The "Tipping Point" and Health Care Innovations: Advancing the Adoption of Beneficial Technologies

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In opening the first session of this conference on speeding the diffusion of innovations, I am tempted to ask whether we need to defend our purpose. In the face of renewed health cost escalation, in a sector that is overwhelmed by the rate of production of new knowledge and innovations, why should we be concerned about advancing the rate of adoption of innovations? As Joe Newhouse pointed out in a recent article in Health Affairs, healthcare may be the most inefficient of all sectors in its ability to extract value resources consumed *(Newhouse, 2002).* Are we prepared to cope with the onslaught of emerging technologies on the horizon and to manage the changes threatened by current evidence-based innovations and new technologies?

The answer is probably no. But this leads to two further questions, both eminently reasonable. First, does this matter – can we do anything to slow the rate of discovery? – To which the answer is probably no, as well.

Secondly, ***as challenging as the pace of innovation is, should we desire to halt or even slow it?*** Two recent articles by David Cutler and Mark McClellan and by Joe Newhouse consider this question. Cutler and McClellan concluded that "medical spending as a whole is worth the increased cost of care," because new technologies that typically cost more than the technologies they replace still produce health improvements that are, on balance, more valuable than the costs *(Cutler, McClellan, 2001).* Newhouse is concerned about the effects of the escalating rate of introduction of new technologies, and the challenge of evaluating technologies that continue to evolve, but he is reluctant to slow the rate of technology development because of the associated benefits *(Newhouse, 2002).* In other words, much of the onslaught of innovations in medicine is valuable, even if we have done a poor job of harvesting the benefits and winnowing out unnecessary or harmful innovations. Cutler and McClellan stressed the policy relevance of their findings and suggest that public policy should encourage technological progress rather than focus on avoiding waste by delaying the adoption of technology *(Cutler, McClellan, 2001).*

The rate of adoption for evidence-based technologies and innovations varies widely, and slow rates of adoption for many beneficial technologies contribute to the inefficiencies of the health sector noted by Newhouse. Adoption is not always prolonged, of course. The rate of Swan-Ganz catheterization to treat Medicare heart attack patients rose rapidly after introduction, almost quadrupling between 1984 and 1991 *(Newhouse, 2001)*. The rate of adoption for drug eluting stents is expected to surpass this within the first few years of use. In some cases rapid adoption itself creates a problem; the most egregious case of this was the widespread diffusion of high-dose chemotherapy with autologous bone marrow transplantation for breast cancer without adequate evidence for efficacy. As we learned in that case, and in the case of electronic fetal monitoring, it is extremely difficult to reverse the utilization of a widely diffused technology even with strong evidence (of continued lack of efficacy) to support the reversal.

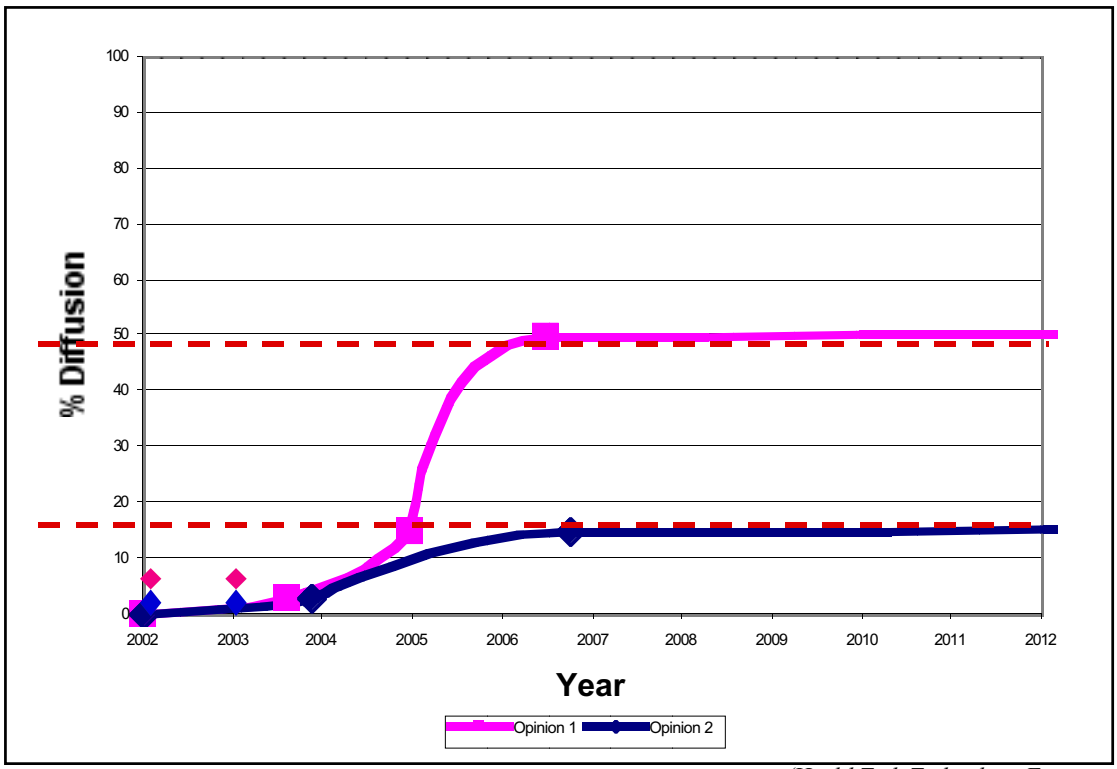
Many potentially beneficial innovations are not rapidly diffused. Cochlear implants first reached the market in 1978, and while the devices have improved over the years since then, Medicare reimbursement limitations and, more recently, private insurance denials of coverage have slowed their diffusion. Last year the Centers for Medicare and Medicaid Services (CMS) adjusted Medicare reimbursement for cochlear implants in a move to support broader diffusion and patient access. The Institute of Medicine (IOM) pointed out in the Crossing the Quality Chasm report that economic penalties and the lack of incentives are often critical in delaying the diffusion of innovations that improve quality. Potential improvements in care processes, such as the appropriate use of antibiotics to treat community-acquired pneumonias, fail to be adopted because hospitals suffer financially when they are reimbursed under lower-rate DRGs for appropriately-treated patients that experience fewer complications *(IOM, 2001).* Intensive insulin therapy for Type I diabetics, as another example, usually requires a team approach which is not recognized in Medicare

reimbursement. On a more optimistic note, the requirements of the National Committee for Quality Assurance (NCQA) for plan and provider certification have produced a steady increase in rates of evidence-based diagnostic and therapeutic interventions for significant chronic diseases such as diabetes.

What more can we do to speed the diffusion of evidence-based innovations and technologies? For our purposes, I will use the broadest definition of technology: the practical application of knowledge, or a capability given by the practical application of knowledge *(Merriam Webster Unabridged Dictionary, 2003).* This includes medical devices, pharmaceuticals, biotechnology and information technology, and also procedures, techniques, and processes of care. For the moment, I will begin with the subset of beneficial innovations and new technologies that are considered 'evidence-based.'

The question before us is how to speed adoption – not a gentle push, but a sharp jolt is needed. We can see what this would look like sketched against a diffusion curve derived from Rogers' work in Figure 1 (Rogers, 1995). In this case, a group of experts on the development and assessment of anti-microbial pharmaceuticals was asked to estimate the possible trajectory of prophylactic use of a staph aureus vaccine for elective device implantation surgery over the next decade. In technology forecasting, we seek to apply an understanding of the drivers and barriers that will affect future patterns of diffusion, much as health services researchers have begun to study patterns of diffusion retrospectively and concurrently. Drivers and barriers are forces, trends and events that will propel or delay the diffusion of an innovation.

Figure 1
Prophylactic Use of S. Aureus Vaccine
for Elective Device Implantation Surgery



(HealthTech Technology Forecast, 2002)

In technology forecasting, a divergence of expert opinion provides opportunities to better understand the drivers and barriers and environmental context that will influence technology diffusion. In this case, experts selecting a low end-of-decade penetration of the eligible population emphasized the probable barriers to diffusion: the rarity of infected implants, the involvement of organisms other than S. aureus in many infections, the variation in practice among surgeons, and the practical impediments to administering the vaccine in surgeons' offices due to storage conditions required to maintain an effective vaccine. Experts favoring higher penetration emphasized the high cost and morbidity of infected implants, and the potential advantage of avoiding even a small number of infected orthopedic, cardiac, and brain device-related infections *(Health Technology Center, 2002)*.

Drivers and barriers play out across three phases in the life of an innovation: (1) technology development, including the invention or discovery of the innovation, demonstrations and clinical trials (Phase I-III); (2) launch, including approval, coverage, reimbursement decisions; and (3) dissemination, including experimentation, acceptance, integration into standard processes of care, and post-market (Phase IV) trials. A force or event may constitute a driver in one phase, and a barrier in another, or may change its effect during a single phase, as reimbursement rates have for cochlear implants. At any point in time, the constellation of drivers and barriers surrounding a technology will produce a *natural rate of diffusion*.

This conference was convened, however, because we are not satisfied with the natural rate of diffusion for many technologies. We'll spend the next two days trying to understand the drivers and barriers that influence diffusion for a series of different types of technologies and identifying strategies that we believe will advance their diffusion. If we are successful, and the strategies we identify are eventually adopted, we would hope to see an inflection in the diffusion curve as a result. This will mean that for the technologies in question, an improvement in the rate of has occurred and therefore an improvement in clinical care, patient satisfaction or efficiency of use should result.

The deliberations of the IOM Committee on the Quality of Healthcare in America *(2000-2001)* are particularly relevant to our discussion of drivers and barriers. The Committee was charged with determining how the country could reach a "threshold change", or improvement, in the quality of healthcare in America within the next decade. They concluded that "you can't get there from here." Individual clinicians, and even health provider systems, cannot be expected to bootstrap themselves into a higher level of quality performance without substantial change in the larger environment *(IOM 2001)*.

This goes to the heart of the relevance of Malcolm Gladwell's The Tipping Point to my topic today. The Tipping Point was written to explain the phenomenon of social change as the result of individual behavior, and especially of certain influential individuals whom he called the "mavens," "connectors," and "salesmen." The "mavens" are the recognized experts on a subject. An academic medical center, for example, might have stellar researchers in endocrinology. Their adoption of a new innovation would cause colleagues who knew of it to consider adopting that innovation as well. But on their own, the mavens are often studiously focused on a small world of expert knowledge. It is the "connectors" who spread the word of technology to the broader world, linking influential people and ideas to create the interest and curiosity that attract early adopters like honey. Finally, the "salesmen" take the ideas spread by the connectors and get their acquaintances to actually try out an innovation. Gladwell gives us examples from Paul Revere's ride to the market strategies of Hush Puppies; his underlying model is the spread of epidemics, in which contagion spreads rapidly when the right combination of factors is present *(Gladwell)*. In this presentation I combine some of his terminology and theory with Everett Rogers' well-known work on the diffusion of innovations, *(Rogers)* in order to identify strategies that will help us advance the adoption of new technologies.

In the course of this presentation I will discuss the need to expand our consideration of evidence-based innovations to include the potentially disruptive effects of technology still in development. I will detail key drivers and barriers we must study in order to develop strategies for advancing diffusion of technologies and innovations, and suggest new approaches to research, policy formulation and assessment. Finally, I will urge increased employment of the two strategies that the IOM Committee on the Quality of Healthcare in America emphasized most strongly: economic incentives and information technologies.

A startling proportion of evidence-based technologies and innovations have not been fully diffused *(IOM, 2001)*. We might consider focusing our efforts only on those technologies and innovations that have been fully vetted as evidence-based. But technology marches on – and emerging technologies will disrupt many evidence-based devices, drugs, procedures and practices before they reach full diffusion. Some of these disruptions will be positive: minimally invasive cardiac surgery promised great improvements over the risks of open coronary artery bypass surgery (CABG) in the early to mid-90s, but was sidelined by the advent of percutaneous transluminal coronary angioplasty (PTCA) with coronary stents because this disruption improved outcomes without open surgery. Other potentially disruptive findings will sputter and fail: electronic fetal monitoring (EFM) was introduced in the 1950s and spread rapidly; when later studies found that EFM was no more effective than auscultation – findings that should have disrupted the use of EFM – physician preferences and the economic realities of the delivery system prevailed. Today it is still used in 80% of labors in the U.S. (Banta 2001).

We should consider, therefore, ***including the potential impact of technologies still under development*** as we develop strategies to speed the diffusion of beneficial innovations. Because these technologies are not yet fully evaluated as specific products or services, they should be treated as classes of technologies rather than specific products. For example, a group of devices and services now under development that use wearable sensors for the remote monitoring of patients with chronic disease should be considered first as a class, and then in assessments of individual products as they reach further stages of development. If the probable impact on quality of care or efficiencies of care is beneficial, then strategies should be pursued to support its further development, for appropriate demonstrations and trials of the actual impact, and for its possible introduction into use. As progressively more rigorous tests of the evolving technology demonstrate its continued promise and eventually its efficacy, the strategies to support its development can become more focused and intensive.

This attention should be reserved for innovations that are both potentially beneficial and disruptive, as described by Christensen in The Innovator's Dilemma. Disruptive technologies enter the market on the periphery, carving off pieces of business that mainstream dominant firms frequently dismiss; their products are often simpler and cheaper, offer less features and offer less satisfaction to customers than more dominant technologies. It may not be of much comfort to note that the dominant firms in each sector remain largely unaware of the gathering clouds on the horizon, and concede small fringe markets to the disruptive upstarts quite readily *(Christensen)*. For a current example, consider the Roomba, (Figure 2) a novel robot vacuum cleaner that is marketed to upscale young customers who value their time disproportionately in comparison to housewives who still constitute the bulk of the market. It is cheaper than a traditional vacuum cleaner if the labor cost of vacuuming time are taken into consideration, has far fewer bells and whistles than the average vacuum cleaner, and has limited functions (it doesn't do drapes or spider webs). In healthcare, the disruptive technologies of interest to us are those that will have major effects on important care processes – including evidence-based innovations still in the process of diffusion. Table 1 compares examples of established technologies with disruptive technologies in healthcare.

Figure 2. The Roomba

Table 1

Disruptive Technologies Applied to the Diffusion of Technology

Established Technology	Disruptive Technology
Physicians	Advanced Practice Nurses
General Hospitals	Outpatient Clinics, Home Care
Open Surgery	Arthroscopic and Endoscopic Surgery
CABG	Angioplasty
MRI + CT	Ultrasound
Office Visit	Email Consultation

(after Christensen, 1997)

As we review the list in Table 1, however, we can begin to ***distinguish two types of disruptive technologies and innovations***. Some, such as arthroscopic surgery and intensive insulin therapy (IIT) for Type I diabetics, are direct improvements or replacements for the actual devices, drugs, or procedures used in patient care. Technologies of the second type – such as email – are disruptive because they may enable an increased rate of adoption of evidence-based care. The IOM recognized that most of these enabling technologies fall in two large categories: those offering economic (reimbursement) incentives, and information technologies. Citing the need for substantial increases in funding for information technology, an IOM report observed that, "Our attempts to deliver today's technologies with today's medical production capabilities are the medical equivalent of manufacturing microprocessors in a vacuum tube factory" *(IOM 2001).* Newhouse also cites reimbursement and information technologies as key to realizing the potential benefit of evidence-based medicine, together with health services research *(Newhouse 2002).* Some innovations, particularly the closed-loop systems that will obviate patient or provider direct management (e.g., an "artificial pancreas" consisting of a continuous glucose monitor linked to an insulin pump), manage to combine both direct clinical innovations and enabling technologies. A short list of examples of enabling technologies is found in Table 2.

Table 2

Disruptive Technologies Applied to the Diffusion of Technology

Established Technology	Disruptive Technology
Journals, CME	Decision Support Integrated into CPR
Accreditation	Leapfrog Initiatives
Media Coverage	Direct-to-consumer Advertising
Patient Education	Closed-Loop Systems

Perhaps the most notable example of this second group of disruptive technologies is the application of information technology to the remote monitoring and management of chronic disease. While a number of such innovations in information technology have been developed, one of the most thoroughly evaluated has been the Health Hero platform that combines a patient information appliance (a small table-top device in the home), a data center, and an Internet-based service facilitating the daily activities of patient- and population-based care management. Marked improvements in measures of self-management and decreased dependence upon emergency services and hospitalizations have been reported in a variety of studies that used this device to support home-based telemedicine for an uninsured, high-risk diabetic population, for asthma self-management for a high-risk pediatric population and for care coordination for an adult population with chronic diseases including hypertension, heart failure, COPD, and diabetes. Health Hero and similar applications of information technology to the management of disease are 'enabling' technologies, because they enhance the capacity of health providers to deliver evidence-based care. They are also 'disruptive' technologies, because they offer substantial improvements by disrupting and displacing previous systems of care and associated business relationships.

Understanding the drivers and barriers that affect diffusion rates will open the door for strategic action. The IOM Chasm report identified the most important drivers for progress in quality as investment in information technology and changes to the reimbursement system for healthcare *(IOM, 2001).* A number of important strategies that relate directly or indirectly to these drivers are already being pursued. CMS issued new reimbursement codes for technologies in early stages of adoption several years ago, although there are a number of barriers to the effective use of the codes. CMS, Federal Liaison to HealthTech, is participating with HealthTech in an exploration of the data needs for coverage decisions on new technologies affecting the Medicare population. These data needs can be addressed during Phase III clinical trials or during other demonstrations before the technologies are evaluated by the FDA or are requested as demonstrations in instances where products are not subject to FDA evaluation. The examination of data needs is an effort to improve the information available for coverage decisions and, where appropriate, reduce the current delay between FDA action and CMS decisions. The IOM has convened a Clinical Research Roundtable to better define the role of purchasers and payers in the clinical research enterprise and to help speed the evaluation of technologies, which are important to the populations they serve. The FDA is grappling with appropriate review processes and criteria for hybrid products such as inhaled therapeutics. Purchasers have begun to lend market support to evidence-based medicine (EBM) innovations through the Leapfrog group and 'pay for performance' initiatives. A wide range of public and private actors, including the Veterans Health Administration, the Department of Defense and HHS, the eHealth Initiative, the IOM and the Markle Foundation, have recognized the urgent need for data standards to support interoperability and quality improvement in clinical care, and are collaborating on solutions.

Each of these initiatives or activities is manipulating a series of drivers and barriers that affect the staging of the development, launch and diffusion of innovations. Drivers are events or circumstances that will foster a technology's adoption and diffusion; barriers are events or circumstances that will hinder or halt a technology's adoption and diffusion. Staging refers to the progression of new products from the developer's workbench through preliminary deployment and the approval and coverage processes (where applicable), to commercial market introduction and acceptance, and also to factors affecting the expansion or contraction of current alternatives where they exist. Table 3 lists the drivers and barriers that affect the diffusion of innovation most significantly.

TABLE 3
Drivers and Barriers Affecting the Diffusion of Technology
Strategic Potential to Advance Diffusion

DRIVERS AND BARRIERS	DEFINITION	STRATEGIC POTENTIAL	EXAMPLES
Technology Breakthroughs	Critical advance in science and technology that supports product development.	Low	▪ Thrombolytic therapy for acute myocardial infarction ▪ Laparoscopic cholecystectomy ▪ Inhaled pharmaceuticals ▪ Remote chronic disease monitoring
Target Conditions	Diseases or conditions to which a technology will be applied based on scale, cost, severity.	Low	▪ LVAD for CHF ▪ Inhaled insulin for diabetes ▪ Monoclonal antibody radiopharmaceutical diagnostic scans for prostate cancer metastases
Convergence of Technologies	The combination of two or more technologies to enable novel diagnostic or therapeutic solutions.	Low	▪ Power management and In sensors ▪ Image guided surgery
Competing and Substituting Technologies	New products used to diagnose or treat the same conditions as an existing technology.	Low	▪ Minimally invasive procedures (Mid-CAB vs. PTCA with stents) ▪ Multidose vs. continuous subcutaneous insulin infusion (CSII) for diabetes ▪ Drug-eluting stents vs. brachytherapy for CAD ▪ Cardiac diagnostics, PET, other scans ▪ Imaging for spinal disease
Liability	Institutional liability and individual practitioner malpractice liability; privacy; confidentiality; fraud and abuse.	Low-Medium	▪ Electronic fetal monitoring ▪ Autologous bone marrow transplantation for solid tumors ▪ Vaginal birth after caesarean section ▪ OIG audits of pacemaker implants in Medicare ▪ HIPAA

Table 3 Continued

DRIVERS AND BARRIERS	DEFINITION	STRATEGIC POTENTIAL	EXAMPLES
Regulatory Approval	Authorization to market a new technology, for use in specified populations and diseases or conditions.	Low – Medium	▪ Bioartificial liver ▪ Hybrid drug-device products ▪ Hybrids of cultured epidermal cells and scaffold products
Coverage	Inclusion of a service or product utilizing a new technology as an insurance benefit.	High	▪ Autologous chondrocyte transplantation for knee cartilage defects ▪ IDET for herniated lumbar intervertebral discs ▪ Implantable pressure monitors for heart failure ▪ LVAD as destination therapy for CHF
Reimbursement	The amount paid to providers for services or products using the new technology, and the structure of reimbursement.	High	▪ Autologous bone marrow tranplantation ▪ Pediatric immunizations ▪ Intensive insulin therapies ▪ Remote monitoring of chronic disease
Workforce	Changes in and availability of the skills, competencies and workers required to utilize a new technology, and the impact of that technology on workforce performance and satisfaction.	High	▪ PACS ▪ Angioplasty for acute MI ▪ Laparoscopic cholecystectomy ▪ Minimally invasive surgery ▪ Ultrasound in primary care setting ▪ Centralized reading of digitized images ▪ Telemedicine ▪ Service robots for hospital supplies
Cost	Operating costs of utilizing the technology once acquired, and cost to purchasers, payors, and society for the enhanced intervention.	Low	▪ IT Security ▪ Sensors for remote monitoring ▪ Cochlear implants ▪ Bioartificial liver ▪ LVAD as destination therapy
Capital Requirements	Capital costs of acquisition of a new technology.	Medium	▪ PACS ▪ PET ▪ Gamma knife ▪ Interventional robotic suites ▪ Sensors for remote monitoring

Some drivers and barriers - though important - are less practical targets for strategies to accelerate adoption and diffusion. The first five drivers and barriers listed in Table 3 are only moderately plausible as public or public-private interventions to speed the diffusion of innovations. Other drivers and barriers have a significant impact on the diffusion of innovations and offer valuable opportunities to accelerate diffusion through public, private and joint public-private action.

Leadership And Culture: Extending Rogers' Framework to the Organizational Level

In both *To Err is Human* and *Crossing the Quality Chasm*, the IOM Committee on the Quality of Healthcare in America underscored the importance of systems in healthcare. Errors, inappropriate practice variation, and outright poor quality care are all much more the result of systems failures than those of individuals. The solutions, the Committee suggested, therefore lie in organizational strategies to change the functioning of the organization and the behavior of individuals. What can we learn, then, about organizational strategies with regard to advancing the uptake of beneficial innovations? Can we, in fact, take an evidence-based approach to learning which organizations are most successful in adopting beneficial innovations, what factors make them successful, and how their success can be propagated?

Unfortunately, as recent literature indicates there is only limited evidence for our purposes. Friedman and Goes summarized research on the adoption behavior of hospitals with regard to new technologies since the late 1980s; the studies are few, and mostly limited to very high-cost imaging technologies (*Friedman, 2000).* But let me make a leap here, and speculate that Rogers' characterizations of Innovators and Early Adopters among individuals can be extended to healthcare organizations as well. Our experience at HealthTech – a non-profit membership research organization that forecasts the impact of emerging technologies in order to advance the adoption of beneficial technologies – leads me to speculate that health delivery systems and health plans that are interested in identifying potentially beneficial technologies early in their development, and in the selective adoption of these technologies before competitor organizations adopt them, are behaving as the organizational equivalents of Innovators and Early Adopters. There is even a small piece of data to support this in Teplensky's study of hospital acquisitions of MRI, in which a strategic interest in technological preeminence explained more of the adoption of MRI and CT by U.S. hospitals than profit maximization or clinical excellence (*Teplensky 1995).* In other words, if the IOM reports and several decades of research on the adoption of quality improvements suggests that organizations should be our focus, perhaps we can apply the same framework for the spread of innovation among organizations as Rogers proposed for understanding individuals.

Rogers and Gladwell agree in their characterization of Innovators and Early Adopters as visionaries and risk-takers, in comparison to the risk-averse Late Adopters and Early Majority who seek incremental improvements. As Friedman points out, "The acquisition of new technology can be one of the most critical decisions a senior hospital executive makes, and it can have dramatic effects on the organization." (Friedman, 2000) A 2000 report by the Healthcare Financial Management Association discussed the need for healthcare executives to anticipate the impact that new medical technologies will have on demand and capacity requirements. "Determining these requirements is critical but difficult," they report, calling attention to the high-risk nature of early adoption, and adding that "the healthcare industry lacks a centralized resource that tracks such developments and assesses the impact on hospital service-line demand and capacity requirements" (Myers, 2002).

Intuitively, this makes sense. The organizations that have taken risks in acquiring many types of emerging technologies play a key role in Rogers' critical dynamics of innovation diffusion, including relative advantage, trialability, observability, communications channels, opinion leaders and infrastructure. The Institute for Healthcare Improvement is, in one sense, a network of Innovators and Early Adopters who have explicitly sought to demonstrate beneficial innovations in medical care to the Early Majority, Late Majority and Laggards. The utility of this framework could be further investigated in the recent spread of hospitalists for acute care. Wachter's recent review of the literature found that in 19 studies over the past 5 years, there was a consistent pattern of improved efficiency (reduction in hospital expenditures and length of stay), without harm to patient satisfaction or clinical quality *(Wachter, 2002).*

The idea that strategies to advance the adoption of innovations should be focused on healthcare organizations more than on strategies to change individual behavior, follows directly from the IOM Chasm report's conclusion that "you can't get there from here." In reviewing the evidence for success with strategies operating at the level of the individual or small cluster of providers – the "micro-system" – the IOM Committee said that "trying harder" wouldn't do; strategies that operate at the systems level will be necessary. Specifically, for the improvement of clinical quality and the rapid adoption of evidence-based innovations, the investment in information technology will be critical. This, in combination with evidence-based care processes, the Computer-based Patient Record and decision support systems, and reimbursement changes to remove the existing penalties for quality improvement, will create the conditions for substantial progress.

> "Carefully designed, evidence-based care processes, supported by automated clinical information and decision support systems, offer the greatest promise of achieving the best outcomes from care for chronic conditions…Moreover, such efforts to improve quality must be supported by payment methods that remove barriers to integrated care and provide strong incentives and rewards for improvement."
> *(IOM, 2002)*

Building new approaches for health services research and technology assessment

Healthcare organizations interested in the early adoption of beneficial, evidence-based innovations face a particular challenge because the evidence in the early stages of market penetration is just that – early. Ian McDonald has written a very thoughtful article about the need to combine the methods of four fields: quality assurance, technology assessment, clinical epidemiology, and evidence-based medicine, in order to provide local information on the application of emerging technologies and to continue gathering information about clinical and patient experiences with these technologies as they are broadly diffused *(McDonald, 2000).* Newhouse also reviewed the difficulties inherent in the assessment of emerging technologies, noting that "e*vidence-based medicine labors under the onslaught of new knowledge,"* and suggesting that information technology may make it possible for us to develop new capacities for tracking the effects of new technologies after they enter the market. "It is not just a problem of keeping up," he says. "At any one time, some procedures are sufficiently new that their efficacy has not been established for substantial numbers of patients…By the time any trial is complete, a better procedure or drug may have appeared…And any delay to accrue more patients simply increases the chance that the results from the trial will be out of date when they appear." *(Newhouse, 2002)*

Green has a particularly interesting take on the problem of the continuous evolution of technologies. *(Green, 2001)* "Many forthcoming medical advances – growth factors, tissue engineering, gene therapy, attachable prosthetic limbs, and implantable computers – are so new that as yet there is no clinical experience with them," he writes. These are truly disruptive technologies, and Green points out that the guideposts we normally use to judge their efficacy and safety will be scarce and often inadequate. He suggests that evolutionary theory may provide a model for understanding this phenomenon: that "evolution passes, at times, through innovative cycles of progress- when diversification of design leads to perfections of form – with the concomitant production of many unsuccessful models." He gives the example of the evolution of device designs for total knee replacements that began in the 1960s. "Some of these implants are, by modern standards, bizarre-looking." But, "not surprisingly, all total knee replacement implants now resemble the normal knee and consequently are difficult to distinguish from each other." Early bicycles and computer operating systems - and perhaps the SUVs of today – are further illustrations

of the process of diversification followed by testing and elimination of less successful designs. Green's analysis may seem obvious, but it has useful implications for research and regulatory policy. Research, instead of seeking a 'final assessment,' should become continuous and collaborative across a wide variety of care settings and applications of the technology. Regulation, he suggests, should add a new stage to the approval process that would indicate that the technology or innovation is entering a post-market period in which consumers and providers will benefit from continuous gathering of information and from an understanding that not all the risks are yet understood.

The decision by healthcare organizations to implement an innovation requires information not dissimilar to that needed for coverage decisions by CMS or private payers. In a number of forums, including the IOM Clinical Research Roundtable, CMS and health plans are working to have the key endpoints and outcome measures needed for coverage decisions incorporated into clinical trial designs and other research on new technologies. Important study elements that interest CMS, and payers in general, are eligibility or patient entry criteria, duration of follow-up, subgroups in which the technology may be effective, the extent to which effects on health outcomes can be generalized beyond narrow study populations, substitution effects and technology increasing effects.

Part of this broader research agenda could also be an exploration of the experience of clinicians and patients with new technologies, and the value they place on this new component of care. Fuchs and Cox provided insight into this question in a survey of clinicians. Because most patients do not have experience with a wide range of medical interventions, the authors focused on physician assessments of the relative value of medical innovation. By asking generalists rather than specialists, to avoid prejudice in favor of technologies associated with specific specialties, they attempted to learn which innovations were of greatest benefit in patient care. The physicians' responses were remarkably consistent, suggesting that such assessments might be useful in combination with other evidence for the value of new technologies (Fuchs, 2001).

Conclusion

I doubt that anyone attending this conference is worried that drug-eluting stents will fail to diffuse rapidly in American medical care. In general, we're less concerned about the diffusion of new procedures and devices or pharmaceuticals when reimbursement, physician and hospital competition, and marketing to physicians and now consumers all constitute powerful drivers, and when the new technology or innovation does not threaten to disturb or frustrate physicians. Instead, we're concerned about innovations that improve the quality of care but don't fit these criteria. Many of those innovations are 'enablers,' and depend upon information technologies to varying extents. They make it more likely that evidence-based diagnostic and therapeutic interventions will occur, and clinical care goals will be achieved. The barriers to adoption are quite high, because many of these technologies disrupt current economic relationships and cultural patterns within the health professions and healthcare institutions. So, I would argue, some of the drivers have to be disruptive as well.

What would "disruptive drivers" be? They could include Gladwell's Mavens, Connectors, and Salesmen as individual agents of change, or as healthcare delivery systems and health plans organizing change. But we may need to add a new driver or agent at one level higher: more regional or national in scope, with greater weight. This could be an 'enforcer' – a regulatory approach that mandates certain behaviors. But most of us have grown skeptical about that approach – it backfires too often. Instead, we can identify a series of 'systemic re-enforcers' that will help to propel adoption and diffusion. To give three examples, these might include reimbursement for chronic disease monitoring devices and services, national physician licensing for telemedicine *(Jacobson, 2000)*, and a certification requirement for novel surgical techniques using virtual training techniques. The main

systemic reinforcers, as we've noted above, are information technologies and reimbursement.

How successful can we be in attempting these strategies? Rosenau compared the U.S. approach to technology assessment, adoption and utilization with that of France and Quebec in 2000, and found that the management of medical technology in the U.S. was profoundly - and adversely - affected by attitudes surrounding planning versus market competition, government regulation, the balance between decentralization and centralization, and linkages to policy-making (Rosenau, 2000). The adoption of many information technologies and clinical technologies is substantially more advanced in European countries than in the United States. McClellan and Newhouse have argued that, on balance, technological innovation is a major source of continuous improvement in the productivity and value of American healthcare, even though we are still markedly inefficient in extracting that value. The challenge to us in the next two days is to identify the strategies that will propel us forward. Thank you.

A Literature Review for the diffusion of emerging technologies in healthcare is included in the conference materials. I would like to thank my colleagues at HealthTech, Dr. Wade Aubry and Wil Yu, for their collaboration in preparing this presentation and the literature review.

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