

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH State-of-the-Science Conference: Diagnosis and Management of Ductal Carcinoma In Situ (DCIS); Notice

Notice is hereby given of the National Institutes of Health (NIH) State-of-the-Science Conference: Diagnosis and Management of Ductal Carcinoma In Situ (DCIS) to be held September 22–24, 2009, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on September 22 and 23, and at 9 a.m. on September 24, and will be open to the public.

Ductal carcinoma in situ (DCIS) is a condition in which abnormal cells are found in the lining of a breast duct. As “*in situ*” means “in place,” this means the abnormal cells have not spread outside the duct to other tissues in the breast. Also referred to as intraductal carcinoma and stage zero breast cancer, DCIS is the most common noninvasive tumor of the breast.

DCIS is most often discovered during routine mammograms, presenting as very small specks of calcium known as microcalcifications. However, not all microcalcifications indicate the presence of DCIS, and the diagnosis must be confirmed by biopsy. Magnetic Resonance Imaging (MRI) has also been used more recently as a diagnostic tool, but questions remain about the impact of the test on patient outcomes. Since the implementation of screening mammography, the rate of new DCIS cases has increased dramatically.

DCIS currently accounts for approximately twenty percent of screening-detected breast cancer, but its true prevalence is challenging to measure because nearly all affected individuals are asymptomatic. By most reports, the risk factors associated with the development of DCIS are similar to those for invasive breast cancer: increased age, family history of breast cancer, previous biopsies, history of hormone replacement therapy, and older age at first childbirth. Tamoxifen, a hormonal drug, has demonstrated a reduction in the incidence of DCIS among high-risk women.

Although the natural course of the disease is not well understood, DCIS can become invasive cancer and spread to other tissues. It is also a marker of increased risk for developing cancer elsewhere in the same or opposite breast. However, not all DCIS will progress to invasive disease, and it is thought that DCIS can be present in

some individuals without causing problems over a long period of time. Recent research suggests that DCIS is a spectrum of disease and that certain tumor characteristics may be strong or weak risk factors for subsequent invasive breast cancer. Unfortunately, it is currently not clear which lesion types are more likely to become invasive, leading to difficult treatment decisions for patients and providers.

Because of this uncertainty, DCIS patients are typically treated promptly following diagnosis and have a generally good prognosis. Standard DCIS therapies include breast conservation, with or without radiation or mastectomy, depending on patient and tumor characteristics. Sentinel lymph node biopsy may also be recommended to high-risk patients since this is the area where cancer spread is often first detected. Hormonal therapy may also be used in an effort to prevent DCIS recurrence and to lower the risk of developing invasive breast cancer. However, these drugs’ potential side effects must be weighed carefully.

Since the natural course of DCIS is not well understood and treatment benefit may depend on specific tumor and patient characteristics, the treatment of DCIS remains controversial. To examine these important issues, the NIH National Cancer Institute and Office of Medical Applications of Research will convene a State-of-the-Science Conference from September 22–24, 2009. The questions to consider include:

- 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?
- How does the use of MRI or sentinel lymph node biopsy impact important outcomes in patients diagnosed with DCIS?
- How do local control and systemic outcomes vary in DCIS based on tumor and patient characteristics?
- In patients with DCIS, what is the impact of surgery, radiation, and systemic treatment on outcomes?
- What are the most critical research questions for the diagnosis and management of DCIS?

An impartial, independent panel will be charged with reviewing the available published literature in advance of the conference, including a systematic literature review commissioned through the Agency for Healthcare Research and Quality. The first day and a half of the conference will consist of presentations by expert researchers and practitioners and open public discussions. On

Thursday, September 24, the panel will present a statement of its collective assessment of the evidence to answer each of the questions above. The panel will also hold a press conference to address questions from the media. The draft statement will be published online later that day, and the final version will be released approximately six weeks later. The primary sponsors of this meeting are the NIH National Cancer Institute and the NIH Office of Medical Applications of Research.

Advance information about the conference and conference registration materials may be obtained from American Institutes for Research of Silver Spring, Maryland, by calling 888-644-2667 or by sending e-mail to consensus@mail.nih.gov. The American Institutes for Research’s mailing address is 10720 Columbia Pike, Silver Spring, MD 20901. Registration information is also available on the NIH Consensus Development Program Web site at <http://consensus.nih.gov>.

Please Note: The NIH has instituted security measures to ensure the safety of NIH employees, guests, and property. All visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the security measures at NIH, please visit the Web site at <http://www.nih.gov/about/visitorsecurity.htm>.

Dated: May 20, 2009.

Lawrence A. Tabak,

Acting Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recruitment of Sites for Assignment of Corps Personnel Obligated Under the National Health Service Corps Loan Repayment Program (ARRA and FY 2010)

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: General notice.

SUMMARY: Under the American Recovery and Reinvestment Act of 2009 (ARRA), additional funds are available to expand the National Health Service Corps (NHSC) through its programs to provide access to, and improve quality of, primary health care for millions of underserved Americans. The HRSA is

therefore announcing an approximate 16-month funding cycle for new NHSC Loan Repayment applications and awards. During this 16-month cycle, the NHSC Loan Repayment Program will accept applications for loan repayment awards until all funds are expended. The policies described in this notice will be effective for all NHSC loan repayment awards made using ARRA funding from June 2009, to September 30, 2010, and all NHSC loan repayment awards made using fiscal year (FY) 2010 funding (if funding is appropriated) from October 1, 2009, to September 30, 2010. Provisions regarding assignment of NHSC Scholarship Program participants for the upcoming program year will be announced through a subsequent Notice.

The listing of entities, and their Health Professional Shortage Area (HPSA) scores, that will receive priority for the assignment of NHSC Loan Repayers (Corps Personnel, Corps members) for this period is posted on the NHSC Web site at <http://nhscjobs.hrsa.gov/>. This list specifies which entities are eligible to receive assignment of Corps members who are participating in the NHSC Loan Repayment Program, and Corps members who have become Corps members other than pursuant to contractual obligations under the Loan Repayment Programs. Please note that not all vacancies associated with sites on this list will be for Corps members, but could be for individuals serving an obligation to the NHSC through the Private Practice Option.

Eligible HPSAs and Entities

To be eligible to receive assignment of Corps personnel, entities must: (1) Have a current HPSA designation by the Office of Shortage Designation, Bureau of Health Professions, HRSA; (2) not deny requested health care services, or discriminate in the provision of services to an individual because the individual is unable to pay for the services or because payment for the services would be made under Medicare, Medicaid, or the Children's Health Insurance Program; (3) enter into an agreement with the State agency that administers Medicaid and the Children's Health Insurance Program, accept assignment under Medicare, see all patients regardless of their ability to pay, and use and post a discounted fee plan; and (4) be determined by the Secretary to have (a) a need and demand for health manpower in the area; (b) appropriately and efficiently used Corps members assigned to the entity in the past; (c) general community support for the assignment of Corps members; (d) made

unsuccessful efforts to recruit; (e) a reasonable prospect for sound fiscal management by the entity with respect to Corps members assigned there; and (f) demonstrated a willingness to support and facilitate mentorship, professional development and training opportunities for Corps members. Priority in approving applications for assignment of Corps members goes to sites that (1) provide primary medical care, mental health, and/or oral health services to a primary medical care, mental health, or dental HPSA of greatest shortage, respectively; (2) are part of a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care; (3) have a documented record of sound fiscal management; and (4) will experience a negative impact on its capacity to provide primary health services if a Corps member is not assigned to the entity. In order for a site to be eligible for placement of NHSC personnel, it must be approved by the NHSC through the successful submission of a Multi-Year Recruitment and Retention (R&R) Assistance Application. The R&R Application approval is good for a period of 3 years from the date of approval.

Entities that receive assignment of Corps personnel must assure that (1) the position will permit the full scope of practice and that the clinician meets the credentialing requirements of the State and site; and (2) the Corps member assigned to the entity is engaged in full-time clinical practice at the approved service location for a minimum of 40 hours per week with at least 32 hours per week in the ambulatory care setting. Obstetricians/gynecologists, certified nurse midwives (CNMs), and family practitioners who practice obstetrics on a regular basis are required to engage in a minimum of 21 hours per week of outpatient clinical practice. The remaining hours, making up the minimum 40-hour per week total, include delivery and other clinical hospital-based duties. For behavioral and mental health providers, at least 32 hours of the minimum 40 hours per week must be spent providing direct clinical services. At least 21 hours of the 32 clinical hours per week must be spent providing direct patient counseling during normally scheduled office hours in an ambulatory outpatient care setting. For all Corps personnel, (1) time spent on-call does not count toward the 40 hours per week and (2) no more than 8 hours per week can be spent performing practice-related administrative activities. In addition,

sites receiving assignment of Corps personnel are expected to (1) report to the NHSC all absences, including those in excess of the authorized number of days (up to 35 work days or 280 hours per service year); (2) report to the NHSC any change in the status of an NHSC clinician at the site; (3) provide the time and leave records, schedules, and any related personnel documents for NHSC assignees (including documentation, if applicable, of the reason(s) for the termination of a NHSC clinician's employment at the site prior to his or her obligated service end date); and (4) submit a Uniform Data System (UDS) report. The UDS allows the site to assess the age, sex, race/ethnicity of, and provider encounter records for its user population. The UDS reports are site specific. Providers fulfilling NHSC commitments are assigned to a specific site or, in some cases, more than one site. The scope of activity to be reported in UDS includes all activity at the site(s) to which the Corps member is assigned.

Evaluation and Selection Process

In approving applications for the assignment of Corps members, the Secretary shall give priority to any such application that is made regarding the provision of primary health services to a HPSA with the greatest shortage. For assignments made under the NHSC Loan Repayment Program resulting from loan repayment awards made using ARRA funding from June 2009, through September 30, 2010, and loan repayment awards made using FY 2010 funding (if funding is appropriated) from October 1, 2009, to September 30, 2010, HPSAs of greatest shortage for determination of priority for assignment of Corps personnel will be defined as follows: HPSAs (appropriate to each discipline) with scores of 10 and above are authorized for priority assignment of Corps members who are participating in the Loan Repayment Program. HPSAs with scores below 10 will be eligible to receive assignment of Corps personnel participating in the Loan Repayment Program only after assignments are made of those Corps members matching to those HPSAs receiving priority for placement of Corps members through the Loan Repayment Program (*i.e.*, HPSAs scoring 10 or above). Placements made through the Loan Repayment Program in HPSAs with scores below 10 will be made by decreasing HPSA score, and only to the extent that funding remains available. All sites on the list are eligible sites for "volunteers"—*i.e.*, individuals wishing to serve in an underserved area but who are not contractually obligated under the NHSC Scholarship or Loan Repayment

Programs. A listing of HPSAs and their scores is posted at <http://hpsafind.hrsa.gov/>.

In order to implement the statutory directive to place NHSC clinicians in the highest need areas and to assure appropriate geographic distribution of NHSC resources, the number of new NHSC placements through the Loan Repayment Program allowed at any one site for the assignments/awards covered by this notice is limited to the following:

HPSA Score: 0–9

Primary Medical Care

No more than 10 allopathic (MD) or osteopathic (DO) physicians; and no more than a combined total of 10 nurse practitioners (NPs), physician assistants (PAs), or CNMs.

Dental

No more than 10 dentists and 10 dental hygienists.

Mental Health

No more than 10 psychiatrists (MD or DO); and no more than a combined total of 10 clinical or counseling psychologists, licensed clinical social workers, licensed professional counselors, marriage and family therapists, or psychiatric nurse specialists.

HPSA Score: 10–13

Primary Medical Care

No more than 12 allopathic (MD) or osteopathic (DO) physicians; and no more than a combined total of 12 NPs, PAs, or CNMs.

Dental

No more than 12 dentists and 12 dental hygienists.

Mental Health

No more than 12 psychiatrists (MD or DO); and no more than a combined total of 12 clinical or counseling psychologists, licensed clinical social workers, licensed professional counselors, marriage and family therapists, or psychiatric nurse specialists.

HPSA Score: 14–26

Primary Medical Care

No more than 15 allopathic (MD) or osteopathic (DO) physicians; and no more than a combined total of 15 NPs, PAs, or CNMs.

Dental

No more than 15 dentists and 15 dental hygienists.

Mental Health

No more than 15 psychiatrists (MD or DO); and no more than a combined total of 15 clinical or counseling psychologists, licensed clinical social workers, licensed professional counselors, marriage and family therapists, or psychiatric nurse specialists.

Application Requests, Dates, and Address

The list of HPSAs and entities that are eligible to receive priority for the placement of Corps personnel may be updated periodically. Entities that no longer meet eligibility criteria, including those sites whose NHSC 3-year approval has lapsed or whose HPSA designation is withdrawn, will be removed from the priority listing. New entities interested in being added to the high priority list must submit a Multi-Year Recruitment and Retention (R&R) Assistance Application to: National Health Service Corps, 5600 Fishers Lane, Room 8A–30, Rockville, MD 20857, fax 301–594–2721. These applications must be postmarked on or before the submission deadline date of March 26, 2010. Due to the availability of additional funds through ARRA, applications submitted by clinicians for loan repayment will be processed as they are received. Therefore, we strongly encourage all sites to have current NHSC-approved R&R applications and vacancies on file. Site applications submitted after this deadline date will be considered for placement on the priority placement list in the following application cycle.

Entities interested in receiving application materials may do so by calling the HRSA call center at 1–800–221–9393. They may also get information and download application materials from: <http://nhsc.hrsa.gov/applications/rraa.asp>.

Additional Information

Entities wishing to provide additional data and information in support of their inclusion on the proposed list of HPSAs and entities that would receive priority in assignment of Corps members, must do so in writing no later than June 29, 2009. This information should be submitted to: Mark Pincus, Director, Division of Site and Clinician Recruitment, Bureau of Clinician Recruitment and Service, 5600 Fishers Lane, Room 8A–55, Rockville, MD 20857. This information will be considered in preparing the final list of HPSAs and entities that are receiving priority for the assignment of Corps personnel.

Paperwork Reduction Act: The Multi-Year R&R Assistance Application has

been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB clearance number is 0915–0230 and expires September 30, 2011.

The program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

Dated: May 22, 2009.

Mary K. Wakefield,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Public Comment on Tribal Consultation Sessions

AGENCY: Office of Head Start (OHS), Administration for Children and Families, HHS.

ACTION: Notice of public comment on Tribal Consultation Sessions to be held on July 7, July 21, and July 23, 2009.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, Notice is hereby given of one-day Tribal Consultation Sessions to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal governments operating Head Start (including Early Head Start) programs. The purpose of the Consultation Sessions is to discuss ways to better meet the needs of Indian, including Alaska Native, children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, Section 640(l)(4)].

Date & Location:

The Consultation Sessions will be held as follows:

July 7, 2009—Denver, Colorado.

July 21, 2009—Kansas City, Missouri.

July 23, 2009—Mystic Lake, Minnesota.

FOR FURTHER INFORMATION CONTACT:

Nina McFadden, Regional Program Manager, American Indian/Alaska Native Program Branch, Office of Head Start, email nina.mcfadden@acf.hhs.gov or (202) 205–8569. Additional information and online registration are available at <http://www.hsnrc.org>.