

Health Care vs Sick Care; Eradicating Heart Attacks through Health Care

病状管理から健康管理の時代へ

～日頃からの健康管理で心臓発作を未然に防ぐ～

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Abstract

In most countries specially in the United States, the word “healthcare” in the Healthcare System is a misnomer! Most of our rapidly rising healthcare expenses are spent on “sick care”, i.e., treating late stage symptomatic diseases that could have been detected and treated earlier. For example, in the past 30 years, while major developments occurred in the treatment of symptomatic atherosclerotic cardiovascular disease (i.e. heart attack and stroke), very little innovation has happened in the early detection and primary prevention of these fatal events. In fact, since the initial (post Framingham) wave of “risk factor” awareness in the 1960s, and the birth of statins in the 1980s, no major innovation has come to the primary prevention field. With the much debated rising healthcare costs and the sweeping legislation of “Obamacare”, we now have an unprecedented opportunity to turn our healthcare into its true definition of health care. This can happen by mandating preventive care, investing in early detection and treatment of subclinical diseases before they become symptomatic or deadly, and shifting the healthcare from hospital to home. Early detection of asymptomatic atherosclerosis with novel noninvasive tools such as coronary CT and carotid ultrasound as recommended by the SHAPE (Screening for Heart Attack Prevention and Education) Task Force presents as an innovative approach to advance cardiovascular healthcare and ultimately to eradicate heart attacks in the 21st century.

1 Introduction

Imagine living and working without PCs, Internet, mobile phones, emails, and Google. As hard and primitive it sounds today, it was the life and work before 1980 for most people around the world. It is amazing to see the extent of new developments occurred in the field of communication and information technologies only in the past two decades. Sadly, the same cannot be told about the field of healthcare. In the past two decades, our life expectancy has not meaningfully increased, instead our weight and obesity rates went up significantly, the incidence of diabetes doubled, and other risk factors of chronic diseases have become more frequent than before. The irony in our healthcare system starts with the word “healthcare” itself which is a misnomer. Our current system is not a “health care” system, rather almost entirely is focused on “sick care”. Most of our healthcare dollars have gone to treat sickness rather than preventing it, over 80 % of the so called healthcare budget in the US is spent on secondary prevention (e.g. preventing second heart attack or death after the first heart attack) and doing so yielded very little increase in our life expectancy. Primary prevention must be the focus of the healthcare industry not in the periphery. Interestingly, our major advancements in the healthcare field

that could possibly match the type of advancements made in the communication field such as the Internet and PC, has only occurred through the primary prevention of infectious diseases using vaccines. Vaccines are the best examples of effectiveness of primary prevention. After vaccine, prophylactic drug therapies have proven to be the most effective strategies. In the history of medicine and mankind, preventive vaccination strategies and prophylactic antibiotic therapies have saved more life years than all other advanced surgical and medical innovations. The main reason is that most advanced medical and surgical solutions aim at treating late stage diseases which by definition are late in terms of opportunities for extending lives. A vivid example of this problem and the dilemma of health care v.s. sick care can be seen in the field of atherosclerotic cardiovascular disease (ACVD) caused by ischemic complications of arterial atherosclerotic plaques manifested primarily through sudden cardiac death, acute coronary syndromes and stroke. ACVD is the leading cause of death and disability in most developed countries, and is dramatically increasing in the developing nations. Recent developments in the areas of basic and clinical atherosclerosis have opened doors to new avenues for early detection and treatment of those at risk of a near future events namely “the Vulnerable Patient” [1][2][3].

The majority of the cost of medical care in the cardiovascular field is directed to the treatment of the first heart attack and subsequently for the prevention of the second heart attack, very little is spent on the prevention of the first heart attack. For example, a surgical treatment for coronary artery disease is reimbursed in tens of thousands of dollars, however, a hundred dollar preventive screening test for detection of coronary or carotid atherosclerosis is rejected by the Medicare and insurance companies.

2 Primary v.s. Secondary Prevention

Prevention of ACVD is categorized into primary prevention and secondary prevention. Primary prevention can be defined as the prevention of the first heart attack or stroke, while secondary prevention deals with the prevention of the second / recurrent heart attack or stroke. Neither the concept nor the practice of primary prevention existed for ACVD prior to the 1950's when pioneering epidemiologists such as Ancel Key, Jerry and Rose Stamler, William Kannel, Henry Blackburn and others, reported convincing epidemiologic associations between high fat diet, high serum cholesterol, high blood pressure, smoking, physical inactivity, etc. (termed "risk factors") and ACVD. As noted above, in the past decades, great progress has been made in the early detection and management of risk factors as well as the diagnosis and treatment of symptomatic ACVD, particularly acute coronary syndromes (ACS). However, very little has been accomplished for asymptomatic ACVD, which accounts for the majority of sudden cardiac death, silent MI and silent stroke. Unlike most cancers, ACVD remains asymptomatic (subclinical) for decades. Even though the majority of asymptomatic ACVD can be detected and treated, no screening test is currently approved by federal agencies and made available to primary care physicians. Current traditional risk factor based assessment strategies have clearly proven to be insufficient [4]. Despite major accomplishments in reducing the age-adjusted incidence of death from coronary heart disease and stroke (which is partially because of reduced case-fatality rate), the prevalence of ACVD and its associated morbidity, e.g. heart failure, have steadily increased in the past few decades. The incidence and prevalence of most risk factors (except for smoking) have increased or not changed. With the rapidly growing epidemic of obesity, the war against ACVD-prone life style is lost. It is obvious that our society is not getting more primary prevention. The time has come to adopt

new paradigms, beyond screening for traditional risk factors, and the SHAPE initiative (discussed later) can serve as a great example of innovation in primary prevention.

3 Secondary Prevention: Where the Money Is?

As stated in the subject of this article, primary prevention is in a dire need of innovation and investment. Investment in preventive cardiovascular healthcare must go far beyond general recommendations to the public to consume healthy foods, exercise, and avoid smoking. Although issuing educational guidelines and updating the food pyramid are needed, there is much more to be done for preventive cardiovascular healthcare. With the growing number of expensive modalities in the tertiary cardiovascular care arena (e.g., drug eluting stents, cardiac resynchronization therapy, and left ventricular assist devices), the cardiovascular healthcare budget is increasingly absorbed into an area with minimum opportunities for adding productive life years. While it is universally agreed that the opportunity for prevention of death and saving quality adjusted life years is far greater in primary than secondary prevention, it is disappointing to see a very small portion of the total cardiovascular care budget is routed towards the primary prevention. The currently allocated budget for cardiovascular screening (one cholesterol and blood pressure test every 5 years) is woefully inadequate for prevention of the number one killer. (Fig. 1)

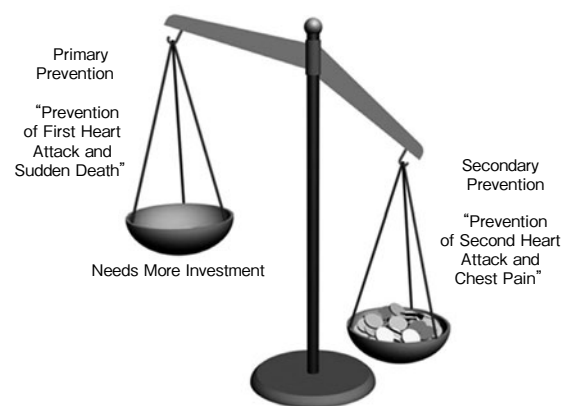


Fig. 1 Primary prevention is outweighed by secondary prevention. More investment is needed in primary prevention.

4 SHAPE: an Innovation in Cardiovascular Health Care

In the era of Google, mobile Internet surfing, remote robotic surgery, sub-millimeter non-invasive imaging, and

nanotech enabled mass proteomic assays, having millions of people (many of whom are indeed health conscious) living with, but unaware of, coronary or carotid atherosclerotic plaques is tragic and simply unacceptable. Physicians and researchers are responsible for taking actions and for helping the medical community to take full advantage of new knowledge and technology to save lives particularly in the very productive segment of the society (<75 years). After all, if investment in seat belts and airbags (which are low in cost-effectiveness) with proper regulatory provisions can be sold to automobile makers and users, investments for prevention of the number one killer should work, and shall save many more lives.

SHAPE roots from the Screening for Heart Attack Prevention and Education (SHAPE) Task Force, an initiative of the Association for Eradication of Heart Attack (AEHA), a grass roots organization founded by me in 2001 and supported by other cardiovascular physicians and researchers in the field of Vulnerable Plaque. The mission of the organization is to eradicate heart attacks in the 21st century. After publishing the SHAPE Task Force report which, received worldwide attention, AEHA changed name to become the SHAPE organization (Society for Heart Attack Prevention and Eradication). The SHAPE Task Force published the SHAPE Guidelines in 2006 [3] which, in a nutshell, recommends moving beyond traditional risk factors of atherosclerosis for preventive risk assessment. The SHAPE Task Force calls for screening for asymptomatic (subclinical) atherosclerosis in addition to testing for its risk factors. SHAPE also recommends intensive

treatment of individuals without risk factors but with atherosclerosis as measured by Coronary Calcium Score and or carotid Intima-Media Thickness. (Fig. 2)

5 Legislation for Primary Prevention (Health Care)

The regulatory bodies and governmental agencies play a central role in the much needed shift from secondary to primary prevention. Currently, preventive cardiovascular healthcare strategies are predominantly based on general recommendations and guidelines for heart healthy life styles. Unlike the treatment of symptomatic ACVD, in which innovative technologies are easily and increasingly adopted, in the primary prevention of ACVD, the adoption of new methods and technologies has been extremely slow. This becomes obvious when comparing the number of companies exhibiting at preventive cardiology conferences versus interventional cardiology or cardiovascular surgery meetings. Without creating new opportunities by the federal agencies for business developments in the field of primary prevention, it will be hard for the field to grow and fulfill its promises. Attracting investments in free and capitalistic societies can only be successful if ROI is greater than competing business opportunities. For example, in cardiology practice, ROI in the prevention of the first heart attack is much lower than ROI in the prevention of chest pain after the first heart attack. Obviously, the current investment paradigm is faulty, since primary prevention can save many more lives and results in

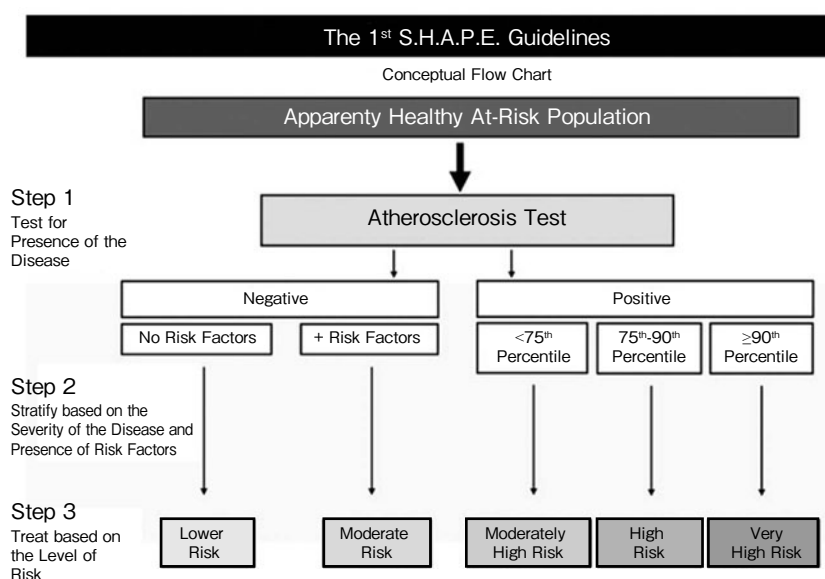


Fig. 2 The 1st SHAPE Guidelines proposed by the SHAPE TASKFORCE in 2006.

more productivity by reducing premature death and disability. But the fact is that return on investment in the primary prevention takes a long time and private investors are not interested in investing for 20 or 30 years, the government should. Once the entrepreneurs, businessmen, and, subsequently, the physicians and the entire healthcare industry realize the opportunity for return on investment in preventive care, a new path will be open to unprecedented progress in public cardiovascular healthcare. Until then, very few are willing to invest in the primary prevention, the same way very few investors are interested in increasing national education level or building schools and bridges. In this line, the SHAPE Task Force helped introduce the first of such legislative initiatives in the United States to Texas legislature. The Texas Heart Attack Preventive Screening Bill (HB1290) which was inspired by the SHAPE Guidelines passed the Senate and became law in Texas effectively January 2011. The law mandates insurance coverage for noninvasive imaging of asymptomatic atherosclerosis (coronary CT and carotid ultrasound) in the Framingham Intermediate Risk population [5][6].

Although passing the Texas Heart Attack Preventive Screening law is considered a monumental milestone for shifting cardiovascular healthcare to primary prevention and has set the stage for other states to follow, it is far from adequate for the ultimate goal of eradicating heart attacks. Additional policy reforms, such as the following, must be seriously considered by the legislative and executive bodies to address the number one killer.

- 1) Provide more reimbursement incentives for preventive healthcare technologies than at present

- 2) Empower primary care physicians to utilize state-of-the-art preventive diagnostic technologies
- 3) Enforce “pay for benefit” 2 strategy instead of the existing “pay for service” system, and exercise it in all layers of medical care (primary, secondary, and tertiary)
- 4) Give incentive and funding priorities through NIH, NSF, and other federal research funding agencies to fund proposals with innovative technologies focusing on primary prevention.
- 5) Empower consumers to take charge of their health. Reducing legal barriers particularly for accessing safe and effective drugs such as statins with minimum needs for
- 6) Give economic incentive (such as tax breaks) to the medical industry for any future products they bring to the market focusing on the primary prevention.
- 7) Give economic incentive (tax breaks) to at-risk populations to reduce their burden of CVD risk, e.g., weight loss, stop smoking cessation, cholesterol and blood pressure lowering
- 8) Increase the tax on smoking, both consumers and providers.
- 9) Shift cardiovascular prevention from the hospital and doctors’ offices to the home; give incentive to home health monitoring companies and reduce legal barriers for mass adoption of practicing telemedicine and tele-healthcare.
- 10) Mandate insurance coverage of screening and treatment of asymptomatic (subclinical) atherosclerosis.

In conclusion, to build the “Field of Dreams” for preventive cardiology and ultimately for the eradication of heart attacks, the government and healthcare policy makers need to take the first step to build the ground.

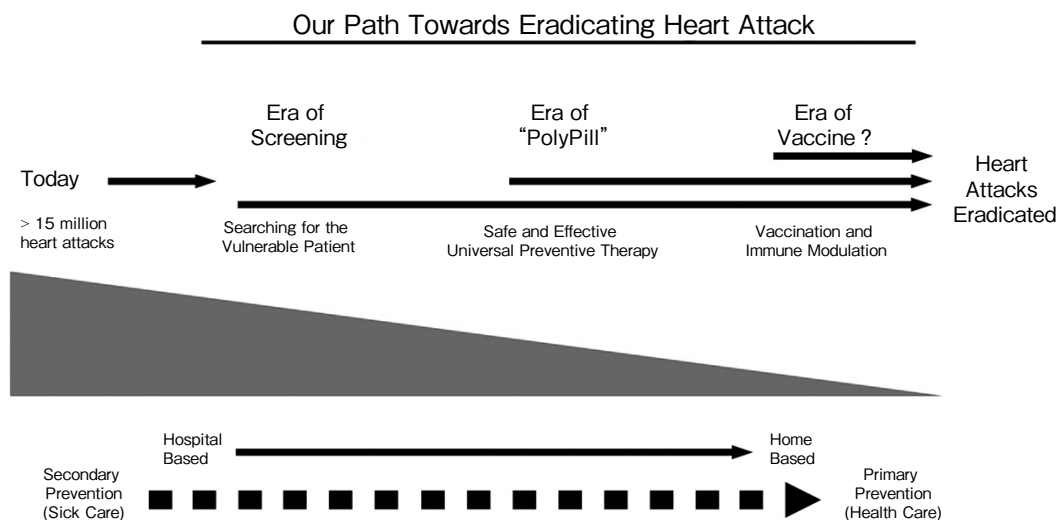


Fig. 3 A roadmap to the eradication of the worldwide epidemic of heart attack and stroke.

6 Heart Attacks Can Be Eradicated!

The heart attack epidemic inherited from the 20th century (over 15million heart attacks every year), makes it difficult for most people to imagine a future where heart attack is totally eliminated. Nonetheless, the mission of eradicating heart attacks is no more challenging than the mission of landing humans on Mars and much more achievable than eradicating cancers. The vision for a heart attack-free future can become a reality in the 21st century, and can result in a major step up in the life expectancy of the mankind, if our healthcare system becomes health care, and the care shifts from hospital to home. **Fig. 3** illustrates a likely path to arrest the worldwide epidemic of heart attack and stroke.

Heart healthy life style assisted by innovative technologies in Personalized Preventive Medicine will be able to shift the existing expensive in-hospital sick care to the future less expensive out-of-hospital health care [7][8].

7 Conclusion

Innovation is urgently needed in the field of primary prevention of cardiovascular disease. The SHAPE initiative and the Texas Heart Attack Preventive Screening Law are an example of such initiatives but by no means are sufficient. Heart attacks can be eradicated in the 21st century if the medical community, including academia, industry, and healthcare policymakers shift their investment from the treatment of events that have already occurred to prevention of the event, i.e. “locking the barn door before the horse is stolen”. In the subsequent manuscripts published in this Issue of Current Atherosclerosis Report, leading members of SHAPE present updates on clinical trials and scientific studies related to risk assessment for the primary prevention of ACVD.

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《 About the Author 》

Morteza Naghavi, M.D.

Dr. Naghavi is an innovative physician scientist in the fields of cardiovascular medicine and biotechnology. He has founded four medical companies and is internationally recognized as a leader in heart attack prevention initiatives. As a former cardiology faculty at the University of Texas Health Science Center in Houston and Co-Director of the Vulnerable Plaque Research Department at the Texas Heart Institute, he made several inventions and contributed to creating the field of "Vulnerable Plaque", the immediate underlying cause of heart attacks.

Through his years of leadership in the field of early detection and prevention of cardiovascular disease, Dr. Naghavi founded the Society for Heart Attack Prevention and Eradication (SHAPE) and is the past-Chairman of the SHAPE Task Force, a non-profit coalition. Dr. Naghavi has over 25 inventions and is passionate about transforming new ideas into healthcare solutions.

Pioneering work by Dr. Naghavi and colleagues at the Texas Heart Institute led to the foundation of Volcano Corporation (NASDAQ: VOLC), a leading cardiovascular diagnostic company. Following the successful public offering of Volcano Corporation in 2006, Dr. Naghavi founded and invested in several startup companies including Endothelix Inc., ThermaRx Inc., IC Therapeutics Inc., and Personalized Weight Management Inc.

Dr. Naghavi is currently the CEO of CardioNexus Corporation.