Fostering Innovation in Medicine and Health Care: What Must Academic Health Centers Do?

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Abstract

There is a real need for innovation in health care delivery, as well as in medicine, to address related challenges of access, quality, and affordability through new and creative approaches. Health care environments must foster innovation, not just allowing it but actively encouraging it to happen anywhere and at every level in health care and medicine—from the laboratory, to the operating room, bedside, and clinics. This paper reviews the essential elements and environmental factors important for health-related innovation to flourish in academic health systems.

The authors maintain that innovation must be actively cultivated by teaching it, creating "space" for and supporting it, and providing opportunities for its implementation. The authors seek to show the importance of these three fundamental principles and how they can be implemented, highlighting examples from across the country and their own institution.

Health innovation cannot be relegated to a second-class status by the urgency of day-to-day operations, patient care, and the requirements of traditional research. Innovation needs to be elevated to a committed endeavor and become a part of an organization's culture, particularly in academic health centers.

During his 2011 State of the Union Address, President Obama[1] noted, "The first step in winning the future is encouraging American innovation." Innovation, of course, has been a significant part of America's past as well as its present. Vulcanized rubber. The telephone. The polio vaccine. Magnetic resonance imaging. The Internet and e-mail, Google, iTunes, and Facebook. Next-generation DNA sequencing.[2] These were all game-changing innovations that have transformed our society.

There have been many forms of innovation in drug- or device-related biomedicine. Numerous authors and commentators have also emphasized the real need for innovation in health care *delivery* in addition to more traditional forms of drug- or device-related biomedical innovation.[3] It is well recognized that health care faces the linked challenges of access, quality, and affordability. There is general agreement that these issues can only be addressed successfully through new and creative approaches, which requires health care environments that promote innovation.

Such innovation must be allowed and encouraged to happen anywhere and at every level in health care and medicine—from the laboratory, to the operating room, bedside and clinics, and behind the scenes as well. In this article, we contend that innovation must be actively cultivated by teaching it, creating "space" for and supporting it, and providing opportunities for its implementation. We review the essential elements and environmental factors important for much-needed health innovation to occur, and make recommendations regarding the key steps health systems should take.

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Acad Med. 2013;88:00–00.
First published online
doi: 10.1097/ACM.0b013e3182a32fc2

What Is Innovation?

Let us begin with a definition for innovation. Management guru Peter Drucker defined innovation as "change that creates a new dimension of performance."[4] Michael Porter[5] said that "innovation includes both improvements in technology and better methods or ways of doing things. It can be manifested in product changes, process changes, new approaches to marketing, new forms of distribution, and new concepts of scope." Today, these two perspectives are particularly relevant to health and medicine because our health care systems need a new dimension of performance as well as a structured approach to turn current challenges into opportunities that transform the health care system itself.

When we consider innovation in health care delivery and medicine, we must first recognize that innovation can be stepwise, or it can be transformative. The former proceeds along a linear path, taking the next logical step in improving process in order to yield better outcomes. This type of innovation, as exemplified by continuous quality improvement, is important. In the rest of this article, we focus on transformative innovation in discovery science and delivery science.

Transformative innovations, such as those mentioned in the introduction, are game changers, and leapfrog current approaches to push the envelope of what we believe is possible. They are based on nonobvious insights that are then translated into novel, bold solutions. Such transformative innovations can revolutionize the status quo, as it did for the treatment of peptic ulcer disease (PUD).

Transformative innovation in discovery science

For many years PUD had been attributed to an imbalance between gastric acidity

and the integrity of the gastric mucosa. As a result, drastic surgical procedures such as vagotomy, gastrectomy, and Billroth I and II were developed because acid-suppressing medical therapy was often ineffective. The surgical treatment of uncomplicated PUD was rendered obsolete, however, when Barry Marshall and Robin Warren discovered that PUD was in fact due to bacterial infection with *Helicobacter pylori*. This discovery revolutionized the treatment for PUD. Today a drug regimen consisting of two antibiotics and a proton pump inhibitor successfully eradicates PUD in over 90% of cases.[6]

Marshall and Warren had to overcome deep skepticism of their findings, but they benefited from supportive environments, even from skeptical superiors. After finishing his training at Royal Perth Hospital, Marshall was offered an endoscopy post at Fremantle Hospital by Ian Hislop, who himself had a background in gastritis from his training at the Mayo Clinic. In his Nobel lecture, Marshall[7] quotes Hislop as having said to him at the time: "Barry, this is intriguing data. I think you're wrong but it is a curious finding and we need to look into it."

It was at Fremantle, where Marshall was permitted to continue his research, that he demonstrated in dramatic fashion (by ingesting a beaker of *H. pylori*) that the bacterium identified by Warren was in fact a pathogen capable of causing the symptoms of PUD, with Hislop himself performing the endoscopies and biopsies of Marshall that proved their hypothesis. Furthermore, a hospital-sponsored travel grant made it possible for Marshall to travel to a major international meeting to present these findings, an opportunity that he said was crucial to changing the minds of the scientific community.[8] An enabling environment was key to Marshall's groundbreaking work.

Transformative innovation in delivery science

Transformative innovation applies to delivery science as well as to discovery science. Delivery science studies the approaches to developing the most efficient ways to deliver care with improved outcomes. In *The Innovator's Prescription*, Clay Christensen and colleagues[9] propose two distinct approaches to improve efficiency and outcomes for care delivery: "solution shops," which are ideal for diagnostic dilemmas and treating complex chronic illnesses, and "focused factories," which are used in multistep but standardizable care pathways. More specifically, focused factories aim to streamline processes and reduce variability to increase quality while lowering per procedure or per episode costs. Both models have the potential to be disruptively innovative, a phrase coined by Clay Christensen, which is commonly defined as a process, service, or technology that dramatically changes or leapfrogs the status quo in such a way that it eventually becomes the new norm. However, one key challenge in health care, of course, is how to achieve this increased efficiency without dehumanizing patients.

Today some of the best examples of health care focused factories are found in developing countries, where limited resources are often the norm. The Aravind Eye Care System in India is one such exemplar. Since being founded in 1976, it has treated 29 million patients and performed 3.9 million eye surgeries and laser procedures, at a fraction of the cost in the United States or the United Kingdom. By the 1990s, each Aravind surgeon was performing 2,500 surgeries per year, whereas in other hospitals in India surgeons were doing 300 surgeries per year.[10] Aravind's process innovation enables tremendous productivity, clearly beneficial in a nation with 25% of the world's blind and where four million individuals develop cataracts each year.[11]

Another example is LifeSpring Hospitals in India, which has delivered more than 11,000 babies through use of improved processes mixed with "right-skilling" to have the most cost-effective, properly trained individuals performing specific tasks. Both Aravind and LifeSpring are examples in which care is made accessible to a much larger patient population at a fraction of the cost of usual specialty care, because of the combination of process streamlining and improvements in the appropriate use of human capital.

This "focused factory" concept has also been adopted and tested by health care systems in the United States and other developed nations. One famous example is the Shouldice Hospital in Ontario, Canada, a focused factory concentrating almost exclusively on the surgical repair of new hernias. Using focused factory approaches, it has been able to design the flow of patients through the operating room to match the time required to repair the hernia. Also, for most surgeries, general anesthesia is not administered; instead, a sleeping pill is given with a local anesthetic to the surgical site, which enables the patient to be ambulated more rapidly after surgery, ultimately decreasing the amount of time spent in the hospital.[12]

How Do You Foster Innovation?

Innovations can and should occur anywhere in health care. Academic health centers (AHCs) in particular have long been traditional hotbeds of innovation, where health-oriented discovery science takes place. AHCs are where there is access to patient populations, data sets, and biological materials necessary for translational research, and where countless opportunities to identify and explore unmet medical needs exist. Many scientific breakthroughs that have dramatically improved human health, such as statins and some HIV medications, have been made within academic medical settings.

Over the past decade, 8 of the last 10 Nobel Prizes in Medicine and Physiology were awarded for research conducted in AHCs, including last year's prize.[13] In addition, much of evidence-based medicine comes from data generated from clinical and health outcomes research led by investigators in AHCs.

AHCs have also contributed significantly to innovation in care delivery. The story of the first physician assistant (PA) program, launched at Duke University in the 1960s, is an example. The then-chair of medicine, Gene Stead, already interested in the idea that skilled midlevel providers could assist physicians, became aware of a North Carolina physician who delegated independent care responsibilities to an assistant that he had trained.[14] Stead also observed that military medics returning from the Korean and Vietnam wars, with their training in basic medical care, could be capable of effectively assisting physicians with additional formal training.

On the basis of these observations, and being in a position to implement change, he saw an opportunity to improve

patient care by creating a novel type of health care provider, and in 1965 he implemented a new training program for them at Duke that enrolled four former Navy medical corpsmen. Today there are over 75,000 licensed PAs in the United States.[15,16]

Given how innovation has played a critical role in transforming health care, we must now turn our attention to the question "How do you foster innovation?" Understanding this is vital to the future of health care and medicine. We believe that there are three steps to cultivating innovation: teaching it, supporting it, and implementing it.

Teaching innovation

Many believe that innovation is innate and therefore not teachable. Roberta Ness,[17] the dean of the School of Public Health at UT Health in Houston as well as the director of the Center for Innovation Generation, disagrees. She argues that environment significantly influences innovative abilities; the problem is that current medical school curricula have made students overly respectful of traditional ideas. The Innovative Thinking Curriculum that she developed teaches creativity and imagination skills by taking learners through four stages: overcoming barriers to creativity; providing methods for thinking "out of the box"; addressing individual and group dynamics; and finally, allowing students to practice using these innovation tools.

Another important goal of Ness's curriculum and others like it is to remove the fear of failure. This is particularly relevant to a hierarchical profession such as health care, where the fear of saying something "stupid" or outlandish is ingrained early on in one's career. To remove the fear of failure, AHCs must do more than tell faculty to not fear failure. There must be structures and clear incentives for faculty to pursue new ideas.

Supporting innovation

Support must come from an innovation-friendly environment, as well as dedicated resources of money, time, and infrastructure.

Environment. First, one should create the "space," physical or virtual, for innovators to mix and interact. In a 2004 *BusinessWeek* article that came out 18 months after the introduction of the iPod and iTunes online music store, Steve Jobs was asked, "How does Apple do it?" His answer:

> Apple is a very disciplined company, and we have great processes. Process makes you more efficient. But innovation comes from people meeting up in the hallways or calling each other at 10:30 at night with a new idea … [i]t's ad hoc meetings of six people called by someone who thinks he has figured out the coolest new thing ever and who wants to know what other people think of his idea.[18]

In other words, collisions of ideas are critical. Co-location, gathering spaces, and more formally, interdisciplinary institutes become strategies to enable fortuitous, chance encounters that can lead to unconventional collaborations. These, in turn, can yield transformative results.

Clusters can also be developed around themes and emerging ideas. Many AHCs and universities have established interdisciplinary entities that encourage faculty to interact around themes outside their departmental silos. At Duke, signature institutes such as the Institute for Genome Sciences & Policy and the Duke Global Health Institute serve as interdisciplinary hubs for scientists, clinicians, policy experts, lawyers, ethicists, economists, and students from across the university to collaborate to push the frontiers of the genome and global health, respectively.

Bio-X, a Stanford University initiative that includes the Biodesign program, fellowships, and so forth, focuses on improving patient care through the development of innovative technology. It also fosters interdisciplinary research across areas such as medicine, physics, computer science, chemistry, and engineering in order to address life-sciences-related challenges. Bio-X has reported impressive achievements in translating basic research to patient care and commercialization, particularly in medical devices.[19]

Although innovation can be fostered through clusters and collisions, it can also be cultivated by going in the opposite direction: cloistering, which is the sequestering of a team to focus singularly on developing an idea. The development of the Tata Nano, one of the world's cheapest production automobiles, personifies this approach. Ratan Tata wanted to create a car that was affordable for India's growing middle class. Instead of having the traditional team of senior engineers and the sedan group tackle this issue, Tata instead cloistered a group of younger engineers and charged them to start from scratch to design a low-cost, high-quality, mass-producible automobile. The outcome was a car costing $2,500, dubbed "The People's Car."

The evolution of the Hewlett-Packard's (HP's) inkjet printing division exemplifies the importance of cloistering to fostering disruptive innovation from within. In the early 1980s, laser printers were the profit center for HP. However, a separate group was encouraged to work on developing the inkjet printer concept, without interference from the dominant laser printer group and its concerns about cannibalization. As a result, inkjet printing not only was allowed to come into being but also was able to flourish; it became HP's profit center and drove its dominant position as the market leader in this category. It is reasonable to assume that HP might not have survived had it instead left itself vulnerable to an external competitor, rather than creating this internal competitor to its own business model.

Resources. Supporting innovation requires money, time, and infrastructure. More specifically, the ability to innovate depends on how funding is awarded, how people's efforts are allocated, and how institutions are organized.

Funding. Let's take a look at grant funding. Traditional funding mechanisms often discourage, if not prohibit, out-of-the-box thinking. Too much emphasis is placed on preliminary data and investigators with track records. This favors low-risk applications from very established investigators. Although this approach has its benefits, it diminishes risk-taking innovation based on newer ideas, possibly limiting the types of breakthroughs that are seen and/or the rate of progress on any given front.[20]

To address this long-standing issue, Tachi Yamada, the former head of research at GlaxoSmithKline and then-president of the Global Health

Program at the Gates Foundation, created the Gates Foundation Grand Challenge Explorations in order to stimulate transformative innovation in global health that would not be bound by traditional requirements of having preliminary data and lengthy, detailed proposals. Instead, only one- to two-page proposals were required, and awards based on the soundness and promise of the ideas proposed. This is high-risk, high-reward research. In a *New England Journal of Medicine* "Perspectives" piece describing the program, Yamada[21] wrote that "new ideas should not have to battle so hard for oxygen."

The National Institutes of Health (NIH), under Elias Zerhouni's leadership, has also been trying to provide researchers with more oxygen for their novel ideas through several avant garde programs. The New Innovator Award program encourages highly innovative, high-risk research and provides support for new investigators without preliminary data. And the Pioneer Award program also stimulates innovative thinking by awarding scientists who propose transformative approaches to important biomedical and behavioral research challenges.

More recently, the NIH director's Transformative Award Initiative (formerly known as the Transformative Research Project) was established in order to provide support for highly innovative and risky research projects with the potential to disrupt what were once fundamental paradigms. To support innovation in health care delivery, the Affordable Care Act established the Center for Medicare and Medicaid Innovation,[22] which funds projects testing new payment and service delivery models, such as accountable care organizations, as well as other projects important to the future of health care, such as new approaches to graduate nursing education.

Supporting nascent ideas and taking more risks on innovation is an area where AHCs and philanthropy can also make a difference. AHCs and research institutions should develop seed or incubator-accelerator funds to support early-stage discovery and translational research to bridge the bench to bedside shortfall, or what has been coined the Valley of Death.[23] The unrestricted dollars from philanthropy can support cutting-edge concepts and ideas that are deemed too early or risky by the traditional funding agencies.

Time. In addition to funding, having the time to innovate is just as critical. Time for innovation is particularly scarce on the care delivery side, where patient care and day-to-day operations are all-consuming and usually the main priorities. Therefore, it is critical to have an alignment of people at all levels of the organization who value innovation and commitment of leadership to support it. Protected time for innovative pursuits is necessary at all levels, but especially for those individuals who have a propensity and drive for innovation. Special programs may also be created to cluster innovative thinkers and provide the environment and time to support them.

Infrastructure. Another important element needed to foster and facilitate innovation is appropriate infrastructure. For example, institutions can support translational research and improve investigators' productivity by creating a central entity that facilitates translation, providing linkers and connectors from discovery to proof of concept and first in human.

More specifically, the development of cores provides natural economies of scale by concentrating the necessary technical expertise rather than diffusing and isolating them in separate labs. This, in turn, should enable essential services to be provided with high fidelity and at a reasonable cost. Such services could include genotyping and expression analysis, animal husbandry, stem cell handling and production, protein and other biological manufacturing, first-in-human clinical testing, and biocomputational and statistical support, among others.

In translational research, commercialization is the pathway to human use. Universities, to the extent possible, should facilitate novel industry relationships, enable licensing opportunities, and create start-ups to support health care delivery innovations. The missing piece in many academic institutions is a core resource that focuses on project management, shepherding novel discoveries to human application, and from there to populations. At Duke Medicine, the Duke Translational Medicine Institute fills much of this role in medical innovation, serving as a linker and connector from discovery to support for proof-of-concept and first-in-human studies to clinical research to community engagement.

In addition to supporting innovations through access to shared physical space and funding, integrating ideas into actual care delivery within health systems is a key component to ensuring their long-term success. Examples of this support include the creation of internal units that take innovative ideas from concept to new care delivery models. The University of Pittsburgh Medical Center (UPMC) Health System has been a leader in facilitating innovation and allowing a culture of innovation to permeate through the health system, as has a cooperative at Group Health in Seattle that has been established to drive innovations in care delivery.[24–26]

At Duke Medicine, a newly launched Duke Institute for Health Innovations (DIHI) will provide the environment, funding, and protected time for its faculty to work on health care delivery, strategy, and policy. DIHI will serve as the umbrella for diverse initiatives ranging from mentorship programs in an anchor high school in Durham for life science and health professions to Bio-I, a forum and fertile space where creative faculty from diverse disciplines can address unmet needs articulated by clinical faculty and health system leaders.

The approach is simple yet profound. The need to facilitate the introduction of and overcome barriers within academic health systems to new care delivery models and training paradigms not yet established is something that has long been an obstacle to innovation. Efforts like DIHI and those at UPMC and Group Health are a needed force as we transition from supporting innovation to implementing it.

Implementing innovation

Roger Glass and his colleagues wrote an editorial in *Science* on the subject of implementation science, noting: "Many evidence-based innovations fail to produce results when transferred to communities … largely because their implementation is untested, unsuitable,

or incomplete."[27] In other words, evidence is not enough: Knowing how to implement things is also critical.

Madon et al[27] went on to describe the need for "a framework for research translation," a quantitative, scientific framework that engages different disciplines, and is capable of analyzing

> biological, social, and environmental factors that impact implementation, both to develop and test community-wide, multi-sector interventions that are not testable in clinical settings, and to identify how proven clinical interventions should be modified to achieve sustained health improvements in the "real world."

Such an approach to implementation, that takes these factors into account, has been used in certain areas, such as treating serious conditions like multidrug-resistant (MDR) tuberculosis (TB). Paul Farmer and Partners in Health used what was called a directly observed therapy model in areas such as Haiti, which was one of eight priority nations that the World Health Organization identified for targeted effort to reduce the MDR TB burden. This model used family members and community health workers to observe therapy in the home. With this approach, treatment success increased from 73% in 2000 to 82%.[28]

An important point regarding implementation is that innovators must have opportunities to implement their discoveries or the successful results of a trial. Institutions such as AHCs need to provide structured opportunities and processes for innovations to be introduced, evaluated, and disseminated. This begins with making better use of one's own research and clinical data and figuring out efficient, but controlled, ways of granting innovators access to understand the opportunities for new approaches to care and assess best practices. In short, AHCs must become rapid learning health care organizations, a concept championed by the Institute of Medicine.

The infrastructure to support implementation has to be in place as well. To this end, a unit has been established within the Duke University Health System to facilitate the integration of innovations into care delivery in a more systematic fashion. The mission of the Innovation Development, Evaluation, and Applications Group is twofold: to help the health system innovate in care delivery in ways that are aligned with strategic objectives, connected to innovators and great ideas from across the campus; and to leverage homegrown delivery-related innovation within Duke Medicine for the benefit of society at large. One key to fulfilling this mission is close collaboration with the faculty connected to DIHI, mentioned earlier.

Innovation Is Now a Need, Not a Want

Innovation in health care and medicine has traditionally been deemed a necessity in developing nations because of limited resources. However, given the challenges such as decreased philanthropic funding and declines in reimbursement facing health care during this era of health care reform, one could argue that innovation is also becoming more of a need than a want in the United States. Therefore, institutions must actively commit to cultivating innovation by *teaching it, creating "space" for and supporting it, and providing opportunities for its implementation.*

Innovation cannot be relegated to a second-class status by the urgency of day-to-day operations, patient care, and the requirements of traditional research. Innovation needs to be elevated to a committed endeavor and become a part of an organization's culture. In fact, in many ways, the primary aim of academic medicine *is* to innovate across its different missions.[29] As Peter Drucker[30] noted, "The enterprise that does not innovate inevitably ages and declines. And in a period of rapid change such as the present … the decline will be fast."

Funding/Support: This work is made possible through the generous support of Karl von der Heyden and the continuing support of the Duke Endowment.

Other disclosures: None.

Ethical approval: Not applicable.

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