85th Meeting of the National Cancer Institute (NCI)
NCI Council of Research Advocates (NCRA)
National Institutes of Health (NIH)

Virtual Meeting

March 9, 2022

Members Present

Ms. Anjelica Davis, Chair
Ms. Melinda Bachini
Mr. Yelak Biru
Dr. Victoria Buenger
Ms. Melissa Buffalo
Ms. Annie Ellis
Ms. Jennifer Pegher
Ms. Kristen Santiago
Ms. Jacqueline Smith
Mr. Kevin Stemberger
Dr. Nicole Willmarth

Speakers

Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations (OGCR), NCI

Dr. Katrina Goddard, Director, Division of Cancer Control and Population Sciences (DCCPS), NCI

Mr. Ryan Hohman, Vice President of Public Affairs, Friends of Cancer Research, Washington, DC

Ms. Nancy Lenfestey, Advocacy Program Manager, St. Baldrick's Foundation

Ms. Sarah Milberg, Director, Government Relations and Advocacy, St. Baldrick's Foundation

Dr. Norman (Ned) Sharpless, Director, NCI

Ms. Maureen Clark Szemborski, Program Analyst, Office of Government and Congressional Relations, NCI

Dr. Emily Tonorezos, Director, Office of Cancer Survivorship, NCI

Ms. Michelle Tregear, Chief Programs Officer, National Breast Cancer Coalition

Ms. Amy Williams, Acting Director, Office of Advocacy Relations (OAR); Executive Secretary, NCRA, NCI

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Welcome and Opening Remarks

Ms. Anjelica Davis and Ms. Amy Williams

Ms. Williams opened the meeting at 12:00 p.m., welcomed Council members and attendees, and reviewed the meeting agenda. Ms. Davis called the meeting to order, reviewed the conflict-of-interest rules for the meeting, confirmed that a quorum of members was present, and provided brief opening remarks.

NCI Director's Update

Dr. Ned Sharpless

Dr. Sharpless reported on progress around the Fiscal Year (FY) 2022 appropriations spending bill. The proposed budget includes $6.9 billion, a $35 million increase over FY 2021. Until a federal budget is approved, the government will operate under a Continuing Resolution (CR), which holds interim paylines for R01s, R21s, and other grant mechanisms at a very conservative level. Noting the steady increase in appropriations NCI has enjoyed since 2015, Dr. Sharpless expressed hope and expectation that the approved budget will allow for improved paylines.

Dr. Sharpless presented an overview of the commemoration of the 50th anniversary of the National Cancer Act of 1971, which unified the Nation's fight against cancer. The observance offered an opportunity to take stock of accomplishments and acknowledge that, despite many important advances, cancer remains the leading cause of death in the United States.

The White House has made clear that the supercharged Cancer Moonshot is a priority of the Biden-Harris Administration. Over the past 25 years, the cancer death rate decreased steadily from 215 per 100,000 in 1990 to 145.9 in 2019. The new White House mortality goal calls for cutting the cancer death rate in half (i.e., 73 deaths per 100,000) within the next 25 years. Dr. Sharpless noted that cancer mortality has declined in nearly every state. However, some areas of the country and some population groups have not done as well, which underscores the connection between cancer health disparities and the intersection of mortality, geography, and race. Achieving the White House mortality goal will require progress in multiple areas, including prevention, screening, improved therapies, and continued success in tobacco control.

The President and First Lady Biden have announced a call to action on cancer screening to catch up on the estimated 10 million cancer screenings missed because of the COVID-19 pandemic. NCI will work with its designated cancer centers and other networks to make clear that cancer screening is a national priority. Possible approaches for getting cancer screening and care back on track include identifying and implementing better ways to conduct screening at home, through mobile services, and through community health networks and ensuring that everyone equitably benefits from available tools to prevent, detect, and diagnose cancer. Blood-based multi-cancer detection tests (MCDs) are one technology of great interest across the federal government. NCI has issued a Request for Information (RFI; NOT-CA_22-033) on readiness of MCDs for NCI-sponsored clinical utility screening trials.

Dr. Sharpless described NCI activities and policies to ensure kindness and mutual respect in the workplace. These include clear policies; tool kits and training; incorporation of anti-harassment into onboarding exercises and annual performance evaluations; and a workplace civility anti-harassment program coordinated by a committee of senior representatives.

Dr. Sharpless summarized progress in NCI-funded studies and research initiatives.

- A study co-authored by the NCI Division of Cancer Control and Population Sciences (DCCPS), Centers for Disease Control and Prevention (CDC), and extramural researchers used accelerometer-based measurements to estimate preventable deaths. The study found that a small increase in physical activity could avert 7 to 17 percent of deaths per year, suggesting that a small behavioral change at the population level could have an important impact on cancer.
- The Childhood Cancer Data Initiative is a proving ground for technologies with potential applications to adult cancer. Beginning this spring, tumor tissue from around 3,000 children with hard-to-treat cancers will be sequenced and characterized each year. The National Childhood Cancer Registry seeks to integrate data for research purposes, serving as a sort of pediatric version of the Surveillance, Epidemiology and End Results (SEER)-Centers for Medicare & Medicaid Services (CMS) registry.
- Cervical cancer remains a significant opportunity for improving health equity through prevention. Despite progress in cervical cancer screening, human papillomavirus (HPV) testing, and HPV vaccination, Hispanic and black women have higher rates of cervical cancer than do women of other racial and ethnic groups; women in rural regions (e.g., Appalachia) have a higher incidence of cervical cancer mortality than do women in urban areas. The Federal Cervical Cancer Collaborative is a U.S. Department of Health and Human Services partnership to achieve the Cancer Moonshot goal of accelerating cervical cancer control in Health Resources and Services Administration (HRSA)-supported and safety-net care settings and aims to speed uptake of new screening and management guidelines and uptake of HPV vaccination. A recently published study found that the 9-valent HPV vaccine would prevent nearly all cervical precancers (84%) and invasive cancers (90%) among major racial and ethnic groups. Adding HPV35 to vaccines could prevent a small percentage of cancers, with greater potential impact among black women. These findings highlight important considerations for future vaccine design.
- Investigators conducted an epidemiological analysis that revealed important clues about why some treatments work better in some patients than in others. They connected a genetic variant of human leukocyte antigen (HLA) to poor clinical outcomes across immunotherapy agents used in cancer treatments. The HLA variant may serve as a useful marker for response to treatment.
- A study that assessed fecal microbiota profiles, dietary habits, and use of commercially available probiotic supplements in melanoma patients found higher dietary fiber was associated with significant improvement in progression-free survival of patients receiving immune checkpoint blockade (ICB) treatment. A larger study is needed to understand the interaction between the gut microbiome and response to ICB treatment.

Dr. Sharpless announced the appointment of Dr. Brigitte Widemann as Special Advisor to the Director for Childhood Cancer. The Special Advisor position denotes the special concerns around childhood cancer treatment and outcomes. Dr. Widemann was selected based on her international reputation in this field, her collaboration with NCI intramural researchers, and her familiarity with NCI's childhood cancer portfolios.

Discussion

Ms. Davis thanked Dr. Sharpless for his report.

- Ms. Ellis asked about equitable distribution of funding for population groups and regions that experience poorer outcomes. Dr. Sharpless mentioned the congressionally mandated Institutional Development Award (IDeA) program that broadens geographic distribution of NIH funding. NCI can be effective by issuing funding opportunity announcements (FOAs) that address specific populations to promote health equity in rural and underserved areas.
- Ms. Santiago noted the importance of using consistent terminology for biomarker testing to increase clarity for patients and improve provider-patient communication. She asked whether there would be value in establishing a federal collaborative for lung cancer similar to the Cervical Cancer Collaborative. Dr. Sharpless responded that trans-government efforts work best when there is a specific need that ties into agencies' missions. For example, environmental exposures in lung cancer likely will be of interest.
- Ms. Davis asked about approaches to implementation of the multi-cancer blood test and the role of the U.S. Food and Drug Administration (FDA). Dr. Sharpless noted multiple scientific considerations, such as overtreatment, but a number of agencies are interested in regulating this test. Obtaining their approval will require development of a clear set of research questions toward conducting clinical trials (CTs).
- Dr. Buenger asked about the role of advocates in supporting work being done under the reinvigorated Moonshot. Dr. Sharpless noted that advocacy likely would be asked to weigh in on immediate priorities and timelines. Requests for information will be issued to solicit input from key stakeholders.

DCCPS Director's Update

Dr. Katrina Goddard

Dr. Goddard provided an update on DCCPS, which focuses on cancer across a continuum of etiology, prevention, detection, diagnosis, treatment, and survivorship. Crosscutting areas of interest to the Division include communications, surveillance, health disparities, decision-making, dissemination of evidence-based interventions (EBIs), healthcare delivery, epidemiology, and measurement. DCCPS aims to reduce the number of people who get cancer, improve early detection and treatments for better outcomes, prevent improper diagnosis, minimize short- and long-term side effects, and, ultimately, increase survivorship.

Over the next decade, the Division hopes to expand evidence-based approaches and screening tools, improve research on machine learning and artificial intelligence, emphasize the importance of diet and exercise, develop prognostic tools for diagnosis of cancers such as ductal carcinoma in situ and prostate cancer, study the impact of climate change on health and behaviors, provide cancer survivors with clinically relevant information and supportive caregiving, and focus on patient-centered communication, care, and coordination.

Participant engagement is vital to research perspectives and data analysis. DCCPS relies on principles of engagement consistent with those outlined by the Patient-Centered Outcomes Research Institute (PCORI). Participant engagement is an ongoing, bidirectional, mutually beneficial collaboration between participants, their communities, and researchers. Participants are included as an integral part of all phases

of research. Community outreach and engagement (COE) involves activities across all research programs (e.g., basic, clinical, population science) focusing on basic science or community implementation of EBIs. NCI-designated cancer centers (NCI-CCs) have received supplemental funding to support COE such as an academic-community partnership between members of the LGBTQ community and basic science researchers to advance research related to the metabolic pathway of HPV-related cancers; development of a "Citizen Scientist Brigade" that will do rotations with basic science research teams; collaboration with a community partner that trains promotores to adapt and implement an e-cigarette prevention program in low-income Hispanic communities; and a series of "deliberation events" with tribal nations to discuss how the CC handles tissue and data from American Indians/Alaska Natives.

The Improving the Management of Symptoms during and Following Cancer Treatment (IMPACT) Consortium is designed to accelerate the use of effective symptom management systems that collect patient-reported data to support clinical responses consistent with evidence-based guidelines. IMPACT will evaluate adoption of integrated electronic systems for monitoring and managing patient-reported symptoms in routine cancer care via partnerships between research centers and community-based organizations. IMPACT patient representatives will participate in the Steering Committee, working groups, and consortium meetings to provide feedback.

The Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network aims to promote and support direct engagement of cancer patients and post-treatment cancer survivors as participants in cancer research. PE-CGS uses such approaches for rigorous cancer genome sequencing programs to better understand cancer patients' experience and help them stay better informed. Network participants include NCRA member Melinda Bachini.

Health disparity and health equity initiatives focus on understudied populations and populations with higher disease burden. The DCCPS portfolio also includes research to identify and address structural, social, economic, cultural, psychological, behavioral, and biological mechanisms contributing to health disparities across the cancer control continuum.

Over the last 20 years, the number of DCCPS awards and the dollar amount awarded to projects focusing on health disparities has increased. In FY 2021, 76.5 percent of funded awards included a specific component or aim related to health disparities. DCCPS identifies gaps in the research portfolio using a data-driven approach informed by the current portfolio, past investments, and data from cancer control efforts and NCI's 2021 Annual Report to the Nation on the Status of Cancer. CDC and SEER data trends reports show widening disparities in incidence and mortality of many cancer types when comparing rural to urban populations. Portfolio analyses showed DCCPS had few projects focusing on rural cancer control.

In the past year, DCCPS also has expanded SEER program coverage from one-third to one-half of the U.S. population. This expansion enables reporting of trends in more refined clinical categories such as histologic subtype, biomarker status, treatment categories, and important population subgroups. For example, the percentage of Hispanic with cancer represented in the SEER registry increased from 45 percent to 69 percent.

DCCPS studies modifiable risk factors such as tobacco use. Adolescent tobacco patterns have become increasingly complex given the greater availability, marketing, and promotion of a diverse set of tobacco products. Existing treatments for smoking cessation developed for use with adult cigarette smokers have shown limited success among youth. There is a critical need for well designed, adequately powered,

behavioral intervention randomized controlled trials (RCTs) for adolescents that consider the developmental and behavioral aspects of tobacco use in this population.

DCCPS is committed to establishing nutrition interventions to improve cancer treatment-related outcomes in cancer survivors. Adiposity, poor fitness, and diet are associated with worse outcomes in cancer survivors, including dose interruptions and toxicities. Approximately 35 percent of U.S. cancer survivors are obese and have poor body composition; less than 17 percent meet general physical activity guidelines, and many have poor fitness. The period just before treatment initiation and during treatment are key timeframes for improving diet and fitness; yet few studies have focused on this period. A new program focused on treatment-related outcomes will be announced in April.

Dr. Goddard outlined DCCPS engagement in trans-NIH nutrition research. DCCPS scientists and the NIH Office of Nutrition Research (ONR) are leading efforts with the Automated Self-Administered 24 Hour (ASA24) Dietary Assessment Tool. Innovation in digital technology will refine ASA24, reduce respondent burden, and further address measurement error. It is the first Common Fund program with a primary and central focus on nutrition research, but ONR has many other nutrition efforts under way to focus on precision nutrition, food insecurity, and nutritional health disparities.

Human interaction with the environment has implications for cancer risk and control, such as physical exposures to radon or ultraviolet (UV) radiation, air and water pollutants, unsafe consumer products, and chemical exposures encountered at work. These exposures can occur repeatedly over a lifetime, have cumulative effects, and play a substantial role in the burden of cancer. The World Health Organization estimates that between 12 and 29 percent of cancers are attributable to environmental factors, not including potentially preventable behavioral or lifestyle factors such as smoking and alcohol consumption.

The International Agency for Research on Cancer has classified more than 120 agents as carcinogenic to humans and more than 400 agents probably or possibly carcinogenic to humans. The Agency has considered the impact of climate change on health; for example, the Oregon wildfires made the air unhealthy to breathe. Measuring exposure is a complex process that involves long-term, prenatal, and parental factors. Researchers must consider timing, changes in exposure over time, and the need for advanced geospatial methods as people relocate.

Discussion

Ms. Davis thanked Dr. Goddard for presenting a helpful summary of DCCPS work.

- Ms. Davis asked how DCCPS activities align with CDC cancer programs. Dr. Goddard reported that she is speaking directly with CDC leadership and other Division work aligns closely with CDC, FDA, HRSA, and other partner organizations on specific topics and programs.
- Dr. Willmarth asked whether there are plans to expand SEER coverage of states that have seen smaller changes in cancer mortality rates. Dr. Sharpless noted that some states opt to participate in CDC's National Program of Cancer Registries rather than SEER. Together, the two cover the entire U.S. population.
- Ms. Davis asked how individual, group, or other research advocacy organizations can partner with DCCPS. Dr. Goddard suggested reaching out to investigators and local organizations that conduct research.

- Ms. Davis emphasized the importance of SEER researchers building engagement with advocates and families.
- Ms. Davis asked Dr. Goddard to describe her vision for the future of health equity. Dr. Goddard emphasized the need for change in the workforce to address health inequities, diversity, and health disparities.

Office of Cancer Survivorship Update

Dr. Emily Tonorezos

The NCI Office of Cancer Survivorship (OCS) was created in recognition of the unique and poorly understood needs of the growing number of individuals who survive cancer for a long time. OCS works to enhance the quality and length of survival of all persons diagnosed with cancer and to prevent, minimize, or manage adverse effects of cancer and its treatment.

Over the last year, OCS developed a model to encompass stages of cancer survivorship that includes individuals diagnosed with early-stage cancer, metastatic cancer, and end-stage cancer. Goals of care include treatment with curative intent, treatment intended to prolong life, and end-of-life care. OCS refined the definition of a *cancer survivor* to reflect advocacy input. An individual is considered a cancer survivor from the time of diagnosis throughout the balance of life. Survivors include those living with cancer and those who are free of cancer.

The NIH Office of Emergency Care Research sponsored the Cancer-Related Emergency and Urgent Care Meeting held in December 2021 to develop research recommendations toward improved outcomes in survivors experiencing or at risk for urgent and emergency cancer-related complications. Many people residing in rural areas receive cancer treatment in urgent care and emergency room (ER) settings due to inaccessibility of these services. There are many challenges to providing adequate care to cancer survivors who must seek care in these settings.

NCI is participating in the trans-NIH Understanding and Addressing Misinformation among Populations that Experience Health Disparities initiative (RFA-MD-22-008). The Initiative aims to improve trust in scientists, understand the proliferation of misinformation (e.g., sources of spread, vulnerable populations, links to health outcomes), and foster health, science, and digital literacy. The Request for Applications (RFA) is especially relevant to cancer survivors who experienced fear and uncertainty during the COVID-19 pandemic and became unwilling to attend long-term, in-person follow-up appointments. Dr. Tonorezos cited a *Journal of Clinical Oncology* paper highlighting Dr. Paul Nathan's work with childhood cancer survivors; the paper suggests that there is no difference in COVID-related ER visits and hospitalizations among cancer survivors than among the general population.

An NCI Cancer Center Cessation Initiative (C3I) Tobacco Treatment Program monitoring cessation in cancer survivors since 2018 has reached over 63,000 oncology patients. C3I has shown the need for more research on tobacco cessation among cancer survivors because of the complexity of health behaviors within this population.

NCI published the RFI Leveraging Clinical Trial Populations (NOT-CA-21-036) in 2021 to encourage survivors to participate in CTs and to provide them with long-term follow-up after treatment.

Dr. Tonorezos described financial hardship supplements to cancer centers. The NCI P30 Cancer Center Support Grant provides supplemental funding to promote collaborations between NCI-CCs and the

Cancer Therapy Evaluation Program's Experimental Therapeutics Clinical Trials Network. This supplement aims to characterize facilitators and barriers to financial hardship screening and use this information to develop and test new screening tools, scale up the current model of symptom screening to collect and document information about financial hardship in electronic health records, and implement and assess an evidence-based financial navigation program in community practices. Supplements funded 11 NCI-CCs; 3 led to successful applications for additional research funds, and 2 were leveraged or expanded to support patients' financial needs.

The Health Information New Trends Survey (HINTS) studies a population of survivors linked to data within the SEER registry. These survivors are asked about information-seeking practices, Internet use, information related to COVID-19, health behaviors and utilization of healthcare, treatment side effects, return to work, primary cancer site histology, and date of diagnosis. Investigators may use these data to deepen their understanding of survivor information sources.

The Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act supported three reports from the Agency for Healthcare Research and Quality (AHRQ): children transitioning to adult-style or adult-based care; care model assessment; and disparities and barriers to long-term follow-up for childhood cancer survivors. Few studies have examined organizational or higher-level barriers that may prevent childhood cancer survivors from participating in long-term follow up. In January 2022, NCI released a Notice of Special Interest (NOSI) to study disparities affecting healthcare utilization and health outcomes among childhood cancer survivors (NOT-CA–22-029). This NOSI aims to address the full spectrum of factors related to childhood cancer survivors.

Dr. Tonorezos noted topics of recent OCS Director's webinars. These include Dr. Stephen Kimani on health disparities and barriers to care in Malawi (January 2022); Dr. Simon Rosser on disparities among sexual and gender minority prostate cancer survivors (February 2022); and Dr. Lixin Song on the use of technology to improve supportive care for cancer survivors and family caregivers (March 2022).

Dr. Tonorezos reported that Dr. Michelle Mollica has joined the Office as Senior Advisor responsible for developing, supporting, and promoting research efforts focused on cancer survivorship. She is scientific lead for several recent FOAs focused on specific aspects of survivorship care.

Discussion

Ms. Davis thanked Dr. Tonorezos for providing an update on OCS.

- Ms. Davis asked whether the HINTS sample accounted for race and ethnicity, if the study was representative of all cancers, and whether nutrition was monitored. Dr. Tonorezos responded that the three registries included in the study covered different ages and cancer types but were not fully representative. It is unlikely that nutrition is included in HINTS; however, several exciting studies of nutrition in cancer survivors have been funded.
- Dr. Willmarth asked about care for patients diagnosed with brain tumors in an ER setting. Dr. Tonorezos agreed that ER diagnosis is particularly important for survivors of childhood brain tumors. The challenge is providing the right information.
- Ms. Davis asked how SEER and other programs align with CTs to better characterize quality of life for cancer survivors. Post-COVID survivorship work identified gaps in care, high risk of recurrence, delayed surveillance, and an inability to schedule appointments. Dr. Tonorezos responded that telehealth approaches and CMS support will improve access to care. HINTS was established to acquire more information about survivors' experiences. The STAR Act will

provide more evidence to identify uniquely susceptible populations.

- Dr. Buenger noted that the Coalition Against Childhood Cancer is preparing for reauthorization of the STAR Act and emphasized the importance of informing the community about reauthorization. She complimented the work OCS is doing related to the Act's survivorship piece. Dr. Tonorezos mentioned a Government Accountability Office (GAO) report on the STAR Act. Dr. Buenger asked for information about the GAO report and other sources for dissemination to the public.
- Ms. Ellis asked how the theme of ending cancer relates to people living with cancer, the expanded definition of *cancer survivor*, and alignment among research, funding, and patient communities. Dr. Tonorezos observed that survivorship is a priority in that it involves treatment for life extension and improved quality of life; there is no sense that survivorship is competing against prevention or treatment efforts for shared resources. The cancer survivor definition applies to late effects of metastatic or end-stage cancer and aims to be inclusive of all individuals living with or having lived with cancer.
- Ms. Davis asked how OCS defines a good quality of life for a survivor and how this aligns with finding the right treatment for survivors. Dr. Tonorezos responded that survivors and family members must be the ones to define a meaningful life for themselves. The role of OCS is to translate, promote, and elevate what survivors and families have to say. Research should support the goals of survivors, family members, and caregivers.
- Mr. Biru commented that the new definition of survivorship is important to those with incurable cancers.

Legislative Update

Ms. Holly Gibbons and Ms. Maureen Szemborski

Ms. Gibbons and Ms. Szemborski presented an overview of authorizing legislation relevant to NCI, including FY 2022 and 2023 appropriations, the America Competes Act, Cures 2.0, the Advanced Research Projects Agency for Health Act (ARPA-H), and the PREVENT Pandemic Act.

Ms. Gibbons noted that the current CR expires February 11, and a proposed extension expires March 15, 2022. She acknowledged the devastating situation in Ukraine and its recent effect on financial negotiations for the FY 2022 omnibus package. Senate Judiciary Hearings for confirmation of Judge Ketanji Brown Jackson will affect the Congressional Calendar.

Ms. Gibbons summarized funding levels in the proposed budget, including $45 billion for NIH and $6.9 billion for NCI, and $1 billion for ARPA-H. Omnibus policy provisions of interest to the cancer research community include extensions of telehealth flexibility and FDA authority to regulate synthetic nicotine not derived from tobacco plants. The latter has created regulatory challenges regarding flavored e-cigarettes.

The President's federal budget proposal for FY 2023 is expected in the coming weeks, kicking off the FY23 appropriation cycle.

Ms. Gibbons listed upcoming retirements within leadership positions and committees relevant to NCI: Senators Blunt, Burr, Leahy, and Shelby and Representatives Brady, Butterfield, Kinzinger, Price, Roybal-Allard, and Speier. These individuals chaired or served on key committees and caucuses

including Biomedical, Childhood Cancer, and Rare Diseases.

Ms. Szemborski reported that retention of telehealth flexibilities would require action by Congress. Related proposals include the Connect for Health Act and the Cures 2.0 Act. In addition to making telehealth flexibilities permanent, Cures 2.0 aims to address CT diversity by dovetailing several NCI efforts in this area, authorizes appropriations for NIH research efforts on long COVID and antibiotic resistance, and authorizes the establishment of ARPA-H.

Both sides of the House and Senate support enhancing America's ability to lead research innovation on the global stage. The Senate and House bills (U.S. Innovation and Competition Act, America Competes Act) are very different. The America Competes Act includes reauthorization for Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs set to expire at the end of FY 2022. A conference committee is developing a package that includes priorities of both chambers.

A draft bill requiring Senate confirmation of the CDC Director—Prepare for and respond to existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemic Act)—was released January 25.

Discussion

Ms. Davis expressed appreciation for the update.

Ms. Gibbons and Ms. Szemborski encouraged Council members to contact them with questions and offered to set up a follow up discussion on the STAR Act reauthorization.

Research Advocacy Training Programs

Mr. Ryan Hohman, Ms. Michelle Tregear, Ms. Sarah Milberg, and Ms. Nancy Lenfestey

Ms. Davis welcomed representatives from three exceptional advocacy programs who joined the meeting to share highlights of their advocate training programs.

St. Baldrick's Foundation: Ms. Sarah Milberg, Director Government Relations and Advocacy, and Ms. Nancy Lenfestey, Advocacy Program Manager

St. Baldrick's is a volunteer- and donor-powered charity committed to supporting research to find cures for childhood cancers and give survivors long and healthy lives. It is the largest nongovernment funder of childhood cancer research grants.

The St. Baldrick's Foundation training program, Creating Advocates through Research Education (CARE), was made possible by an educational grant from Bayer HealthCare. The training provides an overview of key terminology, concepts, and processes involved in clinical trials and drug development. The program aims to train childhood cancer patients, survivors, and caregivers to support them in integrating their perspectives into the research process.

An environmental scan of existing cancer advocate training programs revealed that most were geared primarily toward cancer in adults. This led to the formation of an advisory committee to develop a childhood cancer-focused curriculum. Members include researchers, clinicians, and parents of children with cancer.

Initially planned as a one-day, in-person training session with experts and speakers introducing topics, COVID-19 made this impractical. St. Baldrick's pivoted to a two-pronged approach that includes 12 modules of online training and a comprehensive resource guide for reference and reinforcement after training. The convenience of this model enabled involvement of more participants than a day-long, in-person session.

Recognizing that complex topics may be difficult to absorb, St. Baldrick's took steps to optimize accessibility of resource guide content to increase comprehension and retention. Enhanced design elements such as animation and graphics, color schemes, audio narration, and layout were employed to fit different learning styles. Quizzes are included at the end of each module.

Following online testing in November 2021, two rounds of participants have completed the training. Trainees provide feedback via a survey; responses inform improvements to the training for each rollout. Feedback shows graduate learners felt the training is comprehensive, easy to navigate, and includes an appropriate level of detail; they report that narration is helpful for retaining information and the resource guide will be useful for future review.

Friends of Cancer Research: Mr. Ryan Hohman, Vice President, Public Affairs

Mr. Hohman presented work from the Friends of Cancer Research (*Friends*), a leading U.S. advocacy organization working to drive collaboration among partners from every sector to power advances in science, policy, and regulation that speed lifesaving treatments to patients. *Friends* aims to provide patients with the tools necessary to effectively communicate with researchers, developers, and regulators to improve and advance health outcomes.

Friends created a resource for the advocacy community through progressforpatients.org, a free-access, self-guided online training platform that allows users to learn at their own pace. The training resource is designed to equip patients to understand CTs and empower them to ask questions and provide input. The resource has reached a variety of audiences, including recently diagnosed patients who are considering participation in a CT as well as every type of patient advocate.

The training comprises four modules on the FDA, research and development, regulatory flexibility, and advocacy. Each module takes an average of two hours to complete and includes quizzes to improve retention and understanding. The last module, "Advocacy in Action," offers jumping-off points for patients and caregivers to see how advocates have changed the face of cancer and other types of research.

Over 500 patients and advocates have completed the training in the past five years, and more than half have gone on to participate in drug development and the CT regulatory process. More than 70 percent came to the resource through existing partnerships with patient advocacy organizations.

Friends provides an advocate matchmaking service designed to connect qualified advocates with public and private partnerships.

Project Trained Empowered Advocates for Community Health (TEACH) was developed by *Friends* to empower black women through education and outreach to effectively engage with researchers and clinicians and increase participation of black women in cancer-focused clinical trials. *Friends* expanded its advocacy education work in collaboration with the Black Women's Health Imperative and Stand Up to Cancer and created the online education course as a tool for black women across the country to learn more about their health and how to empower themselves and future generations. *Friends* now has trained more than 100 Empowered Patient Partners.

National Breast Cancer Coalition: Ms. Michelle Tregear, Chief Programs Officer

The National Breast Cancer Coalition (NBCC) perceives advocates as essential to advancing progress toward ending cancer. Advocates' challenge is to question everything related to cancer, collaborate on meaningful issues, explain the advocate perspective, report to constituencies, and provide accurate oversight. Advocates are responsible to a patient constituency (e.g., via a patient organization); affected by the specific disease or condition; and knowledgeable, trained, and confident about participating in research and decision-making processes around science and medicine.

NBCC developed the Project Leadership Education Advocacy in Development (Project LEAD) to partner with scientists to design breast cancer research, become involved with CTs, write on breast cancer issues, present work at conferences and meetings, review proposals for research programs, and serve on decision-making boards. NBCC also created the Project LEAD Institute, a six-day course designed for the public to cover basic science, immunology, and epidemiology to promote advocacy development.

Development of Project Lead began with an initial meeting of scientists to develop the key competencies within the curriculum. Faculty and instructional designers drafted and revised course materials and provide annual updates to all core courses. Adult learning principles built into the program include one-hour lectures as the primary means of presenting new material, lectures interspersed with multiple small group discussions of content facilitated by prior LEAD graduates and faculty or postdocs, case study analyses, group projects, and pre-work completed asynchronously in the month prior.

Project LEAD graduates from all 50 states and 35 countries act as resources to local communities, interpret information, perform scientific peer review and clinical trials, form national policy committees, and serve as members of Artemis Project research teams. They have helped shape the research agenda, strengthen evidence-based medical policies, change breast cancer conversation and focus, and create a model for other advocacy groups, PCORI, the Department of Defense (DOD), NCI, AHRQ, FDA, etc., and international advocacy efforts.

Ms. Tregear described the DOD Breast Cancer Research Program (BCRP), which was brought about through NBCC advocacy. More than 100 advocates serve on the BCRP integration and peer review panels.

Discussion

Ms. Davis expressed appreciation for the work these three groups are doing. NCI greatly appreciates the work they are doing to improve cancer research. She asked them to share advice and lessons learned from their experience developing and providing training.

- Mr. Hohman commented that it is best not to reinvent the wheel. It is better to make programs known and learn lessons from other programs. Ms. Milberg emphasized the importance of defining goals. Ms. Tregear recommended checking what is available in emerging programs in cancer and other disease-specific fields, as well as learning the process of committee selection and how to work with a committee, be flexible, and use available tools.
- Dr. Buenger asked how the three groups teach advocates to advocate for the larger community with the expectation that they will report to their constituencies. Ms. Tregear responded that training facilitators can incorporate community-building and boundaries within settings that model NBCC's advocacy mission. Mr. Hohman commented that there is a balance because sometimes "I" statements have value.

- Ms. Davis reported that there is a research efficacy program that values in-person meetings for advocates to practice responding to questions and engaging with scientists. Researchers must practice how they interact with patients and be able to facilitate communication without judgment.
- Ms. Ellis asked how advocates are screened for training, including the bare minimum of time a new advocate needs and how organizations address situations when someone invests the time but is not a good fit. Ms. Tregear responded that recruitment is broad and does not consider financial circumstances or location. Training is scholarship based. Training may be harder for younger women with families whose voices need to be represented to reflect the diversity of breast cancer. Ms. Milberg commented that it is important to recognize that the program is intensive and should start with new people who have an interest in research, but it will be placed on the website for public review.
- Dr. Buenger commented that bereaved parents within the childhood cancer community are valuable resources. Ms. Lenfestey agreed that the passion of the bereaved parent is unparalleled. Ms. Milberg commented that most advocates are not patients and their perspective is different. The program therefore has attempted to recruit survivors to provide these perspectives. Mr. Stemberger emphasized that advocates often are bereaved persons.

Closing Remarks and Board Administration

Ms. Anjelica Davis and Ms. Amy Williams

Ms. Williams thanked Mr. Hohman, Ms. Lenfestey, Ms. Milberg, and Ms. Tregear for their presentations on advocate training programs and their thoughtful comments during discussion.

Ms. Davis noted that the board must approve the minutes of the 85th NCRA meeting. Ms. Pegher made a motion to approve. Ms. Ellis seconded the motion, and the motion passed unanimously.

Ms. Davis thanked Council members for their active participation throughout the meeting. She requested their input on topics for the next meeting.

Ms. Williams noted that Council meetings will continue to be virtual at least through July 2022. Guidance on in-person vs. virtual meeting platforms will be updated this summer.

The meeting adjourned at 3:55 p.m. EST.

Certification

I hereby certify that foregoing minutes are accurate and complete.

July 5, 2022
_____ /S/
Date Anjelica Davis
Chair
NCI Council of Research Advocates

July 5, 2022
_____ /S/
Date Amy Williams
Executive Secretary
NCI Council of Research Advocates