Is a Paradigm Shift in US Healthcare Reimbursement Inevitable?
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The fundamental goal of health care is to increase longevity and optimize physical, psychological, and social well-being at the individual, community, and society levels. An optimal healthcare system should fulfill these goals in an efficient and cost-effective manner. Although we believe that our healthcare system in the United States is going in the right direction, there is certainly room for improvement.1 In the present article, we review some of the shortcomings of the present system and offer an alternative philosophy that might facilitate a more viable and efficient approach to healthcare expenditure.

Fundamental Concerns About the Current Reimbursement System
In the present environment, health care is generally viewed as an expense, and, because “costs” are managed by budgets, this translates into a fiscal mindset in managing health care. Naturally, this attitude generates a pattern of fragmented thinking. That is, the individual components of healthcare cost, such as pharmacy and hospital inpatient admissions, are considered independently, whereas total healthcare value and other important patient outcomes are overlooked. This fiscal mindset also does little to encourage the provision of quality care because reimbursement is based more on quantity. The natural consequence of this is exemplified by the results of a recent study in which patients received only 55% of the recommended care.2 The failure of the current system to promote quality care is also apparent in the infrequent use of incentives for preventive care or proactive disease management. Indeed, such services are often not reimbursed. In short, the focus is on episodic care rather than on encouraging proactive health management. This contributes to the current environment in which 50% of Medicare dollars are being spent on 5% of the Medicare population.3 Finally, a cost-based system fails to consider broader societal benefits of improving health, such as increased productivity and improved quality of life.

Our criticism of the current system does not imply that budgets should be unlimited or disregarded in healthcare planning but simply that an approach based on budgetary concerns has many unintended consequences that adversely impact the effectiveness of the system.

Impact of the Cost-Based System on Innovation in Drugs and Devices
In the current system, emphasis is often placed on immediate medical costs. Regrettably, this focus on price rather than value can limit reimbursement for and thus access to medically innovative therapies and devices. These restrictions in reimbursement are created through various barriers, including preferred drug lists/formularies, prescription limits, coverage and payment decisions, and prior authorization programs. Dissemination of innovative products is also hampered as a consequence of a bureaucratic system that focuses on price and monetary costs.

In short, there is little in our system that encourages or rewards effective and efficient use of technology, with the result being that underuse, overuse, and misuse are common.4,5 Moreover, if this focus on dollar cost continues, there is a danger of price controls being introduced, either directly

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or indirectly (through reimportation), accompanied by a further threat to future innovation. Paradoxically, it is these innovative therapies that are key to improving health outcomes in a cost-effective manner.

**Promoting a Pipeline of Medical Innovation**

Medical advancement through research and development (R&D) in prescription drugs and devices has had a dramatic impact on US health and healthcare provision. Innovation has shifted surgeries from highly to minimally invasive, and therapies from late-stage disease treatment through early treatment to prevention. In addition to improving health at the individual and societal levels, there are a number of health-care innovations that have resulted in dramatic monetary savings. For example, intraocular lenses and related medical technologies for cataract surgery return $95,000 per patient per year in net benefits through clearer vision and resultant independent living. In addition, by adding an average of 12 years to the life expectancy of low-birthweight infants, technology returns $200,000 per infant per year. In the case of heart failure, cardiac resynchronization therapy, a relatively new innovation for improving cardiac function in heart failure patients with symptomatic left ventricular dysfunction, has been shown to reduce rates of hospitalization due to progressive heart failure and mortality by 29% and 51%, respectively, suggesting a substantial favorable impact on this costly and common problem. A great potential exists for significant future savings. For example, an innovation that reduces cancer death rates by 1% would translate into savings of almost $500 billion dollars.

Although the price of drugs is currently the subject of much political debate, a recent study reported a direct relationship between the price of the product and that pharmaceutical product’s ability to improve health-related quality of life. It has also been reported that the costs of innovation for many commonly used therapies are outweighed by the benefits they provide. Indeed, results of a recent analysis conducted at the National Bureau of Economic Research concluded that, although use of a newer drug resulted in an average $18 increase in prescription costs, there was a corresponding $71 reduction in nondrug spending, primarily as a result of reduction in hospital costs. Together with these considerable savings that technology has bestowed, we cannot forget the views of the public on medical innovation. Americans report both a greater interest in new medical discoveries and higher expectations for medicine’s ability to cure disease than do Europeans. In this same study, Americans also showed a higher resistance to cost constraints on medical treatments and technologies.

Innovation plays a central role in advancing the quality of health care, but it is a costly process; a recent study from Tufts estimated the cost of developing a new drug at more than $800 million. If innovation is to continue, there must be sustained investment in R&D, and adequate reimbursement for innovative products with value to society will be essential. For this to occur, the cost-effectiveness of medical treatment in the broad sense, encompassing hospital costs (both inpatient stays and outpatient visits), rehabilitation and nursing home costs, and working days lost because of illness and disability, must be considered. To illustrate, consider the declining rate of disability in Americans ≥65 years, much of which is the result in advances in medical technology and pharmaceuticals. According to a study by Manton et al, the relative decline in chronic disability is decreasing faster than the 1.5% decrease suggested as necessary to preserve the fiscal stability of Medicare until 2070, and the associated drop in nursing home use alone translates into Medicare savings of $18.9 billion.

Many valuable medical interventions are not widely adopted, at least in part because they are not considered to be cost-effective. Yet, in many cases, these interventions are actually far more cost-effective than nonmedical interventions mandated or recommended by regulators to improve the safety and health of the population, such as the bans on asbestos and the establishment of standards to reduce radionuclide emissions. If applied rationally and equitably, cost-effectiveness considerations could, in some instances, provide support for funding to be moved from nonmedical interventions of lesser value to those medical innovations offering greater value. If cost-effectiveness analyses end up being used as merely another cost-containment mechanism, however, “we are destined to be trapped at our current level of therapeutic efficacy forever.”

Policies must also be formulated to encourage the reimbursement and dissemination of innovative therapies. In some regards, we are already on the right path. Legislation was recently enacted to improve reimbursement to providers who are using new technology that substantially improves the health of Medicare beneficiaries, thereby improving timely access. To date, however, only one new medication (drotrecogin alfa [activated]; Xigris [Eli Lilly and Co]) and, more recently, the INFUSE Bone graft/LT-CAGE Lumbar Tapered Fusion Device [Medtronic, Inc] have met the Centers for Medicare and Medicaid Services (CMS) standards. Recently, CMS has also created 2 new diagnosis-related groups (DRGs) to increase reimbursement for percutaneous vascular procedures involving the new drug-eluting coronary artery stents. It is encouraging that this transpired at the time of Food and Drug Administration approval for the stents. Although the initial payment rates for the new DRGs are inadequate to reflect the cost of the new stents, the availability of some incremental payment facilitated the timely provision of this valuable therapy. We hope CMS will act soon to revise DRG payments to more closely align with the actual cost of this valuable new therapy. However, these are steps in the right direction and should serve as examples of how to promote the broader use of financial incentives to encourage medical innovation.

Unfortunately, in other avenues, there are signs that we are taking the wrong direction. There is failure to achieve consistent reimbursement for diagnostic technologies, and...
this clearly limits their use, slows dissemination, and impairs access—for example, in the case of contrast echocardiography. In addition, the recent decision by CMS to cover only a subset of a new patient population shown to benefit from implantable defibrillators, despite full coverage by private payers, will leave many seniors at risk for sudden cardiac death.

To achieve the level of financial return necessary to support future R&D, there are several important issues to consider. Drug pricing is a key factor in the reimbursement process, and it is essential that drug pricing, as well as medical technology reimbursement, be market based. In part, this necessitates that reimbursement for new technologies be dependent on the value they bring to patients and society. Market-based pricing ensures the funds required for continued investment in future R&D. On the other hand, price regulation stifles innovation, as is readily apparent in Europe, where price controls have contributed to a major decline in the productivity of R&D and a marked decline in the competitiveness of pharmaceutical industries. The United States is currently the only country to support pharmaceutical innovation through market-based pricing and produces the lion’s share of the world’s best-selling drugs. Profitability and thus reinvestment in R&D can also be augmented by minimizing the delay in getting drugs and devices to market through their prompt approval, particularly in the case of novel agents where rapid availability will also translate into more patients receiving treatment. Finally, we must ensure that policies are enacted to guarantee diffusion of innovative medicines and devices to all those in need. Again, lessons can be learned from Europe where, because only a limited proportion of the population may receive available treatments because of cost-containment strategies, medical treatment can sometimes be construed as suboptimal.

An Alternative Approach to Healthcare Reimbursement: Foundations for a New System

We propose a new approach to healthcare reimbursement, one that judges healthcare interventions and innovation not just on the basis of fiscal cost but also in terms of value, as measured from a system, patient, and societal perspective. This dictates that we consider health care as an investment and evaluate products and services in terms of their return on investment. Using this approach, healthcare management would focus on improving the timeliness and manner of care delivery to optimize the resulting clinical, quality-of-life, and economic outcomes. Cost control would result not from delaying or limiting access and controlling unit costs but from avoiding unnecessary or inappropriate interventions and encouraging quality care.

This approach would require dramatic changes in how we pay for health care and what we pay for. In short, the reimbursement system would need to directly reward specific provider and patient behaviors that it wants to encourage, including those that target prevention. Reimbursement to providers would also be based on commitment to the overall health of an individual and community. The federal government is certainly starting to realize the importance of this, as evidenced by the recent launching of a 3-year pilot project in which participating hospitals are ranked publicly on the basis of quality measures and are rewarded with incremental reimbursement according to the level of care provided. Reimbursement mechanisms would also support improvements in information and decision support systems that allow providers to monitor and improve the quality of care. In the case of the patient, their active and informed participation in healthcare decision-making would be encouraged. In this regard, they would be given objective assessments of the value of healthcare options and share more directly in the costs of health care. This would discourage inappropriate or excessive utilization. However, continuous monitoring of the outcomes, both intended and unintended, of such cost sharing would be essential to ensure that any negative impact on the quality of care, especially in vulnerable populations, is minimized.

Finally, for the patients of today and those of the future, the system would encourage the use of innovative drugs and medical devices. There would be incentives for the system to rapidly adopt, appropriately reimburse for, and promptly disseminate new innovations, such as drugs and devices that improve patient outcomes. These developments are the cornerstone of our ability to improve patient care in a cost-effective manner.

The Imperative for Innovation: Meeting the Expense of Future Health Care

If health care is an investment, then is innovation worth the future return? Environmental changes in the United States and globally suggest that medical innovation is and will continue to be more than just “nice to have.” It will be an essential part of the solution to an emerging crisis. Shifting demographics over the next 20 to 40 years will create huge challenges to our ability to provide and fund health care. Specifically, with the aging of the “baby boom” generation, we can expect an increasing focus on dealing with chronic and degenerative diseases. The potential costs of this are staggering, and more effective treatments will be critical to our ability to control these costs.

Let us take Alzheimer’s disease as an example. Alzheimer’s currently affects an estimated 4 million Americans and costs US society approximately $47K per patient per year. Unless treatment options improve dramatically, an estimated 10 million will suffer from Alzheimer’s by the year 2050, and the future expenditure on this debilitating disease will be huge. Treatments that could delay the onset of disease by as little as one year would result in 770,000 fewer cases in 2047 and create enormous savings.

In the case of cardiovascular disease, the cost in medical expenses and lost productivity is estimated to reach more than...
$351 billion in the United States this year.\textsuperscript{22} Heart failure alone affects nearly 5 million Americans and costs the nation more than $24 billion.\textsuperscript{22} With an aging population and a marked increase in the prevalence of both obesity and type 2 diabetes, the incidence of coronary artery disease, heart failure, and stroke is undoubtedly set to increase, with a concomitant financial burden.

Higher healthcare costs are thus inevitable, in part because of aging populations but also because of the growing demand for quality health care from an increasingly wealthy and informed society. The central question then is, “Can we afford to pay more for health care?” The proportion of gross domestic product spent on healthcare costs has risen from 5% in 1960 to 13% in 1999 and is set to rise further. However, as personal wealth grows and absolute spending increases, we can afford to spend a greater dollar amount and share of income on health care.\textsuperscript{23} This is not to say that we should be cavalier with our healthcare spending. The goal must be to improve quality while controlling costs. To achieve this, appropriate strategies must be developed through a collaboration of payers, consumers, and providers, as well as the pharmaceutical and medical technology industries. The important role of innovation in ensuring an efficient and effective system and reducing the prevalence of and burden of disease must be recognized, protected, and encouraged, and all stakeholders must play a part.

\textbf{Concluding Remarks}

We believe that the current US healthcare system supports some of the finest health care worldwide. There is no room for complacency, however. Its sustainability is questionable, and major change is essential to address the evolving fiscal crisis while ensuring the provision of quality health care. Health care must be seen as an investment because promoting a healthier nation will improve quality of life, increase productivity, and promote economic growth. With the increasing burden of chronic disease, such an investment is not a luxury but a necessity. Public policies to encourage the development and dissemination of innovative pharmaceuticals and devices are a key step in attaining these goals and will dictate the future of health care.

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\textbf{References}


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