

Editorial

Modernizing Medicine: Demonstrating a Policy of Prevention

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An undisputable fact of the 21st Century is that health care spending continues to escalate. In the United States, 15 percent of the country's gross national product is spent on health care and 75% of those costs are attributable to chronic disease. Chronic diseases account for more than 70% of all deaths in the U.S., two-thirds of which are caused by heart disease, cancer, stroke, chronic obstructive pulmonary disease, and diabetes. Globally, 17 million people die each year from cardiovascular disease. Furthermore, recent figures from the World Health Organization predict that cardiovascular disease will be the most common cause of death in developing countries by the year 2020.

Few people dispute the growing body of evidence that prevention is effective through risk factor modifications such as smoking cessation, exercise, and diet change. Scientific evidence and cost-effectiveness measures suggest preventive services can postpone disease and disability, permitting older adults to maintain functional independence and quality of life.

Early detection and treatment of preventable chronic diseases is an investment in America's future as a healthy, productive nation. With such a backdrop, legislators in the U.S. approved sweeping changes to Medicare – the health care program for those over 65 – including coverage of preventive medical tests and procedures, including mammograms and prostate and colon cancer screenings.

The same day that President Bush joined leaders in Washington, DC signing hallmark Medicare legislation, an FDA Cardiovascular and Renal Drugs Advisory Committee met in Gaithersburg, Maryland to discuss whether aspirin should be recommended for primary prevention of myocardial infarction. This was the third time the FDA has convened a committee on this subject since 1989 to examine if there was adequate evidence to substantiate the benefit and lack of harm for a daily dose of aspirin to prevent a first heart attack.

In 1989, aspirin was recommended by the FDA advisory, but overruled by the agency. In 2003, the FDA committee reviewed data from published studies with over 55,000 patients in five large-scale randomized trials. Four studies demonstrated a significant benefit in reducing first heart attacks. Two were stopped early because the benefit was overwhelming, which made it unethical to withhold treatment from those in the control (placebo) group. The minor side effect was uncommon stomach bleeding and very rare stroke.

Despite the demonstrated evidence and the endorsement of low dose aspirin for individuals at risk for a first heart attack from the U.S. Preventive Services Task Force,

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the American Heart Association, the American College of Cardiology, the American Diabetes Association, the FDA committee voted against recommending this prevention regimen for Americans.

Without getting in to the intrinsic discussions that included a savory need for evidence to present a definitive definition of a narrow interpretation of efficacy, this decision demonstrates medicalization over public health. Advancing primary prevention with low dose aspirin would reduce the number of heart attacks in the U.S. by over 100,000 per year.

While the Committee request to have data from a number of studies unequivocally demonstrating the relationship to avert death for thousands who choose to take the 100 plus-year-old drug, this would be a questionable multimillion dollar cost at the expense of heart disease prevention. Yet, since this is such a low cost drug, costing pennies a day without any proprietary industry sponsor, spending such resources for studies to offer further support would be misguided.

Many people criticize the policymaking process fraught with multiple inputs – scientific evidence, consumer advocacy, and political expediency, among others – the recent Medicare decision will advance public health. The FDA advisory process hopefully is just that – advisory. This may still present an opportunity for ethics, reason and disease prevention to win out as policymakers choose to balance multiple interests to advance health.

For the record, I will follow the professional organizations and multidisciplinary U.S. preventive task force and take my low dose aspirin each day. It is up to all of us who practice “health communication” to discriminate amongst evidence and advance disease prevention, health promotion, and ethical, efficacious treatment by promoting prudent policymaking. While the ideal for evidence-based medicine is an important goal, it is the health of the public that should be the ultimate guide, rather than the intrinsic need for certainty of scientific evidence.