

**78th Meeting of the National Cancer Institute (NCI)
NCI Council of Research Advocates (NCRA)
National Institutes of Health (NIH)**

**NIH Campus
Bethesda, Maryland**

Monday, May 20, 2018

Members Present

Mr. David Arons, Outgoing Chair
Dr. Gregory Aune, Incoming Chair
Mr. Rick Bangs
Ms. Julie Fleshman
Dr. Sue Friedman

Ms. Danielle Leach
Ms. Jennifer Pegher
Mr. Roberto Vargas
Ms. Amy Williams, Executive Secretary

Speakers

Dr. Jaime Guidry Auvil, Director, Office of Data Sharing, NCI
Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences, and Acting Director, Center for Global Health, NCI
Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations (OGCR), NCI
Ms. M.K. Holohan, Director, OGCR, NCI
Dr. Douglas Lowy, Acting Director, NCI
Ms. Candace Maynard, Senior Program Manager, Office of Communication and Public Liaison, NCI

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Welcome

Dr. Gregory Aune and Ms. Amy Williams

Ms. Amy Williams opened the meeting at 9:30 a.m. and welcomed the Council members. New members Mr. Roberto Vargas and Ms. Jennifer Pegher introduced themselves. New member Ms. Anjee Davis was unable to attend. Dr. Gregory Aune reviewed the conflict of interest guidelines for the meeting and the meeting agenda.

Budget and Legislative Update

Ms. M.K. Holohan and Ms. Holly Gibbons

Ms. M.K. Holohan reviewed the composition of the 116th Congress. Ms. Holohan reported on the status of the fiscal year (FY) 2019 and 2020 budgets.

- In FY 2019, Congress coupled the Labor–HHS and Defense spending bills. Funding for the NIH in FY 2019 increased by \$2 billion, which includes a \$74 million (M) increase for the NCI. A total of \$400 M has been appropriated for the Cancer MoonshotSM in FY 2019.
- The FY 2020 President’s Budget Request includes a 12 percent reduction for the NIH, a 14.6 percent reduction for the NCI, and an allocation of \$50 M for a new Childhood Cancer Data Initiative.
- The FY 2020 budget request is based on the Budget Control Act of 2011. Congress will need to pass a law to establish budget levels that will allow growth in the NIH and HHS budgets, as well as vote on increasing the debt limit.
- NCI staff attending hearings of the House and United States Senate Committees on Appropriations in April 2019 heard bipartisan support for increasing the NIH budget.

Ms. Holly Gibbons identified recent Congressional briefings and events to which the NCI was invited and reviewed implementation of the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018 (Childhood Cancer STAR Act).

- Many of the NCI’s interactions with Congress are through congressional briefings and events. NCI experts are invited through foundations, nonprofits, advocacy groups, or cancer-related caucuses to participate as presenters and panel members.
- Such events provide an opportunity to update Congressional staffers, advocates, and members of the community on the return of the country’s investment in cancer research.
- Upcoming Congressional briefings and events include the Small Business Technology Council Award to NCI’s Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs on June 11, 2019; the American Association for Cancer Research (AACR) e-cigarette briefing featuring representatives from the NCI, U.S. Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) on June 12; and the AACR briefing on human papillomavirus and cancer prevention on June 27, 2019.
- The Childhood Cancer STAR Act was signed into law in June 2018 with strong bipartisan support in both the Senate and House and directs the NIH and NCI to focus on childhood, adolescent, and young adult cancer survivorship research, as well as on

biospecimen collection and biobanking resources. In January 2019, the NCI released a request for applications (RFA) for research directly aligned with the Act. Applications currently are under review.

- The NCI convened the Enhancing Biobanking for Childhood Cancers meeting on May 13, 2019, with representatives from the childhood cancer research and advocacy communities, to discuss challenges and opportunities in this field, particularly emphasizing specimen collection and clinical trials. A meeting summary will be available soon.
- Other provisions in the Childhood Cancer STAR Act focus on ensuring that childhood cancer expertise continues to exist on NCI advisory bodies, including NCRA. The STAR Act also stipulates that the National Cancer Advisory Board, a presidentially appointed board, will have a permanent seat for a member with pediatric expertise.

Discussion

- Dr. Aune asked about current legislation, specifically mentioning Congresswoman Debbie Wasserman Schultz's bill regarding cancer survivorship. Ms. Gibbons explained that the OGCR encourages offices and committees that are developing legislation to initiate a formal request for technical assistance from the NCI as early as possible.
- In response to a question from Ms. Danielle Leach regarding Senate interest in creating a caucus on cancer survivorship similar to the House's Congressional Caucus on Cancer Survivorship, Ms. Gibbons stated that she has not heard of such interest. Members of the Senate, however, are welcome to join the House caucuses.
- Mr. Vargas noted that researchers at the University of California, San Francisco (UCSF) have partnered with local advocates and policymakers to develop policies to limit access to e-cigarettes and asked about policy efforts being undertaken at the federal level. Ms. Gibbons noted that several proposals are underway, including one recently introduced by Congresswoman Rosa DeLauro. Ms. Holohan added that the NCI, although not a regulatory agency, is following activities of federal regulatory agencies that are currently working with the e-cigarette industry, such as the FDA. She suggested visiting the websites of the American Cancer Society or Tobacco-Free Kids for further information on federal efforts. Ms. Gibbons suggested that if Mr. Vargas has a government relations colleague at UCSF, that individual should attend the AACR briefing planned for June, which will likely include updates from the FDA and CDC.
- In response to a request from Mr. David Arons, Ms. Holohan elaborated on appropriations report language. The reports that accompany spending bills come from subcommittees and provide more details than the bills. Report language may include observations recognizing, for example, that a particular program or research area exists. Report language also may contain requests for an update. Congressional staffers receive requests for report language from organizations and lobbyists and work with the NIH and NCI to obtain input on such questions as whether the language is an observation, a direction, or an earmark that cannot be moved. When the report language is finalized, it is formally released to accompany the legislation that has passed. The President's Budget Request is accompanied by a volume of "significant items" from the reports about which Congress has requested more information. If a report is requested, the reports go directly to the appropriations committees that have requested them.

NCI Director's Update

Dr. Douglas Lowy

Dr. Douglas Lowy, Acting Director, NCI, updated participants on long-term trends in cancer mortality, NCI activities, the NCI budget, and future areas of emphasis for NCI research.

- Dr. Lowy noted that the last few decades have shown a sustained decrease in mortality rates for most cancer sites. Only a few have increased, the largest being liver and bile duct cancer.
- The latest Annual Report to the Nation on the Status of Cancer—a joint effort of the NCI, CDC, and North American Association of Central Cancer Registries—will be published soon. This year's report will focus on young adults with cancer.
- NCI has formed two new working groups, the internal Working Group on Screening and Early Detection and the Board of Scientific Advisors ad hoc Working Group on Prevention. The Screening and Early Detection Working Group will address screening as a standard of care for high-risk populations and improvements in standards of care. The Prevention Working Group seeks to prioritize important areas in cancer prevention research that may warrant additional resources.
- Dr. Lowy identified four areas of emphasis in future NCI research: childhood cancer, investigator-initiated research, health disparities, and drug resistance.

Childhood Cancer

- NCI and NIH pediatric cancer research grants have increased from 600 in 2014 to more than 1,000 in 2018. NCI awards represent more than 80 percent of pediatric cancer research awards. Mortality rates in pediatric cancer declined by 20 percent from 1999 to 2014, primarily resulting from research on cancer treatment. Advances in leukemia and solid tumor treatment, however, have lagged behind, and pediatric cancer treatments can result in long-term side effects.
- Echoing Ms. Gibbons on what the Childhood Cancer STAR Act directs the NCI to address, the NCI and extramural researchers are exploring ways to improve quality control, sharing of biospecimens, and integration with related systems, such as databases, to allow optimal use of biospecimens.
- The President's Budget Request for FY 2020 includes \$50 M per year for 10 years for childhood cancer research. Proposals for using the funds include the Childhood Cancer Data Initiative, with the goals of federating disparate databases, making them interoperable, and augmenting information about childhood cancer treatment and outcomes. Aggregate information may allow greater insight into why some children relapse while others do not and lead to more tailored treatment and better outcomes.

Investigator-Initiated Research

- The FDA approved a large number of cancer drugs in 2018, most of which resulted from investigator-initiated research. The NCI provides strong support for investigator-initiated research, with a 30 percent increase from 2014 to 2018 in the number of major research

grants, as well as a 25 percent increase in the number of awards to young investigators. Research Project Grant (R01) applications increased by almost 50 percent from 2013 to 2018. A consequence of the growth in applications is that demand is more than twice the supply, with a budget increase of only 20 percent. Beginning in FY 2020, the annual Cancer MoonshotSM allotments will decrease by more than 50 percent. Continued support of investigator-initiated research will require working within the NCI's regular appropriations.

Health Disparities

- Cancer health disparities affect underrepresented minorities and rural populations. African Americans have higher mortality rates than Caucasians, although the gap between the two populations has been decreasing.
- In the past, the incidence of cervical cancer was significantly higher in African Americans than Caucasians, although the gap is closing. The NCI is supporting research into self-sampling for cervical cancer screening, which potentially will be approved by the FDA within 3 years.
- Compared to urban areas, rural areas face the challenges of higher rates of poverty, lower educational attainment, a higher proportion of elderly individuals, lower access to health services, and higher rates of behavioral risk factors, such as tobacco use and obesity. Disparities in cancer mortality between rural and urban areas continue to increase, although mortality rates have decreased in both populations. One NCI goal is to prevent disparities between urban and rural areas from increasing.

Therapeutic Resistance

- Therapeutic resistance takes two forms—primary resistance, in which a patient does not respond to treatment, and secondary, in which a patient initially responds to treatment but then becomes resistant. Therapeutic resistance is the primary reason that patients succumb to cancer. Dr. Lowy provided examples of several treatment advances that help combat drug resistance, such as the new medication lacrotrectinib, a kinase inhibitor, which the FDA approved in 2018 for any tumor type with the abnormal TRK fusion protein.

Dr. Lowy thanked outgoing NCRA chair Mr. Arons for his commitment and constructive involvement in leading the NCRA.

Discussion

- Mr. Arons asked Dr. Lowy for his perspective on what is at stake in terms of the decreasing appropriations for cancer research, to help advocates articulate their budget concerns. Dr. Lowy suggested pointing to examples of patients who are alive today because of advances in cancer research, as well as pointing to those who have died to highlight the need for more research. To date, the return on investment in cancer research has been extraordinary. The dramatic increase in grant applications is unique to the NCI

among all NIH Institutes and Centers, which presents a significant opportunity to advance cancer research.

- In response to a question from Ms. Julie Fleshman regarding the increase in R01 grant applications, Dr. Lowy explained that the number of applications submitted per applicant has increased, rather than the number of new applicants. The number of applications for pediatric and immunotherapy research has increased substantially.
- Mr. Vargas inquired about the specific strategies being considered to address health disparities, including the types of studies and training of racial and ethnic minority researchers and those in rural areas. Dr. Lowy noted that the NCI is working to strengthen cancer research among minorities through early training programs and cited a pilot program to visit middle schools and increase students' interest. New research related to disparities includes exploration of the reasons behind American Indians' increased risk for renal cancer and higher rates of liver cancer among multiple racial and ethnic groups.
- Dr. Aune noted that the goals of the Childhood Cancer Data Initiative also could apply to health disparities and asked how advocates can help that Initiative succeed. Dr. Lowy suggested participation in a June meeting sponsored by the NCI that will bring advocates, researchers, and patients together to develop a framework for the initiative.
- Discussing whether current data sets have a good representation of minority and rural patients, Dr. Aune asked how health disparities affect the completeness of data sets. Dr. Lowy noted that the NCI is beginning to discuss best practices for treatment of children who cannot travel to major cancer centers and whether consolidated data can help develop best practices.
- Mr. Arons mentioned a new kinase-inhibitor medication that the FDA has approved to treat many different types of cancer. In response to a question about its implications, Dr. Lowy suggested that the NCI could consider the feasibility of translational research that focuses on targets that account for a high percentage of tumors. He noted that having effective inhibitors is critical, and he anticipates progress in pancreatic cancer research through the RAS Initiative, even before development of a KRAS mutation inhibitor.

NCI Data Sharing

Dr. Jaime Guidry Auvil

Dr. Jaime Guidry Auvil reviewed the work of the Office of Data Sharing (ODS), a new component of the NCI Center for Biomedical Informatics and Information Technology (CBIIT).

- Dr. Auvil defined data sharing as the practice of making research data and metadata available for use by the broader research community. Ninety percent of research participants want their data to be shared with other researchers, and 80 percent are willing to share data with for-profit entities. Concerns about marketing, data theft, discrimination, and potential legislation exist, but research participants thought that the benefits of data sharing outweigh these concerns.
- Data sharing increases statistical power and scientific value by integrating data from multiple studies, and it enables and facilitates reproducibility and validation of research results, investigation of a wide range of research questions, and innovation of methods and tools for research.

- The mission of the ODS is to create a comprehensive data-sharing vision and strategy for the NCI that advocates for the proper balance between broad and equitable data sharing with the needs of the research and participant communities.
- More than one entity in the NCI addresses data sharing. The ODS will help centralize data-sharing efforts, including helping to develop, coordinate, and advise on the ethical implementation of data sharing and management policies and practices.
- NIH and NCI data-sharing policies state that investigators must share any information necessary to understand, develop, or reproduce published research.
- The current NIH data-sharing plan stipulates that final research data from NIH-supported activities must be broadly available within 1 year of acceptance on PubMed Central. All Cancer MoonshotSM-funded projects must make publications available within 4 weeks.
- The ODS is setting up an Economic, Ethical, Legal, and Social Issues program for data sharing.
- Current barriers to interoperability include lack of standardized formats for data and metadata standards; lack of searchable, interconnected data repositories; and lack of broad consent language or uniform consent processes. Policy and procedural obstacles include lack of resources to format data files, inability to effectively track and manage data digitally, and the lack of criteria for how to choose the best database to house data. ODS is exploring options to alleviate these barriers.
- Efforts across the NCI to enhance data sharing include promoting open access licenses; supporting the development of standards and metrics for broad data interoperability; and working with NCI departments, offices, and centers to implement data-sharing policies and procedures.
- The NIH data management process includes three types of data distribution: unrestricted access, registered access requiring a sign-in step, and controlled access for certain types of data that may be identifiable. Genomics is the largest area in which the controlled access process is used.
- Using the Childhood Cancer Data Initiative as an example—the goals of which are to federate, augment, and use data to improve treatments and outcomes—Dr. Auvil outlined a cancer data ecosystem that encompasses multiple steps in integrating a vast array of cancer research data, from basic research to clinical care. Many entities are involved in building the ecosystem; the NCI Cancer Research Data Commons, a data-sharing project within the CBIIT, is one component.
- One aspect of connecting patient-level data is developing privacy-preserving patient record linkage across multiple data sources, data types, and research studies. An encrypted unique patient identifier allows linkage of diverse data across multiple databases.
- The ultimate goal of data sharing is to support precision oncology, which requires deep biological understanding; advances in scientific methods; advances in tools, informatics and technology; and advances in data management and analytics.

Discussion

- In response to a question from Mr. Rick Bangs, Dr. Auvil explained that the ODS is enlisting subject-matter experts to identify data types that are useful to share in addition to clinical trials data.

- Participants discussed whether the ODS would address the incorporation of electronic health records, development of consent materials for low-literacy or non-English-speaking patients, and workforce development to staff the new data initiatives. Dr. Auvil explained that these activities are not within the ODS' purview, but they are being pursued by other groups within the NCI and NIH.
- Responding to a question from Dr. Aune, Dr. Auvil explained that most information regarding whether data requests have resulted in new publications or successful grant applications comes from the National Center for Biotechnology Information; the ODS is working to extract NCI-specific information.
- Dr. Aune referred to the cancer data ecosystem and asked how advocates can develop and apply the ecosystem to pediatric patient populations, as well as others. Dr. Auvil noted that educating the scientific community about the benefits of bringing data together and the ways in which data could be used would be helpful.

Rural Health Program

Dr. Robert Croyle

Dr. Robert Croyle presented about accelerating rural cancer control research and noted that the NCI began focusing on rural health as an area of research at the same time as other agencies, such as the CDC, Centers for Medicare and Medicaid Services, and the Robert Wood Johnson Foundation. The NCI uses the U.S. Department of Agriculture's Rural-Urban Continuum Codes to define rural for funding purposes.

- Approximately 14 to 15 percent of the U.S. population lives in rural (i.e., non-metropolitan) counties. Echoing Dr. Lowy, Dr. Croyle noted the characteristics of rural areas in terms of lower access to health care.
- Portfolio analysis revealed that only 3 percent of NCI Division of Cancer Control and Population Sciences (DCCPS) grants focus on rural populations, and Dr. Croyle noted the need for good quality data, absent of confounders (e.g., politics, emotion).
- A DCCPS 2017 report showed an increased in cancer mortality in rural populations, when compared to urban populations.
- Even as overall mortality from cancer has decreased, per the Annual Report to the Nation on the Status of Cancer, the rural-urban disparities have grown, and the trend in cancer mortality rates in rural versus urban populations is diverging, rather than converging.
- NCI's Rural Cancer Control Research Initiative started in May 2016; the NCI, through outreach and planning efforts, has engaged the rural health community to develop ideas on how best to address rural health disparity.
- Dr. Croyle elaborated on the NCI's role as a research agency in leveraging the scientific community and supporting partnerships and training, noting that some established NCI investigators are long-time rural health researchers.
- The Center to Reduce Cancer Health Disparities grants contain rural health components, and the National Community Oncology Research Program conducts outreach to rural areas.
- Dr. Croyle announced that the NCI has partnered with the Federal Communications Commission to address the broadband health connectivity gap in U.S. rural areas.

- NCI Cancer MoonshotSM initiatives and NCI-designated Cancer Centers are addressing rural cancer control research, and the NCI has scaled up funding opportunities from administrative supplements to RFAs to support rural health research.
- The NCI Cancer Trends Progress Report is an online resource on population cancer data accessible to the public.
- Dr. Croyle closed by noting the remaining challenges in rural cancer control research and future directions.

Discussion

- In response to a question from Dr. Aune regarding whether the trends in mortality would change geographically if lung cancers were excluded, Dr. Croyle explained that although lung cancers are the leading driver of mortality in the United States, mapping other cancers, such as colon cancer, also shows disparate rates in rural areas.
- From the Board's perspective, Dr. Aune asked about the goals of the initiatives supporting rural cancer control research. Dr. Croyle replied that a major focus of the NCI as a cancer organization is to connect with the rural health organizations. Policy makers have requested that the unintended consequences in opening non-sustainable rural health clinics and access to care in term of Medicaid expansion be closely monitored.
- Mr. Vargas wondered how the multidisciplinary collaborations were addressing such barriers as access to care or social determinants of health. Dr. Croyle explained that the greatest need is to join non-NIH funds that can pay for services to NIH monies for research. Forming partnerships at the local level and engaging small, rural health-related organizations are two other options.

NCI Cancer Information Service (CIS)

Ms. Candace Maynard

Ms. Candace Maynard provided an overview of the NCI CIS, a program that has been operational since 1975. The CIS provides up-to-date cancer information to the public, disseminates the NCI's key messages and latest cancer information, and directly interfaces with the public.

- The CIS is not a replacement or substitute for a clinician or health care services.
- The CIS is located in Seattle, Washington; is contracted with the Fred Hutchinson Cancer Research Center; and is staffed by approximately 60 cancer information specialists and smoking cessation counselors. Fifty percent of the staff are bilingual.
- The CIS is a free multilingual service, which can be accessed by phone, postal mail, live chat, email, or public inquiries.
- The five most frequent request are for information about a specific cancer type, treatments and managing side effects, hospital or clinic screening programs, available support or economic assistance, and obtaining a physician or second opinion.
- The former CIS Director retired in December 2018, and this is a transitional period for the group.
- The CIS will be transitioning to a new email address, NCInfo@nih.gov; upgrading to a dedicated queue for clinical trials; and increasing promotions and outreach efforts.

- The Revitalizing a Natural Resource campaign was launched with the goal of increasing external and internal use of the CIS. Four primary audiences were identified and reached through NCI social media outlets, stakeholder networks, and paid social media advertising. A specific call to action for each target group was developed. The NCI Office of Communications and Public Liaison will disseminate the deliverables (i.e., main messaging tools), and all products created will be sharable.
- The CIS creative concept development started in December 2018. One concept—highlighting “can” in cancer—was developed, pretested, previewed by NCI leadership, and finalized. Ms. Maynard described the targeted promotional effect.
- In closing, Ms. Maynard remarked on the CIS’ long history with advocacy groups and invited the NCRA to continue the conversations with the CIS staff.

Discussion

- Mr. Bangs encouraged exploring partnerships with the NCI Clinical Trials Network.
- Mr. Arons pointed out the opportunities for the CIS to interact with the NCI Intramural Research Program (IRP). Ms. Maynard explained that efforts have been focused on designing messaging for the IRP and program staff. Because of time constraints, only a small portion of the available products was discussed. The CIS is planning a May 30, 2019, product release to the external community.
- Ms. Maynard commented on the CIS’ long-standing relationship with the research community. The CIS supports accrual to large-scale clinical trials, including the NCI MATCH trial.
- In response to a question from Dr. Aune about messaging to youth, Ms. Maynard noted that most of the interactions are with patients and pediatric patients in the higher age categories (e.g., age 18 and higher). Messaging is tailored to the questions received.
- Mr. Vargas wondered about plans for disseminating non-digital products and ensuring access in rural areas. Ms. Maynard explained that implementation plans for access in rural populations will be through health care providers, and messaging is designed for that audience.

Closing Remarks

Dr. Gregory Aune

Ms. Amy Williams

Ms. Williams thanked all the participants for attending the meeting. Dr. Aune reviewed the meeting main messages and remarked on future engagement in promoting the Childhood Cancer Data Initiative. Members shared their perspectives on NCI’s ODS, the efforts of the rural health program, and the CIS outreach.

The meeting adjourned at 3:40 p.m.

Certification

I hereby certify that foregoing minutes are accurate and complete.

8-6-2019

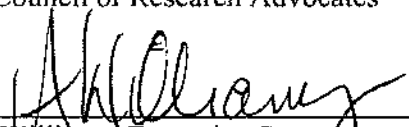
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Gregory Aune, Chair
NCI Council of Research Advocates


Amy Williams, Executive Secretary