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My newspaper days ended more than 20 years ago, but still they resonate. That’s partly because you can find almost any sort of eccentric in a newsroom: They’re the last bastion of the unemployable.

Joe stood out because, although he enjoyed the bedlam and shenanigans, he was as normal and good a guy as you’d want to meet, and would be accepted in any business. (So, of course, we nicknamed him “Mr. Normal.”)

Joe had an abnormal burden to carry as a parent, however. He had three children, and his middle child suffered from inflammatory bowel disease. There were always new medical treatments, then, when they failed, operations, and then hope for a normal life. Finally. Then—damn!—a relapse, and yet another anguished go-round for what the family prayed would be the last time. It never was.

I caught up with Joe about 10 years ago at a bar in Doylestown, Pa. In the course of some soul-spilling Joe told me that, “Someone very close to me died.” His daughter.

“Did she die of that disease, Joe?”

“Yes, you could say that.”

I didn’t press. Some years later, I met another colleague who told me that Joe and his wife found their daughter. She’d hung herself from a tree on their property rather than go through yet another operation. She was in her early 20s. It haunts me.

Our story on IBD (page 13) investigates just how all-consuming that problem can be. Depression is just one of the many deviling byproducts. Patients with IBD often have many tests, trips to the emergency department, and hospitalizations for severe pain that is not caused by IBD, but related to mental health disorders.

It can be living hell. Read the story. For Joe’s sake.

How IBD Became One Parent’s Nightmare

By Frank Diamond

M
Fresh Faces: Molina’s Theresa Blanco

This 39-year-old director of medical affairs for Molina Healthcare of Florida is also a mother of six. So she knows how to manage.  By Frank Diamond

Insurers Help in Harvey, Irma Cleanup

Health plans are making it easier to see an out-of-network doctor, get a new copy of an insurance card, or replace lost prescriptions.  By Jan Greene

Cover Story

Apply Whole-Person Care to IBD

About 1.6 million Americans suffer from inflammatory bowel disease. Patients often have high rates of depression and anxiety.  By Lola Butcher

On the Ledge Between Life and Death

The author describes the horrible effects hemophagocytic lymphohistiocytosis had on his nephew.  By Robert Calandra

The Shadow Knows

Prices of older drugs have gone up when new treatments are introduced. Congress is looking into shadow pricing.  By Ed Silverman

Don’t Ignore That PBM Behind the Curtain!

“Transparency!” The call goes out from all corners of the health care system. PBMs counter that they actually help control costs.  By Robert Calandra

Original Research

Diabetes Care Management Teams Falter

Studies comparing team care of diabetes with traditional care should be redesigned, say researchers.

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How IBD became a parent’s nightmare.

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ACOs can help improve end-of-life care.

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Ignore customers at your peril

Why the ACA is so wobbly.
ACOs Could Jump-Start Better End-of-Life Care

The potential for ACOs to improve care and save money has been examined from many vantage points, and here’s one more: how ACOs can facilitate better end-of-life (EOL) care. A post on the Health Affairs blog last month offered insight into just what ACOs can bring to this process.

Authors Julia Driessen of the Graduate School of Public Health at the University of Pittsburgh and Turner West, the director of the Palliative Care Leadership Center’s Bluegrass Care Navigators in Lexington, Ken., argued that while the applicability of ACOs to many areas of care delivery have been much examined, “discussions of the impact of ACOs on EOL care are conspicuously absent.”

There is a lot of variation in EOL care and in utilization of Medicare’s hospice benefit. The median length of stay (LOS) in hospice is 17 days; the average is about 72 days. “While some variation should be expected as the needs of individuals at the end of life are different, part of this variation is attributable to the design of the Medicare hospice benefit,” the study stated.

That’s mainly because Medicare hospice need is based on prognosis. That contributes to variation because “terminal illnesses do not always follow a predictable course,” Driessen and West pointed out. They specifically cited dementia, which can be difficult to predict and therefore lead to long and excessive LOS.

The authors also said that while ACOs cannot currently influence patients’ choice of hospice provider, it may be in their interest to work more closely with doctors who help patients and their families make those decisions. ACOs could, for example, provide physicians with information about the varying quality of hospice providers.

Driessen and West wrote that doctors steering patients to better hospice providers would have a two-part effect. “First, the EOL experiences for beneficiaries will improve as they will be receiving care from high-performing hospice providers. Second, poor-performing hospice providers will lose market share and consequently will be forced with the choice of improving or becoming irrelevant in their communities.”

In addition, Driessen and West argued that ACOs might also help improve palliative care, the step before hospice for people living with serious illness.

Hospital Association: Cancel MU Stage 3

Do away with Stage 3 of the meaningful use program, the American Hospital Association (AHA) urges CMS. The three stages of CMS’s Meaningful Use program use incentives to encourage hospitals and other health care providers to improve their electronic health records system for Medicare beneficiaries.

Stage 3, set to begin next year, will place an untenable burden on the association’s 5,000 members, wrote Thomas P. Nickels, the executive vice president for government relations and public policy, in an August 25 letter to Rep. Pat Tiberi, the chairman of the House Subcommittee on Health. CMS recently made Stage 3 optional for next year, but the AHA wants the entire thing tossed by removing the 2018 start date altogether.

An addendum to the letter offers suggestions on how the government can provide regulatory relief. Hospitals are already overloaded with “burdensome and unnecessary” meaningful use regulations, the AHA claims, and there’s no clear evidence that they help patients.

“These excessive requirements are set to become even more onerous when Stage 3 begins,” the AHA says. “They will also raise costs by forcing hospitals to spend large sums upgrading their EHRs solely for the purpose of meeting regulatory requirements.”

The letter echoes one that the AHA sent to then President-elect Trump back in November. In that letter, AHA President and CEO Richard Pollack also made a broad appeal to lift the regulatory burden on hospitals.

“Reducing the administrative complexity of health care would save billions of dollars annually and would allow providers to spend more time on patients, not paperwork,” Pollack wrote last November.

The meaningful use effort falls under the Health Information Technology for Economic and Clinical Health (HITECH) Act. HITECH was part of the American Recovery and Reinvestment Act of 2009.

In addition, the Merit-based Incentive Payment System (MIPS) under MACRA includes a meaningful use component, although it does not apply to hospitals.

Briefly Noted

Better cooperation between providers and health plans would speed up the shift to value-based health care, according to a Quest Diagnostics-Inovalon survey. And that transition will continue no matter what lawmakers might cook up, respondents believe. About 8 in 10 physicians and health plan executives said they believe the transition to value-based care will continue regardless of policy changes spearheaded by the federal government. The survey was conduct-
ed in April and included 302 primary care physicians and 150 health plan executives…. The American health system isn’t at all prepared to defend itself against cyberattack, reports the Sacramento Bee. The connectivity that enamors so many contains some risk. “From insulin pumps and defibrillators, and on to expensive CT scanners and MRI machines, medical devices are increasingly connected to networks,” the newspaper reports. “Patient medical records are online. When networks go down, physicians say it is like operating in the dark.” The headline on the story: “Cyber criminals’ next deadly target: Grandpa’s pacemaker”.…. Emergency department staff can be the first line of defense in trying to prevent elder abuse. Often, visits to the ED are the only time providers get a chance to determine if an elderly person’s been abused, Kaiser Health News reports. ED doctors look for specific injuries. “For example, radiographic images show old and new fractures, which suggest a pattern of multiple traumatic events,” Kaiser reported. “Specific types of fractures may indicate abuse, such as midshaft fractures in the ulna, a forearm bone that can break when an older adult holds his arm in front of his face to protect himself”…. When Nora Harris, 64, was diagnosed with Alzheimer’s disease in 2009, the Oregon resident signed an advance directive preventing her life from being prolonged when the disease got worse. Those directives usually give named agents the power to withdraw artificial hydration and nutrition, but when that same nourishment is offered by hydration and nutrition, but when that same nourishment is offered by

Markets with fewer payers see lower hospital costs, doc visit prices

I nsurer concentration in a market has the ability to reduce hospital costs for some specialties in highly concentrated provider markets, according to a recent study published in Health Affairs.

Researchers Richard Scheffler and Daniel Arnold, both of the University of California–Berkeley, computed market concentration by service area for insurers, hospitals, and primary care physicians, cardiologists, hematologists/oncologists, orthopedists, and radiologists. Using commercial claims of about 50 million insured people, they also figured out hospital and doctor visit prices from 2010 to 2014. They found that insurers were able to reduce hospital admission prices by 5% in markets where both insurers and providers were highly concentrated. In such markets, they also reduced the fees of cardiologists, radiologists and hematologists/oncologists by 4% to 19%, according to Scheffler and Arnold. Primary care and orthopedics prices weren’t affected. The bargaining power that insurers have in highly concentrated provider markets allows “insurers to capture a significant amount of monopoly rents that providers get in those markets. What is missing is a market mechanism that will pass these reduced prices on to consumers in the form of lower insurance premiums,” Scheffler and Arnold stated. They concluded that “it would seem to be only a matter of time before further intervention in and regulation of the health insurance market by state and federal legislatures, as well as private market innovations, will accelerate.”

Average regression-predicted physician visit prices, by physician and insurer market concentration, 2014

Source: Scheffler, RM, Arnold, DR, “Insurer Market Power Lowers Prices in Numerous Concentrated Provider Markets,” Health Affairs, September 2017

—Frank Diamond
Medical Malpractice Reform: A Fix for a Problem Long out of Fashion

The House has passed legislation that the AMA and others endorse. But the sense that there is a malpractice crisis has ebbed and Senate action is unlikely.

By Richard Mark Kirkner, Contributing Editor

You may remember Y2K: anxiety that computers would crash, trains would stop running, and the electric grid would shut down. Turns out it was hype, and at 12:00:01 on Jan. 1, 2000, the world kept functioning.

Around that time, there was also what was called “the medical malpractice crisis,” when doctors’ malpractice premiums spiked and lawsuits were reaching an all-time high. That same year, a presidential task force called medical errors a “national problem of epidemic proportions.” In late 1999, the Institute of Medicine came out with its To Err is Human report that said as many as 98,000 people die every year from otherwise preventable medical errors.

That was a long time ago, and state tort reforms have all but relegated the malpractice crisis to the history books. But there’s good news for those of you into all things retro: The House of Representatives just voted to fix the malpractice crisis. In June, the House passed HR 1215, the “Protecting Access to Care Act of 2017,” by a 222–197 margin, with 17 Republicans joining the majority of Democrats to vote against it.

What HR 1215 would do

The legislation would apply to any health care provided through federal programs or supported by federal subsidies. It would cap noneconomic damages like pain and suffering in malpractice cases at $250,000, limit lawyers’ contingency fees, and allocate damages proportionately to all parties involved. That is, it would do those things if it became law, but it probably won’t.

“When a bill comes out of the House with a vote like that, it goes to Senate in a very weakened state,” says Joanne Doroshow, who has followed the legislation as executive director of the Center for Justice and Democracy, a consumer rights organization founded by Doroshow, a former staff attorney for Ralph Nader. GOP opposition in the House has diminished any Senate incentive to take up the legislation, she says.

But if Y2K isn’t retro enough for you, sponsor Richard Hudson, Republican of North Carolina, boasted in a press release that the legislation is modeled on “successful reforms implemented in California in 1976.”

Break out the bicentennial garb!

Crisis? What crisis?

HR 1215 may be the classic example of a solution looking for a problem. At last count, 32 states have adopted some type of limits on medical malpractice claims. As those regulations have taken hold in the past dozen years or so, the sheer number of medical malpractice claims has dropped off. “The malpractice reforms we have in place now across the county have been pretty effective,” says Paul Greve, executive vice president of the benefits consulting company Value of medical malpractice payments on behalf of doctors, 1991 to 2015

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<th>Year</th>
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<td>1991</td>
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<td>2000</td>
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Source: Public Citizen, the Medical Malpractice Scapegoat, Feb. 28, 2016
Willis Towers Watson. “They’ve helped drive down the number of claims and suits.” But Greve also points out that the rising number of large verdicts and settlements in excess of a million dollars has caused concern and cut into insurer profits.

As Hudson’s bill crawled through the House, Public Citizen compiled a report on malpractice trends from 1991 to 2015 based on data from the National Practitioner Data Bank and the Bureau of Labor Statistics. When analyzing malpractice trends, there are two factors to look at: the total number of claims paid and the total value of claims paid. The total number of claims paid on behalf of physicians—Public Citizen’s data does not include hospital-paid claims—peaked at 16,529 in 2001. In 2015, the total number of claims paid had fallen to 9,043.

With regard to the value of claims, the Public Citizen analysis showed that it also peaked in 2001 at $6.7 billion (in 2015 dollars). However, inflation-adjusted payouts have inched up since 2011, and the proportion of payouts of $1 million or more has also crept up, from 7.7% in the 1992–1996 period to 8% between 2009 and 2014, according to a separate analysis of the practitioner data bank conducted by Allen Kachalia, MD, chief quality officer at Brigham and Women’s Hospital in Boston, and his colleagues. They reported their results earlier this year in JAMA Internal Medicine.

By many measures, malpractice premiums are also declining. For example, in 2014, total premiums were 20% lower than their 11-year peak in 2006, according to A.M. Best data. In 2015, medical liability premiums accounted for 0.29% of overall national health care costs, half of what it was in 2003, according to Public Citizen’s analysis.

**Trends behind the trends**

The decline in malpractice claims could be related to a host of factors, says Kachalia, including the effect of state-level tort reform, care getting safer, and some organizations taking a more proactive approach to resolving cases of injury so patients feel less of a need to sue.

Greve says the response to the Great Recession is evidence that the public may have soured on suing. “The most dramatic proof to me is that, every time we’ve had an economic downturn in the past, we’ve seen civil litigation go up,” he says. “That did not happen in 2008.” Michael C. Stinson, vice president of government affairs and public policy for PIAA, the trade association for the medical liability industry, points to another factor: safer medicine. That’s probably a function of hospitals embracing safety protocols and things like checklists, he says. “Just being more aware of how to make health care better and safer for everyone involved has definitely had an impact,” he says.

**Leave it to the states**

Any time the federal government gets involved in anything that states have traditionally regulated, the question always comes up if the feds are overstepping their bounds. In 2012, when the House considered attaching federal malpractice legislation to another bill, the National Conference of State Legislatures opposed it.

National medical malpractice legislation has long been a goal of many physician professional organizations. But there are dissenting voices in the medical community. One belongs to Jeffrey Singer, a general surgeon in Phoenix and a senior fellow at the libertarian Cato Institute. “I don’t think it’s constitutional unless we’re dealing with interstate issues, and most medical malpractice is intrastate civil tort law,” he says of HR 1215. “I just don’t think the federal government has a role to play.” Allowing federal involvement even when federal dollars are at stake, is a “slippery slope,” he says. “If we go down the road of allowing federal intrusion into areas that are constitutionally the province of the states based upon federal subsidies or funding, almost no program and no person can feel safe from federal intrusion.”

No one interviewed for this story sees a return to out-of-control malpractice premiums, even as trends tick up slightly. Stinson, at PIAA, says an argument can be made that as medical care delivery starts to cross state lines because of telemedicine, a national medical tort standard may take its place. “We think it’s important to have a uniform playing field across the country so that a physician based in Indiana doesn’t have to worry about, when they’re talking to a patient via Skype, whether or not that patient is in a state that has no reforms or has better reforms,” Stinson says.

But that probably won’t be enough to get the Senate to take it up. **MC**
Otezla was approved by the FDA in 2014 as a treatment for plaque psoriasis and psoriatic arthritis. Right out of the starting gate it captured some attention for being the first new small-molecule drug for psoriasis in decades. Otezla—the generic name is apremilast—also exploited a new mechanism of action as the first inhibitor of phosphodiesterase 4 (PDE4) that results in increased expression of both anti-inflammatory proteins and reduced expression of their pro-inflammatory counterparts.

But despite the glow of the limelight and its uniqueness, Otezla found itself in a predicament. Among some clinicians it came to be viewed as an expensive, plain-Jane drug that didn’t really produce any major gains in the clinical outcomes that mattered. This rather dim view was reflected in a study published last year in the *Journal of the American Academy of Dermatology*. The study, funded by Abbvie, was an indirect comparison of two agents using results from existing studies for each drug. The results showed no statistically significant difference between Otezla and methotrexate in the Psoriasis Area and Severity Index 75 (PASI 75) score, a measure of the degree of skin plaque improvement in patients with 75 meaning 75% clearance. Lead investigator April Armstrong, MD, at the University of Southern California and her colleagues calculated that the annual incremental cost for Otezla to achieve one additional PASI 75 responder would be $187,888.

Otezla got better news from the Institute for Clinical and Economic Review (ICER) in Boston. ICER studied the value of Otezla relative to the increasing number biologics for plaque psoriasis, which include Humira (adalimumab), Enbrel (etanercept), and Remicade (infliximab) plus relative newcomers like Stelara (ustekinumab) and Cosentyx (secukinumab). ICER reported in November 2016 that the wholesale acquisition cost of a month’s supply of Otezla was $2,586 and that the net cost after discounts was $2,069. At those prices, the comparative effectiveness gurus determined that Otezla is cost effective within an acceptable quality-adjusted life year (QALY) range of between $100,000 and $150,000. And if the net cost of $2,069 per month is used, Otezla looked to be a relative bargain, coming in at a cost of less than $100,000 per QALY gained.

But doctors, other clinicians, and patients don’t typically have QALY calculators at their fingertips (although perhaps there can and should be an app for that).

Because Otezla’s price was set at about $2,600, many clinicians look at it in comparison to the biologic agents. And Otezla, despite having the nice sheen of a newcomer, does not match the performance of the biologics. Moreover, a new cohort of biologics with potentially better performance was in the offing. Cosentyx arrived in 2015. Its phase 3 studies showed 70% of patients achieved clear skin (PASI 100) or almost clear skin (PASI 90) at the end of 16 weeks. The clinical trial for the newest biologic, Tremfya (guselkumab), has shown that 80% of patients achieved the PASI 100 or PASI 90 measures. In Otezla’s clinical trials, only 40%, 33%, and 29% of patients achieved the PASI 75 score. Taltz (ixekizumab) and Siliq (brodalumab) are the two other new biologics.
Tally marks in the plus column
Yet despite all of this competition, Otezla is solidly on track to achieve blockbuster status. Celgene’s recent financial report says Otezla’s worldwide sales increased to $358 million in the quarter ending June 30, 2017, up from $241 million the year before. Express Scripts’ 2016 drug trend reported a one-year 79% increase in utilization.

Celgene has been aggressively detailing the drug and offering assistance programs, and those efforts explain some of the growth. But experts say several other factors have come into play.

For one thing, Otezla is considered to have a better safety profile than its old-school competitor, methotrexate, which requires lab monitoring for signs of liver damage. Experts also recommend taking folic acid with methotrexate to reduce the risk of other side effects such as upset stomach. Otezla does not require laboratory prescreening or ongoing monitoring. An added bonus is that Otezla has the potentially advantageous side effect of causing some weight loss.

Otezla also has a few advantages over the biologics. It doesn’t, for example, require testing for tuberculosis and other infections.

Otezla’s most common side effects are diarrhea, nausea, upper respiratory infection, and headache. Patients are at some risk for depression and suicidal thoughts, and reduced dosing is required in cases of kidney impairment.

Fewer on biologics than expected
Ultimately, though, Otezla’s growing popularity may be related to the diverse nature of treating and managing plaque psoriasis.

Otezla’s growing popularity may be related to the diverse nature of treating and managing plaque psoriasis.

in treatment are sometimes necessary.

For this and other reasons, the treatment guidelines for psoriasis are not a simple, step-by-step strategy of first do this, then do that, and so on, explains Andy Behm, an Express Scripts vice president. Treatment recommendations are flexibly tied to the severity of disease. Mild disease is treated with topical therapies such as corticosteroids, vitamin D analogues, or tazarotene alone or in combination with phototherapy. Moderate to severe disease usually requires use of systemic agents such as methotrexate, cyclosporine, acitretin or the biologics.

The variability in treatment strategies and the availability of many different products and medications along with the option of combination therapy can benefit dermatologists financially, and influence treatment choices.

This flexibility in the use of traditional treatments has an impact on the use of biologics. “If you read the drug trend reports or news sources, you get the impression everyone is on a biologic,” says Behm. “But that is not the case. Our data show a very small percentage of dermatologists dabble in biologics. They tend to be conservative with biologics.”

Michael Siegel, vice president at the National Psoriasis Foundation, says that “a lot of patients and providers are not comfortable with biologics. There is still a lot of interest in topicals and the full range of oral medications—and light therapy is developing as well.” He says an underlying reason for this interest is that providers want to have the option to change treatments and move to higher levels of therapy if their patients are not responding.

So Otezla may find a sweet spot because of the limited use of biologics along with flexible treatment strategies that allow for a lot of judgment about what’s best for the patient.

Otezla’s growing popularity may be related to the diverse nature of treating and managing plaque psoriasis.

CALL FOR PAPERS
MANAGED CARE is seeking article submissions. We welcome a wide variety of manuscripts, including drug class reviews, disease state management reviews, pharmacoeconomic analyses, strategies for coping with medication errors, and outcomes research. Interested? Write to our managing editor, Frank Diamond, at frank.diamond@iconplc.com.
Teresa Blanco, DO, does more managing in a day than most of us do in a month. And it’s only partly because she’s the director of medical affairs for Molina Healthcare of Florida. The 39-year-old Blanco is also the mother of six, her children ranging in ages from nearly 2 to 12. Her home life strengthens some of the skills needed for her job. “It helps me multitask,” jokes Blanco, who’s been in her present position at Molina since 2015. Then, seriously: “I can review cases, and get into a meeting, get insight, give advice to our nurses. [Being a mother] helped me become very patient.” She’s the first doctor in her family and, yes, of course, her parents Manuel, a CPA, and Maria, a retired national sales trainer for a pharmaceutical company, are very proud. (Her husband, Miguel, does promotions and marketing for radio. He’s proud as well.)

Part of a team
Blanco works with three other medical directors. Three (including Blanco) are stationed in the company’s Doral, Fla., office (outside of Miami; Blanco went to Tennessee when Hurricane Irma hit), while one is out in the field visiting hospitals, physician practices, social service organizations, and government offices. Blanco’s team reports to the Florida health plan’s chief medical officer, Mark Bloom, MD.

Most of Molina’s members are either Medicaid beneficiaries or people getting insurance on the ACA exchanges. Because of its background in Medicaid, Molina—at least initially—turned a profit on the ACA exchanges, though it’s gone through some tougher financial times recently.

One of the attractions of working for Molina, Blanco says, is that the company very much keeps in mind employees’ desire for work-life balance. Hers is an eight-hour day, but it’s a full and hectic eight hours.

“We work from beginning to end,” says Blanco. “I mean, just before this call, I was on a peer-to-peer that was taking a bit longer than it usually does, which is why I had to postpone our interview for a few minutes.” Peer-to-peer consultations involve discussing possible courses of action for a patient with the treating physicians.

Blanco earned a bachelor’s degree in science at the University of Miami, and her medical degree from Nova Southeastern University in Fort Lauderdale. She interned at Westchester General Hospital in Miami, where she also completed her residency.

Her job at Molina consists mainly in making coverage decisions, anything from pediatrics to hospice to oncology. “Anything that comes to our desk,” she says, “whether it be a long-term care member who needs extra hours for home health, to whether or not a pediatric case needs a CT...
of the brain.” Blanco makes the final decisions, but they can be appealed by a member, doctor, or hospital.

Blanco’s job also entails making prior authorization rulings, asking physicians why certain tests were ordered, deciding whether treatment criteria should be overridden, making sure that patients are seen by the appropriate specialists, and that they are prescribed the right medications at the right time. In addition, she speaks to hospitalists to discuss whether certain admissions were necessary, and to relay information about patients that the hospitals may not have on record.

This sounds somewhat like her job entails saying “no” a lot, an assumption Blanco takes pains to dispel. “We do think about what’s best for our members,” she says. “It’s not so black-and-white. We have things that we have to review, and there are a lot of gray areas.”

For instance, say something a patient needs is not covered by Medicaid or an ACA plan. Blanco helps members find what they need by working with Molina’s Community Connectors (community health workers) who help connect members to local community and not-for-profit organizations. “We help them find it, whether it’s a bedside commode or home care visits or transportation. That’s what we do on a daily basis.”

Keeping track of costs

On the other hand, “Absolutely, cost is taken into account. That’s another reason we’re here.”

For instance, Blanco will determine whether the care a patient might seek at a hospital can be delivered in a less expensive venue, such as an urgent care center. “We do daily rounds here, so we go through all of our patient admissions on a daily basis, and we review for medical necessity,” she says. “We also, most importantly, prepare and help our members with discharge planning.”

These decisions come with a lot of input; the insurer’s interdisciplinary teams get together once a week. They are composed of nurses, case managers, community health workers, health coaches, supervisors, pharmacists, and medical directors.

Tough year for Molina

In sum, “We’re very much on top of our members and their needs, and we’re trying to make sure that they have everything they need before they are discharged, and that no one is missing anything.”

It’s been a rocky year at Molina. In May, the board fired the CEO, J. Mario Molina, and the CFO, John Molina. They are sons of the founder of the company. In July, the company announced it was laying off 10% of its workforce.

Blanco says her job hasn’t changed. “I was drawn to Molina in large part because of its mission to provide quality health care to people receiving government assistance, and that mission remains the same today.”

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Insurers Relax Rules, Help Members After Hurricanes Harvey, Irma

Deadlines were loosened and out-of-network fees, waived. Insurers, like providers, have preparedness plans, but some see a need for closer coordination with other stakeholders.

By Jan Greene

The image of intrepid doctors trudging miles in dirty floodwaters to get to their patients in Houston’s disaster zone gets a lot of attention, and deservedly so. A less dramatic but necessary role is played by health insurers helping members get care in unusual and trying circumstances in all the Southern states affected by Hurricanes Harvey and Irma.

Health plans operating in Harvey’s aftermath said they responded by making it easier to see an out-of-network doctor, get a new copy of an insurance card, or replace lost prescriptions. Insurers set up telephone help lines and eased specialist referrals.

Some of that response was prompted by a Texas Department of Insurance request that insurers “do the right thing” by suspending some of the restrictions that could hamper members’ ability to get care, and have it paid for, when they have lost key documents or are living in a new area. These include waiving penalties on out-of-network care, extending filing deadlines, offering 90-day prescriptions, and paying providers promptly.

The biggest health insurer in the state, Blue Cross Blue Shield of Texas, with 1.5 million members affected by the storm, said it would comply with the department’s request. The company has assigned a team to not just answer member questions but to call some of them to offer help with emergency resources. Patient clinical summaries available on its patient and provider portals helped members explain their medical history to a new doctor.

Humana officials said they had staff reaching out by phone or email to more than 300,000 members who are identified as being in Harvey’s path, with more than 242,500 phone calls already placed checking on member welfare. More than 3,000 Humana employees work in the affected region, with 800 of them dealing with the potential of flooding; supervisors checked on them and offered help, said a Humana media relations manager.

In Florida, insurance officials asked health plans to make it easier for members to get prescriptions ahead of the storm, anticipating logistical problems afterward. Many of Florida’s major health insurers said they were loosening the rules for members after Irma, and many were making significant cash contributions to recovery funds.

Preparedness metrics needed

A 2013 survey of health insurers by America’s Health Insurance Plans found that 85% maintain emergency teams, 59% have physical emergency operations centers, and 40% have an emergency call center. Most (71%) said they are prepared to temporarily suspend prior authorization rules.

The survey found less preparedness in health plans’ connections with emergency planning officials, with several plans indicating challenges in knowing whom to contact in case of a disaster or public health emergency. Just 30% of plans participated in preparedness drills with external stakeholders, though most said they are interested in doing so.

Researchers looking at the AHIP data found some areas for improvement in disaster planning, noting that a minority of insurers in the survey were using specific metrics to assess their emergency preparedness efforts, such as percent of critical systems tested. They suggested the industry develop measures, perhaps borrowing from other industries and tailoring them to health insurance’s unique challenges.

The researchers also recommended better connections between health plans and local health officials, and urged insurers to become involved with local and regional coalitions of health care organizations that maintain relationships so they can share information and resources in an emergency.

Note: An earlier version of this story was first published on the Managed Care website on Sept. 7, 2017.

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For nearly three decades, Lawrence Kosinski, MD, wrapped up almost every appointment with a patient with inflammatory bowel disease (IBD) the same way: “Call me if anything changes.”

They never called.

“They see them in the ER when they are deteriorating and I say, ‘Why didn’t you call me?’” he says. “And they say ‘Oh, doc, I was too busy.’ Or ‘I thought it would go away.’ Or ‘I didn’t want to bother you.”

Kosinski and his colleagues at Illinois Gastroenterology Group, a 53-physician practice in the Chicago area, recently developed a patient-engagement strategy that dramatically changes their interactions with patients diagnosed with IBD. One result: Per-patient hospital inpatient costs fell by more than 50% in the first year.

Miguel Regueiro, MD, a gastroenterologist at University of Pittsburgh Medical Center, teamed with a psychiatrist to develop an integrated care model that anticipates behavioral health problems that often accompany IBD. In the first year of a pilot, emergency visits and hospitalizations dropped by more than half.

And in Nashville, the Inflammatory Bowel Disease Center at Vanderbilt University Medical Center sees patients from 27 states when their frequent trips to the emergency room confound their hometown gastroenterologist. Their initial appointments last up to four hours, including assessments by a psychologist, a social worker, and a dietitian.

“Once they come to see us for a consult, we can usually reduce or eliminate their ER visits by addressing the whole patient,” says David A. Schwartz, MD, the center’s director.

More important than the reduced hospital use and the cost savings, these programs are sparing young people from many of the most dire IBD complications, which often occur when they are in school or starting careers and families. Most Crohn’s patients are diagnosed in their teens and 20s; ulcerative colitis is typically diagnosed when a patient is between 30 and 40 years old.

“We’re talking about bowel obstructions, abscesses, fistulas, surgeries, colostomies, ileostomies,” Kosinski says. These doctors are all enthusiastic proselytizers for “whole-person care” that goes beyond diagnosing IBD and treating symptoms as they emerge. Their work is getting a fair amount of attention, and a handful of practices—mostly at major academic medical centers—are joining their small movement.

But none expect their innovations to become the standard of care anytime soon.

**Not just a GI problem**

Crohn’s disease and ulcerative colitis—described collectively as IBD—are autoimmune disorders that affect about 1.6 million Americans, according to the Crohn’s & Colitis Foundation. Ulcerative colitis is inflammation and ulcers in the lining of the large intestine only. Crohn’s disease involves inflammation anywhere along the digestive tract.

The causes for either condition are not known, although researchers believe genetic and environmental factors contribute to the development of both diseases. What is known: The diseases are incurable, so patients—and the insurers who cover their medical costs—are strapped with the burden for decades.

Patients with IBD have annual direct health care costs averaging $12,000 to $20,000 per patient, although the range is much larger than that.
Patients with mild symptoms or whose disease is in remission typically can be treated with relatively inexpensive maintenance therapies. But for those being treated with Remicade, Humira, or one of the other biologics, the costs go way up. A year of Remicade or Humira treatments in a physician’s office can cost more than $30,000; in a hospital outpatient department, it may be triple that or even more. And for those whose symptoms are poorly controlled who require multiple diagnostic tests or end up hospitalized, the costs can be astronomical.

In recent years, GI specialists have come to understand that IBD often means dealing with more than just the physical aspects of an inflamed gut. Patients have high rates of depression, anxiety, and chronic pain that lead to suffering, high utilization of health care services, and expense. Patients with IBD often have many tests, trips to the emergency department, and hospitalizations for severe pain that are not caused by active inflammation from Crohn’s or colitis, but related to mental health comorbidities, Regueiro says. Psychosocial issues—including illness perception, difficulty with coping, and a variety of unhealthy behaviors and stresses—can make poor health even worse. Patients with IBD sometimes struggle with issues beyond the boundaries of immediate physical and mental health concerns. They are, for example, more likely to have marital and family problems than healthy people. Because they often need time off from work to manage their illness, regular employment can be elusive. The challenges of accessing, paying for, and complying with treatment can be overwhelming.

Despite that recognition, most GI practices do not help patients address mental health or psychosocial issues that are integral to their disease.

For one thing, GI practices are not accustomed to coordinating care with other disciplines. Medical social worker Marci Reiss started the IBD Support Foundation 11 years ago. The not-for-profit outpatient service provides psychosocial support and education to IBD patients and their families in southern California. Even though GI specialists agreed that their patients would benefit from her group’s services, they were not proactive in heading off problems.

“Doctors were remembering to refer patients only if the patient was sobbing in their office or facing a complicated surgery or a major treatment overhaul,” she says. “You want to help before they get to a crisis.”

While many gastroenterologists do recognize their patients need more proactive care, says Joel V. Brill, MD, chief medical officer of Predictive Health in suburban Phoenix, most are not set up to offer the array of services that would benefit them.

“It takes resources, and not every practice is organized in a way to move from being reactive [to patient crises] to incorporating nurses, pharmacists, dietitians and social workers into the practice to identify and reach out to patients,” he says.

Before they do that, practices need access to medical and pharmacy claims data to understand how often their patients are going to the ED or urgent care in search of relief from chronic pain or other symptoms. And they need to merge those claims data with their patients’ clinical data to identify patterns that would suggest better treatment approaches.

“Do most practices have the resources to do that?” he says. “The answer is no.”

**Can’t be too intrusive**

Jenetha Piecz is a busy mom who teaches horsemanship—trail riding, jumping, basic dressage—and preaches the importance of the relationship between rider and horse.

“Does your horse come greet you at the gate, even if you aren’t carrying a treat?” she writes on her website. “Does your horse stand for you to mount, allow you to groom him while he stands quietly?”

She can focus on that passion for horses because her Crohn’s disease—diagnosed nearly two decades ago when she was in her early 30s—is under good control. But the memories of being so ill she could not care properly for her children, of wondering if she wanted to continue living, are never far away.

After trial and error, Kosinski found the right mix of drugs to keep Piecz’s disease in check. But she is grateful for the patient-engagement protocol his practice uses to monitor her symptoms remotely every month.

“It gives me peace of mind that I’m connected with him,” she says. “He is having a look at me every month even though I’m not going in for an appointment.”

HHS is evaluating Project Sonar—the care management program that Kosinski and his group uses—as initial appointments for particularly problematic patients can last up to four hours, says David A. Schwartz, MD, of Vanderbilt University Medical Center. He heads the Inflammatory Bowel Disease Center.
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Payers move to support new models of IBD care

The best way for insurers to support chronic care management for patients with IBD is not yet clear. Early efforts include a shared-savings payment model and cash support for team-based care.

Care delivery model #1
Blue Cross Blue Shield of Illinois uses an intensive medical home contract to support a new care-delivery model for patients with Crohn’s disease and ulcerative colitis. Illinois Blues is in the third year of its arrangement with Illinois Gastroenterology Group in suburban Chicago and has recently entered into similar contracts with three other practices.

Under the contracts, the physician practices are paid a care-management fee and are eligible for adjustments in that payment if they reduce the overall costs of care and improve outcomes for IBD patients while using Project Sonar, the care-management program developed by Lawrence Kosinski, MD, and others at the gastroenterology group.

In addition to monthly “pings” via smartphone, the program hinges on a nurse care manager who assesses the patient’s medical and psychosocial needs, develops and monitors an action plan, helps to coordinate care among the patient’s providers and, when needed, connects the patient to a physician for immediate evaluation of emerging problems.

The benefits accrue to patients and payers alike. For the year that ended Nov. 30, 2015, a group of 185 patients enrolled in Project Sonar had 10% lower costs than the previous year, according to data that Kosinski presented at Digestive Disease Week, one of the major professional meetings for gastroenterologists. Their inpatient costs fell by 57% because they had fewer health crises requiring admissions, while the costs of infusible biologics increased by 9%, according to Kosinski.

“We’ve found $6,000 in savings for each patient who actively engages with the IMH [intensive medical home] via the smartphone care coordination tool,” Donna Levigne, the insurer’s divisional senior vice president for health care delivery, said in a written response to questions.

Reviewing the first two years of performance under the group’s shared-savings contract, Kosinski sees how proactive chronic care management is changing health care utilization, but there’s also a problem. Inpatient costs drop substantially—for his practice, they are down by about 60% over two years—but drug costs increase.

“We’re seeing a lot less morbidity, but we’re seeing a dependence on very expensive biologic medications,” he says. Overall costs are 8% to 10% below what they were for the same patients before they enrolled in Project Sonar, but significantly below the $500,000 a year to the Total Care–IBD program. The notion is that behavioral and psychosocial support can lower overall costs of care.

When a three-year pilot launched in July 2015, its co-directors—gastroenterologist Miguel Regueiro, MD, and psychiatrist Eva Szigethy, MD—were shooting for a 2% reduction in emergency department visits and inpatient admissions. In fact, ED visits fell by 52%, and hospitalizations by about the same proportion, Regueiro reported in a presentation last fall at the American College of Gastroenterology’s annual meeting.

Regueiro says behavioral health services are responsible for those results, at least in part. Whether that decreased utilization will continue over time remains to be seen. Chronically ill patients sometimes have trouble sticking with therapy, and the Total Care–IBD team is looking for ways to keep adherence high.

“We’re doing a lot of remote telepsychiatry and remote monitoring for their psychosocial care,” Regueiro says. “So we’re not asking patients to come into the office and that seems to be engaging them longer term.”

UPMC and the health plan are looking for a payment method that will sustain the medical home care model after the pilot ends next summer, says Regueiro.

In a three-year pilot at UPMC, ED visits fell by 52%, and hospitalizations by about the same proportion.

Care–IBD serves as the principal provider for high-utilizing IBD patients, responsible for all aspects of their medical, behavioral, and psychosocial care.

UPMC Health Plan provides about $500,000 a year to the Total Care–IBD program. The notion is that behavioral and psychosocial support can lower overall costs of care.

Beyond private payers, the federal Physician-Focused Payment Model Technical Advisory Committee has recommended Project Sonar as an Advanced Alternative Payment Model under MACRA. The recommendation is under consideration by HHS.

Care delivery model #2
At the University of Pittsburgh Medical Center (UPMC), the Total Care–IBD specialty medical home involves a care team that includes a psychiatrist, a social worker, nurse coordinators, certified nurse practitioners, and a dietitian. Following the tenets of population health management, Total Sonar cut costs of treating IBD patients the first year by 10%, says Lawrence Kosinski, MD, who developed the program being used by Blue Cross and Blue Shield of Illinois.

Project Sonar
the basis for one of its new payment methods, and Piecz sent an email endorsement to the department. “Crohn’s disease goes from zero to 60 in hours,” she wrote. “SonarMD has its finger on the pulse of the patient so that preventive measures are taken if they need be.”

Another patient sent an email saying Project Sonar is keeping her out of the hospital. “I can’t tell you enough the difference this has made in my life,” that patient wrote. “I only hope everyone has the opportunity” for proactive care management. Not likely.

That’s because of fee-for-service medicine and the relative value unit system that determines which services generate good money. For 30 years, that system has told physicians that procedures are more important than chronic disease management. Incentivized to become what Kosinski calls “colonoscopy factories,” most GI practices do not have the staff and infrastructure required to help patients manage a complicated disease that will last their lifetime.

“Frankly, there isn’t much money in it for them,” Kosinski says. “And it is much easier to just go to the endoscopy lab and crank the colons all day.”

By contrast, good IBD care requires interacting with patients more frequently—and with a delicate balance of persistence, patience, and compassion. Yet many patients with chronic illnesses are weary of interacting with medical professionals. Kosinski’s practice uses a mix of technology—an app that asks patients to report their symptom levels once a month—and nurses who call to check on those who do not respond.

Too much of a leap
Practices that offer chronic care management for IBD must invest in team-based care, and the team can be large. At Vanderbilt, for example, after a psychosocial assessment, a nutrition assessment, and a psychological assessment, a new patient is examined by a gastroenterologist—and then meets with a pharmacist to be educated about the drug regimen.

“And at the very end of the visit, the social worker will come back in and wrap up any loose ends and become the central point of contact for the patient,” says Schwartz, the director.

On future visits, patients see whichever members of the team are appropriate. “We know that about 40% of patients will have significant anxiety and depression, and that dramatically affects outcomes,” he says. “They can see that provider during their medical visit so there is no stigma of going to a separate mental health visit.”

At Illinois Gastroenterology Group, the Project Sonar care model works differently but has similar “whole-person” goals. For starters, patients are assessed for depression and anxiety, psychosocial issues, and biological markers of risk for severe IBD. About 75% of patients consistently respond to the monthly “ping” from the phone app; those who don’t will get a call from a nurse care manager to check on their health status.

“You want to help before they get to a crisis,” says Marci Reiss, founder of the IBD Support Foundation. But too many doctors refer patients to the foundation only when the patients are in dire straits.

Where payers come in
Like many conundrums in health care, the challenge of improving IBD care stems from the way America’s health system pays for care. Physicians know what they should be doing but most cannot afford to do it without more money from insurers. And payers are reluctant to pay more because they don’t fully trust that the physicians will deliver on their promises of better care at lower overall cost.
That's why another stakeholder group is paying to test innovative care models that integrate medical and psychosocial care. “The pharmaceutical industry is paying for these studies,” Reiss says. “For them, the gain is more appropriate use of their drugs.”

The funding may also be a way for drug companies to curry favor with doctors who are in a position to prescribe a medication worth millions in sales.

Reiss’s IBD Support Foundation developed a standardized model to embed psychosocial care into an IBD practice, and it has been implemented in practices at University of California–San Diego, Mayo Clinic, University of Southern California, Texas Digestive Disease Consultants, and Vanderbilt. Each of those practices received funding for the services from pharmaceutical grants.

Some payers are stepping up their support of a broader approach to IBD care in hopes that investing in improving care will cut costs in the long run by heading off hospitalizations, trips to the ER, and possibly use of expensive medications. The University of Pittsburgh Medical Center is integrated with UPMC Health Plan, the largest insurer in the Pittsburgh market. When health plan analysts noticed that members with IBD were using health services, Kosinski’s jaw dropped. More than half of the money that BCBS of Illinois spent each year on his patients with IBD was for complications—bowel obstructions, colostomies, and others—that required inpatient care. Only 3.5% of its outlay for those patients went to Kosinski’s physician practice. Fewer than a third of the patients hospitalized for a Crohn’s complication had seen their gastroenterologist in the 30 days before the admission.

“IBD goes under their radar screen,” Kosinski says. “Most insurance companies are focused mostly on cardiovascular disease and diabetes.”

Nonetheless, when Blue Cross Blue Shield of Illinois provided the data he needed to understand the way his patients with IBD were using health services, Kosinski’s jaw dropped. More than half of the money that BCBS of Illinois spent each year on his patients with IBD was for complications—bowel obstructions, colostomies, and others—that required inpatient care. Only 3.5% of its outlay for those patients went to Kosinski’s physician practice. Fewer than a third of the patients hospitalized for a Crohn’s complication had seen their gastroenterologist in the 30 days before the admission.

What if gastroenterologists could help patients manage their IBD and avoid expensive complications? That got the insurer’s attention.

The Illinois Blues offered a contract that pays for proactive chronic care management and rewards Kosinski’s practice for lowering the total cost of caring for IBD patients while improving outcomes. The insurer is working to spread his Project Sonar to GI practices across the state, but other payers are slow to take it up.

“We have presented to numerous Blue Cross plans around the country, and we haven’t gotten a bite yet,” Kosinski says. “It’s like pushing on a glacier, but we keep pursuing it.” Still, pushing on a glacier is easier than convincing physicians to change their practices in a way that, without major payer support, will ruin them financially.

“I don’t want to sound negative about doctors, but they still make money by seeing more patients and doing more procedures,” he says. “You have to have the payers change the game. And then the providers will adapt.”

Lola Butcher writes about health care policy and business topics. She lives in Springfield, Mo.
Young Man Battles For His Life Against Rare Autoimmune Disease

The author’s nephew suffers from a rare form of familial hemophagocytic lymphohistiocytosis. His organs shut down and he’s placed in a medically induced coma. Meanwhile, costs mount to $4.9 million, most of it paid by an employer-sponsored health plan.

By Robert Calandra

A few weeks before Christmas, in the toy-littered playroom on the pediatric intensive care unit of the Children’s Hospital of Philadelphia (CHOP), my sister Denise and her husband, Peter, sat on a sofa, caved in against each other, listening to the doctors.

Nine months of helping Luca, 26, their only child, battle hemophagocytic lymphohistiocytosis (HLH) had left them mentally, physically, and emotionally drained. I was asked to join the consultation to fill in the gaps of things they didn’t—or couldn’t—take in or process.

Since March, Luca had endured a series of raging fevers, countless emergency room visits and hospital admissions, and a diagnosis of lymphoma that took several nerve-wracking days to eliminate.

He had been prescribed massive courses of body-altering steroids, followed by rounds of chemotherapy, a medically induced coma, kidney rescuing dialysis, a bout with blood poisoning sepsis, and a now second life-saving medically-induced coma.

In the surreal setting of a hospital playroom, David T. Teachey, MD, an HLH expert at CHOP, and Aaron Donoghue, MD, the PICU attending physician, had come to tell us they had done all they could. The disease was causing Luca’s organs, especially his kidneys, to shut down. If his kidneys didn’t start working on their own in the next few days, there is nothing more they could do.

My nephew was a young man standing on the edge of a ledge between life and death, balancing on his heels.

HLH is a rare disease that results in an out-of-control immune response turning on the body. It may be inherited in an autosomal recessive manner or triggered by an infection. The symptoms include fever, enlarged liver or spleen, cytopenia, and neurological abnormalities.

HLH’s first assault on Luca’s life came almost a decade ago when he was a junior in high school. It started with mononucleosis. But there were other symptoms that didn’t fit with mono. So he went to see his pediatrician. “She said he had HLH,” remembers Denise. “She had just lost a patient to it so she knew the signs and symptoms.”

After a week at CHOP and two months of steroids Luca was his old self. HLH should have been in the rearview mirror of his life. And it was until March 2016 when after feeling “perfectly healthy,” Luca spiked a 104 degree temperature. A CT scan showed inflamed lymph nodes throughout his body. Steroids worked awhile but the disease started to take off again.

Teachey gave Luca three choices. “Chemo,” says Luca, “which he said he didn’t think would work; have a bone marrow transplant, the ultimate cure if you have the gene; or die. I asked what would happen if I didn’t do anything. He said you can’t stay on steroids so ultimately you will die anyway.”

A bone marrow transplant absolutely terrified Luca, partly because of a book he had read that outlined everything that could go wrong with a transplant. He chose chemotherapy. “My idea was to get the chemo to put it into remission and 10 years from now they might have some kind of gene therapy,” Luca says.

Days before beginning chemotherapy, Teachey called. The good news: They had a bone marrow donor match. The bad: His blood work showed that Luca had familial HLH—and a rare form at that. Still, Luca elected chemo, which he tolerated well, but continued treatment with steroids added 85 pounds to his slender 5’8” frame. In late
October doctors reduced his steroid dose. His HLH went into overdrive. For several days Luca laid in bed with a fever, guzzling bottles of water like happy hour beers. On November 2 he was emergently admitted to Pennsylvania Hospital, where he coded. The next day Luca was transported across the city to CHOP. He would not step outside again for six months. Before he was transported, a doctor at Pennsylvania Hospital had one last piece of advice for Luca.

“He said, ‘Luca, you better put on your boxing gloves, because you’re in for a hell of a battle,’” Luca says.

Luca was 25 when he fell ill. Because of the popular ACA provision that allows children to stay on their parents’ insurance, he was covered. The family’s insurance is through my sister’s job as human resource manager for Children’s Surgical Associates, the surgical group practice at CHOP.

Her plan is Independence Blue Cross Personal Choice High Deductible. She has a $3,000 annual deductible, but her employer covers half of it. The co-insurance is 10% until a maximum out-of-pocket limit of $5,500.

A few years out of college, Luca worked mostly odd jobs while pursuing a writing career. But last fall it was clear that Luca wasn’t going to be able to work. He was turning 26 in November and would have to go on Medicaid. At the beginning of November, Denise petitioned Independence Blue Cross to approve him as a disabled dependent. The company agreed.

With all that Luca, my sister, and my brother-in-law have been through, it would have been much worse if they hadn’t been financially protected by good, employer-provided insurance. As of June 28 of this year, the bill for Luca’s care was a staggering $4.9 million, of which the family has paid $6,288.54, or about a tenth of 1%. HLH is one of the many rare autoimmune diseases that can be unimaginably expensive to treat. Even with their excellent insurance, the family still has had to dip into their savings and take out a home equity loan because of the loss of income from Peter’s business, an auto repair shop in the Queen Village neighborhood of Philadelphia.

Peter’s shop is a fixture in his neighborhood. So while his customers weren’t having their cars repaired, they still contributed to the family. A local bar held a benefit while others randomly sent checks. Denise’s co-workers gave her gift cards and monetary donations. A family member ran an “HLH Sucks” T-shirt sale. All the money went into an account set up to pay Luca’s bills.

“If it wasn’t for all of those people doing what they did….” Denise trails off. “There are a lot of gifts that came from what we went through. There are good people in this world who are loving and caring. It is a blessing when you are on the receiving end of it.”

While the rest of the world went about its business, my sister and Peter spent most of November and December 2016 in CHOP’s intensive care unit. Luca was put into a medically induced coma to allow his body to rest while they treated the HLH. Two huge monitors hung on the wall to the right of his bed tracking his vital signs. We watched those numbers like nervous stock market investors. It was a bear market when his blood urea nitrogen rose. A higher platelet count made us bullish.

Things were going well and Luca was getting ready for the bone marrow transplant but he became septic. This time the medically induced coma was necessary to save his life.

As that meeting in the playroom at CHOP with Teachey and Donoghue wound down, my sister had one last question. It was flu season and the hospital was allowing only four visitors per patient. Would the hospital allow people to say good-bye. The doctors said they would make the arrangements. After the meeting Denise and Peter took a walk.

“Pete said we can really lose him,” Denise remembers. “He said, ‘We were blessed to have him for 26 years. If this is God’s plan, then it’s God’s plan and we have to learn how to accept it and go on. It will be hard but we will.’”

Sometime in the early morning hours Denise and Peter were startled awake by a very excited doctor.

“We know where the sepsis is and we can treat it,” Denise remembers. “He said, ‘We were blessed to have him for 26 years. If this is God’s plan, then it’s God’s plan and we have to learn how to accept it and go on. It will be hard but we will.’”

Sometime around 7 p.m. on February 15 of this year, a nurse entered the room with a bag half filled with what looked to me like a thick tomato sauce, hung it on the pole and attached it to a line going into a central line inserted in Luca’s chest. An hour later he had a new, but inactivated, immune system. Six months after transplant Luca did suffer a short period of graft-vs.-host disease that affected his skin. But now he wants to start rebuilding his life.

“I can honestly say that I feel good, my body feels a lot better,” says Luca, who wants to write screenplays. “I think this has made me a better person, a stronger person.” The experience “hasn’t changed my goals or aspirations. But I think it has pushed me to another level that most people don’t get to.”

Robert Calandra is a health care writer in Philadelphia and a regular contributor to Managed Care.
Congress Puts ‘Shadow’ Pricing Of MS Drugs in the Spotlight

Prices of older drugs go up when new treatments are introduced. The difference between list and net price is also getting some fresh scrutiny.

By Ed Silverman

In the middle of what was already a steamy August, a pair of Congressional lawmakers turned up the heat on drugmakers over their pricing for multiple sclerosis treatments.

They wrote seven companies to explain not only “skyrocketing prices,” but a practice known as shadow pricing in which a drugmaker increases the price of an existing medicine to match the price hike or higher price set for a new drug launched by another company.

For instance, the price of Avonex, which is sold by Biogen, had a list price of $8,720 at the time it was launched in 1996, but it climbed to nearly $44,800 in 2012 and then to $86,300, according to the letter sent by the lawmakers to the drug companies. During that time, several other MS treatments became available.

“The prices of more than a dozen new MS therapies have increased sharply in the past decade, nearly in lockstep with new, more expensive entrants into the market,” wrote Democratic Reps. Peter Welch from Vermont and Elijah Cummings from Maryland in an August 17 letter. They also lamented the fact that competition has failed to mitigate the trend.

Of course, this is hardly a revelation. A study published in Neurology two years ago found that costs for three older medicines, which were launched between 1993 and 1996, rose by statistically significant amounts after a new type of treatment became available in 2002. A similar pattern of rising prices continued as still newer medications were approved by regulators between 2010 and 2013.

The trend, however, shows no sign of abating. But depending upon where they direct their investigation, the lawmakers may wind up shining an uncomfortable spotlight on payers, not just on drugmakers, which have taken a beating in Washington these past three years over how they price their products.

Here’s why health plans should pay attention: The lawmakers are focusing on rising list prices—and we all know that no one pays a list price. But we also know that list prices have a big impact on a patient’s out-of-pocket cost, and for plans, this may be the rub.

“The challenge is that when patients are paying co-insurance, they do so as a percentage of the list price, not a percentage of the price net of any rebate,” explained Roger Longman, who heads Real Endpoints, a research firm that tracks reimbursement issues. “And that is a real issue.

“So you could argue that, as list prices go up and the net prices remain more or less stable, which is my assumption, the actual net cost to the payers may, in fact, be slightly falling, because the patient is paying a larger share of the expense.”

But whether net prices are remaining all that stable is debatable. A report issued last year by Massachusetts Attorney General Maura Healey found the average annual growth rate in net prices for MS drugs ranged from 10.2% to 15%. In 2011, each drug had a net price of about $3,000 per month, but by the end of 2015, the net price paid by health plans was between $5,000 and $6,000.

Some pharmacy benefits managers say price-protection clauses dampen the effects of manufacturer price hikes. But while these clauses may insulate the PBMs and the health plans, they are unlikely to help consumers, says Susan Scheid, vice president of pharmaceutical trade relations at Prime Therapeutics. That’s because insured consumers are stuck paying for medications based on list prices.

Drugmakers, for their part, rely on coupons to help consumers to lower their costs, but even then net costs might still be rising as price hikes cycle through the system. “Payers are insulated to a certain extent, but it still raises the net cost,” says Scheid. “At some point, it has to reset.”

Of course, not all multiple sclerosis treatments are created equal—some are pills and others are injectables. And due to different mechanisms of action, not all are interchangeable, which means insurers have less flexibility in limiting coverage. This suggests there is sufficient demand for access to nearly all of the drugs, making it tougher for payers to negotiate formulary placement or rebates.

The congressional investigation might peel back the onion on the convoluted MS pricing practices. The lawmakers, after all, are focused on the average consumer, and as long as net prices continue to rise, this category of drugs is going to get attention.

Ed Silverman founded the Pharmalot blog and has covered the pharmaceutical industry for 20 years.
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Time To Lift the Curtain On PBM Wheeling and Dealing

They say their deals need to be kept private so they can drive a hard bargain with manufacturers. But employers, consumer groups, and legislators are calling for more PBM transparency.

By Robert Calandra

For all the money he spent on his MBA, Ted Okon says the best life lesson he ever received cost him $80. It came from a guy dealing Three Card Monte on a New York City street corner. He was up $40 but in no time lost that $40 plus $40 more. So what lesson did he learn?

“It showed me that you can’t win a rigged game,” says Okon, executive director of the not-for-profit Community Oncology Alliance. “And right now PBMs have a rigged game akin to that Three Card Monte where they basically control all the terms.”

The Community Oncology Alliance is among several groups fed up with the PBM industry’s infamously convoluted pricing schedules and contracts. It’s time, they say, for the industry to make its murky business practices Windex clear.

“We’d like to see a tone of more candidness and straightforward communication about what money is being spent for what and what value is being returned to patients and people who pay the bill so we can move past the sloganeering and finger pointing that we are seeing so much of now,” says David Lansky, president and CEO of the Pacific Business Group on Health, a 75-member, not-for-profit organization of medium and large private employers and public agencies.

But indignant calls for more PBM transparency are on a loop, according to Brian Henry, vice president of corporate communications for Express Scripts. They first happened decades ago and cycle around every so often. More telling than the message is its provenance, argues Henry.

“It is predominately pharma companies and pharmacies,” he says. “If we were transparent with them it has been shown many times over that they would use that information to actually raise prices, not lower them.”

True, pharmaceutical companies and pharmacists have pushed for transparency, and they are among the noisiest in the current hue and cry. But this time, they have plenty of company. Every sector of the health care economy that deals with prescription drugs—insurance plans, employers, doctors, state legislatures—want PBM pricing decoded.

The widespread agitation is fueling some bipartisan support for legislation that would force more openness about PBM discounts and pricing. In early March, Georgia Republican Rep. Doug Collins introduced HR 1316, the Prescription Drug Price Transparency Act, with Democrat Dave Loebsack of Iowa as a cosponsor.

A few weeks later, Oregon Sen. Ron Wyden, a Democrat, submitted C-Thru, the Creating Transparency to Have Drug Rebates Unlocked Bill. Co-sponsored by his fellow Democrats, Sens. Sherrod Brown of Ohio and Heidi Heitkamp of North Dakota, it hasn’t garnered any Republican support so far.

“As dysfunctional as Washington is, as tough as it is to get anything moving, I think this is an issue that is bipartisan,” says Okon, whose organization advocates for community oncology practices across the country. “There is a growing concern and awareness that this is out of hand.”

Meanwhile, lawsuits against PBMs are also piling up.
The website PBM Watch, a not-for-profit organization with the goal of educating consumers about issues surrounding PBMs, notes that in the past few years “numerous federal or multidistrict cases” have been filed against CVS Caremark, Express Scripts, Optum Rx, and Prime Therapeutics. According to the website, the lawsuits stem from a variety of issues including clawbacks of consumer copays; fraud; misrepresentation to plans, patients, and providers; unjust enrichment through secret kickback schemes, and failure to meet ethical and safety standards.

But it just isn’t true that PBMs aren’t transparent enough or are deliberately obfuscating so they can greedily stuff their pockets, pushes back Henry. Express Scripts’ clients, he says, receive about 90% of rebate money. They can also demand an audit at any time of any aspect of their contract to ensure that Express Scripts is adhering to it chapter and verse.

What is true, he says, is that drug prices have increased significantly in recent years, so PBMs, as the prime negotiators with the manufacturers about price, have a larger role than they did five or 10 years ago. Nailing down exactly how much of the prescription and specialty drug market the big three PBMs control can be a bit slippery. But Okon estimates that CVS Caremark, Optum Rx, and Express Scripts control between 80% and 85% of the market.

“We are in a different position, and maybe a more important position, than we have ever been before,” Henry says. “But that’s because pharmacy costs have gone up and drug costs have gone up and you need us to drive it down.”

Industry critics counter Henry, saying that as the PBM industry has grown, the major companies have constructed a complicated, secretive pricing system and cooked up contractual language so confusing that it would tie a linguist in knots. Transparency advocates want contracts simplified so they know exactly how much PBMs are receiving from administrative fees, discounts, rebates, and side deals, and how much of that money is passed on to their customers, insurers, and employers. It is the only way, they say, to assure that the interests of patients and employers are being protected.

“We don’t have confidence that the system right now is treating patients and employers fairly,” says Lansky. “We need our suppliers to give us that confidence with more transparency and clearer information flow among all the components.”

One way to regain that confidence in PBMs, says Linda Cahn, founder of Pharmacy Benefit Consultants in Morristown, N.J., is for PBMs to become more transparent. Until that happens, clients will need consultants like Cahn to comb their existing PBM agreements to clean up their contracts. A long-term solution will require large insurers and employers to flex their market power muscle and demand changes. Or just maybe a new type of player will emerge, one that does things differently.

Swallowing bitter pills

There was a time when Okon believed that PBMs served a “valid purpose.” Not anymore.

“PBMs now, in my book, are destructive and adversely impacting patient care and they are fueling specialty drug prices,” he says.

The discernible edge in Okon’s voice when he talks about the PBM industry was honed by reading documented cases from community oncology practices with a retail pharmacy or a dispensing facility where PBMs have switched dosages and swapped out drugs without consulting the patient’s physician. In fact, COA has published two volumes of “horror stories” of PBMs getting in the way of patient care.

“These are real-life stories, they are verifiable, and the stories keep flowing in,” he says. “You have an entity that gets in the way of a patient getting his medication, not facilitating it. That is absolutely, positively wrong.”

In the past few years, Okon says, the number of specialty oral cancer drugs has risen dramatically. In turn, PBMs switched from charging a $3 to $5 fee per prescription at retail, to tacking on a percentage of up to 11% per prescription. “Why can they do this?” asks Okon. “The answer is, because they can.”

PBMs make money in several ways, starting with reimbursing a pharmacy slightly less than what it is paid by the insurer or employer that hired them to manage the group’s pharmacy benefits. For example, an insurer or employer may pay $87 for a medication. The PBM may reimburse the pharmacy $85 and keep the $2 difference, which is called the spread.

But the PBM may have also negotiated a $15 rebate on that medication. Depending on the contract language, all or most of that rebate is supposed to be passed straight through to the insurer or employer. According to Henry, each Express Scripts client decides how much, if any rebate money, the PBM may keep. Most clients, he says, allow Express Scripts to take 10% or 11%. 

When it comes to drug costs, it’s a rigged game, says Ted Okon of the Community Oncology Alliance. “Right now PBMs have a rigged game ... [and] basically control all the terms.”
Administrative fees are another way PBMs make money. Administrative fees can cover things like processing claims for clients, offering solutions to control specialty drug costs, managing adherence programs, and developing narrow networks.

But critics say that over time, all the terms and conditions governing the average wholesale price of a drug; how much of rebates, discounts, and coupons are passed through to the client; what constitutes an administrative fee, and how side deals with manufacturers are reported have been relabeled or otherwise morphed to take on a different meaning. There seems to be no standard, agreed-upon language or definitions.

“One contract equals one contract,” Henry says. “It is not off the shelf. It is tailored to the needs of that client. We work with them to get the value that they realize and we are rewarded for bringing down those costs and realizing better outcomes.”

That’s not the way John Norton sees it. The public relations director for the National Community Pharmacist Association says his members are offered take-it-or-leave-it contracts where PBMs set the terms and conditions, including reimbursement levels, anytime audits, and monetary clawbacks. And if a small pharmacist doesn’t take it?

“We’ll go out of business because insured patients will pay more if they still use our pharmacies,” says Norton, whose members operate one and two stores located in population centers of 50,000 or less. “They can steer our own patients with chronic conditions or who use specialty drugs to their mail order pharmacies and we can’t do anything about it.”

Direct and indirect remuneration

Norton says his members would just like PBMs to address direct and indirect remuneration. It works like this: Say a pharmacist dispenses a prescription on September 1 and is reimbursed by the PBM later that week. Close the books, right? Not quite. During its quarterly reconciliation, the PBM can claw back more money from the pharmacist.

“You make a certain amount of money on that script, but a portion of that money is probably going to be taken away from you at a time of the PBM’s choosing,” Norton says.

Even the Pacific Business Group on Health, whose membership includes some Fortune 500 companies, feels it has little choice but to play by the industry’s rules because the three major PBMs pretty much follow the same business playbook and with seemingly little incentive to change.

Rather than concentrate on a drug manufacturer’s initial pricing decision, Lansky and Pacific Business Group focus on trying to identify the loopholes that allow costs to be tacked on between factory and patient. The actual prices paid by the plan sponsor are generally impossible to decipher because of rebates, discounts, and administrative fees loaded into the supply chain, including PBMs. One example is the recent disclosure about PBMs covering high-cost brand drugs instead of generics to get the rebate.

“The supply chain is an incredibly complex, layered system constructed so that one can’t really tell who is being paid what for what,” Lansky says. “The entire pipeline is acting in the dark and ultimately it is the employer or government payer and their beneficiaries who pay a higher price for all of this lack of clarity.”

And there are 15,000 drugs with various dosages, packaging, and pricing. The Pacific Business Group companies that have hired pharmacy experts consultants to go over their PBM contracts with the finest of fine-tooth combs have found that dollars are divvied up in a way that isn’t always in their best interest.

One example, Lansky says, is the use of coupons and copay assistance discounts to motivate patients to use a certain drug. The out-of-pocket costs for the patient may be lower because of the PBM but the drug may cost the insurer or employer more. Another hidden cost is the price for various doses on a formulary, says Lansky. The PBM should choose the dosage that brings the highest value to the plan sponsor and the patient.

“Consultants have pulled out example after example where the PBM has turned the formulary to its advantage and not to the customer’s advantage,” he says. “That creates a lack of confidence that the PBM or health plan is acting fully in your best interest.”

The key to finding out if your PBM is working in your best interest, Cahn says, is to ferret out the drug-by-drug rebate and the drug-by-drug total money collected and passed through data.

“With those two sets of information you can figure out if the PBM is acting in your interest or, instead, favoring certain drugs because the PBM is getting scads of money it’s retaining and not passing through.”

In a recent National Rx Coverage Coalition blog post, Cahn dissected a publicly available draft of a contract between Express Scripts and Genesee County, Mich., which is about 75 miles northwest of Detroit.
and includes the city of Flint. In her critique, Cahn noted that the contract fails to spell out what share of its rebates Express Scripts will pass on to the county. Cahn also quoted from a financial disclosure that Express Scripts attached to the draft contract that says Express Scripts “often pays an amount equal to all or a portion of the formulary rebates it receives to a client based on the client’s PBM agreement terms.”

“As a plan administrator or fiduciary, you need to find out whether your plan is receiving ‘all’ or ‘a portion of’ the formulary rebates that your PBM obtains from manufacturers,” she wrote. And if you are only receiving a portion, she continued, you should determine how much you might otherwise save if your PBM passed through 100% of all formulary rebates. “It’s something plan administrators need to be aware of,” Cahn said in separate discussion with Managed Care.

Express Scripts also outlined a number of administrative services for which it receives payments in the financial disclosure documents, according to Cahn. Express Scripts’ administrative fees in Genesee County’s draft contract are “calculated based on the price of the rebate drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price (AWP), or (ii) 5.5% of the wholesale acquisition cost (WAC) of the products.” As a result of that provision, Cahn wrote, when there is an increase in either the volume of the drug sold or the drug’s price, Express Scripts’ administrative fees will also likely increase.

“That’s a lot of money,” Cahn said, “and potentially a conflict of interest.”

The Genesee County draft contract, according to the blog post, also stipulates that the money from all of the administrative services “are not part of the formulary rebates or the other manufacturer fees that it collects.” The financial disclosure also clearly states that any other financial benefits Express Scripts collects from manufacturers—discounts for its subsidiary pharmacies, payments for selling data, running therapy adherence programs, providing drugs for clinical trials—it retains for itself.

Cahn calls this the “rebate relabeling game.” The bottom line is if a PBM calls a payment a rebate, it will pass through all or some of the money to the client. But, she says, a “manufacturer administrative fee” or anything by another label goes straight into the PBM’s pocket. In Cahn’s opinion, “every client should insist that its PBM pass through 100% of all manufacturer benefits—and 100% of all other payments—that manufacturers pay to its PBM.”

** Legislative movement**

Given the current environment in Washington, it’s hard to predict the fate of the two pieces of pending legislation. The bill introduced by Wyden would require PBMs to publicly post aggregated data about rebates and discounts from manufacturers for medications that are part of Medicare Part D and Medicare Advantage plans. The bill would also disclose “spread pricing,” which is the difference between payments PBMs make to pharmacies compared to payments PBMs receive from health plans.

The Collins bill would require PBMs to update their WAC lists for Medicare Part D, Tricare, and FEHBP every seven days. It outlines the appeals process for pharmacies to dispute reimbursements. The bill would also prevent PBM-owned pharmacies from sharing patient information and mandating patients use those pharmacies.

Lansky and PBGH would like PBMs to provide transparency about net-of-rebate and all other fee prices.

But Lansky and PBGH don’t think the political environment is right to push for regulatory or statutory changes concerning PBM transparency. Instead, the group will continue to work with its partners in the supply chain, including manufacturers and the PBM industry.

“We see our members, as buyers in the market, having a powerful market influence,” he says. “If they want to exert pressure on their current supplier and PBM, they can do that through contract renewal negotiations, including bringing in the right consultants to more closely scrutinize the contract and collaborating with stakeholders and with each other to test new and innovative approaches.”

Lansky thinks large employers will start to bring their market power to bear. He believes that large insurers and employers will begin to show more interest in smaller PBMs.

“The large PBMs have the obvious advantage of volume purchasing and being able to achieve favorable rebates and discounts,” he says. “The smaller PBMs may not have the best discounts but their models might mean more transparency and allow for employers and patients to keep more of the savings. Additionally, they might be more willing to innovate with employers...
in terms of formulary or benefit design. Purchasers are increasingly recognizing the need to look beyond rebates and focus on total cost of care instead.”

The National Community Pharmacist Association’s Norton says his group will continue advocating for changes in PBM contracts through state governments where they have had some success. At least 22 states have crafted a total of 39 laws that try to reign in PBMs. Proposed legislation will compel the industry to adhere to fair and uniform pharmacy audits to anti-mandatory mail order requirements.

“We have been able to get a lot of states to create more transparency when it comes to generic reimbursement,” he says. “The states are not as difficult, although when a PBM gets particularly concerned about how a law might impact them they go the legal route.”

Norton’s association has filed an amicus brief with the U.S. Eighth Circuit Court of Appeals in support of an Arkansas law being challenged by the Pharmaceutical Care Management Association, the PBM national association. If upheld, the law would require PBMs to be more transparent in determining generic prescription drug reimbursement to pharmacies.

The Community Oncology Alliance’s Okon, once a proponent of PBMs, says the big three have become a virtual monopoly and should be broken up. Smaller, more competitive PBMs, he says, would be more responsive and not block cancer patients from getting the medications they need. And he would end all back-end rebates—those that are not passed on to patients—in Medicare Part D to put an end to “this arbitrage game of list and net that the PBMs are playing.”

He’s “not jumping up and down” that a bill will pass, but he does expect Washington to weigh in with legislation possibly this fall.

Not going to happen, is Cahn’s take on a legislative remedy. The state laws, she says, are a “hodgepodge” that are “barely scratching the surface of the problem” or “sufficiently comprehensive” enough to have an impact. And the idea of federal legislation relief is “very farfetched.”

Cahn is advising plans and employers stuck with a bad contract to file what is known as an accounting procedure. The procedure would allow the client to determine exactly how much money the PBM is collecting and not passing through. And then she pondered another possibility. “It’s easy to imagine a new entity could come into the market and blow up the existing PBM business model,” she says. “They could do it differently. A Walmart or Costco or Amazon could create an entirely transparent PBM.”

Robert Calandra, a regular contributor to Managed Care, is an independent journalist in Philadelphia with more than 20 years experience writing about health care.
Novartis’s Kymriah: Harnessing Immune System Comes With Worry About Reining in Costs

FDA approval of the CAR T-cell therapy for leukemia could usher in an era of genetically engineered, individually tailored immunotherapies. But tap those brakes. Long-term results are in short supply—and there’s that $475,000 price tag.

Thomas Morrow, MD

For a parent, hearing the word leukemia may stir up one of the deepest forms of dread. It remains one of the most common types of childhood cancer, although leukemia can affect people of all ages. The name leukemia comes from the Greek leukos for white and heima for blood. The disease presents with a dramatic production of abnormal white blood cells. If not successfully treated, that uncontrolled production of white blood cells can cause death.

Leukemia is divided by the onset—acute or chronic—and by the type of cell—myeloid or lymphocytic. Thus, there are four primary types: acute and chronic myeloid (or myelogenous) leukemia (AML and CML) and acute and chronic lymphocytic (or lymphoblastic) leukemia (ALL and CLL). The lymphocytic group is further divided into the type of lymphocyte involved, T or B lymphocytes.

B-cell acute lymphoblastic leukemia (B-cell ALL) is the most common malignancy among children in the United States. Each year, about 5,000 American children and teens are diagnosed with B-cell ALL. Current therapy consists of multiagent regimens, and the cure rate exceeds 85%. But approximately 15% of children and young adults with ALL will relapse. In addition, between 2% and 3% of patients will fail induction therapy, a condition termed refractory. Collectively, refractory and relapsed B-cell ALL (r/r B-cell ALL) remains one of the leading causes of cancer death in children.

Treatment options for the estimated 600–700 American pediatric and young adult patients with r/r B-cell ALL each year include attempting reinduction with chemotherapy, targeted therapies, and stem cell transplants. But overall survival is dismal, measured in months.

That may all change very soon.

Not in Kansas anymore

In July, the Oncologic Drugs Advisory Committee of the FDA unanimously recommended approval of Novartis’s new gene therapy for ALL, which during its development was called tisagenlecleucel, or sometimes by its investigational moniker, CTL019. On August 30, the FDA approved tisagenlecleucel, which Novartis is marketing as Kymriah. Hurricane Harvey dominated the news that week, but the Kymriah approval was right up there in the news cycle.

The FDA billed it as the first gene therapy in the United States, which led to some debate about semantics and exactly what should be deemed gene therapy.

High drug prices are not news these days. Still, there was a lot of reaction when Novartis announced that it was pricing Kymriah at $475,000. Wall Street investors were dismayed because some analyses indicated that a price of $750,000 might be justified. But consumer groups and others didn’t let Novartis off the hook. “While Novartis’ decision to set a price at $475,000 per treatment may be seen by some as restraint, we believe it is excessive,” wrote David Mitchell, founder of Patients for Affordable Drugs, a consumer group that is campaigning against high drug prices. “Novartis should not get credit for bringing a $475,000 drug to market and claim-

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Note: An earlier version of this story was first published on the MANAGED CARE website on Aug. 31, 2017.
expressing cells. They exhibit immunological endurance and produce long-lasting remission.

The manufacturing process for Kymriah is necessarily personalized because it starts with the patient’s own T cells. Patients have blood drawn in the same way that blood is drawn for a blood donation. Leukapheresis separates white blood cells (specifically the monocytes) from the red cells and serum, which is returned to the patient. The cells are frozen and shipped to a special Novartis facility in New Jersey for processing. A dedicated team, which works on just one project at a time, handles each patient’s cells.

After thawing, cells undergo a “cleansing” to remove all unneeded cells—such as monocytes and B-lineage lymphoblasts—that are detrimental to CAR transduction and growth. T cells are then activated in the lab and exposed to a “self-inactivating minimal lentiviral vector” that has the CD19 CAR transgene on board. The lentiviral vector is a modified HIV-1 virus—yes, the genome of the virus that causes AIDS. The needed CAR genetic material is introduced into

Color-enhanced scanning electron microscope image of a CAR-T lymphocyte (beige) attacking a leukemia cell (red).
the T cells and is incorporated into the genome of these cells in a process called transduction.

The transduced cells are grown in the special Novartis facility, washed and cryopreserved. After some testing, they are shipped to the site of care where the “drug” is infused into the patient in a weight-based dosing formula. This whole process can take weeks, and patients stay on standard treatment while they are waiting.

Documents filed with the FDA oncological committee went into detail about the HIV-1–sourced lentiviral vector. Obviously, great care was taken in the selection, design, and testing of the vector and the resultant vector-transduced cells. The researchers paid particular attention to the risk that the vector might lead to a secondary cancer or produce a pathogenic virus. Earlier forms of vectors used to transfer genes in experimental gene therapy demonstrated the ability, over time, to become capable of replication. Later generations of retroviral vectors were designed to prevent that from happening by selectively removing genetic material. Scientists start with the HIV-1 genome and remove all nonessential HIV-1 sequences such as those that produce the protein envelope and the accessory proteins needed for replication. The genes are then transferred to the patient’s T cells in small packets that are unlikely to recombine to “create” a viable virus.

Kymriah was first studied in a phase 1–2a trial to assess long-term persistence, in vivo proliferation, anti-tumor activity, and safety in patients with r/r and incurable B-cell malignancies. Promising results in this trial resulted in two trials, B2205J, a single-arm phase 2 trial, and B2202, (the pivotal trial), an international, multicenter, single-arm, open-label, phase 2 trial. The patients were between the ages of 3 and 21 at the time of diagnosis. Both B2205J and B2202 had nearly identical study designs and similar patient profiles in the enrollees. Cumulatively, all three trials included 147 treated patients.

Results were astounding, given the failure of conventional therapy and seriousness of the illness in this group of patients. Overall response rates in the three trials ranged from 69% to 95% and complete response rates ranged from 60% to 89%. The estimated relapse-free rate among responders at Month 6 was 75.4%. Median overall survival was available for only one trial at the time of the filing, but at 33 months it was impressive compared with other treatments.

The adverse events included cytokine-release syndrome (a class effect related to the mechanism of action); neurological toxicities—including aphasia, tremor, seizures, confusion, and encephalopathy—and a number of others that are typical of cancer treatment (tumor lysis syndrome, febrile neutropenia, prolonged B cell aplasia). Of note: No adverse events associated with the lentiviral vector were observed.

Who is going to pay?

Kymriah is nothing if not complex. Its development brings together the most cutting-edge technology of our time.

The results are stellar, but remember this is still not considered a cure. Kymriah was approved by the committee based on phase 1 and 2 trials, for which long-term follow-up is still required to determine medium overall survival because data were not available at the time of the application. Not enough people had died to reach a 50% level—good news, but it reflects how desperate the need is in this disease.

The price of Kymriah is going to be an issue, although it probably won’t be long before another, even pricier drug is approved. Relatively few people have r/r B-cell ALL, so payer budgets can probably absorb the cost of Kymriah without completely collapsing. But the CAR-T approach can be applied to other receptors, and researchers are busy investigating how to use it as a treatment for other cancers. The hope is that this is just the beginning of the CAR-T era in oncology.

Novartis is pursuing some value-based arrangements that may help blunt the effect of the high price of Kymriah—arrangements that could set important precedents for other drugs and other companies. So, for example, Novartis has approached CMS and some insurers about an outcomes-based approach that would limit charges to patients who respond to the drug in the first month. And Novartis may be moving toward charging different prices for different indications.

Still, it is hard not to be nervous. Are we on a collision course with therapies based on virtuoso 21st century science getting hopelessly ensnared in the messy reality of how drugs are priced and paid for?

Somewhere over the rainbow there may be a solution.
Given this issue’s focus on autoimmune disease, which includes a host of lifelong chronic conditions, I can’t help but consider the role of health insurance in this country. For many, it bears resemblance to other insurance products such as fire or auto coverage: It’s there in the event of an emergency, but the hope is that it will never be needed. But for people with a chronic autoimmune disease, where consumption of health care products and services is a regular and ongoing reality, health insurance becomes something entirely different: a financing mechanism for expenses that would otherwise be unaffordable.

Insurance works on the premise that across large populations it is possible to predict the probability of adverse events occurring, to estimate the likely costs associated with those events, and to distribute those costs over the insured population in the form of premiums.

The ACA initiated two major streams of industry activity that challenge this foundational insurance principle: first, the rise of population health management and, second, dramatic expansion of the individual insurance market via public and private exchanges. Seven years later, both are struggling.

Economics aren’t working out

Population health management is built on the notion that prevention, early intervention, and proactive management of chronic disease can reduce the incidence rates of costly episodes. In pursuit of these reductions, payers and providers have introduced waves of new partnerships in structures such as joint ventures, ACOs, and clinically integrated networks. They have layered on new approaches to care coordination and have invested heavily in big data and analytics. They have collaborated in ways never attempted previously.

So far, these efforts have yielded advancements in quality and reductions in utilization. But the economics are not penciling out. The cost of innovation is outstripping the financial return on investment. As a result, the participants remain dependent on their old business models to support what amounts to experimentation in the new.

Against insurance principles

As for the individual health exchanges, one need only look to the headlines to know they are up against the ropes, with staggering double-digit annual premium increases and many insurers backing away entirely.

The issue, it seems, is that when individuals purchase health insurance, they do so intending to use it. Seems intuitive, but it is in conflict with that foundational insurance principle I mentioned earlier and is the turning point where insurance becomes a financing vehicle. For the underwriters, this has been a wake-up call about consumers and consumerism in what had previously been a classic “b-to-b” arrangement.

The real opportunity involves bringing these two streams together. It may be complicated, but is it too much to ask for health care that delivers consistently better outcomes while offering a range of participation models designed to meet the different needs of various customer segments?

Not everyone thinks so. Organizations of all stripes—from payers and providers to technology giants (think Apple and Google), from retailers (think Amazon and Walmart) to Wall Street financiers—are working feverishly to crack the code. This is leading to entirely new innovation focused on breaking down the biggest barriers to rendering the vision into reality. They’re just getting started.

But while there is good reason to be optimistic, overhauling the health care system is much like overhauling a 747 in mid-flight. Tinkering can be done relatively safely but major re-engineering is fraught with risk.

All that said, do we really have a choice? For tens of millions of Americans, including those with chronic autoimmune disease, the innovation can’t come soon enough. They need sophisticated health care to treat their diseases—treatment that can make their lives immeasurably better—without bankrupting them in the process. So buckle up—new insurance models are already taking flight.

Zachary Hafner leads the Advisory Board’s strategy consulting practice.
The health care industry, including managed care organizations, is notorious for ignoring the customer experience. But with regulations limiting differentiation between products, health plans must rethink consumer experience to meet expectations of today’s consumers, who seek convenience, quality, and speed from their health care organizations.

Many health plans understand they need to connect more effectively with their end customers, but technological, cultural, and other obstacles are in the way. One of the biggest challenges is the indirect nature of the relationship with members, as consumers typically access their health care through employers, hospitals, or doctors.

Value-driven care models present an opportunity for health plans to deliver superior customer service, but there’s also a risk that they’ll become even more removed from the customer if the models are viewed simply as a way to shift risk to providers.

On the technology front, most payers are just starting to explore technologies to collect data, drive customer insights, and manage customer relationships.

And at a cultural level, creating a truly memorable and high-quality customer experience requires a massive shift in thinking by all employees in an organization. High-performing organizations in other consumer-facing industries have technologies and employees at every level focused on providing an excellent customer experience. These organizations should become examples for payers to follow.

In the future, payers will have much more direct interaction with members. Informed patients will be making choices about their health care like they do any other purchase—by assessing cost, quality, and the experiences of other customers.

Because payers will become more integral to this process, now is the time to adopt the following four best practices:

- **Take a consumer perspective.** Members have typically expected very little from their health plan. A member’s experience with his or her health plan only started when something went wrong. Payers need to first get the basics right, then think through how to use value-driven care models and engage with partners like providers and employers to get closer to members as they think about a more holistic health experience.
- **Reinvent data and analytics.** The best customer-service organizations capture real-time data to address customer needs. However, health plans have routinely measured member risk and medical cost on a retrospective basis. By analyzing real-time customer touchpoint data and risk insights, health plans can quickly take action to create much more meaningful customer-relationship management, including care management.
- **Become relevant at the point of care.** For value-driven care models to work, both health plans and providers need to align around the customer experience through benefit design and member engagement. Health plans should offer recommendations and facilitate clinical decisions with data and analytics rather than putting up hurdles and requiring permissions. For many health plans, this will require a significant shift in culture and their business model. Value-driven models have aligned financial incentives, but the member experience will fall short unless payers rethink point-of-care member engagement.
- **Be proactive.** Health plans must proactively engage with customers at each point of interaction, in much the same way that major web retailers consistently make suggestions to a customer based on previous shopping habits. Technology can help track behavior patterns and identify opportunities for positive, proactive engagement with your customers.

Customer experience has long been neglected in health care, but as competition intensifies and consumers become more discerning, health care organizations will have to adjust. Forward-thinking health plans already recognize the importance of customer experience in value-driven care. It’s time for the rest of the industry to catch up.

Erik Swanson is an executive director in the Advisory Health practice at Ernst & Young. The views expressed here are those of the author and do not necessarily reflect the views of Ernst & Young.
Diabetes Care Management Teams Did Not Reduce Utilization When Compared With Traditional Care: A Randomized Cluster Trial

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Director, Chronic Care Program, Santa Clara Valley Medical Center, (Retired)

INTRODUCTION
Health care redesign identifies new approaches for treating chronic disease to improve outcomes, increase satisfaction, and lower resource utilization (RU) (Berwick 1996). To deliver these improvements, policy makers propose systematic changes to traditional primary care delivery, including institutional disease management, case management, care management (CM), the chronic care model (CCM), guided care, transitional care, personalized care, and the patient-centered medical home (PCMH). Some elements included in these models have been enumerated (Wagner 1998, Boult 2008, Coleman 2006, Coulter 2015, Berenson 2008, Stellefson 2013). They include: 1) registries and information systems, 2) self-management support, 3) decision support, 4) care managers in multidisciplinary teams (CMT), 5) delivery-system redesign, and 6) change in community resources and public policy. Researchers have used randomized controlled trials (RCTs), quasi-randomized studies, and cohort studies to evaluate implementation of specific elements of these models (Peters 1995, Davidson 2007, Shojania 2006). Reviews and policy statements based on these elements propose that deployment of some of these models will lead to quality and utilization benefits (Weingarten 2002). The American College of Physicians website promotes implementation of the CCM (Allweiss 2015) and a PCMH (ACP 2016). A large portion of literature on transforming the delivery of care stresses how these models will improve the care of people with chronic illnesses, and PCMHs have been promoted as benefiting all patients. However, the paucity of high-quality evidence (Shojania 2006, Stokes 2015, Hussey 2009, Kolbasovsky 2011, Solberg 2007) substantiating success in lowering cost, decreasing RU, increasing access, and improving satisfaction and quality should give those eager to implement these models some pause. A review by Jackson (2013) cited several factors needed to create a valid body of literature.

Results of rigorous studies of CMT and elements of that model have shown improved process without showing benefits in clinical outcomes, RU, or costs (Norris 2001, Loveman 2003, Goldman 2014). The large-scale comparison in the Health Dispari-
ties Collaboratives demonstrated improved process measures for only two of three disease states within safety-net institutions. No improvement in clinical outcomes, RU, or costs was demonstrated (Landon 2007).

Optimism for the various CM templates stemmed from early studies (Davidson 2007, Wagner 2001, Diabetes 1993). In a 12-month RCT, Aubert showed a statistically significant reduction in HbA1c for patients managed by a CMT versus those receiving standard care (1.7 vs. 0.6 percentage points, \( P=.001 \)) but did not find reductions in hospital admissions, patient satisfaction, or RU (Aubert 1998). Norris et al. (2001) reviewed 72 studies and found no economic effect. They concluded that external generalization of results for self-management was limited with respect to quality improvement and RU. Typically, evaluations of successful PCMH programs are reports of case-controlled designs (Higgins 2014). In a 15-center Medicare review of care coordination studies, Peikes (2009) reported no benefit in cost or RU with CM or CMT. In a meta-analysis, Stokes (2015) stated, “Current results do not support case management as an effective model, especially concerning reduction of secondary care use or total costs.”

Evaluation of the effect of CM is vulnerable to negative and positive spillover effects. This is due to the statistical aberration of clustering. In safety-net institutions, an additional source of misinterpretation is due to diversion of fixed resources to benefit an intervention group while depriving control and nonstudy patients.

This study looks at RU during reorganization of traditional primary care physician (PCP) practices. It compares RU by patients with diabetes who were cared managed with those managed traditionally. Additional outcomes include comparison of RU for all patients in these physicians’ panels to identify “unintended consequences” as suggested by Jackson (2013). Comparisons required a cluster adjustment, which was also suggested by Jackson. Results reflect overall RU by the panels.

**METHODS**

**Subjects and setting**

The study was a prospective RCT in a safety-net institution. The institutional review board (IRB) approved this study as a quality-improvement program based on the planned implementation of an organizational care delivery change. The IRB approved the consent for physicians participating in the study. There were no adjustments to the study protocol during the entirety of the study.

A query of a registry with 16,824 diabetic patients identified 18 PCPs, each caring for >300 patients with diabetes working in one Federally Qualified Health Center. These physicians were included as potential subjects if they were board-certified in internal medicine, practiced at the study site for more than five years, and were willing to participate as members of Group 1 or Group 2 (Figure). The IRB approved a cluster randomization scheme that randomized each PCP by a study coordinator using a computer-generated, random-number scheme in an opaque sealed envelope. After consent was obtained, a blinded study coordinator opened the envelope. The study’s principal investigator consented and randomized 12 PCPs to Group 1 or Group 2 depicted in the Figure. The intervention group, Group 1, consisted of 5 PCPs assigned CMTs. The control group, Group 2, consisted of 5 PCPs that continued with traditional care. Each group had one alternate physician randomized in case a physician left similar to the way juries have alternate jurors.

**Patients**

A system-wide electronic Health Information System (HIS; Invision, Siemens, Malvern, Pa.) maintained a list of all patients with their assigned PCP. Patients diagnosed with diabetes by their PCP had been entered into a proprietary registry (DM, FileMaker Pro v. 6.0) either upon referral for diabetes education or abstraction from a one-time query of the HIS (ICD-9 codes 249.**, 250.**, 357, 362.0*, 366.4, 648.0*). A patient’s relationship with a specific PCP determined the patient’s group assignment. Prior to and during the baseline year of the study, the PCPs established the approach to diabetes care guided management.

The study lasted three years. Patients maintained their initial group assignment for the duration of the study and for analysis. Patients in both groups had an opportunity to attend a series of standardized self-management educational sessions (Norris 2001) discussing monitoring of blood sugar, adjusting lifestyle and medication based on test results, diet, exercise, and coping with chronic conditions and complications.

**Group 1 and D-CMT**

CMTs were formed as part of an operational change of the daily routine of care delivery (Solberg 2007). Three certified diabetic educators (CDEs) from the Diabetes & Metabolism clinic were reassigned to a Group 1 PCP to join a care-manager team (D-CMT). To be assigned, the CDE met specific criteria: 1) a current RN or PharmD license; 2) certification as a diabetes educator; and 3) passing an internal examination certifying familiarity with the protocols for medication adjustment, aspirin use, statin initiation, blood pressure treatment, microalbuminuria screening, and management. A medical assistant (MA) was assigned to worked exclusively with the D-CMT. The team thus consisted of a Group 1 physician, a care manager, and the MA.
D-CMT members assumed extended roles. The PCP authorized the D-CMT to use all the management protocols for their patients with diabetes. D-CMTs implemented elements of the CCM program with emphasis on information technology, patient self-management, practice reorganization, and protocol-driven management. Patients were encouraged to call their PCP first, 24/7, for new problems or questions. The D-CMT worked with coaches from the MacColl Institute for practice facilitation during the study (Coleman 2009). D-CMT met routinely to discuss patients failing to achieve a clinical goal according to regular registry reports. The PCP provided backup for exceptions falling outside the guidelines. Patients agreed to contact by D-CMT to receive recommendations for management of medication and testing. The registry automatically generated reminders, results, and alerts. Medication adjustments followed protocols. D-CMT scheduled patients for follow-up after admission to a hospital, emergency department (ED), or urgent care (UC). The PCPs managed their remaining paneled patients with the assistance of regular clinic staff.

**Group 2 and D-TC**

The traditional care (D-TC) followed routines, guidelines (ADA 2005), and protocols developed by practice consensus over 10 years with individual variations. Groups 1 and 2 had information systems with read-only access available for demographic information, clinical laboratory, diagnostic radiology, a separate picture archiving system, and access to guidelines and protocols, all through a nonintegrated clinical IT system. The system did not have registry functionality. Although Group 2 shared in the continuing medical education programs presenting the CCM model, there was no proactive effort to provide access to a registry or point of care access to guidelines or to initiate a redistribution of tasks according to skill level, training, aptitude, and interest among staff. A head nurse managed the practice of the 18 physicians. An assistant head nurse worked with 8–10 physicians and was assisted by MAs whose assignment to specific physicians varied through the week.

Group 2 practiced in the same clinic as Group 1. Group 2 physicians to receive recommendations for management of medication and testing. The registry automatically generated reminders, results, and alerts. Medication adjustments followed protocols. D-CMT scheduled patients for follow-up after admission to a hospital, emergency department (ED), or urgent care (UC). The PCPs managed their remaining paneled patients with the assistance of regular clinic staff.

**FIGURE**

**Schematic of study organization**

Random selection of 10 participants from among 18 potential physicians

*Cumulative number of patients in the respective panels

*Total number of diabetic patients in each arm

D-CMT = diabetes care management teams, D-TC = diabetes traditional care
worked without a team structure. CDEs reported to a remote Diabetes & Metabolism clinic and provided consultation and self-management educational sessions on an ad hoc basis (Norris 2001). Eight CDEs shared an MA and had no access to the registry. Group 2 received ad hoc laboratory and radiological results per that PCP’s routine practice.

**Protocols**

The divisions of endocrinology and primary care wrote management guidelines and protocols for diabetes and the cardiovascular cluster of diseases. The pharmacy and therapeutics

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**TABLE 1**

Baseline characteristics of Groups 1 and 2

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>9,708</td>
<td>9,988</td>
</tr>
<tr>
<td>Age, years</td>
<td>55.2 ± 14.9</td>
<td>54.2 ± 15.0</td>
</tr>
<tr>
<td>Gender female (male), %</td>
<td>53 (47)</td>
<td>51 (49)</td>
</tr>
<tr>
<td>Language, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>74.5</td>
<td>73.6</td>
</tr>
<tr>
<td>Spanish</td>
<td>11.3</td>
<td>13.5</td>
</tr>
<tr>
<td>Vietnamese</td>
<td>3.4</td>
<td>2.7</td>
</tr>
<tr>
<td>Other</td>
<td>10.8</td>
<td>10.2</td>
</tr>
<tr>
<td>Financial class, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Managed care</td>
<td>61.2</td>
<td>61.2</td>
</tr>
<tr>
<td>Medicare</td>
<td>8.5</td>
<td>8.3</td>
</tr>
<tr>
<td>FQHC</td>
<td>26.7</td>
<td>26.3</td>
</tr>
<tr>
<td>Other</td>
<td>3.6</td>
<td>4.2</td>
</tr>
<tr>
<td>Marital status, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>37.2</td>
<td>37.2</td>
</tr>
<tr>
<td>Married</td>
<td>28.8</td>
<td>28.4</td>
</tr>
<tr>
<td>Other</td>
<td>25.1</td>
<td>25.3</td>
</tr>
<tr>
<td>Divorced</td>
<td>8.9</td>
<td>9.1</td>
</tr>
<tr>
<td>RU by panel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital admission rate (CI), %/yr</td>
<td>12.1 (9.1, 15.1)</td>
<td>11.9 (10.9, 12.9)</td>
</tr>
<tr>
<td>Hospital LOS (CI), mean days</td>
<td>3.7 (3.69, 3.71)</td>
<td>3.79 (3.78, 3.80)</td>
</tr>
<tr>
<td>Readmission rate (CI), %/yr</td>
<td>15.5 (12.4, 18.6)</td>
<td>14.8 (11.8, 17.8)</td>
</tr>
<tr>
<td>Emergency room visits (CI), %/yr</td>
<td>13.3 (10.2, 16.4)</td>
<td>13.4 (13.3, 16.5)</td>
</tr>
<tr>
<td>Urgent care visits (CI), %/yr</td>
<td>15.1 (11.1, 19.1)</td>
<td>12.7 (8.7, 16.7)</td>
</tr>
<tr>
<td>HbA1c, mean (CI); mmol/mol (SD)</td>
<td>7.8 (7.7, 7.9); 62 (9)</td>
<td>7.7 (7.6, 7.7); 61 (6)</td>
</tr>
<tr>
<td>Hospital admission rate (CI), %/yr</td>
<td>10.1 (9.2, 11.0)</td>
<td>10.6 (9.6, 11.5)</td>
</tr>
<tr>
<td>Hospital LOS (CI), mean days</td>
<td>3.7 (3.6, 3.7)</td>
<td>3.8 (3.7, 3.8)</td>
</tr>
<tr>
<td>Readmission rate (CI), %/yr</td>
<td>21.0 (19.6, 21.9)</td>
<td>20.0 (18.7, 21.1)</td>
</tr>
<tr>
<td>Emergency room visits (CI), %/yr</td>
<td>22.3 (20.2, 24.2)</td>
<td>22.9 (21.0, 24.8)</td>
</tr>
<tr>
<td>Urgent care visits (CI), %/yr</td>
<td>22.2 (19.9, 24.5)</td>
<td>17.9 (15.6, 20.2)</td>
</tr>
</tbody>
</table>

CI=95% confidence interval, D-CMT=diabetes care management team, D-TC=diabetes traditional care, LOS=length of stay, RU=resource utilization
committee approved the protocols before implementation. The protocols conformed to national guidelines with annual updates (ADA 2005).

**Registry**
A mature database (DM, FileMaker Pro, v. 6.0) was available to the D-CMT. The registry included robust query capabilities with algorithms that identified individuals failing to reach goals and in need of management (Peterson 2008). The registry produced lists of patients for D-CMT with clinical details. The D-CMT contacted patients based on these reports. The number of tests performed divided by the number recommended by guidelines determined compliance. Lists identified patients requiring additional assistance in accomplishing their self-management goals. Lists included notification of a patient’s admission to the hospital and a monthly update on visits to the ED and UC. D-TC received no reports.

**Outcomes and statistical analysis**
The primary outcome was the change in RU rates between the two groups during the baseline and Year 3 of the study. RU included panel rates of admissions to the hospital, ED, and UC. An assumed 2% absolute reduction in urgent care visits would be meaningful with an observed UC visit rate of 13 visits per 100 patients per year. An 80% likelihood of detecting a change at the $P<.05$ level required 9,000 panned patients and 300 diabetic patients per group. Based on historical data, 5 PCPs in each group would achieve this power. After randomizing 12 PCPs, the last two PCPs were designated alternates. The study excluded the remaining six PCP panels.

Effects were calculated using prespecified criteria. Intention-to-treat design included the entire panel of patients in Groups 1 and 2 as well as the subset of patients in the diabetes registry within those panels (D-CMT, D-TC). Statistical comparisons used standard statistical software for Student’s $t$-tests for continuous variables and a chi square for dichotomous values. An intracluster level adjustment used a rho, $\rho$, value of 0.01 with 10 clusters (Killip 2004). The unit of measure for RU is a rate of visits to a resource annually.

Extended stays due to socioeconomic factors and regional cost idiosyncrasies precluded the usefulness of cost data. Readmission rates were determined for patients readmitted within 30 days of a discharge for any cause. Significance is reported by confidence intervals or $P<.05$.

**RESULTS**
For the entire group of PCPs, the average practice experience was 14 years (median 13 years) at the same clinic. The average age was 40, and median, 35. Group 1 had two male PCPs and three female PCPs and Group 2 had three male PCPs and two female PCPs, with all boarded in internal medicine. The 10 physicians randomized to Groups 1 and 2 had combined panels of 9,708 and 9,988 patients respectively (Table 1). The panels averaged 1,969 (Group 1=1,941; Group 2=1,998) patients. Baseline characteristics of the patients were similar (Table 1). D-CMT averaged 370 patients with diabetes while D-TC averaged 385 patients.

**Panel results**
Both Groups 1 and 2 had a decrease in UC visits from Year 1 to Year 3 (Table 2). The within-group decrease was not significantly different for either group ($-2.5% \ [-2.1, -2.9%], -1.7% \ [-1.3, -2.1%]$) (mean + CI) Groups 1 and 2, respectively ($P=.73$).

Groups 1 and 2 increased ER utilization, with visits rising by 3.8% (3.5, 4.1%) and 3.6% (3.3, 3.9%), respectively (Table 2). The within-group increase was not statistically significant ($P=.11$). Combining the UC and ER visits for the respective groups represents the total number of unanticipated visits. The groups had baseline combined ER and UC visit rates of 28.4 and 26.2 visits per 100 patient-years, respectively ($P=.61$). The combined encounters of Group 1 increased 1.3 visits per 100 patient-years, compared with an increase of 1.9 visits per 100 patient-years for Group 2. The number of visits per 100 patient-years for UC ($P=.71$) and ER ($P=.87$) and the combined totals ($P=.86$) did not differ significantly.

The change in admission rates between baseline and Year 3 for Groups

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**TABLE 2**
Change in visit rates for both groups

<table>
<thead>
<tr>
<th>Site</th>
<th>Group 1</th>
<th>Group 2</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Panel size, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urgent care visits (CI), % per year</td>
<td>-2.5 (-2.1, -2.9)</td>
<td>-1.7 (-1.3, -2.1)</td>
<td>.73</td>
</tr>
<tr>
<td>Emergency room visits (CI), % per year</td>
<td>3.8 (3.5, 4.1)</td>
<td>3.6 (3.3, 3.9)</td>
<td>.90</td>
</tr>
<tr>
<td>Hospital admissions (CI), % per year</td>
<td>-1.4 (-3.3, 0.5)</td>
<td>-1.9 (-3.9, 0.0)</td>
<td>.28</td>
</tr>
<tr>
<td>Readmission rate (CI), % per year</td>
<td>7.5 (4.4, 10.5)</td>
<td>3.7 (1.5, 5.8)</td>
<td>.31</td>
</tr>
</tbody>
</table>

Percent change in visits to the respective clinical site. A positive number indicates an increase in visits from baseline to Year 3.
1 and 2 was similar. Within-group changes in hospital admissions for both groups was an insignificant decrease between baseline and Year 3 \((P=.63)\). This decrease was not statistically significantly different in comparing the 2 groups (Table 2). By Year 3, the length of stay had increased by 1.1 (0.7, 1.5) days for Group 1 and 0.6 (0.5, 0.7) day for Group 2. Group 1 stayed 4.8 (4.7, 4.9) days, with Group 2 staying 4.4 (4.3, 4.5) days \((P=.01)\).

The readmission rate for Groups 1 and 2 increased. The readmission rate did not differ within groups. The difference between the two groups was likewise not statistically significant \((P=.79)\) (Table 2).

**D-CMT and D-TC results**

The D-CMT group had similar reductions in UC visits to D-TC (Table 3). By contrast, ER visits had a similar increase for both D-CMT and D-TC (Table 3). Admissions to the hospital decreased for D-CMT, with an insignificant difference compared to the reduction seen for D-TC (Table 3). There was a greater than twofold increase in the readmission rate for D-CMT, but this difference was not statistically significant compared with that of D-TC (Table 3). Combining all visits to these sites, there was no statistical difference between the two groups. \((P=.69)\)

**DISCUSSION**

Studies have shown that implementation of a CM model may improve process measures and have variable improvement in intermediate outcomes for patients receiving the intervention (Davidson 2007, Chin 2007). According to several sources (Stokes 2015, Hussey 2009, Kolbasovsky 2011, Holtz-Eakin 2004, Jackson 2013), insufficient evidence exists showing that CM programs reduce overall spending, reduce RU, or improve clinical outcomes. In addition, the body of literature supporting CM has yet to identify essential elements for an effective program (Wasson 2017). According to several sources (Stokes 2015, Hussey 2009, Kolbasovsky 2011, Holtz-Eakin 2004, Jackson 2013), insufficient evidence exists showing that CM programs reduce overall spending, reduce RU, or improve clinical outcomes. In addition, the body of literature supporting CM has yet to identify essential elements for an effective program (Wasson 2017).

This study contributes a randomized evaluation of RU between primary care models across entire panels in an integrated safety net institution. In addition, it demonstrates equivalent RU among diabetic patients actively care managed with appropriate statistical adjustments for cluster randomization.

Failure to demonstrate a benefit is not proof that CM cannot influence RU. As pointed out by Wasson, the typical approach to PCMH and CM is to regulate process and measure compliance. Perhaps this approach misses the essence and value of clinical care, which is doing “what matters to patients” (Wasson 2017). As Rothman (2005) demonstrated, using a similar design, improvement in HbA1c can be observed despite a lack of improvement in RU. Boult’s “guided care” approach (Sylvia 2008) relies on


Berkovitch DM. A primer on leading the improvement of systems. BMJ. 1996;312(7033):419–425.


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