Unlike most industries, the health care system wastes an enormous amount of money. A shocking IOM report outlines what plans need to do.
Diabetes care is complex and requires that many issues, beyond glycemic control, be addressed. One issue is medication adherence. Medication adherence may prevent hospitalizations for diabetes complications.

Another major issue is hypoglycemia. Not only is it a barrier to successful diabetes management, but it can also be very costly:

- **ER-to-inpatient costs:** $10,362
- **ER plus outpatient costs:** $986
- **Hospital admission costs:** $7,317

However, you may not be informed of all your members’ hypoglycemic events. In a multicenter, retrospective medical record review of 3 academic emergency departments, 83% of hypoglycemia visits, often excluded in prior hypoglycemia analyses, were coded as “diabetes with other specified manifestations,” while others may not be reported at all.

For these reasons, diabetes management costs may be even greater than you know.

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New Feature Focuses On Biotechnology Issues

By John Marcille

W e’re all time travelers. It’s just that we only move forward and, not to get gloomy, for only a relatively short span. We don’t go back. If we could we might — out of curiosity — leap 3,800 years to when Babylon’s King Hammurabi issued his code for physicians. This is the subject of our story on page 30. That story itself is a time traveler. We published it in 1997 and it remains one of our best-read pieces on the Web, so we’re serving it up in print again.

Most things in this world don’t last long. For instance, our sister publication, Biotechnology Healthcare, was launched back in 2004. This high-quality publication highlighted extremely interesting articles and departments, as evidenced by reader feedback and expert writers’ contributions.

However, as I am sure you have read, almost all magazines are suffering declines in advertising pages. We have regretfully suspended publication of Biotechnology Healthcare.

Even so, it will not disappear entirely. It is now a regular feature in Managed Care, beginning with this issue. It starts on page 23. And why not? Management of biotech drugs is of increasing (I would argue crucial) interest to our readers.

Which brings us to our cover story on page 12 by contributing editor Joseph Burns. He investigates what the Institute of Medicine calls the “learning health care system,” one that’s continuously focused on process improvement.

The idea is to create a model that systematically eliminates waste. The good news is that we already have the tools. In fact, some corners of health care do it quite well.

The trick now is to make the whole system follow suit. Such an accomplishment would be hailed for a long time. Maybe not as long as Hammurabi’s Code, but why not shoot for the stars?

Clinical judgment must guide each clinician in weighing the benefits of treatment against the risk of toxicity. Dosages, indications, and methods of use for products referred to in this publication may reflect the professional literature or other clinical sources, or may reflect the clinical experience of the authors, and might not be the same as what is on the approved package insert. Please consult the complete prescribing information for any products mentioned in this publication. MediMedia USA Inc. assumes no liability for the information published herein.
Cover Story

A Learning System to Drive Out Waste  
Create health care structures that focus on process improvement.

Focus on Biologics

Aiming at a Moving Target in Rheumatoid Arthritis  
Health plans need to manage both infusion and injectable drugs.

Pipeline: Another Cancer Vaccine, Another Retreat  

Trends: 2012 Drug Approvals Won’t Be Easy on Budgets  

Managed Care in Hammurabi’s Day  
Some of his dicta sound eerily familiar.

Coverage With Evidence Development  
Cover promising drugs and technologies while evaluating them.

Data Wave to Improve Predictive Modeling  
More and better data could transform population management.

Highmark PCMH Just a Step to Bigger Things  
Primary care focus lays foundation for accountable care organizations.

Managing in the Midst of Rapid Change  
With proper planning, detrimental effects can be mitigated.

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Back in 2009, the newly installed Obama administration included a $27.3 billion carrot for health care providers in a special provision of the economic stimulus bill that lawmakers hoped would trigger an IT revolution in health care. Under the new law, hospitals and doctors could both earn significant federal subsidies for adopting electronic medical records, a system upgrade that has long been held out as a Holy Grail among those looking to improve the quality and lower the cost of care in America. The offer came with 700 pages of “meaningful use” rules laying out the specifics on what the tech investment had to accomplish.

For doctors to qualify for the subsidy, which could reach amounts up to $44,000 per physician, they had to complete Stage 1 beginning in 2011, with a simple set of demands on capturing and sharing data.

Stage 2 — advancing clinical processes such as communicating electronically with patients — was spelled out with new regulations last fall and arrives in 2014, or after providers spend two years meeting Stage 1 requirements.

Stage 3, promoting improved outcomes, marks the final passage, with an initial 2016 deadline.

Even at the beginning, though, some leading provider groups were wary of the federal program, concerned that subsidies would be accepted by doctors who weren’t entirely aware of what they needed to do to clear each of the three hurdles in time. And with the second stage looming, physicians and hospitals are resisting what they see as an unreasonably short time line for the early adopters.

The backlash is coming as the industry ponders the implications of a major review of the whole movement to upgrade IT in health care, with Rand analysts pouring cold water on their own fevered expectations from back in 2005. Rand now says that even with the federal subsidies, the $81 billion in savings it projected as the payoff for widespread adoption of the electronic health record (EHR) and the electronic medical record has never materialized, in part because adoption lagged. Given the number of inherent problems, Rand doesn’t expect the savings to appear soon.

But, some major insurers are concerned that if providers get their way and delay or water down the meaningful use requirements, it would interrupt an upgrade that includes some big advantages for major health insurers looking to improve efficiency.

The AMA backlash

In mid-January, American Medical Association CEO James Madara spelled out physicians’ objections to the whole process in a 20-page letter to Farzad Mostashari, who heads the Office of the National Coordinator (ONC) for Health Information Technology.

Among his assertions:

• HHS was being too exacting with doctors.
• Every physician, regardless of practice, had to meet the same goals.
• No one on the government side has evaluated the progress of the meaningful use provisions through Stage 1, which should happen before new rules are laid out on future requirements.
• Mostashari’s office has certified more than 2,000 EHR products without really evaluating their usefulness or considering what happens to the doctors whose vendors stop seeking certification or just dump the product.
• The government should consider that some of the basic IT building blocks needed to create a fully interoperable structure — things like identity authorization, con-
sent management, privacy and security issues, data validation — are still under construction.

The federal rules are too focused on primary care doctors, Madara added, forcing specialists to meet requirements that have little to do with the way they practice medicine. So it’s time, he says, to stop, reassess how doctors are doing on the first two stages, change the penalties, and lower the federal bar on performance.

**Never materialized**

It wasn’t supposed to be like this. About eight years ago, Rand looked into its crystal ball and envisioned widespread IT adoption that would shave $81 billion in health care waste. But the rosy IT future and the big savings envisioned back in 2005 never materialized, writes Rand’s Arthur Kellermann and Spencer Jones in a recent article published in *Health Affairs*. While IT adoption has increased, with significantly more EHRs in use, the pace has been slow, and there has been at best a marginal improvement in care and quality, with too many systems being adopted in a rush to get the federal incentives. And there remains considerable justifiable fear among the holdouts that EHRs present some huge challenges.

Lack of interoperability, for one.

“The health IT systems that currently dominate the market are not designed to talk to each other,” the authors write, with the systems designed to offer a way to “build brand loyalty than giving patients access to records.” Small providers have resisted the incentives, leery that anything they buy could become quickly obsolete or unsure how future federal regulations will influence the technology, says Kennedy, who moved from WellPoint to Aetna as CEO of its “accountable care solutions” effort. To get a more efficient and effective system, he says, you need to build on a few fundamentals.

The financial incentive is one key, says Kennedy. No matter what tools are provided to physicians, until you tie them to financial incentives on improved outcomes, you can’t make real progress on efficiency and care.

Interoperability is another. The systems being deployed today are essentially an electronic paper chart, Kennedy says. “You can’t really influence the cost of care unless it is shared across multiple members of the care team.” The technology has to be centered on the patient, but today’s EHRs are largely office-centered, he says. The average person with a chronic illness can have from five to 30 providers, and few are connected.

“The adoption rate has been growing, and more incentives helped,” says Deborah Green, the chief operating officer of the American Health Information Management Association. “But with the incentives, we got a greater rush to adopt without selecting the right system.”

Design flaws persist, with the technology often getting ahead of the practice of medicine, says Green. Doctors, for example, can cut and paste into EHRs, but often in such a way that everyone getting that data doesn’t know if the information is current or historical.

Bigger challenge

Documentation using EHRs can take longer, which pushes frustrated physicians back to paper charts, says Green. And interoperability isn’t just challenging for two organizations. The way many vendors customize systems can make it hard for people in the same organization to see data. Too many doctors also never considered the bigger challenge of adjusting the way they practice medicine to enhance the positive effects of the technology.

“We have to align incentives,” adds Green. Adding incentives for better coordination of care with payments to reward outcomes is the best way to improve delivery systems.
Transparency Depends On Consumers’ Rational Thinking

Changing the way doctors are paid could save over $1 trillion in health care costs, but physicians can’t do it on their own. One of the ways health insurers can help is by joining together to facilitate payment reform, says a study by UnitedHealth Group.

The Affordable Care Act promises a greater emphasis on price transparency in the hope that knowledge of what services cost will encourage better decisions on the part of consumers.

“This reasoning, however, relies on the tenuous assumption that consumers incorporate price information rationally,” according to findings in the Journal of Consumer Research.

In the research article, which involves an analysis of a set of studies, two patient groups interpret what the price of flu shots means for the risk of getting the flu.

One group is told that the shot is $25; the other, $125. Everybody is told that insurance covers the shot, but the consumers told that it costs $25 think that the risk is greater and that they should get it.

“Specifically, consumers believe that lower medication prices signal greater accessibility to anyone in need, and such accessibility thus makes them feel that their own self-risk is elevated, increasing consumption,” says "Price Inferences for Sacred Versus Secular Goods: Changing the Price of Medicine Influences Perceived Health Risk,” which is scheduled for the April 2013 issue of the journal.

Consumers consider most health care services to hold “sacred” value, “one that a moral community implicitly or explicitly treats as possessing infinite or transcendental significance.”

Such goods do not function in the marketplace the way that other goods do. “We differentiate sacred and secular goods by their lifesaving status — a cancer medication that could prevent death would be considered sacred, while a cosmetic medication that could prevent wrinkles would be considered secular.”

One might intuitively conclude that when people are given a choice between two “sacred” goods, they would consider the higher-priced medication to be more needed, but that isn’t the case; consumers actually believe that low prices signal high need.

Pediatricians’ Careers Influenced by Debt

Mean educational debt for pediatric-in-training increased 34 percent from 2006 to 2010, from $104,000 to $139,000, and that may be pointing some of those doctors to a career as a primary care physician or a hospitalist.

A study in the journal Pediatrics looked at graduating resident surveys from 2006 through 2010 that were generated by the American Academy of Pediatrics.

It found that nearly 3 in 4 pediatricians have educational debt when they leave residency, and more than a third are in excess of $155,000 in debt.

“Graduating residents with higher debt would consider the higher-priced medication to be more needed, but that isn’t the case; consumers actually believe that low prices signal high need.”

Pap Guidelines Followed — Mostly

Millions of women who have had hysterectomies have gotten Pap tests despite recommendations nearly a decade old that say such tests are not needed and might actually do more harm than good.

The overall news about Pap tests is actually encouraging, though. A report in the January 3 issue of Morbidity and Mortality Weekly Report, a publication of the Centers for Disease Control and Prevention, notes that guidelines for Pap tests are in fact being more closely followed, especially by women younger than 30.

Those guidelines have been laid
down by three organizations: the American College of Obstetricians and Gynecologists, the American Cancer Society, and the U.S. Preventive Services Task Force.

“In late 2002 and 2003, when the three organizations updated their guidelines, they all recommended that most women having had total hysterectomies for benign reasons should no longer be screened regularly, and the USPSTF recommended that women [65 and older] with a history of normal screening results should no longer be routinely screened,” the report states.

The percentage of women 18 to 21 who said that they’ve never been screened increased from about 24 percent in 2000 to about 48 percent in 2010; Pap tests are not recommended for women under 21.

In addition, Pap testing within the last three months for women 30 and older declined from about 73 percent in 2000 to about 59 percent in 2010. An improvement, for sure, but not so much as the authors would like to see.

Cigna Sees Promise In Disability Program

A Cigna program that seeks to predict — and intercept with guidance and treatment — employees likely to miss work because of conditions that are chronic, that are likely to recur, incompletely resolved, or that are developing showed a 15 percent reduction in short-term disability claims for those employees. The study of 118,000 workers appears in the Journal of Occupational and Environmental Medicine.

The company used what it calls the Absence Prediction and Prevention program — which relies on predictive modeling to identify employees likely to go on disability in the next 12 months — and employs nurses to work with these people. “Short-term disabilities impact productivity in the workplace, but often don’t register with other predictive or risk assessment strategies that focus on future medical events,” says Robert Anfield, MD, Cigna’s CMO for disability plans.

For example, earlier Cigna research showed that people who have been out of work on family medical leave for a family reason were 50 percent more likely to have a subsequent short-term disability claim for behavioral illness than those on family medical leave for other reasons, but this risk may not be identified through the person’s medical claim history.

The employees were in Cigna’s disability and medical plans from Oct. 1, 2009 through May 31, 2010. Employee groups ranged from 2 to 21,431.

Two incentives were offered: an $80 gift card for completion of the initial health assessment by the nurse and a $120 gift card for participating in the program itself. The employees were divided into control and intervention groups.

At the 12-month follow-up, according to analysis of claims, there was a lower incidence of short-term disability in the intervention group than in the control group.

Briefly noted

Workers aren’t nearly as healthy as they think they are, says a study sponsored by the National Business Group on Health. Nearly 90 percent think they are in good shape. The reality is that more than half of survey respondents are overweight or obese. In addition, employees severely underestimate how much of their health care costs are covered by their employers.... The FDA approved more drugs in 2012 than it had in any year since 1996. It approved 39 new medications and biological products, up from 30 in 2011 and 21 in 2010. Pharmaceutical companies, still feeling the effects of many drugs switching to generic status, of course welcome this development.

— Frank Diamond

Social media mesh with dual eligibility

The consulting company PricewaterhouseCoopers, which prefers to call itself PwC now, placed caring for people with dual eligibility among its list of the top 10 health care industry issues in 2013. The people who qualify for both Medicaid and Medicare are considered to be the country’s sickest and poorest people, falling “through the cracks of two programs that were not designed to work together.”

PwC’s study “Top Health Industry Issues of 2013: Picking Up the Pace of Reform” says that $320 billion was spent on dually eligible people in 2011, accounting for 39 percent of total Medicaid and 31 percent of total Medicare spending.

The Centers for Medicare & Medicaid Services hopes that health insurers will help to manage the costs, and social media might be one of the tools. “Some duals may be receptive to using digital communication for diabetes maintenance, weight management, disease management, and chronic care programs,” the study states. PwC finds that such people “are more likely than other consumers to use social media for health care purposes (63 percent compared with 40 percent).”

Interest in using social media

Have you and a doctor, nurse, or other caregiver ever communicated in the following ways about a health question you had?

<table>
<thead>
<tr>
<th></th>
<th>Dual eligibility</th>
<th>Other consumers</th>
</tr>
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<tbody>
<tr>
<td>E-mail</td>
<td>42%</td>
<td>24%</td>
</tr>
<tr>
<td>Text messages</td>
<td>21%</td>
<td>7%</td>
</tr>
<tr>
<td>Neither of the above</td>
<td>52%</td>
<td>74%</td>
</tr>
</tbody>
</table>

Insurers Expand Usefulness Of Oncology Pathway Efforts

These programs tend to operate on the fringes of cancer care, but a movement to make them more central gains favor

By Thomas Reinke

Oncology pathway programs have demonstrated some ability to control costs, but these programs have not seen wide acceptance by physicians or health plans. Health plans have been cautious about tackling the required shift in practice patterns and payment arrangements, while oncologists have not seen the need to make changes that many believe jeopardize their practices.

In spite of slow uptake, or perhaps because of it, Aetna is in the midst of an ambitious project to move pathway programs from the fringe of cancer care into a central role. The company is working with pathway vendors on pilots across the country that provide a head-to-head comparison of pathway tools in different settings.

“Our latest development is that we are re-working existing pilots that have proven value and expanding our pilots to new situations,” says Aetna’s oncology expert, Ira Klein, MD. “We are looking for ways for these programs to be more broadly applicable.”

Other payers are working on slightly different approaches to pathways and there is some indication that the nature of these programs, particularly the highly structured approach to managing care, may change dramatically.

Aetna has a longstanding relationship with Texas Oncology, which is affiliated with US Oncology, and that arrangement has been renewed and expanded says Klein. US Oncology has the only electronic health record with a fully integrated pathway program, IKnowMed, and it is installed in many US Oncology practice sites, including Texas Oncology.

The relationship between Aetna and Texas Oncology has resulted in a couple of studies that focus on the clinical and financial effect of pathways. A report on 184 newly diagnosed breast, lung, and colon cancer patients delivered at the December 2012 American Society of Clinical Oncology meeting said that in the first 12 months of treatment, pathway patients had about 16.5 percent fewer inpatient admissions, 36 percent fewer inpatient days, and 40 percent fewer emergency room visits than nonpathway patients. The results were attributed to therapy management, nursing support calls, and end-of-life planning.

Klein said the total cost reduction was about 10 percent. “Texas Oncology has been using pathways for several years and what we find is that in the first one to two years, practices reduce drug costs. After that they move on to broader care management that cuts hospital and other costs. The last savings will be in end-of-life care.”

Aetna is expanding its pilots with other pathway vendors. “Our pilot has expanded to five states,” says Bruce Feinberg, DO, chief medical officer at P4/Cardinal Health.

Eviti

Aetna also has a new pilot program, using a slightly different form of guided treatment, from a relative newcomer, a company called Eviti. “We offer a broader clinical decision support platform, with a complete database of treatment options that go beyond pathways,” says vice president Clynt Taylor. Eviti provides access to a wider range of treatment regimens than the common three or four included in pathway programs. Oncologists have access to clinical guidelines, 1,000 evidence-based treatment options, published studies, and clinical trials for 120 cancers. “We take a consultative approach process rather than directing care.”

Taylor says the treatment options display regimen details and toxicity, comparison of outcomes, and costs.

Aetna’s pilot program with Eviti in New York and New Jersey will go beyond most pathway setups where a practice implements the vendor’s software. Aetna is providing the software to its...
participating oncologists and will be linked to Eviti in oncology offices through Aetna’s health information exchange, iNexx. That connectivity will allow practices to receive patients’ benefit information while channeling information on physician orders and treatment plans to Aetna.

Perhaps Aetna’s most innovative initiative is a medical home pilot in eastern Pennsylvania. “The medical home will be in the oncology practice but allow the oncologists to be medical neighbors to primary care physicians to coordinate comprehensive care,” says Klein. “This is going to be interesting. The medical home will add value to both practices but it is going to require more direct collaboration.” Primary care physicians will be responsible for managing comorbidities while the oncologists direct cancer care.

Klein says that there are many types of oncology practices. “We can’t pick the winner in pathway applications. This is analogous to smart phone technology where Blackberry was a leader that eventually lost ground to Apple and Android products. We want to expose oncologists in different settings to these systems and let the systems evolve. We’re going to let the market pick the winner.”

Aetna’s objectives go beyond finding the best pathway system. One is to expand direct connectivity with practices through iNexx, the health information exchange. That connection will increase data exchange for care management, prior authorizations, and claims.

Connectivity is also a major component in Aetna’s accountable care organizations. “A longer term goal is to create a cancer care guidance tool that works for multiple payers, so practices can use one or maybe two systems across all payers, and payers can use the data to develop contracts that are specific to each practice. Practices get efficiency and consistency and payers get well organized information that they can attach to their own claim data to get more specific analytics.”

Aetna wants to reform payments to all payers and to bring a uniform payment methodology to medical oncology. Klein emphasizes, “When I say all payers I include Medicare.” Medicare still allows oncologists to use the buy-and-bill payment arrangement, but private payers are attempting to change that through episode payment, shared savings, and increased payment rates for cognitive services.

“Payment will shift from drugs to value and outcomes and it will be more accurate for each form of cancer,” says Klein. “We are interested in matching contracts to practice setting and type. This refined contracting will be driven by technology.”

Other health plans are also working on new approaches to oncology care management. WellPoint has taken a dramatically different course. It is working with IBM’s Watson group on more intelligent and flexible cancer treatment software. Watson is known as a cognitive system that learns to combine patient information such as notes from an electronic health record with other data to build knowledge and make custom decisions. A WellPoint news release says it is working with IBM and oncology experts at the Cedars Sinai Cancer Institute in Los Angeles to develop Watson as a physician’s assistant to develop more targeted treatment decisions. Separately, IBM is working with Memorial Sloan Kettering Cancer Center on other aspects of a cognitive system for cancer.

**More flexible system sought**

The idea of a more flexible system for medical oncology than the highly structured pathway programs is appearing elsewhere.

Prime Therapeutics has announced a working relationship with Eviti’s clinical decision support tool that presents many regimens, rather than three or four alternatives. Taylor says Prime will make Eviti available to its network oncologists without requiring them to participate in a formal pathway arrangement.

Even the terminology is changing: Vendors increasingly use the term clinical decision support rather than pathways.

The more flexible approach is intended to overcome physicians’ reluctance to use pathways. “The wider use of pathways will evolve in the direction of an oncology benefit manager similar to radiology benefit manager,” says P4’s Feinberg.

He says this approach is likely to appeal to physicians who want to maintain their autonomy in decision making and to health plans that have viewed formal pathways as very difficult to implement.
Physician assistants turn away from primary care

Twenty percent fewer physician assistants chose to go into primary care in 2010 than in 1996, according to a recent study in *Annals of Family Medicine*. “Although the absolute number of PAs working in primary care has increased overall, the percentage of PAs in primary care has declined from 50.8 percent in 1996 to 31 percent in 2010,” the study states.

The study (http://tinyurl.com/Assistant-study) notes that health care has a problem with primary care. Fewer physicians are taking that career path at a time when — thanks to the Affordable Care Act — the system will begin relying more heavily on PCPs. However, the study adds that “Demographics associated with an increase likelihood of primary care practice among PAs appear to be similar to those of medical students who choose primary care. Knowledge of these characteristics may help efforts to increase the number of primary care PAs.”

The study, in the January/February issue, defines primary care as family medicine, general pediatrics, and general internal medicine. Women, Hispanic and PAs over age 40 are more likely than their colleagues to go into primary care. “Overall, we found that PAs working in primary care have demographic characteristics similar to those of medical students who choose general primary care specialties,” the study states. “A 2010 systematic review determined that six factors are associated with a medical student’s commitment to primary care practice: female sex, older age, Latino ethnicity, lower socioeconomic status, receipt of a National Health Service Corps scholarship, and intention to practice in primary care at the time of medical school matriculation.” The study says that the PA profession might want to consider pushing “policy measures that successfully increase the number of primary care clinicians, including loan repayment, improved levels of reimbursement for primary care physicians, and expansion of Title VII, Section 747 of the Public Health Service Act, which aims to increase the quality, size, and diversity of the primary care workforce.”

Percentage of physician assistants practicing in primary care by demographic characteristics: point estimates and 95% confidence intervals

Trend in the percentage of primary care PAs by year of graduation from 1975 to 2008

% of PAs in primary care practice

Are We on the Way to a Real ‘Learning Health Care System’?

The fact that we waste hundreds of billions a year is all the more infuriating because we have the ability right now to stop the hemorrhaging

By Joseph Burns
Contributing Editor

call it the $750 billion question. That’s the estimate for how much the U.S. health system wastes each year, according to the Institute of Medicine. In a report IOM published in September, Best Care at Lower Cost: The Path to Continuously Learning Health Care in America (http://tinyurl.com/IOM-Learning), the IOM detailed how $750 billion was wasted in 2009 on unnecessary services and excessive administrative costs and by failing to eliminate fraud.

It’s a staggering figure, but here’s perhaps a more staggering fact: We already know how to eliminate it, says Brent C. James, MD, the chief quality officer and executive director of the Institute for Health Care Delivery Research at Intermountain Healthcare in Salt Lake City.

“If we could just deploy our existing knowledge, we could get rid of the waste and inefficiency and save about 25 percent of the $3 trillion budget that the United States will spend on health care this year. The problem is that one person’s waste is another person’s income, but from a health plan’s viewpoint, any waste it can eliminate will be almost all savings. So how do you make it happen?” asks James, a member of the IOM committee that wrote the report.

“Pervasive inefficiencies, an inability to manage a rapidly deepening clinical knowledge base, and a reward system poorly focused on key patient needs, all hinder improvements in the safety and quality of care and threaten the nation’s economic stability and global competitiveness,” the report says.

While health plan medical directors, pharmacy directors, and health plan executives are engaged in improving care delivery processes, their efforts are inadequate, says James.

“I’m sure they will say that they’re already doing these things, but if they read the report they will see that they aren’t because the report sets the standards one step beyond where most plans are today,” he says. “Some of the ideas in the report are extremely powerful and amazingly thoughtful. It sets a vision for a much better future, one that is achievable.”

The aspects of the report that address waste are significant, James adds, and it’s important for all providers to focus on how they can improve care delivery and learn from other health care organizations such as Intermountain that have boosted efficiency successfully.

But the more compelling and lasting lesson from the report is that it is possible to establish a health care system that is continuously focused on process improvement — a system that continuously learns.

To embed quality, safety, and patient-centeredness into care delivery, health plans can apply engineering principles, such as total quality management, six sigma, lean, and plan-do-study-act cycles, among other continuous learning approaches.

Systems engineering

Here’s an example of how a team at Intermountain’s LDS (Latter Day Saints) Hospital increased the survival rate of patients on ventilators by applying systems engineering principles when standardizing care protocols, the report says. Clinicians created a guideline for managing ventilator settings when treating patients with acute respiratory distress syndrome. In the first four months of use, the guideline was
continuously improved, undergoing 125 changes. The result was increased patient survival from 9.5 to 44 percent while saving physicians time and the hospital money.

“How would you build a system that is capable of learning from every case in a formal, defensible way?” James asks. “That is one of the biggest challenges we face in health care. The evidence we have for what’s best for patients covers only about 15 percent to 25 percent of the care we deliver. That means that 75 to 85 percent of the time, there is no evidence about what’s best. The lack of evidence manifests as massive variation.”

**Essential point**

Another challenge health systems face is the need to get patients more engaged in making decisions about their care, the report says. This point is essential for managed care organizations, says James B. Conway, MS, a senior fellow at the Institute for Healthcare Improvement and an adjunct lecturer at the Harvard School of Public Health.

“Care should not be delivered so much to patients or for patients but with patients, because greater patient engagement is associated with better patient experience, health, and quality of life and better economic outcomes,” he says.

The report itself says, “A learning health care system is anchored on patient needs and perspectives and promotes the inclusion of patients, families, and other caregivers as vital members of the continuously learning care team.”

To be fair, health plans have a formidable task in engaging patients and eliminating waste because most do not actually deliver care. The report cites dozens of examples of health systems that have cut waste, improved care delivery, and saved money, but only a fraction of the examples come from stand-alone health plans. The reason for this discrepancy is simple, James says.

“An insurance company cannot truly manage care because it doesn’t deliver care. By working at a distance, it does not execute the care delivery processes,” he says. “By the way, the leadership of the health plans we work with say they have struggled with this idea through the years. Conversely, it’s much easier for an integrated health system like ours, which has an affiliated health plan.”

Gary S. Kaplan, MD, the chairman and CEO of the Virginia Mason Health System, believes that any organization can adapt procedures to eliminate waste and inefficiency. A practicing internal medicine physician, Kaplan says Virginia Mason has applied the principles of the Toyota Production System, known as one of the world’s most efficient production companies.

“Any organization can take a page from what we’ve done in adapting those principles to health care,” Kaplan says. “Our work is based on lean principles, and the essence of those principles is finding and removing waste in the processes associated with delivering care to patients. As long as you have processes for delivering services or products, you have opportunities to improve them, and removing waste is the key way. We have actually included health plan team members in several of our lean improvement events and had two health plan executives join us on one of our Virginia Mason study missions to Japan.

“Any organization can benefit by applying lean principles to improve its processes. From our experience in applying the Virginia Mason Production System (VMPS) to thousands of processes — clinical and nonclinical — we know there is considerable waste. When you use the tools of VMPS to identify and remove waste, the processes become more streamlined, and efficiency and quality naturally improve.”

**Formal improvement event**

The IOM report says Virginia Mason has worked to eliminate waste and inefficiency in the delivery of care since 2002. “It is a daily part of work at VM and is integral to the organization’s success. All leaders attend mandatory VMPS leadership training, are required to lead at least one formal improvement event each year, and are expected to routinely coach and train staff members in how to improve their work using VMPS tools and methods. Managers from many areas routinely put in time at the Kaizen Promotion Office, the team that guides improvement work.”

Since beginning this initiative, VM has com-
completed 1,280 continuous-improvement activities, and had multiple years of improved profitability. To reduce variability, the report says, VM embedded evidence-based decision rules for providers at the point of ordering advanced imaging. The result was reduced delays for imaging, no unnecessary tests, and lower costs. The rate of MRI for headache was cut by 23.2 percent and for lumbar by 23.4 percent. The sinus CT rate was cut by 26.8 percent, the report says.

A focus on eliminating waste is essential for the health system to succeed in providing care to millions of uninsured Americans under the Affordable Care Act, says Eric B. Larson, MD, MPH, vice president for research at Group Health Cooperative. “I don’t see how we can care for the people we are obligated to care for at a price we can afford without making a huge effort to reduce waste,” he says. But doing so will not be easy, he adds. The 381-page IOM report shows how dozens of health care systems have cut costs while improving patient outcomes, but introducing these improvements will be difficult because some patients (and their doctors and families) may want new costly and potentially wasteful life-saving technologies.

“Our goal has to make care affordable, but that task is daunting,” he says. “Some experts believe the health system needs to go through a massive crisis before it’s fixed. I hope not, but that means people like medical directors will have to take the message of the report to heart to work quickly to implement what works and to spread the word about successful innovations.”

In August, Larson and colleagues published an article in the *Annals of Internal Medicine*, “Implementing the Learning Health System, From Concept to Action” (http://tinyurl.com/Concept-To-Action).

**Plan-do-study-act**

They explained how Group Health used a rapid-learning model when creating a patient-centered medical home and opioid-safety prescribing ini-

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**Here’s how one system improved outcomes in labor and delivery**

To eliminate waste and improve outcomes, the IOM report, *Best Care at Lower Cost*, emphasizes that all health systems should use information systems to their fullest capacity.

“A learning health care system captures the care experience on digital platforms for real-time generation and application of knowledge for care improvement,” the report says.

The need to use information systems more effectively is one of the most important recommendations in the report because information systems foster continuous learning, says James B. Conway, MS, a senior fellow at the Institute for Healthcare Improvement.

As an example, the report says, in 1996, Intermountain Healthcare in Salt Lake City started an initiative to extend full management oversight to high-priority clinical processes. Since then, Intermountain has put more than 60 processes, representing almost 80 percent of all care delivered, under what it calls active management. This means clinicians are following evidence-based best practice guidelines blended into their clinical workflow and that data systems track guideline variance along with intermediate and final clinical and cost outcomes.

By employing this system in obstetrics and gynecology, Intermountain cut inappropriate elective inductions by 28 percent to less than 2 percent, saving $10 million in maternal and newborn costs annually, the report says.

The initiative also cut the Cesarean-section rate so that it is about 40 percent lower than the national average, saving $50 million.

Another result: Women spend 750 fewer hours in delivery per year, freeing up resources for the delivery of an additional 1,500 infants, the report says.
An adaptation of the plan-do-study-act (PDSA) improvement protocol, the rapid-learning model is similar to the approach other health plans have used, but more iterative. The steps in a rapid-learning approach are:

- Identify problems and potential solutions
- Design care processes and evaluations based on evidence
- Implement the plan in pilot and control settings
- Evaluate the implementation efforts
- Adjust by using evidence to make continual improvements

**Disseminate findings**

Sarah M. Greene, MPH, a director of strategy and business development at Group Health and co-author with Larson and Robert J. Reid, MD, PhD, says health plans often struggle to manage properly the considerable information they have on care processes.

“Health plans and health systems receive and generate knowledge continuously but a lot of it is tacit knowledge that does not get recorded anywhere. Everyone knows what to do next but because it’s not documented, we have not solved the problem about how to harness the knowledge we have. How we learn efficiently and effectively is something we have not addressed well.

“That’s why now we don’t rely purely on protracted research designs,” she adds. “Instead, we use evaluation approaches that are rigorous yet expedient. Similarly, our dissemination models are more nimble and don’t rely on the long cycle of peer review.”

The opioid-prescribing safety initiative arose from research that showed rising opioid misuse and abuse in persons receiving opiates for noncancer pain at Group Health and elsewhere, according to the *Annals* article. In a pilot phase, Group Health added guidelines on opioid use and a care plan template to its electronic medical record, did online clinician training, and issued standardized patient education materials. These steps led to stronger partnerships between researchers and clinical leaders so that they can improve the guidelines over time, Greene says. Group Health is evaluating the opioid safety initiative.

Jed Weissberg, MD, the senior vice president for hospitals, quality, and care delivery at Kaiser Permanente, takes a different approach to learning, saying the most effective methods involve engaging providers emotionally.

Kaiser has worked with staff in its hospitals and provider groups to explain how and why to apply the techniques of process improvement, he says. “You have to engage both the hearts and the minds when you give people a set of tools for process improvement,” he adds.

“When our Northern California Hospital System was introducing an initiative to reduce hospital-acquired infections, they called a meeting and hundreds of caregivers attended. They started that meeting with the story of how people had lost significant function as a result of such an infection and they even had a patient on stage that day. Or they talked about people who lost their lives. Introducing this initiative in that way captures the heart so that you can then engage the mind when you give people the tools they need. Then, they can go back and apply them in a disciplined way,” he says.

In addition, any provider who has seen the negative effects on patient care from using a poor process or one that lacks needed redundancies or sufficient safeguards may be more willing to work on a process improvement program than one who has not experienced a system failure that resulted in patient harm, he says.

“I worry about the person who has to implement a process improvement protocol and has never experienced a patient being harmed by the system. How do you engage those providers to be concerned and aware of the possibility of potential harm when that person has never had anything like that happen?”

Perhaps more than any other providers, pathologists and directors of clinical laboratories understand the need for lean production systems and for introducing process-improvement protocols. The largest regional clinical laboratory in Kaiser’s system is certified to ISO 15189:2012. The International Standards Organization (ISO) says medical
laboratories can use ISO 15189:2012 to develop quality management systems and to assess their own competence.

“Labs have such high volume that even minuscule problems can have very material effects on patient safety,” Weissberg says. “This standard is geared toward internal assessment and constant vigilance to processes and what can go wrong.”

The lessons that labs have learned about process improvement are straightforward because most lab processes are repeated dozens if not hundreds of times each day, making process improvement ideal for labs. Health plans, however, have a wider variety of processes, and physicians and other clinicians deliver most of their care processes.

**Fad that will fade?**

For this reason, critics say lean production systems and other process-improvement protocols cannot be applied to physicians and other clinicians. Therefore, this focus on them is a fad that will fade.

Weissberg disagrees. “This is not the flavor of the month. It’s been going on for many years. The giants of industrial management concepts Joseph Juran and W. Edwards Deming had something to teach American health care, and, finally we are getting the message.” The author of the *Quality Control Handbook*, Juran created the 80–20 rule, also known as the Pareto principle. Deming was a process improvement consultant who proposed the PDSA cycle, which is a continuous learning protocol.

Following the work of Juran and Deming, industrial companies have used lean methods to improve processes and promote their compliance with quality standards because it allows them to compete internationally by demonstrating their commitment to delivering highly reliable products and services.

When Blue Cross of Tennessee introduced a bundled-payment program last year, its employer clients recognized the approach as designed to standardize care delivery, something they had promoted for years, says Inga Himmelwright, MD, the Blue Cross medical director.

Unfortunately, health plans have not learned from employers the value of implementing quality improvement methods, says Lloyd Provost, MS, a consultant with Associates in Process Improvement and a senior fellow at the Institute for Healthcare Improvement (IHI).

“When there is a crisis in an industry, most of the companies in that industry will start to adopt process improvement systems,” he says. The auto industry is a good example. When hard times hit in the late 1970s, Toyota already had a quality improvement system, but other companies did not. Toyota thrived, while others struggled.

“In most industries those companies that don’t do well follow those that do well and those that do well have continuous quality improvement programs. But that’s not true in health care,” Provost says.

Only a few health plans have adopted quality improvement methods and others have not because they have not faced a crisis; instead they have raised prices each year, Provost says. But a crisis is coming because of health reform and there will be pressure to reduce costs, meaning those health plans that don’t have quality improvement processes in place could struggle.

Marc Hafer, president of Simpler Consulting, agrees that a crisis is coming. Hafer advises health care companies on process improvement.

“We have run out of money,” he says. “In the past, we talked about quality improvement in health care but it was always deferred because we just continued to raise fees with no end in sight.”

Perhaps health plans could learn from health care systems in other parts of the world, suggests Weissberg. “In Sweden, health care providers believe they have two jobs,” he says. “First, there is the job they do every day, and second, they have to figure out how to do their jobs better.”

“Years ago, we would joke about how the hot business concept was re-engineering health care when it was never engineered in the first place, but now health care is engineered and it’s much better off than it was,” he adds.

They have not eliminated the waste in the health system. Far from it. But providers who are putting these concepts in place recognize the opportunity they have to answer the $750 billion question.
There’s a lesson for health plans in the way treatment of rheumatoid arthritis (RA) is changing. "The trend today is to try to attain complete remission," says Patience White, MD, a practicing rheumatologist and vice president at the Arthritis Foundation. "We are approaching arthritis like oncologists approach cancer. Doctors are interested in getting patients completely symptom-free because it means better long-term outcomes and reduced disability.”

Those outcomes go beyond the disease itself. "Data show people who have long-standing RA die earlier," says White. "If you control RA, emerging data indicate that patients don’t have as many cardiovascular complications." There has been a link between RA and cardiovascular disease for several years, White says; what’s new are findings suggesting that if you control RA, the risk for cardiovascular disease decreases.

RA treatment remains one of the top priorities in specialty pharmacy, with three biologics — Humira, Embrel, and Remicade — that rank in the top 20 for expenditures. Equally important, RA therapy varies widely because of aggressive treatment, increased utilization of biologics in early treatment of the disease, and switching because of nonresponse or intolerance.

Health plans have made progress by chipping away at the fundamental challenges of managing costs. "Our position is that we are managing the entire category of medications from a formulary perspective," says David Lassen, PharmD, chief clinical officer at Prime Therapeutics, a PBM owned by multiple Blue Cross plans.

Lassen says there are many additional opportunities for health plans and PBMs to work together to control costs and utilization in RA. An example he cites is the current aligned strategy developed between Prime and its Blue Cross clients to prefer Humira in the formularies of its Blue Cross owners in an effort to improve the cost of care.

RA has several effective tumor necrosis factor (TNF) inhibitors, including Embrel and Remicade, but there are insufficient data to recommend one over the others. Humira has a strong efficacy and safety profile and it is commonly chosen as the product to beat in head-to-head studies.

Health plans and PBMs are working to implement advanced therapy and outcomes management strategies across all medications. In RA, though, they are shooting at a moving target because of today’s more aggressive treatment objectives. Rheumatologists are increasingly committed to driving to the ultimate goal of disease remission, with new medication strategies that are producing changes in treatment protocols and the use of biologic and nonbiologic medications.

That moving target implies that health plans have to be diligent in keeping up with new treatment approaches.

In 2010, the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) updated the definition and categorization of early and established RA to treat patients earlier in the disease process.
Then, a few months ago, the ACR published new treatment recommendations to reflect the new criteria. The ACR said its expert panel “recommended more aggressive treatment in patients with early RA than in the 2008 ACR recommendations.”

**Goals**

The first recommendation in that report is to strive for remission or low disease activity in all patients with early or established RA. “Treatment is now focused on treat-to-target and tight control with the target of remission, which wasn’t feasible a few years ago,” says Jeffrey Curtis, MD, of the University of Alabama, Birmingham, an RA researcher who worked on the ACR’s new recommendations.

“The idea of treat-to-target is taken from diabetes with its hemoglobin HbA1c target of seven,” says Curtis. “That number gives everyone the same clear goal, and it serves as the basis for measuring success.”

The 2012 EMD Serono Specialty Digest provides a profile of where health plans are with various aspects of managing RA’s specialty products. In many cases, health plans are still fine-tuning approaches to managing costs and utilization and providing access to the biologic agents.

The report says prior authorization (PA) is required for 85 percent of injectables and 78 percent of infusion biologics. The primary reason for PA is to verify indication. In terms of more advanced objectives, 32 percent of health plans with PA for injectables said that managing preferred products is the primary goal. Channeling preferred products is the goal 25 percent of the time for infused products. Just 20 percent of health plans said PA is primarily aimed at ensuring failure for first line medicines in a step therapy protocol.

As health plans move to more advanced management of RA biologics, says Lassen, overall management of RA must be done across the full spectrum of the injectable and infused products. “To truly manage this category we need to track and coordinate the pharmacy side with the medical side,” he says.

There is a dramatic disconnect between medications administered through the pharmacy benefit and those handled via the medical benefit. In 2011, 85 percent of self-injectable biologics were processed through the pharmacy benefit, while 81 percent of infusion products were handled under the medical benefit, according to the 2012 Serono Specialty Digest.

Tracking all of the RA medications across both benefit channels would help health plans understand the extent of double and triple therapy, the movement from conventional disease-modifying antirheumatic drugs (DMARDs) to biologic DMARDs, and biologic switching.

“You might think that the movement would be from oral DMARDs to self-injectables to infusion products, but we’re seeing the use of infusion products first and moving to a self-injectable,” says Lassen.

“Better information on utilization will help us in many ways,” says David Lassen of Prime Therapeutics. Managers must focus on both infused and injectable products.

“Better information on utilization will help us in many ways, such as with analyzing changing patterns for Remicade in comparison with other TNF inhibitors,” he adds.

Understanding the utilization of RA biologics across the medical and pharmacy benefits may help health plans keep up with the changes in treatment. The ACR’s 2012 recommendations and EULAR are moving toward increasingly aggressive therapy.

The ACR said that its new recommendations for aggressive therapy stem from “the thought that joint damage is largely irreversible, so prevention of damage is an important goal” as well as “data that early intensive therapy may provide the best opportunity to preserve physical function and health-related quality of life and reduce work-related disability.”

**Control the disease**

“Rheumatologists want to employ sure-fire ways to control the disease earlier in its course,” says White. “The stepwise approach is out. If a treating rheumatologist is looking at lab results that show the patient is having a severe course, you may start prednisone, methotrexate, and a biologic all at once to control the disease as soon as possible and then withdraw drugs as the patient does better. There are growing concerns that some health plans are shifting the cost of these RA medications to the patients through higher copays and even coinsurance that can result in lower adherence rates and increase rates of disability.”
The triple therapy that White describes is consistent with the ACR’s 2012 treatment recommendations for early RA patients with high disease activity and poor prognosis.

“We continue to see prescribers using more and more biologics in the RA population,” says Lassen.

As Curtis explains, remission in established RA is difficult to achieve, which explains why treatment now focuses so heavily on bringing it about as early as possible. “In routine practice the remission rate for patients with established disease is in the range of 10–20 percent,” he says. “For patients with early RA — say six months or up to one year — the rates are in the 30–40 percent range. That’s why there’s a push to treat more aggressively.”

About 1.3 million people in the United States have RA. Within two years of diagnosis, people with rheumatoid arthritis may experience moderate disability, and after 10 years 30 percent are severely disabled. Approximately one-third of people with the disease stop working as a result of it.

Measuring progress

The emerging idea of treat-to-target and the need to monitor whether more aggressive treatment is working highlight the need for tools that measure treatment results.

“The changes in clinical practice are being coupled with a trend to measure RA disease activity,” says Curtis. “One tool used is the health assessment

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2012 recommendations for rheumatoid arthritis speed up therapy management

The American College of Rheumatology’s 2012 revised treatment recommendations for rheumatoid arthritis reinforce a continuing trend toward early and aggressive treatment. The new recommendations emphasize the goal of remission or minimal disease activity. They also clarify medication therapy for early and established disease, different levels of disease activity and indicators of poor prognosis.

Below are some definitions and highlights of the ACR’s recommendations for nonbiologic and biologic disease-modifying antirheumatic drug (DMARD) therapy in RA patients.

**Early disease** is defined as duration of less than six months. Established disease is ≥6 months. Disease activity is categorized as low, moderate, high, or clinical remission.

**Remission** is commonly measured with the DAS28-ESR or CRP. It is defined as a tender joint count, swollen joint count, C-reactive protein (mg/dl) level, and patient global assessment of disease as ≤1 for each variable, or a simplified Disease Activity Score of ≤3.3.

**Poor prognosis** is one or more of these items: functional limitations, extra-articular disease, positive rheumatoid factor or anti–cyclic citrullinated peptide antibodies, and bone damage.

**DMARD therapy for early RA**

The recommendation for treatment of early RA in patients with a good prognosis and low, moderate, or even high disease activity is traditional DMARD monotherapy, including hydroxychloroquine (HCQ), leflunomide (LEF), methotrexate (MTX), minocycline, and sulfasalazine.

The recommendation for early RA patients with poor prognosis and either moderate or high disease activity is double or triple nonbiologic DMARD therapy. As an alternative, for early RA patients with high disease activity and a poor prognosis, the ACR also recommends an anti-TNF biologic with or without methotrexate; however, infliximab (Remicade) is an exception; it is to be used only in combination with methotrexate.

The recommendations for patients with established RA are divided into two pathways, one for patients with low disease activity without poor prognosis, and one for everyone else — patients with moderate or high disease activity and those with low disease activity plus a poor prognosis.

DMARD monotherapy is recommended as initial therapy for patients with low disease activity and good prognosis. Therapy progresses to multiple nonbiologic DMARD therapy and then to adding or switching to an anti-TNF biologic. If an adverse event occurs with anti-TNF therapy the recommendation is to switch to a non-TNF biologic.

The initial recommendation for patients with poor prognosis or moderate or high disease activity is methotrexate monotherapy or combination nonbiologic DMARD therapy. If there is deterioration or no improvement, the ACR recommends adding or switching DMARDs or adding or switching to an anti-TNF biologic, abatacept (Orencia) or rituximab (Rituxan). If there is a lack or loss of benefit, then biologic switching is recommended.

In most cases the ACR recommends reassessing results at three-month intervals, but there are exceptions that call for a reassessment after six months.
questionnaire, the HAQ. But those assessments are not very thorough or useful. I liken them to the Brooklyn HAQ: You know — How ya doin? It is not specific and quantitative.”

**Treat-to-target approach**

Curtis continues, “The problem is that in the United States most doctors do not measure anything; we use the Brooklyn HAQ. If I write down that the patient is doing well, how useful is that in measuring progress? How do you compare doing OK from last visit with doing well this visit?”

The treat-to-target approach with formal measurement of progress could help health plans in their efforts to improve therapy outcomes.

In the Serono survey, only about 5 percent of health plans said the primary purpose of PA is to monitor response to therapy in RA. The survey report did not indicate how this monitoring occurs. In the United Kingdom, treatment recommendations for RA include drug-response monitoring and specific targets for drug response.

To promote progress measurement, in May 2012 the ACR published an article that recommended six disease activity measurement tools that could be used at the point of care. The six are:

- Clinical Disease Activity Index
- Disease Activity Score with 28-joint count, erythrocyte sedimentation rate (DAS28-ESR) or C-reactive protein (CRP)
- Patient Activity Scale (PAS)
- PAS-II
- Routine Assessment of Patient Index Data with three measures (RAPID-3)
- Simplified Disease Activity Index (SDAI)

These tools encompass different combinations of patient and provider assessments of swollen joints, patient assessments of pain or disease activity, provider assessments of swollen/tender joints, and lab tests.

The six were selected because they are sensitive to change; discriminate well among low, moderate and high disease activity states; have remission criteria; and are feasible to perform in clinical settings, the authors said.

Measurement is also addressed in the ACR’s 2012 treatment recommendations, of which Curtis is a co-author. “We said there are 10 to 15 things you could measure, and there are several useful tools, but unfortunately there is no best one,” he says.

While treat-to-target and measuring treatment progress may help clinicians improve outcomes, they face an obstacle that will take years to resolve. There is widespread recognition that good comparative effectiveness data about the biologic DMARDs are not available.

In April 2012 the Agency for Healthcare Research and Quality published an update of the comparative effectiveness for the corticosteroids, traditional DMARDs, and biologic DMARDs used for RA. The key questions included the extent to which the medications reduced disease activity and maintained remission and their use in subpopulations based on disease state, prior therapy, demographics, concomitant therapies, and comorbidities.

The expert panel reviewed 258 published articles encompassing random controlled trials, head-to-head studies, and mixed treatment comparisons. The review included a meta-analysis comparing the relative efficacy of biologic DMARDs and comparing withdrawal rates from placebo-controlled trials. A multiple-treatment comparison (MTC) meta-analysis was used to compare the relative efficacy of biologic DMARDs with a primary efficacy outcome of the ACR 50, which determines if a 50 percent improvement was achieved.

In the end the evidence did not support the superiority of one oral DMARD over another. One limitation was the wide range of methotrexate dosing in the trials. The data for biologic DMARD comparisons came mostly from observational studies and findings from MTC meta-analyses the panel conducted.

**Weak evidence**

Those MTC meta-analyses suggested that Enbrel has a higher probability of improving disease activity than do most other biologics, but this was relatively weak evidence which should be interpreted with caution. Limited evidence precluded firm conclusions about the superiority of any conventional or biologic DMARD over another or about whether one combination was better than another in early RA.

The need for comparative effectiveness data on RA therapies is increasing rapidly as recommended treatments move toward aggressive early therapy and formal tracking of therapy outcomes.
As anyone who has watched the field with some regularity knows, cancer immunotherapy is a tough field to hoe. Provenge is the only therapeutic vaccine for cancer to make it all the way to U.S. Food and Drug Administration approval, and it’s struggling to gain market share. Many more — see GVAX, Canvaxin, and FavID — looked lively in phase 2 studies, only to die a quiet death after fizzling in phase 3.

Add Stimuvax to the list of those stumbling on a bigger stage. Merck and Oncothyreon’s immunotherapy for patients with unresectable, stage 3 non–small-cell lung cancer failed to demonstrate a statistically significant overall survival benefit compared with placebo. Though researchers said they would pull back to take a closer look at favorable data in some study populations, the FDA rarely approves a drug on the basis of subgroup analyses if it missed its primary endpoint.

“It’s now becoming clear that therapeutic cancer vaccines might be most efficacious in earlier-stage cancers, after they are treated and have minimum residual disease,” analyst Dee Kotak wrote on Seeking Alpha’s Web site in the days that followed. Some vaccine developers have made the same contention: Get in early to give the immune system time to rev up. But payers, who tend to view Provenge’s cost as additive to — rather than in place of — chemotherapies, are likely to look for hard evidence of earlier-stage efficacy and cost offsets before giving high-cost immunotherapies favorable formulary positions.

Still, the field remains a hotbed of research, with clinical trials underway for therapeutic vaccines designed to treat bladder, blood, brain, breast, cervical, kidney, lung, skin, pancreatic, and prostate cancers.

Ovarian cancer drug fails
Eisai faces the same challenge that Merck and Oncothyreon share — making lemonade out of patient subset data — after its ovarian cancer candidate, farletuzumab, went sour in an 1,100-patient trial. Farletuzumab failed to show a statistically significant progression-free survival benefit in women with relapsed disease. The Japanese manufacturer said it would evaluate what it believes may be encouraging subpopulation outcomes to determine a new development strategy for the molecule.

Meeting roundup: American Society of Hematology
54th Annual Meeting, Dec. 8–11, 2012

Ariad Pharmaceuticals turned heads with response data for ponatinib (Iclusig) in patients with chronic-phase, chronic myeloid leukemia. Just days before receiving FDA approval for its tyrosine kinase inhibitor (see table), Ariad touted a 47 percent major response rate in patients given ponatinib who had stopped responding to treatment with dasatinib (Sprycel) or nilotinib (Tasigna). Investigators studied 449 patients, all of whom received ponatinib.

In a population that’s difficult to treat because treatment resistance is inevitable, patients and physicians welcome new therapeutic options. But ponatinib comes with a price that may give some payers pause — $9,580 a month.

Multiple myeloma (MM) and chronic lymphocytic leukemia (CLL) are two other tough-to-treat blood malignancies with an expanding array of therapeutic options. Celgene presented data for pomalidomide — a thalidomide derivative — showing that progression-free survival was double in MM patients given the drug with low-dose dexamethasone (3.6 months) vs. those treated with high-dose dex alone (1.8 months). Patients had failed an average of five previous regimens. In a separate study, 71 percent of treatment-naive patients with CLL showed complete or partial response to Pharmacyclics’ ibrutinib, which silences gene communication pathways that enable cell proliferation. In this phase 2, open-label study, ibrutinib prevented disease progression in 96 percent of these patients after two years.

Gilead closer to hep C filing
Gilead released positive topline results of the first of three phase 3 trials of sofosbuvir (formerly GS-7977), part of an all-oral, interferon-free regimen for hepatitis C. In patients with genotypes 2 and 3, a cocktail of sofosbuvir and ribavirin left no detectable sign of the disease in 78 percent of patients after 12 weeks.

Gilead will roll out data from two more phase 3 studies this year, with an eye toward a mid-year FDA filing.

Did you hear?
An FDA advisory committee voted 14–0 to recommend approval of GlaxoSmithKline’s H5N1 avian flu vaccine. The unanimous vote stood in contrast to 2007, when the world was in panic over bird flu and hungry for any vaccine. At the time, Sanofi Pasteur sent the FDA a first-
A generation H5N1 vaccine that provided protection to only 45 percent of adults who got the highest dose.

The FDA held its nose and approved the Sanofi vaccine anyway, conceding that it was safe but not necessarily effective.

Another FDA advisory committee voted 8–4 to recommend approval of Novo Nordisk’s long-acting insulin analogue, degludec (Tresiba), but attached what could be a costly string: Concerned about heart risks, the panel also agreed to recommend that Novo Nordisk conduct a cardiovascular study prior to formal marketing approval. Should the FDA ultimately require the study, it could delay the launch of degludec by as much as a year.

Now that natalizumab (Tysabri) is marketed with a test to detect whether a patient harbors the John Cunningham virus (JCV), Biogen Idec wants the FDA’s blessing for first-line use of the powerful multiple sclerosis drug. Natalizumab is generally reserved for patients with advanced cases of relapse-remitting MS because it carries the risk of progressive multifocal leukoencephalopathy (PML). Exposure to JCV is required for the development of PML.

—Michael D. Dalzell

All clinical trials described in this column are phase 3, randomized, controlled studies unless otherwise specified.
For years, we’ve heard about the coming tidal wave of specialty drugs. In 2012, 25 of them crashed ashore as big pharma and small biotechs continued the pursuit of personalized medicine.

Biologics and other specialty therapeutics made up almost two thirds of new molecular entities approved last year, and their record number furthered the upward trend in approvals since the fast-track process was made law in 2007.

Notably, 12 of the 25 were orphan drugs, and at least seven carry six-figure prices for a year’s worth of treatment — increasingly common for drugs that address rare conditions, sometimes in populations of fewer than 1,000.

2012 drug approvals won’t be easy on pharmacy budgets

New approval | Xtandi | Cometriq | Stivarga
---|---|---|---
Indication | mCRPC | Medullary thyroid cancer | mCRC
Cost per month | $7,450 | $9,990 | $9,350
Competing products | Zytiga ($5,495/mo) | Caprelsa ($10,000–$12,000/mo) | Zaltrap ($11,063/mo)
Jevtana ($6,400 per 3-week cycle) | Provenge ($93,000/single course) | Erbitux ($4,032 loading dose, $2,880 weekly dose)
Provenge ($93,000/single course) | | Avastin (~$5,000/mo)

Sources: FDA, Express Scripts

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Oncology agents: Not your average formulary decisions

Eleven drugs approved in 2012 were for oncology. Most are targeted agents sure to strain pharmacy budgets, but because of coverage mandates or the paucity of treatments available for their indications, they are unlikely to meet stiff payer resistance. For instance, Erivedge ($7,500 a month) is the first drug approved to treat advanced basal-cell carcinoma, giving it all but a free pass to the formulary.

The cost of addressing unmet needs

<table>
<thead>
<tr>
<th>New approval</th>
<th>Cost per month</th>
<th>Competing products</th>
</tr>
</thead>
<tbody>
<tr>
<td>XTANDI</td>
<td>$7,450</td>
<td>Zytiga ($5,495/mo)</td>
</tr>
<tr>
<td>COMETRIQ</td>
<td>$9,990</td>
<td>Jevtana ($6,400 per 3-week cycle)</td>
</tr>
<tr>
<td>STIVARGA</td>
<td>$9,350</td>
<td>Provenge ($93,000/single course)</td>
</tr>
</tbody>
</table>


---

*In CRC=metastatic colorectal cancer
*In mCRC=metastatic, castrate-resistant prostate cancer

Published average wholesale price, before rebates

Competing does not imply substitutable.

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Michael D. Dalzell
Hammurabi’s Managed Health Care — Circa 1700 B.C.

The roots of modern managed care go back to prepaid health plans of the 19th century, but many of the concepts we use today were embraced in ancient times. The Babylonians had a system with many parallels to the present one.

By Allen D. Spiegel, PhD

At the dawn of civilization, about 4,000 years ago, nomadic Semite tribes developed a managed health care system. Using cu-neiform, a hieroglyphic writing, they inscribed the concepts on clay tablets and chiseled them into stone between the 17th and 21st centuries B.C.

Adapting the existing edicts, King Hammurabi of Babylon incorporated these managed care precepts in the Codex Hammurabi, a huge stone stela erected about 1700 B.C.:

- Rates set for general surgery, eye surgery, setting fractures, curing diseased muscles and other specific health care services.
- Fees set according to a sliding scale based on ability to pay.
- Owners to pay for health care for their slaves.
- Objective outcome measurement standards to assure quality of care.
- Outcomes information management to include data collection and evaluation.
- Consumer and patient’s rights to be publicized, explained and made known to all.

Not only that, but marketing and advertising activities promoted adoption of the plan.

Just verdicts

In the Codex prologue, Hammurabi characterized his compilation of judicial decisions: “These are the just verdicts that Hammurabi, the experienced King, has imposed to establish firm discipline and good governance in his country.”

Judgments followed the traditional and harsh “eye for an eye, tooth for a tooth” punishments of the Semite tribes. As we will see, physicians were well rewarded, but when they failed, the penalties were considerable.

Defining population coverage

Codex Hammurabi clearly indicated that physicians merited public esteem and were to be re-
warded with adequate fees, carefully prescribed and regulated by law.

Everybody under Babylonian rule was covered by the Codex's managed health care system, but not all received equal treatment. Distinctions existed among the three social classes: awelum (upper class), mushkenum (middle class) and wardum (slaves). A Medicaid-type coverage for slaves required their owners to pay for health care services. Of the 282 edicts, 15 mentioned physicians, veterinarians, barbers, or wet nurses.

Establishment of a fee schedule

Regardless of social class, access to medical care was unrestricted. There was no capitation and no level of uncompensated care. Codex Hammurabi established uniform fees for service with a sliding scale based on ability to pay and seriousness of the procedure, something like diagnosis-related groups in present-day hospitals. Awelum paid most, mushkenum less. The wardum’s owner paid least.

To understand the fees, consider comparative economics: A free craftsman earned 5 to 8 grains of silver per day, taking about one year to earn 10 to 14 shekels (one shekel equaled 180 grains of silver). A wooden door cost one to two shekels; earthenware jars were sold for from one-fourth to two-thirds of a shekel; a wooden tray for carrying on the head went for one-half shekel; and a middle class dwelling rented for about five shekels a year.

Here are sections of the code and the fees prescribed:

§206 If a man strikes a freeman in an affray and inflicts a wound on him, that man may swear, “Surely I did not strike him willingly,” and he shall pay the surgeon.

§215–217 If a surgeon has made a deep incision in the body of a gentleman with a lancet of bronze and saves the man's life or has opened a carbuncle in the eye of a man with a lancet of bronze and saves the eye, he shall take 10 shekels of silver. If the patient is a freeman, he shall take 5 shekels of silver. If the patient is a slave, the master of the slave shall give 2 shekels of silver to the surgeon.

§221–223 If a physician set a broken bone for a man or cure his diseased bowels, the patient shall pay five shekels of silver to the physician. If he be a freeman, he shall give three shekels of silver. If it be a man’s slave, the owner of the slave shall give two shekels of silver to the physician.

§224 If a veterinary physician operate on an ox or an ass for a severe wound and save its life, the owner shall give to the physician 30 grains of silver.

Credentialing providers

Priests administered magico-religious medicine with three types of healers: Baru (diviner), Ashipu (exorcist) and Azu (physician). Another category consisted of doctors of an ox or an ass (veterinarians). Gallabu (barbers) branded slaves, performed plastic surgery to remove markings, and did dental surgery. A Baru, essentially an internal medicine specialist, practiced hepatoscopy, believing that the liver was the seat of the soul and center of vitality. Diagnoses were made by consulting a concisely coded model of a sheep’s liver.

Just who was Hammurabi?

Babylonia, Mesopotamia, Iraq: They’re all the same place, more or less, the area between the Tigris and Euphrates rivers known as the “cradle of civilization.”

A great military commander, Hammurabi consolidated small states in the vicinity after ascending to the throne on the death of his father, Sinmuballit, in 1792 B.C.

Rightly or wrongly, he is more widely known for Codex Hammurabi, or Hammurabi’s Code, a collection of 282 judicial decisions from the latter part of his reign that is the largest such collection that has survived from the period.

The stela (column) on which it was inscribed was discovered in 1901 and given to the Louvre, where it remains today.
But while a patient could consult any willing provider, some providers risked the penalty of death or dismemberment mandated in Hammurabi’s Codex.

Azum were educated in priestly temple schools and students learned from the clay tablets and practical experience. An Azu diagnosed ailments by listening to the patient’s accounts, not by physical examination.

Pharmaceutical benefits

There was no extra charge for medications. More than 250 medicinal plants, 120 mineral substances and 180 other drugs were combined with alcoholic beverages, bouillon, fats, honey, milk in various forms, oils, wax and parts and products of animals. Medications were ground, strained and filtered for ointments or plasters to spread on a piece of thin leather to apply. Narcotics came from hemp, mandragora, opium and solium temulentum. Prescriptions specified enemas, laxatives, lotions, ointments, pessaries, pills, poultices, powders, salves and suppositories. A patient’s prescription could be “enveloped in the aroma of burning feathers and liberally dosed with dog dung and pig’s gall.”

There was no limitation on referrals or consultations. Kings and aristocrats secured the services of renowned physicians, lent the doctors to their allies and sent them “to visit the courtesans whom they loved.” Baru, Ashipu and Azu readily exchanged treatment regimens. Denial of care is not mentioned, although one clay tablet text warned medical students “not to touch a patient who is likely to die.”

A Baru or Ashipu was not accountable because gods, demons or evil spirits caused treatment outcomes. But an Azu could be held accountable.

An Azu prescribed drugs and medications, performed surgery, set fractures, palliated visible sores and treated snakebites. Medical instruments included bronze lancets, metal tubes to blow remedies into bodily orifices, tubes to be used as catheters and spatulas. When an Azu used a “bronze lancet” or other means to heal a patient, he was accountable for direct human error or aggression.

Eye for an eye

If a patient died or was seriously injured, the outcome was easily observed and the “eye for an eye”

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Outcomes-based fee schedule

This chart outlines fees and penalties for successful and unsuccessful procedures. There are no fees for unsuccessful bone setting and sinew mending because outcomes are usually not fatal; operations can be repeated until the result is satisfactory. Omission of fees for mushkenum (the middle class) indicate that the scribe failed to copy a section containing a penalty. Awelum were the upper class; wardum were slaves.

<table>
<thead>
<tr>
<th>Successful operations</th>
<th>Awelum</th>
<th>Mushkenum</th>
<th>Wardum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting bone or mending sinew</td>
<td>5 shekels</td>
<td>3 shekels</td>
<td>2 shekels</td>
</tr>
<tr>
<td>General operation</td>
<td>10 shekels</td>
<td>5 shekels</td>
<td>2 shekels</td>
</tr>
<tr>
<td>Operation on eye</td>
<td>10 shekels</td>
<td>5 shekels</td>
<td>2 shekels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unsuccessful operations</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting bone or mending sinew</td>
<td>loss of hand</td>
<td>——</td>
<td>slave for slave</td>
</tr>
<tr>
<td>General operation</td>
<td>——</td>
<td>loss of hand</td>
<td>——</td>
</tr>
<tr>
<td>Operation on eye</td>
<td>——</td>
<td>——</td>
<td>slave’s price</td>
</tr>
</tbody>
</table>

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Seal of a Babylonian Azu with reverence to the gods, a self-portrait and depictions of bronze knives, cups and needles. Translation: O Edinmagi, servant of the god Girra, who helps mothers in childhood, Ur-Lugaledina the physician is your servant. (From A. Leix. Medicine and the Intellectual Life of Babylonia. Ciba Symposia 1940; 2:663 — 674.)
penalty imposed. But significantly and mercifully, judges omitted any references to the Codex in their recorded decisions and were guided by tradition, public opinion and common sense.

Quality, outcomes and penalties

Quality-of-care edicts in Hammurabi’s Codex left no margin for error: Health care providers had to be flawless or lucky:

§194 If a man gives his child to a nurse and the child die in her hands, but the nurse unbeknown to the father and mother nurse another child, then they shall convict her of having nursed another child without the knowledge of the father and mother and her breasts shall be cut off. (A wet nurse was paid about 3 shekels)

§218 If a physician operate on a man for a severe wound with a bronze lancet and cause the man’s death, or open an abscess in the eye of a man with a bronze lancet and destroy the man’s eye, they shall cut off his fingers.

§219–220 If a physician operate on the slave of a freeman for a severe wound with a bronze lancet and cause his death, he shall restore a slave of equal value. If he open an abscess in his eye with a bronze lancet, and destroy his eye, he shall pay silver to the extent of one-half his price (average prices for male slaves ranged from 16–30 shekels).

§226 If a barber has excised a slave’s mark without the knowledge of his owner so that he cannot be traced, they shall cut off that barber’s forehand.

§227 If a man has constrained the barber and he excises the slave’s mark so that he cannot be traced, they shall put that man to death and shall hang him at his own door. The barber may swear, “Surely I excised it unwittingly,” and then go free.

Penalties included burning, drowning, hanging, impalement on a stake, bodily mutilation and monetary fines. But quality-of-care penalties were adjusted by social class with the opportunity to escape death or mutilation by paying a monetary fine.

Medical records

Practice standards were written on the clay tablets and recorded by the temple schools. Outcome measurements were specifically identified in the Codex, as were the severe corrective actions for improving the practice of medicine. How much more total can “total quality management” be than to cut off the hands of the offending health care provider?

Thousands of clay tablets recorded descriptions of ailments, including abscesses, colic, gallbladder trouble, rectal prolapse and venereal disease. Forty tablets interpreted dreams and described prevention of nightmares. Medical care data documented ailments, causes, treatments and therapy outcomes. A clay tablet chart systematically and routinely entered the physician’s name and relevant data.

Deselection of providers

Hammurabi’s Codex specified the harshest form of deselection possible. If the physician erred through omission or commission, his fingers or hands were cut off, immediately stopping his practice. This severe punishment for negligence supposedly weeded out physicians incapable of delivering adequate care. In addition, it prevented these physicians from practicing in a different locality. Obviously, such a penalty discouraged a physician surplus.

Codex Hammurabi anticipated communication problems such as “gag rules” and “patient protection laws.” Providers were commanded to follow the edicts on the stele to assure patients of their rights. A huge stele was erected on the grounds of the major temple in Babylon for everybody to read.
tablets duplicated the Codex and were distributed throughout the nation. Hammurabi, who had a rather high opinion of himself, specifically advised all those seeking justice that the Codex would tell them what to expect:

“Let the oppressed man who has a cause come before my statute called ‘King of Justice’ and then have the inscription on my monument read out and hear my precious words, that my monument may make clear his cause to him. Let him see the law which applies to him, and let his heart be set at ease!”

Codex Hammurabi strictly enforced compliance through severe penalties. If they were not satisfied, patients could seek justice from a legal system. However, there is no evidence of either prosecution or defense lawyers in Babylonia.

While there was no managed care organization from which to disenroll, Babylonians could move up or down the social class ladder and thereby change their level of health care.

**Marketing and advertising the Codex**

In the Codex introduction, Hammurabi lavishly applied the ancient advertising and political rule that if you say something loud enough, often enough and in grandiose language, people will believe it.

With 16 lines of blessings and 282 lines of calamitous curses for noncompliers, Hammurabi invoked the gods and repeatedly glorified his benevolent actions undertaken for the benefit of his subjects:

“Anum and Illil … called me by name Hammurabi … to make justice to appear in the land, to destroy the evil and wicked that the strong might not oppress the weak…. My words are choice, my deeds have no rival; only for the unwise are they vain, and for the profoundly wise they are worthy of all praise.”

He proclaimed himself “a god among kings, imbued with knowledge and wisdom.”

But despite all of the high-powered hyperbole, history views Hammurabi as a leader who cared for his people and had great military, managerial and diplomatic skills.

**Lessons from antiquity?**

In the fervent rush to employ managed care, our society may in some ways be re-entering the realm of an ancient medical care system. Aggrieved health care consumers may welcome a move toward harsh penalties in the name of justice and/or simply for revenge, though it isn’t necessarily the providers who would suffer.

In the late 1980s, Babylonian clay tablet cookbooks from 1700 B.C. resurfaced to reveal what one observer called “a cuisine of striking richness, refinement, sophistication and artistry.”

It isn’t far-fetched to suggest that, with appropriate language changes, the prologue and epilogue of Codex Hammurabi present lofty moral and ethical goals that managed care organizations might emulate:

“...to cause justice to prevail in the land, to destroy the wicked and the evil, to prevent the strong from oppressing the weak … to further the welfare of the people …. I brought health to the land; I made the populace to rest in security; I permitted no one to molest them … I restrained them that the strong might not oppress the weak, and that they should give justice to the orphan and the widow....”

Allen D. Spiegel, PhD, MPH, was a professor of preventive medicine and community health at the College of Medicine, State University of New York, Health Science Center at Brooklyn, N.Y. With Florence Kavaler, MD, he was co-author of Risk Management in Health Care Institutions: A Strategic Approach (Jones and Bartlett, Sudbury, Mass., 1997). His New York Times’ obituary in January 2007 says that Dr. Spiegel was “the editor/author of more than 20 texts that became classics in their subject areas, widely used in schools of public health and programs in health care management.”
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With increasing pressure to reduce health care costs, physicians and payers are finding themselves in the midst of a debate over access to the latest, most advanced treatments, tests, and other health care services. While patients and physicians are eager to embrace these innovative treatments, coverage by insurers often lags far behind the pace of innovation. Creative solutions are needed to resolve this catch-22 of no coverage without data, no data without treatment, and no treatment without coverage.

Recently, the Centers for Medicare & Medicaid Services (CMS) signaled that it may have found a model that private payers could adopt. By re-examining its Coverage with Evidence Development (CED) policy, CMS may broaden access to innovative therapies by establishing a transparent and faster pathway to coverage.

CED provides payment for new and/or innovative treatments while simultaneously generating clinical data to demonstrate the treatment’s effect on health outcomes, including comparative effectiveness. The goal of the program is to support innovation and the timely collection of data while helping payers make evidence-based decisions that improve health outcomes for their beneficiaries.

An improved CED process could not only help Medicare figure out which patient populations would be best suited for particular therapies; it could also have implications for commercial payers who could adopt a similar approach for their beneficiaries.

Why CED is changing

CED was developed in 2000 for coverage policies that focused on certain items and services that CMS believed were promising but lacked sufficient data to support coverage or for instances where CMS had additional questions that weren’t answered by the available evidence. Recognizing its value, CMS is now planning CED’s next phase, which will hopefully be better defined so that it can promote innovation and comprehensive patient care.

In May 2012, a meeting was held at the CMS headquarters in Baltimore to examine more ways to use CED. The discussion was lively, with both CMS and commercial payers expressing a desire to explore ways in which data could be collected while at the same time ensuring that the treatments they pay for are beneficial to patients.

Payment with accountability

With health care costs continually on the rise, there is increased consideration of whether many treatments and tests are warranted. CED can provide access to treatment while allowing the payer to monitor associated costs and clinical outcomes. One way is through patient registries, which support data collection on new treatments to evaluate them against existing ones. This allows providers to benchmark how well their patients are doing compared to others, helping to identify better dosing schemes, patient management issues, and other factors that may support better overall outcomes.

Unlike most clinical trials, which are generally limited to academic centers, registries are more accessible to the greater patient population, as they can be implemented by community-based physicians. Registries can help answer questions that are unanswered by narrowly designed clinical trials. They can also be kept open for many years, allowing physicians, researchers, payers, and patients to continually evaluate treatments as the science evolves in a particular field of study (See “Registry Tracks SBRT for Prostate Cancer” on Page 37).

With CED, safety is the top priority and for it to be successful, there must be strong collaboration between payers and providers where realistic expectations are set for evidence development and transparency.

Through the CED process, payers and providers...
could mutually agree on a timetable to check the data for adverse events along the way. From the beginning, the registry would be used to help the payer ensure that each service provides outcomes meeting the standard of care, if not better. After a reasonable period, the payer could make a policy determination as long as the data met the agreed criteria.

Promoting innovation

All too often, the unintended consequences of policies designed to benefit a population end up stifling innovation, hurting the economy, and limiting patients’ access to lifesaving treatments.

To understand this, it’s helpful to look at how innovative services and treatments are developed. After funding years of research, product development, and fulfilling regulatory requirements, companies that manufacture drugs and devices find themselves in a race against the clock to get their products to market and generate revenue before their patents run out. The problem with the current payment system is that by the time a multiyear process of data collection ends and the technologies deemed sufficient for widespread payer coverage, they often run the risk of becoming outdated. The result is a loss of innovation and reduction in competition.

Working hand in hand

Clinical trials and CED are, in fact, complementary. While randomized clinical trials are the gold standard, they are also costly, time-consuming, and often fail to recruit enough patients willing to be randomized against a treatment they view as outdated. If properly implemented, CED can complement clinical trials by collecting “real world” data that can be generalized to the broader patient population. Another key benefit to the CED process is that competing technologies can be compared side by side, which empowers the private payer to revise policies as the evidence develops.

Can CED be applied within the private payer community?

Payers at the May 2012 CMS meeting discussed how CED could be put into practice for the private payer community. Most private insurers voiced support for medical innovation, as it builds both the art and science of medicine. The payers’ concern is to ensure that access to new technologies is provided responsibly. It is critical to have programs that effectively manage the introduction and spread of new technologies and services. Programs like CED can work for payers when they are well-planned and include multiple components and tools.

Registry tracks SBRT for prostate cancer

Today’s treatment options for prostate cancer are diverse. With such a large portion of the population affected by prostate cancer, payers are eager to determine which therapies work well and which ones may not.

With the age demographic of prostate cancer generally being men of Medicare age, combined with the pressures CMS faces to control costs, it comes as no surprise that CMS held a meeting two years ago on radiation therapies for localized prostate cancer. With no comparative randomized study results available to demonstrate which option is most effective, patients and physicians were then, and remain today, left to choose from a long list of options, each of which present different risks and benefits. In the absence of definitive head-to-head data, several of the 2010 meeting participants and panelists proposed registries as a way to try to answer some of the questions on comparative effectiveness.

Shortly after the 2010 meeting, the first CED prostate registry was developed to help fill in some of the evidence gaps in the area of radiation therapy. In June 2010, the Registry for Prostate Cancer Radiosurgery (RPCR), a Florida-based multi-institutional, internal review board-approved observational trial (ClinicalTrials.gov NCT 01226004), began enrolling prostate cancer patients nationwide. Patients received an advanced treatment called stereotactic body radiation therapy (SBRT), a noninvasive approach to treating prostate cancer that offers patients a combination of benefits that other treatment options, such as conventional radiation therapy and surgery, do not. In the two years since the registry was introduced it has been widely adopted and now has the participation of over 40 hospitals and centers across the United States and has enrolled over 1,000 men. Outcomes data for the RPCR registry were presented at the May 2012 Medicare Evidence Development & Coverage Advisory Committee meeting convened by CMS.

As the first registry of its kind, the RPCR registry serves as a successful example of how a revised CED policy would support medical innovation while benefiting payers, patients, and providers. Through this cost effective approach, evidence is collected through a safe and effective mechanism which promotes access to care. As a complement to randomized clinical trials, registries are a great opportunity for facilities not affiliated with academic institutions to make their real-world experiences count.
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Predictive modeling (PM) has grown to be a linchpin of care management. Health plans, integrated delivery systems, and other health care organizations (HCOs) increasingly channel their patients to interventions based in part on what they deduce from predictive models that have traditionally been run against databases of administrative claims. In this arena, the Affordable Care Act (ACA) is likely to exert a profound effect. ACA-influenced trends that will affect how HCOs use predictive modeling in the coming year include:

- Increased adoption and use of electronic health records (EHRs), including enhanced access to EHR data, such as family history, lab results, prescription utilization, prior successful/unsuccessful treatments, and treatment compliance
- Enhanced emphasis on population-based patient care management
- An intense focus on clinical, operational, and financial performance and cost rather than cost alone

Let’s look at the implications of these trends for predictive modeling and population health management.

With the rapid expansion of EHR implementation, which extends through accountable care organizations (ACOs), medical homes, and individual practitioners’ offices, the ability to gather data that can enhance predictive modeling performance has improved dramatically. Growing numbers of HCOs, including physician practices, are routinely utilizing EHRs. In fact, close to 40 percent of physician practices use some form of an EHR system, according to an annual survey from the Center for Health Statistics of the Centers for Disease Control and Prevention.

Other HCOs have experienced similar results in their physicians’ utilization of EHRs. Hospitals and health systems are more than halfway along in their adoption nationwide, although many face challenges associated with “meaningful use” requirements for federal funding. Still lagging larger physician groups and systems are small and rural health care providers. However, a growing number of health care experts, including the Care Continuum Alliance, see predictive modeling as an opportunity to prevent complications, control readmissions, generate more precise diagnoses and treatments, predict risk, and control costs for a more diverse array of population segments than previously attempted.

PM in real-time and on the fly

The process of risk assessment and prediction will become increasingly flexible, fluid, and dynamic. As HCOs implement systems that are capable of adding deeper, more compelling data to EHRs, clinicians and public health officials will be better positioned to develop and implement more focused predictions affecting care interaction. For example, real-time access to drug databases could reduce the number of prescriptions issued for commonly misused drugs, according to a 2012 study in the Canadian Medical Association Journal. HCOs will increasingly rely on predictive modeling to review

David Bodycombe is assistant scientist and managing director of the ACG System at the Johns Hopkins Bloomberg School of Public Health. According to its Web site, the ACG system “measures the morbidity burden of patient populations based on disease patterns, age, and gender.”
and re-engineer care processes, possibly leading the Food and Drug Administration to become more involved in the oversight of predictive models.

**Increased availability**

New data streams will become available to providers, payers, and government as EHRs draw from a broader array of data to create more complete insight into patients and the care delivery process. Current data used in quality reporting may be inaccurate or incomplete, according to a study published in the *Journal of the American Medical Informatics Association* (JAMIA). As HCOs gain access to data from more varied sources, such as health risk assessments, behavioral assessments, laboratory results, and pharmacy prescriptions (filled and unfilled), the impact of predictive modeling will increase.

Further, the integration of this richer, more encompassing patient data may have a powerful effect on the quality of patient care, including the resolution of potentially confounding treatment directives and instances of over- and under-treatment. The performance of predictive models will also become increasingly more credible with $R^2$ values exceeding 0.30.

Progress has already been made in various health care environments. Kaiser Permanente has begun a project to link patients’ genetic data with EHRs to better understand how genes, health behavior, and environmental factors interact to cause disease. Clinicians will soon use EHR data to track pain medication usage. This will allow for a more comprehensive approach to limiting the misuse of such medication and will enable people and organizations with access to the data to identify patients who may be “seekers” of such medications, according to a study in the *Archives of Internal Medicine*.

Plans and providers will tap EHRs to facilitate communication with large groups of patients — potentially in the millions, as already documented by Stanford University researchers in JAMIA.

Predictive models will expand to include a much broader array of risks, including outcomes, procedures, compliance, and safety. As an example, Columbia University and Massachusetts Institute of Technology (MIT) researchers have already used EHR data on gender, ethnicity, prescriptions, and medical history to build an algorithm that helps to predict an individual’s health. Each is placed on a risk trajectory and tracked. Advances in predictive modeling may make it possible to predict and therefore influence inflection points in this trajectory that may result in more positive population health outcomes.

New types of data will allow for a more sophisticated understanding of varied risk pools. For example, access to lab data could provide HCOs with more accurate profiles of disease severity. Meanwhile, more sophisticated health risk assessment data will give HCOs a better sense of the depth of a patient’s social network and financial resources, which often affect treatment outcomes. We will be able to develop population-based interventions that focus on commonly occurring disease patterns or phenotypes.

HCOs will ultimately organize populations into subgroups that are highly amenable to specific actions or interventions, including nutrition therapy, physical activity, weight management, health literacy tutoring, and self-management education.

This increases our ability to provide the appropriate care at the appropriate time. It also affects costs by identifying populations at the highest risk for commonly managed diseases and providing target interventions that will affect patient outcomes and quality of care. The bottom line will be much more specific and therefore effective intervention strategies.

**Improved accuracy of critical data**

Even if EHRs do not achieve their full potential within the next several years, HCOs can still use their nascent EHR data to enhance what is already being gathered through administrative claims. EHRs could be used to improve information capture within administrative claims, providing improved diagnostic accuracy, while systems that can take advantage of the new data streams evolve.

The growth of ACOs and patient-centered medical homes points to industrywide interest in longitudinal, coordinated, and integrated care. Risk sharing arrangements, including contracts with ACOs, medical homes, and health insurance exchanges will demand population health management and facilitate even more rapid adoption of predictive modeling.

HCOs must be ready to quickly identify subpopulations that are at greatest risk and are open to the kinds of interventions that will control or mitigate these risks. The increased availability of EHR-derived data will help HCOs segment popula-
tions by level of risk and overcome the limitations of claims databases.

Health care reform has introduced many incentives to improve outcomes and patient safety. When the federal government launched its accountable care program, it did so with a lengthy set of measures it will use to make payments based on the quality of visits, rather than the quantity. The new norm will be to evaluate care based on value — units of quality care delivered per unit of cost.

Challenges remain. Outcomes are difficult to measure and often require expert opinion. Until recently, we have not had enough data to measure performance. This is changing. Collection of performance data is now mandated in Medicare and Medicaid and is being widely adopted in managed care. The rest of the commercial payer sector will probably follow soon, and the result will be a growing domain for predictive modeling. Access to new data sources will improve our ability to model performance.

Predictive modeling will help enhance HCOs’ clinical, financial, and operational performance, although an HCO’s ability to attain top performance goals will vary according to levels of compliance within managed populations. New sources of data will make performance modeling more accurate, timely, and realistic.

HCOs must realize that they will only succeed in population health management with shared ownership of goals with other sectors. These sectors include physicians, hospitals, payers, employers, social service organizations, and public health agencies that together will:

- Define the issue and target population
- Recognize external and internal baseline strengths
- Set measurable consensus goals
- Develop a plan
- Implement initiatives
- Analyze progress

The promise of predictive modeling for population health management can be achieved as long as HCOs understand its inherent shortfalls and focus on maximizing benefits such as enhanced clinical decision support and highly personalized health plans. Collaboration is key to successful predictive modeling.

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We don’t run our Question & Answer feature every month. That’s because we don’t talk to just anybody.
Highmark’s Accountable Care Future Starts With Expansion of PCMH Model

A patient-centered medical home pilot project yields results that lead the health plan to launch a major effort

By Frank Diamond
Managing Editor

As Highmark greatly expands its patient-centered medical home, the Pittsburgh-area insurer does so with the idea that the PCMH will lay the foundation of even more encompassing systems: accountable care organizations.

Highmark’s PCMH relies on primary care physicians, as do all PCMHs, and that’s where health care reform starts but not necessarily where it ends, says Paul Kaplan, MD, senior vice president for provider strategy and integration.

“We acknowledge that this is a journey, and accountable care organizations cannot be successful unless you have the right infrastructure,” says Kaplan. “You need to give the doctors time to get organized, to experiment until they find what works. But we do intend to move into the ACO world and we’re having discussions with health system entities.”

Start with primary care

Michael Fiaschetti, Highmark’s president for health markets, says, “The medical home is the foundation of the broader accountable care organization. When you think of the large systems that own hospitals and groups, you start with the primary care doctors and all the members who those doctors serve.”

Energized by the results of a PCMH pilot program, Highmark, a Blue Cross & Blue Shield affiliate, is expanding the initiative this year to include nearly 1,050 primary care physicians in more than 100 practices. They serve about 170,000 patients.

The pilot, begun in 2011, included 160 PCPs in 12 practices that cover about 45,000 members.

In the pilot:

• Inpatient acute admissions dropped 9 percent.
• Thirty-day readmissions dropped 13 percent.
• Seven-day readmissions dropped 14 percent.
• Per-member, per-month costs for patients with coronary artery disease dropped 5 percent.
• Per-member, per month costs for diabetics dropped 3.5 percent.

The basis of the pilot and what now drives the expansion is that physicians are paid more for delivering better care. “We’re not going to compromise quality for cost,” says Fiaschetti. “This isn’t the old days; that may have happened 20 years ago at some of the old HMOs. There will be huge returns because we’ll eliminate many emergency visits, unnecessary admissions, and unnecessary readmissions.”

Kaplan says that specialists will probably play an outsider role in how the PCMH functions. “Our view is that we start by reorganizing and re-empowering primary care doctors. Just as when you build a home it needs a strong foundation, we see PCMH as one brick in the foundation of the house.

“Specialists will be involved as we need to create the infrastructure for the primary care physicians and the specialists to improve communications with each other. Eventually the PCMH really is a collaboration between the primary care physician and the specialist based on real-time useful information exchange and real-time ability to communicate.”

Mature doctors

All doctors are not equal when it comes to who’s ready to become part of a PCMH or can use “real-time data” effectively and efficiently. “We’re already having discussions with the more mature doctors in the system about accountable care and how to make it work,” says Kaplan. “The less mature doc-
tors — we need to help them get to the point where they have the capability, because our goal is that 75 percent of all our primary care doctors will be part of a PCMH and will be working very effectively and efficiently with their specialist physicians.”

**Innovation encouraged**

Meanwhile, the PCMH encourages innovation. For instance, the members of one practice huddled over the appointment book at the end of the shift to see which patients were scheduled for the next day.

“One doctor would say, Mrs. Smith is coming in tomorrow,” says Kaplan. “But I also look after Mrs. Smith’s four kids. Let’s pull the charts of the children and see if they’re up to date on their immunizations.”

Two of the children in this particular instance were not. “So the doctor said to the team, Give Mrs. Smith a ride and have her children come with her. Ask Mrs. Smith if she’s willing to let the two not-up-to-date children get up to date while they’re here. That saves her from having to come in a second time with her kids.”

In this way, PCMHs encourage effective visits, says Kaplan. “People are busy. They don’t want to have to go back to the doctor frequently when a lot of things could be addressed at once.”

He also tells the story of a practice that wanted to reduce ER admissions. “They got together with some patients and the hospital staff and they realized they could do one very simple thing: Leave Monday mornings completely open with no appointments and guarantee patients who called that they would be seen on Monday. Their ER utilization dropped. People who were sick over the weekend, but not bad enough that it was life-threatening, waited to see the doctor because they were guaranteed that they could get in.”

As Fiaschetti puts it: “Lower costs for the patient, lower costs for the system. It is going to take a different approach, a much tighter alignment between Highmark and physicians than we’ve had in the past.”

The insurer will be sharing much more information. “Data about services that have been provided to these members, data about clinical information about these members,” says Fiaschetti. “For example, the actual sugar levels of the diabetic patient and what can be better done to control those levels so that those patients have a better quality of life, stay out of the emergency room and, God forbid, stay away from being admitted to the hospital.”

Kaplan adds, “The goal is to ensure that the practice of medicine is fun for doctors. Doctors are working harder and harder and aren’t always convinced they’re catching the patient at the best time. By creating a team environment in which the doctor can hand patients off to other members of the team, the doctor focuses on the things he does best.

“They are all practicing at the top of their license. The goal is to create a different infrastructure in which the doctor can more effectively know the patient he’s touching and when he should be touching him. That useful information passes to the physician in real time or as close to real time as we can make it.”

Practices will be encouraged to take the team approach, says Fiaschetti. “In their offices they would have a care coordinator [often a nurse provided by Highmark] who could spend time with the chronically ill patients and get them the right level of care and the right education and coordinate their care more intensely. In exchange we will provide higher incentives to the physicians for better managing those patients based on certain quality parameters and based on certain cost parameters.”

**Disease management**

One thing that should work better is disease management, says Kaplan. “Doctors weren’t able to do disease management, so the insurers took on this task. But if a physician tells a patient, I’ll have a staff member call you tomorrow evening to remind you to take your medications so that this becomes a habit for you, then “The patient is more likely to pick up the phone. He’s less likely to do it if the insurance company is making a cold call. This takes time, and we need to better reward the physicians for his time. But we also need to have the infrastructure so the doctor can have a team that knows what the doctor wants for each patient. We know that we will have happier patients and we will actually have happier doctors.”
As the provisions of the Affordable Care Act continue to be implemented, dramatic changes are taking place with far-reaching implications for every area of health care. How, then, to manage these changes successfully?

Possibly the most important aspect to consider is not deciphering what the changes are but how to implement them. Unfortunately, many provider, payer, and employer organizations overlook the effects of change on their organizations. But with some thought and planning, the detrimental effects of change can be mitigated. Here’s how.

To begin, most people do not like change, especially if things have been working fine for years, time is limited, and now there is a new system or procedure for routine tasks. It’s no different in the health care environment. Resistance to change is deeply embedded in our human psyche and health care professionals and organizations are not immune. Many theories have been developed over the years providing some explanation of how we process change. Some have been adopted by the health care field to provide a framework for medication adherence and related health behaviors. However, most center on the cognitive aspects of adapting to change.

This discussion, however, focuses on a change theory that centers not on the cognitive processes but on emotion.

Scott Guerin, PhD, is a psychologist and director of government and policy systems at the Access Group, a professional services firm specializing in health care communications and strategy consulting in the pharmaceutical and biotechnology industries.

Change theory based on Elizabeth Kübler-Ross’s five stages of grief is unique because it emphasizes the emotional impact experienced during times of change that can have a negative effect in the workplace. One key component of this theory is that people adapt to change just as they adapt to grief and loss, meaning that when something changes in the environment, a person moves through the stages of grief (denial, anger, bargaining, and depression) before arriving at the final stage of “acceptance.”

This is not a linear progression; a person does not have to move through the stages sequentially but may progress, regress, get stuck, or move quickly through the stages. We have all seen examples of this where a new procedure or idea is presented and the immediate reaction is the first step of “denial” as seen in statements like “This isn’t going to work” or “I’m not doing it.” However, with some preparation, an organization can minimize the impact of change. First, it is important to understand how change and loss are related.

**Change as a loss**

Simply stated, change is related to loss because when something changes we experience the loss of what was. Obviously, just as there are varying degrees of change, there are varying degrees of loss. For example, a few years ago I was working for Magellan Health Services and one of my responsibilities was to facilitate on-site workplace training sessions for employer groups. A commonly requested training session was on managing change and stress in the workplace. On several occasions the managers told us that they could see a negative reaction in their employees even if something simple changed, such as having to park in a new area, or having to use a modified computer system.

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Managing Rapid Change

In the Health Care Environment

Wrenching transformation in many forms is starting to be felt in many parts of the system. Here are ways to help resistant employees get on board.

By Scott Guerin, PhD

Managing change starts by understanding the emotional fallout involved and directly approaching each situation in your organization with thorough planning, communication, empowerment, and patience, argues author Scott Guerin, PhD.
Expanding on that idea, researchers Nancy Lorenzi, PhD, and Robert Riley, PhD, at the University of Cincinnati in studying the effects of implementing changes in large medical informatics systems stated that “For many people, organizational change is perceived as a threat of personal loss, whether the threat is real or not,” and that the threat can range from job security to the disruption of routine.

Imagine a small medical group transforming into a patient-centered medical home (PCMH) that requires significant changes in procedures, routines, and service offerings. For many organizations that are moving to a patient-centered medical home model, effectively managing change can be seen as the key to a successful transition.

**Changing to a medical home**

With expertise in working with group practice transformation projects, Cari Miller is the director of advocacy and program operations at the New Jersey Academy of Family Physicians. For 15 years she has worked with more than 300 physicians in 500 locations across the country, assisting medical groups in achieving PCMH recognition and in other practice transformation projects. She and her team provide education and assistance in developing and monitoring work flows, data collections, and documentation needed to assist with NCQA’s PCMH recognition process. In Miller’s experience, “it is an understatement to say that transforming a practice to a new care delivery model is disruptive.”

Miller suggests that organizations considering, or in the process of, making significant changes in work flow or standard operating procedures consider the following steps to minimize the disruptive aspects of change within the practice.

**Planning is one key to successfully unlocking and initiating change within an organization.** For change to have a chance within an organization, all involved need to know “where they are heading and how they are going to get there.” Without this vision, it will be difficult, if not entirely impossible, for those engaged in the changes to understand the need for change and what the change will result in.

**One of the most overlooked components is communication.** To assist in the change effort, messages must be communicated consistently, concisely, and clearly, as much as possible, to foster the new vision, direction, and strategy. This will also help to avoid conflict and to be able to rapidly, efficiently, and effectively address conflict when it does arise. There is never enough communications.

**Focus on empowering action, in which barriers and challenges, real and perceived, are addressed and removed.** This can be accomplished by ensuring that processes are in place to suggest and request feedback and insight from all. In addition, encourage outside-of-the-box thinking to foster risk-taking and support nontraditional roles, initiatives, and plans.

**Recognize that change takes time.** The process must be planned, anticipating the barriers and challenges that will be encountered and developing and deploying plans to address, mitigate, and overcome these obstacles.

Miller’s points relating to planning and communication are two key ways to minimize the disruptive effect of change in an organization. For example, David Caldwell, PhD, of Santa Clara University in California and colleagues surveyed physicians from 37 specialty departments in a large health care organization regarding their support of a new customer service program. The study team investigated how a large health care organization implemented significant changes in care delivery services involving new systems and structures including new call centers and a larger staff. The researchers reported that “direct and relentless communication” helped build support for the transition in addition to involving current staff members in the implementation process.

While there are significant changes in how health care is provided, how health care is purchased is changing just as fast. As a result, employers offering health care plans have to adjust to the changing marketplace in addition to addressing employees’ concerns.

**Change with benefits**

Consulting with large national employer groups about benefit designs and coverage, David Hay of David Hay Associates has been addressing employee concerns about changes in benefit packages for over 25 years. Hay sees how the fluctuation of health care options affects employee perceptions and offers insight into how to manage these situations.

According to Hay, with the economic challenges and the medical inflation rates that employers have faced over the past several years, employers have modified their plan designs in ways that employees...
perceive as “take-aways.” Without a doubt, most employees have been asked to shoulder an increased share of their health care costs. At the same time, however, employers are offering employees opportunities to reduce their out-of-pocket expenses by engaging in behaviors that promote individual health while also “bending the trend” in claims costs. It can be a win/win, but the challenge is in convincing employees that the new situation is in their best interests and not just another take-away.

Hay recommends “a plan design that reflects a true commitment to employee wellbeing — a culture of health in which healthy behavior results in savings for the employee — and an effective and consistent communication plan that explains the new design and the incentives for healthy behavior well in advance of open enrollment.” Another key aspect of managing organizational change is understanding that changes will be more acceptable if people understand that the benefits of the new program will outweigh the risks of maintaining the status quo. This is echoed by Christopher Worley, PhD, associate professor of organization and management at the Graziadio School of Business and Management at Pepperdine University in his statement, “Change is more often resisted than supported in organizations because people rarely are given the chance to understand the reason for the change.”

Changing steps

Whether the changes affecting our organizations and members are planned or thrust upon us, stakeholders in health care organizations, medical practices, employer groups, and pharmaceutical manufacturers can significantly alleviate the detrimental effects of change. This can be accomplished by understanding the emotional aspects of change and directly approaching each situation with thorough planning, communication, empowerment, and patience.

References


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How a Large Hospital System Profited by Putting Patients First

UCLA Health System went from bad to best, using a plan that emphasized increased respect for the patient

By Peter Boland, PhD

The subtitle of this book — Leadership Lessons for Creating a World-Class Customer Experience from UCLA Health System — distinguishes this publication from the plethora of articles and health care conferences touting how a particular hospital “puts the patient first.” Most hospitals have little idea of what patients and families value most because they are locked in a provider-centric mindset steeped in clinical paradigms. There is a world of difference between how providers act and speak and how patients and families perceive quality and caring.

Joseph Michelli, the author, is an organization development consultant who has chronicled how Starbucks and Ritz-Carlton perfected the art of customer experience and set the bar for other service sectors. He pierces the complicated veil of hospital-speak and presents an easy-to-read case study of how one eminent medical institution confronted the reality of patients giving them low marks for quality and service.

Significant problem

As with any successful change-management program, the journey toward excellence began with admitting that there was a significant problem and then making a top-to-bottom commitment to setting clear goals, establishing and tracking performance benchmarks, and holding everyone accountable — even those without direct patient contact. It started with the CEO modeling and mentoring a service-centric culture throughout the institution. Patient satisfaction surged from the low 30s to 95 percent systemwide. UCLA Health System is now recognized as the top academic medical center in the country in terms of patient satisfaction.

UCLA Health System had already demonstrated five key business principles that were catalysts for further change: commit to care, leave no room for error, make the best better, create the future, and service serves us. This foundation enables the health system to implement specific communication behaviors for employees. The template includes six broad behaviors:

- Connect with the patient or family members using Mr./Ms. or the patient’s preferred name.
- Introduce yourself and your role.
- Communicate what you are going to do, how it will affect the patient, and other needed information.
- Ask for and anticipate patient and/or family needs, questions, or concerns.
- Respond to patient and/or family questions and requests quickly.
- Exit, courteously explaining what will come next or when you will return.

In addition to respectful communication guidelines, two-dozen “world class practices” were instituted on aspects of courtesy, professionalism, and respect. The act of securing a behavioral commitment from employees improved their day-to-day behavior at the medical centers.

One of the overriding objectives was to increase the consistency of service delivery. This meant fostering compassionate relationships with patients and their families. It required each employee to embrace a cultural shift marked by emotional engagement. Operational objectives were established to promote customer-centric...
outcomes and employee behaviors. Service professionalism meant developing service skills and an investment in facility-wide training and coaching while establishing new criteria for hiring.

**Listening**

The organization developed tools to create a healing environment and to maintain positivity among hospital personnel. Listening became a hallmark of showing respect and created a sense of being present as important life events take place. Part of the service culture included elevating patient safety (“do no harm”) as the highest operational priority, anchored in the organization’s values, mission, and purpose. One of the medical center’s mantras became “what you task gets done.”

To move beyond “safety reactivity,” safety priorities were converted into objectives and performance metrics were established. De facto safety leaders were sought out to influence safety policies and the behaviors of their peers. Suggestions from staff members were sought systematically, and patients were encouraged to take an active role in contributing to safety.

The UCLA Health System believed that consistent delivery of high quality care is a matter of brand integrity and is closely linked to overall quality performance measures. The institution committed itself to deliver outstanding outcomes every time, in terms of clinical quality as well as service quality in the eyes of patients and families.

The institution was mobilized toward a common goal of excellence in customer service, which is driven by employee-patient engagement. Michelli drew on his extensive background in helping leaders create compelling customer service experiences and dynamic workplace cultures. He cited numerous empirical findings from wide-ranging sources to validate the impact and value of customer service excellence. For example:

- Even in difficult times, 50 percent of consumers will pay more for better service.
- Only 14 percent of customers report that they leave a business for product reasons.
- Sixty-eight percent will sever a customer relationship because a staff member treated them poorly.
- Companies that are successful in creating both functional and emotional bonding with customers have higher retention rates (84 percent vs. 30 percent) and greater cross-selling ratios (82 percent vs. 16 percent) than companies that are not.
- The average value of a customer is 10 times the initial purchase.
- The cost to attract a new customer is six times the cost to save one.
- Low-service, low-quality companies average 1 percent return on sales and lose 2 percent market share a year.
- High-service, high-quality companies average 12 percent return on sales and grow 6 percent a year.

Such documentation provides a compelling rationale for health care systems to invest in customer service excellence and make it a top priority. Excellence in customer service at UCLA Health System followed from employee-patient engagement. That meant that employees were to be advocates for patients, which meant taking the time to get to know them and their individual circumstances and demographic situation. This evolved into the concept of ROE — return on engagement. It also led to greater profitability, increased customer loyalty, more referrals, positive staff morale, and strong community support.

Michelli’s book is filled with hundreds of diagnostic checklist items that can be readily adopted by hospitals and health systems committed to becoming truly patient-centric. Summaries for each of the 11 chapters encapsulate the main points of how to lead and implement the transformation. *Prescription for Excellence* is just that, a practical and comprehensive guide to delivering better care while improving the bottom line. It is a significant contribution to understanding what it means to be truly patient-centric and to understanding the steps needed to place patients and their families at the center of care.
Total Knee Replacement Using Patient-Specific Templates

A summary of ECRI Institute’s Emerging Technology Evidence Report

Managed care leaders are striving to make evidence-based decisions about new and emerging health technology. MANAGED CARE and ECRI Institute have collaborated to disseminate bimonthly summaries of the Institute’s Emerging Technology Evidence Reports. ECRI Institute is an independent not-for-profit organization that researches the best approaches to improving patient care by analyzing the research literature and data on clinical procedures, medical devices, and drug therapies.

Total knee replacement using commercially available patient-specific templates takes images from preoperative computed tomography (CT) or magnetic resonance imaging (MRI) scans to create single-use patient-specific templates intended to align knee implants.

Surgeons use one of two methods to align knee implants. Using the more widely accepted method, the surgeon aims to resect the bones in the proper orientation in all planes so that the implant aligns to the mechanical axis of the leg. Generally, up to a 3° deviation from the mechanical axis is accepted to minimize the risk of implant collapse, wear, loosening, instability, and postoperative pain. An alternative alignment method uses three kinematic axes to align the knee implants. This kinematic-based alignment method considers the relative relationships of the femur, patella, and tibia through all flexion angles without applied force. Regardless of method, suboptimal alignment has been associated with shortened implant longevity and poor patient outcomes.

Conventional instrumentation used during total knee replacement includes intramedullary and extramedullary guides to assist with proper orientation of femoral and tibial components. The use of conventional instrumentation has been reported to result in misalignment in approximately 28 percent of total knee replacements. Intraoperative computer-assisted navigation was developed to address alignment errors with conventional instrumentation. The use of intraoperative computer-assisted navigation has been reported to decrease the incidence of misalignment approximately threefold compared to conventional instrumentation.

Total knee replacement using patient-specific templates is an alternative to conventional and intraoperative computer-assisted approaches for patients who are able to undergo MRI or CT and wait several weeks for processing and creation of the templates. During the surgery, the surgeon places the patient-specific templates on the ends of the patient’s distal femur and proximal tibia and adjusts the position of the customized contact faces of each template until locating the exact fit to the bone. In some models, cutting guides within the templates specify where the surgeon should cut the bones, while other template models guide the insertion of pins, which then are used to place standard cutting guides. The surgeon creates the bone cuts, places the component replacement pieces, and uses cement to hold the pieces in place.

Purported benefits of using patient-specific templates during total knee replacement include the following:

- Improved alignment
- Decreased operative time
- Increased patient throughput
- Decreased instrumentation
- Reduced risk of fat embolism and intraoperative bleeding due to minimal bone removal (i.e., no intramedullary canal reaming)
- Decreased tissue loss
- Shorter recovery
- Reduced postoperative pain
- Decreased incidence of infection
- Lowered costs

Key questions and findings

1. Is the clinical efficacy (i.e., alignment, pain relief, stability, range of motion, function, quality of life, activities of daily living, etc.) of total knee replacement using patient-specific templates equal to or greater than existing alternative approaches?”

2. How long does the use of patient-specific templates take compared to existing approaches?”

3. What is the cost comparison between the use of patient-specific templates and existing approaches?”

4. Who are the potential beneficiaries of patient-specific templates?”

5. What are the potential limitations to the use of patient-specific templates?”

6. What are the potential barriers to the adoption of patient-specific templates?”

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durability, revision rate) of total knee replacement using patient-specific templates better than that of total knee replacement using conventional instrumentation or intraoperative computer-assisted navigation?

This question cannot be answered because of a lack of data on all but one outcome. A very small amount of low-quality data were available on range of motion of patient-specific templates compared to conventional instrumentation, but these data were insufficient to conclusively answer the question. No data were available to address the computer-assisted navigation comparison.

2. Are the perioperative outcomes (i.e., intraoperative blood loss, conversion to conventional total knee replacement, operative time, post-operative pain, length of stay) of total knee replacement using patient-specific templates equivalent to those of total knee replacement using conventional instrumentation or intraoperative computer-assisted navigation?

This question cannot be answered because of a lack of data on all but two outcomes. A very small amount of low-quality data were available on blood loss and operative time of patient-specific templates compared to conventional instrumentation, but these data were insufficient to conclusively answer the question. No data were available to address the computer-assisted navigation comparison.

3. How do the adverse events of total knee replacement using patient-specific templates compare to those of total knee replacement using conventional instrumentation or intraoperative computer-assisted navigation?

This question cannot be answered because of the very small amount of low-quality data available on adverse events of patient-specific templates compared to conventional instrumentation. No data were available to address the computer-assisted navigation comparison.

4. What adverse events are reported for total knee replacement using patient-specific templates?

Two small studies that looked at adverse events during use of patient-specific templates reported that no adverse events occurred.

Coverage and payment

The U.S. Centers for Medicare & Medicaid Services (CMS) has no national coverage determination regarding use of patient-specific templates during total knee replacement. Thus, coverage decisions are left to the discretion of local Medicare carriers.

ECRI Institute routinely searches 11 major private, third-party payers that publish their policies online. Our searches found one major payer with a policy that denies coverage for patient-specific templates and 10 without a specific policy. MC

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For inquiries about this report or membership in ECRI Institute’s Health Technology Assessment Information Service, e-mail htais@ecri.org.
Relapsing Multiple Sclerosis Patients Can Look to Second Oral Agent

The recent approval of Aubagio (teriflunomide) provides an opportunity to conduct head-to-head trials in this expanding treatment category

Thomas Morrow, MD

Multiple sclerosis, a debilitating immune disorder that affects the brain and spinal cord, was probably first described around 1200 in a young Icelandic woman named Halldora who suddenly lost her vision and mobility but recovered a week later, a common initial presentation of MS.

A millennium later, a French neurologist, Jean-Martin Charcot, actually named the disease (sclerose en plaques) and described what later became known as Charcot’s triad: nystagmus, intention tremor, and telegraphic speech. Although not unique to MS, they are common along with cognitive disorders, also described by Charcot.

Although there are many theories, the exact cause of MS is unknown. What is known is that the farther from the equator a person lives, the more likely the development of MS. The main theories posit some sort of infectious agent, but despite extensive research, no definitive cause has been found.

Diagnosis is not straightforward because the clinical course of the disease varies. Many symptoms can occur in other diseases. But once it is diagnosed, there are several patterns of progression: relapsing remitting, secondary progressive, primary progressive, and progressive relapsing.

There is no cure; current therapies aim to delay the onset of progression and are called disease-modifying drugs. None of the approved disease-modifying drugs actually provides immediate relief. Conversely, corticosteroids are used for acute symptoms, but do not actually modify the long-term course of the disease.

The first disease-modifying drugs were interferons and copaxone, both approved in the mid 1990s. Since then there has been a flurry of development for MS. Currently approved therapies include:

- **Interferon beta-1b**: brand names Beta-serone and Extavia
- **Interferon beta-1a**: brand names Abvenox and Rebif, each having its own dose and delivery form
- **Glatiramer acetate**: Copaxone
- **Natalizumab**: Tysabri
- **Fingolimod**: Gilenya (See the August 2010 Tomorrow’s Medicine column), the first oral MS therapy

**Latest approval**

The latest approval, teriflunomide, is manufactured by Genzyme, a Sanofi company, and marketed under the brand name Aubagio.

Teriflunomide, the second oral medication approved for chronic treatment of MS, was approved in late 2012. Teriflunomide is a pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of multiple sclerosis.

Available in 7 and 14 mg tablets given once per day, teriflunomide is approved for relapsing forms of MS. Both doses have demonstrated the ability to reduce the rate of relapses and MRI progression of disease activity. Only the higher dose has been shown to decrease the disability progression.

Teriflunomide was studied in 844 patients in placebo-controlled clinical trials in patients with relapsing forms of MS. Roughly three-fourths of the patients were women; the mean age was 38.

Study 1 was a 108-week trial randomized 1:1:1 with either 7 mg (n=368) or 14 mg (n=358) of teriflunomide or placebo (n=360). The pri-
mary endpoint was annualized relapse rate (ARR). Mean disease duration was 5.33 years and mean Expanded Disability Status Scale (EDSS) was 2.68 at baseline.

**Noted in all age groups**

The ARR was significantly reduced in patients in both dosage forms. This beneficial result was noted in all age groups, in baseline disease activity levels, in prior MS therapies, and in both men and women. The time to disability progression was significantly reduced only in the 14 mg per day group.

Several MRI variables were studied, including total lesion volume and hypointense areas of the brain (both hallmarks in MRI imaging of MS) and number of gadolinium enhancing lesions. All of these beneficial outcomes were statistically reduced in both dosage forms as compared to placebo.

Study 2, a randomized double-blind, placebo-controlled study comprising 179 patients, had a primary endpoint of unique active lesions/MRI scan at baseline, 6 weeks, 12 weeks, 18 weeks, 24 weeks, 30 weeks, and 36 weeks. This study also demonstrated a statistically significant improvement associated with both doses.

Teriflunomide has a black box warning for severe liver injury, including liver failure in patients treated with leflunomide, also indicated for rheumatoid arthritis. Leflunomide is metabolized into teriflunomide, so there is already clinical experience with the primary active metabolite. The PI states, “A similar risk would be expected for teriflunomide because recommended doses of teriflunomide and leflunomide result in a similar range of plasma concentrations of teriflunomide.”

Of course concomitant use of teriflunomide with other potentially hepatotoxic drugs may increase the risk of severe liver injury. There is also a pregnancy risk within the black box.

Teriflunomide stays in the serum for a long time — up to two years. The PI specifically details a mechanism to accelerate the elimination with cholestyramine and activated charcoal that can accomplish a 98 percent reduction in teriflunomide in plasma concentrations within 11 days.

Other warnings in the PI come from more than a decade of experience with leflunomide as well as the safety studies of teriflunomide. They include bone marrow effects, risk of infection, peripheral neuropathy, hyperkalemia, acute renal failure, skin reactions that include Stevens-Johnson syndrome, blood pressure increase, and interstitial lung disease. Other less serious adverse reactions include alopecia, diarrhea, nausea, and paresthesia.

Although, in general, the concomitant use of two immunosuppressive or immunomodulating therapies is suspect, safety studies in which teriflunomide was concomitantly administered with interferon beta and glatiramer acetate for up to one year did not reveal any specific safety concerns. But the PI specifically states that the long-term safety of these combinations has not been established.

Over the past 18 years MS has gone from a disease that for all intents and purposes was untreatable to one where a significant percentage of patients will have a positive long term outlook. Although there are no head-to-head trials with teriflunomide against any other medication, it is hoped that access to a new mechanism of action to treat this neurologic disease will give even more people a long, functional life.

**A challenge**

I personally would like to challenge those involved in managing large populations (PBMs and national health plans, for example) to do virtual head-to-head trials using existing data sources to see how patients do on the various therapies over time. It seems within our reach to measure and compare long term outcomes within large systems of care using patient outreach, and a variety of data sources such as disability claims, pharmacy benefit data, medical insurance data, and electronic medical record data.

Perhaps using the Medical Avatar that I described last month would facilitate this approach.

These new medications, along with large-scale comparative effectiveness research, are part of the exciting future of Tomorrow’s Medicine. [Me]

The author is a director in the value-based health department at Genentech. He has had no other industry affiliations in the past three years. The views expressed in Tomorrow’s Medicine are the author’s alone.
Two years of data show a 6 percentage point improvement in compliance

UnitedHealthcare’s outcomes study unveils some impressive numbers, and now the company sets its sights on prediabetes.

Compliance with evidence-based medicine requirements in 6 areas:

<table>
<thead>
<tr>
<th>Year</th>
<th>Diabetes health plan members</th>
<th>Nonparticipants</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>59%</td>
<td>59%</td>
</tr>
<tr>
<td>2010</td>
<td>72%</td>
<td>60%</td>
</tr>
<tr>
<td>2011</td>
<td>75%</td>
<td>61%</td>
</tr>
</tbody>
</table>

SOURCE: UnitedHealthcare

Launching a value-based insurance design (VBID) program is a one-sided relationship in the beginning. The enrollee receives free medication and doctor visits, but the health plan won’t know where it will lead for at least two or three years.

“I think the industry is waiting to hear results, and now that we have them, we’re going to see a lot more energy and innovation about value-based insurance design,” says Karen Mulready, director of product development at UnitedHealthcare. The results she speaks of come from a two-year study the insurer recently released. Researchers tracked 620 people in the company’s diabetes health plan, measuring compliance with six treatment and testing requirements such as doctor visits and screenings for blood sugar, cholesterol, kidney function, and eye disease.

Seventy-five percent of program enrollees complied with the requirements, compared with 61 percent of people with the disease who were not in the program.

**Claims data**

In addition, 21 percent of participants saw a reduction in their health risk scores, which are used to project costs. In fact, despite the upfront expenditure by the plan, overall health care costs grew 4 percent more slowly for participants than for nonparticipants. UnitedHealthcare says that the two-year analysis, begun in 2009, included all medical costs for preventive care and treatment along with “payment of financial incentives for plan participants.” Company officials say that a more in-depth analysis of the program’s effect on cost and outcomes will be made when there are three years worth of claims data.

Benefits that are offered include free diabetes-related prescription drugs and medical devices and copaymentless doctor visits. Just how much a patient can save depends on the number of doctor visits and the type of medication and frequency of dosage. On average, patients save about $500 a year.

“We’re using the plan design as an incentive,” says Mulready. “When I’m out talking to members at enrollment meetings or health fairs, I’ve been told that this is really something people like. It’s not having that monthly payment when they need to fill their prescriptions for their diabetes. People are becoming more compliant. We’re seeing that their disease is not progressing.”
The 620 study participants were compared with 9,175 diabetics working for 106 employers that didn’t offer the program but shared certain characteristics with the participating companies, including size, type of industry, health benefits offered, and salary levels. Overall, about 30 employers and organizations — including Hewlett-Packard, Affinia Group, New Orleans, and the American Postal Workers Union Health Plan — participate, enrolling about 15,000 diabetics and people with pre-diabetes in the program.

“Our employers have been thrilled with the results,” says Mulready. “I’ve had a number of people from companies that do not participate contact me directly for information.”

This year 10 new companies and organizations, with about 70,000 covered lives, are joining, and Mulready says that’s a testament to how much awareness has grown about diabetes. “This always comes up. It is an ongoing issue every year for employers. Because of the type 2 increases and because of the obesity epidemic, this is a growing concern for everyone.”

Employers may offer it as a stand-alone health plan or as an enhancement to an existing plan. “We’re able to integrate all of those programs,” says Mulready. “We not only have a value-based plan design, but we also have coaching through our disease management program.”

Mulready says it’s family-oriented. “This type of condition puts a chronic financial burden on the family as a whole,” says Mulready. “This program not only enables them to have access to wellness tools and educational tools, but it removes a financial burden.”

Members of the diabetes program use a portal that offers information about their condition and a personalized scorecard so they can monitor their progress towards completing their “health action requirements,” says Mulready.

The emphasis on prediabetes is crucial. Sam Ho, MD, UnitedHealthcare’s executive vice president and chief medical officer, says that the goal “is to slow the progression of the disease for people with diabetes, and in as many cases as possible, to reverse the condition for people at the prediabetes stage.”

About 27 million Americans have diabetes and another 79 million have prediabetes, according to the Centers for Disease Control and Prevention. The disease costs the country about $195 billion a year, and half of all Americans might get it by 2020, according to the UnitedHealth Center for Health Reform and Modernization. It costs about $4,400 a year to treat an employee who has no chronic conditions. UnitedHealthcare notes that “For people with diabetes without the complications that often afflict people with the disease, the annual cost is $11,700, a figure that rises to $20,700 for diabetics with complications, such as heart disease and kidney failure.”

The UnitedHealthcare program focuses on compliance with good reason. According to the CDC, noncompliance is a major reason that treating diabetes can be difficult — more than 80 percent of diabetics do not follow doctor advice on how to manage the disease.

The compliance rate for participants in the diabetes plan increased 6 percent over two years. “Next year what we want to do is study not only on diabetics, but also prediabetics,” says Mulready. “Because one of the objectives of the program is to really educate and inform the prediabetics so they do not progress into becoming a diabetic.”

**Prediabetes**

The insurer plans to take the same approach as in the two-year study on diabetes. “We will monitor the progress of prediabetics who were continuously enrolled in the plan for two years,” says Mulready. “We will be looking for changes in compliance, impacts on cost, and changes in health risk scores. One of the main objectives of this study will be to determine the impacts the diabetes health plan has on preventing people with prediabetes from converting to diabetes.”

As the CDC numbers indicate, there’s a lot riding on the results.
One way of confronting growing costs is by accelerating bundled payment arrangements, according to a Commonwealth Fund study that looks at ways to slow down the rate of increases. “More-inclusive bundled payments in which a single payment is made for all care provided during an episode of care involving a hospital stay — including physician services — would provide incentives for teamwork and accountability for the total costs of care and outcomes associated with hospital episodes of care.”

The Commonwealth study, “Confronting Costs: Stabilizing U.S. Health Spending While Moving Toward a High Performance Health Care System” (http://tinyurl.com/costs-study), offers a wide range of approaches to do just as the title suggests. The goal is to hold health care spending to no more than “the rate of long-term growth in the economy while improving health care quality and outcomes.”

Among those approaches is bundled payment for acute care episodes. Bundling payment would “make it easier for patients as well as payers to compare and access the total costs of care and quality for certain procedures and conditions such as hip replacement surgery, appendectomy, or heart bypass surgery.”

Everybody agrees that something needs to be done. The cost of premiums already amounts to 23 percent of median family income. “If projected trends continue, the average premium for a family plan would exceed $24,000 by 2021 — the equivalent of 31 percent of median family income, intensifying pressure on family budgets across the country,” the study says.

Meanwhile, total business, household, and federal spending on health is expected to increase from $2.9 to $5.5 trillion in the next 10 years.

Health spending is a problem for the private sector as well as public programs. “While spending on publicly funded programs is currently a focal point of federal budget debates, for the past several years both Medicare and Medicaid spending per enrollee have been growing at rates well below spending for those who are privately insured.” The slower rate of growth for public programs is expected to continue over the next decade.

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**Medicare vs. employer-sponsored**

Average annual per-capita increases, actual and projected

- **GDP per capita**
  - 2008–2011: 2.7%
  - 2011–2021: 3.2%

- **Medicare**
  - 2008–2011: 4.5%
  - 2011–2021: 4.6%

- **Private insurance**
  - 2008–2011: 3.3%
  - 2011–2021: 3.3%

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**Average family premium as a percentage of median family income, 2013–2021**

- **2013**
  - GDP: 3.8%
  - Medicare: 4.5%
  - Private: 4.4%

- **2021**
  - GDP: 6.0%
  - Medicare: 4.5%
  - Private: 4.6%

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**Projected national health expenditures by source, 2013–2023**

- **U.S. government**
  - 2013: 31%
  - 2023: 35%

- **Households**
  - 2013: 20%
  - 2023: 25%

- **Private employers**
  - 2013: 25%
  - 2023: 30%

- **State, local government**
  - 2013: 5%
  - 2023: 5%

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