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Health System Reform: The Value And Price Of Innovation



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HEALTH SYSTEM REFORM: THE VALUE AND PRICE OF INNOVATION

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Introduction

There will be a presidential election this year and it is already evident that reform of the health system is one of the public's highest priorities. This public concern offers the first real window of opportunity for change in over a decade. During this time a number of the basic assumptions about health care have changed. For decades the debate about health care revolved around quality, cost and access. It was assumed that maximizing all three simultaneously was not possible. Further, it was assumed that it was important to focus on cost and access since access to the system would also assure access to high quality care. Good data indicated that failure to provide access resulted in undesirable health outcomes. It was also a given that better quality cost more and that decreasing payments for services would reduce quality.

However, the recent set of IOM studies beginning with *To Err is Human* demonstrated that quality and even safety were by no means assured and that better quality when defined as including efficiency might actually be cost saving.

These observations, coupled with growing angst about the health system, have fueled the ongoing debate about health system reform. In this paper, we will examine the role that innovation might play as we grapple with reforming this nation's most complex social and economic institution.

Innovation

In most retreats of health care professionals, they state that they value innovation highly. It is not clear, however, that all would agree on what they mean by innovation, therefore, we need to define what we mean. Innovation is the successful exploitation of new ideas. The economist's addition to that definition is that it must increase value. Thus, innovation is the introduction of something new and valuable. Since there is a natural limit to what can be accomplished by doing the same things better and better; innovation should also provide the capability of improvement beyond what can be accomplished simply by reorganizing and reengineering. We should seek innovation that sets a new baseline from which improvement can proceed. This definition requires not only an idea but its implementation.

The idea may or may not be creative in Bronowski's terms (see page 22), it could simply be the logical solution to a problem. In health care, innovation theoretically could create a new vision for the entire system. The new vision could then direct organizational change, thus improving the way in which we operate. New knowledge should underpin organizational change and be the way we approach problems and educate the next generation of health professionals. Finally reimbursement should facilitate or at least not hinder reform.

Innovation in health care must take into account a few additional concerns.

First and foremost, the need for health care services will not stop while we are innovating. Thus, any innovation must assume that while moving from idea to execution an acceptable level of care is assured to the public . The greater the change produced by innovation, the more critical it is to assure a safe, effective transition period. This concern may dictate the use of pilot programs and/or may limit the number of participants to a manageable size.

Second, one person's increased value may be another's burden. Consider the already tense relationship between insurers, purchasers and professionals, or the tension between the pharmaceutical and device industries and hospitals and physicians.

Third, the number and variety of stakeholders necessitates an acceptable process of inclusion in decision making. The failed Clinton Plan almost certainly owed a part of its failure to being a too closed process.

Innovation could be as narrow as a better billing service or as broad as reorganizing the delivery system. We will try to work from the broadest view down to other critical aspects of the system.

Innovation at the system level would seem an obvious need in circumstances when more than half of the population is unhappy about health care and the gap between theoretical or perceived best practices and actual care are disturbing. There are even models of success at the international, national and local levels to learn from. But there is no consensus on what design is best for this country and even less on the policies to get us there. We lack adequate mechanisms for bringing all stakeholders into the process. One could argue that the demographic and geographic variation in this country make differing opinions reasonable, even necessary. One might seek solutions that are national with standards of access and performance agreed to but allowing for variations in structure and financing.

The advantage of starting at the system level is that it provides a framework into which narrower improvements may be seen as supporting the broader vision or not. Presumably when we have to choose between options, it would focus us on those that support innovation in the broader system.

We have gone as far as we can without actually stating something about the broader system. According to the Institute of Medicine, the purpose of our health care system is to continuously reduce the impact and burden of illness, injury and disability and improve the health and functioning of the people of the nation.

To accomplish this, it would focus on improving:

- *Clinical quality*, which encompasses effectiveness, safety, timeliness, and equity.
- *Patient-centeredness*, an attribute of care that reflects the informed preferences of a patient and the patient's significant others, as well as timeliness and equity.
- *Efficiency*, defined as achieving the highest level of quality for a given level of resources.

I will start with a modest proposal: my own vision of the health system. Our system of care should maintain and/or restore the health of as large a proportion of our population as possible. When it cannot protect or restore health, it should protect functional autonomy and relieve suffering. This proposal increases the importance of preventive and rehabilitative services as well as of long term care. Since patients, providers, policymakers and payors will have different priorities and will value differently the many aspects of the system, we need performance standards that address all of their concerns. None of the parties at interest can or should control the entire framework for defining quality.

If we had agreement on the goals of a system, we could begin the debate on how to reorganize to meet these goals. We would ask who, what, where and how health care should be delivered. When we need data to answer those questions, we would be defining one agenda for research. The more firmly we base our answers on evidence, the more strongly we can insist on performance measures. We would be served best by a system that includes all who receive

care. Basic benefits will have to be defined and insured, but there would also be the option for additional coverage. We will have to have competition not only for care but for coverage.

Once we have ground rules for coverage we can then let market forces operate. Managed care in its best form will continue to be important, but must focus on the care provided and be based on data. Of course in my vision we must continue to invest in research and innovation.

Since we are clearly not doing as well as needed to execute on this proposal, we need to think about how such a system would differ from the present. Are there some models of such a system? Could innovation help move us towards such a system and if so, who would lead and how could we catalyze and gain support for such innovation?

System Change

International Models

There are numerous models of health care that might direct our attempts at innovation. In Europe comprehensive health coverage is already universally available. Therefore, efforts have focused on the content and organization of health care in each country.

Denmark has many of the most successful innovations as defined by public satisfaction. Care is organized as patient-centered primary care. Coordination of care is critical as is its twenty-four hour availability. The system is supported with excellent information technology. Telephone

and email services are available and physicians are paid for these services while patients have no cost sharing for physician or hospital services.

The Dutch have also focused on primary care availability with success even though they have a large percentage of solo practitioners. They have accomplished these levels of public satisfaction while implementing government-sponsored managed competition.

Germany offers extensive quality benchmarking for hospitals - three hundred indicators for twenty-six conditions. These measures are used to target and improve performance at weaker hospitals. They have also focused on disease management and have clinical guidelines for chronic care.

The United Kingdom has an elaborate system for practice evaluation which though of high quality is still a bit too slow and cumbersome. Nevertheless, incentives for quality targets have dramatically changed practices and by the way increased expenses.

Nearer to home is the Canadian system. It is held up as a model of what we might accomplish but, recently it has come under fire from growing public unrest with the availability of services. The Canadian system is however a provincial one and might be a instructive for State reform.

These models of system innovation might serve as a stimulus to us to adopt or to adapt some of them to health care in the United States but they are not likely to be easily transferred. It is worth noting that aspects of care which are by now routine in other countries may still be innovative when brought to the U.S.

Unfortunately, primary care which seems most important in the success of these countries' systems is actually in short supply in the U.S. In parts of this country, one cannot even hire primary care physicians, let alone get an appointment with one. We have also been slow in providing the information technology infrastructure to hospitals and physicians necessary to do the kind of practice evaluation carried out in Europe.

USA Models: Federal

This country also has models of the federal government providing comprehensive health care. There is the example of the VA health system which in a few short years has improved the organization and delivery of care and has demonstrably improved safety and outcomes. The VA system seems to work well enough for its defined population but it is not clear how readily it could be expanded to include the broader population with its needs for pediatric and women's health care.

The military health care system, extended to dependents, deals with more of these latter issues but recent public criticism of its quality make it a less attractive model. The Indian health service does provide comprehensive care to a circumscribed population. The federal employee health benefits program provides coverage with more choice for patients but, until recently, less attention to content.

Medicare, the most expensive federal program, until recently has focused primarily on coverage. However, Medicare is now attempting to value performance. It is experimenting with ways of documenting the desired level of performance and paying for it. Conversely, it is not paying for egregious/adverse events.

The variety of federal programs , none of which have been copied or expanded, suggests that the attempts to direct care more broadly from a federal level is at least difficult and at worst not sensible.

USA Models: Other

Delivery of health care is a local phenomenon and monitoring it at least at present is as well. Therefore, effective system design is more likely to be carried out at the level of cities, states or regions. To get a sense of the variation to be addressed, imagine designing a care system for New England with its dense population, ten medical schools, plethora of high technology

resources and short distances. Now consider the University of Washington's efforts in the WWAMI program addressing the needs of Wyoming, Washington, Alaska, Montana, and Idaho with one medical school and thousands of miles between services.

While it might be possible to have a national policy governing equity, content, and coverage, the organization to deliver on these directives would necessarily have to take into account the great demographic, geographic and economic variations in this country.

States have also been experimenting with improved coverage and better documented care.

Massachusetts perhaps the most visible recent experiment, has employer and individual mandates, an innovative mechanism to manage coverage and a process for matching coverage to better care.

Non-governmental systems of health care guaranteeing a standard of care and the rationalization of resources have had some success. Examples such as Group Health of Puget Sound or Kaiser in northern and southern California indicate that improved systems of care are possible. Partners HealthCare in Boston and Barnes Jewish Christian Hospital System in Missouri demonstrate that academic centers can also be included in integrated systems. Note that the scope of these systems is at best regional and they are of sizes to allow effective management.

Thus, while the Federal government, alone or in a public/private partnership, may define benefits, and assure safety and equity of a health system, the actual development and implementation of better systems of care will occur most effectively at the regional and state level. Of course, the federal government will still have to continue its financial underpinnings of any new system. This will likely be through modification of Medicare and Medicaid programs.

A step that might facilitate our move towards system redesign is an exciting development of the Commonwealth Fund's Task Force on a High Performance Health System. The Commission with broadly representative viewpoints has agreed on the definition of a high performance health system and created metrics for evaluating the level of performance of countries and states. The first report "*Why Not the Best?*" developed by the commission has generated wide public interest. For the sake of discussion I have included Table 1 that outlines the Commonwealth Fund's description of a high performance health system.

Table 1

Commonwealth Fund:

1. *Automatic Affordable Coverage for All* – Extend comprehensive and affordable health insurance to all and ensure seamless transitions in coverage so that no one goes without coverage. The Commission recommends sufficient financing to attain his goal within a reasonable period of time. Financing should be a shared responsibility of federal and state governments, employers and individual households and other stakeholders.

2. *Aligned Incentives for High Value Care* – Ensure that American families can afford health coverage and health care, and that incentives are aligned to achieve economical and effective use of money spent on health care. Effective progress in slowing the growth in health care costs requires fundamental provider payment reform that would:

- Reward results in achieving both high quality and prudent stewardship of resources;
- Move away from the current reliance on fee-for-service payment to one of shared provider accountability for the

total care of patients; and

- Correct the imbalance between primary and specialty care.

3. *Accountable Coordinated Care* – Organize the health care system to make it easy for patients and families to navigate our complex health care system and receive excellent care from providers that are linked with each other and with hospitals, other services, and the broader community. To mend the fragmentation, waste, and complexity that currently exists, the organization and delivery of health care services should be restructured and should promote primary care delivered in patient-centered medical homes. The goal for the future should be a choice for every patient of receiving care through an integrated delivery system, accountable care network, or other organized delivery system that provides and coordinates a wide range of health care services, including primary and specialty physician services, hospital care, and rehabilitation care.

4. *Aiming Higher for Quality and Efficiency* – Invest in public reporting, technical assistance and the infrastructure that supports the health care system to help all providers and care systems deliver the best care possible to their patients in a culture of innovation and

improvement. Sufficient funding and leadership should be committed to achieve universal implementation of electronic information systems within five years, including an electronic health record with all a patient's pertinent information accessible to the patient and to all the health care professionals caring for that patient.

5. Accountable Leadership – Provide the national leadership and collaboration and coordination among private sector leaders and government officials that are necessary to achieve national goals for a high performance health system. A national entity or consensus process should be established to develop national aims for health system performance, specific priorities and targets for improvement, a system for monitoring and reporting on performance, and recommending the necessary practices and policies required to achieve those targets.

There is growing agreement about the components of a high performance health system. The Commonwealth Fund Task Force has provided metrics that can be applied internationally, nationally, or regionally. The fact that their study shows that virtually no place or system uniformly achieves best practices, enforces our need to think about system redesign. In a subsequent publication the Task Force presented more detailed data on state by state performance. Though a number of states had glaring deficiencies, it is encouraging that those found to be most deficient have been most responsive in seeking ways to improve their performance.

Clearly, innovation, at the national level will not be transforming or even likely. Probably innovation will be generated at the regional, state or city level. States producing legislation have generally focused on coverage rather than content. However when coverage is linked to performance measures, it may actually improve quality as well as access. It is also possible that when more people are covered, providers will be more willing to experiment with changes that would be otherwise too financially risky.

The stimulus for innovation at the system level ought to be the obvious need to improve care efficiency and effectiveness and that there are already models of success such as Kaiser or the VA, both of which operate within fixed budgets. But the barriers to such system redesign are obvious. There is a lack of consensus about the best design and means for getting there.

Although there are some models of success, there is a paucity of acceptable ones. Furthermore, there is at present is no mechanism for bringing all the players into the process.

In summary, there are aspects of health system reform which reside at the Federal or national level. The Federal government should be responsible for setting standards as for benefits and for information technology. Obviously it is responsible for setting the reimbursement standards for programs such as Medicare/Medicaid/and any restructured financing of a reformed system, but it also ought to be responsible for establishing ground rules for other reimbursement systems to assure equity in the system. The Federal government is presumably responsible for deciding on safety and efficacy of drugs and devices via the FDA. It has not, however, developed means of evaluating procedures and has not done well in determining comparative effectiveness between drugs, devices and procedures. These comparative evaluations and measurements of cost effectiveness are essential in reforming the system. These measurements are so critical to any national health system that they require the credibility of a combined public/private process or a more independent Federal system such as the Federal Reserve System.

Organization

The failure of numerous efforts at the federal level and the growing number of exciting experiments at the state and local level suggest that the latter areas ought to be the sites for

innovation. If we had general agreement on acceptable standards for the system, we could address the way in which one would organize within those sites to deliver care. The potential clinical and financial value of such reorganization should stimulate investment in innovation. The barriers to organizational change include the diversity of sites and organizations, inertia, and distrust of change within such complex organizations, the cultural challenges and the potential financial risks.

The unit of organization may be a single health professional such as a physician or nurse practitioner with or without the availability of a pharmacy. Organizational complexity will increase when it includes several health professionals and a rural clinic or hospital. At this level of complexity, components will have to be linked by adequate communication systems and transportation capacity. The communication systems based on good information technology can also be used as expert systems for providing updated consultation. Telemedicine can be of great help and although it has been used for some time, a more widespread and innovative use of this approach is important for sparsely populated areas. Clearly access for patients and coordination of professionals are essential elements for delivering the standards of care which although set nationally, must be able to be delivered in rural and semi-rural settings.

Another level up in organizational complexity is represented by groups of health professionals, physically or virtually connected, affiliated with one or more community hospital. At this level,

specialized professionals and services are more readily available. The effectiveness of this organization will again be a function of geography and infrastructure. At this level some structured relationships to more advanced care such as tertiary care hospitals as part of or separate from academic health centers is desirable. The addition of academic health centers provides highly specialized experimental and expensive services.

The complexity of these latter organizations has demanded integration of services to achieve efficiencies and to improve quality. There are opportunities for innovation in defining primary responsibility for care and coordination of services: the equivalent of what pediatricians have defined, as “medical home.” Also it is essential to provide information infrastructure to reduce duplication of and loss of tests, to assure access to records and to permit better communication frequently without additional costly visits. The Electronic Medical Record (EMR) has proven to be an excellent tool for monitoring and assuring quality. Patients should be able to have their medical records consolidated. These records should be portable for the patient and accessible by health providers. This goal has proved more complicated than having EMRs for physicians, but it must be ultimately achieved.

The role of integrated health systems is being more readily accepted but there are important challenges demonstrated by recently established systems.

Integrated systems of care whether real or virtual, are an essential element of improved quality and efficiency. To establish a smoothly functioning system requires choices at several levels.

First, one must choose between centralized or distributed forms of governance. Generally, some balance between the two is effective, but there needs to be an ultimately responsible place for contentious decisions. In fact, the role of governance in coordination of efforts is an important decision. If the integration of care is seen as revolution rather than evolution, achieving cooperation will be harder. Finally, physicians, the most threatened and most mobile participants should have a role in governance.

The organization of the management group faces many of the same choices about centralization versus distribution of responsibility. There is always tension between the system and its component parts. Physician participation is critical, particularly in demonstrating that management adds value and is not an unnecessary burden.

The role of physicians in clinical organizations and performance should be obvious, but the independence and competition of those being integrated make this area particularly challenging.

If the physicians believe that integration benefits their patients, that they are themselves aided by integration, that integration is inevitable, and if the reward system values integration, reorganization will proceed.

Physician participation, obvious for clinical services, has proven as important in management and governance. The critical role of nursing, other health professionals and the effectiveness of team care, has allowed experiments in reorganizing care to improve quality and efficiency.

The role of management in organizational change requires special comment. Organizations that have focused on immediate results have not up until now embraced a culture of innovation.

Bringing research inquiries to management by using scientific methods to create new insights is just beginning to gain traction. When remembering that management is now responsible for vast resources that ultimately affect patient care and the ability of health professionals to perform, adding rigor to their inquiries seems necessary.

Thus, one of the great challenges in innovation in health care is to design operational entities that are true to the principles of a high performance system and are appropriate to the population needs and the geography with which that they are faced.

Research

None of this will be worth the effort if we do not do a better job of defining the content of care.

This is the area where creativity is most valued because it is the area in which research beginning at the fundamental level advancing through translation to clinical application is required. The support of fundamental and undirected research as a federal responsibility in the modern era dates from Vannevar Bush at the end of WWII. While Bush's classic "Science the Endless Frontier" provides a too simplistic model of research, it nonetheless establishes the need for new knowledge and creates a Federal role in supporting that research.

Bush saw basic science moving through translational steps to exploitation for the public's benefit. Though this linear-directional model was useful in gaining public understanding of the value of science, it did not give enough weight to exciting discoveries moving in the opposite direction. For example, we knew the value of vaccines and used them before we had real knowledge of microbiology and immunology. In fact, the latter fields developed in part to explain the success of vaccination. The public has continuously valued research but too often has been exposed to an unproductive debate about the value of fundamental science versus the value of applied science. I like Pasteur's view. He said there is no such thing as applied science. There is only science and its application and one without the other is like a tree without branches and leaves.

It is worth remembering why we do research and why the public supports it. First to quote myself: We do research because science is one of the few universal endeavors; it has its own ethos, its own language and its own rules, which should be understandable in any country. The ground rules for establishing a postulate for designing an experiment, for collecting data and for presenting those data are universal, and because they are universal we can debate the interpretation of those data. All who participate come to share a body of knowledge to which we have all contributed, and we are all responsible for shepherding this knowledge and moving it forward. If one accepts this idea, the science that generates new knowledge and raises new questions is more valuable than the science that reaches an end by answering the question at hand. Thus begins a hierarchy of values within the scientific community and for the support of science.

Second, we embrace creativity as defined by Bronowski. Bronowski said that creativity is seeing the connection between things that were not previously seen to be connected, so that, when you finish explaining what you have seen, there is a new way of looking at it; and everybody else, once the connection has been explained or demonstrated, will then say “Of course, I now see that.” In this definition of creativity you find no distinction between research in basic science and that in clinical science. The methodologies vary, but creative research can be done with old methods, and mundane research with the latest methods. Methodology does not define creative research but may facilitate it.

I like Bronowski's definition because the opposite of creation is simply chaos and not destruction. In health we have too often defined creative research by discipline (ie., genetics, physiology, cardiology) rather than by the unique insight that it brings to whatever question is being addressed. We have valued creative and undirected fundamental science above the application of science to the improvement of the public's health. The public, however, supports research at the basic level because it has been promised that basic observations will be translated into health benefits. The narrow view of bioscience as going from the basic science through translation to clinical application is almost certainly only a part of the process. In fact in many circumstances as noted earlier, clinical observation has driven back through inquiry to stimulate basic science.

The question of whether the most creative science which simply leads to further inquiry is more valuable than the application of that science to the improvement of health is a debate to be avoided since if either view dominated, it would injure the biomedical research enterprise.

We also do research because it brings recognition and with it promotion and/or access to resources. Research also leads to new products or procedures with true financial returns on investment.

Support for biomedical research at the federal level has for decades been the responsibility of the NIH and NSF, and more recently the VA, the EPA and Department of Defense. States wishing to attract life sciences have been known to compete with each other in funding research. Obviously foundations and industry according to their missions or responsibilities have also funded biomedical research. I could not imagine that such funding would not be sacrosanct. In fact, it has not been, with NIH funding flattening or decreasing in real terms over the last few years. The impact of uncertain or inconsistent funding has created problems for academic institutions and indirectly the industries that depend upon that research. There are numerous challenges in research-based industries such as the pharmaceutical, device and biotechnology sectors. These industries are clearly driven by innovation but generating that new knowledge and getting return on investment is getting progressively more complex. This country has had an excellent record of capitalizing on a university-industry partnership and has kept us in the lead in the generation of new intellectual property.

Scientific research is one of the key drivers of innovation. Any discussion of science and health requires an expanded view of what are the sciences of health. Over the past century biology has assumed the primacy in the sciences of health and might be viewed in terms of attraction to bright young people as comparable to physics a century ago. One could argue that the explosion of biologic research which has fueled changes in health care and other industries such as biotechnology nonetheless provides too narrow a view. Going forward it is almost certain

that the sciences of health must include mathematics, chemistry, computer science, neuroscience, nutrition, behavioral sciences, and international health. In view of the dimensions of the health care system, one might also add management science to this list.

As the cost of research increases, there is growing pressure for enhanced research productivity. There is also a growing pressure to demonstrate that there are benefits from the research that is supported. What is asked for is more effective translation of basic science to clinical application, better evaluation of emerging scientific areas to guide investment to where clinical need is the greatest, not simply where commercial opportunity is perceived.

These pressures and opportunities logically lead to calls for more efficient transfer of knowledge between academia and industry in both directions.

With apologies to Vannevar Bush for criticizing his linear model, I am now using it to illustrate the traditional contributions of academia and industry to bringing an idea to a product (Table 2). To the extent that this process can be made more efficient, without sacrificing safety, everybody is benefited. Recognizing that a high percentage of drug uses are off-label and that devices are continuously improved in use, the post marketing period would seem a particularly fertile area for innovation.

Table 2

Academia

Industry

BASIC IDEA

Basic Sciences
Engineering
Medicine
Management

Basic Sciences -Physical
Engineering
Basic Engineering Concept
Computer Ware

CONCEPT OF DEVICE

Knowledge of Disease

Knowledge of Design
Strategic Goal
Focus on Product or Process

PROOF OF CONCEPT

Broad Meaning
Clinical Insight
Laboratory Champion

Team Approach
Sharp Focus

CLINICAL PROTOTYPE

Design Clinical Studies
Generalize Potential Uses

Manufacturing
Examine Potential Uses
Move to Specific Diseases

PRODUCTS - EVALUATION

Design Clinical Trials
Explore Other Potential Uses

Design Clinical Trials
Manufacturing
Focus on Product

MARKETING

Opinion Leaders

Marketing Plan
Marketing Team

POST MARKETING MODIFICATION

More Skilled Use
New Uses - Same Design
New Uses - New Design

Better Devices
Better Manufacturing
New Design
Improved Marketing

Managing a relationship between academia and industry should be possible but it has certainly proved difficult. New mechanisms of organizing the exchange must protect both parties' interest. It is critical to explore ways to achieve the proper balance between commercially-sponsored research and have room for not-for-profit support.

A special case is research into management of the enormous enterprise and its vast resources. Management research is systematic inquiry designed to affect decisions, actions and results of organizational leaders and line managers that uses recognized scientific methods and that results in peer-reviewed publications or work of comparable quality. This is research beyond what would be included in analysis that is usually a part of managerial decision making, but not intentionally publishable according to scientific standards.

Any organization must address the content of care - the content would require identifying and introducing best practices and continuously informing best practices with new knowledge. New knowledge might be fundamental, drawing on our expanded view of the sciences of health. It must include integrated biology (systems biology) and translate our knowledge into improved prevention, diagnosis and treatment. Clinical trials and population-based research should provide a foundation for evidence-based practice and public policy. A critical part of the application of new knowledge is the ability to evaluate new technology and to place it in proper perspective. Care should be organized with great flexibility for the varying populations and

geographies of this country to meet the aims of the health care system described above and to ensure the content is continuously updated by new knowledge. The organization of the care should dictate the needed infrastructure and clearly health promotion and its availability are essential. The desired structure and content should direct reimbursement which should align financial incentives to catalyze the desired outcomes.

To sustain these changes and directions would also require innovations in health professions education which have been slow to emerge.

Education of the Professions

Medicine is a learned profession. The best definition of a profession is Brandeis'. Slightly modified, he said that a profession has the following characteristics (responsibilities): 1) The keeper of body of knowledge, a portion of which is derived from experience. It is responsible for advancing that knowledge and passing on to the next generation. *The mandate to teach and do research* - 2) It has a code of ethics which includes a component of service to others. *Stewardship of knowledge and skills which should be made available to others* - 3) It sets and enforces its own standards. *The mandate to define and enforce best practices* - 4) It values performance above reward. These professional responsibilities are the social contract between the profession and the public. Fulfilling this contract is the basis for the public providing the profession with autonomy and respect.

It is really the first responsibility that encourages innovation, but all can be seen as appropriate areas for innovation when engaging in the debates about health system reform.

The education of physicians needs to be broadened to include all of the sciences of health as well as ethics and political science. The obvious value of a shared knowledge base with nursing, public health and allied professions speaks to the need for a common core educational experience for students in all of these fields. The expanded global economy and the ease of travel have reminded us of the importance of public health as a part of international health.

All students should be trained in problem definition, data collection and statistical analysis. The clinical experience should more closely mirror clinical care needs. It should reflect the value of teams and of the coordination of care. It should teach the importance of accepting primary responsibility for a patient and/or family.

Educating teams of health professionals addresses cross professional concerns. Educating individuals over a career is also critical. It is possible to do a much better job of coordinating educational content and experience from undergraduate to medical, to post graduate to continuing career needs.

A bias of mine is that historical context is useful for understanding how we have gotten into complicated situations. It also may guide to what has and has not worked in directing change.

Finance

I have purposely left any comment on financing the system and its possible reorganization until the end. This gives me a perverse pleasure since almost all efforts at health care reform over my time in medicine have focused on finance and not on health care.

With the efforts of the IOM and the Commonwealth Fund and its recent efforts to reward performance, we are getting closer to defining what performance we actually want.

Performance should ultimately be based on well-controlled clinical studies. It should also value other desired qualities such as patient-centered care and efficiency. It should reward absolute levels of quality as well as improvement in the quality of care delivered.

A more complicated challenge is to foster coordination of care. Therefore, rewards should be provided to caregivers who are the principal responsible source of care (Medical Homes). Since our ability to provide care and to monitor the care delivered depends on adequate information infrastructure, the reimbursement system should provide for equipping, maintaining and upgrading of information technology. If we wish to have health care providers furnish data and

ultimately make it public, we should take some responsibility for providing information technology. If the Hill Burton Act could be justified as being in the public interest when there was a clear need for more hospitals, a similar and less expensive investment to provide the needed information infrastructure should follow similar logic.

Similar approaches for management decision making would seem reasonable, even required.

The payment system should support a care system which has the capacity to moderate expenses.

It is worth commenting on how financing can catalyze innovation.

Small investments can stimulate major responses. At Partners HealthCare \$300,000 was provided for five or six, \$50,000 to \$60,000 seed grants. The ground rules for applying were that there be co-principal investigators (from MGH and BWH) and then the science would dictate an award. Over ninety applications were received and six were funded. But more than twenty of the other applicant groups pursued other funding and continued to work together.

Larger investments that are directed at well defined needs may have remarkable ROIs For example, at MGH investing \$1.5 million/year for five to ten years allowed the development of infrastructure for clinical/translational research that provided important well attended

educational programs and resulted in outside funding several times the investment.

Truly innovative programs such as The Center for Integration of Medicine and Innovative Technology (CIMIT) have led to collaboration between the Hospital, the Medical School, Draper Labs, MIT, Boston University and industry. The program, seeded with funds from Partners, has continued successfully for ten years and has spawned other similar programs in the U.S. and has been the model for the Wellcome Trust establishing similar sites in the U.K.

Mission related strategic investments such as The Disparities Solutions Center and the Institute for Health Policy have records of sustained scholarly output that in many cases can be translated into better care or better informed policy.

These examples of stimulating innovation are from a time when mission and opportunity were aligned and resources were sufficient. A more telling example of the relationship between resources and innovation occurred with the founding of Partners HealthCare. At that time in the early 1990s, there was an economic downturn in Massachusetts and managed care was increasing in strength. The result was that twenty percent of the beds at the MGH and fifteen percent of the beds at the BWH were closed. One possible solution would have been for each of the institutions to have hunkered down and waited for a new equilibrium in funding. Instead stimulated by traumatic cost containment efforts, the two institutions created Partners

HealthCare, an integrated health care system. The merger of two academic institutions to create a regional health system was certainly innovative at the time. Partners HealthCare required changes in governance, the organization and staffing of management, coordinated decisions about clinical services, and even a restructuring of the research and education activities. This development which went well beyond cost-cutting in response to cost conscious reimbursement illustrated that innovation need not be dependent on increased availability of resources.

Partners subsequently developed into a highly successful regional health system with a strong academic base. Success led to the availability of resources that funded the mission driven programs described earlier. The experience with innovation in good times and bad leads to some speculation about the impact of health reform resulting in greater cost consciousness.

Assuming that a reformed health care system would, as the IOM suggests, be cost-conscious, how might such a shift in emphasis affect innovation.

One might speculate that cost-consciousness would neither stimulate or reduce innovation, but might refocus it. At the broad system level, it would certainly stimulate innovation in the organization and management of an inefficient system with gaps in care and unnecessary duplication of efforts.

It would enforce the need for better technology assessment and measurement of comparative

effectiveness. Measuring comparative effectiveness should allow better calculations of cost-effectiveness which could then inform reimbursement. The critical nature of these assessments makes clear the need for a trusted process for these determinations. This need should stimulate innovations in the structure and process of technology assessment.

The FDA serves as the base for determining safety and efficacy of drugs and devices. Cost consciousness should pressure the FDA to improve its efficiency and perhaps expand its responsibilities.

The effect of cost-consciousness on drug development is less predictable. It was assumed for example that cost containment efforts would make investment in me - too drugs less attractive. But in fact second to market drugs, innovatively promoted more than repaid the companies investment in R&D and provided a frequently cheaper competitor to the first to market drug. The impact of cost containment in pharma's decisions to develop drugs with smaller market potential is unclear. The effect and cost consciousness in devices has also been hard to predict. It stimulated the innovation and adoption of a cost-saving technology such as the auto analyzer, but delayed the use of the clinically effective CT scanner.

Procedures are not regulated by anyone, but their introduction has been affected by reimbursement decisions. These decisions have not always been based on solid comparative

effectiveness data and institutions may be more wary of investing in these advances of cost-consciousness is too influential.

The effects of cost-consciousness at the organizational level might well be biphasic. The need to reorganize for efficiency would stimulate innovation. The need to organize for different geography and demography should also stimulate innovation. The risk to these efforts would come when the new and better, but far from perfect organization, is deemed good enough.

The challenge to innovation would come if instead of starting with the definition and goal of the system followed by the financing requirements, we started as usual with the financing. The risk would be that in trying to control expenditures we were too prescriptive about the structure and content of the system before we had the chance to innovate.

Research support would almost certainly continue to support creative (innovative) research. There might be more pressure to support clinical trials, but their expense has usually cooled enthusiasm where resources are constrained. High risk research would more likely be funded by institutions and/or philanthropy.

There are numerous efforts at funding innovations across the country with resources coming from operational surpluses, royalties from intellectual capital and even venture capital arms of

universities and medical centers. A more structured set of communications in this area might stimulate successful investment and avoid repeating errors. Given the charitable nature of most health providers it seems appropriate to expect some level of investment in innovation to improve quality.

Conclusion:

The health care system of this country is clearly in need of major reform or reorganization. Innovation defined as providing something new that actually works surely has a role to play in this process. (Table 3)

Table 3

STIMULI AND BARRIERS TO INNOVATION

	<u>Stimuli</u>	<u>Barriers</u>
System} Design}	<ul style="list-style-type: none"> -Clear need -Potential to improve care efficiency and/or effectiveness -Models of success 	<ul style="list-style-type: none"> -Lack of consensus on design and/or means of getting there -Paucity of acceptable models of success -Absence of mechanism for bringing all players into the process -Dependence on political process
Organization} of care }	<ul style="list-style-type: none"> -Clear need -Multiple attempts to reorganize -Potential clinical and financial value of reorganization 	<ul style="list-style-type: none"> -Diversity of sites and organizations -Inertia -Distrust -Cultural -Financial
Content}	<ul style="list-style-type: none"> -Need and opportunity -Evidence of ROI of research -Valuing research -Need for population-based data -Need for comparative-effectiveness process 	<ul style="list-style-type: none"> -Flat NIH filing -Varied valuing of research: <ul style="list-style-type: none"> -Individual vs. population -Fundamental vs. applied -Inconsistent funding – hard to build teams

There are numerous examples of more effective healthcare systems internationally and in the U.S. Unfortunately almost all fail to be generalizable to a nation as geographically, demographically, and culturally diverse as ours.

Thinking about where innovation is most needed and balancing those need against possibilities of success leads me to a simple conclusion. National standards for care, quality, access and equity may be achievable but real innovation, assuring that the standards are met, will require creativity, trial and error at the state or regional level. The numerous possible organizational solutions at those levels are where innovation should be sought. Lessons learned at these levels can be expected to feed back and improve national standards.

To be sure that we improve the quality of care as well as its efficiency requires investments in research. Research is inherently innovative, but to be sure the best products, procedures and services are provided will require innovative assessment mechanisms, probably in the form of government/private partnership.

To facilitate change will require a work force educated to be flexible and interactive. Numerous efforts at reforming health professions education are underway and should be supported.

Finally, the financing of health care reform should pay for what is appropriate and cost effective and not pay for what is ineffective or harmful and that would be quite innovative.

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