82nd Meeting of the National Cancer Institute (NCI)
NCI Council of Research Advocates (NCRA)
National Institutes of Health (NIH)

Virtual Meeting

March 10–11, 2021

Members Present

Ms. Anjee Davis, Chair
Ms. Malinda Bachini
Mr. Rick Bangs
Mr. Yelak Biru
Ms. Annie Ellis
Ms. Danielle Leach
Ms. Kristen Santiago
Ms. Jaqueline Smith
Mr. Kevin Stemberger
Dr. Nicole Willmarth

Speakers

Dr. LeeAnn Bailey, Branch Chief, Integrated Networks Branch at NCI, Center to Reduce Cancer Health Disparities (CHCRD)
Mr. Rick Bangs, Chair, SWOG patient Advocate Committee, SWOG Cancer Research Network (SWOG)
Dr. Debra L. Barton, Associate Dean, Research and Rackham Graduate Studies, University of Michigan
Dr. Marie A. Bernard, Deputy Director, National Institute on Aging (NIA); acting Chief Officer, Scientific Workforce Diversity
Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations (OGCR), NCI
Dr. Roxanne E. Jensen, Program Director, Outcomes Research Branch, Division of Cancer Control and Population Sciences (DCCPS), NCI
Dr. Ned Sharpless, Director, NCI
Ms. Maureen Clark Szemborski, Program Analyst, Office of Government and Congressional Relations (NCI)
Dr. Robin C. Vanderpool, Chief, Health Communication and Informatics Research Branch, Division of Cancer Control and Population Sciences (DCCPS), NCI
Ms. Amy Williams, Acting Director, Office of Advocacy Relations (OAR); Executive Secretary, NCRA, NCI

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Day 1: Wednesday, March 10, 2021

Welcome and Opening Remarks
Ms. Anjee Davis and Ms. Amy Williams

Ms. Williams opened the meeting, welcomed the Council members, and reviewed the meeting agenda. Ms. Davis reviewed the conflict of interest rules for the meeting and confirmed that a quorum of members was present. She provided brief opening remarks and encouraged attendees to share stories of the communities they represent and NCI leadership to incorporate these stories into their efforts.

NCI Director's Update
Dr. Ned Sharpless

Dr. Sharpless began by remarking that despite the many challenges, 2020 has been a productive year for cancer research and expects that progress to continue and expand in the future.

He went on to describe a virtual visit to NIH by Dr. Jill Biden during which she expressed appreciation for the work of NCI staff and was informed about recent advances in cancer research. In Dr. Biden's subsequent in-person visit to Virginia Commonwealth University's Massey Cancer Center, NCI's novel work in community engagement was showcased. He also mentioned that President Joe Biden held a bipartisan meeting on cancer in the Oval office.

Dr. Sharpless indicated the recent launch of NCI's communications for the commemoration of the 50th anniversary of the National Cancer Act of 1971 (NCA-50) is an opportunity to inspire cancer researchers and supporters of cancer research. He hopes this campaign will highlight cancer research progress as well as areas where progress is needed. He showed a public-facing video that is part of the NCI commemoration material.

Dr. Sharpless described the progress of the Cancer Moonshot, an effort that includes 240 research projects and initiatives. He noted funding for the Cancer Moonshot will end in 2023 and the continuation of infrastructure will then be supported by NCI's general budget. A significant number of Moonshot investigators had no prior NCI funding and are new or early-stage investigators, an accomplishment that aligns with NCI's objective of training cancer researchers.

He then provided an overview of NCI appropriations for Fiscal Year (FY) 2020 and 2021. NCI appropriations for FY 2021, which included funding for the Cancer Moonshot initiative and the second year of funding for the Childhood Cancer Data Initiative (CCDI), increased by $119 million. He specified NCI conducted COVID-19-related work using $306 million of supplemental funding awarded in FY 2020 for COVID-19 serology research. The appropriations bill also designated $37.5 million to raise the payline for investigators. He then provided an overview of the NCI paylines for FY2021 and highlighted that to date, there has been significant progress in increase of NCI grant paylines.

Dr. Sharpless updated the Council on the CCDI, which has established four new working groups that will focus on different topics including 1) developing the infrastructure for enhancing data sharing and aggregation of new and existing data, 2) gathering data from every child diagnosed with cancer, 3) developing a national strategy to offer clinical grade sequencing and research of molecular characterization, and 4) developing guidelines and approaches to address crosscutting issues. These working groups will be overseen by a Steering Committee, which will be informed by an Engagement Committee. The first Steering Committee was held last month.

Dr. Sharpless shared a few NCI research highlights including a study showing that fecal microbiota transplant promotes a response in immunotherapy refractory melanoma patients; a study showing there is higher mortality in persistent poverty counties—a discovery made using a new paradigm that will facilitate the study of access to care challenges in different environments; and an update of recommendations for lung cancer screening by the USPSTF. He mentioned an ongoing telehealth and cancer care delivery webinar series and a new Request for Information (RFI) aiming to establish evidence base for telehealth care. He highlighted NCI's chimeric antigen receptor T cell (CAR-T cell) manufacturing program and presented a preview of public-facing video describing this effort. Vector production is also ongoing to support this research.

He briefly introduced the UNITE initiative, an effort established by NIH to address structural racism in biomedical research with the goal of ending racial inequity. He then described the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) initiative, a common Fund initiative that is being administered in part by NCI to create diverse and inclusive faculty cohorts at institutions that are committed to the hiring and development of underrepresented minority faculty. A funding plan will be developed soon. Dr. Sharpless shared there has been a strong response from the extramural community.

Dr. Sharpless provided an update on the NCI Equity and Inclusion Program. This program has an Equity Council, which he co-chairs with Dr. Paulette Gray, and five working groups. For example, Working Group 2 (WG2) focuses on ensuring diversity of thought and background in the cancer research workforce, a subject to be discussed during this meeting. He emphasized the significance of cancer research advocates to cancer workforce development and added that it is important that advocacy supports NCI's diversity and inclusion efforts. Working group members are generating new initiatives and plans to ensure that this is a sustainable effort. He shared that he looks forward to the Council's views and advice on these efforts.

Discussion

- Mr. Bangs asked Dr. Sharpless about the scope of the working groups of the NCI Equity and Inclusion Program, and how those activities relate to grantees such as the National Clinical Trials Network (NCTN). Dr. Sharpless explained that initially, the NCI Equity and Inclusion Program is an internal effort; however, there have been discussions about how to best engage the extramural community and obtain their input. Working Group 1 would like to have a summit on a topic related to cancer health-related disparities. Working Group 3 focuses on NCI culture, but group members are interested in learning about what is working in academic institutions. NCI will also be advised on funding opportunities in inadequately funded areas pertaining to cancer health disparities by a new initiative established by a working group led by Dr. Electra Paskett. Dr. Sharpless emphasized NCI is the leading funder of cancer health disparities research and has focused on this topic for a long period of time.
- Ms. Davis asked how Dr. Sharpless envisioned cultivating the representation of research advocates in NCI's research efforts on cancer health disparities. Dr. Sharpless responded that NCI welcomes input of advocacy community on the size, scope, and nature of the health disparities portfolio through the appropriate channels. Ms. Williams highlighted that the NCI Office of Advocacy Relations (OAR) has held discussions about equity and advocacy with advocates and organizations. She indicated there is no specific plan in place; however, NCI would like to discuss potential plans with the advocacy community and encouraged Ms. Davis to follow up with Dr. Sharpless. Ms. Davis stated this discussion was helpful and that the conversation about how the NCRA can invest in research advocates is important.

- Dr. Willmarth asked whether there is an application process for investigators that would like to utilize the NCI's CAR-T manufacturing program. Dr. Sharpless explained that currently there are two trials, which he described as pilot programs. Concurrently, NCI is funding individual sites through supplement mechanisms to create standard operating procedures and conduct trials among other tasks. Dr. Sharpless envisions the creation of a cooperative agreement (U) mechanism network to fund multiple sites to generate requisite infrastructure. The Division of Cancer Treatment and Diagnosis is seeking proposals from investigators in need of a vector.
- Ms. Leach asked what the process is for identification of advocates. Dr. Sharpless indicated individuals are identified internally and are nominated to the NCI's Division of Extramural Activities, which vets the candidates using specific criteria. Ms. Leach added that she has had discussions with others in the NCRA about the recruitment process and how to ensure that diversity, equity, and inclusion principles are integrated in collaboration with the NCI process.
- Ms. Smith asked about additional strategies that are being used to increase representation in clinical trials and whether it is possible to change exclusion criteria based on comorbidities. Dr. Sharpless mentioned the NCI and other national societies are ensuring exclusion criteria are appropriate for cancer trials. The most successful approach to increasing minority accrual is that of the minority-serving sites through the NCI Community Oncology Research Program (NCORP). WG1 in the Equity and Inclusion Program is interested in addressing this issue and the NCI will be seeking external advise on this issue in the near future.
- Ms. Santiago shared that LUNGevity is exploring developing quality measures to increase awareness of the new USPSTF guidelines for cancer screening and added that they would like to collaborate with others. Dr. Sharpless commented NCI welcomes their help and would like broader uptake of this modality and emphasized its large underutilization—with unclear reasons—despite evidence showing lung cancer screening reduces lung cancer mortality. He mentioned there is a lack of adoption of these guidelines by primary care doctors and noted a more integrated and forceful communication around cancer screening is welcome. Ms. Santiago responded LUNGevity is also looking at primary care providers as well.
- Ms. Ellis suggested that overlaying poverty counties with NCI-designated cancer centers and NCORP sites would be helpful. He indicated there are challenging structural barriers to providing care in these communities in addition to access issues and that while telehealth may help, there is much research to be done through NCI and DCCPS. Ms. Davis agreed that telehealth has been helpful. She referenced the impactful study Dr. Sharpless presented that used the persistent poverty paradigm and commended that increasing accrual to clinical trials has been made a priority. Dr. Sharpless commented that persistent poverty does overlap with rurality, but these notions are not the same. NCI is interested in using new research paradigms, including persistent poverty, to help target underserved areas. Ms. Davis added that there are cultural nuances to why clinical care and clinical trial accrual is not high in rural communities, and noted she would like to see if there is an overlay of travel to cancer centers and NCORP sites.
- Ms. Smith shared that she has observed the burden of traveling to clinical trial sites on patients and how it can exclude individuals from participating in a trial. Dr. Sharpless agreed that burden on patients does matter in clinical trial design. NCI cannot directly address this issue but can fund research on these barriers.
- Ms. Davis commented on the challenge of uptake of biomarker testing by health care providers. She asked whether this is an opportunity to increase engagement and buy-in by community practices and what the potential role of NCI with healthcare providers would be.

Dr. Sharpless explained that NCI views its role as supporting the scientific findings that drive care, but it does not provide treatment recommendations. NCI can conduct the research that can be motivating to cancer centers to adopt recommendations based on NCI science.

- Ms. Leach asked whether NCI would conduct a PSA campaign around biomarker testing. Dr. Sharpless stated that is an interesting idea and described the approaches NCI uses to educate both clinicians and patients. He added NCI could possibly generate a more visible resource. NCI could further discuss this with the Food and Drug Administration (FDA).

NIH UNITE Initiative
Dr. Marie A. Bernard

Dr. Bernard shared the events of 2020 put a spotlight on the reality of racial injustice and the responsibility of all to address this issue and prompted a series of discussions that led to identification of initial issues and informed next steps, and culminated in NIH's commitment to address structural racism through the UNITE initiative. Dr. Bernard presented an overview of the objectives and current tasks of the five interconnecting committees in UNITE.

- The U Committee aims to understand stakeholder experiences through listening and learning by soliciting information from internal committees, refining and expanding a qualitative data collection plan, and publishing a request for information (RFI) to seek input on how to improve racial and ethnic inclusivity and diversity of the research workforce.
- The N Committee aims to establish new research on health disparities/minority health/health equity (HD/MH/HE). This group proposed multiple Common Fund initiatives, including an initiative that is focused on investigator-initiated transformative research and Minority serving institutions (MSIs). This group will also examine portfolios with NIH-wide stakeholders and conduct an analysis of current investments in HD/MH/HE research.
- The I Committee is looking to improve the NIH culture and structure for equity, inclusion, and excellence by providing data on the composition of the NIH workforce and leadership to understand barriers. Efforts of this group include expanding recruitment efforts for NIH investigators from underrepresented groups and establishing an anti-racism steering committee.
- The T Committee aims for transparency, communication, and accountability with internal and external stakeholders and works with the Office of Communications and Public Liaison (OCPL) to identify and correct any NIH policies or practices that may have helped perpetuate structural racism. This committee will launch an internal awareness campaign and will diversify the portraiture around the NIH to be more representative of diversity in science.
- The E committee is looking at the extramural research ecosystem and is focused on changing policy, culture, and structure to promote workforce diversity by reporting grantee demographics in an NIH Databook and developing programmatic proposals focused on career pathways, institutional culture, NIH processes, and MSIs.

Dr. Bernard summarized the initial recommendations of UNITE and emphasized that to date 22 centers, institutes, and offices have signed on to support the NIMHD FOA focused on structural racism and discrimination on health disparities/inequities. Internal NIH actions, such as policy changes that promote anti-racism and remove barriers, are also being implemented. She encouraged the scientific community to provide feedback on NIH approaches to advance racial equity, diversity, and inclusion within the research workforce through the RFI published by the U Committee. Dr. Bernard briefly described the UNITE initiative committees' organization highlighting that every institute and center are represented in these committees.

Discussion

Ms. Williams began the discussion by mentioning that as part of the research ecosystem and partners to researchers, research advocates should be aware of the RFI requesting feedback on how to improve inclusivity and diversity in the workforce. She added that it is important that advocates understand how NIH is addressing these issues.

- Ms. Davis asked whether UNITE was hoping to obtain input from the advocacy community and how that input could be framed. Dr. Bernard stated the committees are expecting that multiple research advocacy groups will reach out to their membership and provide a summary of their viewpoints through the RFI. She encouraged advocates to respond to the RFI individually.
- Mr. Bangs asked for clarification of the scope of "diversity" (e.g., how far reaching is the diversity, equity, and inclusion?) that is part of the UNITE initiative. Dr. Bernard responded diversity, equity, and inclusion is aiming to ensure everyone is included at the table. She specified UNITE is focusing on structural racism because of the events of 2020 and emphasized that NIH sees these efforts as beneficial to all in the scientific community. Mr. Bangs indicated it is important to think broadly. Dr. Bernard noted that the committees' constitution (only one institute director and at least one person who is not usually seen in a leadership role chair each committee) has been helpful in thinking broadly.
- Ms. Davis asked that from UNITE initiative's perspective, what challenges early-career investigators face and which structural issues investigators would like to see addressed. Dr. Bernard shared that according to a survey of extramural researchers and institutions, early-career investigators have faced many issues due to the COVID-19 pandemic (e.g., no access to laboratories and colleagues) as well as lack of appropriate mentoring, barriers to success faced by underrepresented groups, and compensation disruptions. NIH is addressing some of these issues and welcomes feedback on how to continue to address these challenges.
- Mr. Biru asked about how NIH plans to ensure that the workplace is devoid of hostility. Dr. Bernard stated that NIH would assemble a steering committee, akin to the anti-harassment initiative, to hear individuals' experiences and consider what systems should be put in place so concerns can be voiced. NIH would also produce an awareness campaign and require that centers and institutions adopt a racial equity plan. This framework could then be used as an example by extramural institutions.
- Ms. Davis asked whether NIH would provide support for PIs to engage in the conversation about workplace hostility. Dr. Bernard explained that a foundational education is needed and would be provided by NIH; however, the format is still under development. Ms. Davis stated this support would be very helpful and would serve to prepare future research advocates.

NCI Equity Council
Dr. LeeAnn Bailey

Dr. Bailey began by mentioning that CRCHD supports the National Outreach Network and recognizes the value and need for research advocates. Dr. Bailey then went on to provide an overview of NCI Equity Council, which is comprised of leaders committed to ensuring NCI has a robust research portfolio to address cancer health disparities, nurturing a workforce that is representative of those it serves, as well as cultivating and sustaining a community at NCI that is diverse in thought and representation.

Dr. Bailey noted that there are parallels between the Equity Council's efforts and the UNITE initiative. The Equity Council also has five work groups that are comprised of members with

diversity in expertise, career development, and race and ethnicity. The Enhancing Research to Address Cancer Health Disparities Work Group focuses on looking at cancer health disparities research and identifying and fostering innovative research to support ongoing efforts. The Ensuring Diversity of Thought and Background in the Cancer Research Workforce Work Group will generate recommendations and proposals for the current training efforts in the NCI intramural and extramural communities. The Promoting an Inclusive and Equitable Community at NCI Work Group directs its efforts to fostering an opportunity for promotion of inclusive and equitable communities within NCI's workforce and across the organization. The Systematic Tracking and Evaluation of Equity Initiatives Work Group evaluates all the initiatives and establishes common metrics and measures of success. The Communication and Outreach for Equity Initiatives Work Group is comprised of OCPL representatives who help with messaging and dissemination of information.

Dr. Bailey indicated NCI is committed to making substantial change in the short term—a Quick Win. She described the Early Investigator Advancement Program (EIAP), as an example. Dr. Bailey closed her remarks by indicating the similarities between the challenges in creating and developing a cohort of investigators and a group of advocates.

Discussion

- Ms. Davis asked what the initial feedback from early-career scientists was and whether there are clear Quick Wins that the EIAP was able to address. Dr. Bailey shared there were a number of applicants, specifically those from underrepresented minority groups, that applied to R01s unsuccessfully, indicating there is a need for technical assistance, mentoring, and training. Thus, a comprehensive approach has been undertaken to nurture those investigators that are in the pipeline as well as those that will be applying.
- Ms. Davis further asked whether senior PIs representing communities of color are involved in mentorship. Dr. Bailey explained that matchmaking is occurring, however, there are few investigators that fit those criteria. The Continuing Umbrella of Research Experiences (CURE) program has a successful pipeline approach. Dr. Sharpless added that there are two schools of thought on how to increase faculty diversity; the pipeline and the cohort approaches. NCI is interested in using both approaches and determining what works best. He noted this is a problem for NCI—there are not enough underrepresented faculty receiving grants.
- Dr. Willmarth asked whether the Equity Council has looked into the peer review process to determine whether there are biases in the selection of awardees. Dr. Bailey stated the UNITE initiative is looking into this. Dr. Sharpless noted the Ginther gap has been a longstanding pernicious problem. The leading hypothesis is that there is implicit bias at time of review. Addressing this issue is challenging; however, it is a top priority for the UNITE effort and the Equity and Inclusion program at NCI, which are developing pipelines and cohorts, and finding novel approaches to solve this issue.
- Mr. Bangs shared that the diversity and inclusion issues are not unique; they exist in other organizations. He asked which entities may provide best, good, or emerging practices in this area. Dr. Bailey mentioned that one subgroup in the Equity Council is focused on conducting a landscape analysis and determining the practices that have worked to capitalize on those elements that have been successful and provide implementation of those elements.
- Ms. Davis asked how the research advocacy can support the ongoing development of early-career investigators. Dr. Bailey mentioned multiple ways advocates can engage in this process at different levels (e.g., study sections, advisory boards). She added that dissemination of information regardless of the setting is critical.

Advocacy and Equity Discussion
Ms. Anjee Davis and Ms. Williams

Ms. Williams transitioned the group to a discussion on how to bring equity to research advocacy. She mentioned OAR, NCI, and the community are an ecosystem and a partnership, and asked members to share their existing perceptions on this issue. Ms. Davis added that specific efforts are essential to intentionally bring in underrepresented populations into research advocacy panels. She mentioned that only in the past 5-6 years they have been able to support patients that represent the breadth of populations and asked members for their thoughts on how NCRA can help develop a pipeline of research advocates that is representative of all communities.

- Dr. Willmarth agreed the community, NCI, and OAR form an ecosystem and indicated that non-profit research funders also play a large role because early-career investigators generally apply for non-profit grants prior to applying for federal grants. More cohesive approaches (e.g., examining biases in peer review) would help keep the workforce diverse. Ms. Davis agreed and added non-profit organizations can encourage diverse representation as early investigators engage with research advocates so that they learn what this engagement looks like.
- Mr. Bangs indicated that a landscape analysis would be helpful. He shared SWOG encountered various challenges (e.g., structural barriers) and described the efforts to address them. For example, they brought in individuals that did not have extensive research advocacy experience. Sharing and building a consensus around this issue would be beneficial.
- Ms. Davis asked what the number of needed research advocates is. Ms. Williams indicated organizations and centers would have to work together to define that number. She noted this is related to the challenge of over tapping good advocates. A key question is how to ensure that there is a cadre of good advocates that can help different organizations. Ms. Davis agreed and noted that replacing good advocates would be a challenge. Ms. Williams added that mentoring as well as bringing junior advocates would be beneficial; however mentoring is not always successful.
- Ms. Santiago noted that advocacy jobs compensation is low. She suggested educating the young workforce about different career pathways, including research advocacy.
- Ms. Davis noted compensation is a relevant issue with underserved populations. Mr. Biru shared that the type of advocate a person becomes depends on factors such as socioeconomic status.
- Ms. Ellis noted that not all members of the Patient Advocate Steering Committee receive compensation, which is a barrier to the recruitment of a diversity of voices—There is no pathway to obtain the experience needed to become part of the Steering Committee.
- Ms. Davis indicated that compensation may influence whether a person becomes involved in advocacy and there is a large disparity in compensation rates. Training on how to participate in conversations around the value of patients' time would be beneficial because advocates are providing valuable input and time. Ms. Smith agreed and shared that advocates may be perceived as self-serving if being compensated; however, people are profiting from advocates' lived experience.
- Ms. Williams and Ms. Davis asked whether members would like to have a separate and focused meeting to fully discuss diversity, equity, and inclusion of research advocates so that contributions would be owned by the community and the output shared by all. Ms. Davis noted there was consensus from the group that this would be a priority for NCRA. A meeting may be set up to discuss diversity, equity, and inclusion of research advocates.

- Ms. Williams will follow up with each member after this meeting to obtain perspectives. She will generate next steps and share them with the group.

Budget and Legislative Update
Ms. Holly Gibbons and Ms. Maureen Clark Szemborski

Ms. Gibbons provided an update on the transition of the Biden administration. She noted all 50 democrats in the Senate are expected to vote in favor of the confirmation of President Biden's nominee for Health and Human Services (HSS) secretary, Xavier Becerra. Vice President Harris will provide the tie breaking vote if needed.

She reviewed Biden cabinet confirmations. To date, 14 cabinet members have been confirmed and hearings for other nominees are underway. The Senate has not yet confirmed Dr. Eric Lander to lead the White House Office of Science and Technology Policy. Dr. Lander joined the administration on January 25 as President Biden's science advisor and along with President Biden and Vice President Harris hosted a bipartisan meeting to discuss opportunities to continue to advance cancer and biomedical research, as mentioned by Dr. Sharpless.

Ms. Clark Szemborski updated the Council on the new 117th Congress. Democrats gained control of the House and are now the majority in the Senate. This is the most racially and ethnically diverse congress in history and has a record number of women. This freshman class of Congress includes multiple people with a scientific background.

Ms. Clark Szemborski went on to provide an overview of House and Senate leadership. Ms. Clark Szemborski then described changes in leadership of the House Energy and Commerce, the Senate Health, Education, Labor and Pensions (HELP), and Appropriations committees.

Ms. Gibbons described the passage of the American Rescue Plan Act of 2021. She then reviewed the timeline of coronavirus relief packages over the last year noting that the American Rescue Plan Act of 2021 does not include funds for NIH but does provide funding to HSS to support all aspects of continued COVID response. This relief package also includes extensive funding and policy provisions to provide relief to families and to support public elementary and secondary schools. Restart costs for research and lost productivity are not included; however, the Research and Investment to Spark the Economy (RISE) Act was introduced in congress authorizing $25 billion in support to U.S. researchers and $10 billion for NIH. Appropriators may aim to address this issue during the FY 2022 appropriations process.

President Biden's budget proposal will be released later than usual, which is not uncommon for a transition year. Ms. Gibbons indicated it is likely that FY2022 could begin with a continuing resolution.

Day 1 Wrap-Up

Ms. Williams thanked Ms. Gibbons and members and outlined the agenda for Day 2 of the meeting; 1) a report from the ad hoc group for clinical trials enrollment and retention and 2) NCI's plans for request of applications related to telehealth research. She reminded members that there was a discussion focused on telehealth during the last 81st meeting and indicated there will be substantial advocate engagement in NCI's efforts on telehealth research.

<u>Day 2: Wednesday, March 11, 2021</u>

Welcome and Opening Remarks
Ms. Anjee Davis and Ms. Amy Williams

Ms. Williams began by thanking presenters and members for the discussion of Day 1 and went on to forecast the topics for the day. Ms. Davis reviewed the conflict of interest rules for the meeting

Centers on Telehealth Research & Cancer-Related Care
Dr. Roxanne E. Jensen and Dr. Robin C Vanderpool

Dr. Vanderpool outlined the timeline for NCI's telehealth activities that emerged after the onset of the COVID-19 pandemic. DCCPS formed the Telehealth Working Group, created a Request for Applications (RFA) P50 Telehealth Centers Concept, and released an RFI requesting information from research communities, health care professional societies, and patient advocate organizations on their experiences with telehealth and perceived scientific gaps in telehealth cancer-related care.

Dr. Vanderpool reviewed the reasons for the dramatic increase in use of telehealth for cancer-related care following the onset of the COVID-19 pandemic and clarified that the p50 RFA is focused on patient-provider (synchronous) telehealth.

Telehealth use to deliver cancer-related care is expected to continue past the COVID-19 pandemic. However, there are multiple research gaps such as a limited established evidence base for integrating telehealth into models of cancer care delivery. Dr. Vanderpool went on to describe the responses obtained through the RFI requesting information on telehealth and telehealth research gaps. In total, 46 responses were received and specific themes were identified.

- What cancer care delivery models are well-suited to telehealth? Respondents reported interest in supportive care options as well as services across the cancer control continuum. Patient education and other opportunities for research were also reported.
- What process and health outcomes can be used to evaluate the delivery of telehealth care? Respondents suggested patient-level (e.g., healthcare utilization), system-level (e.g., cost-effectiveness), and healthcare provider-level (e.g., burn-out of providers) outcomes.
- How can patient-centered communication be supported in telehealth interactions? Respondents raised various questions including how non-verbal cues are interpreted via telehealth.

Health equity concerns were also raised by respondents and were grouped into three areas: benefits, access, and delivery.

- Respondents commented that one of the most significant benefits of telehealth was travel burden for different patients (e.g., medically-fragile patients). Caregivers were also mentioned as benefitting from telehealth care during a webinar.
- There was concern about factors affecting access (e.g., lack of broadband internet connection). Respondents also offered suggestions to address these research gaps.
- There was concern about whether delivery of telehealth is equitable. Telehealth care may be impacted by various factors (e.g., language barriers). Respondents raised other concerns such as whether the patient care experience is comparable to an in-person visit.

Dr. Vanderpool went on to describe the Centers of Telehealth Research for Cancer-Related care P50 RFA, which was created to develop a telehealth-focused evidence base across the cancer care continuum and requests proposals of large and pragmatic trials—focused on health disparities and access to care—that will be conducted in a real-world clinical environment using innovative technology and research methods. The goals of this RFA are to create national centers for advancing cancer-related telehealth research; establish a robust evidence base for patient-centered, sustainable

telehealth models of cancer care delivery; and evaluate and disseminate those evidence-based models. Dr. Vanderpool closed her remarks by reviewing the design of the research centers and illustrating examples of the pragmatic trials and pilot projects.

Discussion

Ms. Davis introduced the discussion by listing some of the comments made by viewers, such as state licensure, expiration of state policies, and need for additional support for access to data plans by underserved groups. She asked the members to share insight into specific questions, health equity issues, or real-world issues patients that could inform research efforts.

- Ms. Smith shared that there is a need for patients to understand their coverage, for insurers to offer blanket coverage for telehealth visits, and for proper reimbursement of these visits.
- Ms. Davis responded that economic studies will drive behavior and shared that state and local societies are fighting telehealth because patients are obtaining care in other states. The rapidly approaching expiration of coverage is also causing anxiety. Ms. Davis noted that there is a policy component to how telehealth is adopted, which may result in insurmountable barriers. She wondered whether there was insight from the RFI on policy issues. Dr. Jensen responded that the RFI responses were obtained in summer 2020 and the healthcare delivery system changes so fast, which makes it difficult to understand it. She noted there is a need for research in the telehealth area and this is an opportunity to ensure telehealth use continues because it is a valuable resource to cancer patients and survivors. Researchers must be flexible as the healthcare delivery system changes. Dr. Jensen predicts the P50 effort will result in strategies that other investigators can adopt. Information on state and federal policies is helpful and must be taken into account by investigators as they conduct their research.
- Dr. Davis stated she has observed that accessing claims data can be a challenge and asked whether investigators could collaborate with large data groups to obtain access to claims data. Dr. Vanderpool noted that claims data has been the main source for telehealth usage over the past year. Dr. Jensen added that the scope of their effort is different; it is expected that investigators will collaborate and support other investigators to determine how to get the data and conduct telehealth research. She asked members to share comments about telehealth specific to cancer patients and survivors because one goal of their work is for cancer patients and survivors from this research.
- Ms. Santiago indicated telemedicine is great; however, some patients like personal connection and are concerned that in-person visits will not be possible. Providers and patients have also commented that they cannot get second opinions due to state licensure issues; which is an issue for lung cancer patients.
- Ms. Bachini noted obtaining a second opinion in different states has not been an issue for patients in her organization.
- Ms. Leach stated that obtaining second opinions has been a challenge for the brain tumor community (clinicians and patients); there are coverage issues for second opinions as well as issues with access to trials and experts in other states.
- Ms. Santiago indicated that it is not clear whether providing an opinion is practicing medicine and many institutions do not want providers practicing medicine where they are not licensed; thus, many physicians have stopped providing second opinions.
- Ms. Davis stated there is a desire and potential for telehealth use to qualify patients for clinical trials. However, there is confusion in the healthcare community about what they can and cannot do to qualify a patient and around what can be done at the home institutions and

the site. This confusion creates barriers. Ms. Leach indicated that for her organization, the FDA has been responsive to clinical trialists and patients as issues have emerged.

- Dr. Jensen noted that as a result of the RFI, they have received comments and have had discussions about how telehealth and care delivery overlaps with clinical trials. She stated that this feedback helps focus their work so that it is beneficial for patients.
- Dr. Willmarth spoke about the ability to bring experts together to consult on cases as a benefit of telehealth. She mentioned she is aware that there are concerns about confidentiality with telehealth use.
- Ms. Davis mentioned this feedback does help formulate the questions that should be asked to better inform telehealth process and research. She asked members to share other thoughts on how to gain better understanding of this topic.
- Mr. Bangs stated he appreciates the work being done by DCCPS and shared that advocates at SWOG are very passionate about COVID-19 adaptations including telehealth research. Advocates have documented concerns, which they would be happy to share, and are currently lobbying for this type of research. He asked how all these efforts would come together across the NCI into a cohesive entity that drives immediate outcomes. Dr. Jensen indicated that efforts like the P50 concept are necessary; however, there are other domains of telehealth that need research. She added they welcome ideas to leverage their resources and indicated that this is a good time to submit grant applications. Ms. Williams will provide contact information to Mr. Bangs for follow up.
- Dr. Vanderpool shared that a webinar will be conducted once the P50 effort is in the NIH guide to inform the extramural community on details (e.g., deadlines). Dr. Vanderpool will share the webinar information with Ms. Williams. She indicated investigators are encouraged to consider the extension of the research to real-world practices and networks.
- Ms. Williams thanked Dr. Vanderpool and Dr. Jensen and noted this is an important project in terms of advocacy awareness and connecting the dots across the cancer landscape. Advocates are well-poised to help inform and bring awareness to this. She added this is the beginning of an ongoing conversation.

NCRA Ad Hoc Working Group on Clinical Trials Enrollment and Retention Report
Dr. Debra L. Barton and Mr. Rick Bangs

Mr. Bangs and Dr. Barton briefly introduced themselves. Mr. Bangs proceeded to describe the composition of the working group and thanked NCI *ex officio* members and Dr. Ann M. Geiger for her leadership and guidance.

This Working Group set to identify opportunities to promote research aimed at identifying the most successful strategies for improving patient enrollment and retention in cancer clinical trials particularly for patients from underrepresented and minority populations. This effort focused on financial costs (i.e., direct and indirect out-of-pocket costs and productivity losses; actual versus perceived) of participation in cancer clinical trials and consideration was given to researchers, clinicians, sponsors, and other health care organizations in addressing financial burdens. The Working Group focused on adult cancer patients and survivors enrolling in and completing treatment, symptom management, and cancer control trials funded in part or total by NCI.

Dr. Barton reviewed the framing questions used to guide the literature review, discussions, and recommendations. Four of seven framing questions related to financial costs whereas the other three questions were related to interventions. The literature review revealed that existing published and ongoing studies were inadequate to address any of the framing questions.

The Working Group's recommendations included the primary framing question, the gap not answered by the literature, the recommendation, and the final outcome. She highlighted that in every recommendation, a main consideration is that underserved populations needed to be included. Dr. Barton and Mr. Bangs proceeded to outline the first six recommendations.

- To determine to what extent costs are a barrier to enrollment in and completing clinical trials the recommendation is to identify specific types of financial costs and concerns, and the extent of cost barriers.
- To determine what specific costs contribute the most to patients not enrolling or completing clinical trials, the recommendation is to develop methodology to collect data for those participating in clinical trials.
- To determine how these cost barriers differ across underserved populations, the Working Group recommends developing methodology to understand the role of social determinants of health in clinical trial participation in diverse populations.
- To determine how specific costs most likely to contribute to patient decisions are distinct from costs of cancer care outside the trial setting, the group recommended generating evidence to understand the role of different types of payers and insurance plans as a barrier or facilitator to clinical trial participation for various populations. A special consideration is how routine care is covered in connection to the clinical trial. Data generated would have substantial policy implications.
- To determine effective approaches to helping cancer patients and survivors overcome cost barriers to participation in clinical trials, the Working Group recommended creating and evaluating interventions aimed at reducing cost barriers, aligning decision-making stakeholders on operational details and specifications, and establishing strong partnerships across stakeholder groups.
- To determine what steps researchers, clinicians, health care organizations, regulators, and policymakers can take to reduce excess participant costs, examining whether COVID-19 related adjustments to clinical trial requirements may reduce cost barriers is recommended.

Mr. Bangs described additional recommendations for NCI, including ensuring that NCI central IRBs and grantees understand the distinction between potentially coercive incentives and justifiable reimbursement. He noted FDA guidance is not clear about this distinction. Ms. Ellis noted that it was disappointing that there was not enough evidence in the literature to make actionable recommendations.

Discussion

- Ms. Davis commented the literature review did not yield evidence as was hoped. She asked whether there is a plan for young onset cancers to be included in a similar study. Mr. Bangs noted the adolescent and young adult segment does bear some of these burdens and the Working Group hoped their effort would benefit others. There is additional need for work and study of costs for that group. Ms. Williams indicated that such a study will be considered for future discussion.
- Dr. Willmarth suggested adapting clinical trial design to reduce the number of visits, which would reduce the cost to the patient. She also noted patients could do more standard of care treatments in the community sites, instead of the clinical trial site; however, this may be prevented by the administrative burden on institutions.
- Mr. Bangs said the Working Group emphasized the need to obtain input from stakeholders (institutions and payers) as well as the FDA. This input, along with establishment of appropriate expectations is critical.

- Dr. Barton agreed that clinical trials may increase costs unnecessarily, and as the Working Group recommended, data is needed to understand and address these issues. The Working Group agreed the lessons learned through the COVID-19 experience should not go to waste.
- Mr. Biru asked how the inadequacy of data and doing nothing as more data is collected balanced. Mr. Bangs responded interventions and collection of data (e.g., landscape analyses) could occur in parallel. Dr. Barton agreed and indicated that there may be some easy goals that could be worked towards while collecting data. Institutions are likely implementing some approaches (e.g., providing transportation) and collecting data, which can be used to inform existing programs. She added that any changes should be implemented only if based on data to prevent wasting resources. Mr. Bangs stated the data gap in the literature was very surprising. There was no specific data on out-of-pocket costs for patients receiving cancer treatment.
- Ms. Davis wondered whether any significant understanding was gleaned from the literature review. Dr. Barton stated the Working Group included all that needed to be informed in the report. She added there was no specificity or comprehensivity in the literature.
- Mr. Stemberger asked whether telehealth has any role and whether it is quantifiable. Mr. Bangs stated that telehealth does play a role and it is possible to quantify it. He noted comparative studies are needed. Dr. Barton agreed.
- Ms. Davis asked if the research stemming from the DCCPS proposed P50 mechanism inform the data gaps the Working Group has identified. Dr. Geiger stated one benefit from such a report is that NCI colleagues and leadership are made aware of the need for data collection. She added that investigators conducting financial hardship studies can be encouraged to include efforts that address clinical trials.
- Dr. Sharpless stated it is unsurprising to see that there are areas with data needs. He noted that the transparency around costs of healthcare is rather poor and highlighted that there is new hospital transparency requirement, which may be a useful research opportunity. He agreed with determining the effective COVID-19 adaptations, including telehealth, and continuing to use them. He asked whether data is indicating that coercive incentives are still poorly understood and causing issues for clinical trial accrual. Mr. Bangs noted that in his experience, there have been many concerns raised around coercive incentives and that these concerns subside as people study the FDA guidance. He noted that this is a new process, this information is not common knowledge, and there is no infrastructure; thus, there will be questions. Dr. Sharpless mentioned that this also depends on interpretation by individual IRBs.
- Dr. Willmarth asked if there are barriers to investigators budgeting reimbursement for expenses to patients enrolled in complex trials. Dr. Sharpless mentioned the FDA guidance and the OHRP guidance extension are opinions that help clarify what classifies as coercive reimbursement. Mr. Bangs shared that that once funding is secured and it is confirmed that a specific reimbursement is not coercive, then implementation questions (e.g., who makes the payment?) can be addressed.
- Ms. Davis thanked the Working Group for the extensive summary.
- Ms. Leach motioned that the NCRA *Ad Hoc* Working Group on Clinical Trials Enrollment and Retention Report be approved. Ms. Ellis seconded the motion. The motion passed unanimously.
- Ms. Williams thanked the members for the helpful discussion and presentation. She thanked the Working Group for their work and for creating research-oriented recommendations for the NCI.

Closing Remarks and Next Steps
Ms. Anjee Davis and Ms. Amy Williams

Ms. Williams commented the information covered during this meeting has been relevant to both NCI and the advocate research community. She asked whether members had questions on next steps or information following these discussions.

Ms. Davis asked how the Council should continue to inform Dr. Sharpless and advise this effort, ensuring that the Council tackles efforts that are supportive and informative of the gaps that were identified by the Working Group.

Ms. Williams noted the group will continue the discussion about equity and research advocacy and the advocate workforce pipeline. She hopes to follow up with members to get their insight and noted the board can help prepare for this subsequent discussion by assisting to conduct a landscape analysis. She asked members to contact her with additional insights into the Working Group recommendations and telehealth so that they can be considered by NCI and be discussed during the next Council meeting. Advocates can offer the real world experience and data that can inform efforts such as telehealth research; the collective patient perspective and advocate voice are needed.

Ms. Williams suggested that members review the meeting summary, archived videocast, and presentations and share additional thoughts to begin preparing the next Council meeting's agenda.

Dr. Sharpless suggested that a future date be set to share NCI's response to the Working Group's report and recommendations.

Ms. Williams thanked members, the advocacy office, and Dr. Sharpless. Ms. Davis thanked everyone for their commitment.

The meeting adjourned at approximately 2:30 p.m. EST.