U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL CANCER INSTITUTE

SUMMARY OF THE 61st DIRECTOR'S CONSUMER LIAISON GROUP MEETING

NIH Campus, Building 31, C-Wing Room 10

Bethesda, Maryland

October 25–26, 2012

Members Present

Ms. Gwen Darien, Chair
Dr. Jeff Allen
Mr. David Arons
Ms. Susan G. Braun
Dr. Adam Clark
Ms. Andrea Ferris
Ms. Joya Delgado Harris
Mr. Jeff Kaufman
Mr. Jon Retzlaff
Mr. Josh Sommer
Mr. Max Wallace

Members Absent

Ms. Linda House
Dr. Michelle McMurry-Heath

Speakers

Dr. Ted Trimble, Director, Center for Global Health, National Cancer Institute
Dr. Christopher Heery, Staff Clinician, Center for Cancer Research, National Cancer Institute
Dr. Kay Dickersin, Director, Center for Clinical Trials, Johns Hopkins Bloomberg School of Public Health and U.S. Cochrane Center
Dr. Mark R. Somerfield, Director of Clinical Affairs, American Society of Clinical Oncology
Ms. Kathleen Castro, Nurse Consultant, Applied Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute
Ms. Patricia Goldsmith, Executive Vice President and Chief Operating Officer, National Comprehensive Cancer Network
Dr. Gail Mallory, Director of Research, Oncology Nursing Society
Mr. John Czajkowski, Deputy Director for Management, National Cancer Institute
Ms. Kelli Marciel, Director, Office of Advocacy Relations, National Cancer Institute

Facilitator

Mr. Robert Mittman

Contents

Thursday, October 25, 2012

Welcome, Opening Remarks

Gwen Darien, DCLG Chair
Kelli Marciel, Director, Office of Advocacy Relations, National Cancer Institute
Robert Mittman, Facilitator

Ms. Kelli Marciel

- Ms. Marciel informed Director's Consumer Liaison Group (DCLG) members that the Office of Advocacy Relations (OAR) is interested in continuing to find ways to improve outcomes for cancer patients, and noted that the advocacy community has a unique role in helping to integrate research findings into practice.
- She introduced the newest member of the DCLG, Mr. David Arons from the National Brain Tumor Society.

Ms. Gwen Darien

- Ms. Darien discussed the importance of the topic, as it is critical to tell the story of how research informs care and how this benefits the public.
- She concluded her opening remarks by providing an overview of the upcoming discussion. She noted that the DCLG meeting will focus on how research is put into practice, including benefits and barriers.

Mr. Robert Mittman

- Mr. Mittman reiterated the meeting's focus – how to optimize the uptake of research in clinical practice.
- He pointed out that while the NCI's role is generating funding and facilitating research, there are many other factors that influence implementation of treatments that have been derived from research.

Assessing the Uptake of Research Findings

Ted Trimble, M.D., M.P.H., Center for Global Health, National Cancer Institute
Christopher Heery, M.D., Center for Cancer Research, National Cancer Institute
Kay Dickersin, Ph.D., Johns Hopkins Bloomberg School of Public Health and U.S. Cochrane Center

Overview of Update of Research Findings
Dr. Ted Trimble

- Dr. Trimble discussed the NCI Clinical Announcement, which is used to bring new information of importance to the attention of clinicians as rapidly as possible.
- An NCI Clinical Announcement is nominated by an investigator(s) and NCI, and the recommendation is forwarded to the NCI Director.
- The release of a Clinical Announcement is timed with the publication of scientific data in support of the announcement.
- NCI Clinical Announcements are rarely issued; the last one was issued in 2006 regarding intraperitoneal chemotherapy for ovarian cancer. Dr. Trimble provided a brief history on the 2006 NCI Clinical Announcement:
    - The announcement encouraged treatment with anticancer drugs via two methods, after surgery, for women with advanced ovarian cancer. The combined methods, which deliver drugs into a vein and directly into the abdomen, extend overall survival for patients by about a year.
    - The two treatment methods are called intravenous, or IV, for chemotherapy delivered into a vein and intraperitoneal, or IP, for chemotherapy delivered into the abdominal, or peritoneal, cavity.

- This particular Clinical Announcement was proposed by investigators from the Gynecologic Oncology Group and SWOG (which at the time was known as the Southwest Oncology Group). An independent panel of various experts was convened to review the data and voted to recommend that NCI issue a clinical announcement. NCI leadership reviewed the proposal and, because of the challenges involved with IP chemo, convened several focus groups. A trans-NCI team was developed for dissemination of the Clinical Announcement.
- Communication/dissemination of the announcement used multiple techniques including: publications, press (with foreign, national, and local releases), television coverage, conference calls with advocacy groups, website postings, and development of education materials.

- Dr. Trimble noted that although the current status of IP chemotherapy is standard at sites active in IP research, it is difficult to track population-based uptake in real time.
- An additional concern is that insurance reimbursement is inadequate for the additional work required from doctors. Administering abdominal chemotherapy requires some training. A few Phase III trials are underway.

Case Study: Oncologists' Acceptance of Immunotherapy
Dr. Christopher Heery

- Dr. Heery noted that the dogma/beliefs for cancer therapy efficacy are largely based on historical data using cytotoxic therapies. Overall survival is the gold standard, and usually progression-free survival (PFS) is a good surrogate for overall survival.
- However, Dr. Heery mentioned that PFS may only indicate benefit while treatment is ongoing and overall survival may not parallel PFS.
- He presented background information on an immunotherapy prostate cancer case study:
  - Sipuleucel-T (Provenge®) is a therapeutic cancer vaccine approved for some men with metastatic prostate cancer.
  - FDA approval of this vaccine (in 2010) was based on results from a randomized, double-blind, placebo-controlled multicenter Phase III trial. Overall survival was the primary efficacy endpoint of the trial.
  - The approval validated the concept of an active treatment approach such as immunotherapy, which is intended to train the immune system to attack cancer cells and potentially get a response.
- Dr. Heery showed the quarterly U.S. sales and William Blair estimates for recently launched therapies for mCRPC (metastatic castration-resistant prostate cancer). Sipuleucel-T (Provenge®) was approved in April 2010 with low sales, indicating slow uptake. On the other hand, the FDA approved Abiraterone (Zytiga®) just one year later, in April 2011, which demonstrated higher sales and a much higher uptake.
- He provided several reasons why uptake for these therapies might have varied:
  - Sipuleucel-T is difficult to administer.
  - Upfront cost is high for the treatment course.
  - Abiraterone can be taken orally, which may make it the preferred first option for some patients, and affects prostate-specific antigen (PSA) numbers (which is what patients typically monitor).
- According to Dr. Heery, the availability of multiple treatment options puts researchers and clinicians in the difficult position to make decisions about which drugs to use in which patients and when.

Advocates' Influence on Clinical Uptake
Dr. Kay Dickersin

- Dr. Dickersin discussed the Consumers United for Evidence-based Healthcare (CUE) program, which is staffed by the Cochrane Collaboration:
  - CUE was formed in 2003 and is a national coalition of 37 health advocacy organizations.
  - CUE's mission is to improve decision-making about health. Members are educated in evidence-based health care (EBHC) decision-making.

- Consumers have different concerns/questions than doctors and scientists and thus CUE's tasks include the following:
    - Building a critical mass of U.S.-based consumer advocates trained to use and communicate the essential elements of EBHC.
    - Increasing partnerships between CUE and decision-makers.
    - Providing online and in-person training on EBHC and critical appraisal.
    - Providing a forum for communication and methodological consultation.
    - Contributing to improving the quality of health care.
    - Increasing awareness of, involvement in, and contribution to the work of the Cochrane Collaboration and other EBHC organizations.
- The CUE's activities are typically carried out through Web presence/videos, online resources and training courses, and in-person meetings.
- CUE also provides a clearinghouse of consumers well versed in EBHC, for decision-makers who seek consumer input.

- Dr. Dickersin noted that advocates are asked to contribute at many levels, including serving on steering committees, advisory boards, guideline panels, and grant review committees.

Board Discussion

- Speakers were asked to indicate significant gaps so that the DCLG can better understand the current situation.
    - Dr. Trimble noted that there needs to be a push-pull of research and the system. He specifically mentioned quality indicators and the importance of addressing insurance reimbursement issues.
    - Dr. Heery believes there is a cost issue, including concerns about funding.
    - Dr. Dickersin believes it is a multi-factorial problem. She noted that education is important, acknowledging that expertise and working together will be vital moving forward. She specifically noted the need for partnerships that help clinicians know which evidence is the best.
- Dr. Trimble and Dr. Heery discussed the importance of incorporating genetics and technology into clinical findings. They believe both are critical, and incorporating them is difficult and time consuming.
- Two suggestions were explored:
    1. Protocols with no uptake (after Phase III).
    2. Uptake of findings (mutations) that are incorporated into research.
- Members and speakers agreed that the essential issue is making information/knowledge more fluid to enable research to go forward more effectively.
- Dr. Heery noted that pre-market controversy was directly related; much of the reason for the scrutiny was cost. A full course of treatment is quite expensive.
- Several people suggested combining expertise and looking at larger issues to see the full/broader spectrum of impact. Focusing on individual problems will not advance the full effort.
- In regards to advocate involvement, it was suggested that patients share data to help others make informed decisions. However, data is often difficult to interpret without doctors' expertise; perhaps doctors can help review the data to identify risks and benefits. A few DCLG members mentioned that data might not be different, but each provider could have their own analysis of the data.
- Additional speakers provided their perspective on the current situation.
    - Ms. Goldsmith agreed that inadequate or absent reimbursement is a critical issue. If individuals are not compensated, nothing will happen.
    - Dr. Mallory noted that patients have been reimbursed for cognitive services (per a recent Institute of Medicine meeting/paper regarding Team Care).
- Ms. Darien concluded by noting that questions asked in research are important in the community, and research and the community influence one another.

Novel Initiatives and Partnerships to Improve Uptake of Research Findings

Dr. Mark R. Somerfield, American Society of Clinical Oncology
Kathleen Castro, National Cancer Institute
Patricia Goldsmith, National Comprehensive Cancer Network
Dr. Gail Mallory, Oncology Nursing Society

NCI Community Cancer Centers Program (NCCCP) National Quality Reporting Initiatives
Ms. Kathleen Castro

- The NCCCP began in 2007 and is designed to build a community-based research platform supporting a wide range of clinical and population-based research across the cancer continuum and to enhance quality of care for patients.
- In 2007, there were 15 NCCCP hospitals; today there are 21.
- To increase adherence to evidence-based patient-centered care, NCCCP developed collaborations with the American Society of Clinical Oncology Quality Oncology Practice Initiative (QOPI®) and the American College of Surgeons Rapid Quality Reporting System (RQRS).
- Lessons learned include the following:
    - Providing data back to the network in a de-identified format allows for discussion of strategies to improve quality and identify ways to overcome barriers.
    - Identifying network quality improvement projects and goals has led to increased quality improvement efforts at individual sites.
    - Using the data to initiate change in how the organization of a site functions (e.g., development of a chemotherapy safety committee).

American Society of Clinical Oncology (ASCO), Institute for Quality
Dr. Mark R. Somerfield

- Dr. Somerfield noted that ASCO is well positioned to help oncology care providers improve uptake of research findings, and this is accomplished through guidelines, practice-based quality assessment, and a rapid learning system for oncology.
- Attitudes toward guidelines have changed drastically over time; clinicians are now more open to using guidelines, and there is a high demand for them.
- New ASCO activities include the following:
    - Exploring cross-organizational collaborations to reduce duplication of efforts.
    - Approving expedited guideline endorsement to review other organizations' guidelines and recommendations.
    - Using formal expert consensus methods.
    - Creating guideline advisory groups to set priorities.
- Patient representatives are on each guideline expert panel.
- ASCO provides clinical tools to disseminate guidelines recommendations, including PowerPoint slides, decision aids, documentation tools, and information for patients.
- The Practice Guidelines Implementation Network (PGIN) includes representatives of guideline end users, including oncologists, oncology nurses, hematology/oncology pharmacists, and oncology practice managers.
- PGIN disseminates ASCO guideline recommendations, and PGIN's evidence-based Clinical Tools & Resources offers community-based oncology perspectives on guidelines, and gives feedback on draft guidelines and clinical tools.
- QOPI® is an oncologist-led, practice-based quality improvement program that promotes excellence in cancer care via a culture of self-examination and improvement.

- The QOPI® Certification Program (QCP™) recognizes practices that are committed to delivering the highest quality of cancer care. QCP™ evaluates an individual practice's performance in areas that affect patient care and safety.
- QOPI® has close to 800 registered practices throughout the U.S. Nearly 400 participate annually and provide more than 25,000 records each round.

National Comprehensive Cancer Network (NCCN) Update
Ms. Patricia Goldsmith

- All of NCCN's materials are widely available free of charge on its website.
- The website has 58 NCCN clinical practice guidelines in oncology (NCCN guidelines), with 146 algorithms updated continuously; there have been 1,100 versions in the past year alone.
- NCCN guidelines from 2011 involve the following:
    - There are a total of 46 guidelines panels and 975 guidelines panel members.
        - Experts volunteer their time and expertise and meet at least once per year.
    - There are 55 updated individual guidelines, with 136 algorithms.
    - In 2011, there were 18,984 guideline downloads.
- In the past six months, the average visit duration to NCCN.org was 10 minutes and 6 seconds; the site is heavily trafficked across the world.
- The NCCN Drugs & Biologics compendium is formally recognized by the Centers for Medicare and Medicaid Services (CMS), and is driving standards of care and standards of coverage.
- NCCN guidelines have also been provided for patients, in a patient-friendly format.
- NCCN will launch a tool by next spring that will allow physicians to have information available at point of care.

Novel Approaches to Improving Uptake of Research Findings in Oncology Nursing Practice
Dr. Gail Mallory

- The Oncology Nursing Society (ONS) promotes excellence in oncology nursing and quality cancer care, and is primarily involved with symptoms management.
- ONS provided synthesized research evidence for nursing and sensitive patient-centered interventions, using NCCN guidelines and working with ASCO.
- ONS synthesized evidence for 20 nursing-sensitive patient outcome topics, and has more than 800 research articles on site.
- Materials from the organization are available in print and on the Web.
- The website has definitions, evidence summary tables, systematic review tables, guidelines tables, assessment tools, research instruments, and references.
- ONS has several strategies to change practice, including education, quality measures, Agency for Healthcare Research and Quality (AHRQ) grants, and several other programs.

Board Discussion

The Board mentioned various ideas for improvements:

- Develop materials that are interactive and are from a trusted source (leaflets are not sufficient).
- Create reminders.
- Require the use of evidence-based guidelines to be reimbursed.
- Consider tying guidelines to certification.
- Provide comparative data and immediate feedback.
- Keep physicians and patients involved in the production of guidelines.
- Create systems that support implementation of guidelines.

- Measure and communicate outcomes of guidelines.

Factors associated with the uptake of clinical guidelines

- There is a lack of continual learning.
    - It is difficult to change a practice once it has been adopted. When clinicians learn something new, they often do not spend time incorporating the new knowledge into practice.
    - Guidelines change often and are based on evidence that is available *today*.
    - Distinction between uptake of research findings in the past and new updates is key.
- Research and guidelines do not always reflect real-life situations.
    - Thinking historically, there have been cases in which a combination of media and advocacy increased the adoption of practices that were not supported by research.
    - If a clinician practices only based on guidelines, he/she would not be practicing good medicine.
    - Distinction should be made between practitioners who use guidelines (not engaged in continuing education and not part of academia) versus practitioners who are ahead of the curve and are aware of emerging research (thought leaders in the field).
    - Patient preferences also need to be incorporated when thinking about treatment.
    - Potential side effects and quality of life are huge decision points.
- Differences exist between health care research and clinical trials research.
    - Health care research data does not adequately describe the patient experience with treatment.

Barriers to bringing the best science into practice

- Money
    - The current incentive structure favors more diagnostic testing.
- Fear
    - Clinicians, particularly those in private practice, may fear adopting anything new.
    - They may fear an inability to keep up with overwhelming amounts of new information.
    - Clinicians may fear lawsuits or have malpractice concerns.
    - Patients, including historically underrepresented groups, may have their own fears about trying new treatments.
- Drug approval
    - Getting clinical research and drugs approved can be difficult, affecting the price of treatments; the cost of some newer treatments is high.
- Diagnosis
    - Clinicians may be unwilling to refer people to a specialist.
    - Misdiagnosis rates are staggering.
- Patients
    - Patients may not know where to get the right care for their condition.
    - The system does not sufficiently consider patient preferences.
    - The ease in carrying out the treatment protocol affects patients' willingness and ability to do it, and thus the clinician's willingness to follow guidelines.
    - Patient preferences can be difficult to elicit.

After being referred to a specialist, patients may be unaware of resources that are available to help them adjust their lives and pay for treatment.

Potential Role of Advocates in Implementing Solutions

- Increase collaborations among professional societies and advocacy groups to develop mutually beneficial strategies.
- Work with advocacy groups and professional organizations to make it easier for clinicians to get new information.
- Reduce the burden of overwhelming amounts of new information. Advocacy groups and organizations can help make it easier for clinicians to get the information they need.

- Patients in rural communities need to be educated about how they can benefit from certain treatments. Generally, people find it difficult to describe their disease and do not know how to look for a specialist; they also may not be aware that a specialist is even an option.
- Find the best ways to reach people at critical decision junctures. Communicate with patients when they receive a diagnosis. A patient navigator could help patients better understand the disease and their options for treatment.
- Patients need to become more involved in the clinical trial process.

Friday, October 26, 2012

NCI Updates

Mr. John Czajkowski

- Mr. Czajkowski noted that the government is facing long-term fiscal realities.
- He described sequestration and its potential effect on NCI.
    - NIH is facing a potential 8.2% budget cut, which would likely be spread throughout the agency.
    - NCI is aware of this but is not planning, prepositioning, or making financial decisions in anticipation. Instead, the institute is reviewing the budget and analyzing where there could be financial flexibility and where cuts might not cause damage.
- He then discussed the transition of a presidential administration, what it means to NCI, and the unique problems that arise in the event of new presidentially appointed leadership.
    - NCI has worked extensively on maintaining continuity through leadership transition.
    - The key is to think long term, regardless of whether or not leadership may change.
    - Transitions can result in "substitute teacher syndrome"; projects remain in limbo until there is stable leadership.
    - It is important that NCI stay on track despite leadership transitions.
- The complexity of NCI's program is unique. NCI's legacy spans both the cancer and biomedical communities.
- DCLG serves a critical function for NCI and its entire leadership. Mr. Czajkowski believes that advocates and NCI need to inform each other, keep each other on track, and speak the truth to each other.
- He also spoke on the importance of sharing the value of NIH/NCI and the need to better integrate stories about the impact of the work being done at NCI. He views the DCLG as an important group to help "tell the story."
- Mr. Czajkowski advised DCLG members to pay close attention to policies that may appear innocuous and bureaucratic, even if they do not specifically mention cancer, because they can actually be important to the cancer community. He provided an example of a U.S. Government Accountability Office (GAO) report on NCI's use of Title 42 to hire experts. This report has real consequences on NCI's hiring process and ability to hire top researchers.

Board Discussion

- Advocacy has come across as self-serving, but it really is about serving the people. At times, it may appear that the primary goal is to maintain our labs and our salaries, but really, we do this work to positively affect people and communities.
- The larger conversation involves helping people understand what government does for them. It was mentioned that a tour of the Clinical Center might be a good way for the DCLG members (especially new members) to see first-hand the value of the NIH.
- The DCLG can help in several ways:
    - Taking advantage of the information already available, and emphasizing it at conferences and in-person events/meetings.

- Challenging people to better inform themselves by being a part of meetings/discussions.
- Creating a map that highlights zip codes that receive NCI funding. This would show the impact that NCI has in communities throughout the country.

Potential Actions and Role of Advocates

- Create a flowchart that explains where to go for certain illnesses, recognizing that there are centers that have particular expertise that community oncologists may not be aware of.
- Encourage more collaboration between professional societies and advocacy groups.
- Reach people at critical decision-making junctures. Almost every diagnosis of cancer is an emotional emergency.
- Harmonize communications of research and the consequences of research choices.
- Use navigators for researching and presenting treatment options early, keeping attention on access to care.
- Conduct research on systems and on policy.

Additional Updates

- Ms. Braun took the lead in putting together an outline for a white paper on drug shortages. The outline is being reviewed by OAR, and some activities related to the paper have been generated.
- Dr. Varmus would like for the DCLG to consider addressing informed consent on genomics research during the next DCLG meeting.

Certification

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

3.15.13
Date

Chair
Director's Consumer Liaison Group

3/15/13
Date

Executive Secretary
Director's Consumer Liaison Group