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July 15, 2015

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To Whom It May Concern:

The Society for Women's Health Research (SWHR) appreciates the opportunity to comment on the U.S. Preventive Services Task Force's (USPSTF) draft research plan for osteoporosis screening. SWHR, a national non-profit organization based in Washington, D.C., is widely recognized as the thought leader in research on sex differences and is dedicated to improving women's health through advocacy, education, and research. SWHR is submitting comments to support the draft research plan with minor revisions while taking the opportunity to formally request further information on the status of research gaps cited in the USPSTF 2011 recommendation statement.

SWHR is greatly concerned with the issue of osteoporosis and sees it as a serious public health threat, especially for women. An estimated 54 million Americans have either low bone density or osteoporosis; nearly 80% of whom are women.¹ Research has shown that sharp decreases in estrogen during menopause significantly increase a woman's risk of bone loss and osteoporotic fractures.² As a result, nearly one in two women over the age of 50 are expected to break a bone due to osteoporosis.³ These fractures can cause significant physical and emotional health problems, impacting quality of life.¹ In fact, 20% of all osteoporotic seniors will die within 12 months due to their fracture-related complications.³

SWHR commends the USPSTF's decision to review the current recommendation on osteoporosis screening, including new research that further explores the benefits and harms of pharmacotherapy to reduce fracture-related morbidity and mortality in high risk populations. The draft analytical framework, proposed key questions, and contextual questions present an excellent strategy to understanding the risk of screening and treatment at multiple points of the disease cycle.

However, SWHR requests USPSTF provide clarification of osteoporosis screening and diagnosis using T-scores and fracture risk for "asymptomatic adults over age 40."

Clarification is necessary, as osteoporosis may not have any

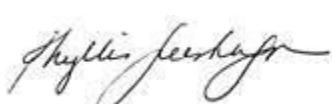
symptoms or such "symptoms" could include a fracture as a result of physical activity rather than low bone density. In addition, would only adults over 40 who have never experienced a fracture be considered "asymptomatic?" If not, what time range would be acceptable (i.e. any fracture occurring after the age of 40 years, within 12 months, within last 5 years, etc...)? Further clarification will be needed to appropriately guide the systematic review, allowing USPSTF to select appropriate studies based on a standardized definition.

In addition, USPSTF should provide clarification on the minimum age selection. SWHR respectfully requests USPSTF to include data supporting the systematic review of studies focused on adults aged 40 years and older, specifically whether this definition is supported for appropriate screening and diagnosis for women and men as distinct subpopulations. As women are significantly impacted by this disorder, data that supports this selection by sex is necessary to understand when appropriate screening should begin.

Finally, in 2011, USPSTF indicated specific research gaps in its recommendation statement.⁴ Research gaps cited focus on osteoporosis in non-white populations (including Asian, American Indian/Alaska Native, Hispanic, and African-American women) and men of all races and ethnicities. At the time of publication, limited data was available on osteoporotic fracture risk in minority women and the benefits of screening perimenopausal women or those experiencing rapid bone loss. SWHR maintains that without reliable data supporting the use of screening and treatment tools in disparate demographic groups, clinicians and patients cannot confidently assess options as the health care system moves towards implementing individualized, precision medicine. As a result, SWHR believes it would be useful to provide a status update on these research gaps. If little-to-no research has been conducted in the intervening time period, SWHR recommends inclusion of these gaps in the draft and final recommendation statement.

Screening for osteoporosis greatly improves the prognosis of the individual through evidence-based treatment and prevention strategies and therefore should be of the utmost importance. SWHR applauds the current "B" recommendation for women at increased risk for osteoporosis and looks forward to a new USPSTF systematic review eliciting further details for health professionals on preventing and treating this debilitating disease.

Sincerely,



Phyllis Greenberger, MSW
President & CEO



Andrea L. Lowe, MPH
Health Policy Analyst

¹National Osteoporosis Foundation. 2015. "Debunking the Myths." Retrieved from: <http://nof.org/OPmyths>

²National Osteoporosis Foundation. 2015. "What Women Need to Know." Retrieved from: <http://nof.org/articles/235>

³National Osteoporosis Foundation. 2015. "What is Osteoporosis?" Retrieved from: <http://nof.org/articles/7>

⁴U.S. Preventive Services Task Force. Screening for osteoporosis: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* 2011;154:356-64.