80th Meeting of the National Cancer Institute (NCI)

NCI Council of Research Advocates (NCRA)

Virtual Meeting

Thursday, July 16, 2020

Members Present

Ms. Anjee Davis, Chair
Ms. Malinda Bachini
Mr. Rick Bangs
Mr. Yelak Biru
Ms. Annie Ellis
Ms. Julie Fleshman
Ms. Danielle Leach
Ms. Jennifer Pegher
Ms. Kris Rhodes
Ms. Kristen Santiago
Ms. Jacqueline Smith
Mr. Kevin Stemberger
Dr. Nicole Willmarth

Speakers

Dr. Ann Geiger, Scientific Director of Cancer Care Delivery Research in the NCI Community Oncology Research Program NCI
Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations (OGCR), NCI
Dr. Doug Lowy, Principal Deputy Director, NCI
Dr. Worta McCaskill-Stevens, Chief of the Community Oncology and Prevention Trials Research Group, NCI
Dr. Ned Sharpless, Director, NCI
Ms. Amy Williams, Acting Director, Office of Advocacy Relations (OAR); Executive Secretary, NCRA, NCI

Contents

Welcome and Meeting Goals 3
NCI Director's Update 3
NCI Serology Studies 4
Budget and Legislative Update 5
NCI NCORP Accrual Discussion 5
NCRA Clinical Trials Working Group 6
Advocacy and COVID-19 Discussion 7
Closing Remarks 8

Welcome and Meeting Goals
Ms. Anjee Davis and Ms. Amy Williams

Ms. Amy Williams opened the meeting at 12:00 p.m., welcomed the Council members, and reviewed the meeting agenda. She introduced Ms. Davis as the Council's newest Chair and Ms. Davis provided brief opening remarks. Ms. Davis then invited each member to introduce themselves, including the Council's newest members: Ms. Malinda Bachini, Mr. Yelak Biru, Ms. Annie Ellis, Ms. Kris Rhodes, Ms. Kristen Santiago, Ms. Jacqueline Smith, Mr. Kevin Stemberger, and Dr. Nicole Willmarth. Ms. Davis reviewed the conflict of interest rules for the meeting and confirmed that a quorum of members was present.

NCI Director's Update
Dr. Ned Sharpless

Dr. Sharpless thanked the Council for the opportunity to speak and began by providing an overview of the current FY 2020 budget, as well as the projected FY 2021 budget. He also provided background on the impact of emergency funding and supplements for investigators in response to the COVID-19 pandemic.

Dr. Sharpless then described what the impact of the COVID-19 pandemic has been on NCI operations, how NCI has responded, and how he expects the pandemic to affect patients long-term, including reduced access to and deferred care, non-standard care, delayed diagnoses, which will lead to increased cancer mortality, disproportionately experienced by under-insured, uninsured, and underserved populations. Dr. Sharpless shared that NCI has estimated a one percent increase in excess cancer death related to the effect of COVID-19.

NCI's COVID-19 in Cancer Patients Study has begun enrolling patients and has been activated at 612 sites across 45 states. Dr. Sharpless continued describing some of the work NCI has enacted in response to the pandemic and previewed Dr. Lowy's coverage of NCI's Serology Study. He also described new flexibilities NIH and NCI are enacting to streamline clinical trial operations and assist grantees, including new policies governing the carry-over of award funding and extensions on application deadlines and required reporting. NCI has also generated new administrative supplements to provide salary funding for up to 80 postdoctoral fellows who may have lost their stipends from nonprofit funders experiencing pandemic-related financial constraints.

Dr. Sharpless then offered the Council updates on current cancer research programs, including the addition of two new treatment arms to Pediatric MATCH, the delivery of recommendations from the Childhood Cancer Data Initiative Working Group, liver cancer biomarker development, a joint effort with PanCAN to develop a cohort examining the association between new-onset diabetes and pancreatic cancer, and efforts to improve and promote racial equity in research, specifically by addressing cancer health disparities, promoting workforce diversity, and creating a more inclusive culture at NCI.

Discussion

- Mr. Bangs asked how the community can help ensure flexibilities instituted to support the clinical trial infrastructure continue beyond the pandemic. Dr. Sharpless agreed many of the changes to cancer research and care provide opportunities for sustained improvements after the pandemic subsides, and that the community will be instrumental in helping emphasize what works. He also mentioned an RFI examining the use of telehealth in cancer care that was issued by the Division of Cancer Prevention and Population Sciences (DCCPS).
- Ms. Smith emphasized that her experience on a trial has made her excited for the prospect of expanded telehealth for cancer care and clinical trial operations. She went on to describe an effort at BMS to improve diversity of the cancer care workforce.
- Ms. Pegher commented that the workforce diversity issue is also something being examined by the Cancer Centers and that her constituents look forward to working with NCI.
- Ms. Davis asked Dr. Sharpless about target metrics for diversifying workforce, and specifically, do we see improved trial accrual rates if we know they're leading programs of their own. Dr. Sharpless mentioned that participants in the NCI CURE program do experience success in research, meaning they obtain NCI R01 funding, which is an important metric for NCI. Alumni of the program have funding rates that are comparable to the rest of the R01 grantees.
- Ms. Ellis asked if NCI has data about CURE program applicants that just miss and whether or not there's a role for the community in offering support to those applicants. Dr. Sharpless mentioned that the fellowship applicants have strong paylines, but that the "close-but-no-cigar" issue is more apparent in the RPG pool and NCI has worked hard to improve those. He also described elements of the CURE Program focused on grantsmanship to help future applicants. He also added that NCI can use "select-pay" to help applicants who are just outside the payline but there's evidence to support a particular applicant due to a modifying factor.

NCI Serology Studies
Dr. Doug Lowy

Dr. Doug Lowy reiterated Dr. Sharpless's point that cancer research is continuing during the COVID-19 pandemic and many NCI researchers returned to campus at the end of June. He also described specific efforts to address COVID-19, including:

- The congressional approval of $306 million to support the development, validation, and improvement of serological testing.
- The Adaptive Coronavirus Treatment Trial (ACCT) examining remdesivir as a coronavirus treatment, which originated at the Frederick National Laboratory for Cancer Research (FNLCR).
- The use of the HPV serology lab at the FNLCR to evaluate serology devices in partnership with the U.S. Food and Drug Administration (FDA). Seventy commercial devices have been evaluated so far.
- The development of a data warehouse and dashboard for tracking seroprevalence of SARS-CoV-2 and the creation of the Extramural Serological Sciences Network (SeroNet).

Discussion

- Ms. Ellis asked what sensitivity and specificity targets the FDA has set for evaluating serological devices and Dr. Lowy shared the target is 90 percent sensitivity and 95 percent specificity.
- Mr. Bangs asked whether or not positivity is binary: either antibodies are present or not, and Dr. Lowy clarified that we still do not yet know what levels of antibodies are protective.
- Dr. Willmarth asked whether these efforts will include the examination of undetected antibodies at the cellular level and he mentioned that NCI and NIAID are collaborating to consider these questions.

Budget and Legislative Update
Ms. Holly Gibbons

Ms. Gibbons provided an update on congressional operations amidst the pandemic, as well as the NCI budget and the next steps in the appropriations process.

- Ms. Gibbons explained that there have been 70 congressional hearings since late February focused on the pandemic and its impact.
- Congress has passed a total of four relief packages totaling $2.6 trillion. Three of the four packages included funding for NIH.
- She reiterated Dr. Lowy's comment that NCI received $306 million in emergency supplemental funding to develop, validate, and improve serological testing and associated technologies.
- Ms. Gibbons also described the progress on FY 2021 budget legislation, including a proposal by the U.S. House of Representatives which would increase NCI's base budget by $54 million for a total of $6.3 billion. She went on to describe the U.S. Senate delaying FY 2021 appropriations until an agreement can be reached on additional COVID-19 relief.
- Ms. Gibbons shared that the assumption now is the federal government will operate under a Continuing Resolution (CR) until after the 2020 elections.

NCI NCORP Accrual Discussion
Dr. Worta McCaskill-Stevens

Dr. McCaskill-Stevens shared with the Council NCI's emphasis on addressing cancer health disparities and presented findings from an analysis of minority accrual through the NCI Community Oncology Program (NCORP) and cooperative groups (and their predecessor programs) between 1999 and 2019.

- 655,160 patients have enrolled on trials over this 20 year period and 122,819 were categorized as minority enrollment (approximately 19 percent).

- Black or African American patients and Hispanic/Latino patients accounted for the majority of minority patients enrolled at nine and seven percent respectively.
- Minority enrollment in Phase III trials went up 27 percent in the last year of data analyzed.

Dr. McCaskill-Stevens emphasized that this data has illustrated several potential avenues for NCI to continue exploring, including:

- Disaggregating accrual within race and ethnicity since culture and country of origin and other areas are important to research.
- Implementing a clinical trial log to expand demographic information collection.
- Including accruals for tissue acquisition studies to address disparities in that area.
- Including quality of life studies as accruals.
- Look into the translation of patient reported outcomes tools.
- Working across research bases and NCTN group initiatives including working groups for elderly, adolescent and young adults, and sexual gender minorities.

Discussion

- Mr. Bangs asked whether or not the data would show accrual challenges among different disease types, and Dr. McCaskill-Stevens agreed segmented the data by disease type would show disparities which is another avenue of potential research interest for NCI.
- Ms. Williams asked Dr. McCaskill-Stevens if there were any lessons learned from this analysis that the community should know and she emphasized that the purpose of sharing this information is to help illustrate additional challenges experienced in certain geographical areas so sites can better understand their communities.
- Ms. Davis asked if the COVID-19 pandemic was expected to challenge the successful accrual of underserved populations and how those challenges should be addressed. Dr. McCaskill-Stevens reiterated Dr. Sharpless's point about flexibilities to improve trial operations in these times should help.
- Ms. Smith asked if there has been any similar analysis looking at the accrual of adolescent and young adults (AYA) to NCI trials. Dr. McCaskill-Stevens agreed this was a unique challenge that NCI is trying to address by bridging institutions and programs that serve both adults, AYA, and children.

NCRA Clinical Trials Working Group
Dr. Ann Geiger

Dr. Geiger offered a brief background on her expertise and role at NCI, and shared she has been appointed Executive Secretary of a new working group under the NCRA. She then offered NIH's definition of clinical trials and shared that low participation is a concern because they often provide a patient's best opportunity for the highest quality of care.

Dr. Geiger reviewed the working group's functional statement and clarified the broad charge will present challenges, but the group is comprised of an expert selection of clinicians, investigators, and advocates. She then outlined the working group's timeline: they will meet throughout the remainder of 2020 and then submit a final report to NCRA and other advisory boards.

Discussion

- Mr. Biru observed that "human subject" (related to NIH's definition of a clinical trial) has negative connotations and Dr. Geiger agreed there needs to be updated terminology, and she prefers the term "participant."
- Ms. Ellis asked whether or not the working group would be looking at financial barriers as well as the barriers facing clinicians' capacity to refer patients to trials and Dr. Geiger agreed these are issues for future discussion.
- Similarly, Dr. Willmarth asked whether or not the group would explore financial incentives for physicians not to refer patients to trials. Dr. Geiger agreed it's a challenge but shared that it's not easily addressed by this working group.
- Ms. Smith shared her experience as a trial participant and that legislative work is being done to assure clinical trials are covered by insurance.
- Ms. Davis asked whether ClinicalTrials.gov would be part of the work of this group and Dr. Geiger shared that it's outside this particular scope but there are other efforts from NCI and the National Library of Medicine aimed exclusively at improving the site.

Advocacy and COVID-19 Discussion
Ms. Anjee Davis and Ms. Amy Williams

Ms. Davis introduced the final session of the meeting and emphasized NCI leadership is eager to learn how the pandemic has affected the community and the working relationship between NCI and advocates.

- Ms. Leach offered that now more than ever NCI and the community should be in communication about upcoming activities to avoid duplicated efforts. Ms. Davis agreed and added that it is also important for community organizations to share information.
- Ms. Williams agreed and suggested that NCI staff be made aware of community events and reminded members that staff are still able to participate virtually to share program updates.
- Ms. Fleshman shared that organizations that work with patients directly could work together to make sure information related to COVID-19 and cancer is spreading farther and faster, especially information about pressing matters like patients avoiding screening or treatment visits for fear of being exposed to COVID-19. Dr. Willmarth agreed and stated avoiding the delay of treatment and screening should be a top priority. Ms. Davis went further to state that one issue her organization has faced has been supporting patients navigating isolation.

- Mr. Biru mentioned that many advocates have connections to support groups that have been meeting virtually and that these convenings could be opportunities to share additional information.
- Ms. Smith described another BMS program, the COVID-19 Advocacy Exchange, a virtual site where patients from around the globe can share information and experiences. She encouraged other members to look at the site and see if it would be helpful to their constituents.
- Ms. Santiago cited information Dr. Sharpless presented on projected increases in mortality and whether that information is available by cancer type. Ms. Williams responded that should investigate further but that the info Dr. Sharpless presented would be made available shortly after the meeting.
- Mr. Bangs encouraged the NCI to consider what barriers will exist to normalizing flexibilities instituted during the pandemic, such as telehealth, and how those barriers can be overcome so that the community is prepared.
- Ms. Ellis shared that a survey she and partners conducted showed patients' concern about being immunocompromised and how that puts them at greater risk during the pandemic outweighed concerns about treatment delays.
- Ms. Davis summarized that health equity has emerged as a priority for the Council and encouraged members to share any data they've collected if they feel like there is valuable information to promote.

Closing Remarks
Ms. Anjee Davis and Ms. Amy Williams

- Ms. Williams reminded members that a summary of this meeting will be made available to all members and the next meeting will be virtual as well.
- Ms. Williams also encouraged members to share any issues or discussions they would like to have at future meetings.
- Ms. Davis encouraged members to share any follow-up thoughts or ideas with her after the meeting. She also described her desire to see an open exchange before the next meeting and that any emergent issues should be shared.
- Ms. Williams agreed and thanked everyone for participating.
- Ms. Davis also thanked everyone and adjourned the meeting.

Certification

I hereby certify that foregoing minutes are accurate and complete.

___August 4, 2020_____ _____ _____

Date Anjelica Davis

Chair

NCI Council of Research Advocates

_August 12, 2020_____ _____

Date Amy Williams

Executive Secretary

NCI Council of Research Advocates