NATIONAL INSTITUTES OF HEALTH
National Cancer Institute
National Cancer Advisory Board

Report of the National Cancer Advisory Board
Ad Hoc Working Group on Global Health

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***Ad Hoc* Working Group on Global Health**

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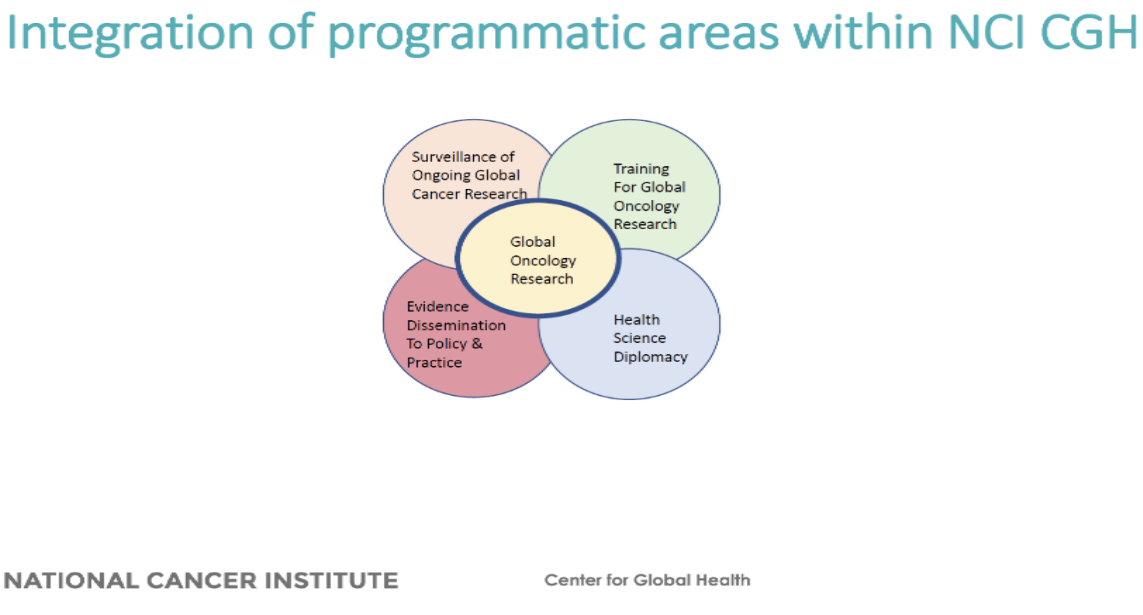
EXECUTIVE SUMMARY

The National Cancer Advisory Board (NCAB) *ad hoc* Subcommittee on Global Cancer Research convened a Working Group (WG) to provide general guidance to the NCI regarding strategic opportunities to enhance NCI's contributions to global cancer research. The Working Group was charged with advising the NCAB and NCI Director on the vision, accomplishments, and operations of the NCI's Center for Global Health (CGH). This included focusing on the mission, prioritization process, goals, and scientific activities of the CGH.

During the Working Group's meeting, presentations were given by NCI leadership, the Director, Center for Global Health, and leaders from various NCI divisions, offices, and centers (DOCs), and programs. The WG members were provided background materials and time was allotted for WG members to ask questions.

After deliberations, the Working Group focused its efforts on those areas that presented particular challenges and opportunities to clarify the overall CGH mission, operation, and integration of current global research efforts.



The Working Group recommends that the NCI refine the mission of the CGH to focus on the five programmatic areas with increased emphasis on research by implementing the following actions for the CGH:

- Consider approaches that encourage integration, coordination, and engagement with NCI Divisions and Centers.
- Be more transparent in the alignment of resources across NCI Divisions and Centers and CGH staff percent efforts allocated to each of the five programmatic areas (see above).
- Embed training and capacity building initiatives within research initiatives to facilitate better alignment across NCI resources and with the overall NCI mission.
- Articulate in the CGH mission statements regarding cancer health disparities and the global burden of the disease.

- Develop a decision-making framework or criteria for selecting projects by leveraging existing models and/or reports, such as the Institute of Medicine report articulating global health frameworks.
- Consider establishing an internal NCI standing oversight committee for the CGH, developing criteria for vetting large-scale projects, deferring decisions on smaller grants to NCI Division and Center leadership, and expanding HPV and cervical cancer efforts to include infection-related cancers broadly as one key focus area.
- Consider ways to integrate the global health research activities being conducted at NCI-designated Cancer Centers, especially research in low and middle income countries (LMICs), and evaluate the feasibility of crediting Cancer Centers for their global research efforts.

Report of the NCAB *Ad Hoc* Working Group

Charge to the *Ad Hoc* Working Group

At its November 2017 meeting, the National Cancer Advisory Board (NCAB) of the National Cancer Institute (NCI) voted to create an *ad hoc* Working Group (WG) to provide general guidance to the NCI regarding strategic opportunities to enhance NCI's contributions to global cancer research. The Working Group is charged with advising on the vision, accomplishments, and operations of the NCI's Center for Global Health (CGH). This will include focusing on the mission, prioritization process, goals, and scientific activities of the CGH.

NCI's International Mandate in Legislation [1]

The National Cancer Act of 1971 and subsequent follow-up legislation specifically emphasize an international presence in directing that NCI:

"…support: (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people;(B) collaborative research involving American and foreign participants; and (C) the training of American scientists abroad and foreign scientists in the United States."

Over the years, NCI's former Office of International Affairs (OIA) mission was to: 1) coordinate the planning, management, and evaluation of the international research, control, and information activities of the National Cancer Program; 2) serve as National Cancer Institute focal point with the Fogarty International Center (FIC), the DHHS Office of Global Health Affairs, the State Department, and other Federal organizations involved in international health activities; 3) coordinate cancer activities under bilateral agreements between the United States and other countries; 4) plan and implement programs for the international exchange of scientists; and, 5) maintain liaison with international agencies involved in the National Cancer Program.

In 2011, the National Cancer Institute established the Center for Global Health (CGH) to help reduce the global burden of cancer. CGH develops initiatives and collaborates with other NCI divisions, NCI-designated Cancer Centers, and countries to support cancer research and cancer research networks, promote cancer control planning, and build capacity in low-and middle-income countries (LMICs).

Introduction

Since 2011, NCI has worked to establish NCI's global research footprint. As such, the NCI is asking the National Cancer Advisory Board (NCAB) *ad hoc* Working Group on Global Health (or Working Group) to consider the research scope and emphasis for the CGH, the Center's integration within the NCI, and the Center's interface with research across the National Institutes of Health (NIH) and in other agencies.

Overview of Extramural Global Health Activities

NCI Global Health Portfolio

NCI's global health grant portfolio is modest regarding foreign or direct awards that have an

[1] https://www.cancer.gov/about-nci/legislative/history/national-cancer-act-1971

international principal investigator. Foreign component awards—grants having a U.S. principal investigator and an international collaborator—are much higher. In fiscal year (FY) 2017, the NCI supported 44 foreign awards in 17 countries and 849 foreign component awards in 77 countries. Of funded projects, 649 were conducted in high-income countries; 121 in upper middle-income countries; 73 in low- to middle-income countries (LMICs); and, 47 in low-income countries. From FY 2014 - 2017, the top 20 countries receiving NCI international grants/projects spanned many world regions; 353 were in North America; 798 in Europe and Central Asia; 281 in East Asia and the Central Pacific; 53 in the Middle East and North Africa; 34 in Sub-Saharan Africa; 30 in Latin America; and, 33 in South Asia. Breast and lung cancers topped the list of the 20 major cancers investigated in NCI international grants/projects.

NCI National Clinical Trials Network (NCTN) International Site Participation

Data from international sites enrolling patients in NCTN trials from 1 March 2014, to 31 December 2017 (excluding Canada) showed that international enrollment comprised five percent of total accruals for member and nonmember NCTN groups. This speaks to the issues regarding collaborations, policy, and regulatory barriers that may constrain conducting NCI-supported clinical trials outside of the United States, apart from Canada. The CGH actively facilitates the relationships for conducting trials internationally, but the NCI's Division of Cancer Treatment and Diagnosis (DCTD) coordinates and leads the trials.

The CGH has been working to address some of the barriers to conducting trials internationally, especially for rare forms of cancer. Although not a key issue for the Working Group, resolving the challenges to international collaborations could be helpful to free up the five percent of CGH staff time currently devoted to this work. NCI emphasized that the capabilities to molecularly sub-classify cancers have improved, and evidence shows that many forms of cancer are rare in the U.S. population. As such, conducting trials in Europe, for example, could help to answer research questions and accelerate progress, i.e., assuming that the regulatory issues are resolved.

NCI Divisions and Centers Global Health Research Portfolios

Global research efforts organized in NCI centers and divisions support collaborative agreements and individual investigator-initiated research in foreign countries. The Division of Cancer Biology (DCB) has awarded three R01 grants to support the U.S.-China Program for Biomedical Research Collaboration and five R21 grants to support the U.S.-Russia Bilateral Collaborative Research Partnerships on Cancer. The advantages of bilateral international relationships—five relationships in total—serve to encourage collaborations, increase cancer research investments, and improve peer reviews. The NCI supports U.S.-based activities, and the partner countries provide support through their own funding mechanisms. The Division of Cancer Prevention (DCP) partners with foreign countries to conduct vaccine prevention trials against cancers with infectious (e.g., human papillomavirus [HPV]-associated) and non-infectious (e.g., Lynch syndrome) etiologies; perform screening/early detection trials for pancreatic and lung cancers and mesothelioma; and, train international scientists in the summer curriculum of NCI's Prevention Fellowship Program.

NCI's Division of Cancer Control and Population Sciences (DCCPS) conducts model-based meta-analysis via the NCI Cancer Intervention and Surveillance Modeling Network (CISNET) to combine diverse clinical trials being conducted in the United States and Europe, including the U.S.-based Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial and the European Randomized Study of Screening for Prostate Cancer (ERSPC). International collaborations are fostered through the Cancer Epidemiology Consortia within DCCPS's Epidemiology and Genomics Research Program.

Support to build a cancer registry is the most frequent request from foreign countries. DCCPS and CGH are leading the implementation of the International Agency for Research on Cancer Caribbean Cancer Registry Hub and are co-funding a grant on the epidemiology of breast cancer in Nigerian women for the Human Heredity and Health in Africa (H3 Africa) project. DCCPS also is supporting two hubs, one in India and one in Peru, for the Global Occupational and Environmental Health (GEOHealth) project. Input is needed on the percentage of NCI investments that should be allotted for building infrastructure versus technical assistance or both. Additional global cancer research priorities include the DCCPS Tobacco Control Program, evidence review synthesis of dissemination of NIH international tobacco control research initiatives, the International Cancer Proteogenome Consortium (ICPC), and the HPV Serology Standards Laboratory at the Frederick National Laboratory for Cancer Research (FNLCR). Other areas of international collaboration include funding opportunity announcements for the NCI Provocative Questions (PQ) Initiative and the Innovative Molecular Analysis Technologies (IMAT) program.

Working Group Findings Regarding Extramural Global Health Activities

- Focusing more on research in LMICs rather than developed European countries would require a mission change for the CGH. However, a primary LMIC focus was favored by Working Group members as a potentially higher priority and more valuable contribution for CGH.
- Maintaining a focus on resource building, which informs decision making and addresses research and health-related questions in the United States will be a challenge.
- The NCI is engaged in a significant amount of global health research in industrialized countries. It is anticipated that this trend will result in an increase in the current portfolio and the scale for global health research activities in the NCI—the challenge is prioritizing these activities.
- The Working Group's charge does not directly include the NIH Fogarty International Center (FIC). The CGH is NCI's lead representative for LMIC programs, but some divisions and centers within the NCI and the broader NIH also conduct research in LMICs. The charge is to provide input on the integration, not the fusion, of NCI intra- and extramural global health activities not under the purview of the CGH into its portfolio to think more cohesively about the research the NCI conducts in LMICs.
- Methods used to resolve an international collaboration in one country would not necessarily be generalizable to all countries. The role of the CGH in helping to establish the ICPC, which currently consists of 31 participating institutions from 12 countries, plus 11 NCI Clinical Proteomic Tumor Analysis consortium (CPTAC) member institutions, which aligns with the Cancer Moonshot℠ , was challenging.
- The pharmaceutical industry has made progress in studying rare cancers and conducting clinical trials on such cancers globally. Industry-sponsored trials are not typically investigating preventative treatments.
- A clear and transparent vetting process for the CGH to prioritize projects should be established.

- In providing justification to support NCI investigator-initiated projects in new collaborative efforts in foreign countries, it was indicated that:
    - Cervical cancer, for example, is prevalent in economically disadvantaged women regardless of the resource setting or geographical location. Therefore, much of the research being conducted outside the United States benefits other countries and has direct relevance to the United States as well. The main barrier to cervical cancer screening that focuses on high-risk individuals in the United States is the U.S. Food and Drug Administration's (FDA's) approval for self-sampling and analyses of those samples.
    - The NCI is actively monitoring global cancer research activities and their direct relevance to the United States.

- The NCI has the opportunity to significantly impact cancer research globally with modest investment, although not all investments may necessarily show outcomes directly relevant to the United States. This is an appropriate goal, but may not always be achievable.
- Strategic priority setting can better identify scientific opportunities that can only be realized through NCI global efforts. For example, HIV preventive vaccine trials conducted by NIAID can only be meaningfully conducted in regions with high prevalence, such as Sub-Saharan Africa. Similar NCI opportunities likely exist for HIV-associated malignancies, Burkitt lymphoma, etc.
- There is a need to balance research efforts across programmatic areas.

The Working Group suggested that consideration should be given to expanding the definition of global health to include health disparities since it impacts all countries.

Overview of Intramural Global Health Activities

NCI's Intramural Research Program (IRP) commitment to global health is principally through its Division of Cancer Epidemiology and Genetics (DCEG), a division of approximately 74 principal investigators. The DCEG is charged to discover causes of or effective interventions for high or unusual rates of cancer, understand the subtypes of cancer that are more prevalent in geographic areas other than the United States, and evaluate the role of high or unusual exposures in causing cancer. In addition, the DCEG conducts epidemiological and prevention research internationally, makes full use of and derives benefits from unique data resources not available in the United States, and explores the role of the genetic contribution to cancer. Furthermore, major public health advances from DCEG's global health research conducted in collaboration with international partners, including carcinogenicity studies and investigations on such infections as HPV, have informed policy and guidelines in the United States.

DCEG's Global Research Portfolio

The DCEG's global research portfolio is conducted in 63 countries, primarily led by the Division's principal investigators and postdoctoral fellows with 46 percent of the postdoctoral fellows training at the DCEG originating from foreign countries. Former global health trainees now are serving in leadership roles at well-known international research centers in their home countries. DCEG's strong research programs in occupational and radiation exposures are unique to the global research community, often are conducted in international locations, and include ongoing activities to assist countries in building the infrastructure necessary for monitoring diseases. Examples of global research include a 20-year collaboration with the Chinese Center for Disease Control and Prevention (CDC) to study exposure to benzene, a known carcinogen, in Chinese workers. Study results revealed evidence of hematotoxicity in humans exposed to benzene at sub-occupational levels led to the 2007 U.S. Environmental Protection Agency (EPA) rule limiting benzene content in gasoline and the adoption of controls on passenger vehicles and fuel containers. Findings from the United Kingdom–NCI Pediatric Computed Tomography (CT) study that retrospectively evaluated the risks of cancer in adolescents from diagnostic CT scans led to a decrease in dose and use of CT scans worldwide. The NCI 30-year collaboration on the Life Span Study (LSS) cohort of Japanese atomic bomb survivors established LSS risk models that are being used in NCI radiation risk assessment online tools for the United States; these tools also were used to inform decisions during the 2011 Fukushima Daiichi nuclear accident in Fukushima, Japan.

Ongoing research studies in Europe include investigations into the genetics of cancers in population-

based case control studies. The DCEG has had a 35-year commitment to research involving breast and cervical cancer studies in Central America and HPV vaccine clinical trials in Costa Rica. South American studies are evaluating upper gastrointestinal cancer and gallbladder cancers, among others. In Africa, Burkitt's lymphoma and breast cancer case control studies are ongoing. The DCEG has a long history of conducting oncology research in Asia that includes more than 150 studies. An example of the public health impact of an observational study is an indoor air pollution study in Xuanwei, China, which showed that installation of chimneys improved stove ventilation and decreased the risks of developing lung cancer. A genome-wide association study of esophageal squamous carcinoma involved pooled and combined analysis that included an individual data-sharing exchange from China, which is the first of its kind for China.

Other IRP Global Health Research Activities

There are other IRP global health research activities which includes the efforts of the NCI IRP Liver Cancer Initiative, a joint effort with the NCI Center for Cancer Research (CCR) and DCEG. This initiative, a premier center for liver cancer research, encompasses epidemiology, basic, and clinical research; the CCR Liver Cancer Program, which includes a global footprint across many institutions; and, such consortia as the Thailand Initiative in Genomics and Expression Research in Liver Cancer (TIGER-LC).

Ways to Accelerate NCI IRP Global Research

The Working Group was informed that the CGH could accelerate NCI IRP global research by:

- Developing and maintaining accurate databases of scientific agreements and research portfolios.
- Reducing barriers to shipping biospecimens and data internationally.
- Developing culturally appropriate informed-consent templates.
- Expanding efforts to foster easily accessible, high-quality biobanking facilities in countries where the NCI conducts research.
- Assisting in training international scientific professionals at all levels.
- Fostering new collaborative activities without complicating delicate political issues.

Working Group Findings Regarding Intramural Global Health Activities

- The new African Postdoctoral Training Initiative (APTI), established at the NIH in partnership with the African Academy of Sciences and the Bill & Melinda Gates Foundation, is attracting attention.
- In supporting training for international researchers, the DCEG uses a research contract mechanism, rather than grants, to support international trainees.
- The aim is to determine how the DCEG-CGH relationship can be integrated. DCEG's priorities are driven by NCI's research concept approval process.
- The DCEG conducts a significant amount of research outside of the United States in LMICs; CGH could play a role in supporting these efforts.
- The CGH offsite staff serves in various capacities and are located across several countries to facilitate close coordination and collaborations, which also benefits the DCEG.

The Working Group commended the DCEG for its efforts but noted the lack of major capacity building efforts nor subsequent implementation efforts in the local countries as part of its portfolio after studies are completed. The epidemiology and genetic studies it undertakes needs to better align with public health priorities to create transformative change, and CGH could provide important support at that intersection.

Overview NCI Center for Global Health

The NCI CGH was established in 2011 primarily to strengthen NCI's global oncology research. The recommendations from the inaugural 2012 stakeholder meeting—which included representatives from NCI Divisions, Offices, and Centers; NIH Institutes and Centers; other Federal agencies, nongovernmental organizations and professional societies; and NCI-designated Cancer Centers—framed CGH's current strategic priorities. The CGH consists of 42 full time employees; of these, 28 are NCI program staff; three are contract program staff; six are contract support staff; four are subject-matter experts (SMEs); and one is dual NCI program staff/SME. Seven research fellows complete the CGH list of personnel. The staff percent effort (i.e., time spent) is divided across the CGH five programmatic areas as follows:

- Strengthen global oncology research—25 percent.
- Surveil ongoing global cancer research—5 percent.
- Strengthen the global oncology research community (e.g., through training)—20 percent.
- Disseminate evidence on policy and clinical practice—35 percent.
- Promote global health diplomacy—15 percent.

Based on FY 2011 to FY 2018 requests and funded projects, the scientific areas to consider for prioritization in the CGH include key foundational elements of cancer research, HPV and cervical cancer screening, clinical trials, and implementation science. Other areas to consider prioritizing include capacity-building for global oncology research and training, affordable cancer technologies, and tobacco control research. However, building cancer registries/health surveillance programs and increasing anatomic pathology capabilities have been the key foundational elements of cancer research supported by the CGH in partnership with: NCI's DCCPS, the World Health Organization (WHO), regional and country offices, the International Agency for Research on Cancer, the International Union for Cancer Control, NCI-designated Cancer Centers, African Strategies for Anatomic Pathology, and the African Organization for Research and Training in Cancer.

CGH identified several potential new scientific areas and next steps, as follows:

- Tobacco control is well supported in other initiatives and could be less of a focus for the CGH.
- Leveraging the NCI PQ Initiative to build partnerships, rather than building them through the Cancer Moonshot℠ .
- Developing and/or establishing affordable cervical cancer screening methods in the United States will affect health care locally and will help to further advance the global health agenda.
- Efforts by the pharmaceutical industry to develop low-cost cancer treatments in low-resource settings would benefit those communities.

Working Group members asked CGH to identify three areas in which the CGH could envision progress. The three areas critical to the global health program were identified as follows:
1) strengthening the global research community, which includes training; 2) supporting research to develop policy; and, 3) implementing other research areas or gaps in research not currently being supported in LMICs.

Impact on Global Health

NCI's global reach efforts expand all resource settings to ensure support. Data from a 2014 report, initiated by the CGH, that surveyed international activities of NCI-designated Cancer Centers from 2012 to 2014, revealed significant research and training investments in the LMICs; investigator-

initiated collaborative projects and Institute-wide initiatives; and, activities not limited to NCI-funded projects. The CGH supported global oncology research at NCI-designated Cancer Centers via the Cancer Center Supplemental Funding Program in 2012, administrative supplements to promote cancer prevention and control research in LMICs in 2015, and Planning (P20) grants to plan and design noncommunicable disease (NCD) Regional Centers of Research Excellence in LMICs in 2015.

Establishing Internal and External Partnerships

From 2013 to 2018, the CGH partnered with NCI-designated Cancer Centers to host satellite global oncology research days prior to the start of the Consortium of Universities for Global Health Annual Global Health meetings. Attendance has risen from 100 to 200 participants over the past 5 years. The CGH partnered with the American Society of Clinical Oncology (ASCO) on development of the *Journal of Global Oncology*, a global oncology research track at ASCO meetings, an International Clinical Trials Workshop, and country/research-specific satellite meetings parallel to ASCO annual meetings.

Regarding research on policy and practice, the CGH works to ensure that the World Health Organization (WHO) and International Atomic Energy Agency (IAEA) recommendations for cancer prevention, screening, diagnosis, treatment, and palliative care reflect best practices and research findings. The CGH also works to ensure inclusion of effective cancer interventions in the United Nations Sustainable Development Goals and the WHO 2013–2020 NCD Action Plan. Furthermore, the CGH works with partners to assist countries in developing, implementing, and evaluating national cancer control plans, best practices, and experiences. Cancer control planning and implementation initiatives have been established. In particular, the International Cancer Control Partnerships (ICCP) and the development of an ICCP portal, an online resource for cancer planners.

Support of clinical trials has been a key scientific area for the CGH since 2011. As such, the NCI has supported trials to build a network to study Burkitt lymphoma treatments in LMICs and has strengthened international collaboration in trials for rare cancers and cancers of the head and neck. Other current and potential new areas to address gaps in research include, for example, tobacco–related oral cancer; focus on liver cancer and its complications; support for other new initiatives, such as the Cancer Moonshot℠ project partnerships in high-income countries; and, expansion of international intergroup partnerships and clinical trials.

Working Group Findings Regarding the Center for Global Health:

- The scope of activities supported is quite broad; therefore, the prioritization of research projects would be challenging and require a clear strategy and process.
- The overall management of the CGH and its portfolio needs to be addressed.
- Despite the broad scope and diverse portfolio, the NCI's CGH has played a critical role in supporting global health research projects that were not supported elsewhere, and raising the overall profile of NCI global activities.
- In terms of the criteria for deciding on the percent effort in each programmatic area and how this relates to future prioritizations, the NCI global health portfolio did not exist prior to the CGH; the percent effort reflects activities not supported elsewhere in the NCI. The current percent efforts were determined by assessing the work the staff does in responding to requests and the support available in each of the programmatic areas.
- The CGH visited many of the Cancer Centers to identify the work being done and has tried to be responsive to investigators' needs raised during these visits.

- In addressing training via the CGH, the goal is to address gaps that include supporting the Fogarty Fellows and Scholars Program, developing the Short-term Scientist Exchange Program, and hosting workshops on specific cancer research topics.
- To assess the global landscape of cancer research and foreign countries' investment in general:
    - The NCI funds research grants and projects in 126 countries, but the CGH is not sufficiently staffed to provide this level of support. The principles for prioritizing work in other countries include (1) national commitment to oncology research and cancer control; (2) scientific opportunities; (3) opportunity to build upon existing research and public health infrastructure; (4) current U.S. NIH, NCI, and/or Centers for Disease Control and Prevention collaborations; (5) cost to the NCI in terms of dollars and staff time; and (6) governance. However, LMICs would be challenged to meet these criteria. Key criteria to consider are the willingness to commit to a program on behalf of governments and the availability of partnerships outside the NCI.
    - Many of the requests for global research are denied due to the lack of infrastructure necessary to conduct the research. Projects supported in other regions of Sub-Saharan Africa are being conducted in partnership with Cancer Centers.
    - Enhanced transparency on the NCI website and a clear framework used to select projects in LMICs to date, perhaps would ensure that efforts are complementary and not duplicated.
    - Support for projects should not be based on need alone—other criteria such as projected impact, feasibility, etc. must be met.

The Working Group noted the Institute of Medicine's (IOM) report that highlighted global health frameworks which could serve as effective models for CGH prioritization.

The Working Group also noted that the CGH's support for research appears to be mostly capacity building in LMICs.

- Assisting countries in strengthening their anatomical pathology capabilities to ensure accurate cancer diagnosis is considered a foundational element of cancer research.
- NCI's investments in the Surveillance, Epidemiology, and End Results (SEER) Program, a cancer registry that is critical to population-based research, as one example.
- Less than $500,000 of the CGH budget in the past six years has supported non-research capacity building.
- Scientific advocacy would be a better classification of the type of support given to strengthening anatomical pathological capabilities, but individual projects on this topic have not been funded. As such, the research question around this topic would need to be developed.
- CGH's support of research versus capacity building is somewhat misleading. In supporting some research projects, capacity building can be a secondary outcome.
- Strengthening anatomical pathology capabilities is not listed as a top priority for the CGH; information on the decision-making process to determine top priorities should be documented. The scientific prioritization usually drives these types of decisions. The key question is whether capacity building is fundamental to the research and, if so, how it would fit into budget allocations.
    - The scientific areas to prioritize described earlier were a result of input from NCI-designated Cancer Centers that indicated that key fundamental elements of cancer research included building cancer registries/health surveillance and anatomic pathology capabilities.
    - The CGH engaged in discussions with ministries of health in other countries on the need for investments to support these types of capabilities. NCI investments ($500,000/6 years) supported workshops and part-time staff to set up local cancer registry offices.

- To support capacity building and research, the CGH investigates options to leverage existing programs, resources, or models, such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

The Working Group expressed concern that the engineering or technical capabilities necessary to maintain affordable cancer technologies developed in the United States by U.S. engineers may not be present in LIMCs. It was stated that the NIH UG3/UH3 Phase Innovation Awards Cooperative Agreement structure ensures that the technologies are applicable to LMICs.

In providing clarity on the prioritization principles regarding burden of disease and global impact, it was indicated that the CGH does not base decisions only on need but also takes other principles into consideration. As such, if producing generalizable knowledge is a potential outcome, a project may be selected.

In terms of additional resources and the budget, the scientific areas prioritized and the programmatic areas within the NCI-CGH portfolio will determine any changes to the annual budget. The current breakdown of CGH staff time across the CGH portfolio is a good indicator of prior budget allocations.

Working Group's Conceptualization of the CGH Mission and Priorities

The Working Group discussed: 1) including language in the CGH mission statement that addresses the burden of disease on vulnerable populations and that reflects ongoing programs and activities; 2) key components for a CGH mission; 3) a framework for criteria and process; and, 4) aligning the CGH programmatic areas to the mission. Those discussions resulted in the following points:

Key components of the mission:

- Use of the term "global health disparities" speaks to vulnerable populations worldwide and aligns with the 2011 U.S. Department of Health and Human Services Global Health Strategy.
- The mission statements of university-level schools of public health may serve as potential models.
- The mission should address how the programmatic activities are coordinated, the balance of staff time across activities, and the inclusion of such key words as "reciprocal innovation" to help to convey the message that supporting global research provides a return on investment.

Developing a framework for criteria and process:

- The NCAB *Ad Hoc* Subcommittee on Global Cancer Research is charged to provide leadership and oversight to the CGH but only convenes once or twice a year. Given the number of incoming global oncology requests and the CGH's ongoing activities, more frequent input from an oversight committee is necessary.
- An oversight process external to the CGH should be established, and major projects should be vetted.
- To address the issue of capacity building in partner countries, the CGH should consider embedding training into the research grants, rather than establishing it as a separate programmatic area.
- The CGH should develop a process for prioritizing projects that is transparent to all entities involved.

Prioritization:

- A redefined mission that aligns with the mission of the NCI will be the first step toward prioritizing global cancer research projects.

- Tobacco control research may not be the best fit for the CGH.
- Infection-related cancers, in general, should be considered as one key focus area.
- Linkage to NCI-designated Cancer Centers, many of which are substantially engaged in global health, is encouraged.

Working Group Recommendations

1. Clarification of the CGH mission statement and goals

- The mission statement should include surveillance of ongoing global cancer research, training for global oncology research, evidence dissemination to policy and practice, health science diplomacy, and global oncology research, with global oncology research becoming the clear primary focus. The other areas should be mediated through this primary focus.
- Addressing vulnerable populations and health disparities should be included in the mission statement.
- The research focus should be on unique scientific opportunities in LMICs, for example, the intersection of infectious diseases and cancer. The working group felt LMICs are where burden and scientific opportunities are greatest, but that diplomacy efforts could include broader international engagement.
- Training and capacity building should be embedded in all research initiatives with a view toward sustainability.
- CGH should have grant-making authority.
- As part of the mission and goals, there should be strategic rethinking about how much of the focus of the center should be on diplomacy, and how much on supporting research. The diplomacy function should continue, but a strategic and impactful research portfolio should grow.
- A separate office within CGH should focus on diplomacy.
- The CGH may want to look at mission statements from successful academic global health programs for models.

2. Enhanced coordination and communication within CGH, NCI, and NIH

- Once the mission is clarified, resources should be defined and aligned with each programmatic area within the CGH as illustrated in the Executive Summary.
- Communication should be clear throughout the CGH so that all staff understand and can articulate the mission.
- A process is needed to better integrate the activities of the Center with other institute activities.
- Research capacity building activities should be better coordinated with the Fogarty International Center, given its long history of working with NIH institutes to support early career development for US and LMIC global health leaders, and to build specific research capacity in LMICs.

3. A clear, consistently applied, and transparent process for setting priorities

- The priorities need to align to the NCI mission and to the priorities of the NCI Divisions and the NCI Director.
- Priority setting should include consideration of issues such as cancer burden, current human and infrastructure capacity, critical mass of cancer center involvement for leverage, governmental structures and commitment, and sustainability.

- CGH should consider key frameworks in this area.[2]
- Metrics are needed to define success, and sustainability should be included as a key metric for any new initiative.

4. **An external advisory group** to CGH (either internal or external to NCI) is needed to review prioritization of new research, diplomacy and other activities, and to evaluate success of activities.

5. **Establish better linkage with Cancer Centers**
   - CGH can better support global health activities at Cancer Centers through larger funding opportunities with clearer long-term goals. (One- or two-year supplements to conduct such activities only produce modest outputs and impact given the pace of progress and start-up time typically needed in LMICs.)
   - Several NCI-designated Cancer Centers are truly exceptional in the breadth and depth of their global portfolios, and could almost function as Global Oncology SPOREs, if an analogous competitive opportunity were considered.
   - The Cancer Centers could play a larger role in capacity building if built into the grants/supplements.
   - A coordinating function with Cancer Centers would be helpful, such as hosting a biannual meeting focusing on global health related issues.

Conclusion

The accomplishments of the CGH and its role in managing NCI's global health resources, and raising the profile and importance of global health at NCI, are highly commendable. The CGH should continue to function in its current role. Working Group members discussed the complex nature of the global health research continuum from capacity building in foreign countries to clinical trials. The Working Group observed that the mission of the CGH is broad and somewhat vague. Integration and coordination of activities across NCI Divisions and Centers, as well as resources, were not well understood. The percent efforts on CGH activities were not always transparent, and presentations provided suggest that much of CGH staff time is spent on peripheral activities, rather than on the main mission.

The Working Group recommends that the NCI refine the mission of the CGH to focus on the five programmatic areas by implementing the following actions for the CGH:

- Consider approaches that encourage integration, coordination, and engagement with NCI Divisions, Offices, and Centers (DOCs).
- Be more transparent in the alignment of resources across NCI Divisions and Centers and CGH staff percent efforts allocated to each of the five programmatic areas (see diagram in Executive Summary).
- Embed training and capacity building initiatives within research initiatives to facilitate better alignment across NCI resources and with the overall NCI mission.
- Articulate in the CGH mission statements regarding cancer health disparities and the global burden of the disease.

[2] "Global Health Risk Framework: Governance for Global Health" National Academy of Sciences 2016 or the now classic article by Christopher Potter and Richard Brough, Systemic capacity building: a hierarchy of needs, Health Policy and Planning; 19(5): 336–345 2004; a doi: 10.1093/heapol/czh038

- Develop a decision-making framework or criteria for selecting projects by leveraging existing models and/or reports, such as IOM report articulating global health frameworks.
- Consider establishing an internal NCI standing oversight committee for the CGH, developing criteria for vetting large-scale projects, deferring decisions on smaller grants to NCI Division and Center leadership, and expanding HPV and cervical cancer efforts to include infection-related cancers broadly as one key focus area.
- Consider ways to integrate the global health research activities being conducted at NCI-designated Cancer Centers, especially research in LMICs, and evaluate the feasibility of crediting Cancer Centers for their global research efforts.

Overall, working group members noted that developing a strategic focus on all levels would be critical to planning the future directions of the CGH. Members commented on their interactions with the CGH, which have been positive, and remarked on the intense overall commitment of its Director and CGH staff to strengthening NCI's global health research.