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Before

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Health Subcommittee  
United States House of Representatives  
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Good morning, Mr. Chairman and distinguished members of the Committee. I am Dr. Ned Calonge, Chair of the United States Preventive Medicine Task Force. This is Dr. Diana Petitti, Vice-Chair of the Task Force. We speak today on behalf of the members of the United States Preventive Services Task Force in thanking you and members of the Subcommittee for the opportunity to explain to the members of this Committee who the Task Force is, to describe how the Task Force goes about doing its work, and to explain the relationship of the Task Force to the Agency for Healthcare Research and Quality and to other federal government entities.

Two and a half weeks ago, the Task Force published, in the *Annals of Internal Medicine*, a set of recommendations about breast cancer preventive services that have drawn a remarkable amount of media attention. The members of the Task Force particularly welcome the opportunity to today explain to members of the Committee the history of how the breast cancer recommendations came about and the timeline for their release, to describe the kinds of evidence that were used to make the recommendations, and to clarify what the recommendations said and what actions the Task Force intended for clinicians and women to take based on recommendations.

The men and women who serve on the Task Force are physicians and academics and scientists who have dedicated their lives to studying medical evidence. We are the husbands or daughters, sons or siblings of people who have suffered with breast cancer. Many of us have lost patients and loved ones to this disease. I myself have lost a mother-in-law, and my sister is in the middle of treatment. We are well familiar with the ruthless horror of cancer, and the role that detection and treatment plays. We certainly know that mammography saves lives.

However, our job as the Task Force is to rigorously review scientific evidence. Politics play no part in our processes. Cost and cost-effectiveness were never considered in our discussions. We voted on these breast cancer screening recommendations in June of 2008 – long before the last presidential election and any serious discussion of national health reform. The timing of the release of the findings last month was determined by the publication schedule of the medical research journal, the *Annals of Internal Medicine*, which peer-reviewed the research.

#### Overview of the USPSTF

The mission of the Task Force is to evaluate the benefits of individual preventive services based on age, gender, and risk factors for disease; to make evidence-based recommendations to primary care clinicians about which preventive services should be incorporated routinely into primary



medical care and for which populations; and identify a research agenda for clinical preventive care. Recommendations issued by the Task Force are intended for use by clinicians in the primary care setting. The Task Force recommendation statements present health care providers with information about the evidence behind each recommendation, allowing clinicians to make informed decisions about implementation into their own practices.

### History of the USPSTF

The Task Force was established in 1984 by the Public Health Service, based on similar work by the Royal Canadian Task Force on the Periodic Health Exam. Then, as now, the members met as volunteers. The Task Force conducted evidence reviews and decided on recommendations to be made to primary care clinicians based on these reviews. These pioneering efforts resulted in the publication in 1989 of the first Guide to Clinical Preventive Services, which was broadly announced with the tag line, "Talk more, test less", and was widely distributed to primary care physicians. A second Task Force was assembled and, using similarly methods, released the second edition of the Guide in 1996. After this, the third Task Force, with a rotating membership and a new approach of continuous reviews and recommendation releases was created, and the Task Force was codified by Congressional mandate as an independent body with the mission of reviewing the scientific evidence for clinical preventive services and developing evidence-based recommendations for the health care community.

Since 2002, the Task Force has issued its recommendations via publication in peer-reviewed journals and has a relationship with the *Annals of Internal Medicine* that permits the editors of the *Annals of Internal Medicine* to publish its recommendations and report about the evidence that support the recommendations.

### Members of the USPSTF

Since 2001 the Task Force has been a standing Task Force of 16 members including a Chair and Vice-Chair. Members are invited to serve for a 4-year term, with a possible 1-2 year extension. The 16 members represent an array of experts in primary care and preventive health-related disciplines including internal medicine, family medicine, behavioral medicine, pediatrics, obstetrics/gynecology, preventive medicine and nursing as well as experts in medical research methods. As the recommendations are intended for use by primary care clinicians, who are the health care providers who actually implement the broad array of screening and other preventive services recommended by the Task Force, the subspecialists who consult on or care for those identified with specific diseases are not recruited by the Task Force but instead are asked to review and comment on the Task Force's work at critical points in our processes.

The Chair of the Task Force is selected by the out-going Chair from among current members of the Task Force. The criteria for selection as Chair are experience in running meetings and a willingness to commit a substantial amount of time to representing the Task Force in public forums and to overseeing the work done by the Task Force. The Vice-Chair is selected by the Chair from among current members of the Task Force after consulting with other members of the Task Force with medical officers at AHRQ.

New members of the Task Force are selected each year to replace those who have completed their appointment terms. Every year, a notice is placed in the Federal Register soliciting nominations for new members. This notice is circulated to all 24 Task Force Partner organizations (Partner organizations are described below) and distributed via AHRQ's prevention listserv, received by more than 22,000 individuals and organizations. Anyone can submit a nomination; self nominations also are accepted. Individuals nominated but not appointed in previous years, as well as those newly nominated, are considered in the annual selection process.



Nominated individuals are selected for the Task Force on the basis of specific qualifications and the current needs of the Task Force for particular areas of expertise. Strongest consideration is given to individuals who are recognized nationally or internationally for scientific leadership within their fields of expertise. Applicants must have no substantial conflicts of interest that would impair the scientific integrity of the work of the Task Force, including financial, intellectual, or other conflicts. The AHRQ Director appoints new members upon the recommendations developed by the Task Force Chairs.

In order to qualify for nomination to the Task Force, an applicant must demonstrate the following:

- Knowledge and experience in the critical evaluation of research published in peer reviewed literature and in the methods of evidence review.
- Understanding and experience in the application of synthesized evidence to clinical decision-making and/or policy.
- Expertise in disease prevention and health promotion.
- Ability to work collaboratively with peers.
- Clinical expertise in the primary health care of children and/or adults, and/or expertise in counseling and behavioral interventions for primary care patients. Members are also selected based on other relevant expertise such as medical decision-making, clinical epidemiology, behavioral medicine, and health economics.

### Topics

#### *Description of Portfolio of Topics*

The Task Force develops recommendations on a broad array of clinical preventive services, which the Task Force calls its “portfolio” of topics. As of November 24, 2009, there were 105 topics in the Task Force active portfolio of topics. These 105 topics are listed on the USPSTF website, <http://www.ahrq.gov/CLINIC/uspstfix.htm>.

#### *Selection of New Topics*

New topic nominations are solicited from the field every other year via a notice in the Federal Register. Topic nominations are also provided by Task Force partners who are drawn from the fields of primary care, public health, health promotion, policy, and quality improvement. Task Force members themselves may also submit topics for consideration.

All nominations for new topics are reviewed by the Topic Prioritization Subcommittee of the Task Force. The members of this Subcommittee evaluate each topic and prioritize them for inclusion in the Task Force portfolio based on the following criteria: public health importance which includes the burden of suffering, the potential of the preventive service to reduce the burden and the potential for the Task Force to impact clinical care. The latter considers such factors as whether there is clinical controversy or uncertainty, whether current practice does not reflect current evidence, or whether there is inappropriate timing in delivery of services. The Task Force prioritizes topics for which there is a known gap in performance and there is the potential to significantly improve clinical practice. The recommendations of the Topic Prioritization Subcommittee for addition of new topics to the Task Force portfolio are reviewed and voted on by the entire Task Force.

#### *Topic Updates*

The Task Force makes every effort to update all topics in the portfolio at regular intervals,



striving to keep evidence reviews and recommendations less than five years old. The Task Force also may retire or inactivate some recommendations made in previous years rather than update the evidence review and issue new recommendations. The Task Force inactivates topics that are: 1) No longer relevant to clinical practice due to changes in technology, new understanding of disease etiology/natural history, or evolving natural history of the disease; 2) Not relevant to primary care setting, because the service is not implemented in a primary care setting or not referable by a primary care provider; 3) has low public health burden; 4) is otherwise deemed out of scope for the Task Force.

#### How the USPSTF Does Its Work

The Task Force does its work in face-to-face meetings, by conference call and by email. The Task Force has three standing Subcommittees, the Methods Subcommittee, the Topic Prioritization Subcommittee, and the Implementation Subcommittee, which meet via conference calls, most often held monthly.

Ad hoc committees, called Work Groups, are designated to address special prevention topics when necessary. A Chair for each ad hoc Work Group is designated by the Chair in consultation with the Vice-Chair. On the November 29, 2009, there are two designated ad hoc Work Groups, the Child Health Work Group and the Geriatrics Work Group. Ad hoc Work Groups meet by conference call.

In-person meetings of the entire Task Force membership are held three times a year for one and a half days in March, July and November. The meetings occur in meeting rooms at the Agency for Healthcare Research and Quality. Scientists from Evidence-based Practice Centers (EPCs) working on topics considered at the meeting attend. The meetings are also attended by AHRQ staff who work as medical officers with the Task Force and representatives of Partner organizations. Preventive medicine residents taking rotations at AHRQ are permitted to attend with the permission of the Chair. Other special guests from partner organizations are permitted to attend with permission of the Chair.

Partner organizations include a list of organizations that have a interest in the work of the Task Force in terms of the recommendations produced. These organizations send a representative to attend and participate in meetings, and the organizations are also consulted for review and comment on the work products of the Task Force at key points along the recommendation creation process. Primary care partners include the American Academies of Family Physicians, Nurse Practitioners, Pediatrics, Physician Assistants; the American Colleges of Physicians, Obstetricians and Gynecologists, and Preventive Medicine, the American Osteopathic Association and the National Association of Pediatric Nurse Practitioners. Policy, population and quality improvement partners include America's Health Insurance Plans, the National Committee for Quality Assurance, and new to the Partner group as of our July 2009 meeting, AARP. Federal partners include the Centers for Disease Control and Prevention, the Center for Medicaid and Medicare Services, the US Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Veteran's Health Administration, the Department of Defense/Military Health System, the Office of Disease Prevention and Health Promotion, and the Office of the Surgeon General.

#### Conflict of Interest Policies and Procedures

Policies and procedures designed to assure that recommendations are free of financial and other conflicts of interest are described in detail in the Task Force Procedure Manual, which is publicly available. Prior to each meeting, Task Force members are required to disclose in writing information about conflicts and potential conflicts—including financial, intellectual, and other



conflicts--that may interfere with their abilities to discuss and/or vote objectively on a specific topic. A committee comprised of AHRQ staff and the Task Force Chair and Vice Chair review each member's disclosures and issues a recommendation on the member's eligibility to participate on a specific topic(s) in one of the following categories:

- A. No action.  
No disclosure or recusal necessary.
- B. Information disclosure only.  
Member may participate as topic lead, and may discuss and vote on the topic.
- C. Recusal from participation as lead of topic workgroup; information disclosure.  
Member may discuss and vote on the topic.
- D. Recusal from all participation; information disclosure.  
Member may not participate as topic lead, and may not discuss or vote on the topic.  
Member will leave the meeting room for all discussion and voting Publicly released recommendations will denote the member's recusal from participation and voting on this topic.

#### Topic to Recommendation and Release of Recommendation

A topic selected as a new topic or scheduled for update moves from this point to recommendation and recommendation release according to the following steps.

A topic Work Group comprising three Task Force members is designated. One member of the Work Group is designated as the "lead." It is the responsibility of the lead to attend every conference call for the topic, chair calls about the topic and to be the primary liaison with other members of the Work Group, with the assigned AHRQ medical officer and the Evidence-based Practice Center.

For each topic, key questions are developed and a systematic review of the evidence for each key question is conducted. These systematic reviews are done by scientists in the Evidence-based Practice Centers who work under contract to AHRQ.

After a topic has been selected, the members of the Work Group and the scientists at the Evidence-based Practice Center collaboratively develop the analytic framework and craft key questions pertinent to evaluating the topic. The analytic framework and key questions are sent out to the Task Force Partners organizations as well as to identified subspecialty experts in the disease topic and other stakeholders, such as subspecialty professional societies, for review and comment. This peer review is used in refining the analytic framework and key questions as deemed appropriate in consultation with the Work Group and the Evidence-based Practice Center scientists.

The Evidence-based Practice Center then conducts a systematic review of evidence for each key question using methods described in detail in the Task Force Procedure Manual. A draft systematic evidence report (SER) is prepared by the Evidence-based Practice Center, discussed with the Task Force Work Group and edited with their direction, then again, this work product is distributed to the Task Force Partner organizations and other identified expert stakeholders, including subspecialists, for review and comment. This peer review comment is summarized and addressed and a final draft of the Evidence Review is completed.

At this point, the members of the Work Group and the Evidence-based Practice Center review the draft Evidence Review. Members of the Work Group then work with an AHRQ medical officer



to prepare a draft recommendation statement reflecting their synthesis of the evidence and using the explicit Task Force methods and grades and evidence. The topic is scheduled for an in-person Task Force meeting for discussion of the evidence and the draft recommendation statement and a vote on the recommendation.

The Evidence Review is distributed to all members of the Task Force to be reviewed prior to the meeting. At the meeting at when the vote is scheduled, the Evidence-based Practice Center summarizes the evidence related to each key question. A Task Force member of the Work Group presents the draft recommendation statement to the Task Force along with the rationale for the recommendation.

After a full discussion of the evidence and the proposed recommendation, which can include input from both federal and non-federal partners, the Task Force members vote on the proposed recommendation or, if deemed appropriate after the discussion, an alternative recommendation. A quorum is required for a vote. A vote is passed if a majority of the total membership, or nine members, vote yes. In practice, however, when votes appear to be very close, an effort is made to craft recommendation language that is acceptable to all of the members and many, though not all, recommendations eventually pass based on a unanimous vote.

After drafting the specific recommendation statement, the statement is once again sent out for Partner and expert stakeholder review and comment, these comments are considered and used to craft the final statement, and the recommendation statement and Evidence Review are submitted for publication. Thus, there are three key opportunities in the process for experts in the disease area to review and provide input for consideration by the Task Force in making a recommendation.

#### Methods for Identifying and Assessing Evidence and Making Recommendations

The Task Force makes its recommendations based on “rules of evidence” that are described in a 99 page Procedure Manual publicly available at the USPSTF website. Additionally, the Task Force has published descriptions of the most salient processes and methods in the *Annals of Internal Medicine*. Publications in the *Annals of Internal Medicine* that describe the processes and methods that the USPSTF in effect now (November 29, 2009) are available on the USPSTF website. These methods were in use when the TF made its recommendations about breast cancer preventive services.

Task Force recommendations are based on consideration of the health benefits and the health harms of providing the preventive service and on the scientific certainty about whether the preventive service “works.” Cost and cost-effectiveness of specific prevention services are not addressed by the Task Force in its deliberations. The Task Force only considers scientific evidence of health benefits and health harms. The Task Force has specifically discussed whether cost should influence a recommendation and has repeatedly voted to leave costs out of all deliberations of whether to provide or not provide a preventive service.

The evidence from the Evidence Review is graded for each key question and for the body of evidence as a whole as “convincing”, “adequate” or “insufficient”. Using at least adequate evidence, the Task Force then considers only two factors in assigning a letter grade along with its template recommendation language. One factor is the magnitude of net health benefit, or the balance between benefits and harms as indicated by the SER, and this is graded as “substantial”, “moderate” or “small”. The other is the certainty of the net benefit, or the level of confidence that Task Force has that the recommendation will not change based on future research, and this is graded as “high”, “moderate” or “low”. “A” recommendations require a high certainty of



substantial net benefit and “B” recommendations require at least a moderate certainty of at least a moderate net benefit. Primary care clinicians are recommended to implement the provision of A and B services for most of their appropriate average risk patients as well as for high risk patients where the Task Force has made an “A” or “B” recommendation. A “D” recommendation requires at least a moderate certainty that the service provides no benefit, or leads to harms in excess of benefits, and primary care clinicians are recommended to not provide these services. Low certainty always leads to a conclusion of insufficient evidence to make a recommendation, which is indicated by making an “I” statement, an indication that more research is needed to fill in the gaps in evidence in order to support and evidence-based recommendation. Finally, a “C” recommendation is given when there is at least moderate certainty of a small net benefit.

#### The C Recommendation/Small Net Benefit

In the 1980s, the USPSTF assigned a C grade in situations where the Task Force concluded that there was "insufficient evidence to make a recommendation." In these situations, the first 1989 edition of the Guide to Clinical Preventive Services qualified the C grade recommendations with language that implied certain actions even in the absence of evidence ("there is insufficient evidence to recommend for or against x, but recommendations for/against the service can be made on other grounds" or that "a prudent person" might undertake to provide the service even in the absence of evidence.

In the 1990s, this practice came under criticism by those who sought greater purity and consistency and who felt that the "other grounds" and "clinical prudence" were not evidence-based arguments. The Task Force created a neutral C recommendation, stating only that the risks and benefits were closely matched and therefore, there was not a recommendation for or against providing the service. It also created the new I or insufficient evidence category, to distinguish between a true lack of evidence (I) and the existence of evidence that net benefit was small (C).

In the period from the late 1990's to 2006-2007, the Task Force came under increasing criticism for failing to give practical guidance about what to do when net benefit was small. Clinicians commonly complained (and reported in focus groups) that the C recommendation gave insufficient guidance for use in the exam room. Clinicians stated that people wanted to know what to do and found the C grade recommendations unhelpful, and most often chose to not offer the service at all. Based on this input, the Task Force concluded that in situations where the net benefit of the preventive service was small (that is a C grade recommendation), the patient should be informed about the potential benefits, harms, and on balance a small overall benefit and then make his or her own informed choice about being tested. In essence, in recommending to the primary care clinician that testing should not be "routine", the Task Force was promoting this informed patient decision-making. Clinicians could be comfortable in recommending the A and B recommendations without much thought, but when faced with a C recommendation, they should talk with their patients and support an informed decision. The Task Force elected to adopt language to associate with a C grade recommendation---"the Task Force recommends against ROUTINE"—that, while intended for consideration for primary care clinicians, has played out in unintended ways in the context of its breast cancer recommendation as interpreted by the public.

#### Relationship of USPSTF to AHRQ

Congress (through Public Law Section 915) mandates that the Agency for Healthcare Research and Quality convene the Task Force to conduct scientific evidence reviews and make evidence-based recommendations for primary care. The role of AHRQ in the process is to support the Task Force in specific activities:



1. AHRQ provides for the face-to-face meetings and conference calls for Task Force members.
2. AHRQ manages the contracts for the Evidence-based Practice Centers to do the Systematic Evidence Reviews under Task Force direction.
3. AHRQ Medical officers provide administrative support to the Task Force and its standing, ad hoc and topic workgroups, and work with Task Force members on evidence reviews for the re-affirmation of topics where the Task Force believes the recommendation is unlikely to change. While present for Task Force meetings and discussions, no medical officer has a vote nor otherwise influences the decisions of the Task Force. Similarly, the Director of AHRQ has no role in or influence on the recommendations of the Task Force, and unlike the medical officers, does not attend during Task Force deliberations.

## **Breast Cancer Preventive Services**

### History of Task Force Recommendations on Screening Mammography

The Task Force first addressed screening mammography as a topic in 1989. At that time, the Task Force recommended screening women age 50-75 every 1-2 years based on randomized trial evidence that screening reduced mortality due to breast cancer in women first screened at this age. With regard to screening younger women, the Task Force stated that “it may be prudent to begin mammography at an earlier age for women at high risk of breast cancer.”

In its 1996 Guide, the Task Force recommendation was in favor of screening women 50-69 every 1-2 years. Mammography screening for women age 40-49 was given a C grade. At that time, a C grade recommendation meant insufficient evidence to make a recommendation for or against screening and was linked with the following statement that the Task Force stated that it “recognized that there may be other grounds on which to base a recommendation for or against an intervention when scientific evidence is unavailable.”

In 2002, the Task Force recommended screening women 40-69 every 1-2 years stating that that the benefits were smaller and took longer to emerge for women who were first screened in the 40’s.

### Recommendation in 2009

On November 16, 2009, the Task Force issued its updated recommendations for breast cancer preventive services in the form of a publication in the *Annals of Internal Medicine*. Based on its evidence review and using its defined “rules of evidence” the Task Force recommendation about screening women age 50-74 was given a “B” grade. The recommendation about screening women 40-49 was given a “C” grade.

The language used to link these grades with advice to clinicians that was used by the Task Force was its standard language. This language has been described in the Task Force Methods manual and in publications.

The Task Force acknowledges that the standard language used to describe its recommendations about breast cancer screening for women age 40-49 did not say what the Task Force meant to say. The Task Force communication of the mammography screening recommendation for women 40-49 was poor. The Task Force makes a commitment to making changes in the way that it communicates its conclusion that will assure that this kind of miscommunication does not occur in the future.

The Task Force appreciates the opportunity to clarify that it recommends the following:



“Women age 50-74 should have mammography every other year. The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.”

The we said is that screening starting at age 40 should not be automatic. Nor should it be denied.

What we are saying is that the decision to have a mammogram for women in their 40s should be based on a discussion between a women her doctor.

Many doctors and many women, perhaps even most women, will decide to have mammography screening starting at age 40. The Task Force supports those decisions.

Timing for Undertaking the Update of Breast Cancer and Timeline

The Task Force issued recommendations about breast cancer preventive services in 2002. In late 2006, discussion of a plan for updating the 2002 recommendation in 2007 with the hope that the update might be issued within 1 year of the 5 year target for updating topics. Because the Task Force undertook updates of a large number of recommendation updates from 2002 at the same time, it was recognized that the 5-year timeline might not be able to be addressed. The alternative--reaffirming the recommendation without conducting an update of the evidence—was not considered by the Task Force because its own rules of evidence require an evidence update.

Process for Breast Cancer Recommendation

The Task Force process for undertaking to make a recommendation is described in detail in the 99-page Methods Manual that the Task Force makes available at its website. The steps have been described in general terms earlier in this testimony. The breast cancer recommendation topic was initiated as other topics and the steps taken progressed as for other topics up to the November 17, 2007 Task Force meeting. When the breast cancer recommendation statements came up for a vote at the November 17, 2007 meeting of the Task Force, unusually, the members of the Task Force could not come to agreement about what to recommend. The following table shows the timeline of progress of the breast cancer recommendation update to the point that the Task Force was unable to agree on what to recommend.

Task/Activity	Date
Breast cancer topic due for reconsideration/new topic	Late 2006- January, 2007
3 member Work Group comprising Task Force members designated by Chair	Late 2006- January, 2007
Evidence Based Practice Center (EPC) selected to conduct systematic review and contract negotiated	Late 2006-January, 2007
Work Group holds conference call with EPC scientists to discuss analytic framework and key questions	January, 2007
Draft of analytic framework and key questions prepared by EPC scientists	February, 2007
Work Group and EPC scientists hold conference call to finalize analytic framework and key questions	February, 2007
EPC scientists conduct evidence review and prepare draft of evidence report	February-October, 2007
EPC systematic evidence review is sent to Partners for peer review	Early October, 2007



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EPC evidence review distributed to Work Group	October, 2007
Work Group and EPC scientists hold conference call at which EPC summarizes evidence for each key question	October, 2007
Work Group drafts recommendation statement	October, 2007
Work Group holds conference call(s) to review and finalize draft recommendation statement	October, 2007
Evidence report (minus full Outcomes Table) distributed to full Task Force 2 weeks prior to meeting	October, 2007
Meeting to vote on RS <ul style="list-style-type: none"><li>• Full Outcomes Table distributed to Work Group and other Task Force members at start of meeting</li><li>• EPC presents summary of evidence report</li><li>• Draft recommendation presented by Work Group member</li><li>• Task Force members discuss recommendation statement</li><li>• Task Force member vote on recommendations but are unable to obtain a majority vote for any presented or modified set of recommendations</li><li>• Task Force members request EPC and Work Group to obtain more evidence on age-specific benefits and harms</li></ul>	November, 2007
TOPIC SENT BACK TO WORK GROUP	



The members of Task Force were not able to come to agreement on a breast cancer screening recommendation based on the initial evidence report because of disagreement about what to say about the balance of benefits and harms for starting to screen in the 40's compared with the 50's. Thus, the discussion by the members of the Task Force centered on the very issues that have moved this topic to the spotlight in the recent weeks---what to say about a starting age or screening. The Task Force was also unable to agree on what to recommend about screening mammography for women age 75 or more years. The issue of what to recommend about screening for women age 75 or more years was a major issue for the Task Force as a focus of its current work has been on providing better evidence-based advice on preventive services for older adults.

Additionally, since 2002, the Task Force has been attempting to provide clinicians with evidence-based advice on starting and stopping age and on screening interval for all of the topics in its portfolio. The need for more specific advice on stopping and starting age and on service interval is a recurring request from primary care practitioners.

It is in this context that the Task Force sought information that would permit a better weighing of benefits and harms.

To accomplish this aim, the Task Force asked the EPC scientists to obtain information on the age-specific harms and potential harms of mammography. The Task Force commissioned a decision modeling study to evaluate the trade-offs of various starting and stopping ages and screening intervals as information to inform its recommendations on screening mammography.

The Task Force considered this evidence at its July 14-15, 2009 meeting. The Task Force decided to make six separate recommendations about breast cancer preventive services—three related to film mammography screening (screening in women age 50-75, age 40-49, and 75+) and one about teaching breast self-examination, one about digital and MRI mammography and MRI for screening, and one about clinical breast examination.

#### Evidence Considered in Making Final Recommendations

In making its final recommendations, the Task Force considered evidence identified in a systematic review of the evidence for six key questions done by the Evidence-based Practice Center that had done a review of the breast cancer topic for the Task Force at the time of its 2002 update; the results of an analysis of data from the Breast Cancer Screening Consortium, and the results of a modeling study commissioned by the Task Force and conducted by the Cancer Intervention and Surveillance Modeling Network (CISNET).

The systematic evidence review addressed six key questions related to breast cancer preventive services. It identified evidence about the effectiveness of mammography based on published reports of randomized, controlled screening trials with specifically updated information from new and more recent mammography trials among women aged 40 to 49 and 70 years and older. It identified evidence on the effectiveness of teaching breast self-examination, the comparative effectiveness of digital and magnetic resonance imaging compared with film mammography, and evidence about the effectiveness of clinical breast examination, based on updated information from randomized trials, comparative studies, and descriptive studies. The systematic evidence review also identified data on the harms and potential harms of breast cancer screening, including false-positive test results, overdiagnosis and treatments for cancers that would never have progressed and low level radiation. Evidence was gathered from multiple sources, including systematic reviews, meta-analyses, and recently published literature.



To assess the follow-up testing and other outcomes of mammography screening, the Evidence Based Practice Center scientists were also asked by the Task Force to include data from an analysis of the Breast Cancer Surveillance Consortium (BCSC) from 2000 to 2005. Finally, the Task Force asked the Breast Cancer Modeling Group of the Cancer Intervention and Surveillance Modeling Network (CISNET) to provide data from comparative decision models that evaluated the trade-offs of various screening strategies with regard to starting and stopping ages and intervals for screening mammography.

The evidence report prepared by Evidence Based Practice Center scientists and considered by the Task Force included 45 pages of text; with references, tables, figures and appendices, it was 120 pages. This complete evidence reports is publicly available at the Task Force website. The report from the CISNET modeling group was 44 pages long and it is also publicly available.

#### Benefits of Screening Mammography

The Task Force concluded from the evidence that screening mammography for women 40-74 has a benefit in reducing death due to breast cancer. The Task Force focused on reduction in death due to breast cancer because this is the benefit of breast cancer screening that has been the focus of randomized trials. The Task Force recognizes that there may be other benefits of screening, such as earlier diagnosis that permits less invasive and toxic therapies, for which evidence is lacking.

#### Harms of Screening Mammography

Preventive services are provided to asymptomatic individuals for the sole purpose of preventing or delaying morbidity, preventing or delaying functional decline, and/or postponing death by decreasing the chances of death due a specific cause. The promise of service delivery for prevention is net benefit. Net benefit is the benefit of the service in achieving its aim—to prevent or delay morbidity or functional decline or to postpone death—minus its harms.

The benefits of screening mammography have been easy to communicate. These benefits are the identification by mammography of something that turns out to be cancer, the treatment of that cancer, and the effect of the treatment of that cancer in prolonging life by preventing death due to breast cancer.

The harms and potential harms of mammography screening have been difficult to communicate.

The easily understandable and commonly used definition of harm is a physical injury that is direct and immediate. Some women report a small amount of pain or discomfort when undergoing a screening mammogram. Pain and discomfort are easily understood as harms of screening mammography based on the commonly used definition of harm. These harms are very, very small.

The Task Force considers as harms not just the physical harms of the screening test and it construes harms more broadly than physical harms. For mammography screening, false positive tests are viewed as a potential harm of screening. It is not, of course, the false positive test itself that carries the potential for harm. Rather, it is the consequences of the positive test. These include the additional imaging and other tests done to follow-up on a false positive, biopsies done for lesions that turn out not to be cancer, and the inconvenience of medical appointments due to false-positive screening tests.

There has been disagreement about the seriousness of false positive tests as a harm or potential



harm of screening mammography. The mention of anxiety and psychologic distress as a harm of a false positive test has, in particular, been ridiculed.

To understand the consequences of a false positive test within the framework of harm that considers anxiety and distress, it is necessary to consider how women enter screening and what happens or might happen to a woman who has a positive screening mammogram.

No matter how hard the concept of screening is explained before a healthy woman is sent to have a screening mammogram, a positive mammography screening test means cancer until cancer is proven not to exist. For some women who have a positive mammogram, the time between a positive mammography screening test and a statement--“there is no cancer”--is mercifully short. For other women, the follow-up of a positive mammography screening test involves more than one additional imaging test, perhaps a clinical breast examination along with a test, a trip to a surgeon.....over a period of time that is not always short and over a period of time that is unpredictable and is not within the control of the woman who has had the positive test. Some women eventually need a biopsy in order to be certain that there is no cancer.

Cancer is a terrifying prospect. Breast cancer carries special emotional weight because the consequences of a breast cancer diagnosis have, in the past, been not only the prospect of death due to breast cancer but the prospect of mutilating surgery. Anxiety and psychological distress in women who have had a positive screening test is documented. The Task Force wants only that screening mammography be done with full knowledge of the potential harms, the frequency of these harms and what is gained by being screened at an earlier compared with a later age.

For screening mammography, there are other harms that are difficult to quantify because so little information about them is available. Some women screened in their 40's are diagnosed with cancer that could be treated just as well if diagnosed in their 50's and some had cancers that would never progress. These women may have been unnecessarily exposed to the harms of treatment, including surgery, chemotherapy and radiation, years earlier than necessary.

More research and more attention to this topic is a pressing need.

A final harm is exposure of the breast to radiation and the risks of radiation. With modern mammography equipment the radiation exposure for any single examination is small. But over time and over examinations, which include the examinations done to follow-up of false positive tests, radiation exposure increases.

#### Net Benefit

The concept of net benefit—benefits minus harms--is central to the Task Force approach. The Task Force maps evidence to an evidence grade recommendation based on evidence of the certainty and the magnitude of the net benefit in categories---“substantial,” “moderate” and “small.” There is no single number that the Task Force uses to place a recommendation in a category. Based on its assessment of the balance of benefits and harms, the Task Force concluded that the net benefit of starting screening in the 40's compared with later is small. Based on this assessment of net benefit, the Task Force gave screening of women 40-49 a C grade.

Mammography starting at age 40 should not be automatic. The Task Force recommends that women in their 40's decide on an age to begin screening that is based on a conversation with their doctor.



Many doctors and many women, perhaps even most women, will decide to have mammography screening starting at age 40. The Task Force supports those decisions.

Timeline

A great deal had been read in to the timing of the release of the Task Force recommendations following its final vote. These recommendations were released in unfortunate and entirely accidental temporal juxtaposition with major events in the health care reform debate. The following is a detailed timeline that shows the events from the vote of the Task Force about breast cancer on July 14, 2008 (also discussed on July 15, 2008) and the release of the recommendations on November 16, 2009 through publication in the Annals of Internal Medicine.

Task/Activity	Date
Task Force leads work with modeling group to commission modeling study	December- January, 2008
Off-line work in progress <ul style="list-style-type: none"><li>Modeling study being done by CISNET</li><li>BCSC analysis being done by EPC scientists</li><li>Revised Outcomes Table being prepared by EPC scientists</li></ul>	February – Early May, 2008
Work Group holds conference calls to hear presentations by EPC and CISNET scientists	Mid May, 2008
Work Group holds conference calls to review and finalize NEW draft Recommendation Statement	July 1 and July 9, 2008
Revised Evidence Report and Modeling Study Report distributed to full Task Force 2 weeks prior to meeting	July, 2008
Meeting to vote on new recommendation statement <ul style="list-style-type: none"><li>EPC scientists present revised evidence report incorporating analysis of BCSC data and revised Outcomes Table</li><li>Modeling scientists present modeling results</li><li>Draft recommendation presented by Work Group member</li><li>Task Force members discuss Recommendation Statement</li><li>Task Force member vote on recommendations</li></ul>	July 14-15, 2008
Work Group finalizes rationale, clinical considerations, and discussion before sending out to Partners for review and comment	January to April, 2009
Recommendation statement document sent to Partners for review and comment	April, 2009
Target month for publication in Annals of Internal Medicine known	August, 2009
Work Group reviews Partner comments Changes are made to the Recommendation Statement in response to Partner comments	September, 2009



Manuscript of Recommendation Statement submitted for publication (Annals of Internal Medicine)	September, 2009
Galley proofs from Annals received and returned	Late September, 2009
Exact date of publication of breast cancer recommendations known to AHRQ and to Task Force Chair and Vice-Chair	November, 2009
Publication in Annals of Internal Medicine	November 16, 2009

Between July 15, 2008 and the recommendation release through publication on November 16, 2009, the Chair and the Vice-Chair of the Task Force were regularly updated on the progress of the breast cancer recommendation. Every effort was made by the members of the Task Force and by those working with the members to assure that the recommendations moved as quickly as possible. There was no interference of any AHRQ employee or government official in the movement of these recommendations through the process.

The process was too long. The long time between the vote and the release of the recommendations is the basis for a review of processes and the development of an explicit plan to make certain that future topics do not encounter delays this long.

Again, the Task Force did not in any way attempt to accelerate or delay these recommendations. The fact is the Task Force members were, depending on the commentator, either naively out of touch or woefully out of touch, with the events in Congress that have now swept up these recommendations.

Expert Review of Breast Cancer Recommendations

The Evidence Based Practice Center Evidence Report on Breast Cancer Preventive Services, the Task Force Recommendation Statement (including clinical considerations, rationale, and discussion), and the supporting document describing the CISNET modeling study were sent for review to Partner organizations as part of the regular process of review that the Task Force requires as part of its methods. The Task Force asks partner organizations to select reviewers based on their expertise in the topic field as scientists.

The specific names of reviewers of the breast cancer prevention recommendation statement are listed in Appendix B6 of the evidence report for the Breast Cancer Prevention topic. These expert reviewers included one oncologist, an expert in modeling, two radiologists, one breast surgeon, and three physician/epidemiologists. Individuals representing the views of the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Family Physicians weighed in. The American Cancer Society provided the Task Force with a statement of its recommendations on breast preventive services. Additional reviewers chosen by the Annals of Internal Medicine are anonymous.

Comments of the reviewers identified by the partner organizations were collated and each was addressed individually and a suggestion made on handling. These suggestions were accepted or changed by the Task Force leads. The comments of specific reviewers were technical and relatively minor. The American College of Obstetricians and Gynecologists expressed concern that the wording of the language for the Task Force C recommendation would be misunderstood by clinicians, patients, policy makers, and insurers.

The Task Force recognizes now the wisdom of the ACOG advice. The communication of the meaning of a recommendation give a “C” grade was poor. Our message was misunderstood.



The Task Force stands behind the evidence and the conclusions based on the evidence.

Mammography at age 40 should not be automatic. The Task Force recommends that women in their 40's decide on an age to begin screening that is based on a conversation with their doctor.

The Task Force commits to improving how it communicates information with particular attention to situations where there are benefits and there are harms and the net benefit is small.

Role of Cost in Making Breast Cancer Recommendations

Cost and cost-effectiveness did not play a role in the Task Force recommendations about breast cancer screening.