NATIONAL INSTITUES OF HEALTH National Cancer Institute Board of Scientific Advisors

Report from the BSA *Ad Hoc* Working Group in Support of Efforts to Enhance Community Cancer Research in Quality Care

December 3, 2024

Table of Contents

Functional Statement	1
Charge to the Working Group	1
Functioning of the Working Group	1
Opportunities Aligned with the NCI Mission	2
Working Group Recommendations	2
Suggested Efforts to Enhance the Ability to Provide High Quality of Cancer Control and Care	2
Suggested Efforts to Increase the Capacity to Conduct Cancer Research in Communities	6
Roster	8

Functional Statement

The NCI Board of Scientific Advisors (BSA) will convene an ad hoc Working Group to provide general guidance related to the development of efforts to increase community capacity to conduct cancer research and to enhance the ability to provide high quality cancer care. The Working Groups recommendation are to ensure that cancer research and the resulting interventions are applicable to and can be implemented in all communities. Of particular importance will be addressing the significant disparities in cancer outcomes in rural communities and in other populations impacted by challenges to optimal care and developing measurable metrics for assessing improvements. In addition, the Working Group will consider how best to identify and engage appropriate partners and recommend criteria (e.g., geography, cancer type, etc.) for consideration in the development of future efforts.

Working Group membership will include select NCI advisory board members, as well as individuals with expertise in community engagement, community-based participatory research, health inequities, cancer clinical trials, implementation science, health policy, and other domains.

The Working Group will advise the BSA, other relevant NCI Boards and Committees, and the NCI Director.

Charge to the Working Group

Dr. W. Kimryn Rathmell, NCI Director, charged the Working Group at its initial meeting on 20 May 2024, to provide general guidance related to the development of efforts to increase community capacity to conduct cancer research and to enhance the ability to provide high quality cancer care.

Functioning of the Working Group

The BSA *ad hoc* Working Group in Support of Efforts to Enhance Community Cancer Research and Quality Care was established in March 2024 and held eight virtual meetings on 20 May 2024, 17 June 2024, 26 June 2024, 29 July 2024, 1 August 2024, 29 August 2024, 13 September 2024, and 4 November 2024.

The Working Group is comprised of members of the Board of Scientific Advisors (BSA), National Cancer Advisory Board (NCAB), and Clinical Trials and Translational Research Advisory Committee (CTAC), as well as ad hoc members. The roster includes individuals with expertise in community engagement, community-based participatory research, health inequities, cancer clinical trials, implementation science, health policy, including ex officio members from several federal agencies.

Opportunities Aligned with the NCI Mission

Working Group Recommendations

The overarching goals of these opportunities are to improve the prevention, early detection and treatment of cancer, which will lead to decreased incidence and mortality rates and reduce health disparities.

We recommend that the initial focus should be on cancers of the lung, breast, prostate, colon-rectum, and cervix. Together these cancers account for about 54% of cancer deaths in the US and for an even higher percentage among many underserved populations. Each of these cancer types has prevention and/or screening, as well as treatment approaches that have been shown to reduce cancer-specific mortality rates. Therefore, initial targeting of these cancer types has the greatest likelihood of reducing overall cancer mortality rates in underserved populations over the next 5-10 years. The various recommendations below should be understood in this context.

Suggested Efforts to Enhance the Ability to Provide High Quality of Cancer Control and Care

As noted above, the Working Group recommends initially focusing efforts on cancer prevention and outcomes in breast, cervical, colorectal, lung and prostate cancers and those that are successful could be considered in other cancers.

- 1. Test community-wide approaches that utilize regionally based public-private partnerships essential to expand the reach of lung cancer screening and would align with local needs and priorities in underserved communities. Consider increasing lung cancer screening by bundling it with other cancer screenings such as annual mammography visits or colorectal cancer screening visits to increase cancer screenings. NCI could have grantees adapt evidence-based cancer prevention and early detection strategies and implement them on a larger scale for underserved populations. <a href="https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/implementation/prevention-early-detection_The project goal would be to advance our understanding of how to build complex, regionally-based public-private partnerships that are essential to reducing the burden of cancer in communities.</p>
- 2. NCI, with partner federal and state agencies and other professional and non-profit organizations, could launch a National Plan to Eliminate Cervical Cancer in the U.S. It would focus on HPV vaccination, HPV screening, and optimal treatment for underserved populations, including minority and rural populations (include NCI-designated cancer centers, NCORPs and community cancer centers). NCI would promote partnerships with the primary healthcare provider community including pediatricians, gynecologists and HRSA-funded health centers, including Federally Qualified Health Centers (FQHCs). NCI and sister government agencies could target funding opportunities to develop interventions to address the barriers for the low vaccination and screening rates.

- 3. Develop culturally sensitive mHealth/apps addressing needs of specific underserved populations. Apps could be used to increase cancer screening, reminders for follow-up care and treatment, supportive care and survivorship, clinical trial information and recruitment. Technology-based tools could also be developed to promote guideline concordant first-line therapies for cancer. Multiple partnerships with CBOs, cancer centers and NCORPs could be explored depending on the target population.
- 4. Develop partnerships between rural/underserved communities and cancer centers to increase the use of biomarker testing in cancer diagnosis. This program would include increasing the awareness for biomarker testing through appropriate education (of institution leadership, clinicians and the public) about the availability and value of testing, facilitate testing, and ensuring timely biomarker-directed treatment. Tailor interventions to reduce access disparities, focusing on geographic, racial, and income-based barriers.
- 5. Pilot Community Health Information Technology Support Hubs/Centers, using cancer center's expertise by working in partnership with anchor organizations (such as FQHCs) in remote or underserved areas to implement effective, evidence-based digital health interventions. These have been successfully implemented for tobacco cessation and cancer survivorship. NCI could create infrastructure (U01 grants) with the goal of developing, testing, and implementing sustainable community cancer control interventions.
- 6. Address the digital divide for rural communities to achieve equity in access to digital health innovations and remote cancer care delivery. A health information technology hub and community digital technology liaison could be established in several rural regions. The health information technology (HIT) hub would provide computing and connectivity infrastructure, while the community digital technology liaison would serve to bridge the needs of the community (e.g. digital literacy, mobile health, etc.) with the HIT infrastructure. These structures could be used to implement evidence-based interventions to improve cancer prevention and screening at the partnering rural community sites (e.g., tobacco cessation, HPV vaccination, CRC screening), as well as cancer survivorship care or access to clinical trials. Telehealth services for individuals with active treatment, palliative care and survivorship care could be piloted through the HIT hub and with the digital navigation provided by the community digital technology liaison.
- 7. NCI and its partners should work with HRSA-funded health centers, which includes FQHCs, to promote and improve access to cancer screenings in underserved communities and expedite access to cancer care and treatment. The initial focus could be on lung, breast, prostate, colorectal and cervical cancers.
- 8. Strongly promote prostate cancer screening for high-risk men, including all African American men, who have a greatly elevated risk of developing and of dying from it. Improve access for underrepresented and rural groups. Studies of risk-based screening using polygenic risk scores, and MRI imaging could help prioritize which patient groups are most critical for outreach to ongoing screening and provision of access.

- 9. Expand the network of NCI-Designated Cancer Center Community Outreach and Engagement (COE) offices to include engaging community health workers/lay health advisors/ promotores de salud to take a community engagement approach to conduct cancer prevention and screening activities in underserved populations. Intervention(s) developed through this approach would be based on developing toolkits with community input and buy-in and implemented using a multi-level approach. One idea is to engage college students (community, tribal and four-year colleges) to assist with the community educational activities, which could also enhance exposure of a new cadre of future cancer researchers. In addition to partnering with local colleges, other potential partnerships could include faith-based organizations, local health departments, Community Based Organizations (CBOs), HRSA-funded health centers and other community care clinics.
- 10. NCI could partner with advocacy and CBOs on pilots, such as FightCRC, the *Colorectal Cancer Care Pilot Project*, which aims to assess and address disparities in CRC cancer screening and treatment, with the goal of developing a scalable model for other cancer types. This pilot could use real-world data to identify care gaps, test intervention strategies, and establish benchmarks for equitable, high-quality care. Insights and successful strategies should inform similar efforts in other cancer domains, creating a framework that can be expanded to improve care for diverse patient populations. NCI could also prioritize grants or research programs focused on addressing health care disparities in colorectal cancer (CRC) outcomes, especially in the early-onset cancer setting.
- 11. Increase genetic testing of cancer patients to help identify germline cancer risk in families (following NCCN guidelines). Provide access to genetic counseling with innovative methodologies including AI (Artificial Intelligence).
- 12. Develop a program to assess cancer genetics in the early-onset cancer population, targeting rural and underserved populations. NCI will partner with CBOs and HRSA-funded health centers, including FQHCs, to conduct education and outreach to target these populations.
- 13. Develop and evaluate innovative patient navigation programs that utilize a combination of in person and virtual methodologies (e.g., large-language-model supported). The combined approach of human and Al-powered interventions has the potential to broaden capacity to help many more cancer patients across underserved, including rural, communities. NCI could support the development of these technologies through an RFA or broad network of NCI-designated cancer centers, NCORPs and other community-based healthcare systems that jointly test and implement the most promising technologies.
- 14. Develop a supplement to both the NCORP Research Bases and the NCORPs which focus on increasing and improving access and delivery of supportive care therapies/interventions (specifically both during and after treatment) to patients, especially to underserved groups (e.g., rural, race/ethnicity, SES, etc.). The focus would be on new care delivery models, not

development of new individual level interventions. The key would be innovative care delivery models.

- 15. NCI could partner with the National Institute on Aging (NIA), The National Center for Complementary and Integrative Health (NCCIH), other Institutes and Centers and the new National Institute of Health (NIH) Communities Advancing Research Equity (CARE) for Health™ initiative, which is a pilot to test the feasibility of a network of research networks that expands research opportunities to the frontlines of clinical care in primary care settings. Also, an important piece would be to require partnerships with community-based organizations with footprints across the country to help with access to cancer screening and early detection programs. For example, the American Cancer Society (ACS) and its community-based programs and offices, libraries, drugstores, etc., could help with community-based services. These could be set up with the notion of supporting pilot demonstration projects focusing on setting up these new models and assessing and refining them. https://commonfund.nih.gov/clinical-research-primary-care
- 16. Partnering with CBOs, HRSA-funded health centers, cancer centers and minority serving institutions, establish a national network linking community-based outreach and education with workforce diversity in a harmonized effort to address the unequal burden of cancer. Adapt, implement, and evaluate impactful, innovative community education, awareness, and outreach activities with an emphasis on culturally responsive, evidence-based models specific to populations of focus to increase uptake of US Preventive Services Task Force (USPTF) recommendations for cancer prevention and screening services, increase participation in NCI clinical trials, and increase genetic risk assessments and counseling related to cancer.
- 17. Engage CBOs partnering with non-CBOs to increase screening for cancer in a nationwide competition (SAMHSA is doing it in behavioral health).

 https://www.challenge.gov/?challenge=behavioralhealthequity
- 18. Develop and test the impact of financial assistance programs that could be available at cancer centers to help advise populations that have limited financial means who are seeking high quality cancer care (implementation science with future focus on sustainability). Partnerships would be needed with local and state governments, non-profit organizations, and insurance providers. Models could include financial assistance programs to cover the cost of cancer screenings for those with economic barriers and collaborations with insurance providers to explore reduced co-pays or waived deductibles for cancer screening. The goal would be to facilitate timely cancer screening and follow-up testing and timely cancer treatment and reduce financial toxicity.

Suggested Efforts to Increase the Capacity to Conduct Cancer Research in Communities

- 1. Scale-up the NCORP.
 - a. Specifically, increase the number of minority-underserved NCORPs. Strategically locate additional NCORPs to include institutions with cancer care delivery infrastructure within high-value target populations of interest.
 - b. Develop NCORP planning grants that would serve as an incubator program to expand the capacity for more underserved communities to participate in clinical research. Also, significantly scale up the NCORP.
 - c. Create an NCORP supplement program to increase the capacity of NCORP sites in underserved communities to improve cancer outcomes, such as those done at NCIdesignated cancer centers. Supplements could also create synergies between NCORP and NCTN LAPS sites to complement efforts and create partnerships and maximize impact.
 - i. https://cancercontrol.cancer.gov/brp/tcrb/cancer-center-cessation-initiative
 - ii. https://cancercontrol.cancer.gov/research-emphasis/supplement/financial-hardship
 - iii. https://cancercontrol.cancer.gov/research-emphasis/supplement/assessing-enhancing-survivorship-care
 - d. Conduct a NCORP landscape survey to better understand the capacity of community sites to evaluate cancer prevention, screening and diagnostic pathways, which could also enhance the ability to screen new patients for clinical trials.
- 2. Leverage Electronic Medical Records (EMRs) to support clinical trials access. Promote collaborations between NCI, partner organizations and EMR systems makers to support clinical research activities. Specifically, leverage the EMR to automate the process of screening patients for eligibility for clinical trials; extract EMR data directly into research databases to reduce errors and data collection burden. Consider raising this topic at the HHS level to convene partners from across government to work on a successful model.
- NCI should educate the many review committees about the importance of designing more simplified and pragmatic trials to increase the number of pragmatic trials that are streamlined and easier to do in more communities, such as the S2302 Pragmatica Lung trial (https://clinicaltrials.gov/study/NCT05633602) and the upcoming CTIU-supported

PROSPECT-Lung trial (CTIU2317-A082304-S2402). There should be a focus on keeping protocol objectives limited to what is necessary to answer the primary research question and reduce data collection burden to keep trials easier for staff and patients. These goals should apply to clinical research across the cancer continuum from prevention trials through those for treatment, survivorship and supportive care.

- 4. Promote the widespread adoption of decentralized clinical trial elements where possible to reduce burden on patient travel and facilitate remote monitoring and measurement to minimize impact on workload at the sites.
- Expand the role of the virtual clinical trials office pilot program as presented by Jim
 Doroshow in June 2024 at the NCAB, to target historically underserved communities such
 as rural cancer centers, cancer centers with large LGBTQ populations and minority
 NCORPs. (https://deainfo.nci.nih.gov/advisory/joint/0624/Doroshow.pdf)
- 6. Partner with community-facing organizations in underserved areas to conduct targeted clinical trials outreach and awareness. HRSA-funded health centers are a natural place to start, in partnership with NCI-designated cancer centers and NCORP sites.
- 7. Partner nationally with groups /companies to help bolster the infrastructure for virtual and digital research. This could include cancer prevention, treatment, supportive care and survivorship research. This would need to focus on larger community infrastructure and at the individual level for device dissemination and access to internet.
- 8. NCI should collaborate on a meeting with ASCO, FDA, industry representatives and other interested partner organizations to continue to work on broadening eligibility criteria in cancer clinical trials and plan to expand modernized eligibility criteria to more industry sponsored trials as well as to monitor the implementation of already established recommendations. This will allow broader outreach and generalizability beyond current patient populations who participate in clinical trials.

 https://ctep.cancer.gov/protocolDevelopment/docs/CTEP_Broadened_Eligibility_Criteria_G

https://ctep.cancer.gov/protocolDevelopment/docs/CTEP_Broadened_Eligibility_Criteria_Guidance.pdf

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute Board of Scientific Advisors

Ad Hoc Working Group in Support of Efforts to Enhance Community Cancer Research and Quality Care

CO-CHAIR

William L. Dahut, M.D.

Chief Scientific Officer American Cancer Society, Inc. Washington, District of Columbia

CO-CHAIR

Raymond U. Osarogiagbon, M.B.B.S (BSA)

Adjunct Research Professor
Department of Medicine
Vanderbilt University
Chief Scientist
Baptist Memorial Health Care Corporation
Memphis, Tennessee

MEMBERS

Smita Bhatia, M.D., M.P.H. (CTAC)

Vice Chair of Outcomes for Pediatrics Professor Division of Hematology/Oncology Department of Pediatrics University of Alabama at Birmingham Birmingham, Alabama

Anjee Davis, M.P.P.A.

President Fight Colorectal Cancer Springfield, Missouri

Elizabeth Garrett-Mayer, Ph.D.

Vice President Center for Research and Analytics American Society of Clinical Oncology Alexandria, Virginia

Christopher R. Friese, Ph.D., R.N. (NCAB)

Elizabeth Tone Hosmer Professor of Nursing
Director, Center for Improving Patient and
Population Health
Associate Director for Cancer Control and Population
Sciences
University of Michigan Rogel Cancer Center
University of Michigan
Howell, Michigan

Michael J. Kelley, M.D., FACP

Executive Director National Oncology Program Specialty Care Services Veterans Health Administration Department of Veterans Affairs Professor of Medicine Duke University Durham, North Carolina

Molly Kisiel

Director, Clinical Content Association of Cancer Care Centers Rockville, Maryland

Mark A. Lewis, M.D.

Director of Gastrointestinal Oncology Intermountain Healthcare Murray, Utah

Karen M. Mustian, Ph.D., M.P.H. (BSA)

Dean's Professor of Oncology and Surgery
Departments of Surgery, Radiation Oncology,
and Public Health Sciences
University of Rochester School of Medicine
and Dentistry
Rochester, New York

Augusto C. Ochoa, M.D.

Deputy Director

LSU LCMC Health Cancer Center

Chair

Department of Interdisciplinary Oncology Louisiana State University Health Sciences Center New Orleans, Louisiana

Electra D. Paskett, Ph.D.

Professor

Marion N. Rowley Chair in Cancer Research Epidemiology The Ohio State University Columbus, Ohio

Lori J. Pierce, M.D.

Vice Provost for Academic and Faculty Affairs Professor of Radiation Oncology Department of Radiation Oncology University of Michigan Medical School Ann Arbor, Michigan

Gladys Rodriguez, M.D.

Medical Oncologist South Texas Accelerated Research Therapeutics (START) Center for Cancer Care San Antonio, Texas

Paul Spicer, Ph.D.

Professor

Department of Anthropology Center for Applied Social Research University of Oklahoma Norman, Oklahoma

Cornelia M. Ulrich, Ph.D. (BSA)

Chief Scientific officer and Executive Director Comprehensive Cancer Center Huntsman Cancer Institute University of Utah Salt Lake City, Utah

Robert A. Winn, M.D.

Director and Lipman Chair in Oncology VCU Massey Comprehensive Cancer Center Senior Associate Dean for Cancer Innovation Professor of Pulmonary Disease and Critical Care Medicine Virginia Commonwealth University Richmond, Virginia

Karen M. Winkfield, M.D., Ph.D. (NCAB)

Executive Director
Meharry-Vanderbilt Alliance
Ingram Professor of Cancer Research
Professor of Radiation Oncology
Vanderbilt University School of Medicine
Nashville, Tennessee

Ex Officio Members

Nelvis Castro

Deputy Director Office of Communications and Public Liaison National Cancer Institute National Institutes of Health Bethesda, Maryland

Loretta L. Christensen, M.D., M.B.A.

Chief Medical Officer Indian Health Service Rockville, Maryland

Ann M. Geiger, Ph.D., M.P.H

Scientific Director
Cancer Care Delivery Research
NCORP Health Care Delivery Research Program
Division of Cancer Control and Population
Sciences
National Cancer Institute

National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Katrina A.B. Goddard, Ph.D.

Director

Division of Cancer Control and Population Sciences National Cancer Institute National Institutes of Health Bethesda, Maryland

Brandy Heckman-Stoddard, Ph.D., M.P.H

Acting Chief

Community Oncology and Prevention Trials Division of Cancer Prevention National Cancer Institute National Institutes of Health Bethesda, Maryland

Douglas R. Lowy, M.D.

Principal Deputy Director National Cancer Institute National Institutes of Health Bethesda, Maryland

Michael Montello, Pharm.D., M.B.A.

Chief

Clinical Trials Operations and Informatics Branch Cancer Therapy Evaluation Program Division of Cancer Treatment and Diagnosis National Cancer Institute National Institutes of Health Bethesda, Maryland

Ann M. Sheehy, M.D.

Chief Medical Officer
Director, Office of Planning, Analysis, and
Evaluation
Health Resources and Services Administraton
Rockville, MD

Sanya A. Springfield, Ph.D.

Director Center to Reduce Cancer Health Disparities National Cancer Institute National Institutes of Health Bethesda, Maryland

Xinzhi Zhang, M.D., Ph.D.

Director, Division of Practice Improvement Center for Evidence and Practice Improvement Agency for Healthcare Research and Quality Rockville, Maryland

Executive Secretary

Andrea M. Denicoff, R.N., M.S., A.N.P

Nurse Consultant Clinical Investigations Branch Cander Therapy Evaluation Program Division of Cancer Treatment and Diagnosis National Cancer Institute National Institutes of Health Bethesda, Maryland