was a pending action, such as an invitation to learn more about a research trial. After the patient responds to the request, the investigator is alerted that the contact is approved and can log on to get the information. When patients change their mind they would be removed from the list of approved contacts on the investigator's side. The patient can also designate databases (e.g., HealthVault) with which she/he wishes to share personal information. .

In a six-message e-mail campaign, investigators found that when recipients got messages containing a link to the organization's web page with a listing of clinical trials accompanied by Private Access "I'm Interested" buttons, 48% created Private Access accounts within 90 days. Furthermore, 87% granted direct contact by investigators. One investigator said that a search of Private Access allowed him to find appropriate study participants in less than a minute.

Dialogue with the DCLG

- Over the past 40 years, only 3% to 5% of adults have participated in oncology trials. This was thought to be because patients did not know about trials or they did not want to participate, or because community oncologists did not want to cede care of their patients to a cancer center. With Private Access, it appears that the situation has been turned on its head by allowing investigators to pull information about potential study participants.
- The Private Access architecture includes trust scores. Patients can file reports that would diminish an investigator's trust score if there is a breach of privacy.

DCLG Discussion Points

The participants reacted to the three case studies (Personal Genome Project, Private Access, and *my*MD Anderson):

- Do not lose sight of the fact that overpromising confidentiality and privacy is damaging.
- Keep the connection between research and clinical care.
- The M.D. Anderson portal is a place for a dynamic conversation with a patient.
- Just asking permission can transform an unwillingness to share data to a willingness to do so. All you need to do is ask.
- The number-one reason that people enter a study is because their own physician suggested it. Bringing the community physicians into the system is critical.
- Some community oncologists are not really up-to-date on clinical trials. There is a clear need for other routes to connect people with trials.
- It will be critical to avoid having patients enter their data numerous times. A single data-entry point (probably the EHR) would be optimal.
- When researchers write informed consent documents for tissue collection, the emphasis is on "informed" rather than on "consent." Is this the same for data? Having a personal health record is very different from crossing over to the tissue realm. The best consents are not granular; rather, they are very general and will allow any sort of future research.
- Keep in mind that the definition of "researcher" might not conform with people's ideas. For example, Big Tobacco conducts some research.
- People do not understand why they cannot have access to what is theirs intrinsically.
- People might not understand that their tissue is going to end up in a mouse. Has there been a survey about putting human tissue in mice?
- Open records would be a tremendous shift that would bring up issues of ownership and agency. If people change their minds about participating in data sharing, what exactly could they revoke? Once the data are out there, it cannot be retrieved from every back-up file, etc.
- People are giving their tissue, data, and money with no accountability to ensure that research dollars and precious data and tissues are being used wisely. Various

organizations, such as Charity Watchdog, disclose how charitable organizations are using donated funds.

- The M.D. Anderson system is a step in the right direction, but it is a shame that the data are not portable. Providing access for community physicians is an excellent feature.

The DCLG discussed what success might look like:

- Clinical trial participation would increase from 3% to 10%.
- Researchers and potential participants would be matched.
- Participation, not just accrual, in research would increase.
- Participants would receive information on the outcomes of trials, including negative results.
- Exclusion criteria would be relaxed to allow participation by the entire population. Some treatments benefit only a small number of people because the trial was so selective.
- People would be better informed about science.
- Negative results would not be considered failures. As Thomas Edison said, "I have learned a thousand ways not to make a light bulb."
- Quality of life is a very important end point. There are other things to consider beyond cures.
- Silos between care and research would be eliminated.
- Patients will be selected to ensure that treatment benefit is maximized and harm is minimized.

From the perspective of patients, given the information learned through the case studies, the DCLG discussed what elements and dimensions should be taken into consideration when developing a synthesized clinical and research database tool that would make optimal use of patients' (consumers') data:

- Privacy and informed consent as barriers to data sharing.
- Accountability for data sharing.
- Incentives and disincentives for data sharing.
- Federated model whereby the data come from the grass roots.
- Consumer participation.
- Researcher participation.
- Collaboration (especially with regard to Native Americans).
- Consumer incentives.
- Hospital incentives.
- Locus of control for data (i.e., clinician driven vs. researcher driven vs. patient driven).
- Ownership and agency.
- Portability and exportability of data.
- Transparency.
- True open access to records.

Additionally, the DCLG discussed critical elements that would need to be part of a data sharing paradigm in order for the advocacy community to become actively engaged in promoting the involvement of their constituents:

- Is exportable to other data systems.
- Advances the best interest of patients.
- Provides the results of research that uses my data.
- Is accessible to and provides wide dissemination of results to Indian tribes, other race/ethnicities, rural areas, and other special communities.
- Avoids having patients re-enter data into several systems.
- Can be built on over time (a compounding system).
- Is equitably accessible for contributing data and learning research results.
- Explicitly states that data will be used to answer critical scientific questions.
- Ensures that data remain open and accessible even beyond the patient's (consumer's) control and knowledge, i.e., the data do not end up in a proprietary system.
- Prohibits use of data in ways that could harm the data provider.
- Provides assurance that data/samples are used in a demonstrably valuable way.
- Offers some constructive learning or feedback (even in the aggregate) in return for contributed data.
- Issues requests for data and provides feedback in culturally appropriate ways.

Interpretive Narratives in Cancer Research and Communication

Mr. Rick Borchelt

Mr. Borchelt serves as the Special Assistant for Public Affairs at NCI. Advocacy for sustained support for science requires an interpretive narrative to generate interest in science among the public. Communication adds value to science in three main ways:

- *Availability*: This aspect is well covered. Information is rapidly delivered to motivated information seekers. The Internet and open-source publishing have led to great breakthroughs in this area.
- *Accessibility*: Information must be provided at a level of sophistication appropriate to the audience using a platform available to that audience and within the aperture of opportunity (the period when people pay attention to information).
- *Interpretation* This is the real weak point. Scientists want to rely on other people to interpret the meaning behind research findings. Effective interpretation means that bits of information are transformed into a picture.

NCI can submit its budget directly to the President; it is not necessary to go through NIH or the Department of Health and Human Services. Through its bypass budget request, NCI can do its own professional assessment of the required funding level.

Regarding the NCI's bypass budget, it is necessary to include messages and information that align with Congress's values, value sets, and personal schema. The bypass document is an "inside-the-Beltway" document that is primarily targeted to Congress and Congressional staff.

According to Mr. Borchelt, the "War on Cancer" is an enduring message, but it is a poor metaphor. A war cannot be won unless 100% of the enemy is vanquished. As long as cancer exists, we seem to be losing the war. Therefore, we need to change the whole public conversation around cancer. The messages should reflect the full story arc from basic biology to cancer care and encompass the process as well as the products of research.

The title of the bypass document is "Changing the Conversation." It is about 90 pages long; the budget is a single page. The bypass themes include the following:

1. Tremendous progress in cancer care, prevention, and survivorship is obscured by our current messaging about what is still wrong. Successes have been brilliant but incremental.
2. Our understanding of cancer as a complex, heterogeneous set of diseases is not mirrored in public understanding.
3. A combination of new tools, new ideas, and new approaches has brought us to the most productive era ever in cancer research.
4. We will never be able to realize the promise of these approaches without accelerated and sustained funding.
5. NCI is requesting a 15% budget increase.
6. The overall health of the NIH budget—and the cancer program portfolio—is as important as the NCI budget itself.

Mr. Borchelt exhorted the advocates to paint an entire picture for their constituencies. It is information, not an information game.

Dialogue with the DCLG

- The budget bypass document is an important tool. The DCLG recommended justifying what is already being spent and proposing cuts to avoid having Congress make the cuts. The bypass document must clearly articulate why another 15% is needed in the budget.
- The overall budget of NIH is important. The advocates try to work with other disease groups, but this collaboration is difficult if their budget areas are cut while NCI's is boosted.
- Be transparent about how funds are being used.
- If there was a time to "build from zero," this might be the time to do it. The portfolio mix is changing to show NCI's shifting priorities.
- According to Mr. Borchelt, the main value of the bypass budget is the narrative, more so than the budget request itself. It is an opportunity for the Director to state where he thinks the science is going and his vision. Dr. Varmus should be seen as a strong and efficient portfolio manager.
- Dr. Varmus prepared an afterword, which is the most important section in Mr. Borchelt's view. The DCLG asked if those pages could be produced separately, as they could be used as a short message that the advocates can deliver to the public.
- Mr. Borchelt explained that some support materials will also be produced.

DCLG Discussion: Opportunities for Advocacy Organizations to Engage

- There is a big push in rare-disease communities to come up with patient registries. That violates the principle of patients having to enter information more than one time. Where do such registries fit in with this effort?
- It was suggested to implement some webinars to encourage more thought and discussion around data sharing and privacy issues.
- We need to move away from an emphasis on harms and liability to a focus on meeting patients' needs.
- People need to be stirred to anger because their data are not being used optimally for the good of humankind. Comparative effectiveness research is also called patient-centered research; this would be a perfect starting point for such discussions.
- Tissue samples should be considered a sacred gift, but it is not realistic to expect that each use will lead to an outcome. Some research is not fruitful.
- As an aspirational goal, advocacy organizations should align their self-interests with the broader interest.
- We need tissues and data from those who do not benefit from a cancer therapy in order to work on the next generation of drugs. In addition, tissues should be collected at the point of resistance—when a drug stops working.

OAR Update

Ms. Shannon Bell

- The Advocates in Research Working Group (ARWG) is preparing an executive summary, full report, and recommendations. The ARWG seeks to take the role of advocates in research to a whole new level. OAR is working with the Office of Personnel Management to identify core competencies related to being an advocate in a research environment. The core competencies will standardize and professionalize the role.
- OAR is working with several organizations on a training repository that will be a community resource. NCI will only be the convener.
- OAR is working with American Association for Cancer Research and ASCO to participate in their annual meetings.
- OAR staff are assisting with some visual aids for Project Cancer Education.
- Regarding the transformation of the cooperative groups, OAR staff are helping to identify tools and resources that might benefit communities.
- OAR will develop some tools, handouts, and slides regarding the NCI budget.
- OAR is hiring some new staff to replace people who have moved on to other opportunities.

Transforming NCI's Clinical Trials System

Dr. Meg Mooney

Dr. Meg Mooney, Chief of the Clinical Investigations Branch, explained that NCI's clinical trials network is composed of cooperative groups interacting to co-develop, co-implement, and co-conduct innovative and practice-changing trials to improve the nation's cancer care. The adult

clinical cooperative groups are being reorganized in accordance with recommendations from the Institute of Medicine (IOM) and other entities. Dr. Mooney gave a short history of the groups, which began in the 1950s. They are funded under cooperative agreements, which are hybrid arrangements between a contract and an R01 mechanism. Groups are permitted to garner funding from industry and philanthropies.

Each year, about 20,000 to 25,000 participants are enrolled on cooperative group trials.

The consolidation is not only administrative but scientific. Among its aims are to prioritize molecular characterization and assign priorities to the phase 3 portfolio. More standardization is needed across the whole system. As currently configured, the groups face disincentives. Extramural peer review will have to change as well.

Efforts to standardize and consolidate data management have taken place over the years. Dr. Mooney mentioned the NCI's Clinical Trials Support Unit. Starting this year, all patient registrations will go through a common system. A central IRB has been set up at NCI that is used in 60% of pediatric trials and about 30% of adult trials. Using the central IRB could help with trials in rare cancers, as institutions may not want to review many protocols that accrue only small numbers of patients.

The reorganization will consolidate the current nine adult oncology groups to no more than four. The transition must be done thoughtfully, as more than 100,000 active participants are on trials now. Dr. Mooney described strategies that may help with the integration. For example, NIH grants now permit multiple principal investigators, which may help with the leadership transition. Additional resources are being provided as incentives to smooth the transition. A distributed data management and operations system will avoid disrupting ongoing trials.

A networked system is better able to perform studies that:

- Are carried out in less common malignancies.
- Require sophisticated imaging modalities.
- Need rapid molecular characterization of tumors.
- Involve access to nationally integrated tissue resources.

The groups will still be the ones to come up with ideas and conduct trials. But the current structure will be transformed to support a system that is functionally a network of groups with harmonized infrastructures. The peer review process will shift to emphasize the role of the group, with a focus on operational efficiency. The cooperative groups are trying to reorganize on their own to garner buy-in. NCI stands ready to help, however.

Funding through 2014 will be provided via supplements until the new funding opportunity announcement is available. The hope is to transition to the new, consolidated system within 2 years. All groups will be reviewed at the same time so that they are synchronized.

Dialogue with the DCLG

- It is possible that there will be a large influx of protocols that have been put on hold until 2014.

- Accrual will probably take a dip as the groups start to coalesce. This could have an impact on cancer research and patients.
- The IOM recommended four cooperative groups, but no real rationale was given. From NCI's perspective, the number of groups could be lower. The ultimate number will probably be based on the sizes of the various groups, what they do, and areas of overlap. Going to one group would be very disruptive. The number of cooperative groups should be a combination of what is practical and what is beneficial.
- The pediatric groups consolidated 20 years ago. The groups themselves see synergies and benefits from networking. Transitions are never perfect, however. Some people will feel disenfranchised.
- The tumor banks are funded through a different program, and so they will have to consolidate first.

Next Steps

- OAR will produce two documents that capture the main themes of the DCLG's dialogue. One will be focused on NCI and scientific audiences while another will be geared more to the lay community.
- The DCLG will provide feedback to OAR about opportunities to engage the broader community about these themes and incorporate them into their own work as they are able.
- The DCLG should provide comments about the consolidation of the adult cooperative groups via the web site.

The meeting adjourned at 4:18 p.m.

Certification

I hereby certify that the foregoing minutes are accurate and complete.

_4, 13 11_
Date

_____
Chair

Director's Consumer Liaison Group

_4-15-11_
Date

_____
Executive Secretary

Director's Consumer Liaison Group