compared with the open biopsy technique in the diagnosis of a breast abnormality?

III. What clinician and facility factors influence the harms of core-needle breast biopsy when compared with the open biopsy technique in the diagnosis of a breast abnormality?

Question 3

How do open biopsy and various core-needle techniques differ in terms of patient preference, availability, costs, availability of qualified pathologist interpretations, and other factors that may influence choice of a particular technique?

Study Eligibility Criteria (PICOTS: Population, Intervention, Comparators, Outcomes, Timing, and Setting)

Population

The population for all KQs is women who have been referred for biopsy for the diagnosis of primary breast cancer (including multifocal and bilateral disease) following self-examination, physical examination, or screening mammography. Studies carried out in women at high baseline risk of breast cancer (e.g., due to BRCA mutations) will therefore be included; however studies carried out in women who have been previously diagnosed with breast cancer and are being examined for recurrence will be excluded [a].

Interventions

For all KQs, the intervention is a core-needle biopsy done to evaluate whether a breast lesion is malignant. Other uses of biopsy techniques (e.g., use of biopsy to examine the sentinel lymph nodes in women with an established diagnosis of breast cancer) are excluded.

Comparators (Reference Standard and Comparator Index Tests)

For test performance outcomes (KQ 1) the reference standard is either open surgical biopsy or follow-up by clinical examination and/or mammography for at least 6 months. The diagnostic performance of each core biopsy technique (each index test) will be quantified versus the reference standard [b]. The comparative diagnostic performance of alternative core-needle biopsy techniques is also of interest [c].

For harms and patient-relevant outcomes (outcomes other than diagnostic performance; KQs 2 and 3) the comparators are:

I. Open surgical biopsy
II. Follow-up by clinical examination and/or mammography for at least 6 months
III. Alternative core-needle biopsy methods (e.g., stereotactic mammography vs. ultrasound to locate the breast lesion; use vs. nonuse of vacuum assistance to extract tissue samples)

Outcomes

I. For KQ 1, test performance outcomes, as assessed by the following measures:

A. Sensitivity (proportion of cancerous tumors detected by the reference standard that are also detected by core-needle biopsy)
B. False-negative rate (proportion of negative findings according to core-needle biopsy that are classified as positive by the reference standard)
C. The underestimation rate for atypical ductal hyperplasia (ADH; proportion of core needle biopsy findings of ADH that are found to be malignant according to the reference standard)
D. The underestimation rate for DCIS (proportion of core-needle biopsy findings of DCIS that are found to be invasive according to the reference standard)

II. For KQ 2:

A. Rate of inconclusive biopsy findings (e.g., inadequate sampling of the lesion)
B. Repeat biopsy rate
C. Subsequent false-positive and false-negative rates on mammography
D. Dissemination (seeding) of cancerous cells along the needle track
E. Patient-centered outcomes (including bruising, bleeding or hematomas, pain, use of pain medication, infections, fainting or near fainting, and time to recover)

III. For KQ 3:

A. Patient-relevant outcomes
  1. Patient preferences for specific procedures
  2. Cosmetic results
  3. Quality of life
  4. Anxiety and other psychological outcomes
  5. Time to complete tumor removal (for women with cancer)
  6. Recurrence rate (for women with cancer, including local, regional, and distant recurrence)
  7. Cancer-free survival and overall survival
B. Resource use and logistics
  1. Costs
  2. Resource utilization other than cost (number of additional surgical procedures [e.g., re-excisions, procedural time])
  3. Subsequent surgical procedures
  4. Wait time for test results
C. Availability of technology and relevant expertise
  1. Physician experience
  2. Availability of equipment
  3. Availability of (qualified) pathologists to evaluate biopsy samples

Timing

Duration of clinical and/or mammographic follow-up must be at least 6 months in studies where open surgical biopsy was not performed.

Setting

Studies in all geographic locations and care settings will be evaluated, including general hospitals, academic medical centers, and ambulatory surgical centers, among others.

Explanation to References in Population and Interventions Sections Above

[a] The original review excluded studies carried out in women at high risk of breast cancer; however, magnetic resonance imaging (MRI)-guided biopsy, which has been identified as a topic of interest for the updated review, is used mainly in this subset of patients. For this reason, following extensive discussions with the TEP (Technical Expert Panel), we decided to broaden the scope of the review to cover women at high risk for cancer. In effect, this will be a de novo review with respect to this population subset.

[b] Most assessments of diagnostic performance quantify the sensitivity and the specificity of each index test—here each core-needle biopsy technique. Sensitivity and specificity are probabilities conditional on true disease status and are noncomparative in nature. The reference standard is used in their definition and is not a ''comparator test.''

[c] That is, differences or ratios of sensitivities and of specificities between alternative core-needle biopsy techniques.

Dated: October 31, 2013.

Richard Kronick,

AHRQ Director.

[FR Doc. 2013–26617 Filed 11–6–13; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–14–0026]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic

summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Report of Verified Case of Tuberculosis (RVCT), (OMB No. 0920–0026 exp. 5/31/2014)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the United States, an estimated 10 to 15 million people are infected with *Mycobacterium tuberculosis* and about 10% of these persons will develop tuberculosis (TB) disease at some point in their lives. The purpose of this project is to continue ongoing national tuberculosis surveillance using the standardized Report of Verified Case of Tuberculosis (RVCT). Data collected using the RVCT help state and federal infectious disease officials to assess changes in the diagnosis and treatment of TB, monitor trends in TB epidemiology and outbreaks, and develop strategies to meet the national goal of TB elimination.

CDC currently conducts and maintains the national TB surveillance system (NTSS) pursuant to the provisions of Section 301(a) of the Public Service Act [42 U.S.C. 241] and Section 306 of the Public Service Act [42 U.S.C. 241(a)]. Data are collected by 60 reporting areas (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean). The last major revision of the RVCT data collection instrument was approved in 2009, in consultation with CDC's Division of Tuberculosis Elimination (DTBE), state and local health departments, and partner organizations including the National TB Controllers Association, the Council for State and Territorial Epidemiologists, and the Advisory Committee for the Elimination of Tuberculosis. No revisions to the RVCT are proposed in this data collection extension request.

CDC publishes an annual report using RVCT data to summarize national TB statistics and also periodically conducts special analyses for publication to further describe and interpret national TB data. These data assist in public health planning, evaluation, and resource allocation. Reporting areas also review and analyze their RVCT data to monitor local TB trends, evaluate program success, and focus resources to eliminate TB.

No other Federal agency collects this type of national TB data. In addition to providing technical assistance on the use of RVCT, CDC provides technical support for reporting software. In this request, CDC is requesting approval for approximately 5,810 burden hours. There is no cost to respondents except for their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Types of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Local, state, and territorial health departments	RVCT Form	60	166	35/60	5,810
Total					5,810

LeRoy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–26693 Filed 11–6–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–14–14BA]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Annual Survey of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Grantees—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

To improve access to cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101–354) which directed CDC to create