# Accelerating Quality Improvement in Health Care

## *Strategies to Speed the Diffusion of Evidence-Based Innovations*

PROCEEDINGS FROM A CONFERENCE

NIHCM FOUNDATION

National Committee for Quality Health Care

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## Credits

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This report was written by Larry Stepnick, president of The Severyn Group, a health care research and consulting firm, and Steven Findlay, MPH, of the NIHCM Foundation.

## Note

The following literature review and three papers were commissioned for this conference. They are available at www.nihcm.org and www.ncqhc.org. Synopses of the three papers appear in the text of this report.

- *Technology and Quality: Considerations for Adoption and Diffusion – A Literature Review* (Prepared by the Health Technology Center), 20 pages
- *The Tipping Point and Health Care Innovations: Advancing the Adoption of Beneficial Technologies* – By Molly Joel Coye, MD, MPH, Wade Aubry, MD, and Will Yu (The Health Technology Center), 18 pages
- *Complexity and the Adoption of Innovation in Health Care* – By Paul Plsek, PhD (DirectedCreativity.com and The Institute for Healthcare Improvement), 18 pages
- *Medical Technology, Innovation, and the Nature of Medical Progress* – By Daniel Callahan, PhD (The Hastings Center), 18 pages

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# Executive Summary

It is a vexing problem. The US health care system runs on an engine of entrepreneurial innovation fueled by technology. And yet, many innovations, technological advances, and proven new treatments are too slowly adopted by doctors, hospitals, health administrators, and health care facilities. At the same time, other innovations and new treatments get diffused *too quickly*, despite insufficient scientific evidence of their clinical utility. This dichotomy is at the heart of the growing movement to improve the quality of care by correcting the *underuse* of many proven treatments and innovations even as we discourage the *overuse* or *inappropriate* use of others.

This report summarizes the proceedings of a conference convened to explore: (a) why the slow diffusion of many health care and medical innovations persists and (b) how to accelerate the adoption of clinical technologies and health service innovations that have been shown to improve the quality and/or cost effectiveness of health care. The conference brought together speakers and participants from health plans, employers, hospitals, medical and provider groups, government, and academia. Speakers addressed the adoption of innovation in a diverse array of topics, from medical devices and surgery to public health, end-of-life care, hospital design, disease management, and information technology.

Speakers broadly concurred that the "diffusion curve" continues to be much longer in health care than in other sectors of the economy – preventing millions of people each year from getting optimal care and impeding progress in enhancing the quality of care and better health outcomes generally. In some cases, speakers said, it can take 10 or more years for an innovation or new treatment to penetrate into full acceptance and widespread use.

With new treatments, the primary reasons for this lag are: (a) the nature of medical practice itself, with its emphasis on the autonomy of individual physicians practicing either alone or in small groups; (b) an inherent skepticism about the "new" versus the "tried and true," even when the tried and true may lack scientific support or be outmoded; (c) the slow pace at which an individual doctor's practice patterns change when they are shaped largely by local peer-group practice patterns; (d) reluctance to be an "early adopter" of treatments (particularly new procedures and surgical techniques) that may carry new risks; (e) lack of clarity about the evidence base for many treatments; (f) a sub-optimal system for the quick transfer of *important* new technical and scientific knowledge to clinicians (i.e., difficulty separating the wheat from the chaff); and (g) the sometimes plodding process that government, regulatory agencies, and private insurers apply to coverage and reimbursement decisions.

With respect to new technology, barriers to quicker diffusion center on cost, anticipated return on investment, regulatory approval, Medicare and Medicaid reimbursement, and private insurance coverage. But these barriers may not always be the dominant forces slowing diffusion. Speakers cited (and this report presents) more than a few innovations and effective care practices that are low-cost and have gained relatively speedy approval and coverage, but which still have been underused for years (e.g., diabetic eye exams, influenza and pneumococcal vaccinations among the elderly).

Health service innovations (e.g., information technology, patient safety measures, hospital design, physician work flow, and clinical team management) that aim to improve the patient's experience and the quality of care are an essential ingredient in high-quality care, but they also face both technical and financial barriers to adoption within hospitals and physicians' offices. The rapid pace of change in medicine and shear volume of new tools being developed adds to the problem, as clinicians and providers struggle to keep up and make smart investments.

Speakers and participants agreed that there is no magic bullet that will accelerate the adoption of evidence-based innovations. Neither is there an easy way to wean providers off unproven treatments as fast as is desirable. They discussed and proposed a broad array of fresh ideas and a number of unifying themes emerged.

Among the most important:

- Payers and purchasers (private sector and government) must begin to "pay for performance" to improve quality. Doing so will speed providers towards use of clinical guidelines, recommended treatment protocols, and evidence-based practice. In addition, the federal government and insurers should consider boosting reimbursement for technologies that, over time, demonstrate substantially improved outcomes.
- A much larger investment should be made (by both government and the private sector) in gauging the usefulness and cost-effectiveness of new technologies and innovations, including head-to-head comparisons of existing treatments.
- The federal regulatory process for approving and deciding on reimbursement policy for new treatments and technologies needs to be improved. The process itself should be as innovative, creative, and adaptive as the innovations being evaluated. The agencies charged with these tasks—the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS)—need to more closely coordinate their activities.
- A high priority should be put on creating and diffusing physician decision-support technology that can help clinicians make evidence-based diagnostic and treatment decisions. Such technology includes laptop computers and personal digital assistants (PDAs) with specialized software and high speed wireless internet access.
- Innovations in two areas hold especially large potential to constrain the rising cost of health care even as they improve the quality of care. These two areas are care at the end of life and disease management programs for the chronically ill. Roughly 15% of the population accounts for 75% of total health care costs in the U.S. – and almost everyone in that 15% has one or more chronic conditions or is nearing the end of life. New "mental models" are needed to replace current misconceptions about how and why people die, and the care they really need at the end of life. Despite excellent emerging models of chronic illness care, and mounting evidence that disease management benefits patients and saves money, diffusion has been woefully slow.
- More federal funds should be committed to foster the uptake of information technology (IT) and electronic medical records, especially as applied to facilities and providers that treat under-served populations. IT is also an effective tool for accelerating the diffusion of other innovations in health care.
- Physician and public health groups can and must do more to push clinicians and administrators to adopt evidence-based innovations faster. They should also help inform their constituencies about which innovations are the most useful.
- Preventive care continues to be underutilized. Enhanced coverage should be based on evidence and the recommendations of the United States Preventive Services Task Force (housed at the Agency for Healthcare Research and Quality) and from *the Guide to Community Preventive Services* developed by the Centers for Disease Control and Prevention. Employers, government, health plans, and providers should collaborate at the local level to increase public awareness of the importance of preventive health services and screening tests to personal health. Rewards for healthy lifestyle changes should also be considered.
- More substantial efforts must be made to help consumers become better informed about the gaps in health care quality, and about how to use information, data, and other resources to choose providers and make health care decisions wisely. Messages should emphasize that disparities in quality can affect the outcome of care.
- Tenacious consumer and public interest groups play a vital role in pushing social change to protect and promote public health (e.g., publicizing the health effects of tobacco and lead, promoting automobile safety, discouraging drunk driving). Clinicians and the health care community should listen to them sooner. The latest movement: childhood and adult overweight and obesity. The goal of substantially altering American eating habits and physical activity levels should be broadly embraced and advocated by all stakeholders.

# Introduction

The two day conference on which this report is based brought together 200 health leaders and stakeholders in an effort to better understand how to accelerate the adoption and diffusion of clinical technologies and health service innovations that have been shown to improve the quality and/or cost effectiveness of health care.

**Nancy Chockley, MBA,** president of the NIHCM Foundation, and **Catherine McDermott**, president and CEO of NCQHC, emphasized the power and momentum of the idea of evidence-based medicine – and the role it is playing in driving health care quality improvement in the U.S. today. Each stressed the challenges inherent in identifying what does and does not work in health care, both clinically and in the delivery of care. Ms. Chockley said the conference's main goal was to advance understanding of why some health care practices take hold and others do not, and how adoption of the best, proven practices can be significantly enhanced. A secondary goal was to stimulate collaboration across health sectors to achieve more rapid health system improvement. Ms. McDermott noted that health care quality improvement has finally emerged as a potent political issue, offering the promise of new resources and commitment.

In introductory remarks, **Samuel Nussbaum, MD**, executive vice president and chief medical officer of Anthem, Inc., who moderated the first day's sessions, said it is now well understood that many proven innovations and clinical breakthroughs diffuse too slowly. He cited research showing that it can take 10 years or longer for even the most definitive clinical trial results to filter down to practicing physicians.

At the same time, other innovations, technologies, and treatments get adopted *too* fast, despite insufficient evidence of their clinical utility. This dichotomy is at the heart of the twin issues plaguing quality of care – the *underuse* of many proven treatments and innovations and the *overuse* of other treatments and innovations for which there is sketchy or insufficient scientific support.

**E. Andrew Balas, MD, PhD,** dean of the School of Public Health and professor of health policy at Saint Louis University, cited eye exams among diabetics as one notable example of persistent underuse. Definitive studies showing the benefit of periodic exams to prevent impaired vision and blindness in diabetics were first published in the early 1980s. Yet the latest published research (in 2000) indicates that only 48% of diabetics got an eye exam in the previous year. A second example is pneumococcal vaccine. Definitive studies published in the late 1970s showed the vaccine's benefit, particularly among older Americans at high risk of bacterial pneumonia. The Centers for Disease Control and Prevention (CDC) has long recommended that everyone age 65 and over be immunized, since pneumonia causes 64,000 hospitalizations and 7,300 deaths per year. Yet CDC data show that only 53% of people age 65 and over were immunized in 2000. (See Figure 1.)

**Figure 1: Landmark Clinical Trials and Their Current Rate of Use**

| Clinical Procedure | Landmark Trial | Current Rate of Use |
|---|---|---|
| Flu vaccine | 1968 | 64% (2000) |
| Thrombolytic therapy | 1971 | 20% (2000) |
| Pneumococcal vaccine | 1977 | 53% (2000) |
| Diabetic eye exam | 1981 | 48.1% (2000) |
| Beta blockers after MI | 1982 | 92.5% (2001) |
| Mammography | 1982 | 75.5% (2001) |
| Cholesterol screening | 1984 | 69.1% (1999) |
| Fecal occult blood test | 1986 | 20.6% (1999) |

Source: Balas EA, Boren SA. Managing Clinical Knowledge for Health Care Improvement Yearbook of Medical Informatics 2000.

Commissioned Paper Synopsis

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

By Molly Coye, MD, MPH, Wade Aubry, MD, and Will Yu, The Health Technology Center

In a world burgeoning with new health care knowledge and technology, do we really need a strategy to speed the rate at which innovations diffuse?

The answer is yes, especially with respect to innovations targeted at improving the quality of care. Mounting research indicates that the benefit of health care service and delivery innovation – even incremental innovation – outweighs the added cost. And much of the recent onslaught of technological improvements in medicine (drugs, devices, new imaging tools) are of indisputable value, too.

The plain fact is that the "natural" rate of diffusion today of many *proven* new health technologies and treatments is not optimal. In fact, it proceeds in many cases at a snail's pace. Take cochlear implants. They first reached the market in 1978, and have been improved over the years. But a confluence of factors, including poor Medicare and private insurer reimbursement, has slowed their diffusion.

Our major challenge today is to better understand the drivers and barriers of diffusion. As we glean them, we must push on the drivers and reduce or eliminate the barriers, when appropriate. One clear barrier is that we have no systematic way of identifying breakthrough innovations early in their development so we can give them the push they need. Important innovations are often left to languish, sometimes for years, because there is no or slow recognition of their value. We need earlier gauges of what is improving care.

Resistance to change is also a factor. We need to identify as early as possible so-called "disruptive" technologies (those that face resistance because they replace outmoded technologies or ways of doing things) and then develop a strategy for promoting their wider acceptance. This happens in other areas of the economy quite rapidly (e.g. consumer electronics), but not in health care. Here are just a few disruptive technologies that did not diffuse rapidly enough:

- Arthroscopic and endoscopic surgery (replacing open surgery)
- Angioplasty (replacing bypass surgery)
- High-quality home care (replacing more costly inpatient care)
- Outpatient clinics (supplanting inpatient care).
- Ultrasound (replacing some MRIs and CT scans)
- Remote monitoring (replacing the need for patients to go to a doctor's office and allowing for inter-hospital consultation)
- Disease management of diabetics and heart attack patients
- Computer- and internet-based information and data in support of diagnosis, medical decision-making, and ordering (replacing slow access to written documents and paper-based systems)

The landmark Institute of Medicine report, *Crossing the Quality Chasm,* identified two barriers in particular that are today impeding health quality improvement: suboptimal investment in IT and a reimbursement system that fails to provide coverage for innovative technologies in a timely manner. Many barriers to IT persist, including security concerns and technical issues surrounding computer coding standards and interoperability. Just as important are the "systems" issues: (a) getting the human beings who run the system to embrace IT and alternative reimbursement systems, and (b) integrating such changes into existing complex systems and organizations (e.g., a hospital or large insurer).

We must also develop regulatory and payment systems that promote competition aimed at the early (but judicious) use of new tools. One path here is to learn from organizations that adapt and change rapidly. Some delivery systems, health plans, and employers clearly act as "early adopters" and "risk takers." Studies indicate that they do so primarily for competitive reasons in the marketplace.

It is absolutely critical to the health quality movement in the U.S. today that we speed the diffusion of those technologies that offer superior clinical results and performance.

In a keynote address based on her commissioned paper for the conference (see page 4 for a synopsis), **Molly Coye, MD, MPH**, CEO of The Health Technology Center, said all new technologies and innovations have natural diffusion "drivers" and "barriers." Regulatory approval (e.g., by the FDA) and insurance coverage are well-recognized drivers of diffusion, as are marketing and advertising. Notable barriers include liability issues, cost, capital investment, worker retraining, complexity of the technology, and facility requirements. These drivers and barriers, in addition to social, economic, and clinical circumstances, conspire, often in unpredictable ways, to yield the rapid uptake of some innovations and the slow diffusion of others.

Dr. Coye told attendees that the adoption of innovations in health care is complicated by the overwhelming pace of change and shear volume of new tools being developed in medicine. It is not humanly possible for clinicians to keep up with all the new beneficial tools, tests, devices, drugs, techniques, and technologies, let alone distinguish them from those that warrant more caution.

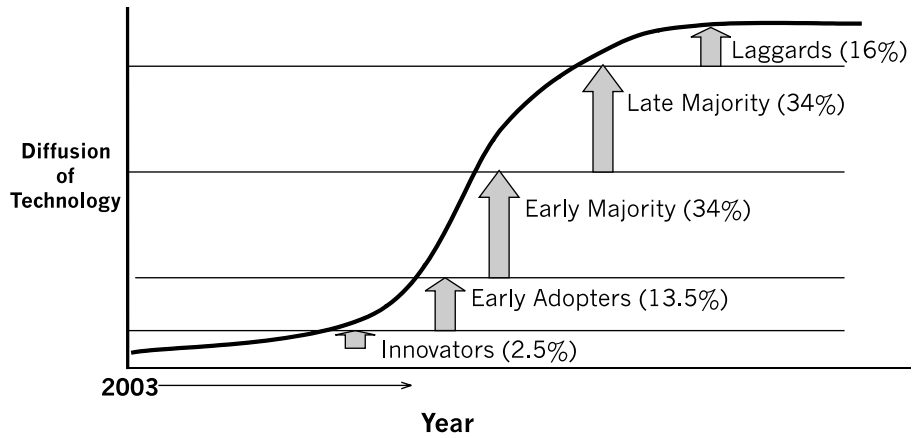
This phenomena presents one of the most serious barriers not only to the practice of evidence-based medicine, but also to the implementation of systems changes that improve the delivery of care. It is a behavioral problem that affects other industries as well. Humans are naturally reluctant to adopt new things until other "early adopters" have done so and proven their worth. (See Figure 2.) But Dr. Coye argues that this process is inadequate in medicine since it denies potentially life-saving care to millions of people, often for years.

**Carolyn Clancy, MD,** director of the Agency for Healthcare Research and Quality (AHRQ), noted that the reluctance to adopt new innovations is an age-old problem in medicine. In 1601, an English sea captain named James Lancaster discovered that lemon juice supplements were a cure for scurvy in sailors. But it took the British navy *194 years* to implement the practice of routinely stocking ships with citrus fruits and supplements. A century later, researchers proved conclusively that the simple practice of hand washing by nurses and doctors when moving from one patient to the next dramatically slowed the spread of infections in hospitals. But the practice did not become routine in hospitals until 30 years later, and doctors and nurses making rounds today still sometimes forget this simple procedure. Yet another example is the stethoscope. Originally developed in 1816, it was met with skepticism and mistrust, and therefore languished as a valuable innovation until the 1860s.

Dr. Clancy believes the challenges today are fundamentally no different than they were in the 17th and 18th century, but that we have far fewer excuses for failing to:

- Discern the best medical treatments through careful, well-designed research.
- Transmit new, fast-evolving knowledge to physicians and other clinicians in a timely manner.
- Get practicing doctors to change their behavior as new knowledge warrants it.
- Translate the discoveries of basic research into practice and action.

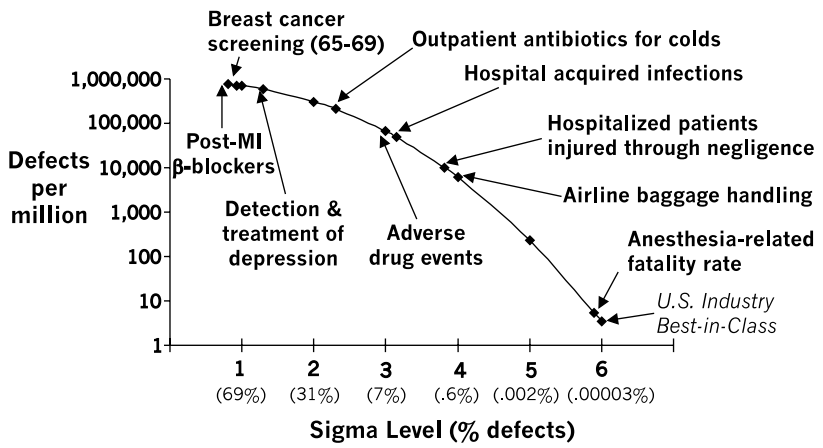
**Figure 2: The Diffusion Curve**



The failure to get innovations and clinical breakthroughs into the mainstream of care means that the vast majority of patients in the U.S. today receive *average* care, with only a lucky few receiving the *best, top-quality* care.

Dr. Nussbaum cited the high profile issue of medical errors as perhaps the most recent and egregious example of diffusion failure. Many technologies and processes now exist that could help identify and prevent medical errors. Yet only a minority of hospitals have altered these processes and invested in systems that can prevent errors. For example, only about 5% of hospitals today have a fully integrated CPOE (computerized physician order entry) system despite evidence that they reduce medication errors by 60%. And still today, years after enormous attention was paid to the problem, hospital error rates remain higher than those for airline baggage handling. (See Figure 3.)

**Figure 3: Healthcare Quality Defects Occur at Alarming Rates**




Source: Modified from C. Buck, General Electric

## Transforming the Health Care System

*In a keynote address, **Newt Gingrich**, former House Speaker and Republican Representative from Georgia, presented material from a new book,* Saving Lives and Saving Money, *he has co-authored with Dana Pavey and Ann Woodbury of The American Enterprise Institute. Much of the book presents case studies of health technology and quality improvement initiatives now underway around the country that Mr. Gingrich thinks should be more widely diffused. Among those:*

- **Electronic ICU monitoring by intensivists**: At Sentara Health System in Norfolk, Virginia, Visicu, an electronic monitoring system, allows intensivists to closely track the vital signs of intensive care unit (ICU) patients. It has reduced hospital mortality among ICU patients by 25%, average hospital length of stay by 17%, and overall costs by $2,150 per patient. Projections suggest that Visicu's e-ICU could save 54,000 lives and $8 billion a year if put to use in every ICU in the nation. Only a handful of hospitals have the system now.
- **An electronic medical record (EMR) system**: The Mayo Clinic in Jacksonville, Florida, began in 1993 to shift to an EMR for all patient care, and completed the transition by 1996. Virtually all clinical orders and transactions, including test orders and results, doctor's patient notes, surgery orders, and drug prescribing, are now done electronically. The system has reduced medical errors, sharply cut the time it takes to access a full patient record, improved the flow of clinical information, and enhanced clinical consultation by allowing simultaneous access to patient medical records. The cost of implementation was a hefty $21 million, but the ROI is considerable, with savings of $3 to $7 million a year, a figure that will grow as the system is improved. Fewer than 10% of U.S. hospitals and doctor offices have shifted to EMR systems thus far.
- **Computer system to authorize inpatient tests**: In December 1999, Vanderbilt University Medical Center in Nashville, Tennessee, modified an existing computer ordering system to require doctors to authorize every test (such as blood tests and x-rays) that had previously been performed routinely and automatically. The idea was, by requiring a simple "click" by the physician, to allow the computer to screen for the necessity

In a provocative keynote address, **Newt Gingrich**, CEO of The Gingrich Group and former Speaker of the U.S. House of Representatives, called for a "transformation of the health care system" through rapid acceleration of quality improvement and the spread of best practices. (See box below.)

The conference was organized in large part around specific categories of medical products, clinical tests and treatments, and health care services. Speakers explored the pace of innovation adoption in their fields, using examples and case studies where possible, and discussed ways to accelerate the adoption of innovation.

## Devices and Drugs: Obstacles to Timely Product Uptake

**Susan Bartlett Foote, JD, MA**, associate professor and head of the Division of Health Services Research and Policy at the University of Minnesota School of Public Health, told conferees that politics as well as science plays a major role in the speed of technological diffusion in health care. Federal regulatory bodies can make or break a technology, and they are not at all outside the political process.

Less well known and understood is that the policy goals and values applied to drug and device approval and reimbursement are often in flux and change over time. For example, over the past 15 years the FDA has waxed and waned with respect to the speed of drug approval. Until the 1990s, the agency was cautious on approvals and oversight. More recently, the trend has been to accommodate industry demands for accelerating the approval process. CMS is charged with making coverage and reimbursement determinations. Ms. Foote noted that there have been periods when CMS paid less attention to that role. Recently, it has been perceived to be more restrictive in terms of coverage and payment for new technologies. This is driven in large part by budgeting constraints and health

of a test. It was conceived after internal analysis suggested that many routine tests were clinically unnecessary. The new system clearly worked, as the medical center has documented a sharp decline in use of these tests. The number of CHEM7 blood tests, for example, declined 40% without any harm to patients, yielding savings of $300,000 a year. The number of portable x-ray tests declined 30%, saving $1 million a year. Mr. Gingrich and his co-authors calculate that if this system were used in hospitals nationwide, the savings would range between $10 and $20 billion a year.

- **Disease management**: Pfizer and Florida's Agency for Health Care Administration teamed up in 2001 to launch a unique statewide Medicaid disease management program. The program is targeted initially at beneficiaries with heart failure, high blood pressure, diabetes, and asthma. Approximately 55 care managers situated at 10 hospitals coordinate the care, tapping into the resources of doctors and clinics throughout the state. Patients also enjoy 24-hour nursing support. So far the program has reduced inpatient admissions by 17% and emergency department visits by 7%.

### Moving from a 20th to a 21st Century Health Care System

| 20th Century | 21st Century |
|---|---|
| Provider-centered | Patient-centered |
| Price driven | Value driven |
| Knowledge fragmented | Knowledge organized |
| Care decisions widely varying | Evidence-based care |
| Slow diffusion of innovation | Rapid diffusion |
| Paper-based | Electronically-based |
| Episodic care | Continuous care |
| Fragmented care | Coordinated care |
| Limited choice | More choice |
| Little quality measurement | Ubiquitous measurement |
| Management by process | Management for outcomes |
| Adversarial government regulation | Collaborative regulation |
| Persistent escalating cost | Overall cost decline |

## The Federal Government's Role in Accelerating Health Care Innovation

**Carolyn M. Clancy, MD,** director AHRQ, told participants that one of her agency's core missions was to create new avenues of "knowledge transfer" in health care. But she cautioned that one reason for the slow diffusion of many new innovations is the issue of "who owns" the knowledge transfer and translation function. Though the federal government is positioned to gather and organize vast amounts of medical knowledge and data on new technologies, there is no consensus that it should be the primary or a major conduit of this data to health care providers. In fact, there is strong sentiment in some quarters against the government playing a central role in influencing the practice of medicine. She said communities want the right to adopt new technologies differently. In addition, she said that one-size-fits-all solutions can and often do backfire.

Dr. Clancy said AHRQ's research at the moment suggests that the best opportunity to improve health care quality in the short term lies in enhanced diffusion of information technology – particularly as it applies to reducing medical errors. The Department of Health and Human Services (DHHS) and AHRQ are currently focusing enormous resources and attention on this issue.

**Richard Dixon, MD, FACP**, director of the Division of Prevention Research and Analytic Methods at CDC, told conferees that there is a need for more "outside-the-box" thinking about the government's role. As a purchaser, the federal government can and should more explicitly promote evidence-based care. For example, the Medicare program could reward nursing homes or hospitals (financially and otherwise) that do a better job administering influenza and pneumococcal vaccinations to high-risk seniors, Dr. Dixon said. And as a regulator, CMS could require organizations to meet certain standards of care as a condition of participation in the Medicare program. It could, for example, require hospitals to permit so-called standing orders, which allow non-physicians to administer certain known-to-be-effective services in a routine and timely manner (e.g., immunizations, beta blockers for post-MI patients) without a doctor's order.

Also as a regulator, the government could enact rules to make proprietary IT systems less of a "black box," thereby promoting standardization and interoperability. Such regulations might encourage greater investment in IT by providers. Finally, as the taxing power, the federal government might investigate creative ways to reward (with tax credits, for example) health care providers for adopting evidence-based innovations.

**Sean R. Tunis, MD, MSc,** chief medical officer and director of the Office of Clinical Standards and Quality at CMS, agreed that the government must become more actively involved and more innovative in fostering quality improvement in health care. To that end, he outlined CMS's multi-pronged approach that includes:

- Clarifying payment and coverage policies.
- Boosting reimbursement for technologies that demonstrate substantially improved outcomes.
- Coordinating CMS and FDA activities. By sharing information and linking FDA activities to internal CMS policy development, CMS can develop coverage decisions in parallel with FDA approval processes, thus speeding diffusion.
- Issuing explicit guidance on CMS coverage standards.
- Improving the efficiency of clinical research by providing early design consultation and prioritizing and supporting clinical research that is critical to the Medicare program.

CMS is also seeking to stimulate quality improvement by disseminating performance measurement and quality data directly to consumers. The agency now has nursing home and home care data available on its web site, with hospital measures to come soon. The agency expects this initiative to galvanize providers into a wide variety of quality improvement activities.

care cost trends, but it can also be a function of agency leadership and politics.

The Bush administration, Ms. Foote noted, has been challenged by the advent of new high-cost devices and drugs that are in high demand. The policy thrust is to question the relative value of these new products over existing technologies and treatments. For example, CMS in late 2002 ruled that a new anemia drug (Aranesp) was "functionally equivalent" to an older drug and thus not eligible for higher Medicare reimbursement. At the same time, CMS has stepped in to advance some technologies when the data show clear evidence of their value. (See the drug-eluting stents example that follows.)

A recent General Accounting Office (GAO) report (released in April 2003) questioned some CMS coverage procedures. The report, *Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities*, concludes that inefficiencies and inequities exist because local carriers and intermediaries are empowered under Medicare rules to make localized coverage determinations, which results in varied coverage across geographic regions. The report also criticized the agency for failing to consult with outside experts when making coverage determinations. The GAO recommended that coverage policy be centralized, but the medical device industry has challenged that conclusion. In late 2003, CMS announced changes in its technology review process. The agency will strive to make coverage determinations in 270 days, put a coverage-tracking system online, and respond to special appeals more quickly.

The GAO report illustrates the difficulty in balancing interests in the design of government decision-making processes. Ms. Foote also argued that the regulatory process itself is not as innovative as it should be. New methods can and should be applied to the evaluation of technologies and the approval process to assure that it is more science-based and can take cost-benefit issues into account when appropriate. There should also be explicit political and policy debate about the role federal agencies play in influencing the speed with which certain technologies are adopted. The process is too often controlled by special interests (such as the industries affected) and not debated openly in a way that the public can understand. If the public wants access to new technologies faster, they should be fully aware of the scientific evidence on value and the potential tradeoffs between costs and access to these technologies.

Complicating matters is that medical technologies often do not fit well into the bureaucratic structures set up to oversee them. More and more devices, for example, are "combination" products; they combine elements of being a drug, device, and a new procedure. (See the stents example that follows.) Such products stem from multidisciplinary research that brings together information technologies with the biological, material, and pharmaceutical sciences. The FDA and CMS have only recently begun to make adjustments to evaluate such products, and more work is needed before they will be up to speed.

## Stents: A Case of Rapid Diffusion

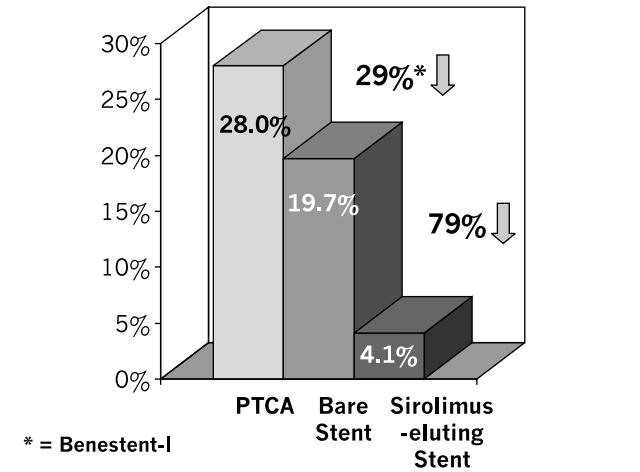
Stents to treat coronary artery disease were one of the most highly anticipated medical technologies to come along in years. They also represent a unique example of an innovation that has diffused relatively rapidly and optimally (for both expected and unexpected reasons), causing a paradigm shift in the treatment of heart disease.

**Paul R. Marshall**, director of health economics at Cordis Corporation (the Johnson & Johnson-owned company that makes one brand of stents), presented the company's perspective. First commercialized in 1994, stents are wire mesh devices inserted in coronary arteries in conjunction with angioplasty to widen occluded arteries. Studies show they reduce restenosis (renarrowing of the arteries after angioplasty) by 30% to 50%. And they virtually eliminate abrupt closures that lead to emergency bypass surgery. Stents have diffused rapidly, with roughly one million being implanted in patients in 2002. Mr. Marshall said the main reason for this rapid diffusion was a decision in October 1997 by federal authorities to increase reimbursement for use of stents in the Medicare population.

Drug-eluting stents represent an improvement that will likely will push stents into the category of being a "disruptive technology" – one that threatens to supplant existing treatments, namely bypass surgery. Drug-eluting stents reduce by three-quarters the 15%-20% rate of restenosis in

patients receiving regular stents. (See Figure 4.) That could save up to $1 billion per year by 2005, a powerful stimulant for the technology's diffusion. The FDA approved Cordis' drug-eluting stent in April 2003. Competitors are expected on the market soon.

**Figure 4: Relative Reduction in Revascularization Rate**
(9-Month Follow-up)




Source: Paul Marshall, Cordis

Mr. Marshall expects use of drug-eluting stents to take off in the marketplace despite its higher cost. Publicity is one reason, but regulators have played a key role as well. In an unusual step, CMS signaled very early (months before the FDA approved the device) that it would cover the technology and the agency set a reimbursement amount. It also issued a unique ICD-9 code, two new diagnosis-related groups (DRGs), and a new ambulatory patient code (APC). CMS will pay hospitals about $2,000 more if a drug-eluting stent is used versus a bare stent (around $14,500 versus $12,500, for example, for treatment of patients who have a heart attack).

But Mr. Marshall acknowledged that many hospitals are concerned about the stents' impact on their overall finances. Hospitals are expected to see their revenues from profitable bypass surgery plummet as a result of drug-eluting stents. For some hospitals, the decline in bypass revenue could be 30% to 50% over the next few years, according to some estimates. Whether this inhibits diffusion of the stent in any way remains to be seen.

## *Prescription Drugs*

A number of prescription drugs have faired almost as well as drug-eluting stents in recent years, with rapid uptakes being driven by aggressive marketing and by physicians and consumers who are eager for new treatments.

**David H. Kreling, PhD,** professor and chair of pharmacy administration at the School of Pharmacy, University of Wisconsin-Madison, said direct-to-consumer (DTC) marketing has boosted the sales of many new drugs, particularly those that treat symptoms that are easily identifiable by consumers themselves. This relatively new form of marketing is an innovation in itself that is changing the dynamics in the prescription drug marketplace.

The question is whether DTC ads are leading to inappropriate prescriptions by creating pressure on doctors to prescribe drugs their patients request. That, in turn, raises an important question about the speed with which new drugs are adopted. Most drugs in the past have been adopted by physicians at a measured pace, as they and their patients became more comfortable with them. But drug company emphasis in recent years on creating blockbuster drugs to boost revenues has spurred significant investments in marketing designed to elicit early adoption by doctors and consumers.

Dr. Kreling suggested the following strategies to ensure that new drugs diffuse at an appropriate speed – i.e., that truly innovative drugs diffuse rapidly while those that offer little or no advantage compared to existing agents diffuse more slowly.

- Greater use of clinical guidelines and prescribing protocols.
- Economic and cost-benefit evaluations of pharmaceuticals.
- Head-to-head trials comparing new drugs to existing agents.
- Directives or prohibitions related to certain kinds of promotion.
- More and better education of physicians and patients, both of whom often lack definitive data to guide their pharmacy decisions.

# Innovation in the Hospital and at the Bedside

Several speakers discussed the pace of diffusion of innovations within the hospital and at the patient's bedside.

## *Surgery*

In contrast to drugs and devices, surgical procedures and innovations are not technically approved by government. (Procedures that involve using new devices, tools, or substances are an exception, requiring FDA approval.) However, as with drugs and devices, government reimbursement under Medicare and Medicaid is critical to the diffusion of many new surgical procedures. In addition, their adoption is driven by research and professional assessment (e.g., guidelines developed by medical associations).

But in all too many cases surgical procedures gain popularity in the absence of definitive evidence that they work, according to **Charles Wilson, MD, MSHA, DSc**, a professor emeritus of neurosurgery at the University of California San Francisco, senior fellow at the Institute for the Future, and advisor to The Health Technology Center. In some cases, surgical procedures lacking an evidence base are used for years before they are proven to be useless – or worse, harmful to patients. Dr. Wilson cited several examples of how surgical procedures have diffused, some too quickly (and inappropriately), some too slowly, and some appropriately.

- **Chymopapain for lumbar disc herniation**: In 1964, a surgeon named Lyman Smith first tried injecting chymopapain (an enzyme) into lumbar discs, building on animal research that suggested this approach was effective in treating disc herniation. By 1974, the procedure was very popular, with an estimated 17,000 patients being treated annually. The simplicity of the procedure (it is easy to learn and do) and aggressive marketing combined to drive rapid diffusion, in spite of skepticism from a handful of surgeons (which was dismissed as "sour grapes" since surgeons lost income because of the rapid adoption of the procedure). But 15 years later, in 1989, a landmark study involving 75,000 patients showed that the procedure offered *no clinical benefit*. This study, along with highly publicized (though rare) cases of fatal complications and paralysis as a result of the procedure, prompted the FDA to withdraw its approval of chymopapain in 1999.
- **Cerebral artery bypass:** This procedure was developed to increase cerebral blood flow in patients who suffered a transient ischemic attack (TIA, which signals a 50% chance of a major stroke within a year) or who have had a non-disabling first stroke. First performed in 1967, the procedure diffused widely in the 1970s. In 1985, a randomized international trial published in the *New England Journal of Medicine* found that it was ineffective in preventing strokes, prompting Medicare to withdraw reimbursement the following year.
- **Endovascular obliteration of intracranial aneurysms**: This technique was first used in 1974, using a detachable balloon. In spite of positive studies that were initially reported in 1982, the procedure was still only used in fewer than 5% of eligible patients, primarily because of a dearth of surgeons willing to learn how to perform it. Following an improvement to the procedure in 1982 (making use of platinum coils), use increased somewhat, but diffusion still proceeded slowly. In 1991, the introduction of a better coil (using electrolytic detachment) began to alter this pattern, and by 1998 endovascular surgery was used in 10% of ruptured aneurysms. Diffusion spread even more rapidly after 1998, and by 2002 endovascular surgery was used to treat 35% of eligible patients. The key drivers of this diffusion were growth in the number of neurovascular stroke units in hospitals, outcomes data that provided comparisons of various treatment approaches, technologic advances in image guidance and the versatility of coils, and reaching a critical mass of neurovascular surgeons who were familiar with the technique.
- **Gamma knife surgery (GKS) for acoustic tumors**: The concept for this minimally invasive procedure was first introduced in 1951, although it was not applied to acoustic tumors until the early 1970s. The first gamma

knife appeared in the U.S. in 1987. By 2002, about 28% of surgeries for acoustic tumors utilized the GKS technique. By 2007, it is projected that GKS will have a 45% market share. The rapid diffusion of GKS has been driven by a few simple facts: it works, it is safe, it is simple to learn and do, and it is now reimbursed.

## Hospital Design

When planning for the building of a brand new hospital began in the mid-1990s, the leaders of Northwestern Memorial Hospital in Chicago saw an opportunity to create a truly unique 21st century institution integrating innovative design with new technologies and tools. By many accounts, the hospital (which opened in 1999) has succeeded, creating a model for others around the world.

**Jean Przybylek, MS, RN**, vice president of hospital operations at Northwestern, told attendees the planning process itself represented an innovation that, in her view, should diffuse rapidly in the industry. It included the following:

- Developing an overall vision to guide the process. Northwestern started from a simple premise: the patient's perspective and experience comes first and drives the design. This meant more than designing for optimum clinical care flow, but also taking into account patient comfort, ease of access to facilities, and ease of movement for patients and their families.
- Creating a physical and working environment that would attract and retain the best medical, nursing, and administrative staff.
- Using a flexible process in which workgroup teams routinely provided input and feedback at each stage of the design process.
- Taking infection control and other patient safety issues into account in the design and construction.
- Designing to allow both integration of today's latest technology as well as technological upgrades over time.

The end result is a unique facility that uses light and space to create a non-clinical ambiance, art and design to enhance the patient experience, and numerous, cozy family visiting and waiting areas to promote socialization. Other innovations include patient rooms wired for fiber optic communications and patient-focused entertainment, and a state-of-the-art infection control system that makes use of a new air flow technique. Since 1999, hundreds of hospital executives from around the world have toured the new facility.

## Care at the End of Life

Substantial improvement and innovation in end-of-life care have already occurred throughout the system. But **Joanne Lynn, MD, MA, MS,** director of the Washington Home Center for Palliative Care Studies and a researcher at RAND Health, believes that end-of-life care in the U.S. is still far from adequate. She discussed the diffusion of three components of end-of-life care: hospice, pain management, and complex care management.

Before the mid-1980s, a small percentage of dying people in the U.S. had access to hospice care. Today, it is available almost everywhere, due in large part to the fact that Medicare covers six months of hospice care for those who qualify (i.e., if a physician and the hospice medical director determine that they have a prognosis of death within six months). Hospice is also covered by most private insurers, although often with restrictions. Hospice care has also diffused because it is a relatively easy business to establish.

But even though hospice care is available virtually everywhere in the country, *only one quarter of all dying people get any kind of hospice service today.* Why? Dr. Lynn cited three core reasons:

- Lack of knowledge about hospice services. Consumers do not understand hospice care. And it is not widely marketed.
- Low patient demand. Many Americans still prefer to manage their own death or rely on family members. They may be in denial or think that entering a hospice facility is tantamount to giving up. Many also opt out of hospice because to qualify they have to forego treatments that might prolong their lives, which of course is a difficult and emotional choice for many people, their families, and their doctors.

- Low reimbursement, which produces a shortage of providers in some areas.

Dr. Lynn said increasing reimbursement would spur growth in hospice care, but that enhanced education of the public and physicians about hospice is also essential.

Like hospice care, end-of-life pain management has improved in recent years. Opioid use in dying patients, for example, has risen tenfold since 1995, driven largely by the development of new and better drugs. Notably, the Joint Commission on the Accreditation of Healthcare Organizations now requires that hospitals have discernable pain management programs. Research has also convinced doctors that more aggressive pain management is safe. And more clinicians have received training (and some even have begun to specialize) in palliative care management.

Still, obstacles continue to stand in the way of more rapid adoption of aggressive pain management in the dying, Dr. Lynn said. For example, recent studies indicate that half of nursing home patients suffer from serious pain problems that are not adequately addressed. Doctors continue to fear that patients in legitimate need will become addicted to painkillers, even though the evidence suggests that they will not. Payment for counseling and multidisciplinary care continues to lag, as does full integration of pain specialists into team care.

Perceived legal barriers also stand in the way. A report released in April 2003 found widespread under-prescribing of painkillers nationwide because doctors overestimate their risk of legal liability if patients misuse the drugs. The report, published in the *Journal of Law, Medicine and Ethics*, estimates that on any given day 75 million Americans are in pain unnecessarily, including 15 million people who have chronic conditions.

Complex or multi-condition care management is another cornerstone of end-of-life care today. Most people who die of old age have multiple conditions, and their death may be precipitated or accelerated by several of these. Programs that are organized to deal with this can not only ease pain and suffering but save money. The Hospice of Winston Salem (North Carolina), for example, built a care management program for the dying that uses care teams and advance care planning. It also trains patients in self-management. Nurses are dispatched to a dying patient's home within an hour of an "exacerbating" event. The program sharply reduced the need for emergency care.

Yet outside of certain parts of the Veterans Administration health system or a handful of group-model HMOs, this model is seldom used for the frail elderly who need it, Dr. Lynn said. Factors inhibiting the spread include the following:

- Medicare does not provide coverage for complex care management, in part because it has not been definitively shown to save money.
- Needed services, such as home evaluation and treatment, 24-hour on-call nursing, and certain types of drugs, are not available or covered by Medicare.
- There is a reluctance to develop care plans for patients who are dying.
- The organization of the delivery system does not support continuity of care.

New "mental models" are needed to replace current misconceptions about how and why people die, and the care they need. (See Figure 5 ) These models should recognize that death often comes slowly and is the result of multiple conditions and causes. Dying patients need help in living this last phase of life as fully as possible, including a customized care plan that involves the family and that conforms to the patient's wishes. To make this type of care more commonplace, Dr. Lynn recommended a realignment of payment incentives to recognize the value of this type of care and demonstration projects to document the value of the approach.

**Figure 5. How Americans Die: Century of Change**

| | 1900 | 2000 |
|---|---|---|
| Age at death | 46 years | 76 years |
| Top Causes | Infection<br>Accident<br>Childbirth | Cancer<br>Organ system failure<br>Stroke/Dementia |
| Disability with dying | Not much | 2-4 years before death |
| Financing | Private, modest | Public and substantial (83% in Medicare) |

## The Next Wave of Biomedical and Health Technology Innovation

*Presentation **by William Dwyer, MBA**, divisional vice president of strategic marketing for the Abbott HealthSystem Division of Abbott Laboratories. Response and comments by **Wade Aubry, M.D.**, senior advisor to the Health Technology Center; **Jerry Parrott**, vice president of public policy and corporate communications at Human Genome Sciences, Inc.; and **Paul Citron, MSEE**, vice president of technology policy and academic relations at Medtronic.*

Mr. Dwyer reminded participants that close to 500 gene therapy treatments have been tested worldwide, with only one positive clinical trial to date. And that was halted due to patient complications. Despite this slow beginning, Mr. Dwyer said he believes that genomics and proteonomics will one day provide treatments not even dreamed about today.

Among the most promising technologies on the horizon:

- Gene therapies that promote new blood vessel growth, with the potential to bypass existing vessels that have life-threatening blockages.
- Diagnostic gene "chips" that can provide a DNA profile of a person, revealing their predisposed risk of certain diseases.
- Disposable imaging capsules that can be swallowed, providing detailed images non-invasively.
- Techniques that let the cells from bone marrow tissue be "morphed" into tissues such as skin, bone, and cartilage, allowing the creation of new skin and tissue grafts.
- Nanometers—small "machines" built from single DNA molecules that will travel through the body to target pathogens.

Mr. Dwyer predicted that cloning will continue to advance at a rapid pace, even if there is a moratorium in the U.S. The field has already moved from the cloning of the first animal from an adult cell in 1996—a task declared impossible in 1985—to the cloning of 50 mice from a single adult mouse in 1998. Mr. Dwyer said he believes that human cloning will be achieved in the near future.

And though it may take a bit longer than people thought a few years ago, the Human Genome Project and the research it has spawned will yield novel drugs and therapies. Techniques will be developed that allow drugs to be tailored to individuals, for example. And drugs and vaccines will be developed with increased speed and at lower costs as well. Mr. Dwyer also foresees a revolution in drug delivery. Aerosol devices, for example, will allow inhalation of vaccines, hormones, and other drugs.

These developments have the potential to significantly lower costs, Mr. Dwyer said. For example, roughly 100,000 ulcer surgeries were performed in 1977. But once researchers discovered the bacteria that causes ulcers, drugs were developed that have replaced this surgery at a fraction of the cost – $1,000 for drug treatment compared to roughly $28,000 for surgery.

The three discussants agreed that despite sounding like science fiction, many of the future technologies Mr. Dywer discussed were within the realm of the possible, if not probable. But whether society is ready for the ethical and financial impact is another issue. Dr. Aubry said that employers and health insurers may be increasingly reluctant to cover some new technologies if health costs continue to rise. Just as some insurers do not cover lifestyle drugs such as Viagra, it is not clear that they will be willing to cover human "replacement parts" and drugs aimed at enhancing normal function. Mr. Parrott concurred with Mr. Dwyer that within the next 20 years drugs will be produced that can be targeted at subgroups of people or even individuals. And within 40 years, it will be possible to "reset" a person's genetic clock, Mr. Parrott predicted.

Mr. Citron cautioned that a variety of forces stand in the way of the "next wave" of biotechnology innovation. These include regulatory uncertainties for breakthrough and combination technologies, legislative limits on stem cell research, delays in reimbursement, and a highly constrained venture capital environment for start-up companies. Mr. Citron called for an examination of the government approval and reimbursement policies that govern potentially life-saving technologies. But Dr. Aubry cautioned against moving too quickly. He said that demand for innovations often precedes evidence of effectiveness (as occurred with autologous bone marrow transplants for breast cancer, for example). Some unproven technologies diffuse too rapidly, putting patients at risk of harm.

# Innovation in Public Health, Prevention, and Disease Management

## *Public Health*

**Stephen Isaacs, JD,** president of Health Policy Associates in San Francisco, highlighted public health success stories of the 20th century, and the lessons they hold for the public health challenges of the 21st century. Among the best known success stories were the eradication of polio and the control of measles, diphtheria, and whooping cough – each of which was accomplished through the unusually rapid diffusion of mass immunizations. Less well known successes include the control of tuberculosis and declines in the following: traffic deaths due to drunk driving, neurological damage from lead, tooth decay, heart disease, stroke, unwanted pregnancy, and smoking. These public health successes offer two critical lessons:

- Tenacious consumer and public interest groups often play a leading role in pushing social change to protect and promote public health.
- Once the evidence is clear, decisive government action to enact laws and regulations to protect public health is essential and successful.

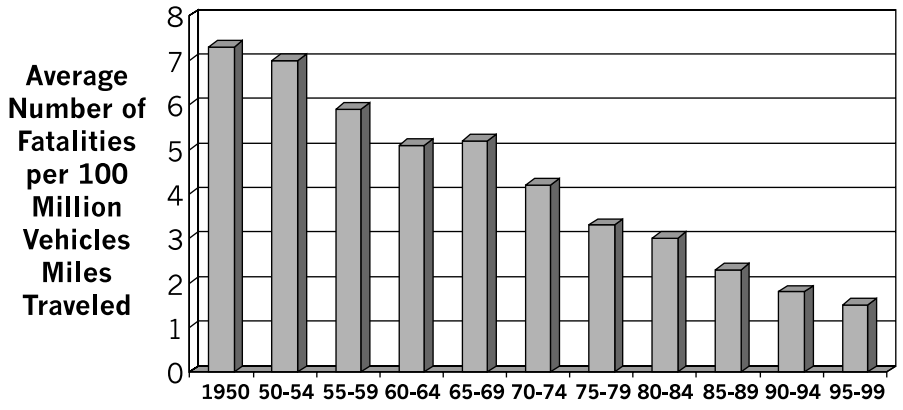
For example, research in the 1930s and 1940s conclusively showed that fluoride in drinking water reduced tooth decay. A small number of advocates and several dental societies spread the news and advocated that fluoride be put in water supplies. State and local laws quickly established the practice, despite bizarre (but popular) claims that such action was a "communist plot."

Similarly, mounting research in the 1950s showed the dangers of lead to childhood development. As a result, groups such as the Natural Resources Defense Council, Consumer's Union, and the Environmental Defense Fund pushed for lead-free gasoline. The Clean Air Act of 1970 mandated the transition to lead-free gasoline, despite a series of lawsuits from industry that threatened to slow down the transition.

The same pattern played out in auto safety, drunk driving, and tobacco control. Ralph Nader and others led the fight for seatbelts and airbags and for greater attention by the auto industry to safety. The net result was the development and widespread use of innovations that car makers initially thought would be too expensive to deploy. Congress in 1966 passed the National Traffic and Motor Vehicle Safety Act. States passed laws as well, including those that require seat belt use.

Mothers Against Drunk Driving (MADD) and Students Against Drunk Driving (SADD) led the fight in the 1980s to curb drunk driving. Several of the leaders of these organizations were motivated by personal loss to launch the initiatives. The movement led most states to pass much tougher DUI (driving under the influence) and DWI (driving while intoxicated) laws. In addition, the federal government has tied the availability of highway funds to states' success rates in reducing deaths from drunk driving and to their willingness to raise drinking ages. People have changed their behavior as well; use of designated drivers is now commonplace, for example. (See Figure 6.)

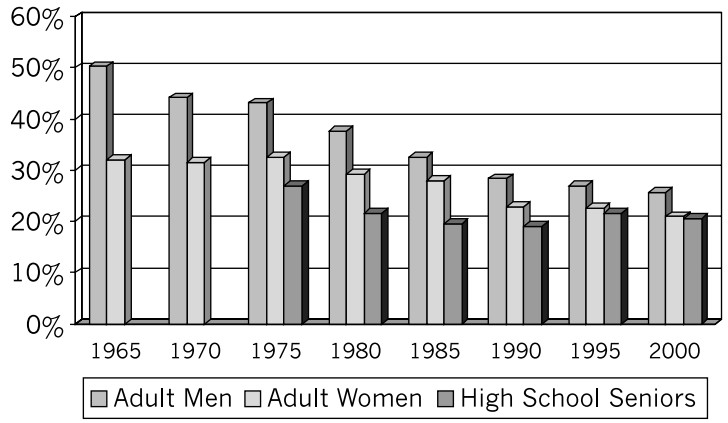
**Figure 6. Decline in Traffic Deaths**




Source: National Safety Council, Accident Facts, 1991 Edition (Washington, D.C. 1991); National Highway Traffic Safety Administration, *Traffic Safety Facts*, 1999 (Washington, D.C., 2000)

The campaign to reduce smoking took longer to reach fruition. Research in the 1950s led early advocates to spotlight the link between tobacco products and cancer and to call for action. In a twist, government, in the person of Surgeon General Luther Terry, took up the cause. A landmark Surgeon General's report in the 1960s led to widespread calls for public health measures. Follow-up reports by future Surgeons General strengthened the case, especially the fact that tobacco is addictive. In 1965, the government mandated the boxed health warning on cigarette packs. The FDA also got involved in the late 1980s when Commissioner David Kessler sought FDA regulatory power over tobacco products. That effort failed, but Congress and most states eventually passed laws allowing restrictions on smoking and bans on cigarette advertising. High profile lawsuits, including the states' landmark case seeking to recoup Medicaid costs related to smoking, also led to widespread changes. (See Figure 7 for data on declines in smoking rates.)

**Figure 7: Decline in Smoking in the U.S.**




Source: CDC, "Current Smoking Among Adults – United States 2000"

Mr. Isaacs said emerging public health problems are tracking past experience. In particular, early

Commissioned Paper Synopsis

## Medical Technology, Innovation, and the Nature of Medical Progress

By Daniel Callahan, Ph.D., Director, International Programs, The Hastings Center

Between 40% and 50% of the persistent rise in health care costs in the U.S. is attributable to new medical technologies and the intensified use of older ones. This presents a difficult problem. As a culture, we are hooked on medical technology, and can not imagine living without it much less being sick without it. On the other hand, there is growing recognition that the inexorable rise in costs and the liberal use of new technologies could someday soon make health care all but unaffordable, forcing unpleasant tradeoffs.

We have reached a point where a basic clash of values is occurring. It is a clash between the value of equitable access to affordable health care for all citizens on the one hand, and that of constant high-tech medical "progress" on the other. We have been living with a model of health care progress that in fact admits little if any limits to the development and use of technology. That model has led, and will continue to lead, to a path of endlessly rising costs and increasingly inequitable care. I believe that model and path must now be abandoned.

In its place we need a new model and framework for defining medical progress. We must start by recognizing that there are three ways of conceiving of medical progress – (a) as a scientific enterprise, (b) a clinical enterprise, and (c) a population enterprise. Our culture for 100 years has put most of its energy and resources into the scientific and clinical enterprise of medicine. That has produced many wondrous breakthroughs.

But we have badly ignored the population frame of reference. The most egregious example of this is our lopsided focus on acute care at the expense of preventive care and chronic care management. Indeed, much of our technology today yields only a negligible impact on the overall health status of the population. And lately we have shifted to an overemphasis on the clinical enterprise – building a vast (mostly profit-oriented) health care and financing infrastructure that has large incentives to deliver the most costly care. Almost everyone agrees that this system wastes enormous resources.

advocates, including several prominent health care groups and philanthropies, are calling for action to reduce a rapid increase in the prevalence of obese and overweight individuals in the U.S. Media attention to the issue is also growing. People are talking for the first time about legislation that would strengthen warning labels on foods, and perhaps even limit the fat content of certain foods. Mr. Isaacs predicted a knock-down, drag-out fight on these issues over the next decade if the proportion of the population that is overweight keeps rising, as expected.

## *Prevention and Screening Services*

**David Atkins, MD, MPH**, chief medical officer for the Center for Practice and Technology Assessment at AHRQ, told conferees that accelerating the use of clinical preventive health services is one of the most powerful paths to improved population health status in the U.S. But while use of some services and screening tests has risen significantly in recent years, use of others has foundered. And even in those areas where improvements have occurred, usage rates remain well below best-practice levels. (See Figures 8 and 9 on page 18.)

This should come as no surprise, since the obstacles to greater use abound. Inadequate knowledge about which services are most effective results in a lack of demand for preventive care services on the part of both physicians and consumers. Inadequate insurance reimbursement also inhibits access. Coverage has improved in recent years but still falls short for some recommend services. Over 80% of employers, for example, provided coverage in 2001 for physical/wellness exams, gynecological exams, and childhood immunizations. But far fewer covered chlamydia screening, smoking cessation programs, cholesterol tests, nutrition/diet counseling, and weight loss programs. Also, employer and health plan coverage of preventive services does not always follow the recommendations of the United States Preventive Services Task Force (USPSTF), a government-sponsored panel of experts affiliated with AHRQ.

We need now to shift back to the scientific enterprise, and a re-orientation to population-based health care. We need to put more resources into basic research, new cures and treatments, and diffusing existing evidence and knowledge more effectively. At the same time, we need a fresh embrace of the goal of maximizing the overall health of the population.

Of course it is not easy to discern which new technologies and innovations truly advance the health of the population and which are of little value. Good measures and barometers must be developed. The chief question we face is this: Is the diffusion of a technology that is very expensive but increases life expectancy by, for example, one year (and perhaps mostly for people over age 75) something we want to diffuse rapidly?

Take the ventricular assist device, for example. It costs $160,000 and increases life expectancy (for patients whose hearts have failed but are not candidates for a transplant) by roughly 400 days, about 250 days longer than if these same patients took the medicines available today. The estimated cost for treating all clinically eligible patients in the U.S. in 2001 was $16 billion. Is it worth it? There is no easy answer.

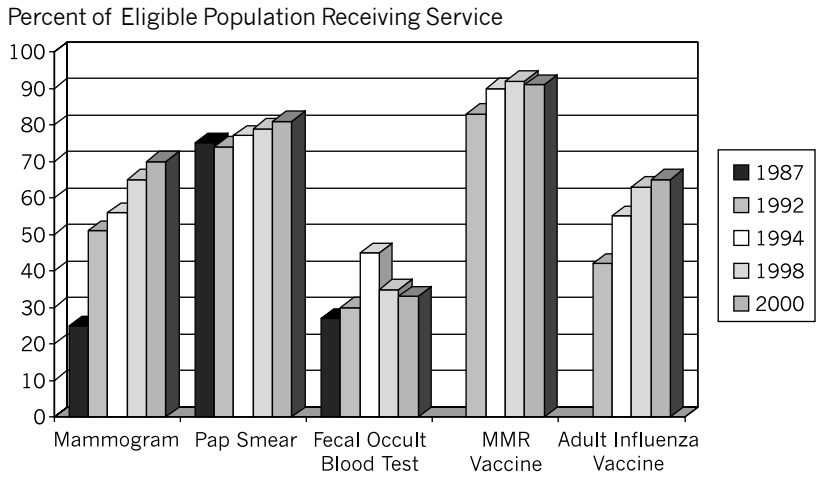
Clearly, some technologies will be of obvious and clear benefit (at low cost). Consensus for rapid diffusion of them will come quickly. Others will require longer evaluation but may be of such low cost that they do not pose problems. It's a third set of technologies that poses the most problem – technologies that are very costly and whose clinical usefulness is not yet proven. We can expect more technologies to fall into this category in the years ahead. This should compel us to develop a rigorous set of cost-benefit analyses that must be applied to them. My modest proposal is this: require manufacturers of costly new medical technologies (as judged by some criteria) to conduct cost- benefit analyses of them. This data would be evaluated by a new government agency that includes impartial outside experts as scientific evaluators.

My aim is not to undermine the engine of medical innovation. Rather, it is to provoke a rational debate about how we should allocate increasingly scarce medical resources, and then to move to a system that rationally uses these resources to the maximal benefit of the population as a whole. I believe this is the responsible course of action to take.

For example, task force recommendations include screening for colorectal cancer but not for prostate cancer, yet more employers cover the latter.

The task force has been systematically evaluating the scientific evidence for many clinical preventive services in recent years. In addition, the CDC sponsors the *Guide to Community Preventive Services* (often referred to simply as the *Community Guide*), which provides public health decision makers with recommendations on population-based interventions. But Dr. Atkins believes it is an uphill battle to make front-line providers aware of the evidence and the ongoing evaluations. All too often they will be swayed by stories in the media rather than by the medical literature.

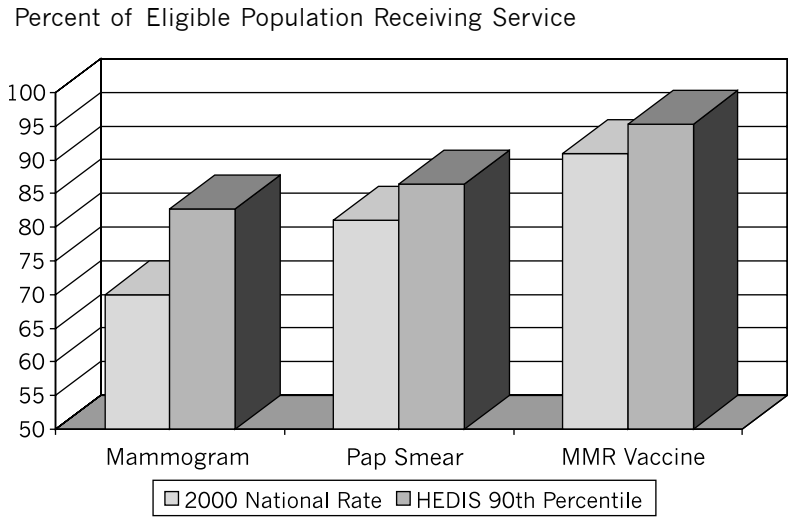
**Figure 8: Increasing Delivery of Clinical Preventive Services**




Source: Healthy People 2000 Review; DATA 2010

**Figure 9: Room for Improvement**

**National Rates vs. Best Performing Plans**




Source: Healthy People 2000 Review; DATA 2010; NCQA, The State of Health Care Quality, 2002

Dr. Atkins recommended that the use of evidence-based preventive services be enhanced by:

- Collaboration at the local level between payers, health plans, and providers to increase awareness of preventive health services and screening tests.
- Providing patients and employees with personalized reminder notices from their physicians, delivered in the mail, by e-mail, or by phone.
- Enhancing coverage based on evidence and the USPSTF and CDC recommendations.
- Creating financial incentives for accessing preventive services, such as reduced copayments and/or deductibles, wellness accounts, and rewards for lifestyle changes.
- Enacting state laws mandating the provision of preventive services.

## *Disease Management*

**David Plocher, MD,** vice president in Cap Gemini Ernst & Young's Health Consulting Practice, said disease management programs are an innovation that should have diffused relatively rapidly. The concept behind such programs is simple and generally accepted by administrators, doctors, and patients. And there has long been evidence that they benefit patients. Yet the adoption and use of disease management has been neither rapid nor smooth.

Many obstacles are to blame, Dr. Plocher told conferees. Chief among these is physician resistance. Put simply, doctors resent being told how to treat their patients and having care coordinated by external organizations. They widely believe that they already have systems in place to coordinate care for high-risk and high-cost patients. They do not want to cede control, due in part to professional integrity, but also because of financial incentives. Doctors resent being asked to spend uncompensated time as a part of disease management teams.

A second potent reason for the less-than-optimal adoption of disease management is the perception–and in some cases the reality–that the costs to operate the programs exceed short-term savings. This has been largely because predictive models to identify the high-risk patients who would most benefit from the programs did not work as expected. Many people with chronic and/or high-cost diseases who could have benefited never gained access or were never identified. At the same time, call centers to coordinate patient care, staffed by registered nurses, proved more expensive than anticipated. In addition, some health plans did not like the idea of outsourcing disease management functions to specialty vendors. Many early contracts were terminated as disagreements arose.

Health plans and disease management vendors are taking steps and making improvements in their systems that are designed to overcome these obstacles. Among these:

- Involving physicians in the planning and design of disease management programs, and limiting physician communications to brief, unobtrusive prompts at the point of care.
- Creating financial incentives for physicians to engage in disease management, including performance-based bonuses.
- Sponsoring provider contact with enrollees/patients, instead of direct plan-to-enrollee communications.
- Improving predictive modeling so that more at-risk individuals are identified and enrolled in disease management programs.
- Reducing costs at call centers through more reliance on technology (e.g., auto-dialing, e-mail communications, and remote monitoring and transmission of vital signs).

## The Imperative of Information Technology and E-Health

No arena of health care innovation is stirring more excitement than information technology (IT). Yet even IT's most vocal advocates caution that hype has surrounded the topic for years. A trail of failed initiatives and business ventures are testimony to overstated promises. Still, several speakers told conferees that IT's time may have finally come.

In his keynote address, Mr. Gingrich said that the rapid deployment of IT is now the glue that will make so many other innovations in health care possible. He called on government and the private sector to make a *massive investment,* and he scolded the health care industry for its failure to embrace IT technologies that are increasing productivity in other sectors of the economy.

Dr. Balas agreed that IT is an effective strategy for accelerating diffusion of other innovations in health care. But so far, he said, widespread adoption of simple IT tools–such as computers in hospitals and physician offices that offer only a few rudimentary software programs and access to the Internet–have in no way had the impact that full use of IT tools could have. For example, computer-based reminder systems (for flu shots, pap smears, mammograms, and the like) led to only a 2% increase in the use of these services between 1992 and 1997, according to one recent study. That is likely higher now, he acknowledged, but still suboptimal. Dr. Balas contrasted this experience with the diffusion of genetically-altered cotton in cotton farming from 1996 to 2001, which enjoyed an average rate of diffusion of roughly 5% a year in several developed and developing countries where it has been approved.

To spread faster, IT must become an integral part of the practice of medicine, not just back office procedures. For example, IT vendors and companies must begin to offer easy-to-use decision-support and diagnostic pathway systems that can help clinicians make testing and treatment choices based on evidence. The key to doing this is improved knowledge management. Just as travelers have moved from conventional approaches to trip planning (reading books, checking maps) to computerized, integrated ones

(using the Internet to generate customized routing), health care professionals must embrace new ways of using and acting on knowledge.

**Randy Spratt**, senior vice president of business processes and diagnostic systems for McKesson Information Solutions, said that new systems under development now (at McKesson and other companies) are a vast improvement over earlier efforts. Mr. Spratt called on academic medicine to develop the content for these systems, including guidelines that have adequate detail (e.g., diagnoses, orders, citations, clinical documentation, and reimbursement documentation). He also urged groups developing guidelines and vendors to adopt the emerging "HL-7" standards, which will make dissemination easier.

## *Adopting IT at a Teaching Hospital*

**John P. Glaser, PhD**, vice president and chief information officer at Partners HealthCare System in Boston, told conferees about that health system's adoption of IT. Formed in 1994, Partners is a 10-hospital system that includes Brigham & Women's Hospital (BWH) and Massachusetts General Hospital (MGH).

Partners' hospitals were early adopters of CPOE systems, with BWH implementing a system in 1991, which spread to MGH in 1997 after the merger. The remaining hospitals in the system

### Financial Incentives to Promote the Diffusion of Innovations

What's in it for me? It's a question that resonates across the health quality improvement landscape. Hospitals and physicians are in the business of providing patient care, easing human suffering, and repairing bodies. But they are also in the business of earning a living and making a payroll. Conference speakers universally concurred that innovations that improve the quality of care will not and can not be optimally diffused in the absence of financial incentives.

Many speakers recommended that payers begin to subsidize and reward quality improvement – by paying providers more when they demonstrate better performance and by footing the bill for some proven technologies and innovations that improve quality of care but may not necessarily accrue to the bottom line right away.

Dr. Sean Tunis told conferees that CMS fully embraces the idea of paying for quality and will soon give it a try. The agency announced in July 2003 a demonstration project that will give $7 million in bonuses in 2004 to hospitals that score well on 35 quality measures. It remains to be seen how quickly CMS can move in implementing a full-blown pay-for-quality program, given some of the methodological issues and barriers involved. But the pilot program should help to identify and overcome some of these barriers, he said.

Dr. John Glaser said it is vital to accurately measure the return on investment (ROI) of quality improvement demonstration projects. There is widespread concern among providers, he said, that new IT systems and other new technologies do not offer a timely ROI. In addition, investment in systems to improve the flow of care compete for resources with technologies (such as imaging machines) that generate revenues for hospitals and doctors.

Dr Sam Nussbaum said health plans are intensely interested in "paying for performance," and many have launched demonstration projects to test the concept. One Anthem initiative, for example, pays bonuses to primary care physicians in New Hampshire who are top performers. The bonuses represent more than 10% of total Anthem payments to the doctors, and they have resulted in significant improvements in the provision of preventive services. (See chart next page.) A second Anthem initiative has 50 Virginia hospitals under contracts that link up to half their annual reimbursements from Anthem to meeting performance goals. A third initiative involves 33 obstetricians/gynecologists in Columbus, Ohio, who can earn up to a 5% bonus by scoring 90% or better on a set of measures, including improving postpartum care, conducting regular mammograms and pap smears, meeting national standards for hysterectomies, and using more generic drugs. The program has boosted quality. For example, 100% of new mothers had a postpartum visit two years after the program was launched, up from 73.3% in 1999.

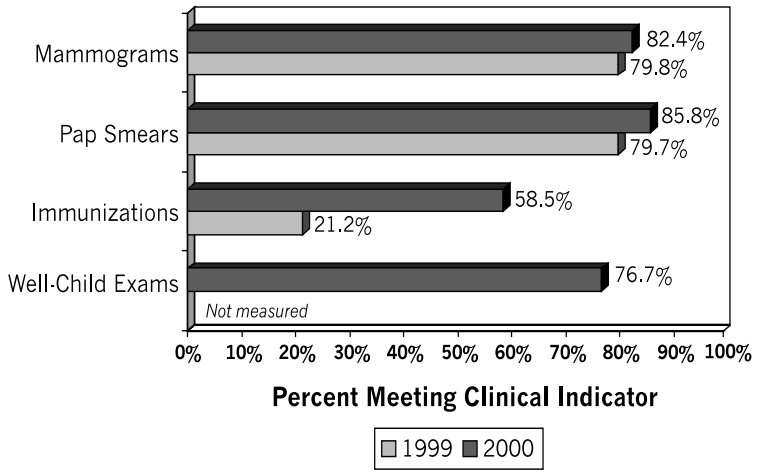
In another targeted experiment, HealthPartners, a large managed care organization in Minnesota, created bonus pools of $7,000 to $44,000 for 20

must integrate CPOE by 2005. While there have been objections and technical issues to deal with, Dr. Glaser said the implementation process has progressed relatively smoothly and with reasonable speed. At present, 26,000 orders each day are entered into the system, 80% to 85% of which are written by physicians. It has already yielded a 55% decline in serious medication errors.

Implementation of an EMR has proven to be more complicated. Early efforts were launched in 1979 at MGH, but foundered. Ten years later BWH tried again, but that effort flagged too. After the merger that formed Partners HealthCare, the system committed itself to implement an EMR in 1996. By 1999, serious objections to the system resulted in a "near-death experience," but by 2002 EMR was back on track as a system-wide priority, with $30 million allocated to the project annually. Today the EMR system has reached reasonable scale, with 1,800 physicians and over 4,000 other clinicians and nurses using it at 58 practice sites. Partners has set a goal of 5,000 physicians using the system in the next few years.

What made both these IT initiatives happen, Dr. Glaser said, was *leadership from administrators and medical staff* who were willing to stay the course because they firmly believed in the need for CPOE and EMRs and in their ability to ultimately produce a sizable ROI. An organized process of adoption and technical integration was also essential.

**Quality Performance: Incentives for Primary Care Physicians**




Source: Sam Nussbaum, MD, Anthem, Inc.

medical groups depending on how well they performed in identifying and counseling smokers to quit. Counseling rates jumped from 32% in 1996 to 53% in 1999. Blue Cross of California, Empire Blue Cross Blue Shield in New York, Aetna, Cigna, PacifiCare Health Systems, and a large employer coalition (The Leapfrog Group, which includes GE, Ford, Proctor and Gamble, and Verizon Communications) have also launched pay-for-performance pilots in the last two years.

Mr. Newt Gingrich told attendees that financial incentives must go beyond rewarding the best-performing organizations. He called for direct subsidies to speed the diffusion of an initial set of specific innovations that are likely to have a major impact on the health care delivery system and quality of care in the future. These include:

- Electronic medical records (EMRs). He called for the creation of financial incentives for every hospital and physician office to use EMRs, preferably one that is nationally standardized. Implementation of EMRs that provide access to expert systems for diagnosis and drug ordering could save up to $80 billion annually, Mr. Gingrich predicted. Such systems could also be vital in helping the nation's providers respond to a terrorist attack.
- Computerized physician order entry (CPOE). Very few hospitals have CPOE systems, and in those that do physicians use these systems only 25% of the time. Payers, including government, need to reward facilities that adopt and use CPOE by offering them a higher level of reimbursement.
- Telemedicine and e-mail consultations. Both have the potential to improve care and should be rewarded.

Speakers cautioned, however, that rewards for high performers and quality improvement must be based on sound criteria and measurement. Efforts must also be undertaken to avoid inducing quality improvement in some areas while letting other clinical areas founder.

To spur broad national hospital investment in IT, Dr. Glaser called for federal funds to partially subsidize its adoption, especially in small hospitals. He also strongly supports the federal government's efforts (now in early stages) to establish a national health care information infrastructure. Both Dr. Clancy and Dr. Tunis agreed with that goal and said DHHS was committed to it. Dr. Clancy noted that the immediate task is to establish health care information interoperability standards as the basis for electronic health data transfer in all activities and projects and among all federal agencies and departments. DHHS Secretary Tommy Thompson announced such an initiative in March 2003. The Consolidated Health Informatics

Commissioned Paper Synopsis

## Complexity and the Adoption of Innovation in Health Care

By Paul Plsek, Ph.D., President, DirectedCreativity

Health care organizations are complex systems. As such they behave in certain ways, some predictable, some not. One key to understanding the diffusion of innovations in health care is to understand the way complex systems behave and adapt to change.

There are essentially three inter-related processes associated with innovation in health care systems: (a) generation or acceptance of new ideas or products; (b) implementation of those ideas, processes, or products into the routine work of the organization; and (c) widespread adoption across the organization.

Opportunities exist at each of these levels to accelerate innovation and improve the quality of care. First, enhancing the generation of new ideas, especially around service delivery in health care, can perhaps best be achieved by a cultural change in organizations. Many organizations, including hospitals, health plans, large clinics, and nursing homes, suffer from process inertia and from fragmented systems. Most are not amenable to new ideas, and some are actually hostile to them. These organizations need to create cultures of innovation.

Many would be well advised to take pages from the books of other industries. For example, 3M Corporation holds its senior managers accountable for generating one-third of their revenues from products that did not *exist* three years prior. An analogous goal in health care would hold managers accountable for improvements in care delivery and outcomes in their areas of responsibility based on changes that have taken place over specified periods of time.

Accelerating the implementation of a new idea poses another set of challenges. The most important of these is overcoming resistance to change. For example, a hospital administrator can mandate implementation of a CPOE system. But as has occurred at several hospitals nationwide, individual physicians may refuse to use it. Coercive strategies are of limited value in such circumstances. A better tactic is to involve the physicians in the process, so that they take ownership of the idea, the need for the change, and the implementation process itself. The lesson here is that the uptake of an innovation is almost always faster when those "on the ground" implementing the change have an investment in it and stand to gain from it – financially, professionally, and emotionally.

Diffusing an innovation throughout an organization also requires overcoming inertia and energizing the "natural" social network systems that exist. For example, every organization has individuals whom the rest of the staff look to for leadership. Studies have shown that focusing on getting these leaders to change their behavior fosters more rapid behavior change among the rest of the staff. Pharmaceutical companies have long used this approach, but it can be effective in changing health system behavior as well.

Creating a context and receptivity for change is also critical. All too often health care organizations that want to alter processes to improve quality fail to lay a foundation that will allow the idea to take off. Organizations that require all decisions to be run up the formal hierarchy, or that allow a few powerful individuals to block changes that they do not personally favor, should not be surprised when innovations do not spread naturally.

Initiative involves 20 federal agencies that will work with roughly 100 medical, technical, policy, management, and subject matter experts to make this goal a reality in the next few years.

## *Getting Doctors to Buy Into IT*

**Katherine Kim, MBA, MPH**, partner in the Health Technology Group LLC and president of Cask Solutions, Inc., presented the results of a study (supported by the California Healthcare Foundation) examining technology adoption in California community clinics, medical groups, and independent practice associations (IPAs). The study of 40 organizations found limited use of IT through 2001. Administrative functions such as electronic claims submission, e-mail, and eligibility verification were the most common uses of IT. There were few IT links to other providers, such as hospitals. But virtually all the groups said that building EMR and disease management systems were high priorities for the next several years.

However, whether the funds will be available to build such systems is in question. Most of the 40 organizations claimed to lack the resources to make major IT investments. In addition, many of the organizations that had built clinical IT systems in the past few years reported some negative experiences. Physicians balked and some administrators were not yet convinced they were yet getting a return on their investment.

For example, one California IPA composed of 2,500 physicians built an automated, web-based system to facilitate communications with managed care plans and among member physicians. But after spending millions of dollars to develop and implement the program over three years, the management team dispersed, the vendor changed priorities, and the system is being dismantled. The group now realizes that it was naive to believe that such a massive change would be possible.

Ms. Kim countered that negative experience with a successful one. A Catholic hospital and a network of 14 city and county clinics in Austin, Texas were having a tough time scheduling visits in a timely manner. Patients spent hours on hold trying to reach the clinics by telephone and were experiencing six-month waiting times for appointments. No-show rates were around 50% for some services.

To address this situation, the providers set out to automate manual processes, better match resources to demand, and improve customer satisfaction by developing a web-based referral and scheduling system with automated scheduling rules and real-time alignment of supply and demand for services. Phased in slowly over several years (beginning with six clinics and the hospital), the system quickly eliminated call center bottlenecks and allowed the clinics to schedule referrals before patients left. The system reduced call volume by 20%, virtually eliminated complaints, and paid for itself within the first year.

Ms. Kim contrasted the California and Austin experiences. As shown in Figure 10, many drivers of adoption were present in Austin that were not in California.

**Figure 10: Comparing the Case Studies**

| Technology Adoption Component | SF | Austin |
|---|---|---|
| Leadership commitment and vision | | ✓ |
| Business case | ✓ | ✓ |
| Clear benefits for each stakeholder | | ✓ |
| Defined need | ✓ | ✓ |
| Innovative product availability | | ✓ |
| Awareness of products | ✓ | ✓ |
| Solution matches to need | ✓ | ✓ |
| Readiness and implementation support | | ✓ |
| Manage behavior change (magnitude, speed) | | ✓ |
| Results tracking evaluation | ✓ | ✓ |

# Better Quality Through Informed Consumer Choice

Quality ratings of health plans, hospitals, and other providers are increasingly available to consumers. If used broadly, this information represents an innovation that could lead to more informed choices by consumers and improved quality, speakers agreed. Recent surveys indicate that consumers are increasingly willing to use quality ratings in making decisions, although relatively few have access to or use such information today. One survey conducted in 2000 found that 38% of consumers would choose a surgeon with higher ratings rather than one they had seen before, up from 20% four years earlier. Only 50% would continue to go to a lower-rated surgeon, down from 76% in 1996. The same survey found that consumers were especially interested in information on medical errors (69% wanted error rate information when choosing a hospital); volumes of specific surgeries (66%); post-surgery death rates (57%); the number of patients who do not receive evidence-based treatments (51%); and how other patients rate quality (50%).

But **David Lansky, PhD,** president of the Foundation for Accountability (FACCT), told conferees that the movement to provide quality information to consumers is in early stages, and that many initial efforts have been of limited value. Because participation is usually voluntary, there has been limited uptake by those being measured. For example, HEDIS (Health Plan Employer Data and Information Set) and CAHPS (Consumer Assessment of Health Plans Survey) data are widely available for HMOs, but not for other types of managed care plans. In addition:

- Many "quality report cards" are not consumer-friendly.
- To encourage participation among health plans and providers, most efforts have deliberately been designed not to discriminate too harshly among those being measured.
- There have been few efforts to "tease out" the factors that are most important to consumers and patients, or to show clear differences in performance.
- Most efforts to communicate information on quality to consumers have been weak.

In short, the consumer information movement thus far has been characterized by passive approaches that provide data but hesitate to provide information that actually assists consumers in making decisions. That approach is shortsighted, according to Dr. Lansky, since consumer involvement is a vital component of the broader effort to improve the quality of health care in the U.S.

Dr. Lansky recommended the following steps to foster wider use of quality measurement and communication to consumers:

- An aggressive public information campaign to raise awareness of quality issues in health care. Messages should emphasize that disparities in quality can affect the personal health of individuals.
- Bold steps to reveal gaps in safety and performance.
- Identification of—and rewards for—excellent plans and providers.
- Development of tools to assist consumers in asking probing questions.
- Highly personalized quality signals that speak to an individual's stage of life and his or her family's health.

FACCT has developed a web-based tool (compareyourcare.org.) to inform consumers about quality issues and help them make choices. It collects data about the quality of care at the physician, medical group, and health plan levels to support consumer choice. Other web sites are also emerging and evolving, including healthgrades.org, Subimo, and Healthscope. Subimo, in particular, is diffusing rapidly through health plan web sites, which contract for its content.

**Charles B. Inlander**, president of the People's Medical Society, agreed with Dr. Lansky that the voluntary nature of most current performance and quality measurement in health care limits its scope and utility to consumers. He called on government to require that quality data be reported by hospitals and physicians.

Mr. Inlander said health care was the "last bastion of non-consumerism" and that organized medicine has until recently put up roadblock after roadblock to obtaining data and useful information on physician performance. He called for better provider-consumer communication by making greater use of modern technology and by providing reimbursement to physicians for playing a vital consulting role with their patients.

**Kevin Piper, MA, CHE**, former director of the National Health Care Purchasing Institute, echoed the importance of "actionable information" for consumers and health care purchasers. He noted that for every $10 spent on research, only $1 is spent trying to get the information disseminated into the health system, with the vast majority of this $1 being spent on publishing. Little effort is made to synthesize, translate, and disseminate research findings so that they are useful to health care decisionmakers. He called for a concerted effort to change the way information is compiled and disseminated.

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