December 9, 2013

Submitted Electronically

United States Preventive Services Task Force
c/o Dr. Robert Cosby
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

RE: USPSTF Draft Research Plan on Screening for Breast Cancer

Dear Chairwoman Moyer and Task Force Members:

As an organization with a long history of advocating for quality in mammographic screening, and of encouraging women and their health care providers to utilize proven screening methods to save lives, the American College of Radiology (ACR) —a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to provide input into the USPSTF draft research plan for breast cancer screening. We recognize that this opportunity for public comment was not available in the Task Force's previous consideration of the breast cancer screening recommendations; in addition to providing a venue for public comment, we are hopeful that the Task Force will embrace the input that is received. We believe the processes of the Task Force, the quality of its guidelines, and ultimately the public's trust in its recommendations can be enhanced by maximizing the input of breast imaging specialists and other experts and by ensuring transparency throughout your deliberations. We offer the following general comments relating to the process of the Task Force as well as specific recommendations related to the research plan.

GENERAL COMMENTS

The Task Force Process Should be Fully Open, Balanced and Transparent

Although the Task Force was created for the purpose of providing supplemental guidance to primary care physicians, USPSTF recommendations now have far broader

public policy implications. They are being used to influence national screening program guidelines, federal and private sector coverage policies, as well as direct-to-consumer screening recommendations. With the passage of the Affordable Care Act, the USPSTF was explicitly granted a prominent role in Centers for Medicare and Medicaid Services' coverage decisions and in the establishment of preventive service coverage requirements for private insurers. With such substantive policy issues at stake, the public trust demands that the USPSTF recommendation-development process be entirely transparent, consistent with other federal agencies that create policy and promulgate regulations.

While we understand that the Task Force is not a formal Federal Advisory Committee and is not statutorily bound to abide by the Federal Advisory Committee Act or the Administrative Procedures Act, we believe that the Task Force should embrace the public transparency and accountability protections afforded by these Acts. With millions of lives affected, it is imperative that critical decisions affecting citizens' access to preventive healthcare services not be made behind closed doors without the benefit and protection of well-established federal agency transparency requirements.

In addition to the broad process protections afforded by the APA and FACA, we urge the Task Force to be transparent in its methodology. It should disclose the input received as part of its public comment periods and explain its analysis of public comments, as well as its rationale for accepting or rejecting the input provided by the public. Furtner]T3(o)-3i1s input uETBT1 0 0 1 118.1 450.31 Tm210 1 118.1 408.ETBT (ly)12(12 Tf86

The Task Force should engage experts in breast imaging

The Draft Research Plan is foundational to Task Force deliberations in that it establishes the evidence that will be reviewed. It is important that the Task Force not limit its critical analysis of the material only to the thinking of its members. Expert peer review is an important tool in parsing out the strengths and limitations of scientific research and in moving the science of medicine forward. The Task Force should take advantage of the insights provided by expert peer review as it gauges the strength and weakness of the studies it considers.

We would also like to use this opportunity to request, once again, that the Task Force utilize expert consultants in breast imaging throughout their deliberations on the topic. Certainly, the process can only be improved by utilizing experts who are familiar with the research in their field of specialty and who understand its merits and limitations. The absence of such consultations was a source of major criticism of its breast cancer screening guidelines in the past. We believe that this will help the Task Force gain a fair, balanced understanding of the data, and that utilization of these experts helps the perception that the Task Force report reflects this fairness. ACR welcomes the opportunity to recommend such subject member experts to you.

SPECIFIC COMMENTS

Key question 1: *In average-risk women age 40 years and older, what is the effectiveness of routine mammography screening in reducing breast cancer specific and all-cause mortality (i.e., final health outcomes), and how does it differ by age, risk factor (e.g., family history, dense breast tissue), and screening interval?*

The proposed USPSTF search dates of 2008-2014 would exclude key data from randomized controlled trials (RCTs). The

patient risk and lead time bias, absence of which causes gross overestimation of the frequency of overdiagnosis.

But the Task Force should dig deeper and should clearly differentiate the three harms which occur at different levels of the chain of events, from detection to diagnosis to treatment of breast cancer. These include “overdetection”, “overdiagnosis” and “overtreatment.”

The term “overdiagnosis” should be used when a breast tissue sample is sent for pathological review and called histologically malignant, but may in truth be benign. Further advances in the molecular biology and pathology of cancer that might ameliorate this situation are being sought but are not yet available. Thus, treatment of an “overdiagnosed” malignancy may be “overtreatment,” and occurs after biopsy is recommended and tissue is submitted for histological review.

The screening process, whether by clinical exam or by mammography, may lead to “overdetection.” This is inherent in any screening process, whether by imaging or palpation. Although this is considered a screening harm, it is unrealistic to expect the screening process to be able to separate malignancies that have the potential to progress from those that do not, since medical science cannot always do this even at the histologic level.

Registry-based approaches which were previously used for the “harms” data should be given less weight because they do not track individual patient outcomes and are subject to bias.

The anxiety a patient may experience from a screening recall should not be equated with the anxiety associated with dying from metastatic disease.

Contextual Question 3: