

**Department of Health and Human Services
National Institute of Environmental Health Sciences
National Cancer Institute**

**Minutes of the Interagency Breast Cancer and Environmental Research Coordinating
Committee Meeting**

February 23, 2011

The Interagency Breast Cancer and Environmental Research Coordinating Committee was convened for its second meeting on February 23, 2011 via live webinar. The Chair of the Committee was Michele Forman, PhD, of the University of Texas, M.D. Anderson Cancer Center.

The meeting was open to the public on February 23, 2011 from 12:00 p.m. to 5:00 p.m. The agenda included a 30 minute session for the purpose of public comment. Notice of the meeting was published in the *Federal Register*.

Members Present

Christine Ambrosone, PhD
Janice Barlow
Beverly Canin
Alice Chang, PhD
Sally Darney, PhD
Suzanne Fenton, PhD
Michele Forman, PhD
Michael Gould, PhD
Sandra Haslam, PhD
Ronda Henry-Tillman, MD, FACS
Karen Joy Miller
Laura Nikolaidis, MS
Vivian Pinn, MD
Marcus Plescia, MD
Kenneth Portier, PhD
Jeanne Rizzo, RN
Gayle Vaday, PhD
Cheryl Walker, PhD
Sheila Zahm, ScD

Ex Officio Members Present

Dale Sandler, PhD
Neeraja Sathyamoorthy, PhD

NIH Staff Present

Jennifer Collins, MR

Gwen Collman, PhD
Caroline Dilworth, PhD
Nonye Harvey, MPH
Christie Kaefer, MBA, RD
Elizabeth Maull, PhD
Retha Newbold, PhD
Sheila Newton, PhD
Britt Reid, DDS, PhD
Les Reinlib, PhD
Heather Shaw, MD, MPH
Deborah Winn, PhD

Other

Marc Hurlbert, PhD, Avon Foundation Breast Cancer Crusade
Marion H.E. Kavanaugh-Lynch, MD, MPH, California Breast Cancer Research Program
Frank Coviello, PhD, Polymedco, Inc.

I. BACKGROUND

The Breast Cancer and Environmental Research Act¹ was signed into law by the President on October 8, 2008, as an amendment to the Public Health Service Act in order to establish a committee on breast cancer and the environment; the committee is tasked with reviewing research conducted or supported by Federal agencies on environmental exposures and breast cancer and making recommendations for innovative research strategies moving forward. The composition of the Presidential advisory committee is to consist of Federal representatives, scientists, health professionals, and people who represent individuals with breast cancer. The Secretary of the U.S. Department of Health and Human Services (HHS), Kathleen Sebelius, delegated the authority for implementing this act in June 2009 to the National Institutes of Health (NIH), and the Director of the NIH delegated the task specifically to the National Institute of Environmental Health Sciences (NIEHS) and the National Cancer Institute (NCI) in July 2009.

The duties of the committee, as set forth in the authorizing legislation, are to:

- Share and coordinate information on existing research activities and make recommendations to the NIH and other Federal agencies regarding how to improve existing research programs that are related to breast cancer research;
- Develop a comprehensive strategy and advise the NIH and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer that would:
 - Result in innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the research portfolio;
 - Outline key research questions, methodologies, and knowledge gaps;

¹ Text of the Act is available from <http://www.govtrack.us/congress/billtext.xpd?bill=h110-1157>.

- Expand the number of research proposals that involve collaboration between two or more national research institutes or national centers, including proposals for Common Fund research, to improve the research portfolio; and
- Expand the number of collaborative, multidisciplinary, and multi-institutional research grants;
- Develop a summary of advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer and other diseases and disorders;
- Make recommendations to the Secretary of HHS:
 - Regarding any appropriate changes to research activities including recommendations to improve the research portfolio of the NIH;
 - To ensure that the activities of the NIH and other Federal agencies are not duplicative;
 - Regarding public participation in decisions relating to breast cancer research to increase the involvement of patient advocacy and community organizations;
 - On how to best disseminate information on breast cancer research progress; and
 - On how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

The timeline for the creation of the Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERCC) has been as follows:

- September 2009—Charter filed
- October 2009—*Federal Register* announcement requesting nominations of committee members
- January/February 2010—Committee selection and beginning of vetting process
- August 2010—Press release announcing the committee
- September 2010—Inaugural meeting of the IBCERCC

On February 23, 2011, the IBCERCC held its second meeting, hosted by the NIEHS and the NCI, via live webinar. Attendees of the meeting included committee members, presenters, and invited participants representing multiple Federal agencies, independent scientists and doctors, and members of the community. The meeting agenda included an overview of the activities that have occurred since the inaugural meeting, presentations covering the special research initiatives of the California Breast Cancer Research Program (CBCRP) and research activities of the non-profit sector, and general committee discussion regarding the draft of the introductory chapter generated by the Chair and the Subcommittee² chairs of the IBCERCC. The meeting included time for the Subcommittee to conduct concurrent meetings from 3:45 pm – 5:00 pm.

II. Welcome and Updates from the Committee Chair

² The Subcommittees of the IBCERCC are the State-of-the-Science Subcommittee (Chair, Michele Forman), the Research Process Subcommittee (Chair, Michael Gould), and the Research Translation, Dissemination, and Policy Implications Subcommittee (Chair, Jeanne Rizzo).

Michele Forman, PhD, Professor of Epidemiology, The University of Texas M.D. Anderson Cancer Center

Michele welcomed everyone to the meeting and updated the group on the activities that have occurred since the September 30 – October 1, 2010 meeting. She informed the Committee that the minutes from the inaugural meeting are available on the SharePoint.

Next, Michele briefed the group on the responses received from the Request for Information³ that was released by NIEHS and NCI on January 13, 2011. The RFI contained 8 questions relevant to the Committee's mandate. NIEHS received four responses from the following organizations: CRAAB (Capital Region Action Against Breast Cancer), Silent Spring Institute (including numerous references), the California Breast Cancer Program, and one reference submitted from American College of Radiology. All of the responses are available on the SharePoint. Michele summarized them using the document prepared by Heather Shaw:

- 1) Need for longitudinal studies following cohorts of females during windows of susceptibility through ages of greatest risk for breast cancer
- 2) Need for new models of cancer causation (see "New Paradigm of Breast Cancer Causation and Prevention" from CBCRP)
- 3) Need for screening methods that can assess multiple exposures simultaneously for contribution to cancer risk
- 4) Need for improved exposure assessment methods (both survey and direct measurement)
- 5) Need for a change in grant review process to increase funded environmental research projects (suggested: relevancy review by agency prior to peer review, increase in number of environmental/health experts on study section panels [my addendum: this would likely mean increasing training opportunities for new and established researchers in cancer/environmental health/toxicology to acquire expertise])
- 6) Need for education of health professionals (MDs/RNs) about environmental contributors to breast cancer risk
- 7) Need for inclusion of all agencies working on breast cancer and the environment, not just federal agencies
- 8) Need for evaluation of more chemicals for potential to influence breast cancer risk prior to approval of use

Michele briefly described the goals of the three subcommittees that were formed as a result of the inaugural meeting. The Subcommittee Chairs have worked together to draft an introduction to the report that outlines the objectives of the report, delineates the problem, defines environment, clarifies the endpoints, describes the organization of the IBCERCC, and describes the subcommittees. Later in the meeting the Committee discussed the introductory chapter.

Michele has engaged in two conversations with Irva Hertz-Picciotto, Chair of the Institute of Medicine (IOM)'s Breast Cancer and the Environment Committee⁴. Some of the activities of the

³ <http://grants.nih.gov/grants/guide/notice-files/NOT-ES-11-006.html>

⁴ <http://www.iom.edu/Activities/Environment/BreastCancerEnvironment.aspx>

IOMs Committee overlap with those of the IBCERCC. Cheryl Walker is a member of both Committees. Irva and Michele have discussed the need for two Environmental Health Perspectives (EHP) papers regarding the reports of the two committees: one that will highlight the similarities and differences of the two reports and another that will be published after both reports are available to address any differences in interpretation between the two reports.

Cheryl provided a brief update on the activities of the IOM's Committee. The Committee met the previous week for three days in San Francisco. The draft of the report is close to being finalized and will undergo peer review. The final report should be completed by August/September 2011 and will be published under the auspices of the IOM. The IOM's report is being underwritten by Komen.

Laura asked who would be writing the two papers. Michele responded that authorship would include Irva Hertz-Picciotto, Linda Birnbaum, and herself.

While there was some concern that the second paper would not be needed, there was general support for both of them. Michael warned that we have to be careful about compromising on any differences. Laura reminded everyone that we have to take our recommendations seriously and to continue to work independently of the IOM.

Janice pointed out that the work of the IOM is confidential and asked if that was true of the IBCERCC. Gwen reminded everyone that in compliance with the Sunshine Act that the work of the IBCERCC is Public.

III. The California Breast Cancer Research Program's Special Research Initiatives on Environment and Disparities

Marion (Mhel) H.E. Kavanaugh-Lynch, MD, MPH, Director, California Breast Cancer Research Program

Gwen introduced Dr. Kavanaugh-Lynch to the Committee. Her presentation was focused on the California Breast Cancer Research Program's (CBCRP) Special Research Initiatives (SRI). In the SRI, the CBCRP has invested \$23 million to address two critical questions: 1) what role does the environment play in breast cancer and 2) why do some groups of women bear a greater burden of disease.

The vision is to identify and support research strategies that increase understanding of, and create solutions to, environmental links to breast cancer and disparities in breast cancer. The goals of the SRI are: 1) to support a coordinated statewide effort to explore innovative ideas and new theories, 2) leverage California's unique and diverse geography and population, as well as scientific resources, and 3) undertake critical studies that significantly move these fields forward.

The rationale for selecting the two questions included California's unique position to address them, underfunding in these areas, and the opportunity to serve as a demonstration project for other funding agencies. The intent was to create new funding mechanisms (not investigator-

initiated grants) that included high impact projects that might not otherwise be pursued that would link together the unique resources of California, including its excellent cancer and pesticide registries.

Dr. Kavanaugh-Lynch described the rigorous planning process that was used to develop the SRI. The requirements for the planning process were as follows: 1) establish of the scientific credibility of the process, 2) ensure transparency, 3) establish accountability, 4) provide for public input, 4) meet stakeholder desires, 5) support research that is useful now, and 6) implied mandate to take risks. The SRI is CBCRP's pool of money for riskier endeavors while the CBCRP's core funding portfolio will continue to produce solid outcomes.

In Phase I, the CBCRP recruited and formed a steering committee to provide guidance. The committee included Julia Brody, PhD, Olufunmilayo Olopade, MD, Sandra Steingraber, PhD, Susan Shinagawa, David Williams, PhD, and Marion Kavanaugh-Lynch, MD, MPH. In Phase II, the CBCRP produced "Identifying Gaps in Breast Cancer Research: Addressing Disparities and the Role of the Physical and Social Environment"⁵. During Phase III, the stakeholders engaged in six regional meetings and teleconferences and generated research ideas. The CBCRP provided information and sought input on the web site and e-newsletter. The CBCRP also held a Research Symposium where stakeholders could learn about and engage in the SRI process. In addition, the CBCRP developed a resources database of 191 researchers and community-based collaborators. Strategy development ensured during Phase IV. During this phase, a 40 person Strategy Team was selected from throughout California and the nation and included advocates, researchers, and clinicians from various disciplines. The Team reviewed prioritization, requested presentations and additional information, and developed the final strategies. Finally, in Phase V, a funding strategy was adopted and implemented to significantly advance understanding of and find solutions to the two initial questions.

The funding strategy included \$23 million allocated to ten initiatives structured as cooperative agreements with active funder participation. The initiatives focused on collaborative and transdisciplinary studies, including creation of research teams proactively. The strategy accommodated both incremental and big-step research utilizing the diverse resources of California to advance research and serve the public.

Dr. Kavanaugh-Lynch briefly described the initiatives that were targeted at addressing the environmental links to breast cancer. Some of them are directed towards chemicals policy and making chemical testing relevant to breast cancer. Another one is aimed at investigating the environmental causes of breast cancer across generations. Others focus on the intersections of multiple factors and the development of models of breast cancer causation and disease complexity.

The CBCRP has decided to not only continue to support the SRI, but they have increased from allocating 30% of the total CBCRP research funds to 50% and have added efforts directed towards breast cancer prevention. Dr. Kavanaugh-Lynch acknowledged that this is a young and messy field of science but she argued that imperfect science is better than no science.

⁵ www.CABreastCancer.org/sri/reports/

Discussion

Ronda asked if the CBCRP is mapping findings to incidence. Dr. Kavanaugh-Lynch explained that they are evaluating whether there is a correlation between certain factors and breast cancer incidence but they are not doing GIS mapping). Their efforts are leading to more population-based messages/public health, rather than individual level recommendations.

Karen asked if there has been any push back since focusing on prevention. Dr. Kavanaugh-Lynch said that the decision to include prevention was just made six months ago and the CBCRP has not received any push back yet. She added that the CBCRP chooses to put people together who agree with the funding mission.

Cheryl provided a contrast between the California and Texas opinion of preventive activities. She explained that the cancer prevention initiative in Texas focuses on secondary prevention (screening and education about existing screening tests).

Gwen inquired further about models of how science is being done in the SRI. Dr. Kavanaugh-Lynch described three models: 1) RFQ (request for qualifications) around a very specific idea formed by agency and more similar to contract research in that the CBCRP tells investigators what to do very specifically, 2) collaborative agreements that involve back and forth with the PI, e.g. pilot grants to 2 different groups for 1 year, then compete for \$5 million after initial period of funding, and 3) RFAs that are investigator-initiated, but bring funded teams together and require sharing resources.

Sue asked Dr. Kavanaugh-Lynch how environment was defined. She responded for SRI that environment refers to chemicals and other substances that women are exposed to outside of their control.

Gwen asked how the programs will be evaluated. Dr. Kavanaugh-Lynch provided examples of outcomes evaluated including 1) how many projects go on to get funding from other agencies, 2) how California is doing overall in obtaining major funding (NIH, ACS, etc.), 3) policy impacts, and 4) interventions launched.

Sally commented on the similarities to children's research in asthma susceptibility. She wanted to know if the CBCRP's model was available. Dr. Kavanaugh-Lynch said that it is not currently published but will be soon.

Gwen asked how research findings being are being disseminated. Dr. Kavanaugh-Lynch's response was that the community agencies involved in the work aid in dissemination of research findings.

Michael asked what definition of breast cancer prevention was used. The response included three areas: 1) population level interventions, e.g. chemical regulation, 2) medical interventions for high-risk women, and 3) better identification of women at high risk for disease, not including individual level interventions or screening (secondary prevention).

IV. Breast Cancer and the Environment Research in the Nonprofit Sector

Marc Hurlbert, PhD, Executive Director, Avon Foundation Breast Cancer Crusade

Gwen introduced Marc Hurlbert, PhD to the Committee. Dr. Hurlbert's presentation focused on breast cancer and the environment research in the nonprofit sector.

Dr. Hurlbert briefly described the International Cancer Research Portfolio⁶, a database of research funded by cancer research organizations throughout the world. He also discussed the Health Research Alliance⁷ (HRA), an organization that fosters collaboration among not-for-profit, non-governmental funders. He mentioned that the group is not cancer-centric. Membership in the HRA has grown steadily since the first year of formal membership availability in 2006 and at the end of last year included 50 member organizations. It represents about \$1.2 billion in grants and over 5,500 research project/year.

Dr. Hurlbert described the Komen Promise Grant Program that issues a special Request for Proposals for etiology, environment, and primary prevention and he briefly touched on three of the grants.

Next, Dr. Hurlbert turned his focus on the work of his organization which has invested \$700 million for breast cancer since 1992, including \$175 million to breast cancer research grants and partnerships. These include partnerships with the NIEHS/NCI's Breast Cancer and the Environment Research Centers, the CBCRP, the National Breast Cancer Coalition, and the Silent Spring Institute.

Dr. Hurlbert provided the Committee with a list of questions that the Avon Foundation is trying to answer through its research funding including:

- 1) Why do so many women, without family history, get the disease?
- 2) What is causing breast cancer?
- 3) Can we develop new ways to prevent breast cancer (primary)?
- 4) Can we develop new tools or devices to monitor changes in healthy breast?

He also provided information on the Avon's public health messaging work, specifically the informational guide⁸ that reaches about two million individuals annually. Dr. Hurlbert elaborated on two initiatives including the 2006-2010 initiative aimed at determining what happens during pregnancy that alters breast cancer risk and the 2007-2011 initiative to develop new diagnostic/monitoring test that can detect early changes in the healthy breast and what early disease will progress to invasive cancer. Information was provided to the Committee regarding the 2010-2012 Inflammatory Breast Cancer Research Consortium that is examining the role of infectious agents or viruses in inflammatory breast cancer etiology.

Dr. Hurlbert described the Love/Avon Army of Women (AOW) cohort. To date, 350,000 women have been recruited and 80% are "healthy" volunteers who have never had cancer. The

⁶ <http://www.cancerportfolio.org/index.jsp>

⁷ <http://www.healthra.org/>

⁸ <http://www.avonfoundation.org/assets/bccguide.pdf>

aim is to support etiology, cause, and primary prevention research and 44 research projects have been launched. An example of a project on night shift workers was provided to the Committee.

Discussion

Karen asked Dr. Hurlbert about the challenges of having a meeting of the minds of larger funders. He responded by saying that it is actually going well and still a work in progress. They are working together to avoid duplication of effort.

Gwen asked whether Project Lead has plans to add environmental health. Dr. Hurlbert said that about two years ago, they updated the curricula to include environment and primary prevention. Laura added that Project Lead is training advocates in all of the areas with a focus on prevention of primary and metastasis.

V. Summary of the Introductory Chapter

Michele Forman, PhD, Professor of Epidemiology, The University of Texas M.D. Anderson Cancer Center

Prior to the meeting, Michele distributed the current draft of the introductory chapter for the report. The chapter outlines the objectives of the report, delineates the problem, defines environment, clarifies the endpoints, describes the organization of the IBCERCC, and describes the subcommittees. The Committee discussed the current draft and the strategy for moving forward with the rest of the report.

Discussion

Sue noted that understanding the impact of timing of exposure is critical in understanding. We need to understand when in the lifecycle the breast is the most susceptible.

Sandy asked what timeframe of federally funded projects will be covered by the summary. Michele said that this would be discussed later in the meeting.

Christine requested clarification of the goal of the report. What are we talking about in defining the problem? Are we restricting to only toxic agents?

Beverly added that defining the problem needs to include exposures.

Michele guided the group towards a discussion on defining environment. The current definition includes acquired, potentially modifiable factors, that vary by characteristics of the exposure (such as dose), and may include tobacco use, nutrition, physical activity, infectious agents, medical treatments, cosmetics, stress, SES, exposure to carcinogens (cancer causing agents) that occur naturally or created and concentrated by human activity.

Gwen asked whether we want to even use the word “carcinogen”. Use of the word narrows the definition of environment substantially. The Committee should be open to other factors besides carcinogens.

Cheryl asked about inflammation. How would we think about contributors to the proinflammatory state? We are talking about a process and processes have an effect on breast cancer.

Marcus suggested including carcinogens and other potential toxins. There is a list of known carcinogens, but also make it clear that we are interested in exogenous factors beyond carcinogens.

Sandy added that the definition of carcinogens provided by Michele was too broad and pointed out that some would disagree that endocrine disruptors are carcinogens. Endocrine disruptors interact as co-carcinogens.

Cheryl asked what the endpoint is. Michele responded that we are interested in measurable endpoints including prevention, incidence of first primary, recurrence, incidence in contralateral breast, and survival

Michele proposed a strategy for the work. She suggested an evidence-based approach to evaluate the state-of-the-science. The Committee will evaluate and synthesize science and infrastructure of research programs and assess the capacity of the community to engage in the identification of issues. The Committee will try to create solutions designed to be self-sustaining practices after the IBCERCC completes its work.

The group debated whether they would review and integrate results treating all results with equity. Christine reminded everyone that not all studies are of the same quality. This resulted in a change of wording to “review, evaluation, and integrate” results from observational research, randomized controlled trials, animal experimental research, and *in vitro* work.

Sue made the suggestion to also include identification of susceptibility and vulnerability factors other than time periods when considering windows of susceptibility.

Laura wanted to emphasize what can be done to mitigate the exposures should be a priority.

The group discussed prevention. The dialogue included the recommendation to distinguish between public health use of “primary prevention” (prevention of first incidence of disease), “secondary prevention” (early detection/screening), and “tertiary prevention” (prevention of progression of disease or complications from disease).

Michele asked that the Committee generate an annotated outline by the May meeting. This outline would then turn into the structure for the report. Each Subcommittee will also need to generate a scoping document for the May meeting.

VI. Subcommittee Breakouts

1. State-of-the-Science Subcommittee

Chair: Michele R. Forman, PhD, Professor of Epidemiology, The University of Texas M.D. Anderson Cancer Center

Subcommittee Members Present

Christine Ambrosone, PhD

Janice Barlow

Suzanne Fenton, PhD

Michele Forman, PhD

Sandra Haslam, PhD

Neeraja Sathyamoorthy, PhD

NIH Staff Present

Debbie Winn, PhD

Jennifer Collins, MR

The objectives of the SOS Subcommittee of the IBCERCC are integrated and dependent on the objectives and activities of the other Subcommittees⁹ of the IBCERCC and include the following: to summarize the state of the literature (both animal and human research); advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer (and related disorders); and identify research gaps.

The IBCERCC SOS Subcommittee held its first meeting via conference call on February 23, 2011, immediately following the live webinar meeting of the full IBCERCC. Attendees of the meeting included committee members and NIH staff. The Chair of the SOS Subcommittee was Michele Forman, PhD. The meeting agenda included discussion on the following: objectives of the SOS, scope of the SOS, delegation of activities, working with federal agency leads and staff, timeline, and conference calls.

Discussion

The group determined that the approach of the SOS Subcommittee will be as follows:

- Address upfront the known risk factors including reproductive and lifestyle factors (e.g. HRT, physical activity, obesity, reproductive risk factors).
- List known carcinogens and then go onto suspected and/or potential risk factors but not definitive to date.
- Stratify research by human and animal experimental models.
- Examine the strength of the evidence in each research area using the WICR and/or IARC criteria and then weight the evidence according to the criteria from one of the organizations.

The group also discussed areas to address for the development of a methods section and these included the following:

⁹ The other Subcommittees of the IBCERCC are the Research Process Subcommittee (Chair, Michael Gould) and the Research Translation, Dissemination, and Policy Implications Subcommittee (Chair, Jeanne Rizzo).

- What are the search terms used?
- What is the time period (years) for the review? The group discussed the previous two years as a starting point.
- Should we use criteria such as the most cited article in prevention? In diagnosis? In treatment?
- What is the scope of the research for ‘advances’ in prevention; diagnosis; treatment?
- Is a focus on progress more appropriate endeavor than on an advance? How do we define progress?

Sue suggested that the SOS Subcommittee could address six categories regarding progress/advances as follows:

- Technology (digital mammography, etc.)
- Genetics (familial/new signals/epigenome)
- Hormonal basis (melatonin/E+P/HRT)
- Breast diagnostic criteria (subtypes/receptor/breast density, etc.)
- Lifestyle modifiers (obesity/smoking/sun time)
- Environmental exposures (DTT, x-rays, etc.)

Each member of the group briefly described their respective area of expertise.

Areas of expertise:

Individual	Expertise	Animal or Human or Both
Christine Ambrosone	Genetic variance in BC; GxE interactions; Risk factors; BC subtypes	Human
Janice Barlow	Exposures from the consumer side; Progress across transdisciplinary teams and from the advocates point of view	
Sue Fenton	Critical periods of development; Exposure assessment; Hormonal regulation of development	Both
Michele Forman	Life course; Exposure assessment; Nutrition	Both
Sandy Haslam	Hormones & normal mammary gland development; Risk factors; growth factors	Animal
Neeraja Sathyamoorthy	Biology of BC; tumor microenvironment	
Debbie Winn	Environmental exposures from Silent Spring; GxE interactions	

2. Research Process Subcommittee

Chair: Michael N. Gould, PhD, Kelly H. Clifton Professor of Oncology, University of Wisconsin-Madison

Subcommittee Members Present

Michael Gould, PhD
Sally Darney, PhD
Laura Nikolaidis, MS
Kenneth Portier, PhD
Gayle Vaday, PhD
Cheryl Walker, PhD

NIH Staff Present

Nonye Harvey, MPH
Elizabeth Maull, PhD
Heather Shaw, MD, MPH

The objectives of the Research Process (RP) Subcommittee of the IBCERCC are integrated and dependent on the objectives and activities of the other Subcommittees of the IBCERCC and include the following: to set research priorities (based on work of the State-of-the-Science Subcommittee), to decrease redundancies across federal and non-governmental organizations, to develop a process for soliciting research, to foster collaborations (based on the work of the Research Translation, Dissemination, and Policy Implications Subcommittee), to highlight peer review issues, and to identify most appropriate models for agencies to work together.

The IBCERCC RP Subcommittee held its first meeting, hosted by NIEHS and the NCI, via conference call on February 23, 2011, immediately following the live webinar meeting of the full IBCERCC. Attendees of the meeting included committee members and NIH staff. The Chair of the Subcommittee was Michael Gould, PhD. The meeting agenda included discussing 1) the outline proposed by Michael, 2) generating a review of areas of funding environment and breast cancer by the various federal agencies, 3) key topics and format for the RP section of the report, and 4) identifying specific writing tasks.

Discussion

Michael reviewed the outline that he circulated to the Subcommittee prior to the conference call. He introduced discussion of the scope of work of the RP Subcommittee, the objectives of the Subcommittee between now and the next scheduled meeting (March 3, 2011), and identified writing groups for the various tasks. Michael asked the committee to look at issues he had identified in the following outline and solicited ideas from the group regarding what the research process should be.

Research Process

- Setting Research Priorities
 - What process to use:
 - Should include scientists and advocates

- Should address all of breast cancer etiology stressing environment and genetics:
- Non incremental – big question with impact.
- Infrastructure, e.g., reduction mammoplasty bank.
- Reducing Redundancy
 - Integrated “listing” of all breast cancer etiology-funded research by the Federal Government.
 - Should we consider integrating State, and non-profit funded research with Federally financed research
- Process for Soliciting Research
 - Joint sponsorship:
 - NIH Institutes
 - Directors Fund
 - Public-private sponsorship
 - Use RFA not RFP so that review is done by specially developed Study Section that could include advocates.
- How to Foster Collaboration
 - Provide opportunities for large project grants
 - Three models:
 - Multiple PIs multi-project (e.g., program project)
 - Center grant (e.g., P50s)
 - Large R01 type grants where PI(s) recruit the needed collaboration as need arises – most flexible and goal focused

Issues with Peer Review

- Identify work teams for each task with timelines
 - Current review is too conservative despite new guidelines. Incremental “for sure” research is favored over high risk projects. There is a need for targeted review sections (e.g., RFA).
 - Scientist-reviewers must be top notch breast cancer experts. This is difficult to achieve. Need a reward system to encourage participation. Also using an RFA approach will allow a one-time commitment by scientist.
 - How to choose advocates who prioritize the need to determine the etiology of breast cancer over developing modest improvements in treatment.
- Identification of most appropriate model systems.

Cheryl asked what the issues were. She thought the outline was right on; and was most excited about the big picture and transformative research - move towards a targeted approach.

Ken asked for where the background information on what the federal government is already doing. NIH Staff is currently working on this but Michael was not sure where they are with this. The question was asked about whether the group should also consider what the private sector is

doing. He urged the group to take a fresh look at the summary and assess what are we are doing well and what are we not doing well, especially with regard to transformative, innovative research (collaborative vs. independent). The group should look at the research literature and determine what is and is not getting easily published. Also, what innovative proposals are not getting funding due to lack of connection to current models? We may be missing some key research approaches because most agencies are tied into traditional ways of thinking.

Gayle informed the group about the DOD peer reviews process whereby DOD recruits reviewers based on what applications are submitted.

Laura has mentioned the NSF program in previous conversations (via email) and mentioned the capability within the government to have the different mechanisms where people are brought together as a think tank where ideas are heard first and the most promising are chosen. This could provide room for the government to do a little more massaging and could be done through contracting in order to get what we want as long as we put into RFA.

Michael asked the group what models are needed to develop innovative and transformative research. Specifically he asked how we catalogue models beyond just the number of grants into categories. How do we group by mechanisms? Do we have innovative models?

Ken mentioned that the Health Research Alliance (HRA) is thinking of how to fund innovation and how to identify models. What models potentially drive innovation? Consider models that drive broader breakthroughs in breast cancer and environment research. We need models that move us in innovative direction versus incremental direction. Foresight model for obesity is a model that Sally mentioned that provides a framework that will allows one to put values in and help you make decision. It will be useful to have some type of framework. Frameworks mentioned were the DPSIR¹⁰ and DPSEEA¹¹. The MEME¹² model was also discussed. Is there a model like this on breast cancer? Are there integrative models in other fields that could be applied to breast cancer?

The systems biology approach allows us to focus on the outcome, etiology, and why the cancer happens. LeRoy Hood's website¹³ shows using systems biology approach for therapy, diagnosis – more complete system. Bob Hiatt's model presented today could be dissemination products at the end of the day. We should keep the focus of resources on outcomes - most immediately impact the outcome.

We should consider an integrated approach where risk is considered rather than hazard to integrate up to the whole body and community levels.

Create a diagram of the different determinants then look at where we know a lot and where we do not - look at within the context. Decide where we need to fill in gaps. The State of the Science Committee will identify gaps and Research Process Committee will identify how to fill in the gaps. That is what processes and models to use that will make the most difference.

¹⁰ DPSIR Framework: http://enviro.lclark.edu:8002/rid=1145949501662_742777852_522/DPSIR%20Overview.pdf.

¹¹ DPSEEA Framework: <http://www.who.int/mediacentre/events/IndicatorsChapter7.pdf>.

¹² MEME Model: <http://www.who.int/ceh/indicators/indicconcept/en/index.html>.

¹³ http://www.systemsbiology.org/Intro_to_Systems_Biology

Consider the environment as an actionable component. What are the big gaps (complexity) and how do we address? New algorithms are needed. There is convergence of a lifestyle - alcohol, rich foods; other convergences for other age groups. Laura suggested that we could focus backwards on what is protective. This may be quicker than teasing out that which is a causative risk factor.

Gayle suggested the use of a pre-proposal/pre-screening method to see how to answer big questions, followed by an invitation of the best to develop full-blown proposal. The pre-proposal is usually about 5 pages or less. We need to be good stewards of PIs time and consider what we are asking them to do and what we are getting – leverage existing technologies.

We need to be going for the innovative idea. Integrate information - NIH does not do a good job. There are lots of breast cancer literature out there that is not digested. Consider the NASA model: Think Tanks are funded to determine where they are and integrate what they want. Also the AACR dream team approach - what the team thought was innovative or the NSF Center concept - fund a collaborative effort. We still do not have a good frame work to look at how all the incremental information fits together and where the gaps are.

Federal agencies do not have the big picture and therefore do not see the gaps and there is no funding mechanism for creating/looking for the big gap. A broad integrative model is absent – animal to human model as with EPA.

Solicit ideas - integrative review then peer reviewed. The current system does not reward the big thinker - but the smaller thinker - quick to produce research findings for publication. Collaborations are not usually innovative. Michael proposed funding innovative thinkers and then they develop the collaborations. You don't have a single innovator that you fund. You can get independent groups and bring together to challenge each other – competition is good. Compete models against each other - learn a lot about what they know and what they do not know - Meta thinking.

Laura suggested we organize the report by listing barriers to progress and then provide our solutions/recommendations to the barriers and new ways the government can solicit research to address the gaps.

3. Research Translation, Dissemination, and Policy Implications Subcommittee

Chair: Jeanne Rizzo, RN, President and CEO, The Breast Cancer Fund

Subcommittee Members Present

Beverly Canin

Alice Chang, PhD

Ronda Henry-Tillman, MD

Karen Miller

Marcus Plescia, MD

Jeanne Rizzo, RN

Shelia Zahm, ScD

NIH Staff Present

Christie Kaefer, MBA, RD

Discussion

The objectives of the RTDPI Subcommittee of the IBCERCC are integrated and dependent on the objectives and activities of the other Subcommittees of the IBCERCC and include the following: to identify successful models as well as gaps in research translation and dissemination, to make recommendations to improve both with an emphasis on breast cancer and the environment; to make policy recommendations to that end; to address areas in which the scientific evidence on breast cancer and the environment supports precautionary public health policy; and to identify methods to expand public participation in the research translation and dissemination processes to more effectively involve patient advocacy and community organizations, environmental health, environmental justice as well as practitioners in public health and health care delivery.

The IBCERCC RTDPI Subcommittee held its first meeting, hosted by NIEHS and the NCI, via conference call on February 23, 2011, immediately following the live webinar meeting of the full IBCERCC. Attendees of the meeting included committee members and NIH staff. The Chair of the Subcommittee was Jeanne Rizzo, RN. The meeting agenda included discussion on the following: proposed goals for the subcommittee and proposed process and timeline for the Subcommittee work.

Discussion

Proposed Goals for Subcommittee

Jeanne developed the proposed goals below from the legislation and current content in the draft IBCERCC Report Introduction chapter and reviewed them with the Subcommittee members to determine whether any modifications were needed.

- 1) Identify successful models and gaps in research translation and dissemination.
 - Shelia thought one aspect of this goal relates to whether we have good ways to communicate what risk means? What works/doesn't work?
 - Examples of successful models could include the Breast Cancer Fund and the California Breast Cancer Program (CBCP), which has Requests for Proposals (RFPs) that require community involvement. Other models to consider include the NBCC.
 - Ronda stated that health care providers have an important role in dissemination. Jeanne asked about involvement of clinicians as part of research grants. Marcus mentioned that CDC issues grants to communities to implement community-based programs that involve clinicians. Ronda and Alice added that clinicians need to be supported in order to spend more time on dissemination because their time is otherwise governed in terms of how many patients they see.
 - Jeanne commented on the need for creation of dissemination and communication systems that use other routes.
- 2) Make recommendations to improve both with emphasis on breast cancer and environment.

- Karen commented on the absence of the word “prevention” in this goal. She would like some clarification also as to what the Committee means when they use the term. Beverly agreed “prevention” should be included but recommended against spending a lot of time on definitions right now because full Committee will continue working on definitions.
 - Beverly asked the question regarding how messages have been transmitted that has had an impact.
 - Jeanne suggested the Subcommittee consider what is needed from federal agencies to assist others with dissemination and commented that access to funders, authors, etc can be problematic at times, and cited the release of the U.S. Preventive Task Force’s mammography guidelines which was not well messaged. Several Subcommittee members agreed this was a good example and Marcus added that if there was more participation, miscommunication could have been avoided.
- 3) Make policy recommendations to address research translation and dissemination.
- Marcus suggested there might be a need for a recommendation for agencies to have clearer guidelines for community participation when implementing programs (not research) and how best to communicate evidence to stakeholders in an accurate way.
 - Beverly thought the Subcommittee could look at wording from the CBCP RFPs, as well as grassroots dissemination issues, to assist with policy recommendations.
- 4) Make recommendations for precautionary public health policy supported by scientific evidence.
- What should the scope of this goal be? For example, the President’s Cancer Panel (PCP) included regulatory policies. Is that appropriate for the RTDPI? Does the PCP go far enough in its recommendations?
 - Karen and Marcus felt it was hard to know what should be recommended in terms of policies until the other Subcommittees complete their work.
 - Marcus thought this Subcommittee could probably some global recommendations could be made in the interim, but this Subcommittee will need time after the other Subcommittees complete their work to discuss these issues again.
 - Shelia suggested examples for generic recommendations could address whether the periodic reports released by NIEHS on carcinogens could have a less cumbersome process or whether federal agencies are making decisions appropriately regarding whether enough evidence has been amassed, etc.
- 5) Identify methods to expand public participation in research translation and dissemination processes.
- Programs that include community members that were cited by Subcommittee members include DoD, NCI Advisory Boards (and possibly peer review of grant applications?), and some NCI-funded studies, such as the Breast Cancer and the Environment Research Program (BCERP) and the Centers to Reduce Cancer Health Disparities (CRCHD).
 - Marcus commented that while community-based participatory research (CBPR) is important, it doesn’t necessarily result in dissemination, so other models need to be considered as well, such as CDC grants to state and local levels, with assumption that they will be participatory. Alice mentioned her organization

focuses primarily on grassroots dissemination (one-on-one communication). Ronda commented that her CBPR model is fairly grassroots.

- Are there evaluation models to evaluate community inclusion? NIEHS has a new evaluation metrics guide for community partnerships.
- 6) Identify methods to more effectively engage patient advocacy, community organizations, environmental health, environmental justice advocates and practitioners in public health and health care delivery.
- Shelia commented that would be stronger to pull together health advocates and environmental advocates.
 - Might be useful to develop a document listing various ways to reach target audiences.
 - Examples of existing listservs discussed: NIEHS (one focused on cancer and the environment and other for Partnerships in Environmental Public Health Program), NBCC, list Jeanne maintains (individuals interested in environment), Ronda mentioned a community-based participation group.
 - Other examples mentioned were “mommy blogs;” the CDC Cancer Coalitions which have used social networking and Facebook; and NCI’s use of the Web, Facebook, and Twitter through its Press Office and to promote smoking cessation.
 - Examples of recommendations to improve understanding of audience needs (and what is already working) include surveys and asking various organizations if they have done market research with target audiences and if so, whether they could share findings (since it is often not published). Jeanne mentioned the Breast Cancer Fund conducted an evaluation and found it to be very valuable.
 - Karen raised some questions related to social media related to misuse of information, how to identify credible sources and who picks up the information.

In general, Shelia and Beverly commented that a lot of the proposed goals above deal with methods and dissemination and there is not much emphasis on new approaches. She recommended the Subcommittee might want to involve others, such as Jennifer Loukissas, the Communications Manager for NCI’s Division of Cancer Epidemiology and Genetics, and Brooke Hardison, one of NCI’s Media Relations Analysts. Christie also offered to share information about NCI’s Centers of Excellence in Cancer Communications Research (CECCRs).

Proposed RTDPI Process and Timeline

The Subcommittee members discussed Jeanne’s proposal to divide into small groups to work on the proposed goals. Shelia thought it would be necessary to do work as small teams then come back to the group to review and discuss.

Jeanne asked the Subcommittee members if they could think of any assistance they might need and asked the group to send any questions they might have on this topic in the next month. NIH staff will help as needed. Some Subcommittee members expressed the need for some assistance with the IBCERCC SharePoint site. Christie will follow up with Jennifer Collins regarding the possibility of a demo or at least circulation of a User Guide. Questions regarding SharePoint can also be directed to Jennifer.

Jeanne would like to scope out a draft document by mid-April and asked the Subcommittee members if that would be feasible. Shelia asked if there are any existing documents that could be reviewed so the Subcommittee would not need to start from scratch. Subcommittee members discussed asking around for information, such as reviews on translation. Jeanne mentioned a review Debbie Winn sent to the Subcommittee Chairs. After the meeting, Christie will send a list of the information currently available on the SharePoint site that might be of use to the Subcommittee.

The Subcommittee members indicated some topics they were most interested in working on as part of a small team:

- Patient advocacy – Karen, Ronda? Alice?
- Communication issues - Shelia (wants to enlist Jennifer Loukissas at NCI)
- Policy issues – Shelia, Jeanne, Marcus
- Models – Marcus
- CBPR – Ronda

Beverly wanted more time to think about where she would be best able to contribute and Jeanne encouraged all to think some more about the topics and additional data they may need. There was some discussion about the possible lack of expertise on the Subcommittee related to communication modalities, especially related to new forms of media.

Regarding future meetings, Jeanne indicated a Doodle poll would be sent soon for next series of meetings after the May meeting.

VII. Adjournment

The meeting was adjourned at 5:00 p.m. on February 23, 2011.

CERTIFICATION

/Michele Forman/

Michele Forman, PhD

Chairperson

Interagency Breast Cancer & Environmental Research Coordinating Committee

/Gwen W. Collman/

Gwen W. Collman, PhD

Executive Secretary

Research Process Subcommittee

Interagency Breast Cancer & Environmental Research Coordinating Committee

Proper signatures

Treat as signed, § 1.4(d)(2)