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

MINUTES of the 53rd DIRECTOR'S CONSUMER LIAISON GROUP MEETING
Bethesda, MD

March 24–26, 2010

Members Present

Ms. Gwen Darien, Chair
Mr. Everett Dodson, Vice Chair
Dr. Jeff Allen
Ms. Susan Braun
Dr. Grace Butler
Dr. Yvette Colón
Ms. Marie Dahlstrom
Ms. Joyce Wilcox Graff
Ms. Cheryl Jernigan
Dr. Deborah Morosini
Ms. Phyllis Pettit Nassi
Ms. Wendy Selig
Ms. Arlene Wahwasuck
Mr. Max Wallace

Speakers

Dr. Anna D. Barker, Deputy Director, NCI
Dr. Marc Ladanyi, Memorial Sloan-Kettering Cancer Center
Dr. Cameron Brennan, Memorial Sloan-Kettering Cancer Center
Dr. D. Neil Hayes, University of North Carolina Lineberger Comprehensive Cancer Center
Dr. John E. Niederhuber, Director, NCI

National Cancer Institute Staff

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

Facilitator

Mr. Robert Mittman

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

At the previous DCLG meeting in October 2009, the DCLG identified three main areas of NCI activity which may benefit from DCLG advisement: cancer genomics research programs, electronic medical records, and risk reduction. The March 2010 meeting was designed to focus on the first of these three areas. The goals of this meeting were as follows:

- To familiarize the DCLG with genomics research and the purpose and progress of The Cancer Genome Atlas (TCGA).
- To update the DCLG about the NCI Executive Committee Retreat and conversations relevant to the DCLG dialogue.
- To debrief the DCLG about the DCLG Genomics Working Group.
- To come to consensus around the role of the community in advancing genomics research and how the DCLG might contribute to overcoming barriers and identifying resources.
- To create key action items for engaging the advocacy community in ensuring the success of cancer genomics research.

Genomics: Scope of the Field and Status of TCGA—Context for the Session and Introductions
Presenter: Dr. Anna D. Barker

Dr. Barker began the meeting by introducing some critical concepts to start the conversation. Personalized cancer medicine refers to therapies that target disease in new and specific ways that require knowing the molecular markers of disease. Identifying molecular targets for intervention will drive drug development, diagnostics, and treatment and also might predict risk. Successful personalized cancer medicine requires knowing the molecular markers of disease.

Dr. Barker explained the importance of biospecimen collection for genomics research, provided a brief overview of the NCI Best Practices for Biospecimen Resources, and explained their purpose. Acquisition of high-quality samples has been a challenge.

TCGA began in 2006 as a collaborative pilot project between NCI and the National Human Genome Research Institute (NHGRI) to identify relevant genomic changes in cancer. TCGA's goal is to integrate information across all levels of the genome, proteome, and epigenome. A systematic, integrated approach requires collaboration among large laboratories and individual R01-funded laboratories using the same standards. The future will include regulation of new biomarkers and drugs. Thus far, most biomarkers have failed the validation process because there was not enough biological information; NCI is hopeful that TCGA will help.

TCGA has changed the research community's expectations for biospecimens and the quality of data and analysis. Dr. Barker spoke about the need to change as a community with this shift in scientific approach.

Cancer Genomics—What Is It? And How Does It Translate into Clinical Advances?
Presenter: Dr. Marc Ladanyi

Cancers are clonal, which means that they arise from a change in one cell's DNA that provides a growth advantage over normal cells. Although there are known cases where one genetic alteration can lead to cancer, most cancers derive from multiple genetic mutations over time. Dr. Ladanyi discussed the five main types of genomic abnormalities.

Cancer genomics has evolved as a field of study over the past two decades. In the early 1990s, scientists studied one gene in a few samples. Now scientists can study all genes in many samples. This capacity for analysis will facilitate personalized medicine: by targeting specific genetic alterations, cancers may be more effectively treated.

Large-scale cancer genomics is the study of large numbers of human tumor samples by comprehensive, high-throughput approaches for one or more alterations across the entire genome. It requires an interdisciplinary effort, known as "team science," including experts in cancer genetics, genome technology, surgical pathologists, clinicians (surgeons, oncologists), biostatisticians, and computational biologists. Numerous types of genomic data are integrated to provide a more thorough understanding of cancer. Bioinformatics is required to process all of this information; integrated datasets are a current challenge.

Dr. Ladanyi discussed several examples of targets for therapy that resulted from genomic studies, including the *EGFR* gene in lung adenocarcinoma and the *BRAF* gene in melanoma.

The TCGA pilot project was designed as a highly organized, integrated, and comprehensive analysis with state-of-the-art technology and continuous public data release. The pilot project aimed to:

1. Provide a comprehensive genomic annotation of three cancer types that would serve as a public resource for cancer research by the broader scientific community.
2. Demonstrate feasibility of a large-scale multicenter coordinated effort in cancer genomics.
3. Accelerate the development and dissemination of genomic and analytical methods.

TCGA brings together multiple institutes across the country that serve as cancer genomic characterization centers; sequencing centers; a biospecimen core resource; and centers for data management, bioinformatics, and computational analysis. Dr. Ladanyi provided an example of how glioblastoma samples were handled, processed, and tested among 10 different centers.

TCGA depends on the donation, collection, storage, and distribution of human tumor samples. In its initial phase, TCGA focused on three tumors: glioblastoma multiforme (GBM) of the brain, squamous carcinoma of the lung, and serous cystadenocarcinoma of the ovaries. Through this project, major genome alterations were identified in a large set of tumor samples. Researchers access the resulting information through a web data portal with close to real-time access.

Dr. Ladanyi answered questions from the DCLG:

- Tumor variability is becoming less of an issue due to improved technology. There is a fairly rigorous quality control process for specimen collection to account for tumor heterogeneity.

Statisticians determined that 500 samples were needed to detect mutations that occur in 2–3 percent of samples.

- Although scientists know that some activities increase cancer risk, such as smoking, many cancers are believed to originate from genetic accidents.
- The amount of tumor tissue necessary for thorough testing can be a rate-limiting factor. Technology will likely advance so that scientists can do more analysis with less tissue.
- TCGA focuses on cancers arising from non-inherited mutations. Large genome-wide association studies that consider inherited mutations also are being performed. Dr. Barker believes that eventually these two types of studies will merge.

Glioblastoma Multiforme—The Disease and What We Learned from TCGA
Presenter: Dr. Cameron W. Brennan

GBM is the most common adult brain tumor and has a high morbidity due to local progression. Surgery is typically not efficient at complete removal of all cancer cells, and combined with radiation and chemotherapy, the survival time is short (12–18 months). The lack of noticeable progress in treatment is surprising given that GBM is one of the most intensely studied solid tumors and has robust mouse models to test the genetics underlying this disease.

There are two types of GBM, primary and secondary, that are clinically indistinguishable but whose genetic mutations are distinct. TCGA focused predominantly on primary GBM, which has mutations in the *EGFR, PDGF,* and *MET* genes. Treatment with tyrosine kinase inhibitors in these tumors showed sporadic responders but was ineffective overall.

One study analyzed the protein PTEN. Patients that responded to EGFR inhibitors had intact PTEN, whereas those without PTEN were unresponsive. Unfortunately, even those patients that responded to treatment had recurrence of their cancer. Considering entire cellular pathways, which are extremely complex, will be required to better understand what combination of targeted drugs is most effective. Despite the challenges of numerous sporadic events, TCGA will allow investigators to dissect this information and search for patterns to stratify patients and direct treatment.

As data are collected and analyzed, the pathways used by cancer cells to proliferate and the proteins affected in those pathways become clearer. As the effect on protein expression in pathways is analyzed, scientists can begin to understand the many ways that changes in these pathways increase tumor growth.

TCGA has allowed the identification of molecular subclasses in GBM which could define treatment options. Other types of data, such as genetic alterations, can be clustered to find patterns. This result exemplifies how TCGA really can be used as an atlas to guide researchers to a better understanding of the molecular hallmarks of GBM, which can lead to new targeted treatment therapies.

The number of mutations and chromosomal aberrations found through TCGA is daunting. A map of these changes will become more complete as research continues. TCGA has provided the most complete picture of GBM to date, and there is still a lot of data to analyze. The new molecular subclasses identified may lead to novel therapeutic targets. Perhaps most importantly,

TCGA has been proven successful as an atlas that can be "referenced" by smaller studies in the brain tumor research community and will likely drive new preclinical studies and the design of future clinical trials.

Dr. Brennan answered questions from the DCLG:

- The blood-brain barrier is not typically a delivery problem for target drugs. There may be many non-genetic influences, such as pressure, that affect delivery.
- Testing tumors for their subclass status will be relatively straightforward, but no biomarkers have been validated to date.
- Industry is using data from TCGA to turn targets into therapies. This process is still in its early stages, and as previously mentioned, targeted therapies do not work in all patients.

The Future of TCGA—Sequencing, Data Integration, Analysis, and Team Science
Presenter: Dr. D. Neil Hayes

Genomics is a revolution comprised of advances in human genetic analysis, computing, and optics. Information is being generated from all sectors.

Traditional genetic analysis could only investigate previously known aspects of the genome, like "looking for your keys under the streetlamp." New methodologies allow researchers to probe the darkness using an unbiased approach to detect changes in the genome. These advances allow thorough, high-throughput sequencing in a short time frame and can detect various types of genetic abnormalities that traditionally would have required separate analysis.

New challenges come with new technology; genomics is complicated by the sheer mass of information gathered. Processes to deal with data integration, visualization, and analysis are needed. Storage, management, and transfer of data are complicated by the vast amounts of data generated for each patient, which can take days to download and weeks to analyze.

Computation of the data allows for the organization of information into patterns that appear to exist among tumor subtypes. The data are compared to known biological pathways to identify changes in tumor behavior and to classify the mechanisms of tumor growth. Although the genetic changes are complex, this formation of patterns negates the previously held belief that cancer is chaotic and unpredictable.

Clinical data also can be incorporated in the analysis with rigorous selection of patients in clinically relevant groups. In this way, progression-free survival can be analyzed and compared among genetic subgroups.

Team science is essential for this analysis. Expertise in multiple arenas, including cancer genetics, bioinformatics, computational biology, and many others is required. Challenges of team science include the logistics of geography, transferring tissues for analysis, and sharing large amounts of information. TCGA investigators communicate through teleconferences and face-to-face meetings to set priorities and make decisions. Division—not repetition—of labor is emphasized. Collaboration in team science is not standard practice in research, and researchers can experience challenges related to academic advancement and future funding prospects.

The acquisition of high-quality samples is critical for genomic research. Advocates are vital to carry this message to the community. Education of institutional review boards is important to allow the process to move forward.

Data produced from TCGA, although still preliminary, are unprecedented. GBM and ovarian carcinoma are currently being analyzed, and 18 more tumors are on the docket. The future of genomics research depends on more tumors and more technology.

Dr. Hayes answered questions from the DCLG:

- Results from different tumor types are likely to overlap at some level and will be interesting to analyze. Future cancer treatments may be used for multiple tumor types depending on the genetic signature. Appropriate combination therapies are likely to be the most effective.
- The International Cancer Genome Consortium (ICGC) is an offshoot of TCGA. NCI is hopeful that ICGC and groups similar to it can learn from the work of TCGA. Currently, analysis of samples cannot be performed in other countries due to restrictions on sharing patient information.
- Although future technology might mitigate the need for high-quality samples, sample quality and quantity must be criteria for current inclusion.
- Pathogens, particularly viruses, may play more of a role in the formation of cancer than currently thought because viruses integrate into genomic DNA and could cause genetic anomalies. The footprints of viruses are being investigated in TCGA.

Summary of Presentations

Presenter: Dr. Anna D. Barker

Dr. Barker acknowledged that although TCGA is a huge undertaking, it is worthwhile, and the President has expressed interest in its continued progress. Dr. Barker listed several ways that biospecimen collection could be improved to aid genomics research, some of which might be considered by the DCLG:

- Existing repositories are generally inadequate; new efforts should improve quality.
- There are too many individual definitions of what to do and how to do it.
- Networking the resources is a possibility but remains difficult.
- Funding depends on costs and could be rate limiting.
- Many samples are defensively sequestered by practitioners and institutions.
- Understanding and embracing a national cancer biobank and evidence-based standard operating procedures are critical.
- Protection of patient privacy and confidentiality and addressing ethical, ownership, and access concerns are paramount.

Sample acquisition and access currently are driving the tumor-type selection for analysis. Groups dedicated to the study of rare tumors must collaborate to gather sufficient resources. Future work will likely be done on multiple tumor-types simultaneously. NCI is hopeful that advocacy groups can aid in tumor sample acquisition; many have expressed interest in working with NCI.

Group Discussion about Genomics Research and TCGA

The DCLG discussed what appears to be a transition from thinking about cancers in a site-specific way to thinking of them in terms of molecular signatures, some of which may be shared among different tumor types. This concept is still in its early stages, but it is important to have these conversations now to have coordination between appropriate groups (e.g., NCI, advocates) and open the channels across groups focused on particular cancers. The DCLG noted that leaders in the advocacy community can help facilitate this cooperation.

DCLG members stressed that the advocacy community has roles beyond sample acquisition in advocating for genomics research but acknowledged that specimens are critical and should be a priority. The advocacy community could mobilize their networks to expand the number of collection sites and engage clinicians around these issues. The process for specimen collection must be standardized and formalized. The consent process should be streamlined and simplified to ensure the rights of access for research in addition to patients' rights.

Genomics research ultimately could identify factors that contribute to cancer formation, which may lead to opportunities for reducing risk. If this is true, it will be important to distinguish increased risk and causality to avoid the appearance of blame.

Debrief of the NCI Executive Committee Retreat and Outcomes Critical to the DCLG Dialogue

Presenter: *Ms. Wendy Selig*

Several members of the DCLG were able to attend the NCI Executive Committee Scientific Retreat in February 2010, and Ms. Selig prepared a summary document for consideration by the DCLG.

The two-day meeting comprised scientific presentations and networking among experts in diverse fields of study to discuss personalized medicine. The meeting was framed to consider personalized medicine in the context of policy and reform. Presenters and participants discussed specific scientific advances as well as a broader view of issues related to the health care system, such as cost, privacy, and quality of care.

Points of consideration that came from the retreat included:

- The status of biomarkers and their validation; a lot a work remains in this area.
- New industry infrastructure needed for diagnostics.
- Biospecimen collection as a priority.
- Issues related to team science among researchers and organizations.
- Data management; the sheer magnitude of the amount of information brings up system and policy concerns.
- The translational research gap (from basic science to the clinic) and how it can be bridged.

Mr. Wallace noted that the scientists seemed eager to engage with advocates to increase awareness and support. Dr. Allen echoed this comment, and Ms. Selig noted that scientists seemed to think of advocates as "knights on white horses" that could solve their problems. Ms. Darien acknowledged that it can be a double-edged sword with respect to the expectations and

involvement of advocates in research. Inclusion at this retreat was considered an important step in the right direction.

Cancer will be cured by a collection of people beyond cancer scientists. Dr. Allen commented that scientists work extremely hard and may feel a degree of external pressure but cannot add more to their workload. Understanding and shared experiences will lead to better cooperation.

Cooperation may need to be incentivized—for tissue collection, team science, and perhaps more. Some changes must be institutional, but NCI could find ways to encourage a change in culture (e.g., in how authorship is viewed).

Ms. Selig said that retrospective analysis was considered a valid aspect of the translational research gap, and Mr. Wallace noted that increased use of electronic medical records will aid this process.

DCLG members agreed that communicating the meaning of "personalized medicine" is important because people may have different perceptions of what the term means.

Debrief of the DCLG Genomics Working Group Activities
Presenter: Mr. Max Wallace

The DCLG Genomics Working Group was created to consider the barriers and opportunities of genomics research and how the DCLG could make an impact. Meeting minutes and a summary document that detailed opportunities for DCLG involvement were provided to DCLG members.

The working group identified four broad areas where the advocacy community could have an impact in moving genomics research forward:

1. Personalized Medicine—create broad understanding about what it is, what is not, and why it is important as well as the potential impact on underserved populations.
2. Genomics Research—educate people about the value of genomics research through discussion of success stories, the value of existing programs, and the potential future value of genomics research.
3. Balancing Directed and Hypothesis-Driven Research—engage the broad community in a dialogue surrounding the balance between scientific approaches and the merit and roles of each.
4. Biospecimens—increase awareness about their importance, encourage the creation of best practices and standardization, identify new sources and opportunities for collaboration.

DCLG Dialogue Around Barriers and Opportunities Identified by the DCLG Genomics Working Group

The DCLG focused on the four areas identified by the DCLG Genomics Working Group to consider how they can best act. The group agreed that community engagement and health disparities should be important aspects of all four topics. The group believes that the advocacy community can really serve to enhance understanding of genomics research. The DCLG agreed that the "so what?" of genomics must be addressed.

Mr. Wallace emphasized the need for the DCLG to take a stand in support of personalized medicine and make it clear that genomics research (and all that it entails, including biospecimen acquisition) is critical to the future of cancer treatment.

Action Planning Around Opportunities to Address Barriers to the Genomics Research Process

The DCLG divided into subgroups to discuss specific actions for the board on the four main topics defined by the Genomics Working Group. Each subgroup was asked to consider the following for each topic:

- Advice to/requests from NCI.
- DCLG actions.
- Individual DCLG member actions.

Below is a summary of the outcomes of the breakout sessions for each group.

Potential Points of Action for Personalized Medicine

Advice to/Requests from NCI

- Lead community-based processes to define personalized medicine in a way that is inclusive of the community at large.
- Lead the process for metrics and outcomes for personalized cancer medicine.
- Maintain and increase emphasis on personalized medicine and decrease health disparities.
- Enhance communications with all populations.

DCLG Actions

- Help develop the definition of personalized medicine and indentify community base.
- Develop appropriate tools to educate the community—tutorials, stories, toolkits.
- Use DCLG tools and resources to educate the community and train the trainers, including a broader range of advocates.
- Define a deadline for implementation of online tools.
- Identify constituent groups in communities to establish or utilize communication networks.
- Engage with the community to promote and sustain two-way communication.
- Define and identify areas for outreach around personalized medicine.

Individual DCLG Member Actions

- Use DCLG tools and resources to educate the community and train the trainers, including a more broad range of advocates.
- Identify constituent groups in communities to establish or utilize communication networks.
- Engage with community to promote and sustain two-way communication.
- Define and identify areas for outreach around personalized medicine.

General Comments

- The definition of personalized medicine needs to be about more than the science behind it; diverse perspectives must be addressed.
- Conversation in the community about personalized medicine revolves around treatment, as opposed to risk reduction.

- Consider explicitly stating the economic benefit behind this health strategy.
- "Personalized" does not mean "individual."

Potential Points of Action for Genomics Research

The goal of this action is to increase science literacy in various audiences, including patients, policymakers, and well people.

Advice to/Requests from NCI
- Leverage funding for genomics research advances.
- Leverage current collaborators' experiences to advertise their importance, and expand cohorts.
- Consider the advantages of participatory research to facilitate progress.
- Identify opportunities, successes, and examples to humanize genomics research.
- Community advocates and NCI should be in partnership to lead dialogue.

DCLG Actions
- Spread the message to begin discussing genomics research with a variety of audiences. For instance, genetic counselors and advocates have interaction with the population and could spread the message. Develop training tools.
- Engage organizations that are not traditional, such as high school science Olympiad and nonscience networks.
- Community advocates and NCI should be in partnership to lead the dialogue.

Individual DCLG Member Actions
- Identify where conversations can take place in each community.
- Spread the message to begin discussing genomics research with a variety of audiences. For instance, genetic counselors and advocates have interaction with the population and could spread the message.
- Engage organizations that are not traditional, such as high school science Olympiad and nonscience networks. Use local celebrities and other nontraditional avenues to reach the community.
- Community advocates and NCI should be in partnership to lead dialogue.

General Comments
- The case for the importance of genomics research should be a central theme. The connection to personalized medicine must be clear.
- The community-based participatory research report for NCI could be an excellent resource. They could also draw from the Education Network to Advance Clinical Trials report.
- This topic could include the transition from thinking of cancer by tissue type to including genetic signatures (and explain that the transition does not detract from tissue-specific research).
- Action steps could include toolkits, webinars, and educational materials.
- Advocacy groups for cancers that harbor a specific mutation (e.g., *BRAF, EGFR*) could be brought together to begin the dialogue.

Potential Points of Action for Directed and Hypothesis-Driven Research

Advice to/Requests from NCI

- Change the review criteria of institutions so that there is less emphasis on the presence of R01s as indicators of success.
- Make success stories available for TCGA and other projects.
- Manage expectations of the general public for timelines and outcomes.
- Emphasize the positive impact of projects like TCGA on R01-funded research and the public.

DCLG Actions

- Provide "political cover" for team science by advocating this type of science on behalf of the community.
- Serve as a two-way street between groups, such as investigators with funding issues, and NCI.

Individual DCLG Member Actions

- Tell the stories of success, highlighting aspects that are relevant to the community.
- Participate in established structures to ensure inclusivity in the research process, including reaching out to registries and other groups.

General Comments

- Stories of success could include intermediate outcomes as opposed to waiting until the research is completed. Caution must be applied in labeling what research is considered "successful."
- DCLG could review data from other science programs or meet with other funding providers to determine how institutional evaluations are performed.

Potential Points of Action for Biospecimens

Advice to/Requests from NCI

- Define tissue types needed and keep the DCLG apprised of needs.
- Consider working with existing aggregated groups (e.g., Indian Health Service) to expand biospecimen collection networks.
- Design a "sales pitch" and provide simple materials (e.g., a one-page information sheet) that could include an explanation of how biospecimens are collected and used.

DCLG Actions

- Develop a list of aggregators that could be potential sources.
- Develop a flow chart for the process of biospecimen collection. Consider how the DCLG would approach groups to encourage participation.
- Identify targets and assess the best way to gain participation. Interact with potential contributors directly.

Individual DCLG Member Actions

- Deliver the message about why tissue collection is important. Develop tare sheets for all levels of participation. Learn from previous experiences about how to improve the process.
- Identify a strategic approach to "aggregate the aggregators."
- Utilize relationships to encourage participation.

General Comments

- Dr. Allen suggested compiling specific lessons learned from the TCGA pilot, including myths to dispel and privacy concerns.
- When defining tumor types needed for study, consider capturing the diversity of the population.
- Consider visiting biospecimen collection sites to create a flow chart of how tissues should be acquired and processed.
- Consider seeking contributors through professional pathology societies or directors of cancer centers.
- Seek information from National Cancer Center programs that are establishing biobanks and learn about their standards of practice.

Mr. Mittman described these preliminary points of action to Dr. Barker for comments. She found the ideas to be impressive, but believed it to be an incredible amount of work and suggested that the DCLG prioritize. Salient points included:

- Policy issues related to biospecimens need to be taken on by groups like the DCLG, including requirements for specimen collection and protections for the use of biospecimens.
- Patient data management policies are a central theme with biospecimens and should be considered by the DCLG. Currently, there are laws prohibiting sharing information even for the purposes of research; these should be reviewed and changed as appropriate.
- Informed consent for biospecimen needs improvement. A concise, universal standard consent should be implemented.
- Reimbursement policies for biospecimen collection should be considered and implemented, including consideration of the appropriate charge per tissue based on time-motion analysis.
- Members should encourage collaboration among advocacy groups with similar goals to assist in sample procurement.
- The group discussed writing a white paper describing the cost savings related to personalized medicine.
- A task force or working group to consider barriers for biospecimen collection may be useful.
- Dr. Barker informed the DCLG that NCI is considering publishing a commentary about the lessons learned through the TCGA pilot program.
- Future programs similar to TCGA are likely, and the DCLG should consider their role in the progress of this type of research.
- Dr. Barker suggested that the DCLG connect with the TCGA communications group to gather information and identify points of collaboration.
- NCI is considering holding a "State of the Science" meeting when data on a specific tumor is released; Dr. Barker suggested that the DCLG help identify the right people to join the discussion.
- Data management is a huge challenge for these large-scale studies, and ideas for infrastructure improvements are needed.

NCI Director's Update—Realizing the Vision of Prescriptive Medicine
Presenter: Dr. John E. Niederhuber

Dr. Niederhuber acknowledged the DCLG members that are rotating off of the board and thanked them for their service.

Cancer rates are rising globally. Less-developed countries will bear the burden, but all countries will be affected economically. U.S. mortality rates have declined in the past 50 years despite relatively stable incidence, suggestive of improved detection, treatment, and prevention.

The National Cancer Advisory Board (NCAB) has been charged with creating a strategic scientific vision for the National Cancer Program and a review of NCI to determine gaps and opportunities to encourage scientific progress in diagnosing, preventing, and treating cancer. A forming working group will issue a report to NCAB in September 2010 on these issues.

NCI's vision of the future is personalized medicine, including drug discovery, therapy, and prevention. There is a paradigm shift in translational science toward molecularly selected patients and target therapies that are proactive, less toxic, and save both time and money. Through the proper selection of patients with validated biomarkers, clinicians will be able to identify which patients will respond to a drug and avoid treating those that will not respond. Due to the complexity of cancer, a recipe of drugs specific to a patient's genetic changes will be used in combination therapy.

Genomic research will facilitate the future of personalized medicine through target discovery and development. Through understanding the numerous genomic changes in cancer, scientists can build a catalogue of biomarkers and predictors to use as a reference in future cancer treatment regimens. TCGA is the pilot phase of this process that proves that a high-throughput, extensive analysis is possible.

Dr. Niederhuber encouraged the possibility of a national cohort of cancer patients. The consent process would allow for access to electronic medical records and patient data and could lead to patient and tumor genomic characterization. He proposed a pilot study of a patient and tumor characterization center that would incorporate data storage and management, NCI structure for analysis, and translation of information into point-of-care diagnostics by practicing oncologists.

NCI has a responsibility to its patients, including using resources wisely, determining individual risk and decreasing or managing risk, developing solutions, and making lasting contributions to alleviating the burden of cancer.

Identifying the Role of the Advocacy Community in Advancing Genomics Research
Facilitator: Mr. Robert Mittman

Before the group began discussing action plans, some points were addressed:

- The caHUB Working Group has advocate representatives, and perhaps they should be solicited to better understand what caHUB is doing and how the DCLG may be able to facilitate or support the group's work. It was suggested that they are working on

improvement of the informed consent form for biospecimen collection and a tare sheet for tissue collection best practices.

- Success stories related to NCI progress were also mentioned; it was proposed that step-wise success stories that can be built upon to tell the full story could be beneficial, as opposed to waiting until the end to tell the story. The convergence of community needs and NCI's proposed actions needs to be made clear to the public.
- The importance of a summary document about "lessons learned" from TCGA was emphasized to avoid pitfalls in future endeavors. Discussions on this point could be made with TCGA communications. This document should be for clinicians and researchers but should be made available in patient-accessible language.
- Aggregators, or points where several groups come together, may be helpful not only for tissue collection but also for advocacy.

The DCLG was asked to define actions related to advocacy for genomics at NCI. The meeting broke into subgroups to draft potential action plan components for addressing critical issues identified throughout the meeting. The results from the subgroup discussions follow.

Policy Issues – *Identify policy issues impacting genomics research/personalized medicine and create opportunities for the community to impact the policies.*

1. Identify big picture issues (engage NCI, IOM, etc)
2. Create a channel for policy issue discussion with other board members
3. Prioritize push points and develop messages
4. Identify 3-5 major issues for the board to consider taking up
5. Engage community partners as appropriate. Explore opportunities to engage existing coalitions or develop one to meet these needs

Moving Toward a Pathway Focused Community – *There is a great deal of value for organizations currently focused on tumor sites to understand where they have common interests, through disease pathways, with other tumor specific organizations and how they can work together to move common interests forward.*

1. Education continues → lessons learned from TCGA
2. OAR/DCLG convenes a group of organizations interested in working together/share common interests
3. The group develops a list of issues, comes to consensus on issues, and identifies and prioritizes action items
4. The group takes action where appropriate

Biospecimen Collection Communications Team – *Use relationships to educate advocates, medical centers, and patients about tissue collection (what happens when it goes right or wrong).*

1. Develop SOP guidance related to what this is supposed to look like
2. Create template for a time/motion experience
3. Perform site visits to try to move this forward

4. Demo a site visit in Seattle at July meeting
5. Prepare process information (tear sheet) in October
6. Recruit advocacy SWAT team by December
7. Determine targets by December
8. Implement target approach by January 2011

Identifying Success Stories – *Identify success stories that can help tell the story of genomics from the human perspective.*

1. Collaborate with DCLG speakers to ID key stories
2. Integrate efforts with TCGA communications team
3. Search published journals for stories
4. Create a publication plan (e.g. newsletters, talks)

Educational Toolkit – *Provide tools that will allow advocates to educate appropriate audiences about the value of personalized medicine. (Marie, Yvette, Arlene, Everett)*

1. Convene a working group to advise/lead the aggregation of existing tools, promote sharing, develop guidelines for use of tools, and help develop appropriate (phase 2)
2. Develop a specialized tool kit to include: Basic presentation templates; modules on specific topics; handouts with definitions, talking points, etc.; appropriate pre and post knowledge tests for the audience; audience evaluations; presenter report back to NCI.

Community Engagement – *Empowering communities to take appropriate personal or group action to address barriers to the realization of personalized medicine/genomics. (Marie, Yvette, Arlene, Grace)*

1. Identify appropriate audiences/partners, create contact lists, and make first contact within three months (phase 1)
2. Collaborate with OAR to identify regional experts engaged in this work who could serve as resources, create a contact list, and contact as appropriate (phase 1)
3. Collaborate with NCI to create culturally and linguistically appropriate print materials that can be used when engaging communities (phase 1)
4. Collaborate with NCI to develop facilitation guides that a community partner can use in leading a dialogue in their community on the importance of these issues (phase 1)
5. Host events to either participate in webinars live or view recorded webinars and facilitate a dialogue following the session around why it matters (phase 2)
6. Coordinate opportunities to share information in conjunction with community events (phase 3)

Action Plan for Informed Consent

- It was recommended that the informed consent documents be reviewed and distilled down to a maximum of 10 primary points, including issues related to privacy protection and how tissue samples are used.

- The subgroup agreed to work with OAR to identify other groups interested in improving the informed consent process for biological specimens.

It was acknowledged that a universal consent document would help alleviate barriers in the current system.

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