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National Institutes of Health State-of-the-Science Conference on the Management and Diagnosis of Ductal Carcinoma In Situ: A Call to Action

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Ductal carcinoma in situ (DCIS) has been the focus of national and international dialogues for several decades. Review of scientific evidence and expert opinions on the diagnosis and management of DCIS have generally resulted in both areas of consensus and continuing controversy. In spite of the consensus elements, the diagnosis and management of DCIS remain an area of controversy. Similarly, the need for a better understanding of the disease biology, natural history, and clinical management of DCIS is ranked highly as a research priority by the public and research communities. The 1998 Breast Cancer Progress Review Group Report, the Institute of Medicine, and an International Web-based Consultation on priorities in breast cancer research have identified the need and priority for translational research in this area (1–3). Experts in the field from the San Antonio Breast Cancer Symposium and the St Gallen Consensus Conference who participated in the international web-based survey, ranked DCIS as third among the top 10 priorities in translational breast cancer research.

The National Cancer Institute has supported more than 70 investigator initiated projects solely or partially focused on DCIS and has funded more than $117 million over the past 5 years. In 2007, the Division of Cancer Control and Population Science held a DCIS workshop on strategies for integrating tumor biology and population sciences, which was designed to facilitate communications and resources sharing among researchers. More recent efforts to identify research agendas to advance the field include single institution working groups, a National Cancer Institute Premalignancy Committee, and a workshop on "Stratified Cancer Prevention: To identify Predictive Epithelial Markers for Breast Cancer Risk and Risk Reduction."

In response to the entire breast cancer community—from advocates to basic scientists, the National Cancer Institute and the Office of Medical Applications of Research sponsored the National Institutes of Health State-of-the-Science Conference, Diagnosis and Management of Ductal Carcinoma In Situ in September 2009.

Five questions were developed for the panel to address:

1. What are the incidence and prevalence of DCIS and its specific pathologic subtypes and how are incidence and prevalence influenced by mode of detection, population, characteristics, and other risk factors?
2. How does the use of MRI or SLNB impact important outcomes in patients diagnosed with DCIS?
3. How do local control and systemic outcomes vary in DCIS based on tumor and patient characteristics?
4. In patients with DCIS, what is the impact of surgery, radiation, and systemic treatment on outcomes?
5. What are the most critical research questions for the diagnosis and management of DCIS?

This monograph includes articles from experts representing a spectrum of disciplines involved in DCIS. The presentations supplemented the Evidence-Based Reports made available to the panel (composed of health professionals and public representatives to provide a balanced, objective, and informed assessment) before the conference to aid in the development of the Panel Statement (4,5). Articles from the Evidence-Based Practice Center speakers are presented at the beginning of the monograph, in sequence of their responses to the five questions, and in an abbreviated form. The expert speakers 1) provided updated results from important DCIS randomized clinical trials; 2) discussed the science and its advances and shortcomings from the perspectives of their respective disciplines; 3) equipped the audience with terminology of the field to facilitate audience participation in the discussions using a didactic approach; and 4) discussed current challenges and trends in day-to-day practice of DCIS diagnosis and management.

In 2010, an estimated 45 000 new cases of DCIS will be diagnosed in the United States. Despite the overall anticipated excellent clinical outcomes for these women, many critical research and practice questions remain unanswered for them. It is also evident, despite the excellent outcomes, that surprisingly little is known about the biology of DCIS to help inform health-care providers of those women who do not carry the highest risk for recurrence of invasive breast cancer. In particular, insufficient evidence is available to tailor treatment approaches that are different from that used for invasive breast cancer.

Paramount to assessing the value of the State-of-the-Science meeting to scientists, clinicians, patients, and the general public is the extent to which new and innovative scientific approaches are developed and supported to advance the science of DCIS. A collaborative effort among researchers and their institutions is imperative to validate existing tools for risk stratification of DCIS subtypes and to use new technologies for the development of new biomarkers of risk. The pathways involved in the disease progression from hyperplasia to DCIS should be studied for its contribution to all of the subtypes. Additional research areas with the potential of more immediate benefit to patient management are those related to the quality of life of women who experience DCIS compared to invasive recurrences and comparative effectiveness research of

current treatments. An example of a comparative effectiveness research topic related to DCIS is that of the use of unilateral and bilateral mastectomies. Information is also lacking on the frequency of assessing hormone receptor status in DCIS, awareness of guidelines regarding hormonal therapy in DCIS, or the extent that hormonal therapy is currently being used in clinical practice.

Collection of tissue specimens for biomarker and gene studies will require protocols for exchanges between academic institutions and the community to ensure quality acquisition and storage of specimens for research. The latter addresses an important gap because of the inconsistent collection of tissue from the completed DCIS randomized clinical trials.

Several areas beyond the charge given to the panel were identified and also warrant further consideration. These areas include 1) a woman's informed consent at the time of screening about DCIS outcomes; 2) how the term "carcinoma" of DCIS affects treatment decisions and quality of life; and 3) communications of known risks and benefits and decision aids for current treatment of DCIS. Postconference activities include an American Cancer Society/National Cancer Institute–sponsored workshop to address DCIS nomenclature and its communications between providers and patients. Increased and sustained interest in research—bench-to-patient and patient-to-bench—has the potential of improving the level of scientific evidence needed for the diagnosis and management of DCIS.

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