

## **Public Comment to the U.S. Preventive Services Task Force**

**October 12, 2015**

Altarum Institute and its Council on Aspirin for Health and Prevention submit this public comment to the United States Preventive Services Task Force (USPSTF) on the draft recommendation statement and draft evidence summaries related to aspirin for the prevention of cardiovascular disease (CVD) and cancer. First, we wish to thank the Task Force for its careful review of the evidence, including a comprehensive analysis of the benefits and risks involved. This is critical because the final recommendation will influence the practice of health care throughout the United States. Second, we agree with the Task Force regarding the conclusion that daily, low-dose aspirin does have primary prevention benefit for appropriately-aged individuals at high risk for cardiovascular disease and colorectal cancer.

Much is at stake in this conversation. Cardiovascular disease is responsible for 30 out of 100 deaths in the United States - and 14 million adults have had a first heart attack or stroke. Additionally, more Americans die from colorectal cancer than any other cancer, except lung, and the mortality numbers are equal for men and women. If a simple, low-cost medication has the potential to prevent these diseases, many lives could be saved every year.

The Council on Aspirin agrees with the Task Force's recommendation that low-dose aspirin use can prevent cardiovascular disease and colorectal cancer in adults ages 50 to 59 years who have a 10% or greater 10-year CVD risk, are not at increased risk for bleeding, have a life expectancy of at least 10 years, and are willing to take low-dose aspirin daily for at least 10 years. Thus, the Council on Aspirin supports this determination, which is consistent with the recommendations of other respected organizations including the American Heart Association, the American College of Cardiology, and the American Diabetes Association that also recommend aspirin therapy for primary prevention among those persons in whom the benefits outweigh the harms.

The Council agrees with the conclusion of the USPSTF that aspirin, when used appropriately, is useful to prevent a first heart attack or stroke in both men and women. This year, an estimated 610,000 Americans will have a first stroke and another 635,000 will have a first heart attack. The finding of the USPSTF that aspirin can reduce the risk of a first heart attack by 22% means that nearly 140,000 first heart attacks could be avoided each year in the United States alone. At the appropriate low doses which are recommended, aspirin also prevented 14% of first strokes which could translate into avoiding over 85,000 such events per year in the United States.

The Council on Aspirin also applauds the Task Force for adding colorectal cancer to the aspirin recommendation, the first time a major U.S. medical organization has issued a recommendation to take aspirin to prevent a form of cancer. There is a substantial body of evidence that suggests aspirin may be a potent yet overlooked weapon in the war against colorectal cancer. Specifically, there is now definitive data that long-term daily aspirin use can lower the risk of developing colorectal cancer, possibly by as much as 30%, though this benefit will not likely be seen immediately. Thus, we support the Task Force's conclusion that taking low-dose aspirin daily for at least 10 years may protect against this disease. In the future, we hope the Task Force will consider the possibility that a distinct aspirin recommendation for colorectal cancer may be reasonable, apart from the cardiovascular disease recommendation. Or, possibly a new recommendation that takes into account aspirin's preventive benefits for colorectal cancer and other cancers.

Altarum Institute and the Council on Aspirin do have some changes to suggest for this USPSTF recommendation statement. First, there are several age and risk groups for which a recommendation has currently not been given, but would be helpful. These include aspirin in men and women of any age at <5% or 5-10% risk. Additionally, there is a lack of guidance for the 70+ age group. Second, it would be useful to consumers and health care professionals to have the Task Force analyze and present aspirin risk and benefit data by gender. Third, data in the decision analysis suggests a different recommendation than was given. We would find it helpful if the Task Force provided an explicit justification for the data used to make its recommendations. Our read suggests that recommendations are based on primary data and meta-analyses of data, rather than on the decision analysis. The approach suggested by decision analysis appears different, regardless of time horizon.

The Task Force's updated aspirin guideline is a positive step, recognizing that the decision to take aspirin is complex. It requires an understanding not only of aspirin's benefits in cardiovascular disease and colorectal cancer prevention, but also of its risks, which include bleeding that can be life-threatening. Taking into account all of these factors is challenging, but necessary for any recommendation to make sense in clinical practice. Without these considerations, we will have difficulty getting to appropriate use of aspirin (i.e. getting the right people to take aspirin and the wrong people to avoid taking it). When the final USPSTF recommendation is released, the Council on Aspirin will promote the recommendation via the Aspirin Project website to make it available to both public and professional audiences. We would also be happy to host facts sheets about aspirin that provide the base rates of ASCVD events as well as the rates of benefit and harm with aspirin use.

The Council on Aspirin for Health and Prevention is a volunteer group of healthcare professionals with expertise in aspirin therapy, cardiovascular disease, and cancer. It is convened by Altarum Institute to identify, discuss, and vet ideas and opportunities for broadening the appropriate use of aspirin. The Council on Aspirin's efforts focus on the provider-patient relationship and the interventions, policies, educational strategies, and systems that influence this relationship.

The Council on Aspirin believes that the decision to start or stop aspirin therapy should be made in consultation with a health care provider. We urge providers to discuss aspirin use for primary prevention with patients to determine when it is appropriate, and for consumers to ask their providers about whether preventive aspirin is right for them. Guidance for doing so can be found at [www.aspirinproject.org](http://www.aspirinproject.org), the educational website developed by the Council on Aspirin that provides consumers and health care providers with information and resources to help them decide together if aspirin is the right choice.

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