MEASURING QUALITY

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Lifitegrast, the active ingredient in Xiidra, is designed to specifically block the interaction of lymphocyte function-associated antigen-1 (LFA-1) and intercellular adhesion molecule-1 (ICAM-1), which is a key mediator of the inflammation behind Dry Eye Disease (DED).1-3

ICAM-1 can play an important role in DED inflammation

Lifitegrast binds to LFA-1, a cell surface protein found on leukocytes, and blocks the interaction of LFA-1 with ICAM-1.1

ICAM-1 may be overexpressed in corneal and conjunctival tissues in DED. LFA-1/ICAM-1 interaction can contribute to the formation of an immunological synapse, resulting in T-cell activation and migration to target tissues.1

In vitro studies have shown that Xiidra may inhibit the recruitment of previously activated T cells, the activation of newly recruited T cells, and the release of pro-inflammatory cytokines—interrupting the perpetual cycle of inflammation.1,4

The exact mechanism of action of lifitegrast in DED is not known.1

Xiidra is the first in a new class of drugs called LFA-1 antagonists.5

Indication

Xiidra (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease.

Important Safety Information

In 5 clinical trials, the most common adverse reactions reported in 5–25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Please see Brief Summary of Prescribing Information on next page.
BRIEF SUMMARY:
Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE
Xiidra™ (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

DOSAGE AND ADMINISTRATION
Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single use container. Discard the single use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25 % of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

USE IN SPECIFIC POPULATIONS
Pregnancy
There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear.

Animal Data
Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg /kg /day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg /kg /day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg /kg /day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

Lactation
There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

Pediatric Use
Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Geriatric Use
No overall differences in safety or effectiveness have been observed between elderly and younger adult patients.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast.
Mutagenesis: Lifitegrast was not mutagenic in the in vitro Ames assay. Lifitegrast was not clastogenic in the in vivo mouse micronucleus assay. In an in vitro chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation. Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD] of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.

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Trust the Process (Measures)

By Peter Wehrwein

When Joel Embiid, the Philadelphia 76ers center, shoots free throws, the home crowd chants, “Trust the process, trust the process.”

The fans are being sarcastic. For the last few years, the team’s leadership has purposely put together absolutely miserable teams. The idea was to guarantee losing records, so the team would, year after year, have high draft picks and, eventually, a roster full of young, talented players like Embiid. The former general manager, Sam Hinkie, preached patience and asked the fans to trust the process.

But as of this writing, the team is 7-21 this season and dead last in its division.

Measurement of health care quality also requires trusting the process, as in process measures (they also go by the name performance measures).

Process measures are roundly criticized. Fundamentally, you are gauging the means to the end when it is the end—keeping people healthy or returning them to health after an illness or injury—that is the purpose of health care. Process measures may also encourage a check-the-box mentality. Measuring how many patients who smoke received smoking cessation advice does not distinguish between the perfunctory admonition and a serious effort to get the person to quit.

But we really don’t have much choice but to trust process measures. The factors that affect outcomes are too varied and outside the clinician’s control. Process measures are more easily measured and relate directly to a clinician’s actions.

The trick is to do the research and identify the processes that most reliably lead to good outcomes—and to ditch the rest.
MEASURING QUALITY

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Factoring in sociodemographics of patients is a good start.

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Donabedian knew that process and outcomes only go so far.

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Now some see it as a way to enhance value-based care.

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But beware. Health care enters uncharted territory with this approach.

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But for the most part, insurers are taking a wait-and-see attitude.

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Make data and techniques in RWE studies rigorous. Establish a gold standard.

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One Step Forward, Two Steps Back 32
If insurers insist that doctors use older, lower-cost drugs first, the burden is on the health plan to respond to doctors’ request for different medications quickly, nimbly, and appropriately. That’s not usually the reaction, though.

Dos, Don’ts of Health Information Technology 37
Challenges abound. They include not overburdening physicians and fitting into an increasingly complex, multilayered informatics ecosystem. Artificial intelligence is a work in progress, but gamification seems to be taking off.

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New drug takes on C. difficile.
Selling Insurance Across State Lines Puts Georgia on the Minds of Experts

Not a one. There have been no takers in one of the states—Georgia—that invites insurers from other states in to sell their products. Republicans, including Rep. Tom Price, President-elect Donald Trump’s pick to head HHS, have long argued that allowing insurers to sell across states lines will increase competition and lower costs.

Georgia has allowed interstate sale of health insurance for five years. As Kaiser Health News reports, the law was seen as a way to offer cheaper health insurance by selling policies that don't follow Georgia's required benefit coverage, such as prostate, cervical, colorectal, and breast cancer screenings.

Some state insurance regulators are skeptical, as well. Louisiana Insurance Commissioner Jim Donelon, told the Wall Street Journal: “That sounds like a silver bullet to solve a major problem, and there are no silver bullets. There are no simple answers.”

Graham Thompson is the executive director of the Georgia Association of Health Plans and sees the idea as a positive change, but with caveats. He told Kaiser Health News that “all health care is local—all health care costs are local.”

New entrants to a state will be starting out cold. Paul Markovich, the CEO of Blue Shield of California, told the WSJ: “In order to offer more value, you will need to have relationships and contracts with the providers in a state.”

“It’s the network, stupid,” Sabrina Corlette, a research professor at the Center on Health Insurance Reforms at Georgetown University’s Health Policy Institute, told Managed Care in June. Building a network from scratch is “very difficult and extremely expensive,” she says. “It requires not only a lot of man hours to go sign up all these doctors and hospitals, but when you’re a brand new carrier with no enrollment, how do you convince a provider to not only sign up with you but to also give you any kind of discount? You have no clout. You have no ability to negotiate a decent rate. If you can’t get a decent rate from your providers, how do you offer a competitively priced premium?”

And there’s been a shift in power over the last decade. Providers now have the upper hand for the most part.

Georgia is not the only state inviting out-of-state insurers in. Maine and Wyoming have passed such laws. Rhode Island’s 2008 statute limits out-of-state policies to neighboring Massachusetts and Connecticut, so some proponents of out-of-state policies think that that's really not going to make a broader market. Kentucky’s law is limited to a feasibility study of allowing states to join forces and create a regional market for health insurance.

Corlette, who coauthored a 2012 report on selling health insurance across state lines, told Managed Care: “There's been a lot of moving and shaking, but I would be absolutely shocked if I heard from an insurance company that one of these state laws was the reason they came into the commercial market.”

John R. Graham, a senior fellow at the National Center for Policy Analysis, a Dallas think tank that argues for market-based approaches to public policy issues, called the idea a red herring. Prices set by the provider network associated with a health plan are the biggest determinant of insurance rates, not the familiar punching bag of state-level mandates, Graham believes. People in New York might get a better rate from an insurer in Utah, but only if they are prepared to hop on a plane and get their medical care in Salt Lake City, he wrote.

Humana Culls Quality Metrics

Humana wants to make it easier for providers to report quality results. The company last month implemented a Clinical Quality Metrics Alignment program (CQMA), which sliced the insurer’s quality metrics from 1,116 down to 208, more than an 80% reduction. HEDIS has also been accused of taking up doctors’ time but now some see it as a way to help bring about value-based care. (See the story on page 16.)

Humana did this by collecting the 1,116 quality metrics from 29 different data sources across the company. Officials vetted the metrics for inconsistencies, duplication, and clinical relevance. Company officials streamlined the metrics with an eye on the health insurance industry’s efforts to standardize measures used to evaluate clinical quality.

CQMA comes on the heels of AHIP’s February introduction of its Core Quality Measurements, which was launched with input from CMS, the National Quality Forum, and various physician organizations. Humana’s program aims to support doctors who are involved in the company’s value-based payment relationships.

Roy Beveridge, MD, Humana’s CMO, said in a company press release that, “Metrics not connected to patient health are obstacles in their transition and distract from the intent of care tied to quality. Through our CQMA program, we hope to greatly simplify quality reporting and alleviate physician burdens.”
The idea is to make quality reporting less arduous for doctors, but just how much of an impact Humana’s CQMA can have on that will have to be seen. According to a 2015 survey by the American Academy of Family Physicians (AAFP) that was sponsored by Humana, 61% of family physicians are paid by seven or more health plans, “which can lead to excessive, inconsistent, and overlapping quality reporting requirements,” according to Humana officials.

Is it any wonder that 49% of physicians are burned out, according to a 2015 Mayo Clinic study. Are they worried about money? Physician practices spend more than $15 billion a year on quality reporting, according to a study in Health Affairs in March.

There’s also this problem, according to the AAFP survey. Many physicians don’t know how a value-based payment system would work. One in four don’t know or are not sure of their practice’s value-based payment strategy or even status, and 32% don’t know if value-based payment models are available in their market. Among those participating in value-based payments, 33% don’t know how the payments are being distributed within their practices (e.g., administration, physicians).

Then there’s the time commitment. More than 90% of physicians cited lack of staff time as a barrier to implementing value-based care delivery.

The survey was sent to 5,000 AAFP members; a total of 779 surveys were completed and 626 were evaluated after a screening process.

Health Plans Wary Of Coming Changes

As part of their frantic lobbying efforts, insurers warn that the Republican Congress and the Trump administration killing the ACA’s individual mandate may be a bridge too far. Insurers also worry that the incoming administration will do away with federal subsidies that help low-income Americans buy coverage on the exchanges. House Republicans have voted to block those subsidies.

“We could see a situation where no carrier would want to offer insurance,” Mario Molina, CEO of Molina Healthcare, tells the Wall Street Journal.

Kirk Zimmer is executive vice president of Sanford Health Plan. Sanford sells ACA policies in North and South Dakota. “We’d have a difficult time staying in the marketplace with the elimination of subsidies or the elimination of the individual mandate,” Zimmer tells the WSJ. In fact, for the most part, insurers want the individual mandate fines higher. Too many younger and healthier people who would broaden the risk pool decide to pay the penalty rather

Hospital safety efforts pay off big time

Nationwide efforts to make hospital care safer appear to be paying off as about 250,000 fewer patients died because of hospital-acquired conditions from 2010 through 2015, according to a study by the Agency for Healthcare Research and Quality (AHRQ). Researchers estimate that on top of the lessening in human suffering, the improved hospital safety saved about $28 billion. Hospitalized patients experienced about 3 million fewer hospital-acquired conditions during that period, resulting in a 21% decline in the rate of adverse events.

For the purposes of this study, hospital-acquired conditions include catheter-associated urinary tract infections, adverse drug events, central line associated bloodstream infections, pressure ulcers, and surgical site infections. As a result of the reduction, AHRQ researchers estimate that about 980,000 fewer adverse incidents of harm occurred in 2015 than would have occurred if the rate had remained at the 2010 level.

Prevented hospital-acquired conditions by type, 2011–2015

<table>
<thead>
<tr>
<th>Condition Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilator-associated pneumonias</td>
<td>0.5%</td>
</tr>
<tr>
<td>Obstetric adverse events</td>
<td>0.8%</td>
</tr>
<tr>
<td>(Post-op) venous thromboembolisms</td>
<td>1.2%</td>
</tr>
<tr>
<td>Central line-associated bloodstream infections</td>
<td>1.3%</td>
</tr>
<tr>
<td>Surgical site infections</td>
<td>2.4%</td>
</tr>
<tr>
<td>Falls</td>
<td>2.9%</td>
</tr>
<tr>
<td>Adverse drug events</td>
<td>42.3%</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>23.2%</td>
</tr>
<tr>
<td>Catheter-associated urinary tract infections</td>
<td>15.2%</td>
</tr>
<tr>
<td>All other HACs</td>
<td>10.2%</td>
</tr>
</tbody>
</table>

Note: Cumulatively, about 3.1 million fewer incidents of harm occurred in 2011, 2012, 2013, and 2015 (compared with 2010). About 42% of this reduction is from adverse drug events, about 23% from pressure ulcers, and about 15% from catheter-associated urinary tract infections.

then enroll for coverage. No matter what transpires, insurers would need time to adjust. “We would love to see a three-year time frame, as long as possible,” Marilyn Tavenner, AHIP’s chief executive, tells the New York Times.

These are warning shots by the industry to legislators who’ve promised to repeal and replace. Replace it with what, exactly? Insurers warn that the administration would need to come up with a plan to make sure 22 million people are not left uninsured. Ten million of those have bought coverage on the ACA market.

Despite the departure of United-Healthcare and Aetna, AHIP still carries some clout on Capitol Hill, and GOP lawmakers are expected to listen carefully to its concerns, according to the Times.

As of this writing, though, too much is conjecture. “We’re doing some scenario-planning,” Joan Budden, CEO of Michigan-based Priority Health, tells the WSJ.

Dire Side Effects Come With Immunotherapy

Immunotherapy has rightly been hailed as a way of treating cancer, enhancing the immune system, instead of weakening it, as chemotherapy does. But there’s a dark side to immunotherapy that doesn’t get much attention, the New York Times reports.

Immunotherapy causes the body to attack the cancer but it doesn’t stop there in some cases. It also turns on healthy tissue in the pancreas, kidneys, bowel, liver, lungs, and heart. These are life-threatening developments that force physicians to weigh the benefits of these “miracle drugs.”

“We’ve heard about immunotherapy as God’s gift, the chosen elixir, the cure for cancer,” John Timmerman, an oncologist and immunotherapy researcher at the University of California, Los Angeles, told the Times. “We haven’t heard much about the collateral damage.”

Timmerman knows this all too well. He recently treated a woman with immunotherapy that “melted away” her cancer. Then, suddenly some weeks later, she got severe cold and flu-like symptoms and died in the emergency department.

The treatments also cause acute-onset diabetes in some patients, and other side effects are starting to get noticed as well.

Most patients do not suffer from severe reactions and, so the thinking goes, let patients deal with arthritis, hepatitis, and diabetes if the alternative is dying from cancer. But often the side effects catch providers off-guard—and not always because they (the side effects) move quickly.

The drugs are so new that many of the side effects have not been noticed, the Times reports.

They appear randomly, often months after treatment and can seem harmless at first. In addition, combo immunotherapy treatments are beginning to be used, and they can increase the risk.

Immunotherapy is moving quickly from clinical trials to hospitals, even hospitals in smaller cities where clinicians may not be as familiar with the risks. While patients’ health is a concern, another one is cost: Some immunotherapy drugs are priced at $250,000 or more per regimen.

William Murphy, of the University of California, Davis, reviews immunotherapy grant requests for the government. He tells the Times that more research needs to be done about the risks.

This comes at a time when pressure mounts on the FDA to come up with a faster approval process.

The recently passed 21st Century Cures Act would speed FDA approval for drugs and medical devices. Opponents argued, to no avail, that the law lowers safety and efficacy standards and contend that the FDA already moves faster than similar agencies in other countries.
Study: Female Docs Save More Lives

Hospitalized patients seen by a female doctor are less likely to die within 30 days of discharge and are also less likely to get readmitted within a month, according to a study in JAMA Internal Medicine that garnered some notice recently. Harvard researchers examined more than 1.5 million hospitalizations of Medicare patients who were treated by general internists at hospitals between January 2011 and December 2014.

The researchers looked at eight common conditions and found a gender difference in all eight. They also stratified patients by risk and the outcome gap was the largest for the sickest patients.

In a related post on his An Ounce of Evidence blog, Ashish Jha, the senior author, described the difference as “modest but clinically significant,” and noted the finding that approximately 32,000 fewer Medicare patients—the study was limited to Medicare populations—would die if male physicians could achieve the same outcomes as female physicians.

This study did not identify the reason for female physicians having better outcomes. But other research has found that female physicians are more likely to follow clinical guidelines and may communicate better with patients.

Yusuke Tsugawa, the study’s lead author, told Kaiser Health News that hospitals “might look at their female doctors slightly differently—as a more valuable professional in the team.” In his blog post, Jha pointed out that recent studies have found that female physicians are paid about 10% less than their male counterparts. “Throw in our study about better outcomes and those differences in salary and promotion become particularly unconscionable,” he said.

Payers Embracing Value-Based Pay

Value-based reimbursement is, indeed, making inroads in health care, and payers plan to be at the forefront of the movement, according to a new survey by McKesson Health Solutions. Sixty-one percent of payers see value-based care as a profitable way to do business, according to McKesson’s survey, and the respondents from payer organizations expect value-based reimbursement models to eclipse fee for service by 2020. Payers expect value-based reimbursement to grow from a third of their business today to a majority of it in five years, according to McKesson’s survey. McKesson surveyed 115 payers of various sizes: 38% covering 100,000 to 500,000 lives, 35% covering 500,000 to a million lives, and 27% covering two million lives or more.

McKesson isn’t the only consultancy looking at value-based health care’s performance. Zachary Hafner, at the Advisory Board, says value-based friendly strategies include “white-labeling products, leveraging capabilities with managing stars ratings, and partnering with providers by bringing fundamental skills in sales, marketing, compliance, and network management.”

Briefly Noted

As providers assume more risk under value-based health care, the use of telehealth increases, according Bernard Tyson, the CEO of Kaiser Permanente. Tyson, as reported by mHealth Intelligence, said that his company conducted 52% of patient transactions using telehealth apps, virtual visits, or online portals. Tyson says that “we are reversing the theory where people have to come to us for everything, so we’ve invested billions in our technology platform”…. Admitting patients to an ICU staffed by nurse practitioners made no difference in mortality rates when compared to ICUs staffed by residents, according to a study in Critical Care Medicine. Length of stay, however, was longer for patients under nurse practitioner care, but researchers said those patients were more likely to be discharged to somewhere other than their homes…. Newly opened court testimony reveals that the differences between Anthem and Cigna might make for an unhappy coupling, should their merger be approved. The testimony is part of the Justice Department’s lawsuit challenging the merger on antitrust grounds. Maybe they should stop the merger on the grounds of irreconcilable differences…. Medical schools are now teaching just how much of a financial burden health care can place on patients, according to Georgia Health News. A survey by the Association of Medical Colleges conducted last year showed that 144 of 145 medical schools now require students to study health care financing…. One of the hopes about retail clinics is that they would help reduce the number of emergency department visits for minor health problems at hospitals in the vicinity. That is not the case, according to a Rand study in the Annals of Emergency Medicine…. Relax, says Marc. E. Agronin, MD, a geriatric psychiatrist and the vice president for behavior health and clinical research at Miami Jewish Health. In an opinion piece in the Wall Street Journal, Agronin says that he’s seeing more people ages 50 to 65 come into his office in a panic that they might have Alzheimer’s or some other form of dementia. Usually, other factors cause the senior moments…. The VA plans to debut online scheduling of medical appointments nationwide in January in the hopes of responding to patients in a more timely fashion, according to the San Diego Union-Tribune. Initially, the online scheduling will be made for primary care appointments, but the VA hopes to add mental health, audiology, and optometry in the future…. A shot of Vivitrol given once a month goes a long way toward helping opioid addicted prison inmates stay substance free once they’re released, but at $1,000 a pop the drug is expensive. In addition, some experts question the drug’s effectiveness and wonder if prison officials have fallen prey to the aggressive marketing by the drug’s manufacturer, Alkermes, according to U.S. News and World Report.

— Frank Diamond
An Old-Fashioned Notion: Stand Behind Your Wares

Outcomes-based contracting for drugs is ready for the mainstream. Before they jump in, insurers and pharma need to solve data puzzles and outcomes conundrums.

By Michael D. Dalzell, Senior Contributing Editor

Pharmaceutical manufacturers—arguably health care’s last holdouts for pay-for-volume—are being pulled into a value-based world. Risk-based contracts between pharma and payers, while still relatively few, are becoming more common, and interest among payers is heating up.

According to the 2016 “EMD Serono Specialty Digest,” 14% of payers in 2015 had at least one outcomes-based contract in place with manufacturers, up from 10% the previous year. Last summer, 63% of health plans surveyed by Avalere indicated “high” or “very high” interest in entering into outcomes-based contracts for the expensive hepatitis C drugs like sofosbuvir (Sovaldi), and 53% said the same for oncology medications.

Wanting to leap in is one thing, actually jumping is another. Experience from the field suggests that measuring the outcomes that underpin risk-based contracts is not always as simple as it sounds. “It’s certainly not easy in the sense that certain conditions take a long time to manifest,” says Wayne Dix, New York-based vice president of SSA & Co. The difference a particular drug is making is also difficult to tease out in complex patients, Dix adds, “and you may not be able to measure it on a patient-by-patient basis but can only reasonably measure it, statistically, over a population of qualified patients.”

Moreover, he says, there are many practical challenges to value-based contracts: administrative overhead, the intricacies of data collection and validation, and understanding how or why the data are relevant to the agreement, to name a few.

What payers are learning

Cigna, for which value-based contracting is a core business strategy, is one of the most active payers in the area of outcomes-based pharmaceutical contracting. Seven years of experience has enabled Cigna to boil criteria for outcomes-based agreements down to a checklist (see the box on the next page). That checklist, says Chris Bradbury, senior vice president for integrated clinical and specialty drug solutions at Cigna Pharmacy Management, lends itself to outcomes-based agreements across a number of conditions, including diabetes, cardiovascular disease, hepatitis C, and, increasingly, oncology.

In its contracts with pharmaceutical manufacturers, the outcomes Cigna tracks tend to be similar to the endpoints that were measured in the important clinical trials of a drug. For instance, in its agreements with Amgen for its PCSK9 inhibitor, evolocumab (Repatha), and Sanofi and Regeneron for theirs, alirocumab (Praluent), Cigna looks for LDL cholesterol reductions equal to or exceeding those seen in the pivotal trials. If reductions meet the LDL target on a population basis, the negotiated price remains in place. Reductions that come up short trigger a rebate.

But Cigna’s data collection often extends beyond the thresholds in question, says Bradbury. “In the case of PCSK9 [inhibitors], you start to look at event rates, where, if you see cholesterol reduction, are you seeing reductions in hospitalization rates?” This sort of offset is not part of a contract’s financial terms—manufacturers’ legal teams hesitate to price for an outcome that’s not on a drug’s label—but the data-collection exercise helps Cigna learn how a drug may influence real-world, downstream costs.

Cigna’s size and structure as an integrated health plan, PBM, and specialty pharmacy give it an advantage many payers don’t have: a vast data repository that makes the operational challenges of outcomes-based contracting relatively easy. “Depending on the drug class, we may have all of the data within our claims information and other patient profiles,” says Bradbury. But in
some cases, he concedes, the company still needs to collect additional data from the individual customer or physician to fill in gaps in claims data. A good example, says Bradbury, is with hepatitis C cure rates. For them, Cigna needs additional data to analyze what’s happening in actuality and get the right population and subpopulation analyses, he says.

For some payers, that can be a heavy lift. For starters, you have to know about the integrity of the data you collect from third parties. “Data quality is almost always an issue when we get involved in a data analytics project,” says Dix. “Assessing whether the data are accurate and cleansing the data often means the difference between having a successful understanding and well-founded insights into the data or not.” Assurance that third-party data were captured correctly are “pretty important,” he adds, when millions of dollars are at stake.

Then there are diseases in which outcomes can be downright hard to measure. Take cancer, where many treatments gain FDA approval on surrogate endpoints, such as progression-free survival (PFS). PFS isn’t always tracked in an electronic health record, however, and when it’s not, a manual record search may be required to determine whether the cancer came back or something else led to early discontinuation of a drug.

Any outcome that is not easily traceable is likely to make risk-sharing agreements impractical, because it will be too time-consuming to figure it out. “The reality is that every single one of these experiments has collapsed under its own weight because the administrative overhead ate up the potential savings,” Express Scripts Chief Medical Officer Steve Miller told a National Comprehensive Cancer Network Policy Summit in 2015, speaking of the complexities of gathering third-party data.

Processes that don’t fit into provider workflows may also jeopardize the ability to collect critical third-party data. Consider a physician who must monitor, say, outcomes and side effects in a subset of patients who take a particular drug. It becomes just one more thing in a clinician’s busy day. “Our experience in health care and other sectors suggests that if the data can be gathered passively, or from sources that are already captured actively at the point of patient engagement, you’re going to be more successful in gathering accurate and complete data,” says Dix.

As data collection and analytics capabilities improve, presumably many of these obstacles will be overcome. Dix believes that MACRA, which makes interoperability among the EMR systems a priority, will eliminate the need for chart-based reviews and will accelerate the writing of value-based contracts.

Another influence, he suggests, is public opinion. “Pharmacy companies have taken it on the chin, rightly or wrongly, in terms of pricing,” says Dix. As patients are exposed to greater cost sharing, he says, they will join payers in demanding that manufacturers stand behind the performance of their products.

Other sectors have learned to shift from mere sellers to problem-solvers, and Dix thinks that’s the promise of outcomes-based contracting for medications.

Accountability is a priority at Cigna, which makes outcomes public after it puts a value-based contract in place. Bradbury believes that the public disclosure and dialogue it generates will create a new form of competition for drugs coming to the market: “We’ve seen, pretty much in every instance when there are more forms of competition, the customer benefits through enhanced innovation and products that deliver more value. We believe these types of agreements are a key component of driving pharmacy benefit management forward.”

A checklist for value-based contracting with pharma

To Cigna’s Chris Bradbury, the three key criteria for whether a drug is a good candidate for an outcomes-based contract are as follows:

- It treats a condition that carries a significant amount of expenditure now or is likely to in the future.
- Outcomes that all parties agree have value and can be readily measured in the short- to medium-term.
- Outcomes that can be analyzed at scale, so that payer and manufacturer can be confident in the results.

The leadership of both payers and manufacturers needs to start with a clear understanding of what a contract is intended to achieve—and why, says Bradbury. Once both have agreed on the measurements for achieving those ends, he says it is critical that they also both know when to walk away from some conclusions as well as understand when the data are insufficient to draw firm conclusions.
Say what you will about the CMS hospital star ratings—and much has been said about them, mostly disparaging—their release accomplished something that’s a rarity in Washington these days: Republicans and Democrats in Congress came together to block them. Last April, 225 House members signed a bipartisan letter to acting CMS Administrator Andy Slavitt to delay the release of the ratings. And CMS did delay the release—but only until July.

The ratings are meant to sum up performance on 64 quality measures with a designation of from one to five stars. That is supposed to give consumers a quick and easy way to assess hospitals on CMS’s “Hospital Care” website, like reviewers use stars to rate movies or restaurants. CMS also uses the star system to rate Medicare Advantage plans and nursing homes, but the hospital ratings provoked a backlash that the other ratings haven’t—evidence of, among other things, the clout of the hospital lobby. When it finally released the updated ratings last July, CMS said that the methodology had been reviewed “after substantive discussions with hospitals and other stakeholders.” But not many of those stakeholders have been happy with the end result.

The problem, say hospitals and some analysts, is that rating hospital quality is not so straightforward. How a hospital delivers care is multifactorial and complex, they argue, so trying to cram all that into a single score is misleading and can end up like rating a restaurant on its parking and signage as much as its food and service.

In an opinion piece in the Nov. 1, 2016, JAMA, Northwestern University researchers Karl Bilimoria, MD, and Cynthia Barnard listed seven concerns hospitals have with the star ratings, from a lack of transparency to a lack of risk adjustment to giving equal weight to elements (such as mortality and readmissions) with “dissimilar clinical significance.”

Jonathan Burroughs, MD, a former health system CEO who now runs a hospital consultancy in New Hampshire, calls the star rating system “a good start,” but says CMS has work to do. The agency has been working with the National Quality Forum and the Agency for Healthcare Research and Quality. “Now they need to shore up their methodology so it’s accurate,” he says.

Therein lies one major complaint about the current version of the star ratings. Burroughs and other critics say they are misleading because they do not take into account the severity or complexity of the case mix a hospital handles. Socioeconomic factors that have a pronounced effect on adherence and other factors that influence outcomes are also missing in CMS’s quality calculus. CMS already incorporates socioeconomic factors into the Medicare Advantage star ratings. Says J.B. Silvers, a professor of health care finance at Cleveland’s Case Western Reserve University and a former member of the Joint Commission, “There are some adjustments made, so if you have a riskier population you’re weighted differently.” Accounting for socioeconomic status more transparently and giving that appropriate weighting in the hospital quality calculation could be steps toward resolving these inequities.

**The Philadelphia story**

These blind spots mean academic medical centers and safety net hospitals fare poorly under the star system, while hospitals in more affluent areas come out looking good, critics say. Philadelphia is a good example. Paoli Memorial Hospital in the city’s tony...
Main Line suburbs got a five-star rating, while about 20 miles away in the western part of the city, the Hospital of the University of Pennsylvania garnered only three stars—even though it is a highly regarded academic medical center that shows up on lists of the best hospitals in the country.

Burroughs worries the current star system will have the unintended consequence of discouraging hospitals from caring for poor or sick people because that will hurt their star rating, and that, he says, is counter to the principles of population health.

In an analysis for the American Hospital Association, Francis Vella, chair of economics at Georgetown University, assailed the CMS methodology, saying that while it gives the impression of being rigorous and objective, it depends too much on the choice of measures and the weighting is subjective. And the absence of socioeconomic factors is glaring. “Two (or more) identical hospitals could have very different outcomes depending on the type of patient they have, where they are located, the type of health issues they typically face, and multiple other factors,” Vella’s analysis says.

Part of the problem with the CMS ratings is that they depend on claims data, says David Baker, MD, executive vice president at the Joint Commission, which does its own rankings of hospitals within service lines like oncology and pediatrics. He uses lung disease as an example. “There’s a variety of different tests to measure the severity of the lung disease, and you’d want to adjust for those things, but none of that information is in claims data,” he says. Other kinds of important information is also missing—in chronic emphysema and bronchitis, for example, one key factor in determining treatment and outcome is whether the patient is a current smoker. “Many of them are,” says Baker, “but we don’t have the data to adjust for that.”

One way to level the playing field for safety-net organizations would be to factor “nonclinical determinants”—socioeconomic, genetic, environmental, and behavioral factors—into quality metrics and outcomes. “They really are the key determinants on whether someone is going to bounce back into the hospital after discharge or not,” Burroughs says. “It has very little to do with what actually happens in the hospital or what’s done by the hospital.”

Besides employing the risk adjustment that Medicare Advantage ratings use, says Burroughs, “CMS needs to do what health plans do all the time, which is to risk-stratify their populations, identify those in

“Once all the data are digital, then big data can kick in and do the kind of analyses that are not all that different from what Amazon does that tell you how many other people liked the same kind of book,” says Robert Wachter, MD.
A LOOK-SEE AT THE STAR METHODOLOGY

The overall Hospital Compare rating summarizes up to 64 quality measures, although not all hospitals have to report on all measures. The rating reflects performance on common conditions like heart attacks or pneumonia, but hospitals may perform more complex services or procedures that the rating does not reflect. The overall rating shows how well each hospital performed, on average, compared to other hospitals in the United States. The most common overall rating is three stars.

The measures are grouped into seven categories: mortality or outcomes, safety of care, readmission rates, the patient experience as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, effectiveness of care, timeliness of care, and efficient use of medical imaging. To be rated, a hospital must report metrics in at least three of those seven areas, so a hospital that reports in only three areas can rank higher than a hospital that reports on all seven categories even though the latter may be performing more advanced procedures on more critically ill patients.

U.S. News & World Report 2016–17 Best Hospital Honor Roll vs. Star Ratings

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* Hospital Compare lists Hospital of the University of Pennsylvania and Penn Presbyterian Medical Center as two separate institutions.

Jonathan Burroughs, MD, worries the current star system will have the unintended consequence of discouraging hospitals from caring for poor or sick people because that will hurt their star rating.

greatest need and at greatest risk and give credit to organizations that care for those high-risk, complex populations.”

Silvers at Case Western Reserve calls these “socio-demographic adjustments” and says they are pivotal. Many quality measures are affected by sociodemographic factors such as living conditions and stress, he notes, and that has been clear for decades. Why would we not expect them to affect CMS quality metrics and the star ratings?

Pulling back the curtain

Another impediment to getting a clearer picture of how hospitals are doing is the hospitals themselves. Historically, hospitals have wanted to obfuscate what they’re doing. They are becoming more transparent, but it’s a slow process—and tools like the five-star ratings system can make them more skittish about pulling back the curtain.

“Zero transparency is the tradition, and traditions take a long time to change,” says Leah Binder, president and CEO of the Leapfrog Group, which reports on hospital quality for consumers and payers. Years ago hospitals had a lot of excuses for their reluctance to open up. One that carried weight was that there were few measures, and those were not very good, Binder says.

But hospital measures started to advance as the internet boomed, changing how consumers shop. “We had a different level of expectation from the public about transparency and the ability to compare providers of services and products, and hospitals were swept up in that,” Binder says. “The combination of having these better measures and having these expectations from consumers gave us a much more robust level of transparency, but we’re still not where we should be.”

To be more forthcoming, hospitals also need to examine their own systems for internal and external reporting. Hospitals frequently report masked outcomes to registries like the American College of Cardiology AFib Ablation Registry and the National Cancer Institute’s Surveillance, Epidemiology and End Results Program. “Is it absolutely necessary that everything in a registry be kept confidential?” Binder asks. “We don’t think so.” Such data could be used to inform
other outcomes tracking tools, and, Binder says, can at least be made available internally to improve quality.

Hospitals can also use validated survey instruments from the Agency for Healthcare Research and Quality and the Culture of Safety Survey, which Leapfrog administers. “There are a lot of ways hospitals can be more transparent, and they should be looking for those opportunities because that’s the next generation of transparency that’s coming, and it’s not going to be optional much longer,” Binder says.

A cacophony of appraisals
Robert Wachter, MD, author of the bestseller The Digital Doctor and professor at the University of California–San Francisco, has long called for improved hospital transparency. He is a member of the Lucian Leape Institute, the think tank of the National Patient Safety Foundation (NPSF). In a 2009 paper, the institute members called transparency “the most important single attribute of a culture of safety.” Another report in 2015, Shining a Light: Safer Health Care Through Transparency, offers more than three dozen recommendations for improving transparency.

Greater transparency may also be a matter of time as electronic medical records become more ubiquitous. “Once all the data are digital, then big data can kick in and do the kind of analyses that are not all that different from what Amazon does that tell you how many other people liked the same kind of book,” Wachter says. “We just haven’t had the data sets to be able to do that work in the past.”

One relatively new problem with measuring and rating hospitals is the sheer number of organizations doing it. Besides CMS, the Joint Commission, and Leapfrog, there’s Truven, US News & World Report, and Consumer Reports. Each has a different way of gauging hospitals, so the public faces a cacophony of appraisals.

And now Yelp is getting into the game. Last year, researchers from the University of Pennsylvania reported in Health Affairs on the role Yelp hospital reviews play in consumer choice. Maybe CMS could learn something from Yelp. The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey is one of seven categories in which CMS evaluates hospitals for the star rating, but the Penn researchers found that HCAHPS doesn’t measure or report the things that Yelp reviewers find most relevant to hospital reviews.

“I don’t read restaurant reviews anymore; I read Yelp,” Wachter says. “In some ways it’s going to become more of a Wild West, not less, as ratings of hospital quality become more democratized and more web-inized and more consumer-focused than what we’ve traditionally had.”

Audit like the IRS
Another way to improve transparency and the quality of data hospitals report is to take a page out of the IRS playbook by doing an audit—in this case, of quality data collection and performance, not finances.

“There are certainly ways to audit those data,” says Northwestern’s Bilimoria. “Other quality reporting programs have instituted audit systems without any issue.” They consist of paper audits, remote audits, and targeted audits. “A system of audits, both random and targeted, would certainly improve the quality of the data,” he says.

Baker of the Joint Commission says that to accurately adjust for differences in patients’ severity of illness across the hospital, chart abstraction is a necessity, and hospitals need to have a system for that. He holds up the Society for Thoracic Surgery as a model for an audit strategy. “They train chart abstractors, and they audit 10% of participating sites,” he says. “So we know how to do this, but it’s hard because it’s expensive. Medicare doesn’t have the ability to spend all the money on all this. But without the hammer of the audit, getting valid, reliable data will be difficult.”

Growing pains
It could be that the art and science of evaluating hospital quality just needs to grow up. “The problem is that the field of quality measurement is still such a young and immature field that there’s that fear that they will be wrong or misleading,” Wachter says.

A big step in the maturation process will depend on some standardization of definitions for quality metrics. Adds Wachter: “In some ways the National Quality Forum was organized around the recognized need for that capacity in the health system; a trusted, arms-length party not dependent on funding from anyone with a vested interest to look at potential quality measures and judge them against the evidence. That sounds good. Turns out it’s also really hard to do.”

The result, in Wachter’s estimation, has been “tremendous disagreement among well-meaning people.” Until they reach a consensus on meaningful measures, hospital quality will be hard to pin down with stars.
The Missing Ingredient In Quality Measurement

Checking the process and outcomes boxes only goes so far. To improve health care quality in a sustainable way, some experts argue, it’s vital to look at the structure of care delivery.

By Thomas Reinke
Contributing Editor

A n elderly man with cancer waited two hours for a scheduled outpatient cystoscopy. When the nurse finally called him in, he asked if the clinic had a patient information sheet that explained the procedure. “Of course we do—I’ll get you one,” she replied, only to return five minutes later saying she couldn’t find one. The man asked if the clinic had a quality assurance committee, and the nurse said yes, but no one paid attention to it.

“Tell the committee Donabedian said they have a problem,” he replied.

The man that health care delivery system was failing was Avedis Donabedian, MD, a University of Michigan professor whose seminal 1966 paper, “Evaluating the Quality of Medical Care,” in The Milbank Foundation Quarterly (today it’s The Milbank Quarterly) had helped launch the field of health care quality measurement. He became known as “Mr. Structure-Process-Outcome” because he had identified those three facets as critical in assessing care.

Donabedian told that story in a Health Affairs interview a month before his death in 2000. Asked about his experience as a patient, his report was “generally positive” but he had complaints. At one point, he said, his urologist and his nephrologist disagreed on the nature of his malady and the best treatment, so they simply left it up to him. He found the hospital floor “a disaster…[with] so many part-time nurses working variable hours.” In part he blamed “poor training and education,” adding that system management doesn’t get taught in medical and nursing schools, and that well-meaning clinicians suffered from “myopia mixed with ignorance.”

“You cannot parse patients into isolated diagnoses; they must be managed comprehensively,” says Don Goldmann, MD, chief science officer at the Institute for Healthcare Improvement.

Donabedian’s famous 1966 paper was based on work commissioned by the U.S. Public Health Service, which asked him to review and summarize the scholarship on quality improvement. The article noted the then-current focus on evaluating outcomes as the quality indicator, then explained in detail that structure and process of care were equally important dimensions that needed to be considered.

THE FATHER OF QUALITY MEASUREMENT

A vedis Donabedian, MD, came up with the process-outcome-structure triad that remains the framework for quality measurement in American health care today. Born in Armenia in 1919, he earned his medical degree from American University in Beirut and a master’s degree in public health from Harvard in 1955. He spent most of his career at the University of Michigan. When he died in 2000, he was eulogized as a giant of public health.

Donabedian was a giant. He was a giant. He was a giant.

The measures most often used today to assess care quality are process measures. Actual outcomes, of
course, are harder to measure than whether a certain action has been taken—checking the feet of a patient with diabetes, for example. But many experts don't think process measures get at the heart of quality. By themselves they can even be an incentive to overtreat. Donabedian might add that even true outcome measures, prized as the best indicators of quality care, don't tell the whole story.

The focus on process and outcomes overlooks Donabedian's insight that the health care system is like any other system. Activities are enabled (and constrained) by the system's structure and functional capabilities. That means the starting point for improving quality and outcomes should be the health care system's structure.

John Toussaint, MD, founder and CEO of Catalysis, an education company for health care leaders in Appleton, Wis., preaches the Donabedian gospel. He sees a need for fundamental change in the structure of the health care system as a prerequisite for better outcomes and cost control. "The path to better value depends upon the systems and processes we build to deliver care," he says. "Better value and patient outcomes require a transformation [in the health care delivery system] across all sectors."

CMS and others have launched an armada of payment reforms, but the way American health care is paid for—a claim is generated by the provider, then paid by the payer—is deeply rooted. "The structure of the delivery system is largely tied to the fee-for-service payment model," says Toussaint. "As long as that mechanism is in place, the fundamental incentive is to admit more patients or do more tests."

ACOs might make a difference, but not the present versions, Toussaint believes. CMS payments in all the current models remain, fundamentally, fee for service. One answer, he says, is for CMS to move more rapidly to global payment in the ACO program that is adjusted for risk and geography. Shared savings is just not potent enough, he says, suggesting that global payment could lead to more complete integration of providers—hospitals, physicians, pharmacies, nursing facilities, and others. That integration, he thinks, can dramatically change financial incentives.

Global payment is part of CMS's Next Generation ACO program. The program's predecessor, the Pioneer ACO program, saw 19 of its 32 members drop out, including the Dartmouth-Hitchcock Medical Center in New Hampshire, where Elliot Fisher, MD, who dreamed up the ACO idea, is located. Perhaps the Next Generation ACOs will be a different story because of global payment.

Toussaint is talking about structural changes that involve aligning the major building blocks of American health care. But structural changes that generate value can also happen at lower levels.

Judge by teamwork

"A major focus currently is on inter-professional health care teams," says Don Goldmann, MD, chief science officer at the Institute for Healthcare Improvement (IHI) in Cambridge, Mass., which is credited with coinining the phrase Triple Aim. It stresses (1) enhancing patients' experience, (2) improving population health, and (3) reducing per capita cost. "If you are going to improve quality or reduce cost it has to be a team effort," he says.

Teams are the focus because of today's increased emphasis on coordinating care, managing the health of populations, reducing gaps in care, and improving patient engagement. But team-based care has been overlooked in some of CMS's value-based payment reforms, says Goldmann. He notes, for example, that MACRA's Quality Payment Program for physicians has no measures of team-based care.

Moreover, most measures in the program do not promote a holistic view of patients nor address their individual needs, cultural context, and living conditions, including social determinants of health. Many patients, especially seniors, have multiple health problems. Goldmann says managing multiple conditions sometimes requires setting priorities and making tradeoffs: "You cannot parse patients into isolated diagnoses; they must be managed comprehensively." The measures in the Quality Payment Program do not accommodate such situations, but rather target specific elements of individual conditions.

Donabedian preached the gospel of system design as the foundation of quality. But he also saw the limits of systems. They may enable clinicians to do their jobs, but whether they actually deliver high-quality care depends on the "ethical dimensions" of the human beings involved. "Doctors and nurses are stewards of something precious," he said in the Health Affairs interview, contending that "ultimately, the secret of quality is love. You have to love your patient, you have to love your profession, you have to love your God. If you have love, you can then work backward to monitor and improve the system."
HEDIS Is the Hassle That Became a Habit

After 25 years, the Healthcare Effectiveness Data and Information Set (HEDIS) is still criticized for focusing on process and taking up doctors’ time. But it has been incorporated into physicians’ workflow and may yet be instrumental in bringing about value-based care.

By Joseph Burns
Contributing Editor

In 1991, the average premium for a family with employer-sponsored health care was less than $1,300, and two thirds of all workers were in traditional fee-for-service insurance plans. One year later, a relatively unknown governor of Arkansas was elected president, and two years after that he introduced his ill-fated health care reform plan.

At the time, managed care plans were going like gangbusters—their 5% share of all workers in 1984 had risen to 26% in 1989 and 50% in 1993. Concerned that capitated payment might lead to poor care for American workers and their families, employers and consultants called for a system to evaluate the quality of care health plans delivered. The result was the HMO Employer Data and Information Set, since rechristened the Healthcare Effectiveness Data and Information Set, a health plan performance measurement tool. American health care has never met an acronym it didn’t like, so that long name gets shortened to HEDIS, which is pronounced HEE-dis. To some ears that sounds more like an infectious disease than a quality improvement tool.

Two and half decades later, HEDIS plays as large a role as it ever has in the evaluation of health plans. More than 90% of managed care plans use HEDIS to collect information on the performance of their physicians in 81 areas of care delivery and service. In 2016, NCQA collected HEDIS data on health plans covering 81% of all insured lives.

Because of HEDIS, health plans collect data on everything from how many times a physician has eligible patients screened for colorectal cancer to what percentage of patients have their hypertension managed to how well patients adhere to immunization schedules.

Assessing care delivery in these 81 areas is important. But what do these assessments tell us? Are patients more or less likely to die as a result of being enrolled in one of the nation’s best health plans? When doctors can check all the appropriate boxes on the HEDIS survey, are their patients healthier than those of a doctor who has no idea if HEDIS data are being collected on his or her patients?

And now there is another important question to ask. Because of MACRA, CMS is introducing new quality measurement requirements this year. Are doctors, already drowning in paperwork, being asked to fill out too many forms when they could be using that time caring for and listening to patients? The fact is that much of the data collection and reporting goes on behind the scenes. Many physicians aren’t even aware that somewhere in their office, someone or

“We have a lot of work to do to clean up the way that measurement intersects with practitioners at the delivery system level,” says NCQA President Peggy O’Kane.
some system is busy scooping up data and plugging in 81 HEDIS measures. But those 81 represent less than 10% of the 900 or so quality measures in use today. It may happen in the background, but all this effort to measure quality is getting burdensome and adds to the cost of American health care.

Even though some physicians consider HEDIS data collection to be a burden, many others have developed sophisticated data systems to collect the numbers they need for quality reporting in the background. What’s more, physicians who embrace HEDIS have come to view it for what it has become, a way to measure their ability to improve patient care and a key to collecting financial rewards for meeting health plans’ quality goals.

‘HEDIS schmedis’

While some physicians today see value in their HEDIS scores, others still echo the complaints heard about HEDIS from its earliest days, when critics noted that most of the measures were limited to the processes of care. Payers—chiefly employers—had no way to know if people were actually healthier than before they enrolled in an HMO—and part of the promise of the HMO was that preventive care would keep people healthier and their health care less expensive. That inability to evaluate patient outcomes is a flaw in HEDIS that remains today. But instead of addressing that flaw, quality measurement organizations have added many more quality measurement data collection requirements and are planning still more. So while HEDIS may be the most important and longest-tenured quality measurement system, many physicians and other providers tend to view it as, at best, a bother.

Here’s a telling comment from a physician interviewed for MANAGED CARE in 2012, the year NCQA added the HPV vaccine as a HEDIS measure. Chuck McKinzie, MD, an ob-gyn in rural Minnesota, said HEDIS was not widely known among physicians in remote parts of the state. “Making it a HEDIS measure will help,” he said of the HPV vaccine. “But out here HEDIS is hardly on anyone’s radar. The doctors in these small rural towns think, ‘HEDIS schmedis!’”

While McKinzie represents a sample of one, his comment is telling, says NCQA President Peggy O’Kane: “I don’t blame doctors for thinking that way. To them, quality measures probably seem like an unnecessary nuisance defined by someone somewhere on behalf of employers or CMS or somebody else.”

Meeting such standards may seem removed from what physicians were trained to do.

“It’s understandable that doctors are feeling frustrated,” O’Kane says. They are asked to spend a good part of every day collecting and reporting data on their own performance, pay for sophisticated systems to collect and report the data, or hire someone to do it for them. It doesn’t end with HEDIS. Now there are new requirements from MACRA that will affect any physician with Medicare patients as well as the data-collection rules that most health plans impose in addition to HEDIS, which physicians can’t blow off because they are often used to determine sizable bonus payments.

Certainly some of the data required to comply with MACRA will overlap with what’s in HEDIS, and some health plans are just beginning to align the goals of disparate data-collection programs.

“That’s a problem that we’re collectively responsible for,” O’Kane adds. “We have a lot of work to do to clean up the way that measurement intersects with practitioners at the delivery system level.” Even something as straightforward as a blood-pressure check can get needlessly complicated because of the proliferation of quality measurements and the differences among them.

Humana’s chief medical officer, Roy Beveridge, MD, agrees that quality measurement takes up an extraordinary amount of physicians’ time. “Having practiced for 20 years, I am sympathetic to doctors’ complaints because each health plan seems to be doing something different from the standpoint of collecting data on quality,” he says. “We’re taking time from providers that they should be spending with their patients.”

Measurement overload

Early last year, Humana, other insurers, AHIP (the health insurance trade association), and 18 specialty societies began grappling with how to reduce the overload. AHIP and CMS released seven sets of clinical quality measures that support what CMS calls “multi-payer alignment.” The core measure sets are designed to align quality measures for physicians and group practices serving patients in ACOs and patient-centered medical homes. The measures apply to physicians in primary care, cardiology, gastroenterology, oncology, ob-gyn, and orthopedics, among other specialties.

Still, HEDIS isn’t going away. “HEDIS scores work
well, particularly for primary care,” says Beveridge. “They’re universally accepted in the United States.” Physicians may not like quality measures in general, says Beveridge, but by now most have gotten used to HEDIS and are comfortable with meeting its requirements. But reaching that comfort level has been expensive. Doctors and medical groups have invested considerable time and money to develop systems that collect and report the required data. Some use their electronic health record (EHR) systems to collect the data, others hire assistants to comb through claims, and many use a combination of the EHR and human handwork.

In October, the Government Accountability Office (GAO) reported that the wide variety of quality measurement systems in use today and the lack of alignment among them can have adverse effects on physicians and other providers and on efforts to improve quality of care. “Misalignment occurs when health care payers require providers to report on measures that focus on different quality issues or define the measures using different specifications,” said the report. Bruce Muma, MD, the chief medical officer of Henry Ford Health System ACO in Detroit, says that different organizations use the 900 quality measures differently. “Every insurer has its own subset of those 900 measures,” he says. “Then, it builds its own pay-for-performance contracts and value-based payments around those measures, and then it builds its own pay-for-performance contracts and value-based payments around those measures. Then it imposes those measures on the doctors in multiple ways by sending us reports, requiring us to submit data, sending people out to our practices to extract data from our charts, and forcing us to have educational programs about their particular metrics that they think are important.”

Oak Street Health is a group practice that uses several electronic tools to collect HEDIS data, says Griffin Myers, MD, co-founder and chief medical officer. Its 75 physicians serve 25,000 low-income Medicaid and Medicare Advantage patients in some of Chicago’s underserved neighborhoods. “Collecting HEDIS data is not all done at the point of care,” says Myers. The data also come from claims, reviews of lab reports, and a variety of other sources.

The data systems at Oak Street Health are sophisticated enough so that Myers and his staff often recognize problems with their HEDIS data before their health plans do, he says. The group contracts with Blue Cross Blue Shield of Illinois, Cigna, Community Care Alliance of Illinois, HealthSpring, Humana, and WellCare, among other plans. “The reason we know about gaps in HEDIS before they do is that we keep all those data in our enterprise data warehouse so that we can submit them directly to the plans,” he says. “That way, they don’t have to audit our charts as they did in the past.”

Myers is not among those who view HEDIS as so heinous. Quality metrics, including HEDIS, are a way to measure the group’s progress toward improving the health of all patients, he says. While he concedes that HEDIS does not capture outcomes, adhering to processes can be an adequate proxy.

“My personal commentary on quality measurement systems, including HEDIS, is that they do not reflect whether we deliver good care or not,” says Myers. Instead, HEDIS reflects whether a physician or group practice is meeting certain minimum standards of care. “Doing these things on the HEDIS scorecard is better than not doing them, and so in that way HEDIS demonstrates our commitment to value-based care and to quality reporting,” he explains. “And to do all these things well, including reporting our HEDIS scores, we need to have a sound infrastructure, which we have.”

Health plans should eliminate all but about 30 to 50 of the best quality measures, suggests Bruce Muma, MD, the chief medical officer of Henry Ford Health System ACO in Detroit. Because of HEDIS, plans collect data on everything from how many times a patient is screened for colon cancer to which patients have their hypertension managed.
HEDIS is a subset of the many different things that we report on because there are many different things that we think are important to care.”

Collecting the number of flu shots dispensed is not a HEDIS metric, Myers says. But Oak Street tracks and reports those data because that is meaningful in terms of the health of the group’s patients. The data collection system even collects data when patients get a flu shot at another facility, such as a Walgreens pharmacy, when a patient is on vacation. “Otherwise, we would never know that and so that would be a gap that we would need to address,” he says.

The data warehouse contains all the patient data that Oak Street Health collects and data on any in-network care. “Because we’re value-based, we’re paying all those claims for all of the care that patients get, whether it’s in our building or not. So we need that data on every patient encounter,” he says.

Data-collection systems like the one Oak Street Health uses are necessary because most physicians are to this day unaware that HEDIS scores need to be collected on every patient encounter, says Anas Daghestani, MD, CEO of the Austin Regional Clinic.

When physicians begin collecting data to comply with MACRA, 60% or more of the data they collect will be based on HEDIS scores, says Anas Daghestani, MD, CEO of the Austin Regional Clinic.

Cost is not part of HEDIS, but, of course, it is an issue that insurers are concerned about. Humana reported that costs for the valued-based MA members were 20% lower than for the standard-issue MA members.

“If you want to drive cost out of the system, you start by making sure that all of your patients get colon cancer screening at the right time, because screening for colon cancer is a lot cheaper than treating someone who develops metastatic colon cancer,” Beveridge says. “Same thing with mammograms, and screenings for prostate cancer and flu shots.”

He waves off the old objection that prevention doesn’t pay because some other insurers may reap the benefit of people staying healthy long after they leave the health plan that paid for the preventive efforts. Humana members stay with the company an average of seven years, according to Beveridge, which may not be long enough to get all of the return on the investment in prevention but it’s enough to get some. Besides, sometimes the return can show up quickly. Flu shots for a plan’s members are a good deal compared with a hospital stay for a complicated case of flu, which could cost up to $80,000, Beveridge explains. And many patients with diabetes will avoid hospitalizations and emergency room visits if their HbA1c levels are kept under control.

FEEDBACK PLEASE!

Any thoughts about this article? Let us know. Send responses to Managing Editor Frank Diamond at fdiamond@medimedia.com.
Health care is rife with measurement. For both providers and payers, the time, effort, and resources dedicated to collecting and reporting data is exorbitant. While most reporting requirements are well intentioned, the proliferation is not adding value and—in some circumstances—does more harm than good. Health care is already complex. All the measurement adds layers of complexity and bureaucracy. And the expense is considerable. A study published last year in *Health Affairs* showed that physicians and staff members in four types of practices (primary care, cardiology, orthopedics, and multispecialty) spend, on average, 15 hours a week per physician dealing with quality measures, which works out to about $40,000 annually per physician and $15.4 billion total.

This is not to say that compliance-driven measurement and reporting is unimportant. Reporting requirements on hospital-acquired infections have contributed to a reduced number of infections and the saving of an estimated 125,000 lives between 2010 and 2015. To support these efforts, standard quality measures with clear definitions and application that can be used industry-wide are being developed.

Still, there are an inordinate number of metrics, measures, and models developed by payers, providers, government agencies, and others that look at similar issues (e.g. quality, cost, experience) but from a variety of perspectives. Some standardization would help but it will provide only a grainy view of an organization’s performance, particularly to those not well versed in the arcana of data science (like 99.999% of patients).

The result is that, ironically, in this era of rapidly increasing transparency it remains curiously difficult for customers—which in health care can include employers and brokers as well as patients—to find useful information to support informed decision-making. The capacity for collecting data on all aspects of health care, including cost and quality, has outstripped the ability for many to use it.

In this data-rich environment, why is it so challenging for payers and providers to make the information relevant to their customers? The answer lies in how they have historically viewed the role of measurement and reporting. Both payers and providers largely see it as a matter of compliance—compliance with government regulations, with contract terms, with aggregator requirements—the list goes on and on.

The good news here is that some forward-thinking players are starting to use metrics and measures to tell stories aimed at attracting, informing, and retaining their customers. A list of data points is not enough. Instead, they must be woven into a coherent story. Easier said than done, right? Here’s where to begin:

1. **Define the stakeholders.** Consumer segments, purchasers, aggregators, and others are all likely key targets for messaging.

2. **Be clear about the value proposition.** Importantly, your value proposition likely differs by stakeholder group, so messaging and the data to support will as well.

3. **Define the measures.** This is not a matter of simply selecting which metrics to showcase with which audiences; we have already established that current reporting is not particularly valuable to customers. Aligning metrics with your value proposition requires careful thinking and articulation of a story line. Your story may require some entirely new measures.

In the absence of such credible and accessible messaging, customers are looking to other sources to distill information. Take customer experience. Virtually every payer or provider has developed its own approach to measuring customer experience. The federal government has gotten into the game with the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), CMS’s measure of the patient experience associated with inpatient hospital episodes. The information has failed to resonate with customers, and they don’t look to provider, payer, or government websites when shopping for services. Instead, they turn to websites that provide information that consumers can relate to, such as Yelp.

And do you want Yelp telling your story to your customers, or would you rather do that yourself? **Zachary Hafner** leads the Advisory Board’s strategy consulting practice.
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Accurate Encounter Data a Must For Medicaid MCO Quality Measurement

By Jason Duhon

With more than 60% of all Medicaid beneficiaries now enrolled in comprehensive, risk-based managed care organizations (MCOs), state Medicaid agencies that want to measure quality of those plans must have quality encounter data. Encounter data capture the items or services received by the member; they are managed care's equivalent of claims in fee for service. CMS also depends on encounter data submitted by state Medicaid programs to maintain the massive Medicaid Statistical Information System (MSIS), a database of claims, encounter data, and beneficiary eligibility information.

Poor encounter data can hinder quality measurement in multiple ways. Encounter data are the foundation that allow state health officials to evaluate the performance of Medicaid managed care plans, understand service utilization, and analyze health quality. States also use the data for budgeting, calculating capitation, and a variety of other payment rates. Fraud and waste-and-abuse investigations often hinge on encounter data.

Unfortunately, collecting and reporting encounter data has long been a trouble spot for both state-level health officials and CMS. The HHS Office of the Inspector General has issued two reports on the problem, the first in 2009 and the second in 2015, about the gaps in encounter data reporting. The 2015 report said that eight of the 38 states viewed did not report any encounter data on time and that another 11 passed on incomplete data.

In April 2016, CMS issued updated guidance on encounter data. The guidance suggested that the failure by states to submit timely, accurate, and complete data could result in CMS disallowing federal financial participation (FFP) on all or part of a state’s capitation payments to Medicaid MCOs. While CMS has not typically withheld state matching funds for deficient encounter performance in the past, CMS indicated it will use these sanctions to obtain encounter data in the near future. FFP accounts for 50% to 75% of the payments made by Medicaid programs to Medicaid MCOs. If CMS disallows even a portion of the federal match, state Medicaid programs can’t be expected to make up the difference.

If CMS does withhold matching funds to states, most states are likely to be more aggressive in taking steps to mitigate any risk to their Medicaid budgets, which are already growing at a phenomenal rate and gobbling up a growing percentage of state budgets. Not only are they more likely to pass down financial penalties, but they are also more likely to consider the long-term viability of MCOs that are out of compliance. Medicaid MCOs can expect tighter contracts, greater oversight and monitoring, and an increased focus on encounter reporting. They can expect states to develop more robust processes and procedures for monitoring MCO performance. Several states already impose penalties on contracted MCOs for failure to provide quality encounter data, such as Arizona, Louisiana, and Texas, among others.

Now is the time for state Medicaid programs to start focusing on collecting high quality encounter data. States need to get ahead of potential CMS sanctions through re-evaluating their contracts and oversight processes. But this shouldn’t be a question of only wanting to please the federal government and avoid financial consequences of some kind. Complete and up-to-date encounter data is absolutely essential for the proper oversight of Medicaid MCOs. Without it, states can’t know what they are getting for their payments to the MCOs, and the MCOs can’t be held accountable.

Jason Duhon is an associate director at Navigant Consulting, a consulting company headquartered in Chicago.
For health plan leaders tasked with finding ways to manage the cost and quality of care delivered to their members, it is frustrating when patients with nearly identical diagnoses and levels of function follow different courses of treatment.

Nowhere is this truer than in post-acute care. In 2013, the Institute of Medicine (IOM) identified post-acute care spending as the primary driver of regional Medicare spending variation. In fact, the IOM report suggested that eliminating post-acute care variation would decrease the overall variation by 73%.

The root of this variation is often a mix of supply-driven demand and misaligned incentives. Areas of the country with high concentrations of long-term acute care hospitals or inpatient rehabilitation facilities often have much higher utilization rates, even if a skilled nursing facility or home health provider could provide care comparable in quality and at a much lower price.

So, what key metrics or statistics should a health plan use to assess its potential to better manage post-acute care?

Here are some ideas:

- **30-day readmission rates for members utilizing inpatient post-acute care.** Readmissions from facilities—directly from a facility or within the days immediately following discharge—are strong indicators of quality.

- **Skilled nursing facility length of stay, adjusted and unadjusted for readmissions.** Skilled nursing facilities are paid on a per-diem basis. The first 20 days of a stay are typically covered 100% by the health plan before a per diem co-pay of approximately $160 kicks in for the member. As a result, a large concentration of discharges occur around Day 20. With high-quality medical care and therapy, average length of stay across a large plan can be decreased from more than 20 days to 15 to 17 days.

- **Post-acute yield following a hospital admission, overall and by setting.** About 40% of Medicare patients receive post-acute care after a hospitalization, but there’s wide variation in that percentage and the level of care based on hospital and regional practice patterns. Yield to an inpatient rehabilitation facilities can range from 2% of discharges to more than 15% percent, depending on the region of the country.

- **Trends in resource utilization groups or levels.** Health plans should measure how their resource utilization group categories for skilled nursing facilities have changed over time. Last year, the Wall Street Journal reported that the percentage of days billed for “ultra high” therapy patients had increased from 7% in 2002 to 54% in 2013. The average charge for an ultra high therapy patient is $560 a day, compared with $455 for a “very high” patient.

In addition to these metrics, companies like mine are introducing new measures that will help both providers and health plans better manage post-acute care. NaviHealth’s proprietary assessment technology, nH Predict, draws from a database of more than a million patient outcomes. Each patient is different, but by identifying similar patients, our predictive analytics can help set expectations for recovery. These personal-level goals are key to ensuring that a patient receives the appropriate therapy and medical care. Our assessment technology can also detect variance between predicted functional recovery and actual functional gain. Variant metrics levels the field, reducing the risk of “cherry picking” healthier patients while recognizing providers that consistently provide the right therapy and medical care.

Empowering care teams to match patients to the right level of care, in the right place, at the right time is critical to success in a value-based care environment. But these factors can’t be managed without the ability to measure them, and that’s the foundation upon which efficiency in health care rests.

Carter Paine is chief operating officer of NaviHealth, a post-acute care management company in Nashville.
New life is being breathed into real-world evidence. The idea of incorporating information collected from circumstances closer to clinical reality has always had intuitive appeal. But real-world evidence has been widely criticized as sounding good but, in actuality, may be unreliable or result in biased results compared to randomized trials.

New data sources, more rigorous study designs, more powerful analytics, and smarter, more appropriate use of studies are lending real-world data some new credibility.

Payers, pharma getting along
For decades, the pharmaceutical industry has used the randomized clinical trial to generate reliable evidence of the safety and efficacy of its drugs. Now the observational study has become a way for companies to build a body of evidence that supports commercialization of their products, identifies opportunities for new agents, and streamlines late-stage clinical trials. Of course observational studies are nothing new. They are the workhorses of nutrition and public health research. But there is momentum building to use them to study the safety and efficacy of its drugs. Now the observational study has become a way for companies to build a body of evidence that supports commercialization of their products, identifies opportunities for new agents, and streamlines late-stage clinical trials.

Drug companies and payers are designing real-world evidence studies together that dig deeper into how medications are used and for whom they are effective, says Jennifer Graff of the National Pharmaceutical Council. Observational studies are nothing new. They are the workhorses of nutrition and public health research. But there is momentum building to use them to study the safety and efficacy of its drugs. Now the observational study has become a way for companies to build a body of evidence that supports commercialization of their products, identifies opportunities for new agents, and streamlines late-stage clinical trials.

Real-world lung study
A prime example is the study that GlaxoSmithKline (GSK) conducted recently with Great Britain’s National Health Service (NHS). The Salford Lung Study was a community-based phase 3 trial of GSK’s Breo Ellipta, a combination of fluticasone furoate, an inhaled corticosteroid, and vilanterol, a long-acting beta2-adrenergic agonist, that was approved as a treatment for chronic obstructive pulmonary disease (COPD). The pragmatic clinical trial, which had few exclusions, included 2,800 patients from 80 general practices plus 130 pharmacies. Extensive data about their total care was drawn from their electronic health records. The study compared patients receiving the GSK agent with patients receiving usual care with several other COPD medications. The goal of the yearlong study was to get as complete a picture as possible of the way patients use their medication, the care they receive on a regular basis for COPD, and additional care they receive for other conditions.

The primary outcome was the rate of moderate or severe exacerbations among patients who had had an
exacerbation within one year before the trial. Secondary outcomes were the rates of primary care contact (contact with a general practitioner, nurse, or other health care professional) and secondary care contact (inpatient admission, outpatient visit with a specialist, or visit to the emergency department).

There was a statistically significant reduction in the rate of moderate or severe exacerbations in patients treated with Breo Ellipta compared with patients receiving usual care.

Typically, randomized clinical trials are designed to test medications in very controlled circumstances with carefully selected patients. By contrast, the Salford Lung Study had more of an all-comers approach with lots of data for researchers to analyze. Drug manufacturers are eyeing high quality, pragmatic trials like this because they can generate data about a drug working (or not working) in specific populations. Perhaps a medication is safer in specific age groups or is most effective when it’s paired with another drug.

Besides, the Salford Lung Study benefited the NHS as much as it did GSK by providing insight into patient behaviors, the utilization of services, and other aspects of their care. The NHS praised the study as a pioneering model that sets a precedent for future studies. The goal is to capture data about the performance of medications in everyday clinical situations rather than conduct a controlled experiment, which, in essence, is what a randomized clinical trial is.

**Head-to-head comparison**

One real-world design of particular interest to providers is the retrospective head-to-head comparisons of different medications. Randomized trials have been used for these comparisons, but they are expensive to conduct—and funding is an issue. The NIH has other priorities, and drug companies don’t want to run the risk of their product not coming out on top. Yet head-to-head comparisons would help providers make better decisions about which drugs to prescribe and, ultimately, might improve patient outcomes. Head-to-head studies can help providers generalize from a very narrow phase 3 trial to a broader population or to identify differences among subpopulations.

Researchers at the Mayo Clinic recently published two head-to-head observational studies of the anticoagulants dabigatran (Pradaxa), rivaroxaban (Xarelto), and apixaban (Eliquis). In phase 3 trials, all three have been shown to be safe and as effective as warfarin, the mainstay of anticoagulants. Warfarin requires frequent lab tests and dosing adjustments, so alternatives are desirable, but some important data on this trio of newcomers—particularly on the risk of major bleeding—has been lacking.

One of the Mayo studies, published online by Chest, was a head-to-head comparison of the three rivals to warfarin. Several indirect comparisons have been published but no direct comparisons, says Peter Noseworthy, MD, an author of both studies.

The study in Chest included data on more than 57,000 patients pulled from a large insurance claims database. Noseworthy and his colleagues found no statistically significant difference among the three agents as far as preventing strokes and other efficacy outcomes. They also looked at inpatient admissions for gastrointestinal bleeding, intracranial bleeding, and bleeding from other sites as a marker of safety. Apixaban was associated with less major bleeding than dabigatran and rivaroxaban, and rivaroxaban was associated with an increased risk of major bleeding and intracranial bleeding compared with dabigatran.

The second Mayo study, published in the Journal of the American Heart Association, compared each of the three relatively new anticoagulants directly to warfarin. The researchers had data on more than 76,000 patients. The results showed apixaban was associated with lower risks of both stroke and major bleeding than warfarin, dabigatran was associated with a similar risk of stroke but lower risk of major bleeding, and rivaroxaban was associated with similar risks of both stroke and major bleeding.

Noseworthy says the head-to-head studies help providers understand the safety and efficacy of the three drugs—and perhaps help them with prescrip-

**WHAT IS A PRAGMATIC CLINICAL TRIAL?**

Pragmatic clinical trials are designed to evaluate the effectiveness of interventions in real-life routine practice conditions, whereas randomized controlled trials (RCTs) are typically designed to test the efficacy of intervention under optimal situations for demonstrating a treatment effect. Pragmatic trials produce results that can be generalized and applied in routine practice settings.

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In comparison to multisite randomized controlled trials, [head-to-head] studies are easier to organize and a good deal less expensive, says Peter Noseworthy, MD, of the Mayo Clinic.
Studying the three medications (four if you count warfarin) together eliminates the work and uncertainty of interpreting multiple trials with different populations and methodologies.

In comparison to multisite randomized controlled trials, these types of studies are easier to organize and a good deal less expensive, says Noseworthy. The complexity is in the analytical methods. “We don’t have the opportunity to prospectively control the study so we have to use sophisticated methods to reduce or eliminate the biases,” he says.

An example of bias, he says, is prescriber preferences. Prescribers have preferences for which drug they prescribed for different kinds of patients. Retrospective studies must account for that or run the risk of attributing results to the drugs that are really the result of patient characteristics. The bias can be reduced through propensity score matching which was used in both studies, says Noseworthy. Once bias and confounding variables are reduced, Noseworthy says the amount of work that goes into analysis of data and determination of results is relatively straightforward.

However, Noseworthy cautions that a single study cannot provide definitive information for generalizing the use of a medication across a broad population or within a specific subpopulation. “We don’t want to make sweeping generalizations from a single study. Instead several studies are needed to fill the gaps that exist in phase 3 trials.”

A checklist
Jonathan Morris, MD, a vice president with QuintilesIMS, says that additional patient data sources like registries, better study designs, and more powerful analytic techniques require broader new methods for generating information for decision making. “Different study designs are appropriate for answering different questions and the proper strategy is to match the study design to the level of question or problem that needs to be answered.”

Because observational studies are still emerging as a study design for pharmaceuticals, new rules of the road may be needed. GRACE Principles (Good ReseArch for Comparative Effectiveness), a nonprofit consortium to improve the quality of observational studies, has come out with a tool called the GRACE Checklist. It was spearheaded by QuintilesIMS and the National Pharmaceutical Council. The checklist includes 11 questions about data and methods such as, Were the outcomes studied valid in other populations? Validation activities have documented the usefulness of all 11 questions in this checklist (see box on this page).

Morris says that does not negate the need for new study designs to fill in for the limitations of random controlled trials. “In 1933, President Roosevelt moved our monetary system off the gold standard and that boosted the economic recovery. Our health care system would benefit greatly if it moved beyond random controlled trials and included other research designs.”

**WHAT MAKES FOR A QUALITY OBSERVATIONAL STUDY?**

QuintilesIMS and the National Pharmaceutical Council are leading the Good ReseArch for Comparative Effective (GRACE) initiative. The GRACE checklist poses 11 questions to ask about an observational trial that shed some light on whether it is a high-quality study.

1. Were treatment and/or important details of treatment exposure adequately recorded for the study purpose in the data source(s)?
2. Were the primary outcomes adequately recorded for the study purpose (e.g., available in sufficient detail through data source(s))? 
3. Was the primary clinical outcome(s) measured objectively rather than subject to clinical judgment (e.g., opinion about whether the patient’s condition has improved)?
4. Were primary outcomes validated, adjudicated, or otherwise known to be valid in a similar population?
5. Was the primary outcome(s) measured or identified in an equivalent manner between the treatment/intervention group and the comparison group(s)?
6. Were important covariates that may be known confounders or effect modifiers available and recorded?
7. Was the study (or analysis) population restricted to new initiators of treatment or those starting a new course of treatment?
8. If one or more comparison groups were used, were they concurrent comparators? If not, did the authors justify the use of historical comparison group(s)?
9. Were important covariates, confounding and effect modifying variables taken into account in the design and/or analysis?
10. Is the classification of exposed and unexposed person-time free of “immortal time bias”?
11. Were any meaningful analyses conducted to test key assumptions on which primary results are based?
Real-world evidence (RWE) is the hot topic this year, a way to evaluate treatments—and make changes on the fly, if necessary—under a new president who thinks the FDA moves too slowly. Put simply, RWE looks at how well new medications and medical devices do after they’ve hit the market, relying on data collected outside of traditional clinical studies.

Many drugs often don’t do well, said Shalilja Dixit, one of the presenters at a recent conference in Philadelphia by EyeforPharma, a worldwide company that seeks to keep the pharmaceutical industry relevant by tracking shifting trends. Dixit, who studies health outcomes for Intercept Pharmaceuticals, said that 49% of drugs do not have the same impact on outcomes that they had in clinical trials. She believes that using real-world evidence can bring that up to 60% to 70%.

21st Century Cures Act

Congress seems to think so as well, as RWE plays a prominent role in the 21st Century Cures Act that passed last month with broad bipartisan support. One of the things Cures would allow is for drug companies to submit various sorts of data to the FDA for use in approving additional uses of medicines, as well as for any follow-up indications for drugs. (See the box below.)

“Treatment patterns and adherence, that’s where real-world evidence really shines,” Thompson said. In some clinical areas, such as diabetes, RWE has already been a “game-changer.”

But not so much of a game-changer that health plans are ready to jump in with both feet. “Payers have a pessimistic view that real-world evidence can help them,” Kelly said at the conference. “Payers have indicated that the most important benefit of real-world evidence for them is better understanding of the cost implications.”

It doesn’t help that respected voices in health care have raised doubts about RWE, at least as it might be utilized under the Cures Act. Reshma Ramachandran, MD, of Johns Hopkins Bloomberg School of Public Health, and Zackary Berger, MD, an assistant professor of medicine at the Johns Hopkins School of Medicine, argued in an opinion piece in STAT that the new law weakens the idea of “FDA approved.” They

**FDA DEFINES REAL-WORLD EVIDENCE**

In an article in the New England Journal of Medicine, several FDA officials, including Commissioner Robert Califf, called the term “elusive.” The evidence comes from many different sources, including claims and billing records, electronic health records, product and disease registries, and personal health devices. In September, the FDA issued draft guidelines for real-world evidence for medical devices that included this definition:

› Real-World Data (RWD) are data collected from sources outside of traditional clinical trials. These sources may include large simple trials, or pragmatic clinical trials, prospective observational or registry studies, retrospective database studies, case reports, administrative and health care claims, electronic health records, data obtained as part of a public health investigation or routine public health surveillance, and registries (e.g., device, procedural, or disease registries). The data is typically derived from electronic systems used in health care delivery, data contained within medical devices, and/or in tracking patient experience during care, including in home-use settings.”

By Frank Diamond
Managing Editor
worry that new drugs would be approved for unmet medical needs without having been tested in specific patient populations. In addition, new medical devices could be "approved based on anecdotal case studies or reports in medical journals, rather than having to be held to the gold standard of testing in clinical trials. On top of that, manufacturers would be able to make changes to these high-risk devices without any FDA oversight."

Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research (CDER), says she’s ready to work to implement the Cures Act, but about RWE, she has some doubts. She joked at a meeting of the Regulatory Affairs Professional Society that “data gathered from health care has always had one characteristic—it’s not very good.”

Wary health plans
There are also doubts on the front lines. Payers question whether RWE captures everything that’s happening with a patient. There are reasons other than therapeutic effectiveness that some medications don’t work (i.e., lack of adherence).

In an email exchange with Managed Care, Kelly cited some of the challenges of wide-spread adoption of real-world evidence. "Real-world evidence is often rejected by real-world payers," Kelly said. "Every insurance plan believes that their plan is unique to other insurance companies. Their population’s treatment circumstances are highly unique."

Kelly said that there should be an exchange of information between health plans undertaking RWE, to gather data on specific clinical and economic issues all payers face and come up with collaborative approaches. We’re a long way from that, though.

But first steps are being taken as some health plans start to use RWE. Kelly mentioned Geisinger Health Plan in particular as having a keen interest.

Would Geisinger rely on RWE gathered nationally? “No,” says Mike Evans, the health plan’s associate vice president for strategy and innovation. “We have to show it in our system, for our patients. Our ethnicity, our social determinants of health are different.”

Thompson agrees. “In terms of a national compendium database—we may never get there,” he says. “There are too many dimensions to consider with the various therapeutic areas, patient segments, and care settings.”

Health plans should have no trouble gathering their own RWE, Thompson says. “The issue is that some health plans tend to reject real-world evidence from outside if it’s not from their plan population. It’s typically deemed irrelevant.”

Integrated systems
Still, integrated delivery systems, such as Geisinger, are fertile ground for RWE. “We’ll look at the literature, absolutely,” says Evans. “We’ll look at national guidelines on that disease state. But then, we’ll also do a data dive, and we’ll look at what’s happening in our health delivery network clinically, and also what we’re seeing on claims data.”

Geisinger compares what its clinicians are actually seeing to what the clinical trials for a medication or product promised. It also compares that to national guidelines. “We say data mining, right?” says Evans. “If we don’t bury the data, we don’t need to mine for it.” Continuous feedback is the mechanism through which RWE functions, says Evans.

RWE as practiced by Geisinger, takes a comprehensive approach, says Evans. “We’ll look at everything that’s involved in that disease state,” he says, including medications, durable medical equipment, procedures, and prior authorizations.

In addition, whether care is delivered in a hospital, clinic, physician’s office, or home. “We compare the efficacies of the different therapies for that disease state in different settings. It’s looking at the real world, what’s really happening for that patient with the disease.”

Total cost of care
Jamie Dodson, Geisinger’s director of pharmacy service, says being an integrated system allows the plan to look at the claims data and the medical data. “We understand that by possibly increasing cost on the drug side, that we’re offsetting cost on the medical side. We’re looking at total cost of care for the patient. What it comes down to is real-world design and seeing those drugs are doing exactly what we thought they would do.”

Evans doubts that RWE can take root in health systems that are not integrated. “They do not have the capability to combine the clinical data with the claims data, are inefficient, and on the cost of their care delivery mechanisms, they are going to continue to increase at an exponential rate that will not be able to be supported or maintained.”

Welcome to the real world. 

"We compare the efficacies of the different therapies for a disease state in different settings. It’s looking at the real world, what’s really happening for that patient with the disease," says Mike Evans of Geisinger.
Real-world Evidence and the ‘Unsticking’ of Health Care Data

By Ramita Tandon

Perhaps no other human enterprise is as dependent on the gathering and analysis of data as health care. Almost every encounter with the health care system—even a basic well visit—begins with a round of information-gathering: a blood pressure reading, a check of the pulse, weight, height, some blood work most likely. And if you are diagnosed with a health condition, the freshets of information become torrents as the calendar fills with appointments and imaging tests, more blood work, and a slew of other tests.

That is just the clinical side of health care for a single patient. Now consider all the data generated by health care research. In late December, when I checked the database of clinical trials maintained by NIH, ClinicalTrials.gov, it included 232,733 clinical trials being conducted in 195 countries with 40,421 of them still recruiting subjects. Now factor in all the different endpoints those trials are measuring. It is mind boggling, the sheer volume of information.

But in health care, we have another problem besides the amount of data and making sense of it. Our data is sticky. It is captured close to where it is originated, tends to stay there, and doesn't get shared—even when doing so would benefit patients, providers, and payers.

Sticky evidence

Real-world evidence could be what we need to unstick health care data.

There's some confusion about real-world evidence because people use the term in different ways. It is best understood as health care information that comes from sources other than clinical trials, especially randomized controlled trials (RCTs). Those sources include, of course, electronic health records and claims data, but also disease and product registries and, increasingly, apps and social media.

Ideally, real-world evidence would be continually looped back into the drug development process. There is a deep reservoir of information about side effects, adherence, and differences in efficacy among subpopulations embedded in the various sources of real-world evidence. That information could do a lot to improve the expensive, time-consuming way we test and research drugs. Real-world evidence can yield early signs about a drug’s efficacy and safety. Structured collection of adverse events can flag problems and supplement data from RCTs. Regular infusions of real-world evidence into research and development could do a lot to improve the way RCTs are conducted. Traditional endpoints, such as the six-minute walk test, may not reflect a treatment's true benefit in the day-to-day life of patients. Data collected from a wearable activity tracker might.

Payers are also interested in seeing robust real-world evidence developed. Data from RCTs can't answer all of their value-based questions about side effects, cost, and effectiveness. Indeed, about two thirds of drugs fail to meet revenue expectations during the first year, partly because the data used for FDA approval often isn't persuasive enough to put a new drug on a formulary. A research model that incorporates real-world evidence can ease the concerns of payers by providing early insights into a drug's or device's performance.

A new gold standard

But concerns that real-world evidence is lowering the evidence for safety and efficacy should be addressed. More clarity from regulators will help, and the 21st Century Cures Act should make that happen. The law says the FDA, in consultation with other stakeholders, must implement a framework for real-world evidence within two years and draft guidance about acceptable standards and methods within five years. But it is also up to pharma, to CROs—to everyone involved—to set high standards for the kind of data and studies that will be acceptable in real-world evidence research.

Some commentators have positioned real-world evidence as undercutting RCTs as the gold standard for proving efficacy and safety. But there's no reason that we can't make the data and techniques used in real-world evidence studies just as rigorous and establish a new gold standard.

Ramita Tandon is executive vice president of commercialization and outcomes for ICON Plc. ICON Plc owns Managed Care.
People are funny about their stools. We all pass solid waste on a regular (or for some, an irregular) basis. This waste is comprised of leftover food material (fiber!) as well as numerous types of bacteria—literally billions of bacteria, and they are the cause of the rather distinct odor of our stool. We joke with new parents about the perils of diaper duty, and most of them look forward to the days when their babies acquire the bowel control of toddlers. Children get a kick out of bathroom jokes but adults dance around the subject and come up with different names for it. In my research for this article I was graced to find over 100 slang terms for diarrhea ranging from “the trots” to “the runs” to the “GIs”—and it deteriorated rapidly from there.

In this country, the vast majority of diarrheal illness is viral in origin and not severe enough to require the intervention of a physician. It’s unpleasant and possibly embarrassing but, basically, just an inconvenience.

But some cases of acute diarrheal illness can deteriorate into a life-or-death situation. One in particular, *Clostridium difficile* infection, is associated with the use of antibiotics. *C. diff*, as it is often called, has become a major scourge of American hospitals and nursing homes. *Clostridium difficile* is not a newcomer to the human GI tract. John Finney and Sir William Osler at Johns Hopkins Hospital described what was likely *C. difficile* infection in 1892. The actual organism was first described about 80 years ago as obligate anaerobic, gram-positive, spore forming, and rod-shaped after being isolated from the intestinal tract of healthy newborns. It was deemed harmless. But because it was tricky to grow, it was named *Bacillus difficilis* before the scientists settled on *Clostridium difficile*. There are numerous strains, some of which produce potentially deadly toxins.

*C. diff*’s innocuous reputation changed after the development and widespread use of antibiotics in the 1940s. Researchers believe that we are protected against pathogenic organisms by the competitive balance among the trillions of bacteria that colonize the gut. When the makeup of the different kinds of bacteria changes and that balance is thrown off, pathogenic bacteria can become dominant, resulting in the symptoms associated with what is then termed a *C. difficile* infection. Antibiotics can wreak havoc in the gut and throw the population of bacteria completely out of whack. The risk of a *C. difficile* infection isn’t limited to when people are taking antibiotics. It remains elevated months after they stop taking them while the gut bacteria are still recovering. Moreover, the problem isn’t limited to just a few antibiotics that physicians...
might avoid prescribing. Nearly all antibiotics have been associated with the development of C. difficile infections.

Currently, C. difficile is now the major cause of antibiotic-associated diarrhea and is responsible for about 1 in every 4 cases. During the last decade and a half, the incidence has increased manifold. Moreover, a previously rare hypervirulent strain, called ribotype 027 (one of several), has now become endemic in many North American health care settings. The CDC reported in 2015 that nearly half a million people had suffered C. difficile infections the previous year, resulting in 15,000 deaths.

Several factors are at play that would worsen the C. difficile situation, including the aging of the American population and the growing use of potent immunosuppressive agents in the treatment of cancer and inflammatory disease.

**Deadly mischief**
The hypervirulent strains of C. difficile wield many weapons that can create potentially deadly mischief. It pumps out toxins A and B, and the toxins bind especially tightly to the target cells. Increased sporulation and mutations in the proteins lining the surface of the bacteria make it “sticky,” so it adheres to the intestinal lining. The toxins are important because they cause cell death, separation of the epithelial cells, increased vascular permeability, and hemorrhaging. As a result, the colon takes on a thin, membranous appearance, hence a descriptive diagnostic name of pseudomembranous colitis. Although toxin A was thought to be the most damaging, toxin B has recently been found to play an increasingly important role.

**Single IV dose**
The pharmaceutical industry has invested time and money into finding treatments for C. difficile. The obvious approach is to kill the actual bacteria. In 2011, the FDA approved a new antibiotic, fidaxomicin (Dificid), which does just that.

Another approach is to try to neutralize the toxins associated with C. difficile. Merck has recently received FDA approval for bezlotoxumab (Zinplava), a monoclonal antibody that binds to toxin B. It is approved as a treatment to reduce recurrence of C. difficile in patients 18 years of age or older who are receiving antibiotic treatment for the infection and for whom there is a high risk of recurrence. Because the antibodies have rather long half-lives, the Zinplava component of treatment consists of a single intravenous dose of 10 mg/kg over 60 minutes.

Of note, Zinplava does not actually treat the infection itself; it has no antibacterial properties and must therefore be used in conjunction with an antibiotic.

Zinplava was studied in two placebo-controlled phase 3 trials. The first enrolled 391 people and the second, 396. Patients received a single dose of Zinplava with concomitant standard care, which consisted of treatment with the antibiotics metronidazole, vancomycin or fidaxomicin. The endpoints included clinical cure, recurrence, and a combination of the two over time, termed sustained clinical response. Clinical cure was defined as no diarrhea for two consecutive days following the completion of 14 or more days of treatment with the antibiotic component of therapy. Sustained clinical response was defined as a clinical cure and no recurrence during the 12-week period following the therapy with Zinplava.

Overall, Zinplava improved the sustained clinical response from 55% to 60% in the first trial (dubbed Modify 1) and from 52% to 67% in the second (Modify 2). The clinical failure rates were similar when combining trials 1 and 2, and the recurrence was reduced by roughly 10% (absolute) in both trials.

Adverse events included an increase in heart failure (primarily in those with a history of congestive heart failure), which resulted in a warning. Other adverse events included a slight increase in nausea (7% vs. 5%), pyrexia (5% vs. 3%), headache (4% vs. 3%) and infusion reactions (10% vs. 8%).

Merck, which expects to launch Zinplava in the first quarter of 2017, has not set a price but it’s expected to be expensive.

Zinplava is a step forward in the efforts to combat C. diff. But it is hardly a panacea. The high price is more evidence that the country needs to come to grips with pharmaceutical expenditures. A search of www.ClinicalTrials.gov shows 253 different C. diff trials testing everything from probiotics to fecal transplant to vaccines against toxins A and B.

But C. diff is true to its origin and nothing if not difficult. We are only at the beginning of the beginning of the war against this nasty infectious disease. X&
Is Step Therapy a Move In the Wrong Direction?

Requiring some patients with chronic conditions to try and fail multiple medications leads to complications and drives up costs, say many physicians. Insurers answer that the trial-and-error approach can be an important way to rein in costs.

By Joseph Burns
Contributing Editor

n theory, step therapy makes perfect sense—from a health plan’s point of view. A physician starts a patient on the lowest-cost medication for the condition in question, and if the patient fails on that drug, the doctor tries the next most-expensive medication. If that doesn’t work, try the next one, and so on.

It’s not as simple as wash, rinse, and repeat. But prescribe, monitor, and re-prescribe as needed can be effective—for some patients and some conditions.

But while monitoring a patient on a low-cost medication, what happens if that waiting causes an acute exacerbation?

Here’s a tougher question: What if the physician knows that trying lower-cost medications is likely to fail, requiring surgery and driving up costs?

Of course, no insurer intends for its cost-control measures to send people with serious health conditions into decline. Indeed, some insurers and managed care experts say step therapy can have the benefit of protecting people from unwanted—and perhaps unknown—side effects from new, expensive medications, in addition to providing the best value.

The complaints about step therapy are a reflection of private insurers having two masters: members and employers that provide coverage for their workers and families, says Jaan Sidorov, MD, chief medical officer for medSolis, a health care consulting company and a member of Managed Care’s editorial advisory board. The members want the latest and greatest, to heck with the expense. Employers and insurers worry about costs. Step therapy does serve the purpose of controlling costs and perhaps avoiding problems caused by newer drugs, in his view. Still, when a managed care company—either a PBM or a conventional insurer—puts step therapy in place, doctors should advocate for their patients, he says. If health plans then insist on physicians using older, lower-cost drugs first, the burden is on the health plan to respond to physicians’ requests for different medications quickly, nimbly, and appropriately.

Step in the wrong direction

But quick and nimble do not often describe insurers’ step-therapy efforts. Just ask Eitan Kling-Levine. In 2014, Kling-Levine was a 22-year-old college student who failed on the first two medications required and within months he needed surgery to remove his colon.

In the fall of 2014, he was studying in Paris when what he thought was a bad case of diarrhea was diagnosed...
physicians, who want the latitude to treat their patients approvals. It is part of the never-ending struggle between one of the mother-may-I approaches to treatment ap-

For decades, health insurers have used step therapy as a key part of our prior authorization program” and that coverage decisions are based on scientific evidence.

Penny wise, pound foolish
For decades, health insurers have used step therapy as one of the mother–may–I approaches to treatment ap-

as ulcerative colitis. His condition was so severe he was forced to return home to Newton, Mass.

His gastroenterologist at Newton-Wellesley Hospital in suburban Boston prescribed vedolizumab (Entyvio), an infused biologic that the FDA approved in 2014 to reduce inflammation in the GI tract. The cost of one dose is more than $5,000 and patients typically need three doses in the first six weeks and then one dose every eight weeks. Kling-Levine had one infusion before his insurer, Blue Cross Blue Shield of Mass-

Unfortunately, some insurers use guidelines that may have been appropriate five to six or seven years ago but not necessarily in 2016,” says Matthew Hamilton, MD, of Massachusetts General Hospital.

each one, you commit your life for three to four months on one drug to see if it works,” says Kling-

Kling-Levine failed each of the lower-cost drugs before Massachusetts BCBS relented and said it had the evidence it needed to pay for Entyvio. But it was too late. He didn’t respond to 14 weeks of treatment with Entyvio. In August 2015, Kling-Levine was admitted to Massachusetts General Hospital for the first of three procedures called J-pouch surgery that involve removing the colon and rectum and reshaping the small intestine.

“It’s two organs they removed that people use every single day, every single moment of your life. Now, I’m totally relearning how my body works and physically getting back to life emotionally and mentally,” says Kling-Levine.

as they believe they should be treated and insurers seeking the lowest costs, Sidorov says. But as doctors increasingly prescribe high-priced biologic medi-

As a strategy, step therapy does not account for the complexity of each patient’s need, say physicians caring for patients with chronic conditions. Their objections tend to fall into three categories. First, step therapy is a classic, penny-wise and pound-foolish strategy, saving money in the short term but driving up costs over the long run. When doctors prescribe biologics, for instance, the costs usually are high initially but may be lower overall if patients stay healthier and avoid additional treatment and hospitalizations. Second, step therapy requires doctors to follow treatment protocols that are often outdated in an era when new therapies hit the market frequently and researchers continually report new findings. Finally, the communication between doctors and insurers that might allow for adjustments and exceptions that would make step therapy less onerous is often slow, kludgy, and poorly managed.

Kling-Levine’s case is an example of how step therapy exacerbated a patient’s condition, says Matthew Hamilton, MD, a gastroenterologist and researcher at Brigham and Women’s Hospital and chair of the medical advisory board for the Crohn’s and Colitis Foundation of America, New England Chapter. In this case and in others, he says, health insurers seem to use twisted logic to focus exclusively on immediate costs.

“If we get a patient on the best, most effective treat-

ment early, that will actually save money because we’ll reduce other costs down the road,” says Hamil-

ton, who is familiar with Kling-Levine’s case but was not his doctor. In Hamilton’s opinion, Kling-Levine would have fared better if he had first been treated with Entyvio.

“We appreciate that biologic medicines are ex-

pensive and that the upfront cost is probably more than insurers normally spend on older medications,” Hamilton comments. “But the biologic medicines have a much higher chance of getting the patient into remission so that you can avoid the complications, the emergency room visits, the hospitalizations, and the need for surgery.” In addition, Hamilton says, there’s a sad irony behind step therapy when insurers require physicians to follow evidence-based protocols but the evidence they use for the basis of their step therapy protocols is dated. “As physicians, we have a good handle on the up-to-date research, and our guidelines reflect that research about which medications to use for which individuals,” he explains. “Unfortunately, some insurers use guidelines that may have been appropriate five to six or seven years ago but not

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necessarily in 2016.”

Severe colitis is an example, says Hamilton. “Our research and clinical experience at the BWH Crohn’s and Colitis Center shows that early in the treatment, we should be very aggressive with medications right from the start,” he explains. “However, insurance companies say, ‘No, you have to go through X, Y, and Z medications before you even get to the more aggressive medications.’ It is completely counterintuitive and not in line with current professional society guidelines for how we should treat moderate and severe colitis.”

Sidorov counters that many new medications come with added hype because pharmaceutical companies promote them as potential miracle cures. “I would argue that many times step therapy has protected consumers from new drugs with unknown side effects,” says Sidorov. “Often a newly released drug will have a lot of marketing behind it so that doctors start prescribing it because it looks like a wonder drug.” But prescribing an older, lower-cost medication known to have fewer side effects might, in fact, be best for the patient, he says.

As in Kling-Levine’s case, physicians treating patients with Crohn’s and ulcerative colitis face problems getting approvals because insurers are unfamiliar with the nuances of how biologics work, says David Rubin, MD, gastroenterology section chief at the University of Chicago Medicine. As happened to Kling-Levine, stopping one to start another can be counterproductive.

“With biological medications, there’s a consequence of interrupting therapy because they are protein-based,” Rubin explains. “If there’s a gap in treatment delivery because you start it but then need to reauthorize it and you can’t get it back, that gap will put the patient at risk for development of anti-drug antibodies. Those antibodies neutralize the therapy, meaning the drug doesn’t work anymore.”

In other words, biologics come with built-in complications that require close communication with insurers, a process that is often cumbersome, wastes time, and delays treatment, Rubin says.

Insurers should heed Rubin’s complaint about communication, says Sidorov. Too frequently, insurers fail to explain their step-therapy protocols to prescribing physicians, frustrating doctors and patients, he says.

Getting insurers to approve a medication he recommends usually requires a series of calls, voice mail messages that go unreturned, or a time frame for appeal that is too short, Rubin says. “Those types of things are completely unacceptable,” he comments. “Insurers have to provide appropriate and timely feedback and an appropriate and timely mechanism for communication and explanations of denials or appeals.”

**ANOTHER WAY TO CONTROL COSTS**

Another strategy that managed care plans use to control infusion-therapy costs is to have patients get infusion treatments at home.

To manage costs, insurers have moved patients needing infusions out of the hospital into infusion centers, says David Rubin, MD, a gastroenterologist at the University of Chicago Medicine. “But even more recently, they don’t want patients to receive it in infusion centers and so they’re requiring patients to get infusion therapy at home,” he adds.

Home infusions may not be as safe as the more costly settings, Rubin explains, because some medications come with an increased risk of anaphylaxis, an acute condition difficult to manage in a home setting.

“You can have an immediate hypersensitivity reaction, which is similar to an allergic reaction, to the drug. And if you develop that reaction, then you are at risk for very serious complications,” he says. Allergic drug reactions occur in between 5% and 10% of all patients. Some home-health agencies don’t train their staff to address such complications properly, Rubin asserts.

“I understand the dilemma that insurance companies face. They have limited resources and these are very expensive treatments,” he says. Therefore, he suggests that health insurers conduct comparative effectiveness trials to identify which therapy should be used for which patients and to identify the most appropriate settings for infused medications. “If they want in-home infusions and there’s a lack of evidence showing it’s safe, why don’t they just collect the evidence they need?” he asks. “Then they’d be in the business of helping us decide which is the most appropriate way to treat these patients.”

Stephanie Vomvouras, MD, vice president and CMO for Blue Cross and Blue Shield of Illinois, responds that her organization does not require any member to get home infusions. “We promote the use of professional providers and services in a number of settings that will allow patients to receive the appropriate level of care,” she says. In many cases, though, the hospital is not the best choice especially if a patient is receiving infusion therapy chronically and doesn’t have a history of complications, including allergic reactions, to IV medications, says Vomvouras. Members can choose the most convenient site, including a physician’s office, a clinic, ambulatory infusion centers, or home infusion, she adds.

At UnitedHealthcare, members prescribed an infused biologic therapy for Crohn’s and colitis would start treatment in an outpatient setting and are not required to get their infusion therapy administered at home, says spokesman Richard Daryl. “But the home is UnitedHealthcare’s preferred site of care given the convenience and flexibility it provides the individual and lower overall cost,” he adds. Home-infusion costs can be as much as a third lower when compared with costs in an outpatient hospital setting, he adds.
Some insurers, such as UnitedHealthcare and Blue Cross Blue Shield of Illinois, respond quickly and often approve medications that Rubin recommends whereas other health insurers can’t be swayed, he adds.

More data needed
Health insurers struggle to make effective choices about step therapy because they often lack the information needed to make informed decisions, says Paul Von Ebers, a consultant with Prospective Health LLC in Fargo, N.D. “The problem insurers face is they don’t know which patients need higher-cost medications and which patients would do well with lower-cost drugs,” he comments. Health plans would prefer to have such data to show who would benefit and who wouldn’t, says Von Ebers, a former CEO for BCBS of Dakota.

Stephanie Vomvouras, MD, vice president and CMO for BCBSIL, says that more communication with physicians is needed in part because the cost of all infused medications is rising sharply. Spending for specialty drugs has risen 15% to 20% annually and the cost of medications for some autoimmune conditions has risen more than 30% in two years, she says. “This trend is expected to continue for the next several years,” she adds.

For UnitedHealthcare, spokesman Richard P. Daryl said, “Greater collaboration and information sharing with care providers is critical at a time when demands are growing on our health care system and people want more options in how to access care in their community.”

Von Ebers concurs that information sharing is critical because some new drugs and biologics produce relatively weak outcomes. Yet a medication that results in a small improvement for most patients may yield a large improvement for a few patients, says Von Ebers, a consultant with Prospective Health LLC.

“A medication that results in a small improvement for most patients may yield a large improvement for a few patients,” says Paul Von Ebers, a consultant with Prospective Health LLC.

Von Ebers agrees, saying health insurers hear most often from patients who complain about rising costs. “Some new drugs are so expensive that it is impossible for an insurance company to charge a high enough premium to cover the cost, so the insurer spreads the cost across all customers,” he says. “For every individual patient who complains that the insurer did not immediately approve a new treatment, there are literally five or more asking, ‘Why does my insurance cost so much when I hardly ever use it?’”

Both Von Ebers and Sidorov make similar points about insurers balancing costs and quality and how the exception to the rule often gets the most attention. “For every patient with a heartbreaking story about how step therapy failed, there are many, many other patients who benefited from step therapy, but we never hear from those people,” Sidorov says.

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Sidorov suggests. Doing so just raises more difficult-to-answer questions.

Von Ebers says step therapy brings into focus the built-in problem with health insurance: It must balance the high-cost interests of the 20% of customers who use 80% of its services against the 80% of customers who use only 20% of services and want low premiums and low out-of-pocket expenses for the services they do use. “It’s no wonder that both groups believe health insurance is failing them,” says Von Ebers.

Some states (Connecticut, Kentucky, Louisiana, Maryland, Mississippi, and Washington) have such laws in place and 15 were considering such legislation.

Benson’s bill would not override a health insurer’s policies, she says, but would allow doctors to better advocate for their patients. She says it is “a reasonable compromise to make sure that the patients who have serious complicated conditions can access the medications they need.” The bill did not pass last year, but Benson, a Democrat, said she would introduce it again this month.

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Health insurers shouldn’t discuss their step therapy programs in the press or any public setting, Sidorov suggests. Doing so just raises more difficult-to-answer questions.

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“Whosoever desires constant success must change his conduct with the times.”

Niccolo Machiavelli

FOR MORE INFORMATION, PLEASE CONTACT LEYANA DACCACHE AT: leyanad@marcusevanscy.com or call +357 22 849397
Health Information Technology: Dos and Don’ts for Today and Tomorrow

The challenges include not overburdening physicians and fitting into an increasingly complex, multilayered informatics ecosystem. Artificial intelligence is a work in progress, but early adopters of gamification could get ahead of their competition.

By Jaan Sidorov, MD, and Akash Randhar

While advocates of health information technology (HIT) emphasize its role in achieving the Triple Aim of lower cost, improved health, and better care (Berwick 2008, Sheikh 2015), insurers and providers are increasingly asking just how HIT translates into greater business efficiencies, better clinical outcomes, and enhanced customer loyalty.

Thanks to the rapid pace of change in HIT, the moving targets of health reform, and the particularities of local health care delivery, “it depends” is really the best answer. However, that doesn’t mean there aren’t some lessons from HIT implementation so far that can be applied across many settings.

In our roles as founders of a health tech company, we’ve observed a number of trends that may inform the collaboration between HIT service providers and buyers. Below, we offer some insights and practical suggestions about HIT and its relationship to evidence-based medicine, clinical workflows, physicians, cost savings, and big data. We also look at the future, sounding a note of caution about whether artificial intelligence will not be ready for widespread adoption any time soon while expressing optimism about the potential for gamification to improve patient engagement.

Today

Evidence-based vs. innovative. While businesses in every economic sector conduct research, health care’s large investment in evidence-based medicine is noteworthy. History, training, and culture have led generations of physicians, health services researchers, academics, and regulators to routinely apply considerable scientific scrutiny as well as skepticism to reports of new diagnostics or treatments. It’s no surprise, then, as providers, insurers, vendors, pharma, and other stakeholders compete for market share, claims of new HIT-based innovations continue to prompt old questions on whether the underlying data are tainted by bias, poor design, limited generalizability, questionable effectiveness, and unknown or unintended long-term effects.

To the frustration of investors and management teams, the pace and proprietary nature of much innovation in HIT is ill-suited to the pace of traditional peer review. Fortunately, the number of biomedical publishers has expanded, and many have expedited their review process and offer online publication. Two telling examples of the risk of failing to take advantage of this are lab provider Theranos and some direct-to-consumer skin care smartphone apps, which rushed to market with little peer-reviewed evidence to back up their claims (Ioannidis 2016, Resneck 2016).

As a result, HIT service providers and their customers should routinely contemplate investing in gathering, interpreting, and reporting their impact on Triple Aim-based outcomes with every customer in a peer-reviewed forum. Innovative health care entities that neglect health care’s reliance on evidence-based medicine and go to market without the benefit of any peer review do so at their peril. While time-consuming and expensive, promotion without accompanying proof can ultimately be far more costly.

This isn’t to say that a fast pace of innovation is bad for the health care industry. However, a careful consideration of the scope of “rollouts” and design of supporting studies can achieve getting the latest in the market quickly while verifying that it is, indeed, the greatest based on well-designed studies. Moreover, as health care evolves so individuals can make treatment
choices based on quality, price, and convenience, researchers can adopt some of the practices used in the retail industry, such as quick parallel studies, to develop evidence that has traditionally come from randomized trials, observational studies, and case series.

The expedient adoption of health technology can be additive, not substitutive. Absent modification of existing job descriptions or workflows, frontline employees who are asked to adopt new technology will have to grapple with additional roles, new policies, unfamiliar procedures, extra oversight, and unforeseen problems. For them, the addition of more HIT—no matter how innovative it might be—inevitably leads to more work. Absent the concurrent assignment of incumbent low-value duties to machines or the dustbin, layering more HIT on top of a group of busy employees turns them into even busier employees. The introduction of HIT often means copying and pasting across multiple applications scattered across two or more devices rather than added efficiency.

Outside the travails of the electronic health record (Mandl 2012), this additive downside to HIT has gone largely unexamined in the peer-reviewed medical literature. Other reports describing this problem have noted the importance of obtaining frontline worker input and fostering collaboration across multiple vendors (Perna 2014). In our experience, importing an HIT solution also should serve as an opportunity to review which legacy tasks can be modified or discarded. Buyers also should be wary of “middleware” and quick fixes, which tend to add complexity over the long term. Instead, they should consider implementing staged rollouts of HIT-based innovations using a plan-execute-evaluate-adjust (“PLEXEVA”) strategy.

Additive work often happens when new technology is not accompanied by adoption of the new ways of doing things by the end users of the technology. Without those changes, the promise of technology will often go unrealized. For a health care organization, that can mean wasted time, money, and employee goodwill.

Whither physicians? While physicians have seen their roles expanded to leading a team of providers overseeing complex care episodes, their expertise remains diagnosis and treatment. Yet, as health reform continues, physicians also are being relied on to fix its unintended consequences. Counting on physicians to make up for the shortcomings of the electronic health record should serve as a warning as HIT’s role expands. Some systems ask doctors to identify the inevitable false-positives of risk-stratification algorithms and repeatedly embed blanket “talk to your health care provider” disclaimers in multiple patient or beneficiary interactions. Buyers and vendors instead should seek technology solutions that facilitate the functioning of the health care team by matching, when possible, any necessary human oversight to the appropriate level of non-physician expertise.

Grappling with insurance risk-transfer. One value proposition for HIT includes the reduction of avoidable health care utilization or costs. However, successfully decreasing claims expense often translates to a combination of 1) a very real loss of provider revenue, and 2) an abstract calculation avoiding health care utilization. Both are reduced further by the direct and indirect costs of HIT’s associated personnel and capital. As the art and science of shared-risk arrangements continue, it should be recognized that as the parallel role of HIT expands, gauging just how it “bends the cost curve” involves multiple care settings and has wide confidence intervals (Asch 2016).

To effectively navigate this challenge, both HIT providers and customers need to account for the health burden of the insured population being served, the impact of social determinants, baseline expenses, insurance claims trends, background cost inflation, and local provider network performance. Without this knowledge, calculations of the economic value of a particular HIT-based innovation in a particular setting for a particular population may not be a question that can be precisely answered.

The irony of less is more. Health care correlations derived from the analysis of huge, multisource datasets need to not only render meaningful insights, but be accompanied by actionable opportunities that can be scaled to available resources. In other words, the “big” of “big data” needs to be boiled down to a manageable number of achievable interventions for a manageable number of patients. For example, while the clinical issues and social determinants underlying an increased risk of rehospitalization have been the subject of considerable research, far less is known about prioritizing and modifying these determinants so that the few patients who are most likely to benefit are selected for the right intervention.

As population health and care management spreads to more and more consumers, the value proposition of HIT will include access to insights that give the greatest impact on cost and clinical outcomes. Once that is achieved, the experience can inform additional interventions for additional numbers of patients in a virtuous cycle of continuous improvement.

The ecosystem and gadgetry. Early versions of HIT were single source, end-to-end, and complex. This has
given way to a networked and decentralized array of smaller and interchangeable billing, claims, health record, laboratory, imaging, data warehousing, and analytics components (Surviving 2016). As a result, health care’s chief technology officers increasingly preside over complex “ecosystems” of local and remote software and hardware. As with other systems, the whole becomes greater than the sum of its parts. The growth of HIT means the merits of upgrading, swapping, or supplementing any part is dependent not only on their individual functionality, but also on their interdependent compatibility and synergy.

Given this reality, the incorporation of consumer apps and monitoring devices into the HIT ecosystem is less revolutionary than evolutionary. While the consumer allure is undeniable, the ultimate value proposition of these apps and gadgets will depend more on their ability to enhance the consumer and provider experience by supporting, for example, patient-centeredness and shared decision making (Moore 2006). Their potential in these and other areas of the Triple Aim has only just begun to be documented in the peer-reviewed literature. The health care app and device vendors that can prove they create value in this ecosystem will have a key competitive advantage.

Tomorrow
Humans plus health tech will still beat either alone. While artificial intelligence promises to completely outsource much complex decision-making to machines, the experience in many nonhealth care settings with established robotics is that computers plus human insight make for greater efficiency and effectiveness than either alone (Automation 2015). In addition, the art and science and associated cost management of health care delivery are still a matter of limited knowledge, insufficient evidence, myriad logic exceptions, and very human irrationality (Eichner 2010). While expedited access to scientific databases and the generation of potential diagnoses and treatments are well within reach, it remains unlikely that medical diagnostic and treatment guidelines will be translated into accurate computer code in the near future (Semigran 2016). The superiority of having live subject matter experts enter the HIT loop for even “simple” clinical tasks, such as giving dietary advice for the treatment of obesity (Ross 2016), suggests that for now, HIT will remain a decision support tool rather than a decision substitution tool.

This is not to say that the change to a more automated approach to management of diseases should be discouraged, but a note of caution about how implementation is warranted. Adopters of cutting-edge HIT should be skeptical about claims that we are on the cusp of HIT that is independent of any human oversight. If implemented prematurely, the result could be a limited menu of one-size-fits-all care options or a high frequency of exceptions. For now, the artificial intelligence version of “Dr. Watson” that is fully independent remains experimental. It is best to leave it in the labs of researchers or to your competitors.

The advent of gamification. Until now, mainstream efforts to improve diet, exercise, medication adherence, or provider appointments have had limited success (Dixon-Fyle 2010). Largely based on 1) educational appeals to improving personal health status or 2) using economic incentives to change behavior, the former has had a disappointing track record, while the latter have substantial cost and regulatory limitations.

Enter the alternative of health care “gamification,” in which consumers pursue healthful behaviors by competing for noneconomic and symbolic awards. This is emerging as a surprisingly effective tool in motivating behavior change, and its science is still evolving. The phenomenon of millions of Pokémon Go users increasing their physical activity levels in the pursuit of virtual avatars is just the latest, if very public, example of the potential low-cost synergies of gamification and HIT (Althoff 2016).

Gamification has been the subject of a considerable amount of applied research (King 2013) and, in contrast to artificial intelligence, may be ready for adoption in many health care settings. Once this tipping point is achieved, the disruptive technologies that support gamification for health promotion and disease management are likely to transform patient education and engagement. As a result, we predict early adopters will have a competitive advantage.

Summary
As HIT service providers rush to provide innovative solutions in the health care marketplace, they will need to manage multiple challenges all at once. They and their customers will need to meet the expectations of evidence-based medicine, deliver on the substitutive promises of innovation, avoid burdening physicians with additional tasks, grapple with risk-transfer calculations, leverage big data in the service of achievable outcomes, and serve as one of many components of an informatics ecosystem that also includes patient apps and gadgetry. While artificial intelligence holds great promise, the even greater complexity of health care decision making means its adoption is likely to be delayed for several years. In the meantime, the limitations of traditional education and incentives and the surprising appeal of handheld games makes “gamification” the next frontier of consumer engagement. HIT vendors and customers that succeed in
these key areas will be the most likely to succeed in achieving the Triple Aim. 

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References


Send us your views and your news! Here is our 2017 editorial calendar.

If you have a related insight, article, program, or policy—we are interested. Contact MANAGED CARE’s editor, Peter Wehrwein, at pwehrwein@medimedia.com.

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Our 3rd annual Year in Preview
RAPIVAB™ (peramivir injection), for intravenous use
Initial U.S. Approval: 2014

BRIEF SUMMARY OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use RAPIVAB safely and effectively. See full prescribing information for RAPIVAB.

---INDICATIONS AND USAGE---
RAPIVAB is an influenza virus neuraminidase inhibitor indicated for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days.

Limitations of Use:
- Efficacy based on clinical trials in which the predominant influenza virus type was influenza A; a limited number of subjects infected with influenza B virus were enrolled.
- Consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use.
- Efficacy could not be established in patients with serious influenza requiring hospitalization.

---DOSAGE AND ADMINISTRATION---
- Administer as a single dose within 2 days of onset of influenza symptoms.
- Recommended dose is 600 mg, administered by intravenous infusion for a minimum of 15 minutes.
- Renal Impairment: Recommended dose for patients with creatinine clearance 30-49 mL/min is 200 mg and the recommended dose for patients with creatinine clearance 10-29 mL/min is 100 mg.
- Hemodialysis: Administer after dialysis.
- RAPIVAB must be diluted prior to administration.
- See the Full Prescribing Information for drug compatibility information.

---DOSAGE FORMS AND STRENGTHS---
Injection: 200 mg in 20 mL (10 mg/mL) in a single-use vial.

---CONTRAINDICATIONS---
Patients with known serious hypersensitivity or anaphylaxis to peramivir or any component of RAPIVAB.

---WARNINGS AND PRECAUTIONS---
- Cases of anaphylaxis and serious skin/hypersensitivity reactions such as Stevens-Johnson syndrome and erythema multiforme have occurred with RAPIVAB. Discontinue RAPIVAB and initiate appropriate treatment if anaphylaxis or serious skin reaction occurs or is suspected.
- Neuropsychiatric events: Patients with influenza may be at an increased risk of hallucinations, delirium and abnormal behavior early in their illness. Monitor for signs of abnormal behavior.

---ADVERSE REACTIONS---
Most common adverse reaction (incidence >2%) is diarrhea.

To report SUSPECTED ADVERSE REACTIONS, call 1-844-273-2327 or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

---DRUG INTERACTIONS---
Live attenuated influenza vaccine (LAIV), intranasal: Avoid use of LAIV within 2 weeks before or 48 hours after administration of RAPIVAB, unless medically indicated.

---USE IN SPECIFIC POPULATIONS---
- Pregnancy: Use if benefit outweighs risk.
- Nursing mothers: Caution should be exercised when administered to a nursing woman.

Revised: 8/2016
It only takes one dose to be treating the flu with Rapivab® (peramivir)™

The first and only full course of antiviral flu therapy in a single dose

- Only one 15- to 30-minute IV infusion required
- Treats acute uncomplicated influenza in patients 18+ who have been symptomatic for no more than 2 days
- Appropriate for many patients, including those who cannot tolerate or may be noncompliant with oral flu treatment and those requiring IV hydration
- Can be used with OTC supportive therapies

Go to www.rapivab.com to learn more and view full Prescribing Information.

Important Safety Information
Rapivab® (peramivir injection) is indicated for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than 2 days.

- Efficacy of Rapivab was based on clinical trials in which the predominant influenza virus type was influenza A; a limited number of subjects infected with influenza B virus were enrolled.
- Influenza viruses change over time. Emergence of resistance substitutions could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Rapivab.
- Efficacy could not be established in patients with serious influenza requiring hospitalization.

Contraindications
Rapivab is contraindicated in patients with known serious hypersensitivity or anaphylaxis to peramivir or any component of the product. Severe allergic reactions have included anaphylaxis, erythema multiforme, and Stevens-Johnson syndrome.

Warnings and Precautions
- Rare cases of serious skin reactions, including erythema multiforme, have been reported with Rapivab in clinical studies and in postmarketing experience. Cases of anaphylaxis and Stevens-Johnson syndrome have been reported in postmarketing experience with Rapivab. Discontinue Rapivab and institute appropriate treatment if anaphylaxis or a serious skin reaction occurs or is suspected. The use of Rapivab is contraindicated in patients with known serious hypersensitivity or anaphylaxis to Rapivab.
- Patients with influenza may be at an increased risk of hallucinations, delirium, and abnormal behavior early in their illness. There have been postmarketing reports (from Japan) of delirium and abnormal behavior leading to injury in patients with influenza who were receiving neuraminidase inhibitors, including Rapivab. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made, but they appear to be uncommon. These events were reported primarily among pediatric patients. The contribution of Rapivab to these events has not been established. Patients with influenza should be closely monitored for signs of abnormal behavior.

Adverse Reactions
The most common adverse reaction was diarrhea (8% Rapivab vs 7% placebo).

Lab abnormalities (incidence ≥ 2%) occurring more commonly with Rapivab than placebo were elevated ALT 2.5 times the upper limit of normal (3% vs 2%), elevated serum glucose greater than 160 mg/dL (5% vs 3%), elevated CPK at least 6 times the upper limit of normal (4% vs 2%) and neutrophils less than 1.0 x 10⁹/L (8% vs 6%).

Concurrent use with Live Attenuated Influenza Vaccine
Antiviral drugs may inhibit viral replication of a live attenuated influenza vaccine (LAIV). The concurrent use of Rapivab with LAIV intranasal has not been evaluated. Because of the potential for interference between these two products, avoid use of Rapivab within 2 weeks after or 48 hours before administration of LAIV unless medically indicated.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

References:

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