

Center to Reduce Cancer Health Disparities
National Cancer Institute

Community Networks Cancer Health Disparities Summit 2005:
Creating a Healthy Future
Through Community Research and Partnerships

July 18–20, 2005
Bethesda, MD

Summary Minutes

In July 2005, the National Cancer Institute's (NCI) Center to Reduce Cancer Health Disparities (CRCHD) hosted the first annual *Community Networks Cancer Health Disparities Summit*. This was the inaugural gathering of 25 grantees participating in the recently funded Community Networks Program (CNP). The Summit's theme was "Creating a Healthy Future Through Community Research and Partnerships."

The Summit brought together CNP Principal Investigators and other research staff; CNP Program Managers and Coordinators; community partners of CNP projects; representatives of the Cancer Information Service (CIS); CRCHD staff, including CNP Program Directors; staff from other NCI Divisions; and others representing diverse populations and disciplines.

The primary aims of the meeting were:

- Becoming familiar with programmatic and administrative aspects of the CNP.
- Sharing experiences in community-based research and project coordination.
- Sharing project designs and objectives through an introductory poster session.
- Discussing principles and practices for conducting cancer health disparities research.
- Learning about the structure, function, and resources of the NCI.
- Learning about opportunities for collaboration with NCI and other Federal agencies involved in addressing cancer health disparities.

Summit participants were provided with a thorough introduction to Phase I CNP activities and core requirements. They also received an overview of the kinds of useful data to be collected, learned how these will factor into the evaluation of the Networks, and collected ideas on how to access the many resources that are available to support community programs.

The agenda included sessions on program evaluation, project coordination, activities for community partners, establishment of CNP best practices, professional training opportunities, and grants administration issues.

July 18, 2005

Concurrent Meetings and Workshops

Evaluation Planning Group—Kenneth Chu, Ph.D., Chief, Health Disparities Research Branch, and Emmanuel Taylor, Dr.P.H., Health Scientist Administrator, Health Policy Branch, Center to Reduce Cancer Health Disparities (CRCHD)

[Unedited by speakers]

Dr. Chu provided general information about plans for evaluating the Community Networks Program (CNP), which consists of a national program evaluation (NPE) across all grantee sites, as well as individual program evaluations (IPEs). Dr. Chu focused primarily on NPE, and Dr. Taylor focused on program evaluation methodology to help programs create IPE plans.

National Program Evaluation of the Community Networks Program

Dr. Chu described the main goal of NPE as measuring how well CNP goals and objectives are being met. A Request for Quotation (RFQ) has been issued to select a program evaluator to support the NPE. CRCHD Program Directors, CNP Principal Investigators (PIs), and the NPE contractor will develop a plan for implementing the NPE. The contractor will collect data needed to make assessments, perform qualitative and quantitative data monitoring, and provide technical assistance, as needed, for program evaluation. Three critical areas for consideration include the evaluation plan, core data elements, and an implementation plan.

Methodology for Evaluation Planning

Dr. Taylor presented information on how to conduct an IPE to evaluate a CNP project's activities and materials. Collection of baseline data should begin before education, research, and training efforts are launched. The cyclical framework of the IPE includes engaging stakeholders, describing the program, focusing the evaluation plan, and identifying evidence (the data to be collected). The program should define its purpose and scope; define activities that will accomplish this purpose; develop questions needed to evaluate the success of each activity; describe outcomes associated with each activity; and identify core data elements necessary to answer the questions. The IPE should include a conceptual framework or logic model that explains how the program should work. In addition, process evaluation—retracking program steps to help determine whether the program can be replicated—should be incorporated into the IPE. The IPE should:

- Focus on issues of greatest importance to stakeholders.
- Work with stakeholders to prioritize needs and evaluation goals.
- Identify feasible strategies (e.g., needs assessment).
- Include both qualitative and quantitative data.
- Include an evaluation timeline.
- Determine staff roles for evaluation activities.

Key Points From Discussion Session

- Individual projects should determine what is meaningful to them (e.g., how they define *cancer health disparities*).
- Grantees are required to send only a summary of evaluation findings to NCI.
- The emphasis for the NPE will be on working together (i.e., Community Networks [CNs], NCI, and the contractor) to create evaluation criteria.
- The contractor will solicit feedback from individual programs for the NPE plan.
- Evaluation outcomes can include changes in perceptions, behaviors, and beliefs that will help reduce cancer health disparities.
- Outcomes must be quantified.
- There is a plan to create a common data set of evaluation elements.

- Data collected on clinical trials should focus on the number of people informed about the trials rather than the number who enrolled. This will provide information about people who made an informed decision about participating in the trials.
- The NPE will not require projects to measure benefits returned to the community as part of participatory research; however, projects may choose to include this information in their IPEs.
- Planning for program evaluation should take into consideration the involvement of numerous interest groups within the community.
- Process indicators (e.g., collaborative efforts and other institutional and organizational aspects of the project) will be an important part of the IPE. These outcomes could also be part of the NPE.
- The role of related policies will be considered in the NPE.
- No additional funds will be provided specifically for the NPE or the IPEs. However, a pilot project (e.g., survey development, needs assessment, impact evaluation) could be proposed in order to obtain additional funding to support these activities.
- Obtaining funds from outside NCI is very important.
 - ◆ The ability to obtain additional funds will demonstrate that projects have leverage.
 - ◆ Outside funding could be requested for non-research activities (e.g., patient education, professional training).
- Key elements for evaluation include increasing peer-reviewed publications and increasing training of minority investigators.

Project Managers/Coordinators Meeting—Frank Jackson, Program Director, Disparities Research Branch, CRCHD

The purpose of this meeting was to help Project Managers/Coordinators explore and better understand their roles and responsibilities relative to CNP goals as outlined in the Request for Applications (RFA). The CNP builds on the success of the Special Populations Networks (SPN) program, and several CNP projects were also part of the SPN program. SPNs were asked share lessons learned during their previous 5-year SPN projects. This was followed by open discussion.

The implementation phases of CNP include developing infrastructure, conducting community-based participatory research and training programs, and establishing program sustainability.

Phase I: Developing Infrastructure

- Establish multidisciplinary professional staff.
- Partner with community-based organizations, prevention programs, cancer research and control institutions, and other government agencies.
- Document partnerships with Memoranda of Understanding.
- Create four or more NCI collaborations.
- Conduct community-based educational activities. (NCI cannot support health care delivery activities through CNP projects.)
- Obtain non-CRCHD funding.

Phase II: Conducting Community-Based Participatory Research

- Involve the community at all levels of program planning, implementation, and evaluation.

- Develop pilot research projects supported by NCI supplements.
- Train researchers (especially members of minority groups) in cancer health disparities. NCI will help find opportunities for young researchers identified by CNP PIs.

Phase III: Establishing Program Sustainability

- Demonstrate a reduction in cancer health disparities achieved through collaborative activities.
- Obtain Federal and/or nongovernmental funding for proposals based on the CNP research.
- Provide evidence-based research findings to policy makers. (NCI cannot lobby or endorse lobbying.)

CNP Responsibilities

- Establish a Steering Committee to set policy and provide overall guidance.
- Establish a Community Advisory Group to link community concerns with CNP activities; this group should meet twice per year. A Community Advisory Group is a critical tool for giving the community a voice in the direction of the project. Project staff must keep this group informed on project plans and activities and must account for any discrepancies between plans and outcomes.
- Establish and maintain collaborations with the NCI Cancer Information Service (CIS) and other community groups. Working with the CIS is mandatory. PIs must notify their Program Directors when projects need print materials and media messages. Messages must be scientifically accurate and convey NCI-approved policies. Grants funds may not be used for unapproved materials.
- Request supplemental funding for pilot projects. Separate applications and peer review are required.
- Provide annual progress reports; Program Managers or coordinators have primary responsibility for preparing these reports.
- Conduct site visits to provide opportunities for NCI to verify statements made in progress reports.
- Seek technical assistance from Program Directors.

Open Discussion—Input by CNP Staff With SPN Experience

CNP staff with SPN experience presented helpful hints for carrying out program responsibilities, suggestions for improving communication within and across programs and projects, practical advice for program management and coordination, and lessons learned.

Rosita L. Edwards, M.A., Asian Tobacco Education and Cancer Awareness Research Initiative (ATECAR), Philadelphia, PA

Ms. Edwards works with Grace X. Ma, Ph.D., C.H.E.S., in Philadelphia. ATECAR's target Asian communities are located in Pennsylvania, New Jersey, Delaware, and New York. The target population includes Chinese, Vietnamese, Cambodians, and Koreans. At ATECAR, Ms. Edwards manages cancer education, tobacco cessation, and other community programs; she is responsible for dissemination strategy and recruitment, as well as training and supervising health educators.

Ms. Edwards advised Program Managers to be flexible and teachable. Each population and agency has a different culture. Program Managers must be willing to change tactics and anticipate unexpected events. For example, an ATECAR cancer education program for 50 people was planned, but one participant died the day before the program began and only about half of the planned number of participants appeared. Thus, it is important to have contingency plans. Ms. Edwards stated, "You cannot do everything by yourself." Teamwork and communication are essential. Patience is important in building relationships with community partners and building research and service capacity within a community.

Joanne U. Tsark, M.P.H., 'Imi Hale, Honolulu, Hawaii

'Imi Hale is the Native Hawaiian Cancer Research and Training Network, the only SPN associated with a community-based organization rather than a university or hospital. The advisory group meets more often than the twice-yearly meetings recommended in the RFA to facilitate intense community guidance on what should be studied and how. There are historical issues related to research in this community; if researchers appear to be outsiders or are condescending toward community members, participation will not be forthcoming.

Ms. Tsark advised Program Managers to involve the community in research projects at the concept stage. 'Imi Hale uses focus groups to learn which issues are important in the community. Junior researchers planning pilot projects meet with the advisory group to encourage them to become engaged in the project; although this adds time to the project development stage, it makes the projects stronger, more meaningful, and more successful. The program fostered trainees from various backgrounds, not just people with a doctorate-level education. Mentoring may require only technical assistance, or it may require long-term one-on-one teaching; everyone has different needs. Ms. Tsark also emphasized the importance of sharing concepts and crosscutting values across CNs.

Regina Gibson, R.N., C.H.E.S., Arkansas Special Populations Access Network (ASPAN), Little Rock, Arkansas

Since Ms. Gibson started at ASPAN in 2000, the staff has grown from 2 people to 28, with more than 15 community partners. Ms. Gibson's management responsibilities are ever changing. For example, after writing the CNP application, the business manager quit before the 20 percent budget revision was completed; that placed the responsibility on Ms. Gibson. Time management is important because Program Managers often have extra responsibilities (e.g., supporting the PI's participation in clinical trials).

Ms. Gibson advised Program Managers to be familiar with their projects' goals and objectives and to solicit clarification if unsure what they are being asked to do. She strongly recommended that Program Managers take thorough minutes of staff and advisory group meetings. (Staff will not take notes but will ask questions later about what was decided.) Minutes must identify action items and who is responsible for them, with detailed timelines. Meeting minutes are also essential for preparing progress reports. The Program Manager must keep track of the number of training events, cancer education sessions, and other statistics related to project activities. In addition, Program Managers and Coordinators must be familiar with the budget at the line-item level because the PI and other investigators must be kept informed about what resources are or are not available.

Joyce Sheats, R.N., M.P.H., National Black Leadership Initiative on Cancer II: Network Project (NBLIC II), Atlanta, Georgia

Ms. Sheats works with David Satcher, M.D., Ph.D., and provides day-to-day oversight of the national office as well as programmatic and administrative support to four regions. She makes sure that fiscal operations comply with NCI and Morehouse School of Medicine policies and that the project is meeting its goals and objectives. Frequent monitoring with checks and balances is important. Ms. Sheats monitors progress in data collection activities and is the key person assisting in developing major documents and reports, including maintaining quality control.

Ms. Sheats considers herself a manager who "thinks outside the box." She consistently mentors staff, believing that if they grow, the project grows. Everyone on the core team brings something to the table. She has an open-door policy, listens to people who are successful, and maintains relationships with anyone who may be in a position to contribute to the project. She advises Program Managers to publish early and often; stop worrying about things they cannot change; and be willing to try new approaches if traditional methods are not working.

Claudia M. Hardy, M.P.A., Deep South Network for Cancer Control (DSNCC), Birmingham, Alabama

Ms. Hardy, who works with Edward E. Partridge, M.D., has many responsibilities as administrative officer and liaison with NCI and the University of Alabama at Birmingham. She supervises a large staff in the home and regional offices, and her office is responsible for training community-based volunteers.

Ms. Hardy tries to think ahead, keep an eye on the big picture, and still pay attention to detail. Her PI does not have time to be fully familiar with government and university regulations and budgetary procedures. Ms. Hardy advises Program Managers to become familiar with their PIs' management and communication styles. The Program Manager should use the PI's time wisely and avoid overloading him or her with unnecessary details, while still providing enough information so that the PI does not experience surprises. The Program Manager must keep the PI aware of major issues. Ms. Hardy noted that different management approaches work with different people (e.g., headquarters staff, field staff, community partners, investigators, NCI, etc.). The Program Manager must be flexible and trust people; others may have new ideas that work better than old ones. Above all, the Program Manager should never react emotionally to problems that arise.

Ms. Hardy believes there is a need for a formalized mentoring program among Program Managers in the CNP: a "buddy system" to provide mutual support and problem solving.

Yosselyn Rodríguez, Latin American Cancer Research Coalition (LACRC), Washington, DC

Ms. Rodríguez is responsible for coordinating activities and administrative tasks for the LACRC's primary institutional partner, the Washington Hospital Center. The Center also works with clinics throughout the Washington-Baltimore region. She advises Program Managers that it is important to develop close relationships with clinic staff in order to create trust, a key to success. Clinics need to understand what the project is doing. The Center has made presentations to the entire staff of each clinic. They have had to provide clinics with assistance in setting up better billing systems. Ms. Rodríguez recommends that Program Managers keep information at their fingertips in order to provide better support for their PIs.

Key Points From Discussion Session

- CIS personnel are very helpful; even those who are not assigned to be CNP liaisons can be a great resource.
- It would be helpful to establish a listserv, Web site, or other formal communication mechanism for CNs, especially for those who are new to this type of community-based project.
- Experienced SPN staff offered to serve as mentors for new participants.

Community Partners Meeting—Virginia Cain, Ph.D., Deputy Director, Office of Behavioral and Social Sciences Research, NIH

Dr. Cain facilitated an open discussion on community partnerships, including partner roles, skills required to be an effective partner, and resources needed to get the job done.

Key Points From Discussion Session

Roles of Community Partners

- Social workers make referrals and connect people with other people. Their role could be broadened.
- Community outreach specialists serve as liaisons between the community and the academic center. It takes a special person to deal with the tension between these two entities, helping the community take ownership of its needs and helping the academic center interact with the community.

- CNs must be strong advocates for the community. Academic centers must work to build strong trust in the communities. Researchers have a reputation for coming into a community to get data but never sharing their findings.
- Outreach partners must be from the community, but this can include regional as well as local communities.
- Project staff must focus on how they will make a difference in the community, using an individual rather than an agency perspective.
- The project must leave the community with skills that will continue to benefit the population after the CNP is gone.
- It is important to emphasize community infrastructure. The project must teach the community to be part of the data-gathering and capacity-building enterprises so that community members understand the research agenda and become involved in its planning. The project should teach the community about survey research and conduct focus groups to develop survey instruments.
- It is important to develop relationships of respect and equality within partnerships. The advisory board must be an equal-opportunity body in which academics are no more important than community members or outreach providers.

Building Relationships

- Projects must begin by building trust. One project spent its first few network meetings allowing the community to express its feelings of anger and mistrust in relation to research; scientific partners were asked to sit quietly and listen.
- Providing access to direct services helps build trust. Projects should try to find funding to treat people without insurance.
- A partnership must be a “win-win” relationship in which different entities work together toward meeting each other’s needs.

Community Education

- Projects can provide technical assistance and resources to community groups (e.g., local government, churches, physicians) that have their own initiatives. This fosters communication about what communities need.
- Projects can provide “Cancer 101” classes that teach basic, but important, cancer information. One effective method is appearances on local PBS television stations.
- Projects can form partnerships with other groups that provide what CNP cannot. For example, CNP projects can work with projects that have grant funds for conducting screening.
- When participating in health fairs, projects should send people who speak the language of the community and can best carry appropriate messages.
- Projects should cater to the actual needs and desires of the community. Academics should remember that they are in the community to learn.
- Projects should be willing to conduct one-on-one outreach. Individual encounters are just as important as large community events.
- Projects should hold forums to monitor progress and get feedback from the community.
- Staff should contact local community-based organizations to learn how to recruit participants in the community.

- Projects should develop coalitions and mobilize local leadership (government, church, fraternal groups, community leaders) in each state or community, regardless of economic or educational level. Community members listen to their leaders.
- Project staff should appear on local television and radio talk shows. It is a good idea to provide a list of topics to be covered.
- Each project should develop a speakers bureau to provide guests for community activities (e.g., church groups, civic organizations, community clubs).
- It is important to meet with as many other organizations as possible to develop a list of referral resources.
- Projects should consider providing incentives for participation (e.g., raffles or door prizes).
- CNP projects must identify individuals who are already involved in cancer-related services (e.g., health departments, hospitals) to learn what they are doing and determine how the projects can augment those activities.
- Researchers need to be culturally competent to educate the community on how to access and navigate the system. They should not talk down to community partners, who understand the wide variety of needs in their communities.
- Projects need to build partnerships with other agencies that can help address barriers related to issues such as lack of transportation and insurance coverage.
- Projects need to have someone navigating participants through the system so that no one “falls through the cracks.” After screening, for example, someone needs to ensure that participants receive the follow-up they need.
- Projects must keep in mind that a substantial time commitment is involved in training community groups.

Resources

- One responsibility of the PI is to navigate relationships with other organizations. Community organizations are looking for ways to address health disparities and would like to use the CNP projects as conduits.
- Projects should develop committees in partnership with other organizations ahead of time so that they will be in place when action is needed.
- CIS can provide guidance on partnering with the community.
- Tobacco Settlement money can be a useful resource for CNP projects.
- Local and state health departments have an outreach agenda. CNP projects should find ways to coordinate with health department efforts and perhaps tap into their resources.
- Projects do not need to “reinvent the wheel”; they should turn to NCI for materials.
- CNP project services should be provided consistently, with flexible hours and locations.
- Messages provided to the community must be simple, accessible, and understandable.
- Project personnel should remind elected officials that the people served by CNP activities are their constituents.
- Local government officials are potential sources of additional support. The U.S. Conference of Mayors has access to money from the Centers for Disease Control and Prevention (CDC). Support from a mayor’s office can speed up the process of establishing community partnerships.

IRB–Human Subjects Assurances—Judith Brooks, R.N., M.S., Public Health Analyst, Office for Human Research Protections (OHRP)

This session covered Federal regulations, Federalwide Assurance (FWA), institutional review board (IRB) review of grant application and subsequent projects, exempt research, informed consent, vulnerable populations, and additional protections.

Federal Regulations

The U.S. Department of Health and Human Services (DHHS) Policy for Protection of Human Research Subjects is published in 45 CFR 46. Originally adopted in May 1974, the rule was revised January 13, 1981, and June 18, 1991. The rule includes three additional subparts: Subparts B–D. Subpart B focuses on additional protection for pregnant women, human fetuses, and neonates involved in research; Subpart C defines additional protections pertaining to biomedical and behavioral research involving prisoners as subjects; and Subpart D covers additional protections for children involved as subjects in research. The 1991 revision, referred to as the “Common Rule,” is the same as 45 CFR 46 but does not include the three subparts.

Three basic protections for human subjects are included in 45 CFR 46: institutional assurance, institutional review boards (IRBs), and informed consent.

Institutional Assurance

An FWA is an agreement between an institution receiving funding (or other Federal support) and the Department that all human subjects research will be conducted in accordance with applicable regulations and standards for the protection of human subjects. FWAs with the Government can involve many different organizations or institutions, such as health clinics, PPOs, etc. Each institution engaged in human subjects research conducted or supported by DHHS must obtain an OHRP-approved assurance of compliance.

An institution’s human subjects research activities, whether or not they are subject to Federal regulations, are guided by the ethical principles in *The Belmont Report* and the Common Rule. Additional terms of assurance include agreeing to comply with other Federal, state, or local laws; understanding the assurance’s applicability; following IRB written policies and procedures; operating within the scope of IRB responsibilities; meeting informed consent requirements; addressing considerations for vulnerable populations; meeting requirements for assurances for collaborating institutions; and obtaining written agreements with collaborating investigators.

Determining Applicability of DHHS Regulations

Research is a systematic investigation designed to develop or contribute to generalizable knowledge. A *human subject* is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or by collecting identifiable private information. Private information is information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. In 45 CFR 46.102(f), *private information* is defined as information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable to obtain the information in order to constitute research involving human subjects. Information is considered identifiable if the subject’s identity is or may be readily ascertained by the investigator or associated with the information.

Exempt Research

Some research is exempt from Federal regulations. OHRP recommends that institutions, not investigators, determine whether the research qualifies as exempt under the regulations. Exempt research categories are as follows: normal educational practices in established educational settings; educational tests, surveys, interviews, or observation of public behavior unless identified *and* sensitive; research using existing data, if publicly available *or* recorded without being identifiable; research on elected or appointed public officials or candidates for public office; evaluation of public benefit service programs; and taste and food-quality evaluation and consumer acceptance studies.

Although research may be considered exempt, IRBs may choose to review the research (usually through an expedited process). This decision is at the IRB's discretion and dependent on institutional policies. PIs should contact their respective institutions' IRB offices for guidance on submitting plans for exempt consideration.

Institutional Review Boards

An IRB is a committee charged with the review of human subjects research to ensure that subjects' rights and welfare are adequately protected. IRB reviews are necessary for several reasons, including: investigators cannot be objective about their own work; people underestimate the risks involved in familiar situations; and people overestimate the benefit of things that are important to them.

An IRB must review and approve proposed research before research activity begins. IRBs conduct three types of reviews: full board, expedited, and continuing. A full board review is the review of proposed research at a convened meeting at which a majority of the members of the IRB are present, including at least one member whose primary concern is in nonscientific areas. IRB members may participate in the meeting by telephone, but not by mail or e-mail. Proposed research must be approved by a majority of those present. Members with a conflict of interest should not be present during the discussion and voting process. If the quorum should fail during a meeting, no further votes can be taken unless the quorum can be restored.

Modifications to already reviewed research plans must be reviewed before they are implemented. The only exemption is when plans are modified to reduce risk to subjects.

Expedited reviews are carried out by the IRB Chair or experienced voting member(s) of the IRB. To qualify for an expedited review, research must carry no more than minimal risk and involve only procedures listed in one or more of the following categories: clinical studies (excluding drug development studies); noninvasive prospective collection of biological specimens; noninvasive data collection used in clinical practice; individual or group characteristics or behaviors; collection of blood samples; collection of data, documents, records, and specimens for nonresearch purposes; voice, video, digital, or imaging recordings for research; and continuing review of projects approved under full board review (no new subjects, minimal risk). In addition, minor changes to previously approved research qualify for expedited review.

A continuing review must be interval-appropriate to the degree of risk and should be set for each protocol. Continuing reviews must be conducted at least once per year; there are no grace periods for continuing reviews. The IRB approval criteria are the same as those for initial full board review. The documentation for continuing reviews should include (but not be limited to) the number of subjects accrued; a description of any adverse events or unanticipated problems involving risks to subjects or others, any withdrawal of subjects from the research, or complaints about the research; a summary of new information relevant to human subjects, especially information about risks associated with the research; a copy of the current consent document; and a copy of the grant application. A copy of the grant application should be submitted with each proposed research project at initial and continuing reviews. For further information, see <http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-01.htm>.

IRB certification is the official notification by the institution to the supporting Federal sponsor that a research project involving human subjects has been reviewed and approved by an OHRP-registered IRB. Research activities involving human subjects may not be conducted or supported by DHHS unless the activities are exempt from, or approved in accordance with, 45 CFR 46. DHHS requires IRB review of each application or proposal for Department-supported human subjects research. See <http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm>.

The grant application can be submitted to the reviewing official or IRB at the time of research project submission. Documentation of IRB actions or evidence that the research has been determined exempt is required. (The Assurance Identification/IRB Certification/Declaration of Exemption Form is available at <http://www.hhs.gov/ohrp/humansubjects/assurance/OF310.rtf>.) Each subsequent project supported by the grant must either be found exempt or certified by the IRB.

Informed Consent

Informed consent is required for all human subjects research except that which has been determined exempt. Informed consent will be obtained prospectively in writing where the language is understandable to the research subject.

An IRB may waive the requirements for obtaining informed consent provided that the research meets all of the following criteria: the research involves no more than minimal risk to subjects; the waiver will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver; and, whenever appropriate, the subjects will be provided with additional information pertinent to the study after they have participated. Informed consent waiver approval must be documented in the IRB minutes.

An IRB may waive the requirements for written documentation of consent in cases where the research presents no more than minimal risk and involves procedures that do not require written consent when performed outside of a research setting or the principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research and the consent document is the only record linking the subject with research. Subjects still give oral, but not written, consent in these cases.

Vulnerable Populations

Vulnerable populations include children, pregnant women, prisoners, and any other group that is vulnerable to coercion (e.g., the mentally disabled, the economically or educationally disadvantaged, students, and employees).

Additional Protections

Investigators should consider limiting access to, securing, and coding or encrypting data.

OHRP Resources

Toll free: 866-447-4777

E-mail: ohrp@osophs.dhhs.gov

Web site: <http://hhs.gov/ohrp>

Collecting Usable Data for Screening, Tobacco, Energy Balance Programs—Robert T. Croyle, Ph.D., Director, Division of Cancer Control and Population Sciences (DCCPS)

Dr. Croyle moderated this session, which provided an overview of the risk-behavior measurement domains that are relevant to the work of the CNP.

Measuring Cancer Screening—Sarah Kobrin, Ph.D., M.P.H., Program Director
Risk Perception, Applied Cancer Screening Research Branch, Behavioral Research Program

Dr. Kobrin provided an overview of existing measures and where to find them, emerging issues in screening measurement, and areas for future research.

A standard vocabulary is needed. Existing measures are likely to have been psychometrically and cognitively tested, and consistent measurement of screening outcomes would allow for consistency and comparability across studies. Examples of inconsistencies include: the definition of *recent* mammogram (measured in yearly intervals?); definition of *repeated* screening (e.g., number of Pap tests in past 6 years or how long before the current Pap smear was the previous one?).

Challenges for measuring cancer screening are as follows:

- Breast—Variations in starting age and frequency recommendations
- Colorectal—Many options, new technology
- Cervical—Variations in frequency recommendations; need for HPV-related questions
- Prostate—No clear mortality benefit; lack of clarity as to how to measure the U.S. Preventive Services Task Force recommendation (i.e., “Have a conversation with your doctor.”)

Four health data surveys were described and compared. The National Health Interview Survey (NHIS) is a national, annual in-person household survey conducted by CDC’s National Center for Health Statistics. NHIS measures a wide variety of health indicators, health care use and access, and health-related behaviors (see <http://www.cdc.gov/nchs/nhis.htm>). The California Health Interview Survey (CHIS) is a random-digit-dialed telephone survey conducted in California every 2 years. CHIS is conducted in multiple languages (see <http://www.chis.ucla.edu>). The Health Information National Trends Survey (HINTS) is a new NCI random-digit-dialed telephone survey of a national probability sample of adults that addresses health information needs and health outcomes and behaviors (see <http://cancercontrol.cancer.gov/hints/index.jsp>). The Behavioral Risk Factor Surveillance System (BRFSS) is a national random-digit-dialed telephone survey continuously conducted by CDC. BRFSS provides state-level assessments of major behavioral risks (see <http://www.cdc.gov/brfss/>).

Guidelines for Cancer Screening

Concerning adherence to guidelines, all four surveys contain “Have you ever had ...?” and “When did you have the most recent ...?” questions for all four cancers. NHIS includes proctoscopy; BRFSS includes clinical breast exam and digital rectal exam.

Behavioral assessments were included in NHIS 2000 and HINTS II. NHIS 2000 included a module for breast cancer risk factors, history of abnormal mammograms and Pap tests, prostate-specific antigen (PSA) and fecal occult blood tests, and a PSA discussion. HINTS II includes discussions on PSA, Pap repeat and intention to retest, and HPV history.

Attitudes and beliefs were collected as follows: NHIS, CHIS, and HINTS ask the main reason screening was sought; NHIS asks the main reason screening was *not* sought; and HINTS II includes questions about beliefs pertaining to HPV and a mental model of colorectal cancer.

National surveys have had little validity testing, especially in minorities, and there is variation among them.

An NCI working group developed a core set of measures of colorectal cancer screening behaviors, including questions related to adherence to and benefits of screening (Vernon et al., Measures for ascertaining use of colorectal cancer screening in behavioral, health services and epidemiological research (CEBP 2004;13:898–905).

The National Survey of Colorectal Cancer Screening Practices asks providers about recommendation and practice behaviors, attitudes about screening, and extent of training in screening procedures.

Emerging Issues at NCI

- The recommendations used to be simple: Have a test. Things are now more complicated.
- Choosing a colorectal test depends on clear benefit, invasiveness, timing, and cost. New process measures are needed.
- There is no consensus on whether mammograms are necessary for women in their 40s.
- PSA for prostate cancer remains problematic. The Behavioral Research Program is looking into factors related to patient-physician discussion.
- Regarding the provider survey, challenges include identifying key areas for speedy assessment and avoiding “socially desirable” responses. To meet these challenges, two versions of the survey (covering different cancers) were developed and vignettes were used (to avoid socially desirable responses).

Future Research

Agreement on conceptualization must precede measurement. It is important to emphasize external validity. Innovation is needed to move away from conventional, time-consuming, self-report measures.

Contact Information

Applied Cancer Screening Research Branch

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<http://cancercontrol.cancer.gov/acsr/b/>

Key Points From Discussion Session

- Existing local studies do not have adequate power to measure the impact of screening on mortality in a population. Anecdotal evidence based on experiences of people screened in the community can be a powerful tool in bringing the benefits of screening to the attention of that community.
- One way to validate national surveys for subpopulations (e.g., subgroups within the Asian population) is to facilitate collaboration among investigators involved in validating surveys for various populations.
- It is becoming more difficult to reach people by telephone, especially among minorities. NCI supports surveys using other sampling methods, including agreements supporting access to members of registries and other preexisting samples.

Measuring Diet and Physical Activity—Linda Nebeling, Ph.D., M.P.H., R.D., F.A.D.A., Chief, Health Promotion Research Branch, DCCPS

Dr. Nebeling addressed existing measures (diet, physical activity) and where to locate them, emerging directions in nutrition and behavior assessment, and future directions and funding opportunities.

The Diet History Questionnaire

The Diet History Questionnaire, which is the foremost instrument in this area, includes a food frequency questionnaire that lists 124 food items, collects data on portion size, and includes dietary supplement questions. Self-administered and optically scanned, the questionnaire is intended for use with adults. Questionnaire responses are compiled in an extensive database of national dietary data. A Web-based

version is scheduled for implementation in September 2005. Extensive cognitive research was performed to ensure ease of use.

Short Dietary Assessment Instruments

Multiple short dietary assessment instruments (screeners) are used to measure specific dietary habits—for example, fruit and vegetable consumption (available in Spanish, Chinese, Korean, and Vietnamese); percentage of calories from fat; and intake of fiber, added sugar, and dairy products. These instruments were developed by NCI and can be self-administered or administered by an interviewer in person or by telephone. Data from these instruments are used to characterize median intakes, discriminate between high and low intake, track changes, examine relationships between diet and other variables, and compare with other studies.

The Dietary Assessment Calibration/Validation Register

The Dietary Assessment Calibration/Validation Register is used to compare estimates from two or more dietary assessment methods. The register includes food records, diaries, dietary recalls, food frequency questionnaires, dietary histories, observed intakes, and biological assessments from 164 studies and 746 publications. The Register facilitates access to the existing body of dietary assessment methodology literature. For further information, see <http://www-dacv.ims.nci.nih.gov/>.

The Glycemic Index Values Database

The Glycemic Index (GI) Values database provides GI values for foods consumed by adults and queried in the Diet History Questionnaire and/or other food frequency questionnaires. (GI measures the glycemic effect of carbohydrate in a particular food compared with an equivalent amount of carbohydrate in a standard amount of glucose or white bread.) Food codes from the USDA Continuing Survey of Food Intakes of Individuals are used as a reference.

Daily Food Checklist

The Daily Food Checklist was designed to capture how often certain foods are consumed. The optically scannable tool comprises a list of foods; over the course of a single day, respondents check a particular food each time they eat it. Checklists are completed for multiple days in order to capture usual intake. The checklist does not rely on memory, and it creates a relatively low burden on respondents and investigators. Based on analyses of 30 consecutive days of checklist reports from the 1996–1997 NCI America's Menu Study, completing the checklist does not change the behaviors it assesses. For further information, visit the Risk Factor Monitoring and Methods Branch Web site at <http://riskfactor.cancer.gov/>.

Physical Activity and Energy Expenditure Measures

Physical activity measures are 20 years behind dietary assessment. Movement assessment devices include pedometers, step counters, motion counters, and accelerometers. Physical activity is measured using behavioral observation and time-motion analysis, diaries, and questionnaires and interviews. Behavioral questionnaires explore motivation and predictors.

5 A Day Custom Survey

The purpose of the 5 A Day Survey is to evaluate fruit and vegetable (F/V) intake and established and new predictors. It will incorporate new questions that assess portion sizes in cups. African Americans will be oversampled. The survey explores the following constructs:

- Social influence and support: “Other people give me a hard time if I eat a lot of F/Vs.”
- Benefits and barriers: “I will have more energy, live a long life.” “F/Vs are not filling or spoil too quickly.”

- Self-efficacy: confidence about eating F/Vs when away from home
- Lifestyle correlates: smoking, alcohol consumption
- Preferences: salty, sweet, tart or sour, meat, low carbohydrate
- Knowledge of recommendations and awareness: How many cups of F/Vs does the Government recommend? What is the name of the national campaign to eat more F/Vs?
- Personal health beliefs: How often do you worry about getting sick? Has worry led you to change what you eat?
- Food shopping behaviors: who, how often (regular and going out of the way), where (other venues, like farmers' markets, pick-your-own), seasonality
- Beliefs about vegetarianism: "Vegetarians are different; I cannot relate to vegetarians."
- Extrinsic and intrinsic motivation: "I want others to see I can do it (external)." "It is important to treat my body with respect (internal)."

In addition, several new constructs will be investigated: sleep, water consumption, television and Internet use, religiosity, practicing yoga, avoiding or restricting certain foods, and social desirability.

The survey includes two additional items on F/V consumption: (1) On average, how many cups of **fruit** (including 100 percent fruit juice) do you eat/drink each day? (2) On average, how many cups of **vegetables** (including 100 percent vegetable juice) do you eat/drink each day?

8-Item Fruit and Vegetable Screener

The 8-item F/V screener is based on a modified NHIS questionnaire and includes frequency and amounts in cups. (A callout box provides one-cup equivalents as a refresher.)

Other outcomes from cognitive testing indicate that knowledge and awareness of F/V consumption recommendations are low; people convey frustration about changing recommendations; and cup equivalents are very helpful.

Trans-NIH Initiatives

The Behavior Change Consortium (BCC) includes 16 sites that use common measures (see <http://www1.od.nih.gov/behaviorchange/>). The BCC summary report is available at <http://www1.od.nih.gov/behaviorchange/summary/summary.htm>.

The Health Maintenance Consortium continues the work of the BCC. Outcomes and findings are not yet available. (See <http://hmcrc.srph.tamu.edu/default.aspx>.)

See also the Health Promotion Research Branch Web site at <http://cancercontrol.cancer.gov/hprb> and Cancer Control PLANET at <http://cancercontrolplanet.cancer.gov/>.

Future Directions and Funding Opportunities

Future activities in this area will involve eHealth and real-time data capture. For an example, see the Bioengineering Approaches to Energy Balance and Obesity (SBIR/STTR) (PA-04-156) program announcement at <http://grants.nih.gov/grants/guide/pa-files/PA-04-156.html>. For funding opportunities, see <http://grants.nih.gov/grants/guide/index.html>.

Key Points From Discussion Session

- Diet is possibly the most diverse factor for those working with minority populations. About one-third to one-half of the survey instruments are available in different versions targeting various populations. NCI is cognizant of these issues and is developing national data sets in an attempt to ensure that

multiple groups are represented. NCI can work with the Department of Agriculture to develop questions targeting special populations or geographic regions.

- Cost and availability of quality foods and unique food preparation methods are relevant to dietary issues for African Americans. Many food programs, such as school programs, do not implement 5 A Day guidelines. The fact that a specific portion of fruits or vegetables is not as filling as a similar portion of meats or carbohydrates is an issue for obese populations. NCI's Body & Soul program is working with African-American churches to bring appropriate messages about diet that are not limited to fruits and vegetables. Environmental and cultural variations and barriers exist; NCI is learning how to engage communities to disseminate food preparation information that promotes health. In terms of measurement, NCI takes into consideration neighborhood variables, including location and hours of operation of food outlets. One problem is that some of the worst sources of food are the best sources of employment.
- The scientific community has sent some mixed messages about obesity. A new NCI survey (to be reported on by Brad Hesse on July 20) focuses on levels of confusion about obesity that are the result of variations in quality and analysis of data on this public health problem.

Measures of Tobacco Use—Stephen Marcus, Ph.D., Epidemiologist, Tobacco Control Research Branch, Behavioral Research Program, DCCPS

The public health model for tobacco use has the following domains: agent (tobacco products); host (consumer or potential consumer); vector (the tobacco industry and others that distribute and promote); and the environment (the context in which agent, host, and vector operate). Most research studies focus on one of these domains.

Agent characteristics include product type, nicotine dose, constituents (e.g., tar, CO) and ingredients (e.g., additives), and market share. Host characteristics include tobacco use behavior, genetic susceptibility, addiction, risk perception, exposure to secondhand smoke, and attitudes about smoking in public. Vector characteristics include pricing strategies; advertising, marketing, promotion, and public relations; corporate sponsorship and donations; and political activism. Environmental factors include state and local tobacco control policies (e.g., clean indoor air, youth access, worksite restrictions); antitobacco marketing; excise taxes; social norms about smoking; and insurance coverage for treatment.

Standard adult smoking status questions include: "Have you smoked at least 100 cigarettes in your entire life?" and "Do you now smoke cigarettes every day, some days, or not at all?" Responses to these standard questions are used to define current, former, and never smokers. Other behavioral constructs include age at initiation, frequency and intensity of use, duration of product use, addiction or dependence, quitting and maintenance history, and methods used to try to quit.

Host items from the Tobacco Use Supplement to the Current Population Survey (TUS-CPS) have been translated into Spanish, Korean, Chinese (Mandarin and Cantonese), and Vietnamese. CHIS host items have been translated into Spanish, Chinese, Vietnamese, Korean, and Khmer (Cambodian).

Tobacco Use Supplement to the Current Population Survey

TUS-CPS is a key source of national and state data on smoking and other tobacco use. It contains about 40 items covering a wide variety of topics, including cigarette smoking prevalence; smoking history (current and past consumption); cigarette smoking quit attempts and intentions to quit; cigar, pipe, chewing tobacco, and snuff use; medical and dental advice to quit; home and workplace policies; and attitudes towards smoking in public places. TUS-CPS data are used to monitor trends in tobacco use, conduct tobacco-related research, and evaluate tobacco control programs.

Validity and Reliability Testing

The following are useful examples of validity and reliability testing:

Caraballo RS, Giovino GA, Pechacek TF. Self-reported cigarette smoking vs. serum cotinine among U.S. adolescents. *Nicotine Tob Res* 2004;6:19–25.

Panter AT, Reeve BR. Assessing tobacco beliefs among youth using item response theory models. *Drug Alcohol Depen* 2002;68:S21–39.

Resources

Resources are available from the Federal Government (NCI, CDC), non-Government organizations (ACS, Legacy, RWJF, ALA), professional associations (Society for Research on Nicotine and Tobacco), extramural researchers (Transdisciplinary Tobacco Use Research Centers), state governments, and state tobacco control organizations. Two of the most useful sources of standardized questions are the CDC Question Inventory on Tobacco (QIT) (host and environment), available at http://apps.nccd.cdc.gov/QIT/index_clt.asp, and the American Legacy Foundation's Tobacco Survey Database (host and environment) at <http://tobacco.rti.org/data/New/index.cfm>.

In addition, the following specific resources were discussed:

- The Society for Research on Nicotine and Tobacco (SRNT) workgroup examined outcome measures used in clinical trials (host). The workgroup developed the following minimum recommendations: use prolonged abstinence as preferred measure plus point prevalence as secondary measure; define treatment failure as 7 consecutive days of smoking or smoking on 1 or more days of 2 consecutive weeks; include noncigarette tobacco use but not nicotine medications in definitions of failure; and report results from survival analysis to describe outcomes more fully.

The SRNT workgroup results led to publication of an article: Hughes J. et al. Measures of abstinence in clinical trials: issues and recommendations. *Nicotine Tob Res* 2003;5:13–25.

Other SRNT workgroups reported on biochemical validation, withdrawal, harm reduction, adolescent outcomes, and statistical issues.

- Wisconsin Transdisciplinary Tobacco Use Research Center (TTURC) (host—addiction and dependence): http://www.ctri.wisc.edu/Researchers/researchers_measures&scales.htm
- Behavior Change Consortium (host): <http://www1.od.nih.gov/behaviorchange/measures/smoking.htm>
- NCI Measures Guide for Youth Tobacco Research (host), http://dccps.nci.nih.gov/tcrb/guide_measures.html, validated youth measures, including advertising receptivity, beliefs and expectancies, smoking susceptibility, dependence, friends or family smoking, mood, problems, smoking behavior, stressors, temptations to smoke, self-efficacy, and validity of self-report.
- Action on Smoking and Health (agent): <http://www.ash.org.uk/html/regulation/html/chemistry.html>
- Tobacco Control Resource Center for Wisconsin (agent, host, vector, and environment): http://www.tobwis.org/tobacco_industry/index.php?category_id=19
- Contract: Laboratory Assessment of Tobacco Use Behavior and Exposure to Toxins Among Users of New Tobacco Products (agent, host): <http://rcb.cancer.gov/rcb-internet/appl/rfp/55009/toc.pdf>
- A new funding opportunity: Testing Tobacco Products Promoted to Reduce Harm (agent), a further examination of new products. For information, see <http://grants.nih.gov/grants/guide/pa-files/PA-04-103.html>.

- The Tobacco Industry Monitoring Evaluation (TIME) Listserv (vector) lists tobacco-sponsored public events in California and ten other comparison states. For additional information, contact tsscruz@usc.edu. Tobacco industry documents (vector) are available at <http://www.library.ucsf.edu/tobacco/>.
- The ImpacTeen State Level Tobacco Legislative Database (environment), at <http://www.impacteen.org/tobaccodata.htm>, covers the following topics: price, tax, and funding; youth access laws; smoke-free air laws; and smoke-free air preemption.
- Campaign for Tobacco-Free Kids (vector, environment): <http://www.tobaccofreekids.org/research/>
- Chriqui JF et al. Application of a rating system to state clean indoor air laws (USA). *Tob Control* 2002;11:26–34 (environment).
- State Cancer Legislative Database Program (environment): http://www.sclcd-nci.net/sclcd_tobaccoratings.cfml
- State Legislated Activities on Tobacco Issues (environment): <http://slati.lungusa.org/>
- CDC/OSH State Tobacco Activities Tracking and Evaluation System (environment): <http://apps.nccd.cdc.gov/statesystem/>
- Office on Smoking and Health State Activities

Future Directions

The Tobacco Informatics Grid (ToBIG) is intended to fill the need for a “one-stop shopping” portal for tobacco control. There are plans to create a community-based sensor network for rapid-response surveillance as part of this effort. The workspace will include tobacco data, people, and resources, as well as standardized core measures across agent, host, vector, and environment.

The ToBIG is part of the Initiative for the Study and Implementation of Systems (ISIS), a transdisciplinary, multi-agency project to apply systems thinking to tobacco control.

Dr. Marcus announced that NCI is holding a planning workshop in August for a National Longitudinal Study of Tobacco Use and Quitting (NLSTUQ). He invited anyone who is interested in participating in the workshop to contact him at sm311j@nih.gov.

Key Points From Discussion Session

- A small group of planners will meet with tobacco control experts, systems thinkers, dynamic modeling experts, network builders and analysts, and informatics experts in September to help determine the future mission and direction of ISIS and ToBIG.

Grants Administration Issues—Crystal Wolfrey, Team Leader, Grants Administration Branch

Roles and Responsibilities in the Grants Process

The Program Director is responsible for the programmatic, scientific, and/or technical aspects of grants. Pre-award, the Program Director initiates and encourages interest in scientific areas of importance to match the Institute’s mission (e.g., developing and writing RFAs and program announcements); prepares funding recommendations, including any programmatic reductions to budgets before funding; and reviews and approves/rejects any changes to the scientific aims that may be necessary because of funding constraints. Post award, the Program Director reviews requests for prior approval, provides scientific input, and recommends approval/rejection; reviews annual progress of grants; and, in the case of Cooperative Agreements, may have substantial programmatic involvement in the project.

The Grants Management Officer (GMO) monitors fiscal and administrative aspects of the project. The GMO is the only NIH official authorized to obligate NIH to the expenditure of funds or to change funding amounts, budget or project period dates, or other terms and conditions of a grant award.

The Grants Management Specialist (GMS) acts as an agent of the GMO, ensuring compliance with laws and NIH/HHS policies and procedures. The GMS analyzes grant applications and budgets; provides technical assistance in interpreting NIH policies and Institute procedures; awards grant funds; and reviews and responds to grantees' prior approval and rebudgeting requests. The GMS can answer questions about completing PHS 398 and PHS 2590 forms, provide guidance on administrative and fiscal aspects of applications and awards, and help navigate NIH grants management information on the Web.

The following Grants Management Specialists have been assigned to the CNP: Catherine Blount, Jennifer Edwards, Funmi Elesinmogun, Priscilla Grant, Galen Gregor, Kimery Griffin, Sean Hine, Lan Hoang, Brett Hodgkins, Brian Iglesias, Amy Knight, Gerard McCann, Teresa Parker, Jennifer Tucker, and Aida Vasquez.

Expanded Authorities and Prior Approval Requirements

Under expanded authorities, the grantee institution has the authority to take certain actions on grants without prior agency approval; however, some actions still require NCI prior approval. When in doubt, projects should contact the appropriate GMO or GMS.

Examples of actions that do not require prior agency approval include:

- First 12-month no-cost extension of a project period.
- Rebudgeting funds between budget categories if not an indication of a change in the scope of the project.
- Use of program income if grantee is not a for-profit organization.
- Transferring performance of work to a third party or changing a third party if not an indication of a change in scope and the third party is not a foreign organization.
- Incurring patient care costs (if not previously approved) or rebudgeting additional funds into or out of this category unless indicative of a change in scope.

Examples of actions that require prior agency approval include:

- Second or subsequent no-cost extension.
- Change of PI or significant reduction in level of effort of the PI.
 - ◆ Significant reduction in the level of effort of key personnel requires NCI prior approval.
 - ◆ *Significant* is defined as a 25 percent or more reduction in effort.
 - ◆ The PI is **always** defined as key personnel.
 - ◆ Other key personnel would need to be specifically named in the terms of the Notice of Grant Award (NGA).
- Change of grantee institution.
- Addition of a foreign component.
- Undertaking activities rejected or restricted as a term of award.
- Need for additional NIH funds.
- Carryover of restricted funds if required by term of award.
- Retention of research grant funds when a career award (K series award) is made.

- Change in scope, including:
 - ◆ Change in aims.
 - ◆ Shift in research emphasis.
 - ◆ Change in use of human subjects or animals.
 - ◆ Significant change in key personnel.
 - ◆ Significant rebudgeting (deviation from a single category committed costs greater than 25 percent of total costs awarded).
 - ◆ Application of new technology.
- Carryover of unobligated balances from one budget period to the next.
- Rebudgeting funds that were specifically restricted in the terms of the NGA.

All requests for NCI approval must be submitted in writing no later than 30 days before the proposed change, signed by the PI and the business official, and sent to both the Program Director and the GMS. Only responses to prior approval requests signed by the NCI GMO are valid. For further information, see the NIH Grants Policy Statement at http://grants2.nih.gov/grants/policy/nihgps_2001/part_iiia_5.htm.

Prior approval requests sent via e-mail must be sent through the grantee business official and must include complete grant number, grantee name, PI name, PI's phone and fax numbers, and a clear explanation of the request with appropriate scientific justification.

Reporting Requirements

The annual progress report (PHS Form 2590) is due 60 days before the project anniversary date, must be a full application (i.e., those awards not under the Streamlined Noncompeting Application Process), and must include a detailed budget for the next budget period. The annual financial status report (FSR Form 269) is due 90 days after the budget period end date; GAB will not issue a pending award if the required FSR has not been received and accepted by NIH.

Closeout requirements include a final financial status report, final invention statement and certification, and final progress report. Failure to submit timely and accurate closeout reports may affect future funding. The 90-day requirement is a term and condition of all NIH grant awards.

Human Subjects Research

Regulations governing the use of human subjects in research are found at 45 CFR Part 46. The Office for Human Research Protections (OHRP) Division of Compliance Oversight reviews institutional compliance with the Federal regulations governing the protection of human subjects in DHHS-sponsored research.

Each institution engaged in federally funded human subjects research must provide written assurance satisfactory to the OHRP that it will comply with the requirements set forth in human subjects regulations (see 45 CFR 46.103(a) at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) unless the research is exempt under 45 CFR 46.101(b). Departments and agencies will conduct or support research covered by the regulations only if the institution has an Assurance approved and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the Assurance and will be subject to continuing review by the IRB.

An institution is considered to be engaged in human subjects research when its employees or agents intervene or interact with living individuals for research purposes or obtain individually identifiable private information for research purposes (45 CFR 46.102(d), (f)). An institution is engaged in human subjects research whenever it receives a direct HHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects.

Obtaining an approved Assurance from OHRP is a two-step process. First, institutions must ensure that the IRB(s) they designate under the Assurance are registered with OHRP. If not, they must submit the registration. Second, they must complete the Assurance application. See the OHRP Web site at http://www.hhs.gov/ohrp/assurances/assurances_index.html for submitting an FWA and <http://www.hhs.gov/ohrp/assurances/> for registering an IRB.

OHRP recently issued a clarification on human subjects research: Research involving coded private information or biological specimens is no longer considered human subjects research. NIH added definitions and clarifications relevant to the *OHRP Guidance to PHS 398* (rev. 9/04) instructions. All grant applications and progress reports involving coded private information or biological specimens submitted on or after January 10, 2005, should follow the revised instructions. (See <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-020.html> and *OHRP Guidance*, August 10, 2004, at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.)

Reminders

NIH requires complete and up-to-date “Other Support” information before an award can be made; this includes all sources of research support. Grantees must report changes in “Other Support” as part of the annual progress report. (See *NIH Guide*, February 13, 2003, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-029.html>.)

Calculation of direct costs for application with consortium or contractual facilities and administrative (F&A) costs has been changed. All applications that involve consortium or contractual F&A costs are to exclude the F&A costs requested by consortium participants from the total direct cost requested for the purposes of complying with any direct-cost caps (e.g., RFA caps, modular budget caps, the over-\$500,000 cap). See <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html>.

All progress reports received on or after May 1, 2005, must use the revised 2590 form, which uses the new definition of *Key Personnel* implemented in the *NIH Grants Policy Statement* (rev. 12/03). “Other Significant Contributors,” introduced in the PHS 398 (rev. 9/04), has been incorporated. See <http://grants.nih.gov/grants/forms.htm>.

NIH implemented the sending of two separate progress report e-mail reminders to the PI in June 2003: One is sent 2 months prior to the due date, and the other is sent 2 weeks after the due date for overdue reports. Commons-registered institutions and PIs have access to due-date information through the Commons Status system, and PIs have access to prepopulated face pages through the Commons Status system. All grantees have access to a searchable list of progress reports due at http://era.nih.gov/userreports/pr_due.cfm. (See *NIH Guide*, August 5, 2003, at <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-054.html>.)

NIH has implemented a central receipt point for all 2590 applications. Grantees need submit only a signed original and one copy. This change is effective with noncompeting progress reports due on or after October 1, 2004. (See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-054.html> and <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-063.html>.) For questions on format, contact format@mail.nih.gov. To view frequently asked questions on format, see <http://www.format.nih.gov/>.

The salary cap restricts the amount of direct salary under a grant or contract to Executive Level 1 of the Federal Executive Pay Scale. The Executive Level I increase was effective January 1, 2005. (See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-024.html>.)

When a conflict of interest is identified, the grantee must notify the chief GMO to assure him or her that the conflict is being managed, reduced, or eliminated and provide additional information, if requested. Financial conflict-of-interest requirements must be addressed in consortium agreements. (See <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html> and <http://grants2.nih.gov/grants/guide/notice-files/not95-179.html>.)

A new public access policy for publications resulting from NIH-funded research became effective May 2, 2005: NIH-funded investigators are requested to submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript—upon acceptance for publication—resulting from research supported, in whole or in part, with direct costs from NIH. (See <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html>.) The policy has three components: access, archive, and advance science. Electronic access to NIH-funded research publications will be available for patients, families, health professionals, teachers, and students. A central archive of NIH-funded research publications will be maintained to preserve vital medical research results and information. An information resource will be created to make it easier for scientists to mine medical research publications and for NIH to better manage its entire research investment.

The NIH eRA Commons Registration is open to all institutions. Authorized organizational officials should register the institution. To determine whether an institution is already registered, see http://era.nih.gov/userreports/ipf_com_org_list.cfm. To register, go to the Commons home page and click the registration link, enter information, and print the signature page and fax it to NIH. It takes 2 to 3 days to process a registration. The Help Desk can assist with any problems.

Commons administration functions include the ability to create and maintain institutional profiles (IPFs) and to create and maintain user accounts and professional profiles (PPFs). Status functions include the following capabilities: display summary and detail grant information, Notice of Grant Award and other documents, progress report face page, and NIH staff contact info; link to study section dates and rosters; submit Just-in-Time (JIT) information; and submit a request for a no-cost extension.

JIT is a new feature that allows grantees to electronically submit IACUC approval date, IRB approval date, “Other support” page for key personnel, and human subjects education information for key personnel involved with human subjects. The feature currently allows only one submission per grant, requiring all data at the same time; a future enhancement will allow multiple submissions.

Commons user support is available through the following:

- eRA Web site: <http://era.nih.gov/>
- *Inside eRA for Partners* Newsletter: http://era.nih.gov/eranews/backissue_partners.cfm
- Commons Web site: <https://commons.era.nih.gov/commons/>
- Commons Demos: <https://commonsdemo.era.nih.gov/commons-demo/>
- Commons Support Page: <http://era.nih.gov/commons/index.cfm>
- Information for Partners: http://era.nih.gov/Projectmgmt/SBIR/sbir_grants.htm
- Commons Help Desk: 301-402-7469, 866-504-9552, 301-451-5939 (TTY), commons@od.nih.gov

“Nuts and Bolts” for New Community Networks (CNs)

This session identified elements that are essential for operating a project effectively and efficiently. Panelists were selected for their longevity with their Special Populations Network projects. Rosita L. Edwards (ATECAR); Regina Gibson (ASPAN); Claudia M. Hardy (DSNCC); Crystal Wolfrey (NCI); Yosselyn Rodríguez (LACRC); and Kipling Gallion (*Redes En Acción*) served on the panel. Most of the panelists had participated in the earlier Program Managers/Coordinators session and simply repeated and expanded on their earlier remarks for this audience.

Ms. Edwards stated that she focuses on community programs and how the programs are implemented. CNs need to be adaptable, flexible, and teachable to better serve diverse communities. She has learned that it is important to support good team relationships. Building networks to achieve success in the community requires patience.

Ms. Gibson stated that being a Project Manager (PM) is sometimes a thankless job. PMs must understand the IRB process and be aware of everything going on within the project, including program plans and the budget. The PM is required to report on all project activities in the annual progress report; detailed minutes need to be taken at all meetings and kept on a shared server so that all meeting participants can have access. She suggested that it would be helpful to create a listserv or other networking or mentoring network for CNP PMs. She advised PMs to make friends with administrative personnel at the highest institutional level.

Ms. Hardy explained that PIs often participate in many activities and have many responsibilities, and PMs need to use the PIs' time wisely. It is important to understand the PIs' management and communication styles. PMs need different approaches to manage headquarters and offsite personnel. PMs must be thoroughly aware of all institutional systems and procedures. Working with community partners requires unique strategies. Attention to detail and perspective on the big picture are equally important. PMs often need to draft correspondence, applications, and other documents for project staff, as well as progress reports. PMs must remember that they represent their programs and should present themselves in a positive light.

Mr. Gallion reported that a national project has different concerns for a PM. Collecting information on all projects is critical; otherwise, the story cannot be told. He recommends using technology but keeping things simple. His project conducts monthly conference calls among the five PIs and among the five project coordinators. Work plans are essential in training; it is necessary to keep the product (e.g., pilot projects) in mind. When planning collaborative work, it is important to keep things simple.

Ms. Rodríguez said that CNs should become familiar with the community and learn about local interests. They must demonstrate a commitment to improving health in the community. Flexibility is necessary because community partners are often overwhelmed and may not be able to commit as much time to program activities as desired. PMs should recognize that community partners may not understand community-based research. CNs need to make presentations that explain what the CNP is doing.

LorrieAnn Santos handles community outreach for the *'Imi Hale* project. Each of the five main Hawaiian islands has a community outreach worker. The project has made a major effort to learn what research interests best meet the needs of each community, achieving buy-in through outreach. The project makes an annual, public report to the community to show that it has addressed community needs and assessed the benefits of its efforts.

Frank Jackson said that establishing a listserv for Program Managers to share information and support had been suggested in the morning session. He indicated that Crystal Wolfrey had joined the panel to address any questions on grants administration and opened the floor for questions.

Key Points From Discussion Session

- Any institutions that have noncompeting NIH grants can register on the Commons Registration System, an electronic research administration system. Information about PIs and NCI contacts, as well as summary statements, is available. The system helps keep users up to date on what is being done in various areas of research.
- It is important for Program Directors (PDs) to know, in general terms, what is going on with projects, as well as provide them with detailed information on any actual or potential problems and plans for new initiatives. PDs should be invited to meetings and to visit the communities the programs serve. PDs' decisions are influenced not only by reports but also by observations made on site. Milestones should be shared with PDs rather than have them wait until the end of the year to receive the information in a progress report.

- Grant restrictions sometimes collide with culturally appropriate ways to work with the underserved community (e.g., reimbursement for food in places where food is culturally significant, compensation for volunteers for their time and travel). Meeting costs are allowable, and reasonable incentives for participation are allowable in certain circumstances. Sometimes, these are institutional issues that can be solved with improved communication within the project. For example, when institutional restrictions prevented incentives because Social Security Numbers cannot be collected, one project provided resources to a community agency or church, which then distributed the incentives. Another project obtained a ruling from the IRS stating that incentives are considered gifts, not wages. PDS may be able to help word funding requests so that they will meet NCI and institutional requirements.
- Panelists described project management software and tools they use. Ms. Hardy uses “old-school” methods with task logs and meeting minutes and does not recommend a “one-size-fits-all” approach because individual management styles vary. Ms. Gibson’s project uses a Microsoft Access database to track presentations and projects such as trainings and screening events. Ms. Edwards uses Microsoft Excel to track information about activities.
- A checklist is available to determine whether a specific activity represents lobbying or education. This would be a good resource for a sharing mechanism, as proposed earlier. CNs cannot engage in lobbying using Federal funds, but it is possible to engage in activities designed to influence policy by presenting evidence-based information. Activities carried out as education programs are not considered lobbying, and legislative briefing sessions are allowed. People with decision-making authority can be included in advisory groups or invited to events or site visits.
- Future session topics should include a session for new CN partners on how to deal with issues related to lobbying versus education, including potential roles partners could play and information on the experiences of established programs. New programs might also benefit from a session giving partners general background on cancer health disparities. The agenda should include more sessions for partners.
- Keeping partners engaged in the program can be a challenge; individual volunteers can be fickle. When support is lost, it is very difficult to restore, and engagement must be nurtured. Partners will come and go over time. Money is not necessary to keep those who are truly committed; however, helping them with expenses helps them continue their commitment. Recognition is the best compensation. Organizational agendas may change over time, and when this happens, keeping volunteers involved may not be a good idea. If agendas remain, but personnel change, it is important to reach out to the new leaders. It is essential to understand the level of involvement they are able to support.
- Building, managing, and communicating with Steering Committees and Community Advisory Groups is vital. Ms. Hardy advised that face-to-face meetings are important for steering committees, especially at the early stages; conference calls can be used after relationships are well established. Projects should conduct meetings in the community instead of at project headquarters. Hawaii has a scientific council and a community council to provide both scientific and cultural guidance and advice. Ms. Gibson’s program provides community profiles and training in cancer health disparities to its local cancer coalitions, then supports them as they plan community activities.
- In Alabama, state cancer control plans are very involved with the development of a comprehensive cancer plan, especially involving early detection and surveillance research. This involvement is similar to what is being done in Arkansas, where a Disparities section has been added to the state cancer control plan.
- The uncertain budgetary climate does not guarantee funds even for the 5 years of a project—let alone the future beyond that period—although it is reasonably likely that the 5 years will be fully funded. Success in Phase I will be a major factor in ensuring continued support.

Operational Hints and Secrets

Ms. Hardy is developing a procedural manual for her project, including describing reporting mechanisms and project implementation. She suggested that each program develop a manual that should include project aims and objectives, who is assigned to do what, and a detailed timeline.

Mr. Gallion stated that new CN people might not know what questions to ask. He suggested that, as questions come up in the future, a system for mentoring and information sharing would be very useful. The system could go beyond the listserv idea to create, with NCI's assistance, a structured, Web-based place for sharing documents and management tools, instruments, focus group guides, etc.

Ms. Santos reported that her project has adapted many tools (e.g., brochures) developed by other projects; these have also been shared with CIS and ACS. However, it is important to obtain permission to use materials developed by others.

July 19, 2005 Plenary Sessions

Introductions and Opening Remarks—Nadarajen A. Vydelingum, Ph.D., Deputy Director, CRCHD

[Unedited by speaker]

Introductions

Dr. Vydelingum welcomed all participants to the second day of the 2005 Center to Reduce Cancer Health Disparities (CRCHD) Community Networks Program (CNP) Cancer Health Disparities Summit. He congratulated the principal investigators (PIs) for having won the awards, stating that more than 60 applications had been received and 25 projects funded. He thanked the following CRCHD staff for their work in support of the CNP and the Summit: CRCHD Program Directors, Disparities Research Branch: Ken Chu, Frank Jackson, and Roland Garcia; Health Policy Branch: Barbara Wingrove, Emmanuel Taylor, and Leslie Cooper; CRCHD staff: Dionne Burt, Jane Daye, Francis Mahaney, Tarsha McCrae, Traci Mitchell, Mary Ann Van Duyn, and interns Bonny Bloodgood, Kimberly Henderson, Carmella Kahn, and Marlesa Moore.

He also thanked NOVA Research Company staff Tara Scibelli and Vicki Butz.

Opening Remarks

The Summit was planned to bring together cancer researchers, community partners, and National Cancer Institute (NCI) staff to share experiences, discuss principles, and consider practices of cancer health disparities research.

The CNP's purpose is to reduce cancer disparities in the community through community-based participatory education, research, and training among racial and ethnic minorities and underserved populations. The goal is to significantly improve access to and utilization of beneficial cancer interventions.

The CNP collaborates with the Office of the NCI Director, NCI Divisions (Cancer Prevention, Cancer Control and Population Sciences, Cancer Epidemiology and Genetics, Cancer Treatment and Diagnosis, Cancer Biology, and Extramural Activities), and the Center for Cancer Research.

The discovery-to-delivery disconnect is a key determinant of the unequal burden of cancer. Barriers to accessing cancer information and care include financial barriers (i.e., uninsured and underinsured);

information and education barriers; systems barriers (e.g., lost laboratory results and provider shopping); physical and geographical barriers; and culture and bias.

Community involvement is a key element in research. Community involvement is frequently missing in cancer research, even in clinical trials; ideas have been imposed on communities without their input. The ideal approach to research includes two-way communication in all phases.

Dr. Vydelingum introduced Dr. Harold P. Freeman, describing him as a thinker and an unrelenting leader whose work has had and will have far-reaching positive effects in cancer care for underserved populations.

Welcoming Remarks—Harold P. Freeman, M.D., F.A.C.S., Director, CRCHD

[Unedited by speaker]

What I See From Where I Stand: The Origin and Current Status of the CRCHD and Its Research Programs

Dr. Freeman presented a historical perspective on the CNP, with examples of research that has made a difference in reducing cancer health disparities for underserved populations. Over the past 15 years, our nation's efforts to close the discovery-to-delivery gaps were reflected in landmark reports highlighting the problem of cancer disparities. Most Government-supported research is at the delivery end of the discovery-to-delivery continuum.

Poverty is one issue; another is race and ethnicity. Dr. Freeman has spent much of his career trying to untangle these issues. Poverty drives disparities, but race and ethnicity are also major determinants. Poor and medically underserved populations experience an unequal burden of cancer; significant barriers to optimal effective cancer education and communication, screening, diagnosis, and treatment; worse outcomes; and more pain, suffering, and death from cancer due to late-stage disease at diagnosis. There is evidence that race in and of itself is a determinant of the level of health care received. Bias, stereotyping, prejudice, and clinical uncertainty among providers in the current health care system may contribute to racial and ethnic disparities in health care.

In 1989, the NCI launched the Black Leadership Initiative on Cancer to respond to the disproportionate burden of cancer in this population. In 1993, the Appalachia Leadership Initiative on Cancer and the National Hispanic Leadership Initiative on Cancer were established.

In March 2000, NCI awarded 18 5-year Cooperative Agreements, referred to as Special Populations Networks (SPNs). About one-half of today's CNP PIs were recipients of SPN grants. This was an effort to shift some of the burden of cancer research from cancer centers into communities, reflecting a major shift in philosophy. Much public education, mentoring, and research, as well as many publications resulted from this effort.

Major goals of SPN grants include focusing infrastructure-building in communities; creating academic or clinical partnerships to enhance minority accrual to clinical trials; promoting participation of minority scientists in research; promoting training opportunities for minority researchers and students; and enhancing awareness and utilization of training opportunities.

The CNP, which grew out of the SPN program, emphasizes strengthening collaborations with other NCI efforts, developing clinical partnerships, and creating Community Advisory Groups. Another new emphasis is on policy research and efforts to bring evidence-based findings to the attention of policy makers.

In 2001, cancer health disparities became a new challenge for the FY2002 NCI Bypass Budget. A 5-year strategic plan was drafted, and Dr. Freeman became Director of the new Center to Reduce Cancer Health Disparities. The CRCHD provides the organizational locus for NCI's efforts to eliminate cancer health

disparities. The CRCHD has identified four strategic categories for action: access; information and communication; collaborations and advocacy; and research.

At this meeting, CRCHD released a new document based on a 2-year study: an analysis of excess cervical cancer mortality, a marker for low access to health care in poor communities. No woman should die from cervical cancer, because it is easily detected and early intervention is very effective; however, there is excess mortality from cervical cancer in certain areas. Black women have high rates of death from cervical cancer in specific geographic areas. The publication highlights the need to intensify health care efforts in regions disproportionately affected by cancer health disparities. CRCHD seeks to apply targeted, culturally appropriate interventions to areas with excess cancer mortality.

The Harlem Patient Navigator Program

In 1989, as President of the American Cancer Society (ACS), Dr. Freeman conducted hearings on poor Americans who had been diagnosed with cancer. The ACS issued its *Report to the Nation on Cancer in the Poor in 1989*. In 1990, the first Patient Navigation Program was conceived and initiated at Harlem Hospital Center, supported by an ACS grant. The Program was established in an effort to provide a local solution to the lethal combination of cancer and poverty.

Dr. Freeman presented demographic information about the ethnicity, median household incomes, and median years of school completed for central and east Harlem. He described the Harlem Navigation project as addressing a very important problem in the cancer care system and providing a potential solution.

There is a very critical window of opportunity to save lives from cancer that occurs between the point of an initial suspicious finding and the resolution of the finding by further diagnosis and timely treatment. The Patient Navigator model promotes timely diagnosis and treatment and aims to ensure seamless, coordinated care and services. Patient Navigators help patients and families negotiate the health care delivery system from the time of a suspicious finding through the resolution of the finding by further diagnosis and treatment.

Dr. Freeman outlined two studies. The first, covering the period 1964–1986, involved 606 breast cancer patients. Nearly all patients were poor; half had no medical coverage; 94 percent were black; and nearly half were incurable at diagnosis. A second study, covering the period 1995–2000, involved 324 breast cancer patients. Nearly all patients in this second study were poor; half had no medical coverage; 70 percent were black; and 26 percent were Hispanic.

Dr. Freeman compared the two studies. He displayed a chart showing the percentage of patients by cancer stage at diagnosis. The second compared the 5-year survival rates for the two studies. Before access to screening and patient navigation (1964–1986), the 5-year survival rate was 39 percent; after access to screening and patient navigation (1995–2000) the 5-year survival rate was 70 percent.

Dr. Freeman concluded that the Harlem Hospital Center Breast Cancer Screening and Patient Navigator Program had led to a reduction of the percentage of breast cancer cases diagnosed at late stages and resulted in a dramatic improvement in survival rates.

The Program did not change the poverty situation, but it did change the impact of breast cancer. This research project had a national impact. The Patient Navigation bill was introduced in the 108th Congress by Representatives Menendez and Price in the House and by Senators Hutchinson and Bingaman in the Senate. It was reintroduced and passed in the 109th Congress and signed into law on June 29, 2005, as P.L. 109–18: Patient Navigator Outreach and Chronic Disease Prevention Act of 2005.

Dr. Freeman stated that disease always occurs under human circumstances. To understand the disease, one must understand the circumstances. Health disparities are caused by poverty or low economic status,

social injustice, and culture. The power and energy of the community must be harnessed. The Community Networks Program represents one strategy to achieve this.

Dr. Freeman announced that he is stepping down as Director of the CRCHD. This is his last time to address this group, but he will continue his efforts to achieve reductions in cancer health disparities.

Meeting Overview/CNP Core Requirements—Kenneth Chu, Ph.D., Chief, Health Disparities Research Branch

Dr. Chu explained that the major purpose of this meeting is to inform CNP grantees about what is expected in the next 1 to 2 years and to introduce participants to each other and to people from NCI, CRCHD, and the Division of Cancer Control and Population Sciences (DCCPS) who can assist them. He asked community participants to stand and noted that the researchers would not be at the meeting if not for the community participants.

Dr. Chu provided an overview of the historical background of the CNP from the National Black Leadership Initiative in 1989 and the National Hispanic Leadership and Appalachian Leadership Initiatives of 1992 to the establishment of the Office of Special Populations Research in 1995 and creation of 18 SPN Cooperative Agreements in 2000. The SPN grants ended in 2004, and 25 CNP Cooperative Agreements were established in 2005.

The SPN started with a goal of increasing cancer awareness. CNs have a goal of reducing cancer health disparities through community-based participatory (CBP) education, research, and training and to significantly improve access to and utilization of beneficial cancer interventions.

CNP funding is \$19 million for the first year and totals \$95 million for 5 years. The 25 CNs comprise 6 national, 7 multistate or statewide, and 12 local programs. Of the 25 agreements, 13 come from SPNs and 12 (48 percent) are new. Dr. Chu described CNs by population distribution: eight African American, four Hispanic, four American Indian and Alaska Native, three Pacific Islander, two Asian, and four generally underserved.

Dr. Chu described the CNP phases. The first phase (years 1–5) focuses on capacity building and education; the second phase (years 2–5) has a focus on research and training; and the third phase (years 4–5) is focused on establishing credibility and sustainability.

Phase I

The objective of Phase I is to increase capacity building to reduce cancer disparities. This involves developing staff, creating partnerships (community, research and training, and clinical), and establishing committees.

The CNP staff includes the project PI, multidisciplinary professionals, a policy analyst, a program evaluator, and a clinical coordinator.

Community partnerships are formed with local community-based organizations and government, and nongovernment organizations; research and training partnerships are formed with universities and other cancer research organizations and foundations; and clinical partnerships are created with primary and secondary prevention facilities and diagnosis and treatment facilities. Partnerships with clinical organizations and Community Advisory Groups are perhaps the most important new components.

The CNP Steering Committee, which must meet at least once per year, includes the PI, the CRCHD Program Director, community leaders, at least three CBP researchers, clinical experts, and others needed to carry out objectives. The Community Advisory Group includes the PI and community leaders, meets at least twice per year, and must have a voice in planning project activities; this group also plays a role in dissemination.

Over the 5 years, CNs must conduct at least four projects in collaboration with NCI groups involved in addressing disparities. CNP access to communities makes collaboration attractive to other NCI components. These collaborations demonstrate the importance of the CNP projects. In general, the collaborative projects will be supported under the core grant, but the NCI groups may provide additional funding. For example, research supplements are available to support and mentor minority researchers.

The most successful potential collaborations further the aims of both the CNP and the partner NCI component or project. The following are examples of NCI collaborations: minority institutions partnered with Cancer Centers; the NCI CURE program to develop minority researchers; CCR intramural clinical trials; DCCPS Centers for Population Health and Health Disparities and other DCCPS cancer disparities programs; Division of Cancer Epidemiology and Genetics studies; Division of Cancer Prevention (DCP) prevention, screening, and early detection clinical trials; and Division of Cancer Treatment and Diagnosis (DCTD) treatment clinical trials.

Once a CNP has developed a project for collaboration with an NCI group, the CNP must follow these procedures: (1) the CNP describes the project in writing (including project goals, objectives, and criteria for successful completion of the project by the CNP) with approval of the NCI group director; (2) the CRCHD Program Director approves the project; (3) the CNP performs the project under the direction of the NCI group director; and (4) the CNP reports progress in its annual report at time of renewal. Upon project completion, the NCI group director evaluates the performance of the CNP.

Another objective of this phase is to increase community utilization of beneficial interventions. This is accomplished through cancer education activities. Primary prevention activities include smoking prevention and cessation, hepatitis B vaccination, and energy balance (obesity control, diet and nutrition, and physical activities). Secondary activities include mammography and clinical breast exams (breast cancer); Pap smears (cervical cancer); fecal occult blood tests, sigmoidoscopy, and colonoscopy (colorectal cancer); and prostate-specific antigen tests (prostate cancer).

Screening can reduce mortality when early cancer detection is followed by early diagnosis and treatment. The CNP does not pay for prevention or screening and early detection services; existing resources should be used. The goal is to educate the community about screening and help people find the resources they need in their communities. Screening efforts should emphasize first-time and repeat screenings for hard-to-reach groups.

If CNs collect information that will be used for future research, they must obtain institutional review board (IRB) approval. SPN cancer education efforts were exempt from this requirement; CNP efforts to reduce disparities require this scrutiny.

Non-CRCHD funding sources for educational and training activities include nongovernment (e.g., ACS, Legacy Foundation, and Komen Foundation) and government sources (NIH, the Centers for Disease Control and Prevention, local and state governments, and other NCI components).

Transitioning to Phase II

Before starting pilot projects, the CNP must meet several requirements. Organizational infrastructure must be in place; a formal partnership must be established with at least one primary or secondary prevention facility; the CNP must have a partnership with at least one cancer research organization to facilitate recruitment and training of researchers; the CNP must have performed at least one cancer education activity to increase community participation in a primary or secondary prevention facility group; the plan for implementation of Phase II must be prepared; and the CNP must have obtained IRB certification of or exemption for the parent grant.

Phase II

The goal for Phase II is to develop CBP research and training programs. CBP research addresses the spectrum of research issues necessary to reduce disparities in the community and includes needs assessments, intervention research (efficacious community-based interventions), and policy assessments and research.

CBP research can include pilot projects for junior investigators. (Pilot projects accounted for many of the papers published by the SPNs.) In order to obtain funding for a pilot project (usually about \$75,000 per project), CNs must submit a ten-page, R01-like grant proposal for 1-year projects on topics that deal with CBP research to reduce cancer disparities. Pilot project proposals are reviewed by NCI and outside peer reviewers. In the past, 30 percent or more of proposed projects were funded.

Another Phase II objective is to train junior researchers (particularly from minority or underserved populations) in CBP research through training or mentoring programs.

Phase III

The goal for Phase III is to establish the credibility and sustainability of the CNP. This is accomplished by reducing cancer disparities in the community, obtaining non-CRCHD funding for research projects, and informing policy makers about CBR that reduces cancer disparities.

Reducing disparities does not mean reducing mortality or survival rates. Given that the CNP is a 5-year program, it cannot reduce mortality or increase 5-year survival rates. However, the CNP can affect process outcomes and some impact outcomes. To demonstrate a reduction in cancer disparities in the community, the CNP must focus on measures that demonstrate positive outcomes.

Positive outcomes include: improving patient and public knowledge, beliefs, attitudes, values, and perceptions about cancer-related issues across the continuum of care; increasing health professional knowledge and sensitivity related to cultural compassion; increasing understanding of issues that impact cancer control among disparate populations; and mobilizing the community to support CNP efforts. Individual changes that demonstrate positive CNP outcomes include increased positive health behaviors (e.g., smoking cessation and improved nutrition) among disparate populations and increased utilization of screening, diagnosis, treatment, and clinical trials services. Community changes that demonstrate positive CNP outcomes include: improved local referral patterns (e.g., to clinical trials); improved provider interactions with disparate groups; increased numbers of health professionals representing disparate populations; increased access to preventive, screening, diagnostic, and treatment services; leveraged funding from other sources to enhance services; and translation of research to practice. A policy change that demonstrates positive CNP outcomes is implementation of effective policies to increase access to such things as insurance, state cancer programs, Medicaid and Medicare coverage, and adequate clinical care. Long-term positive CNP outcomes include: reduced disparities through achieving a shift in diagnosis from later to earlier stages; improving cancer survivorship; narrowing the gap between the discovery and development, and delivery of care for disparate populations; and achieving sustainability of efforts for disparate groups.

Publications are another measure of success. This reflects the academic mindset of NCI and the cancer research community. Additional measures of success include training of minorities as researchers, leveraging funds, developing interventions, and obtaining research grants.

Centers for Disease Control and Prevention (CDC) Programs and NCI Collaborations

State and local CDC programs, including surveillance and screening programs, are key potential partners for CNs.

CDC's Role in Cancer Prevention and Control—Eddie Reed, M.D., Director, Division of Cancer Prevention and Control, CDC

CDC's role in cancer prevention and control encompasses surveillance, programs, partnerships, and management of the movement of cancer control knowledge into the community. Dr. Reed displayed a 2004 U.S. map showing areas covered by the CDC's National Program of Cancer Registries (NPCR) and the NCI's Surveillance, Epidemiology, and End Results (SEER) program.

The collaboration between CDC and NCI has resulted in three publications on U.S. cancer statistics. The most recent, *United States Cancer Statistics: 2001 Incidence and Mortality*, covers about 98 percent of the population. No other disease has surveillance at this level. The publication includes state, regional, and national data; provides rates for whites, blacks, Asians/Pacific Islanders, Hispanics, and children; and covers 92 percent of the U.S. population for incidence and 100 percent for mortality.

Dr. Reed listed a variety of CDC programs, initiatives, and campaigns, including Comprehensive Cancer Control, NPCR, National Breast and Cervical Cancer Early Detection Program (NBCCEDP), cancer awareness programs (for prostate, ovarian, and skin cancer), and Screen for Life (National Colorectal Cancer Action Campaign).

Dr. Reed displayed a map of the CDC's National Comprehensive Cancer Control Program. State representatives work together to describe cancer problems and potential solutions in their areas. The program helps bring together local resources to address those problems.

CDC is developing a series of fact sheets on public health aspects of cancer to educate the public and policy makers. Public messages have been developed on colon cancer screening featuring Katie Couric and Morgan Freeman.

The Science Offered by the CDC—Ralph J. Coates, Ph.D., Division of Cancer Prevention and Control, CDC

Dr. Coates stated that CDC shares the goals of the CNP to reduce disparities through programs (including education and training) and research with community partners to bring research into practice. CDC has developed a wide number of programs to address these goals: for example, Comprehensive Cancer Control, the *Guide to Community Preventive Services*, Racial and Ethnic Approaches to Community Health, Steps to a HealthierUS, National Tobacco Control Program, Nutrition and Physical Activity Program, NPCR, NBCCEDP, Colorectal Cancer Initiatives, Prevention Research Centers, and Cancer Prevention and Control Research Network.

Comprehensive Cancer Control Program (CCC)

The goal of the CCC is to increase coordination, collaboration, and synergism across agencies and organizations at the national, state, and local levels; coordinate across cancer sites and interventions from primary prevention through survivorship; address the range of activities from surveillance through preventive and clinical services to workforce development; and reduce the gap between research- and evidence-based interventions and practice. Opportunities for CNP grantees with CCC include accessing and using resources, coordinating with other local efforts addressing disparities, and collaborating with CCC coalition partners.

Local CCC coalitions develop and implement plans with priority activities for cancer control in their communities. Plans involve a number of initiatives, including policy (e.g., regulations on insurance coverage and access); focus on underserved populations; and include public education and outreach. State, tribal, and territorial CCC coalitions include health departments, cancer centers, ACS regional offices, NCI's Cancer Information Service (CIS), health plans, health care providers, cancer advocacy groups, researchers, and academia. CCC national partners provide leadership, funding, training, and resources and include NCI, ACS, C-Change, and the American College of Surgeons.

Guide to Community Preventive Services

The *Guide* provides evidence-based recommendations on the effectiveness of community interventions to promote health and prevent disease, disability, and premature death, including from cancer. Cancer-related recommendations include reducing tobacco use, increasing cancer screening, increasing physical activity, reducing obesity, improving nutrition, reducing alcohol abuse, and increasing vaccine coverage. Examples of *Guide*-recommended interventions include increased cigarette prices (via taxes) and smoking bans (tobacco control); creation of or enhanced access to places for physical activity; and patient tracking and reminder systems (e.g., for mammography).

People who plan, fund, or implement services and policies for health care systems, communities, and states are the *Guide's* intended users. They include public health departments, health care delivery systems, and purchasers of health care, governments and foundations, community organizations, and CCC coalitions.

The *Guide* can be useful to CNP grantees because its reviews examine evidence on underserved populations and communities included in the intervention studies (e.g., by race and ethnicity and socioeconomic status). The *Guide* identifies research gaps and groups to whom recommendations are likely to apply. CNP grantees can use the *Guide* to identify interventions that have worked in similar communities and populations and to identify gaps in knowledge about intervention applicability. Conversely, CDC can benefit from CNP grantee research by including CNP publications in *Guide* reviews and providing guidance to CDC and partners.

For further information about the *Guide*, see <http://www.thecommunityguide.org/>.

Racial and Ethnic Approaches to Community Health (REACH) 2010

REACH is a cornerstone of CDC's efforts to eliminate racial and ethnic disparities in health. During 2004–2005, CDC provided \$34.5 million to fund 40 projects. REACH supports community coalitions in designing, implementing, and evaluating community-driven strategies to improve health. REACH Breast and Cervical Cancer Screening programs include the Access Community Health Network (IL), Albuquerque Area Indian Health Board (NM), Boston Public Health Commission (MA), Special Services for Groups, Inc. (CA), University of California, San Francisco (CA), and University of Alabama at Birmingham (AL). For information about REACH, see <http://www.cdc.gov/reach2010>.

Steps to a HealthierUS

Steps programs help Americans take steps to be physically active each day, eat a nutritious diet, get preventive screening, and make healthy choices. The program funds community partnerships that use evidence-based strategies. Funding in 2005 totaled \$45.6 million. Steps awardees represent 40 communities in state-coordinated small cities and rural communities, tribes and tribal entities, and large cities and urban communities. For further information, contact nccdosteps@cdc.gov or see <http://healthierus.gov/steps/grantees/2004/StepsCoopAgrmn.pdf>.

CDC National Tobacco Control Program

The National Tobacco Control Program is a comprehensive, science-based program with the following goals: prevention of initiation, cessation among smokers, elimination of secondhand smoke, and elimination of disparities. The program is active in the 50 states; Washington, DC; and 7 U.S. territories. The program includes seven national networks to address tobacco control in populations defined by race, ethnicity, gender, sexual preference, socioeconomic status, and age. For further information, see <http://www.cdc.gov/tobacco> or visit the State Tobacco Activities Tracking and Evaluation System Web site at <http://apps.nccd.cdc.gov/statesystem/>.

CDC-Funded Nutrition and Physical Activity Efforts

Dr. Coates described CDC's State-Based Nutrition and Physical Activity Program to Prevent Obesity and Other Chronic Diseases, displaying a chart to illustrate the percentage of states reporting environmental change efforts. For further information, see http://www.cdc.gov/nccdphp/dnpa/obesity/state_programs/index.htm.

CDC Surveillance Information

Public Law 102-515, enacted October 1992, established the national program of population-based cancer registries in all states. Registries provide uniform, timely, high-quality data. Cancer is reported by those who treat it. The National Program of Cancer Registries (<http://www.cdc.gov/cancer/npcr>) is important to CNP as a data source that supplements the SEER program. Additional data relevant to CNP can be obtained from BRFSS, which provides risk factors and use of preventive services in individual communities (<http://www.cdc.gov/brfss/>). The NBCCEDP provides breast and cervical cancer screening to underserved women (i.e., uninsured and low-income [below 25 percent of the poverty threshold]). Program activities include coalitions and partnerships to reach underserved women; public education and outreach; professional education; screening, follow-up, and case management; and quality assurance and surveillance. Treatment is provided through Medicaid.

Colorectal Cancer Initiatives

CDC initiatives for colorectal cancer include the Screen for Life Campaign, Study of Endoscopic Capacity, National Colorectal Cancer Roundtable, support for state interventions, surveillance of screening practices, patterns-of-care research, and intervention research.

Prevention Research Centers

Prevention Research Centers (PRCs) conduct research to improve health promotion and disease prevention, focus on high-priority public health issues, promote application of scientific knowledge in public health practice, and enhance cooperation between academic institutions and state and local health agencies. In 2005, core funding for PRCs totaled \$29.7 million. Additional funding from other parts of CDC covers specific studies, including cancer. This is an opportunity for CNP grantees to collaborate with PRCs. PRC project examples include improving health in California's Korean-American community and reducing health disparities in rural southwest Georgia. For further information, see <http://www.cdc.gov/prc/>. For grantee profiles, see <http://www.cdc.gov/prc/centers> or contact Barbara Gray at Bgray@cdc.gov.

The Cancer Prevention and Control Research Network (CPCRN) is a collaboration between CDC and NCI. Its goals are to increase expertise in community-based intervention research in cancer prevention and control and to facilitate translation of effective interventions into practice. The primary objectives of the CPCRN are research on: how to disseminate cancer-related community interventions recommended by the *Guide to Community Preventive Services* into communities; effectiveness of community interventions for which new evidence can change a *Guide* finding of insufficient evidence into a recommendation; replication of *Guide*-recommended interventions in populations and communities in which they have not yet been evaluated, particularly underserved populations; and interventions commonly used by community groups and health departments and for which there is insufficient evidence for a *Guide* recommendation.

CPCRN networks are located at Emory University; Harvard University; Morehouse School of Medicine; Saint Louis University; University of California, Los Angeles; University of North Carolina, Chapel Hill; University of Texas Health Science Center, Houston; and University of Washington. For further information on the CPCRN, see <http://www.cpcrn.org/>.

For information about CDC's Division of Cancer Prevention and Control, see <http://www.cdc.gov/cancer>.

Considerations for Evaluation and CMS Collaboration—Richard Bragg, Ph.D., Coordinator, Minority Health Services Research Program, Center for Medicare and Medicaid Services (CMS)

Dr. Bragg stated that he had begun his professional career as a political scientist with an earned doctorate in Political Science from Howard University. After his wife died of breast cancer, he became involved in health care program and policy issues and then changed his focus to minority health and health disparities issues. He spent 3 years in the NCI's Cancer Control Science Program in the Special Populations Studies Branch.

At the Centers for Medicare and Medicaid Services, Dr. Bragg developed and coordinates the Historically Black Colleges and Universities (HBCU) and Hispanic-Serving Institutions (HSI) Health Services Research Grants Programs. These programs are designed to fund limited research projects to support HBCU and HSI investigators in implementing health services intervention research to meet the needs of CMS' African-American and Hispanic beneficiaries. It was understood that minority investigators could provide a unique perspective on the needs and characteristics of minority populations and expertise in interpreting findings.

The 2003 Institute of Medicine publication, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, reached a conclusion relevant to the goals of Dr. Bragg's CMS initiative: the need to increase involvement of minority researchers and institutions in health services research and increase the number of minorities participating in clinical trials. To accomplish the goals of CMS initiatives, the program provides training for HBCU and HSI researchers and faculty in writing research proposals for funding and using CMS data for research. Annual conferences are sponsored to disseminate findings and lessons learned. CMS provides technical assistance in using the CMS data system, but there are costs associated with using this system. For information, contact Maribel Franey at 410-786-0757 or Mfraney@cms.hhs.gov.

The CMS Research Data Assistance Center (ResDAC) helps individuals develop and refine research questions and advises as to whether questions can be addressed using CMS data. For information about ResDAC, see <http://www.ResDAC.UMN.edu/>.

To date, CMS has funded 29 HBCU grants and 20 HSI grants. The HBCU and HSI research projects focus on three areas: (1) intervention research in prostate, breast, and colorectal cancers; diabetes and end-stage renal disease; cardiovascular disease; HIV/AIDS; health promotion; and childhood immunization, among others; (2) quantitative and qualitative research focusing on access and barriers to care, costs of care, quality of care, and utilization; and (3) program evaluation.

The CMS Office of Research, Development, and Information also has a National Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities. Applications were due March 22, 2005. Each of the following four legislatively mandated target populations are required to be the subject of demonstration projects: African Americans, American Indians (including Alaska Natives, Eskimos, and Aleuts), Asian Americans and Pacific Islanders, and Hispanics. The program will fund up to eight grantees to address interventions to facilitate cancer screening, diagnostic, and treatment services.

CMS also provides funding for health services education/outreach and disease prevention activities focusing on community-based activities in the minority community. The projects are in the following areas: immunization, diabetes, and obesity.

CMS has a strong partnership with the National HBCU Research Network for Health Services and Health Disparities. The Network is a national organization of HBCU researchers implementing intervention research aimed at reducing health disparities and improving the health of African Americans and other minorities. Network leadership educates legislators and other key individuals about health services and health disparities intervention research.

The HBCU Research Network has a supplemental issue to the *Journal of Health Care for the Poor and Underserved* to disseminate findings from health services intervention research studies presented during its 2004 research conference entitled *Racial Disparities in Health Outcomes: Research and Intervention Perspectives*. This issue will be published November 2005.

A future activity for the HBCU/HSI programs includes a program assessment report summarizing the research findings, lessons learned, and policy implications for the HBCU and HSI Health Services Research Grants awarded to date, targeting African American and Hispanic American populations. The report will identify any lessons learned regarding effective education, outreach, and interventions related to health behavior change and engagement of ethnic minorities in the health care system.

Beyond Transition: Evidence-Based Decision Making—The Role of Policy in Reducing Cancer Disparities—Barbara Wingrove, M.P.H., Chief, Health Policy Branch, CRCHD

[Unedited by speaker]

When the CRCHD started, Dr. Freeman emphasized incorporating policy research into the organization's mission. This was unique among NCI efforts.

The Health Policy Branch's mission is to promote and support research to develop effective and sustainable intervention strategies; identify and evaluate the effects of changes in key Federal, state, and local policies; and inform policy and decision makers. Branch objectives are to identify, analyze, and summarize existing policies affecting cancer health disparities; increase awareness of the effects of policy on cancer disparities; sustain evidence-based research in the community; and translate efficacious programs to other, similar communities.

Existing policies can either help reduce or help drive the disparities. CNs will assess policies that affect their populations. They need to differentiate between policies that help and those that create barriers.

The Patient Navigator model is an example of a policy that helps reduce disparities. The model identifies a problem: lack of timely access to cancer treatment. The first Patient Navigator program was conducted in Harlem and followed by other programs around the country. Data were presented to legislators, and the Patient Navigator Bill became law in 2005.

One example of how a policy can help reduce disparities resulted from the SPN at the University of Maryland; a contribution to the Maryland Cancer Fund was included on the 2004 tax form. The Harvard University School of Public Health (a new CNP awardee) was instrumental in the development of a Mayor's Task Force Blueprint, a plan to eliminate racial and ethnic disparities in health. Other policies that help reduce disparities include state cancer plans and tobacco policies.

Health policy can be a component of all CNP activities, including research, dissemination, leveraging, sustainability, and replication by others. In Phase I, CNs can leverage CNP activities by obtaining non-CRCHD funding for community-based participatory activities directed at reducing cancer health disparities and develop non-CRCHD funding sources to create sustainable, community-based participatory education and training activities that can reduce cancer health disparities. In Phase II, CNs will develop and perform community-based participatory research—from needs assessments to intervention research to policy assessments—with an emphasis on developing efficacious community-based participatory interventions to reduce cancer health disparities. These interventions may involve assessing the impact of health care policies on reducing cancer health disparities. In Phase III, CNs will provide policy makers at the local, state, and Federal levels with evidence-based information for reducing disparities. Analysis of policy issues should result in information about implementing interventions to reduce cancer health disparities. However, these activities must not include lobbying. Rather, policy activities should offer evidence-based information based on qualitative and quantitative research findings that demonstrate reductions in cancer health disparities.

Policy research can help develop and evaluate more effective tools to measure how the community actually receives services; reduce the time lag in translating research into policy and practice; facilitate interactions among providers, practitioners, patients, and health policy experts to reduce disparities; address the lack of trust felt by many minority communities; and broaden the prevention paradigm beyond early detection.

CNs must ensure that policy makers understand the issues, keeping them informed throughout the research and network-building process and making information user-friendly. Cns must address trust-related issues to ensure that all players in the community work together.

Other health policy activities include understanding the effects of insurance coverage, addressing Medicare and Medicaid reform, helping policy makers understand a policy's potential impact on health disparities, increasing patient and provider education, addressing the importance of social environment, and understanding how policies affect incidence and mortality rates.

Ms. Wingrove urged Cns to watch for windows of opportunity, keep influential people informed, and take advantage of face-to-face exchanges with those who can use research findings. Cns should use peer-reviewed publications to build credibility and anecdotes to communicate on a more personal level.

Key Points From Discussion Session

- CMS data would be helpful to the Cns. (The denominator of interest is all recipients by county; the numerator is incidence of various cancers.) Methods are in place to support use of CMS data, but costs are involved and staff resources limited. Cns are encouraged to contact ResDAC for help with CMS data. CNP PIs are invited to an open-door forum at CMS (usually held every 3 months in Washington, DC) to bring data accessibility issues before CMS leadership.
- A groundswell of local support expressed to representatives is needed in order to encourage expansion of the NBCCEDP with increased funding, adding other diseases where it is thought screening may be of benefit.
- Funding issues prevent inclusion of CMS data as part of a core data set for CNP projects. In addition, there are currency and privacy issues related to archival data in the CMS system. NIH is discussing the possibility of devoting funds to data linkages with CMS.

Programs and Resources: Division of Cancer Control and Population Sciences—Robert T. Croyle, Ph.D., Director, DCCPS

This session was intended to describe selected NCI-supported projects and data sources that CNP projects can use for collaborative efforts. A DCCPS contact list—a subset of scientific and program staff who can talk to Cns about ideas for collaborative efforts—was distributed.

Dr. Croyle stated that DCCPS supports projects that synthesize evidence to help practitioners. Most of the NCI budget goes to research grants; for example, \$398.7 million was expended for grants in FY2004. The DCCPS Web site lists all of the Division-funded research projects and programs.

In collaboration with the National Institute of Environmental Health Sciences, the National Institute on Aging, and the Office of Behavioral and Social Sciences Research, the Centers for Population Health and Health Disparities (CPHHD) is awarding 5-year grants using the P50 funding mechanism in a \$60.5 million initiative. Eight grants with a community-based participation research component have been funded, focusing on scientific integration across multiple levels of analysis: social, behavioral, and biological. For example, the Chicago project focuses on breast cancer in African and African-American women. Dr. Croyle listed the CPHHD principal investigators and their respective institutions: Sarah Gehlert, University of Chicago and University of Ibadan (Nigeria); James Goodwin, University of Texas Medical Branch, Galveston; Timothy Rebbeck, University of Pennsylvania; Richard B. Warnecke,

University of Illinois at Chicago; Electra Paskett, Ohio State University and University of Michigan; John Flack, Wayne State University; Nicole Lurie, RAND Corporation; and Katherine Tucker, Tufts University and Northeastern University. These projects have been made aware of the CNP and the likelihood that they will be contacted by CNs to discuss opportunities for collaboration. For further information about CPHHD, contact Suzanne Heurtin-Roberts, Ph.D., M.S.W., at 301-594-6655 or sheurtin@mail.nih.gov, or visit <http://obssr.od.nih.gov/cphhd/>.

The Centers of Excellence in Cancer Communication Research program has funded four P50 centers. For example, the center at St. Louis University (where Matt Kreuter is PI) focused on the African-American population. For further information, contact Brad Hesse, Ph.D., at hesseb@mail.nih.gov or visit <http://www.cancercontrol.cancer.gov/hcirb/ceccr/>.

DCCPS health disparities collaborations focusing on tobacco use include the *National Conference on Tobacco and Health Disparities Summary Report, 2005*; NCI's *Women, Tobacco, and Cancer Report, 2005*; the Tobacco and Health Disparities Research Network; the Low SES, Women, and Tobacco Policy Meeting (September 2005); and the Fogarty International Center RFA on international tobacco research and capacity building. Contact Pebbles Fagan, Ph.D., M.P.H., at 301-496-8584 or faganp@mail.nih.gov or visit <http://www.cancercontrol.cancer.gov/tcrb/>.

Other DCCPS health disparities collaborations include the NCI-CDC Cancer Collaborative With HRSA Health Centers, and TEAM-Up (with the Office of Educational and Special Initiatives and CIS). TEAM-Up is an implementation and evaluation partnership of NCI, ACS, CDC, and the U.S. Department of Agriculture that is intended to increase evidence-based breast and cervical cancer interventions among rarely or never-screened women.

DCCPS also supports the Native American Cancer Registries (e.g., Native C.I.R.C.L.E.). For information, contact Judith Swan, M.H.S., at 301-496-8506 or swanj@mail.nih.gov.

DCCPS has established survey research collaborations to expand health disparities research. The California Health Interview Survey (CHIS), for example, collects data useful to researchers outside California. See <http://appliedresearch.cancer.gov/surveys/chis/>.

Dr. Croyle described a variety of tools and resources for researchers. These include SEER and the SEER-Medicare Linked Database (<http://seer.cancer.gov>), the National Health Interview Survey (NHIS) Cancer Control Supplement (<http://appliedresearch.cancer.gov/surveys/nhis/>), the Current Population Survey Tobacco Use Supplement (<http://riskfactor.cancer.gov/studies/tus-cps/>), the Cancer Research Network (focused on primary care within managed care systems), Health Information National Trends Survey (<http://hints.cancer.gov>), and Cancer Control PLANET, a portal for public health research and practice (<http://cancercontrolplanet.cancer.gov>).

Dr. Croyle emphasized that the DCCPS is strongly committed to working with the CRCHD.

Dr. Croyle thanked DCCPS Health Disparities Interest Group coordinators Veronica Chollette, Meryl Sufian, and Barbara Guest for preparing handouts.

Health Information National Trends Survey (HINTS): Creating a National Evidence Base for Health Disparities Planning and Research in Communication—

Bradford Hesse, Ph.D., Acting Chief, Health Communication and Informatics Research, DCCPS

This presentation was intended to help participants understand the purpose and utility of HINTS as a data resource, learn ways to use HINTS data, and become familiar with other data resources (e.g., NHIS and CHIS). A great deal of effort is being expended to make data sets like HINTS useful in as many settings and by as many people as possible in order to leverage the investment in building them. The goal is to provide national data that can be applied at the local level.

In a 1999 report, experts recommended creation of a national surveillance program. Such a program would monitor changes in the health information environment over time; explore usage across channels and sources nationally; combine channel usage with knowledge, attitudes, and behaviors; and build an evidence base for researchers, planners, administrators, communicators, practitioners, and policy makers.

HINTS provides surveillance on cancer knowledge, attitudes, and behaviors. The survey can monitor the effect of investments in cancer communication research and enable population-level analysis. Using computer-assisted telephone interviews to create national-level probability samples, HINTS allows fundamental research at a level usually not possible in communications: the national level.

There are many ways to access and use HINTS data. Users can download data directly from <http://hints.cancer.gov>, review and contribute to original research, access population estimates for individual items, and download HINTS Briefs (encapsulated summaries of selected data).

Technical documentation is available, including the sampling strategy, full survey instrument, final report, and weighting instructions. The SAS data set has been cleaned and de-identified. Data are also available through an informatics application. One section presents upcoming research projects and posts the results as they become available.

Dr. Hesse displayed a number of sample data charts from the HINTS Web site, pointing out that charts can be viewed and downloaded for inclusion in PowerPoint slides. Knowledge and behavior maps are being developed. For example, CIS has been using HINTS data to compare CIS with other national cancer and health organizations in terms of public awareness of the organizations.

HINTS data displays have hyperlinks to related data sources. Effects seen in the relatively small national HINTS data set can be enhanced with data from other specialized data sets: for example, CHIS (<http://www.chis.ucla.edu/>) and NHIS (<http://www.cdc.gov/nchs/nhis.htm>).

A new survey is now being conducted, and results should be available in February 2006.

Cancer Control PLANET: A Tool for Improving Program and Research Applications—Jon F. Kerner, Ph.D., Deputy Director, DCCPS

This session offered participants a tour of Cancer Control PLANET from both a program applications perspective (its original purpose) and a research applications perspective (for which its utility is becoming apparent). Participants learned about NCI's commitment to closing the discovery-to-delivery gap and how to navigate the PLANET, link PLANET resources to program applications, and link PLANET resources to research applications.

Dr. Kerner noted that, as Dr. Larry Green has stated, if research is to influence practice, practitioners should influence research. He described intervention research across the cancer control continuum (prevention, detection, diagnosis, treatment, and survivorship) as well as CNP activities along the continuum.

Dr. Kerner described the discovery-to-delivery continuum, explaining that development is a way to link research (discovery) and delivery. Development is usually accomplished as a passive diffusion of information through publications and presentations and, to a lesser extent, knowledge synthesis. Systematic evidence-review resources include *Knowledge and access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials* (AHRQ Pub. No. 05-E019-2) as well as systematic evidence reviews across the cancer control continuum (http://www.dccps.cancer.gov/d4d/info_er.html).

Development should also include replication research, as well as dissemination and implementation research. Research instruments need to be adapted and synthesized for use in program evaluation. Simple and sensitive tools are needed to measure intervention outcome changes in field settings with limited resources for program evaluation.

PLANET identifies five steps for developing a comprehensive cancer control plan or program. Sections of the PLANET can be used to develop grant applications. Dr. Kerner demonstrated this capability, linking PLANET resources to the PHS 398 investigator-initiated grant application form for NIH.

■ Step 1: Assess intervention program priorities (significance).

The PLANET features maps and charts of state cancer profiles. These charts can be modified interactively (e.g., showing all races or all races compared with individually selected racial and ethnic groups). Figures can be saved and pasted into grant applications or manuscripts. (Peer reviewers may prefer figures to data tables.)

■ Step 2: Identify potential research and program partners (collaborators and references).

Users can click on maps to view a list of PLANET partners and then click on “Research Partners” to see a list of funding contacts for NCI, CDC, and ACS by topic area. (Funding contacts for the Agency for Healthcare Research and Quality [AHRQ] will be added soon.) These contacts have said that they are willing to be contacted. Users can find publications by these investigators and invite them to work as collaborators. This information can be used as background literature for the grant proposal.

■ Step 3: Identify effective intervention program approaches and intervention research questions and opportunities (significance and approach).

The site includes a link to the *Guide to Community Preventive Services*, a good source of research questions because it lists evidence for various recommendations, some of which are very limited. When documenting the need to address a research question, researchers should cite the *Guide*.

■ Step 4: Identify intervention programs that may be adapted or disseminated (preliminary studies and approach).

Research-Tested Intervention Programs (RTIPs) can be used in the Research Design section of an application. The RTIP section can be used to find research-tested intervention programs and products (not just from NCI or NIH), review summary information and usefulness and integrity scores for each program, order or download materials to adapt for use in one’s own program, and obtain readability scores for products distributed to the public.

To be included on the RTIP Web site, a program must meet the following criteria:

- ◆ Evaluated in a peer-reviewed research grant
- ◆ Published program evaluation in peer-reviewed journal
- ◆ Adaptable and usable in community or clinical settings

One can use RTIPs to identify program materials to use for a priority population; adapt program materials for another population or for delivery in a related setting; identify programs to include in a replication or dissemination research project; and contact the principal investigator to seek collaboration or consulting support on a project.

■ Step 5: Put proposed program and research activities in a context of state-, tribe-, or territory-specific cancer control priorities (significance).

For research applications, links to state comprehensive cancer control plans provide an important context for intervention research. For program applications to philanthropic agencies, work is in progress to provide information on how to link PLANET information with funding source priorities, with templates that can be used to plug PLANET data into specific application forms and processes.

PLANET users can click on “Contact Us” to submit feedback on the site. Comments are monitored, and user input is taken very seriously.

Other resources for supporting dissemination and implementation research include new Cancer Center guidelines that support dissemination research cores as part of the Cancer Center Support Grant. CNs should contact Cancer Centers to suggest partnerships for dissemination research using this funding source (see pages 24–25 of 9/04 *Guidelines* revision:

<http://www3.nci.nih.gov/cancercenters/download.html>).

R25E PAR now contains language on research dissemination. (See <http://grants1.nih.gov/grants/guide/pa-files/PAR-05-065.html>.)

Dissemination research supplements are refocusing on dissemination of surveillance data. A new Trans-NIH Dissemination Research PAR will be available in October 2005

(<http://grants1.nih.gov/grants/guide/pa-files/PAR-06-039.html>).

Key Points From Discussion Session

- It is doubtful that the R25E mechanism will be made available for minority supplements. R25E is viewed as an education and training grant rather than a research grant; thus, it has not been seen as an appropriate mechanism for minority supplements, which historically have been used as a means of supporting the participation of new minority investigators in research projects.
- RTIP is a partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA), which has a system for registering effective programs. SAMHSA has changed contractors, which has slowed the process. A brochure will be sent to all NCI-, CDC-, ACS-, and AHRQ-funded projects as soon as the new review process is in place (approximately January 2006).

A New Approach to HPV Testing and Cervical Cancer Screening

An Ultra-Brief Introduction: HPV and Cervical Cancer Prevention—

Philip E. Castle, Ph.D., M.P.H., Investigator, Division of Cancer Epidemiology and Genetics, NCI

Dr. Freeman had earlier introduced the concept of cervical cancer as a marker for cancer health disparities. Dr. Castle stated that cervical cancer prevention should be the flagship of cancer prevention. NCI has a number of activities aimed at improving cervical cancer screening.

Cervical cancer remains a significant public health problem worldwide. Each year, almost 500,000 new cases of cervical cancer are diagnosed, and almost 250,000 women die of cervical cancer. The rates are highest in developing countries; the disparity in cervical cancer rates between developed and developing countries is the greatest of any cancer.

Human papillomavirus (HPV) causes virtually all cases of cervical cancer. This knowledge can be used to improve screening. This simple virus provides a good model of carcinogenesis.

There are more than 100 types of HPV, including more than 40 genital types. Approximately 15 types are associated with cervical cancer. The most common are HPV16, 18, 31, and 45. HPV16 is uniquely persistent. Noncarcinogenic types 6 and 11 most commonly cause *condyloma acuminatum*; benign types include HPV 61. HPV is a common sexually transmitted infection. Most women who are infected clear the infection. If the virus persists and secondary factors are present, women can progress to precancerous lesions; if these are not detected, cancer can develop. Intervention is needed at times of viral persistence and when precancer occurs.

Epidemiological studies are being used to determine which types of HPV should be included in testing. Including all types would create too great a burden on women and on the health care system. New DNA tests are providing more sensitive testing based on the detection of HPV, and thus, a negative test provides greater confidence of low risk over many years. Consequently, longer screening intervals for

women identified as being at low risk can be introduced and, thereby, reduce the burden of frequent testing.

Bridging the Gap: Developing Cervical Cancer Screening Programs for Underserved U.S. and International Populations Based on HPV DNA Testing

Dr. Castle turned his focus toward cervical cancer disparities.

Pap screens successfully prevent cervical cancer in the mainstream United States. Unfortunately, Pap screening is impractical for many populations—and it is expensive. Pap screening requires a three-visit cycle (cytology, colposcopy, and treatment). Cytology is an insensitive test (negative tests result in poor reassurance), and repeat iterations (i.e., regular and annual Pap smears) are necessary. Cytology is a poorly reproducible (subjective) test, and it is difficult to maintain performance. Colposcopy is not as reliable as many believe. Finally, the U.S. program costs billions annually. Tests that have better characteristics and require fewer visits per cycle and fewer cycles per lifetime are needed.

Although very promising, HPV vaccines are not a panacea for cervical cancer for several reasons. First, they will not be ready for widespread use in global public health programs for at least 10 years. Second, the duration of protection is still uncertain. Third, these vaccines do not protect against HPV types that cause 30 percent of cervical cancers. Fourth, they do not eradicate an established infection. Fifth, these vaccines are not yet practical, as they are expensive, require cold-chain, and require three injections using needles.

However, HPV DNA testing is more sensitive than cytology for detection of precancerous lesions. As a corollary, a negative HPV test provides significant reassurance for many years. Consequently, a negative HPV test permits a lengthening of the screening intervals and, therefore, may be more cost-effective. It is standardized; quality control is possible; and it can be delivered in developing countries. HPV testing methods must be made easy and affordable, and local adaptation is needed to create self-sustaining programs.

Several self-sampling collection techniques and assays are being investigated. The Mississippi Delta Project is a pilot study of self-sampling and HPV DNA detection. The Project's goal is to determine whether self-collection of cervicovaginal specimens in combination with HPV DNA testing is at least as accurate as cytology screening for detection of cervical intraepithelial neoplasia (or worse conditions). Mississippi will be the first in a series of projects in other high-risk populations.

To address the need for affordable screening, Screening Technologies to Advance Rapid Testing for Cervical Cancer Prevention was launched by the Program for Appropriate Technology in Health (Seattle, WA) to develop a low-cost, point-of-care HPV test. The test may be ready for pilot studies in 2007. Visual methods might be added to HPV DNA testing to increase specificity and evaluate severity.

Other issues that must be addressed include:

- Reduced number of visits per intervention cycle.
- Low-cost and adaptable therapy for local treatment of precancerous lesions.
- Regional capacity to handle cancer cases.

Perfect cervical cancer prevention is not attainable; there is no perfect test. But rates can be reduced dramatically by improving access for underserved women.

Diagnosis and Treatment in Underserved Populations—Jose Jeronimo, M.D., Division of Cancer Epidemiology and Genetics

Women with normal HPV tests are considered healthy; women with abnormal tests have an increased risk for developing cervical cancer. Abnormal screening is followed with colposcopy and biopsy.

The colposcopy procedure involves washing the cervix with 5 percent acetic acid (vinegar) for 1 minute. There are no acetowhite changes in a healthy epithelium; however, an abnormal epithelium shows an acetowhite area. Colposcopy is not enough to determine whether a lesion is precancerous or cancerous. Biopsy is required. Pathologists can then make a diagnosis of precancer or cancer. Most of the time, precancerous lesions are treated via excision (LEEP or cone) or ablation (cryotherapy); hysterectomy is not recommended for precancer and should be performed only when other uterine abnormalities coexist. Under the current conditions, at least three visits are needed for completing screening, colposcopy and biopsy, and treatment.

Alternative approaches based on HPV testing are currently under study. One approach considers performing the HPV test home. If results are normal, testing is repeated after 3 to 5 years. If HPV test results are positive, a 1-day clinic visit is required, during which a visual evaluation (colposcopy or visual inspection) is performed, followed by treatment. The other approach uses a fast and cheap HPV test performed at the health center.

Two projects have investigated ways to improve visual evaluation of HPV-infected women: Guanacaste and ALTS. The ALTS study performed follow-up in 2 years; the Guanacaste in 7 years. The studies involved a combined total of 15,000 women. Visual data from Guanacaste and ALTS were collected for patients with invasive cancer or intraepithelial lesions, women who were healthy at enrollment but developed disease prior to the follow-up, and healthy women who never developed pathological changes in the cervix.

Boundary-marking software tools have been developed to evaluate digitized pictures. The software can be accessed through the Internet. Images will be shown to physicians, who will evaluate them online. This is a research tool that can be adapted for clinical use.

An Internet-based microscope is being used to examine tissue samples. There is a relational database to select images based on specific criteria (e.g., HPV-positive and invasive cancer) or for specific patients over time.

The Cervix Project Database is a multimedia database tool that uses software to link visual data with pathology, HPV, clinical, and questionnaire data currently stored in the study database. Data can be retrieved according to queries stated by the evaluator. For information on virtual microscopy, see <http://archive.nlm.nih.gov/~neve/histeval/histEval.php?user=jeronimo>.

Dr. Jeronimo stated that an approach is needed that allows for longer screening intervals, fewer visits to the clinic, and use of the Internet for training and follow-up of health care providers.

Dr. Vydelingum commented that this is a good example of a research program that has incorporated the delivery aspect and taken into consideration the needs of special populations.

Key Points From Discussion Session

- Although some may be concerned that a 5-year screening schedule will mean that women will not make regular medical visits, this may be the result of underestimating the ability of women to make good decisions about health care. Cervical cancer screening does not have to be women's motivation to visit clinics.
- Repeat HPV infections and multiple-type infections are more common among Native American populations in high-risk areas. HPV testing may not be for everyone. Age at first test should be tailored to each population.
- In South Carolina, researchers are studying the impact of high HPV rates in high-risk areas. They have data on women's attitudes about self-collection of samples and are interested in any behavioral studies on adoption of the new approach. Researchers in the Mississippi Delta went to community health leaders to find out whether this should be done in that area; they incorporate quality control in

their study, but they have not been able to do a behavioral study. The Deep South Network submitted an R01 proposal to study this issue. A reviewer said that it was too early to do behavioral studies on such a new technology.

- Noncarcinogenic HPV is a very stable virus that does not easily change.

Tribute to Dr. Harold Freeman

Frank E. Jackson, Program Director of CRCHD's Disparities Research Branch, presented an impromptu gesture of appreciation to Dr. Freeman, whose leadership has been an inspiration to many, including the staff of the CRCHD. He was recognized not only for his 5 years at the CRCHD, but also for his earlier efforts to reduce cancer health disparities, starting with his work with the ACS on the association of cancer with poverty and continuing with his pioneering work in Harlem and his leadership of the President's Cancer Panel (PCP). Mr. Jackson asked several SPN/CNP PIs and CRCHD staff members to share their thoughts about Dr. Freeman.

Edward Partridge, M.D., of the Deep South Network for Cancer Control, stated that he first learned about Dr. Freeman at a PCP meeting in the early 1990s. He was impressed that a cancer surgeon continued to practice while serving as a leader in issues related to policy and disparities. He said he would consider himself successful if he were called a "white Harold Freeman."

Claudia Baquet, M.D., M.P.H., of the Maryland Regional Community Network Program to Eliminate Cancer Health Disparities, said that she knew Dr. Freeman when he was President of the ACS. At that time, NCI was just beginning to track variations in cancer mortality. When she learned that he was going to take a position at NCI, she worried that his passion might meet with obstacles within the Government. Now he is leaving NCI a more compassionate place, with an awareness of the ethical dilemmas associated with cancer health disparities. Millions of people have hope because of his career.

Judith Kaur, M.D., of the American Indian/Alaska Native Initiative on Cancer, said that Dr. Freeman has the strength and spirituality of an eagle and has taken everyone under his wings. She presented him with an eagle feather.

Jo Ann Tsark, of *'Imi Hale*, stated that Dr. Freeman is distinguished by his kindness, patience, and vision and his willingness to take a chance on the ability of minority people to conduct research and create programs to help their people.

Mr. Jackson said that Dr. Freeman has always taken the high road and never makes anyone feel uncomfortable or embarrassed in any situation. Dr. Freeman has touched him as no other supervisor has in his career. Dr. Freeman encouraged Mr. Jackson during his work with the National Black Leadership Initiative on Cancer (NBLIC), when he was discouraged and almost ready to quit.

Joyce Sheats, R.N., M.P.H., of NBLIC, thanked Dr. Freeman for his dedication and committed service to the CRCHD and to NBLIC as Eastern Regional Chair for several years. He has given inspiration to everyone working to reduce cancer health disparities.

Victor Tofaeano, M.D., of the American Samoa Community Cancer Network, said that it is an honor to be invited to speak about Dr. Freeman. The Pacific Rim has long wanted the Government to do something about cancer, but no one listened until Dr. Freeman came along.

Moon Chen, Ph.D., M.P.H., of the Asian American Network for Cancer Awareness, Research and Training, has known Dr. Freeman for many years. He called Dr. Freeman the Martin Luther King of cancer health disparities because he had a dream and did not let anything get in the way of that dream. Turning the NCI around in direction was more difficult than turning around an aircraft carrier. As leader of the CRCHD, he fostered an inclusive environment. Dr. Freeman is the oncogene of cancer health disparities whose vision has metastasized, as represented by everyone in the room today.

Each member of the CRCHD staff presented Dr. Freeman with a rose. Roses of many different colors were chosen to symbolize the diversity of the people Dr. Freeman's work has touched. Staff members shared thoughts and memories of their experiences in working with him and thanked him for what he has taught them. They also thanked him for raising the consciousness of NCI and NIH and expressed their admiration for his commitment to social justice. He was praised for his skill and persistence in getting new ideas approved by NCI leadership. It is Dr. Freeman's vision that motivated several of them to join the NCI; for others, his mentorship enriched their careers. He was called not only a great African-American leader, but also simply a great American leader.

Dr. Freeman responded that he has received many honors in his 34-year career, including the Lasker Award for enlightening scientists and the public about the relationship between poverty and cancer. What was done and said here today, though, was the highest award he has ever received. The gratitude that has been expressed justifies all of the work he has done to bring cancer health disparities to the attention of the cancer community. He is glad to realize that the seeds he has planted will live on through all the people present.

Dr. Freeman's great-great-grandfather was a slave in North Carolina who was allowed to work off the plantation after his regular work was done and to keep one-half of his earnings. Eventually, he was able to purchase his freedom for \$3,000, which meant that he had had to earn \$6,000. He adopted the name *Freeman* after he was freed. Dr. Freeman thinks about this part of his heritage every day.

Dr. Freeman's upbringing was in a relatively poor but educated family. He was able to attend medical school and become a surgeon. He chose to work in Harlem in 1967 because he wanted to help the people who lived there. He was shocked to see how many women presented with advanced stages of cancer. He understood that his skills were not adequate to cure people in this situation, and this led him to ask why this was happening. The people in Harlem were black and they were poor. He began to think about what it means to be black and poor in America.

As he began to get involved in national organizations, he began to direct this question to the whole nation. By 1986, he had learned that cancer mortality differences between black and white populations were related primarily to poverty. What he learned about the problems underserved people have in navigating the health care system led to the concept of patient navigation.

Serving as Director of the CRCHD has been a wonderful opportunity. He may not have turned the aircraft carrier around, but it may be leaning a little. His advice is to focus first on communities before developing ideas about large-scale solutions that may not address the right questions.

July 20, 2005

Plenary Sessions

Overview of Resources: NCI Office of Communications—Nelvis Castro; Mary Anne Bright, R.N., M.N.; Richard Manrow, Ph.D., Office of Communications

Dr. Chu welcomed participants and introduced Nelvis Castro, Acting Director of the National Cancer Institute's (NCI) Office of Communications (OC). Ms. Castro introduced Mary Anne Bright, Director of the Cancer Information Service (CIS) and Acting Deputy Director of the OC, and Richard Manrow, Associate Director of the OC's Office of Cancer Content Management.

Ms. Bright described the OC's mission: to effectively communicate the most up-to-date, evidence-based information related to cancer prevention, detection, diagnosis, treatment, and survivorship across the United States and around the world toward the goal of eliminating the suffering and death due to cancer. The OC creates, manages, and disseminates cancer information; acts as a focal point for communication within NCI; interfaces with the general public, cancer patients, researchers, the media, health

professionals, volunteer and advocacy groups, and partner organizations; and develops and builds partnerships to leverage resources and improve communications. Ms. Bright outlined Community Networks Program (CNP) phases and core goals, pointing out that each of these activities is likely to have a communications component.

Dr. Manrow described resources the OC offers to assist CNs. The OC can support CNs through information and education resources for investigator and community education and for developing communications and training materials. Many materials are available both on the Web site and in print.

NCI's award-winning Web site, <http://www.cancer.gov/>, provides information for health professionals and the public about cancer treatment, prevention, screening, genetics, symptom management, and survivorship. Much of this information is available in both English and Spanish. The site includes a comprehensive cancer clinical trials registry and clinical trials education materials. NCI's comprehensive cancer information database, Physician Data Query (PDQ), is the source of most of the information. The Web site provides a gateway to tools and services for cancer researchers, up-to-date cancer news, and online information and help from cancer information specialists. Print-based resources are available through NCI's CIS and the Publications Locator.

Dr. Manrow described the home page in detail, including each of the six portals displayed in the navigation area (Cancer Topics, Clinical Trials, Cancer Statistics, Research & Funding, News, and About NCI) and the site's search feature. Search results include editorially selected links believed to be of greatest relevance on a particular topic—called “best bets.” Best bets include a primary term as well as synonyms and misspellings.

The Quick Links section includes a dictionary that defines more than 45,000 cancer terms in lay-oriented language, some with images; the NCI drug dictionary, containing definitions for more than 500 cancer-related drugs; funding opportunities; NCI publications; and a link to Spanish-language resources. The NCI Highlights section features new developments in NCI-sponsored cancer research, including clinical trial results and new reports of interest to the community.

Dr. Manrow explained that for most PDQ information, there is a patient version written at the sixth- to eighth-grade reading level. All PDQ information is in the public domain and can be redistributed or repurposed, with credit and adherence to restrictions associated with use of the NCI and PDQ logos.

Three additional portals are dedicated to topics that are not focused on individual diseases. One is the tobacco and cancer home page, in which all available NCI information related to tobacco and tobacco research has been aggregated. The other two portals are on Energy Balance and Women's Cancers.

The Web site also features an Introduction to Clinical Trials page, Patient Education pages, and NCI Cancer Fact Sheets. The online publication locator is searchable by keyword, type of cancer, audience, and materials for specific population groups.

Ms. Bright said she was pleased that the CIS will partner with the CNs. She thanked the CRCHD for making CIS an integral part of the CNs. She said that cancer health disparities warrant collaborative strategies to leverage the organizations' resources. As an NCI-funded program, the CIS works to advance NCI's Challenge Goal.

Information is available in English and Spanish and via TTY. Online assistance is available at LiveHelp via <http://www.cancer.gov/>, which allows individuals to connect with information specialists for real-time instant messaging. E-mail assistance can be obtained on <http://www.cancer.gov/> by clicking on “Contact Us” or by writing to cancergovstaff@mail.nih.gov.

CIS also operates the NCI Smoking Quitline (1-877-44U-QUIT), available in both English and Spanish, offering one-time smoking interventions as well as callbacks to help a person continue tobacco-free. In 2004, then DHHS Secretary Thompson launched the National Network of Tobacco Cessation Quitlines (1-800-QUIT-NOW), a collaborative among NCI, CDC's Office of Smoking and Health, state-based

tobacco services, and the North American Quitline Consortium. As part of this collaborative, NCI secured a portal number that routes calls directly to state-based quitlines. It was CDC's hope to have state-based quitline services in place in every state by September 2005.

Through the partnership program, CIS supports organizations seeking cancer-related expertise. CIS provides training and skills-building workshops on a variety of cancer-related topics, including clinical trials, evidence-based practices, comprehensive cancer control, and program planning and evaluation. CIS offers coalition-building assistance and linkages to national, regional, and state organizations.

CIS provides access to a premier cancer communication system for testing health communication interventions. Some health communication researchers are conducting studies through the CIS.

In past work with the SPNs, CIS engaged in several cancer control projects and initiatives and worked with SPN grantees to develop education and evaluation tools, publications, and multiple presentations.

CIS is not a funding organization and does not administer grants or supplements. The program is operated through 15 5-year regional contracts throughout the United States.

CIS has very experienced, talented people on its staff, a number of whom have been with the program for many years. They understand the needs of the community.

The Office of Media Relations and Public Affairs promotes journalists' and, ultimately, the public's understanding of cancer research and of NCI programs. The Office facilitates interactions between NCI staff and the media. Services include triaging incoming calls from the media, creating and disseminating press releases, conducting media training, and preparing animations for broadcast use. In recent years, the Office has developed a minority media outreach program. The Office maintains a speakers bureau, administers the NCI Exhibit Program, and promotes and manages the Health Communication Internship Program, which recruits graduate students who spend 6 months to 1 year working in the OC. The Office performs outreach to radio, television, the Internet, and the entertainment industry.

The OC produces the *NCI Cancer Bulletin*, a weekly electronic newsletter. The newsletter features a Director's update and selected clinical trials, as well as highlights of cancer research (which may include interviews with NCI investigators). A subscription link is available on the Web site.

Key Points From Discussion Session

- The OC is exploring the use of emerging technologies to disseminate information.
- CIS has worked with special populations before. CIS is not only a disseminator of information, but also a research partner. CNs can rely on the creativity and expertise of CIS staff to find interesting approaches to measuring the impact of their activities.
- Science writers seminars have been offered 4 times a year, mainly at NCI headquarters in Bethesda, but the program is now expanding to 10 to 12 seminars per year in different cities. The Media Relations Office invites investigators to make presentations and writers to come and listen. This is not considered a news event but, rather, is an educational component intended to help reporters understand the issues. Summit participants were invited to suggest topics to be featured at a science writers seminar.
- The back page of the *Cancer Bulletin* is a community update. Summit participants were invited to contact OC staff to talk about featuring their work in this newsletter.
- The *Cancer Bulletin* is distributed via e-mail to 20,000 subscribers. Summit participants can e-mail the newsletter as well as subscription information to their colleagues.
- Dr. Chu advised new people, who might feel overwhelmed by the quantity of information presented at the Summit, to take it step by step. If there are concerns about procedures or requirements, participants should talk to their Program Directors at NCI; help is always available.

Cancer Prevention Fellowship Program—Shine Chang, Ph.D., Associate Director, Office of Preventive Oncology, Division of Cancer Prevention

Dr. Chang encouraged participants to take advantage of the NIH Grants listserv, a weekly e-mail about funding opportunities.

The Office of Preventive Oncology (OPO) sponsors training opportunities in support of the CNP goal to provide a cadre of well-trained minority researchers who will continue to address efforts to reduce and eliminate cancer disparities. Two of these training opportunities—the Cancer Prevention Fellowship Program (CPFP) and the Summer Curriculum in Cancer Prevention—were the focus of Dr. Chang’s presentation.

CPFP Structure and Activities

Training opportunities provided through the CPFP include:

- Master of Public Health Training
- Mentored Research at the NCI
- Summer Curriculum in Cancer Prevention
- Molecular Prevention Laboratory Training
- Grants Workshop
- Fellows Research Meetings and DCP Colloquia
- Professional Development Activities
- Cancer Prevention Fellows Scientific Symposium

Cancer prevention is a multidisciplinary field. People from a variety of backgrounds apply to train in the field. Dr. Chang described applicant and Fellow demographics. About 100 people apply each year, and about 10 to 15 are accepted. A weekly fellowship research meeting allows for cross-disciplinary discussion and helps prepare Fellows to talk with people from different backgrounds about why their research is important and how it relates to cancer prevention activities.

The CPFP pays for tuition and course fees, course materials, and books during the year in which Cancer Prevention Fellows pursue their M.P.H. degrees. The CPFP also provides a stipend and health benefits during the M.P.H. year and subsequent years in the fellowship program. After they complete their M.P.H. training—particularly if the training has emphasized statistical and epidemiological skills—Fellows qualify for a \$10,000 increase in their stipends since there is much need in the field for people with this kind of training.

The Summer Curriculum in Cancer Prevention is open to everyone with a doctoral degree or its equivalent. The two courses were originally designed for the program Fellows, but they have now been opened to applicants from all over the world. Every year, about 100 people participate, including recipients of K07 and R25 fellowships.

The first course, *Principles and Practice of Cancer Prevention and Control*, is offered over four weeks in July. This course is organized into the following modules: Introduction to the Cancer Problem; Ethics, Law, and Policy; Diet, Nutrition, and Chemoprevention; Biometric Methodology; Cancer Prevention: An International Perspective; Prevention and Control of Organ-Specific Tumors; Behavioral Science and Community Interventions; Occupational Cancer; Health Disparities and Cancer Prevention in Diverse Populations; and Disseminating Scientific Knowledge.

The second course, *Molecular Prevention*, runs 1 week. The course offers a good overview of innovative molecular prevention approaches and research currently being applied in the field. Summit participants

are invited to attend the course at no charge, but an application is required. Those interested in attending next summer should contact the OPO in February 2006 to get on the list.

An annual keynote lecture in cancer prevention is held in July as part of the Summer Curriculum in Cancer Prevention and is open to the public. This year's key lecturer was Dr. John Potter, Program Head of Cancer Prevention and Member of the Fred Hutchinson Cancer Research Center. Summit participants are welcome to attend.

At the end of the summer, a hands-on training in molecular biology techniques is presented to Cancer Prevention Fellows; this is a great opportunity for people who have never set foot in a lab to gain hands-on experience. The course includes a field trip to the NCI Advanced Technology Center to see how microarray analysis is conducted.

Fellows also participate in mentored research, selecting researchers with whom they want to work and choosing opportunities that are most suited to their areas of interest in cancer prevention. This is an important feature because CFPF Fellows are expected to identify and develop their own independent research agenda quickly. The OPO's mission is to train people quickly, get them up to speed, and send them where they can have the most impact.

One of the CFPF's goals is to prepare Fellows with the skills they need to become fully independent researchers and academicians when they leave the Program. Grant-writing skills are critical to success in many contexts, even in the private sector. Even if the application is called a business proposal instead of a grant, the skills are largely the same. For this reason, the Program includes an intensive 4-day grants workshop each January, where Fellows prepare a brief proposal for review by their peers, led by a former Scientific Review Administrator who actually administered grant peer review for the Center for Scientific Review at the NIH. Fellows are able to meet critical people who fund the kinds of research grants they are likely to submit in the future. As a follow-up to the workshop, Fellows submitting grants can participate in a grant writers working group.

Additional training areas include public speaking, time management, scientific writing, and opportunities for field placements at other institutions.

An NCI-FDA joint training opportunity allows Fellows to experience the regulatory review process for pharmaceutical agents and medical devices. Another opportunity within the CFPF offers training in two subtracks: (1) Ethics of Prevention and Public Health; and (2) Clinical Cancer Prevention Research. Fellows in these two subtracks enjoy additional resources specific to their interests in ethics and clinical practice.

The All-Ireland/NCI Cancer Consortium is a multilateral collaboration at the departmental level.

CFPF applications for June 2006 are currently being accepted. The application requires a personal statement of research goals, a professional history, four letters of recommendation, and academic transcripts. Applications may be completed on line or via hard copy. The application deadline is September 1.

The selection process involves a two-level application review by a scientific education committee. The top 30 candidates are invited for personal interviews at the end of October. For details on the Cancer Prevention Fellowship Program, see <http://www.cancer.gov/prevention/pob/>.

Collaborative Opportunities in Evaluation of NCI Educational Priorities—

Lenora Johnson, M.P.H., C.H.E.S., Director, Office of Education and Special Initiatives

Dissemination is the responsibility of every NCI component and program. In support of the NCI Challenge Goal, the Office of Education and Special Initiatives (OESI) develops, implements, and evaluates education and information dissemination programs across the cancer continuum. OESI

programs span the cancer continuum and address myriad audiences. Many programs focus on treatment issues, while others focus on early detection, prevention, screening, psychosocial concerns, and issues impacting family members. OESI recently completed the enhancement of resources on advanced cancer, cancer recurrence, caregiver support of loved ones at the end of life, and provider implementation of strategies in palliative care. In addition, OESI manages NCI initiatives and programs that focus on NCI special priorities in cancer research and treatment and the cancer education models that best target these areas.

NCI OESI seeks out opportunities to more broadly disseminate educational products and programs that have been found effective. For the most part, these efforts occur through partnerships and are aimed at providing tools that:

- Enhance patient-provider communications.
- Promote informed, shared decision making.
- Increase understanding and utilization of complex cancer-related information.
- Provide accurate content and data to use in designing evidence-driven educational programs.
- Provide strategies and approaches based upon the best evidence for specific and profound changes in behaviors (individuals in the community and cancer care professionals).

Moreover, the Office focuses on disseminating evidence-based strategies that reach and affect the largest (an perhaps, most vulnerable) populations. For example, the TEAM-Up program works intensively with partnerships in seven states to reach women rarely or never screened for cervical and breast cancers. These states possess the highest mortality rates for cervical cancer, a disease for which successes in cancer control have already been realized. This project is done with the support of a national partnership that includes NCI, CDC, USDA, and the American Cancer Society.

OESI's program development process involves six phases: needs assessment; program development (formative research data collected through interviews and focus groups across the program audiences); design, implementation, and promotion; evaluation (working closely with people in the field, such as CNs); and maintenance. Careful consideration of the objectives that the program materials are intended to fulfill is one critical aspect of developing products and programs.

Types of Collaborative Opportunities

OESI is taking steps to address literacy issues, moving from a simple literal-translation approach to a transcreation approach. Transcreation goes beyond translating English content to another language; it involves re-creating the product to provide content that is more appropriate for the intended audience. In transcreation, the final product may have an approach or emphasis that is very different from the English product. OESI is currently seeking professionals with expert knowledge in cancer and whose first or native language is Spanish to serve as technical reviewers of content. All "re-created" content undergoes a pilot test and, where resources allow, are evaluated to ensure the effectiveness of Spanish-language cancer education programs. With each project, OESI attempts to gain further understanding of effective dissemination channels for Spanish-speaking populations.

OESI has revised three pamphlets in the *Changes* series: *Breast Changes*, *Cervical Changes*, and *Prostate Changes*. Using design changes and plain-language conversion, the pamphlets were revised from a high school-graduate reading level to a reading level between the 6th and 7th grades. However, evidence from site visits to primary care offices indicates the need to improve comprehension by segmenting the content further and converting it to even lower literacy levels. NCI's resources often provide considerable detailed information; thus, another phase is being addressed in many programs: to adapt products to meet the needs of people with limited reading skills. These may take the form of easy-to-read, illustrated print resources with key information, or they may, after pilot-testing, come out in another format, such as a CD,

video, or flip chart. OESI will address the need for low-literacy resources to be developed as companion pieces for all resources that come out in the near future.

OESI also has plans underway to disseminate the educational resources and research developed by NCI grantees in the field that have been found to be effective. This will help shift attention from development of evidence-driven resources to adaptation of evidence-based resources for broader dissemination.

OESI is also investigating ways to support primary care providers in using culturally appropriate strategies to reach specific populations by developing professional education programs. For example, OESI continues to enhance the *Clinical Trials Educational Series* (CTES), a compendium of content, products, and training materials for intermediaries and end-users. OESI needs people who can test pieces of the CTES in the field, within interventions, and as tools in recruiting participants for clinical trials.

OESI is developing decision-making tools for treatment options (e.g., for prostate cancer). The shift is from providing information “for the sake of informing” to providing tools that support sorting through and choosing the best course from available options.

There are a number of areas where there is still a great deal of uncertainty, and OESI welcomes the opportunity to work with the CNs to better understand these issues and respond to diverse needs. These areas are both content- and contextually oriented. Gaining a better understanding of the use of specific materials and how this might differ across audiences is important. Also, understanding how to optimize the ability to reach specific populations with important cancer educational programs is essential. Areas where there is a need to better understand issues around which content is developed include caregiving and alleviating family and caregiving burdens; health-promotion behaviors relating to risk reduction and early detection; use of complementary and alternative medicine; decision making at the end of life; health care system responsiveness to a growing, changing population and rapidly changing therapeutics; cultural influences on shared decision making; changing attitudes related to participation in clinical trials; and the impact of partnerships in cancer education.

Two pilot dissemination model programs are underway: TEAM-Up and Body & Soul. TEAM-Up is a project involving the seven states with the highest incidence of mortality for breast and cervical cancers in a partnership effort to reach women who are rarely or never screened, using evidence-based programs to reach those women. Body & Soul came out of the early 5 A Day research and other research that provided evidence of the effective behavior change (increased consumption of fruits and vegetables) within African-American faith-based institutions.

For further information, contact Lenora Johnson at 301-451-4056 or johnslen@mail.nih.gov.

Establishing CNP Best Practices

Reducing Cancer Health Disparities Through Development and Identification of Best Practices—Leslie C. Cooper, Ph.D., M.P.H., R.N., Health Scientist Administrator, Health Policy Branch, CRCHD

The CRCHD approach to CNP best practices is a work in progress; definitions and criteria are still being developed. CNP’s goal is to conduct studies that reduce cancer health disparities by empowering communities, improving access to and use of beneficial health interventions, and training racial and ethnic minority researchers.

Community-based participatory (CBP) research brings communities into the project as partners. In CBP research, community-based organizations and groups are involved in helping to design and implement studies. CNs bring community members into studies as partners. Community groups use their knowledge of the community to help researchers understand local health problems and design activities to improve

health care. Community groups also help spread the word and encourage others to participate in studies through networking, presentations, etc.

Evidence-based public health is public health care based on studies reported in the scientific literature. CRCHD's aim is to move from evidence-based theory to best practices based on evidence-based interventions. Best practices are not "self-proclaimed"; they result from evidence- or experience-based research modified or adapted to fit the intended community (e.g., in terms of language, culture, needs, setting, etc.). Once such interventions are found efficacious and effective in one population, they should be replicated in another population or setting (with a control group, if not used before) and submitted to an external body for consideration and acceptance as a best practice. The intervention can then be packaged (along with all key study instruments and materials) and disseminated for possible replication by others and further testing for efficacy, effectiveness, and efficiency, followed by further documentation and dissemination of results and evaluation for possible further replication and evaluation by others.

There are three proposed levels of best practices:

- Developing instruments and interventions at one site; testing interventions and determining whether they are efficacious and effective (with or without controls); documenting results; giving results limited dissemination
- Evaluating validity and reliability of the intervention materials with controls; documenting results and implementing broader dissemination
- Considering instrument transportability, along with availability for further testing for generalizability; efficiency should also be explored

The community must be intricately involved in community-based participatory research. Projects include providing feedback at the onset of a project; comments throughout on the acceptability and delivery of various interventions or activities being conducted as part of the project; strategies for possible adoption of the intervention, and sustainability of the activities beyond the research project and dissemination of information to the community and others. If the community does not buy into an intervention, it becomes just another task completed by the project that may result in a scientific yield, but not necessarily a public health improvement yield to the community. Without sustainability, intervention effects will fade, and disparities will return.

CNs should summarize their research findings and report to their stakeholders (community, scientific community, and policy and decision makers). Different languages are needed to address these diverse audiences. In some forums, community members should accompany researchers to broaden the perspective of the information provided. Findings should be published.

The Assistant Secretary for Health is showcasing best practices in public health from around the country to foster an environment of peer learning and collaboration. Approved best practices are posted at <http://www.osophs.dhhs.gov/ophs/BestPractice/>. Guidelines are provided using a standardized format designed to facilitate rapid review, comprehension, and posting on the Internet.

For more information about best practices, see the following:

- California Center for Health Improvement (<http://www.centerforhealthimprovement.org/>)
- Colorado Department of Public Health and Environment (<http://www.cdphe.state.co.us/ps/bestpractices/bestpracticeshom.asp>)
- National Association of County and City Health Officials (http://www.naccho.org/files/documents/responds_to_bioterrorism.html)
- National Governors Association Center for Best Practices (http://www.nga.org/center/divisions/1,1188,T_CEN_HES,00.html)

- National Guidelines Clearinghouse (<http://www.guideline.gov/index.asp>)
- HRSA's Bureau of Primary Health Care *Best Practice Guidelines* (<http://www.bphc.hrsa.gov/quality/BestPractices.htm>)

Basic Principles: Towards Achieving a Best Practice Intervention—

Terri L. Cornelison, M.D., Ph.D., Program Director, Division of Cancer Prevention, NCI

Best-practice intervention derives and develops from research that is evidence-based, hypothesis-driven (i.e., A is better than B, or A improves C), statistically sound, modified to the intended community, conducted and recorded in compliance with good clinical or research practice guidelines, and reproducible.

Good clinical practice is an international, ethical, and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects. It provides public assurance that the rights, safety, and well-being of trial subjects are protected and consistent with principles in the Declaration of Helsinki and that the clinical trial data are credible.

Protocol Design

When designing a protocol:

- Develop a scientific argument. What is the problem and why is it important?
 - ◆ e.g., Cervical cancer is bad.
- Survey the evidence base. What progress is reported in the literature?
 - ◆ e.g., Cervical cancer is induced by the HPV virus.
 - ◆ HPV vaccine prevents viral infection in animals.
 - ◆ e.g., The vaccine is safe in women.
- Develop a hypothesis. What is your idea and why should it work?
 - ◆ e.g., HPV vaccine can prevent HPV in women.
- Develop specific research aims. What experiments will you conduct to prove your hypothesis?
 - ◆ e.g., Vaccinate women and test for HPV virus.

Researchers must ensure that their studies or interventions are conducted, recorded, and reported in accordance with appropriate standards and guidelines. The institutional review board (IRB) is responsible for determining whether the research is ethical and appropriate in the setting within which it is being done. The investigator's qualifications and resources must be appropriate for the work. The investigator is responsible for trial management, data handling, record keeping, participant confidentiality, and safety monitoring. The sponsor (usually the funding source) is responsible for quality assurance and quality control and, where an agent is being used in a clinical trial, supplying information such as the investigator's drug brochure.

The Division of Cancer Prevention supports Cooperative Groups (Community Clinical Oncology Programs), contracts (Phase I-II Cancer Prevention Consortia), and grants (e.g., R01, R21).

Best Practices and the Role of Cancer Clinical Trials—Doris Browne, M.D., M.P.H.

Clinical trials are important because they translate results of basic research into better ways to care for patients. Cancer clinical trials translate the results of basic scientific research into better ways to prevent, diagnose, or treat cancer. The more people who participate in studies, the faster critical research questions can be answered and better treatments found.

The “gold standard” of a therapeutic clinical trial is the randomized, controlled clinical trial. *Controlled* means that some trial participants will receive a placebo or that the researcher is going to use a historical control; this is intended to minimize bias. The clinical trial can be blinded (single or double). Randomized trials are designed to minimize the bias that may come from the investigator or the designer of the trial. Participants should have an equal chance of being assigned to one of two or more groups where one receives the most widely accepted (standard) treatment and the other gets the new treatment being tested, which researchers hope and have reason to believe will be better than standard treatment.

Cancer prevention trials evaluate the effectiveness of ways to minimize the risk of cancer; these trials enroll healthy people who are determined to be at high risk of developing cancer.

Increased minority recruitment to clinical trials is needed because few minority patients and physicians participate in clinical trials. Most drugs are approved without significant minority participation, and it is expected that approved drugs will work for all, including minorities.

Minorities often do not participate in clinical trials because they are unaware of clinical trials; they do not have access to health care where trials are being conducted; their doctors did not recommend it; and/or they distrust medical research in general. Sometimes they do not participate because of negative past experiences with the health care system or because of cultural beliefs/myths or racial/ethnic discrimination.

There are potential risks to participating in a clinical trial. New treatments or interventions under study may not always be better than—or even as good as—standard care. Even if a new treatment has benefits, it may not work for every subject. There can be potential or unexpected side effects and unknown risks. Participation may also involve inconveniences involving time, cost, and transportation issues. Participants may have to stop taking other medications. In addition, health insurance and managed care providers do not always cover clinical trials.

Minority participation benefits include better-targeted medicines; access to, and experience with, the newest treatments before they are available to others; very carefully watched health; most study treatment at no cost; and the chance to provide scientific help to others.

A number of factors affect whether someone decides to participate in a clinical trial. These include the subject of the study, who is conducting it, the type of study, the location of the trial, risks and benefits of participating in the study, how long the study will last, and what tests are involved.

To improve recruitment, it is important that researchers know their communities and understand the group they need to target. Investigators must be creative and flexible, creating opportunities and thinking “outside of the box.”

CNs can do several things to make clinical trials more successful:

- Enhance clinical trials outreach and education efforts at the institution and in the community.
- Obtain broad representation from community oncologists and other oncology health care providers, government agencies, industry, and consumer advocates.
- Provide effective management and develop performance and outcome measures.
- Ensure diversity among participants; if diversity and cultural competence are an afterthought, the project is already in trouble.

Retaining participants in a clinical trial is not an accident. Retention must be built in from the very beginning of trial design. Retention and adherence begin with recruiting good study subjects and explaining all of the information to them. Communication is the key to success. This will help reduce cancer incidence and mortality and help empower communities.

**Best Practices Overview—Leslie C. Cooper, Ph.D., M.P.H., R.N., Health Scientist
Administrator, Health Policy Branch, CRCHD**

Dr. Cooper provided an overview of the presentations on best practices: establishing a best practice; developing strategies for moving from a best practice to an evidence-based intervention; understanding the importance of randomized clinical trials and other study designs as well; and taking advantage of the tremendous resources available through NCI. She thanked NCI staff, commenting that many individuals had helped put together this presentation, including all the staff at the CRCHD, grantees, and the Turnkey Office Solutions staff.

Dr. Cooper asked participants whether they had a best practice they would like to share. What was the project? Was it effective? Who identified it as a best practice? What are the next steps? She asked a series of questions to determine whether the practice met best-practice criteria: Was it based on evidence in the scientific literature? Is scientific rigor built into the study design and methodology? Does it have the power to indicate that it was a success? Is it effective? Can it be packaged? What kind of documentation and dissemination is there? Has it been submitted to an external body for possible consideration and review using another set of criteria? Can others replicate the project and interventions in other areas? Is it ready for possible submission to a more rigorous test of a possible randomized clinical trial?

Key Points From Discussion Session

- Claudia Baquet, PI for the Maryland CN, described a program for increasing availability of clinical trials to rural cancer patients and their participation in such trials. The program was reviewed by the DHHS and labeled a best practice. Information is available on her project's Web site.
- Joyce Sheats, of NBLIC II, has developed four interventions that have been replicated throughout the four regions served by the project: Stay Beautiful, Stay Alive; Down Home Healthy Living; For Men Only; and Clearing the Air. NBLIC will submit these four interventions to DHHS for best-practice consideration.
- Thoa Nguyen from the University of California, San Francisco, said that there is interest in lay health worker approaches, but there are few data to show that they are effective. His group has published a paper on an interim analysis of a health care outreach program to promote cancer screening in Vietnamese women in California. This is a randomized comparative trial. Mr. Nguyen expressed a desire to share what he has learned and ascertain what others have learned in terms of how to perform this type of community-based work.
- Teresa Guthrie, Program Manager for the Spirit of EAGLES CN, said that this national initiative for American Indians and Alaska Natives has developed a "Cancer 101" curriculum to engage tribal entities in cancer control efforts. The curriculum is designed to educate community members, health professionals, community health representatives, and outreach workers about cancer. A best practice in the making, the initiative hopes to undergo formal evaluation this year. Other populations are using the program.
- CNP projects are encouraged to submit best practices to the DHHS Web site at <http://www.osophs.dhhs.gov/ophs/BestPractice/>. DHHS is interested in working with CNs on this effort. CNs can help by adding to the literature and making intervention materials available. One idea is to produce a summary of best practices for reducing cancer health disparities.

Research Opportunities: NIH National Center on Minority Health and Health

Disparities—Jerome Wilson, Ph.D., M.A., Associate Director for Scientific Program Operations, National Center on Minority Health and Health Disparities, NIH

The mission of the National Center on Minority Health and Health Disparities (NCMHD) is to study the health problems of minority and other medically underserved groups in this country. Its charge is to lead, coordinate, support, and assess the NIH effort to reduce and ultimately eliminate health disparities. In this effort, the NCMHD conducts and supports basic, clinical, social science, and behavioral research; promotes research infrastructure and training; fosters emerging programs; disseminates information; and reaches out to minority and other communities experiencing health disparities.

NCMHD Programs

NCMHD programs include Loan Repayment, Research Endowment, Centers of Excellence, Community-Based Participatory Research and Outreach, Research Infrastructure in Minority Institutions, and Minority Health International Research Training.

Dr. Wilson described two loan repayment programs that are available for investigators involved in disparities research and for extramural clinical research. The Health Disparities Research Loan Repayment Program encourages health professionals to engage in basic, clinical, or behavioral research directly relevant to health disparities issues. The Program seeks to recruit and retain highly qualified health professionals in research careers that focus on health disparities research related to minorities and the medically underserved. The Extramural Clinical Research Loan Repayment Program encourages health professionals from disadvantaged backgrounds to conduct clinical research. The emphasis on clinical research and on individuals from disadvantaged backgrounds highlights the need for the involvement of a cadre of physician-scientists in clinical research.

The Research Endowment Program can be used to strengthen research infrastructure, including: teaching programs in the biomedical and behavioral sciences and related areas; improve physical plants; purchase equipment for instruction and research; support student recruitment and retention, which includes creating merit-based scholarships, establishing or enhancing tutoring, providing counseling, and designing student service programs to improve academic success; support faculty recruitment and retention; provide instruction delivery systems and information technology development in areas that would enhance minority health and health disparities research activities; and establish endowed chairs and programs.

Centers of Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training (Project EXport) is intended to support biomedical and behavioral research and provide training for persons from health-disparity populations. Awards are given for a period not to exceed 5 years, pending annual approval by the NCMHD Director and availability of appropriations for the program.

Developmental Grant Awards are targeted at institutions that are beginning to build their health disparities research programs. Funds will support activities designed to develop or enhance the infrastructure for scientifically meritorious research on the determinants of health disparities.

Exploratory Grant Awards are targeted to institutions that have research programs but need additional funding to develop a health disparities research program. Funds will provide a mechanism to strengthen the infrastructure for minority health and other health disparities research and training and will provide resources to help successful applicants develop innovative partnership models.

Center Awards are designed for research-intensive institutions pursuing research in health disparities. Funds will be used to establish a health disparities research center.

The Community-Based Participatory Research and Outreach (CBPRO) program is focused on disease prevention, intervention research, and implementation of health programs in communities experiencing

health disparities, as well as elucidation of barriers to effective health care and partnering initiatives. The CBPRO program was structured with three phases: (1) a 3-year planning grant to develop an intervention; (2) if the first phase is a success, a 5-year grant to implement the intervention; and (3) if the second phase is successful, a 3-year grant to disseminate the information.

Evidence-Based Public Health

The Scientific Program Operations Team's mission is to provide strategic vision, planning, and leadership to ensure that research conducted and supported by NCMHD has a strong scientific basis. The Center focuses on developing evidenced-based public health.

Health disparities programs must be evidence-based not only in promoting health, but also in promoting evidence-based health care. The aim of NCMHD programs is to improve the health of populations through targeted community-based education, intervention, training, and research.

Selected Examples of NCMHD-Supported Research

NCMHD-supported cancer research includes:

- A comparison of androgen-receptor polymorphism in African-American and Caucasian women with breast cancer.
- A study of barriers to cervical cancer screening among Hispanic women in Boston.
- A study of colorectal cancer among Korean Americans.
- Research on cardiovascular disease through Families Implementing Good Health Traditions for Life and research on diabetes through a study of race and long-term diabetes self-management in an HMO.

Other NCMHD research covers health care access, infectious diseases, mental health, obesity, and substance abuse.

Community-based research applications include Communities Advocating Research Empowerment in Genetics, Research to Prevent Chronic Diseases in African Americans, Community Action for Cancer Prevention and Control, Stroke Research in Multiethnic Communities, and Diabetes and Obesity.

NCMHD collaborations include Resource Centers for Minority Aging Research (NIA/NIH), Centers for Research to Reduce Oral Health Disparities (NIDCR/NIH), Health Disparities Partnerships for Nursing Research (NINR/NIH), Bridges to the Future (NIGMS/NIH), the Osteoarthritis Initiative (NIAMS/NIH), the Los Angeles Latino Eye Study (NEI/NIH), the Jackson Heart Study (NHLBI/NIH), the Barbados Cancer Study (NHGRI/NIH), REACH 2010 (CDC/DHHS), Tribal Epidemiology Centers (Indian Health Service), Racial and Ethnic Variation in Medical Interactions (AHRQ/DHHS), and community-based projects, outreach initiatives, and internship programs (Office of Minority Health/OS/DHHS).

Key Points From Discussion Session

- Several years ago, a grant application to fund a program to serve a rural, white, low-income, Appalachian population was said to be unresponsive to the RFA. The definition of *health disparity populations* includes the minority racial and ethnic groups, the rural poor, and the medically underserved. Today, the Center is very interested in Appalachia as a target area.
- The Endowment Program is tied to the HRSA Centers of Excellence institutions. This RFA is seeking ideas that grow from community concerns, but guidelines require partnership with academic institutions. Non-academic community-based groups often lack the necessary research expertise, and the university often lacks the necessary community competence. A community group can be the lead, but there must be evidence of fiduciary responsibility and a history of having managed grants and money. If the community group leads, it must have a university partner.

- Plans are underway for a program that matches participants in the loan repayment program with potential mentors. Dr. Wilson envisions a scientific forum where loan repayment scholars present abstracts and network with the Centers.
- The FY2006 budget reflects only a very slight increase in funding. Developing new programs will require creative use of available funds.
- The loan repayment programs will continue. NCMHD has the largest loan repayment program at NIH and just sent the announcement for next year.

Training and Career Development Opportunities: Comprehensive Minority Biomedical Branch, NCI—Belinda Locke, M.S., Program Director, Comprehensive Minority Biomedical Branch

Ms. Locke is the Program Director for the Career Development Awards within the Comprehensive Minority Biomedical Branch (CMBB), a part of the Office of Centers, Training and Resources.

The CMBB's goals are to: broaden the participation of minorities in cancer-related research and training activities while encouraging a competitive mindset; raise the competitive research capacity of minority-serving institutions; and raise the level of effectiveness of programs and organizations outside of NCI that have the common goal of increasing the numbers of underrepresented minority investigators in cancer research.

Continuing Umbrella of Research Experiences (CURE)

The CURE program, operating within the CMBB, is intended to increase the number of underrepresented minorities in the scientific talent pool. CURE emphasizes scientific areas of greatest need, including community-based research, prevention, and intervention. CURE also expands and extends the period of training.

Research Supplements

Research supplements are a funding mechanism that supports training as part of ongoing NCI-funded research and can be attached to various mechanisms. These include Research Supplements to Promote Diversity, the NCI Cancer Center Supplements for High School and Undergraduate Research Experiences (P30S), Institutional Clinical Oncology Research Career Development Award Supplements (K12S), NCI Cancer Education and Career Development Award Supplements (R25TS), and Minority Supplements to the Ruth L. Kirschstein National Research Service Award (T32S).

These supplements must be used for the sole purpose of including an individual from an underrepresented population in the grant program. For CMBB purposes, an underrepresented minority is an individual representative of a particular ethnic or racial group that has been determined by the grantee institution to be underrepresented in cancer-related biomedical, behavioral, clinical, or social science research. Underrepresented individuals are not limited to racial and ethnic minorities, but also include individuals representing groups that are underrepresented among cancer researchers (e.g., first-generation college graduates, the socioeconomically disadvantaged, and disabled persons).

Research Supplements to Promote Diversity

Research Supplements to Promote Diversity provide research opportunities for underrepresented minorities at the high school through junior faculty levels. The aim of these supplements is to attract and encourage individuals from underrepresented populations to enter and pursue health-related careers. Up to 5 years of support may be requested for salary, fringe benefits, supplies, and travel. Support will be in the form of an administrative supplement to an active research project grant.

Cancer Center Supplements for High School and Undergraduate Research Experiences

NCI Cancer Center Supplements for high school and undergraduate research experiences (P30S) take full advantage of the community outreach and research capabilities of NCI-supported Cancer Centers to engage the scientific curiosity and promote the potential cancer research careers of promising young high school and undergraduate students. Up to 5 years of support may be requested by any NCI-supported Cancer Center. Annual salary for both high school and undergraduate students should not exceed the state or institutional minimum wage. Supply costs of \$500 annually for each student may also be requested. Total direct costs for the Program may not exceed \$75,000. Support will be in the form of an administrative supplement to an active Cancer Center Support Grant.

Minority Supplements to Institutional Clinical Oncology Career Development

Minority Supplements to the NCI Institutional Clinical Oncology Research Career Development Award (K12S) place promising underrepresented minority board-eligible or certified clinical oncologists in patient-oriented research settings. Up to 5 years of support may be requested by any Principal Investigator of an active K12 grant. Support may be requested for a salary of up to \$75,000 each year plus fringe benefits in addition to up to \$30,000 per year for research-related expenses, tuition, statistical services, travel, etc. Support will be in the form of an administrative supplement to an active Institutional Clinical Oncology Research Career Development Award.

NCI Cancer Education and Career Development Program

Minority Supplements to the NCI Cancer Education and Career Development Program (R25T) place minority pre- and postdoctoral candidates in cancer prevention, control, behavioral and population sciences research settings that are highly interdisciplinary and collaborative. Support may be requested for salary, fringe benefits, supplies, and travel in accordance with the salary structure of the grantee institution. Up to 5 years of support for predoctoral candidates and 3 years of support for postdoctoral candidates may be requested per project period. Support is given as an administrative supplement to an active R25T grant.

Ruth L. Kirschstein National Research Service Awards

Minority Supplements to the Ruth L. Kirschstein National Research Service Awards (T32) support underrepresented minority predoctoral candidates in areas of basic cancer research, prevention, and population-based cancer research as well as support underrepresented minority postdoctoral candidates in interdisciplinary and collaborative settings focused on basic, clinical prevention, and population-based research careers in cancer. Up to 5 years of support for predoctoral and 3 years of support for postdoctoral candidates may be requested. Funds are provided as stipends to graduate students and postdoctoral trainees at NRSA levels. Support is given as an administrative supplement to an active T32 grant.

Research Career Development Awards

Career Development Awards (K awards) are funding mechanisms for individuals. They allow individuals to enter the NIH research system as independent principal investigators, whereas the supplements previously described simply provide additional funds to ongoing research projects for individuals who desire a research experience. K awards include the Mentored Career Development Award for Underrepresented Minorities (K01), Mentored Clinical Scientist Award for Underrepresented Minorities (K08), Mentored Patient-Oriented Research for Underrepresented Minorities (K23), and Transition Career Development Award to Promote Diversity (K22).

Career Development Awards (K01, K08, K22, and K23) are intended to significantly increase the number of underrepresented minorities participating as competitive NCI/NIH-funded cancer researchers. These awards have many common features. The award recipient must be a U.S. citizen or noncitizen national by the time of award. Support may be requested for up to 5 years of research training (except for the K22). A

minimum 75 percent research effort is required. Allowable costs include salary up to \$75,000 plus fringe benefits and supply funds. (Supply funding varies per award.) All K awards can be applied for through the PHS form 398/Career Development Award instructions. Submission dates are February 1, June 1, and October 1. All K award grantees attend an annual professional development meeting that includes a mock review. In the mock review, advanced K candidates go through an actual review process.

Mentored Career Development Award for Underrepresented Minorities (K01)

NCI Mentored Career Development Awards for Underrepresented Minorities support intensive, supervised career development leading to research independence in basic, clinical, prevention, and population sciences. To be eligible, the award recipient must be a minority postdoctoral researcher or faculty member and demonstrate a need for additional supervised training. Allowable costs include salary and fringe benefits as well as supplies for the award recipient.

This award is unique in that one can come in as either a K01, which provides a 5-year mentored experience or as a Phased K01 or as a K01, in which the candidate proposes to be mentored for a period of no less than a year, with subsequent funding as a newly independent researcher. K01 applicants are granted \$30,000 in supply money during the mentored phase. At the point of independence, supply funding increases to \$50,000, and the award becomes transportable, meaning it can be used as leverage in seeking one's first independent position.

Mentored Clinical Scientists Award for Underrepresented Minorities (K08)

The Mentored Clinical Scientists Award for Underrepresented Minorities provides an opportunity for minority health professionals committed to a career in laboratory-based cancer research to obtain specialized experience in biomedical research. The award recipient must be a minority individual who holds a health professional degree or its equivalent or a doctorally trained oncology nurse. Allowable costs include salary and fringe benefits and research development expenses (e.g., tuition, fees, supplies, and training). This award has two unique requirements: (1) the sponsoring institution must have a well-established research career development program; and (2) a mentor is required. (See PA-03-002.)

Mentored Patient-Oriented Research for Underrepresented Minorities (K23)

The Mentored Patient-Oriented Research for Underrepresented Minorities award is intended to provide an opportunity for research-oriented clinicians to obtain research skills required to become independent patient-oriented investigators. The award recipient must have a health professional degree or its equivalent, be a doctorally trained nurse, or have a Ph.D. in a clinical discipline. In addition, the recipient must have completed clinical training and developed a subspecialty, if applicable. Allowable costs include salary and fringe benefits, research development support, and indirect costs (F&A). This program requires patient-oriented research—that is, human subjects research in which there is direct subject-investigator interaction. (See PA-03-006.)

Transition Career Development to Promote Diversity (K22)

The NCI Transition Career Development award provides protected time for advanced postdoctoral or newly independent research scientists in the areas of basic, clinical, prevention, and population sciences. The award recipient must be a prior or current awardee of a mentored research, postdoctoral position (2 years) or an independent position with continuous postdoctoral research training (less than 2 years). Allowable costs include salary plus fringe benefits and supplies. This award has three unique features: (1) maximum of 3 years of support; (2) application without sponsor institution; and (3) R01 or equivalent application submission by the end of the second year of funding. (See PA-05-011.)

Overview of the K Award Process

Applicants should select a program announcement and contact the Program Director. Application submission dates are February 1, June 1, and October 1. Initial reviews for scientific merit are conducted

during June–July, October–November, and February–March. The review process takes 12 to 14 months, so individuals should apply for K awards 1 to 2 years before they actually need the funds. Resubmission dates are March 1, July 1, and November 1 for those who want to renew. The current CMBB-sponsored K awards—the K01, K08, and K23—are undergoing the process of reissuance, and it is anticipated that the new Program Announcements for each of these will be available for the February 1, 2006, submission date.

Additional Information

- For information on K awards: <http://grants2.nih.gov/training/careerdevelopmentawards.htm>
- For a list of NCI-designated Cancer Centers: <http://www3.cancer.gov/cancercenters/centerslist.html>
- NCI contacts for applicants: <http://www.cancer.gov/researchandfunding/contacts>
- CMBB: 301-496-7344; <http://minorityopportunities.nci.nih.gov>
- CMBB Program Director contacts: H. Nelson Aguila, aguilah@mail.nih.gov; Belinda Locke (Career Development Awards), lockeb@mail.nih.gov; Peter Ogunbiyi (Supplements), ogunbiyp@mail.nih.gov.

Key Points From Discussion Session

- CNP Cooperative Agreements (U01s) can receive research supplements.
- Projects can have multiple supplements.
- The CMBB is out of funds for the current fiscal year.

Comment on Behalf of NCI—Rochelle Rollins, Ph.D.

Dr. Rollins commented on a petition circulated during the morning session that focused on maintaining the CRCHD as an independent office reporting directly to the NCI Director. She stated that a petition is not needed to ensure that the Center maintains its status within the NCI. She added that NCI is working hard to keep Dr. Freeman linked to DHHS efforts to reduce cancer health disparities.

Closing Remarks—Frank E. Jackson

Mr. Jackson summarized the events of the Summit and thanked all for their participation. He posed the question: “Why are we here?” He believes that participants made the effort to attend because people are sick and dying from cancer. They came to find out what more can be done to lift the burden of cancer, to lift the scourge of disease from communities. Mr. Jackson asked participants to form a circle of caring, concern, and commitment around the room as Cynthia Norris from the Southwest American Indian Collaborative Network and Dr. Tofaeono from the American Samoa Community Cancer Network offered prayers in their native languages.