Roji News Roundup: Industry Insights from CEO Theresa Hush

written by Evelyn Herwitz | June 20, 2019

From women’s health care to the future of the Affordable Care

Act, Roji Health Intelligence CEO Terry Hush has shared her insights with numerous industry publications in recent months. Here's a sampling of current articles:

Value-based arrangements in ASCs — 3 quotes from an industry CEO

Becker's ASC Review | June 11, 2019

Terry's predictions, based on 25 years of industry experience, for what to expect for the future of risk-based agreements. Hint: Episodes of care and bundled payments will become increasingly important.

The Future of Healthcare: "Make tools available for women so that they can have a real voice in their health" with Terry Hush, CEO of Roji Health Intelligence

Thrive Global | May 4, 2019

In an interview with Christina D. Warner, Terry reflects on why it's essential for women to be active participants in their own health care in order to improve diagnoses and treatment of the unique symptoms and diseases of women. "Only by measuring and improving women's health can we create the foundation for improving health," she says. "But basically, women must drive this change to the finish line because their lives and quality of life is at stake."

What's driving healthcare prices? Not doctors

Medical Economics | April 22, 2019

Terry comments in this analysis of a new study that points to increased hospital prices as the primary reason why health care

costs are rising: “Increased hospital pricing reflects the greater negotiating power that consolidated hospital systems now have with insurance companies. Several studies of healthcare consolidation show that larger systems, rather than creating economies of scale, have driven costs up. Consolidation has increased investments in electronic records and medical technology, the acquisition of physician practices, and higher administrative costs.”

The Future of the ACA

Managed Healthcare Executive | April 12, 2019

In this roundup of industry and academic experts’ assessments of how challenges to the Affordable Care Act will affect people who would not otherwise have access to health insurance, Terry notes that the program has held up under considerable pressure to limit the law’s effectiveness: “It speaks to the demand of people to have healthcare in the U.S.”

Provider Nimbleness Required for Diverse Value-Based Healthcare Models

HFM Magazine | March 1, 2019

As Value-Based Health Care shifts to risk-based reimbursements, Terry outlines three essentials steps providers can take to respond effectively and provide health care of true value.

Aetna, Apple Team Up on Health-Tracking App: Experts React

Managed Healthcare Executive | February 5, 2019

Among five industry experts asked to assess the impact of Aetna

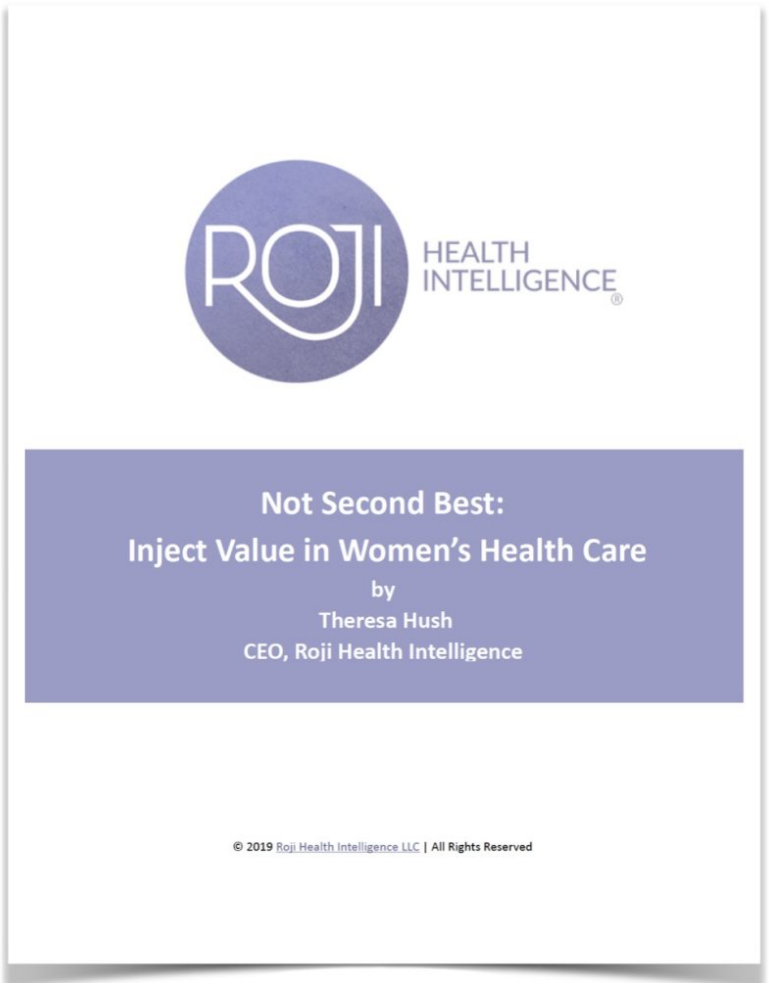
and Apple’s new Apple Watch app, Terry says Attain, which combines activity-driven incentives and rewards with personalized health recommendation, “provides a prized opportunity for Aetna to obtain member fitness data and interact with these members in a new way. Many covered patients will also find it rewarding. But, there’s no silver bullet, and there will be pushback from both providers and patients. The data will raise concerns about the validity of goals developed by the insurer without patient or their provider input.” She also notes that groups with social and financial barriers to meeting goals will view compliance efforts as penalties.

Founded as ICLOPS in 2002, Roji Health Intelligence guides health care systems, providers and patients on the path to better health through Solutions that help providers improve their value and succeed in Risk. Roji Health Intelligence is a CMS Qualified Clinical Data Registry.

Image: Jordan Heinrichs

Get the eBook “Not Second Best: Inject Value in Women’s Health Care”

written by Theresa Hush | June 20, 2019



Six months ago, I started writing about women's health, in response to this simple question: What trends are emerging in health care for 2019? The New Year is filled with predictions about what is coming, and I thought this year's list from health care leaders was too "last-year." Artificial intelligence, medical science advancements in biologicals and genetic therapies, and business consolidation are not coming; they are already here and will simply go further.

Witnessing the debate about health care rights in the country, and the increasing distrust of health care by consumers, I observed that most of those speaking are women. #MeToo started the same way, grabbing hold so that industry after industry had to pay attention. It occurred to me that, along with economic

issues that fall more seriously on women, the converging path of consumerism and #MeToo, combined with health care advocacy, presaged a strong movement for women's health care.

So I predicted that 2019 would be the year that women began a movement for improving their health care. It started a course of discovery that was, frankly, shocking. In a dozen articles I addressed many aspects of the health care problems that women face, where symptoms are dismissed or misunderstood, where treatments are delayed, where therapies are researched and appropriate for men and not women, where women don't have a voice in directing the focus of health care research and treatment despite their clinical or professional status.

Since then, I see the momentum building, and article after article published on issues of health care for women, women's cardiac risk, women's sky-high maternal death rate in this country.

We have compiled all of the articles of the women's health series into a free Roji Health Intelligence eBook for easy download and reading. Here's how to get your copy now.

The question in my mind is this: In a system that wants to move health care toward better value, how should women's health be taken into account? What should providers do to provide better care to women? What should women do to advocate for themselves?

This week, along with the victory of the U.S. women's soccer team, the equity pay issue was broadcast by major news stations. That wouldn't have happened prior to #MeToo. Now I hope that industry leaders and providers, along with women, can

make equity occur in health care.

Get your free copy of *Not Second Best: Inject Value in Women's Health Care*.

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Can Small PCPs Succeed in Medicare's Primary Care First?

written by Theresa Hush | June 20, 2019

Medicare's announced primary care models will provide an interesting test of whether financially-motivated primary care practices (PCPs) can improve hospital utilization, the key outcome measure that will determine provider revenues under the pilot.

While provider risk for costs of patient care is inevitable for most physicians in the future, providers don't have the same potential for financial success. That is especially true for PCPs, whose volume and roles in health care have been eclipsed by specialists and industry consolidation. Whether Value-Based Health Care can restore primary care to a central role of coordination—with the potential for cost reduction—is at the heart of Medicare's primary care models.

PCPs' capabilities to deliver coordinated, accountable care differ widely. Some PCPs still lack electronic health records, while others participate in advanced technology and models of care. The idealized notion that all primary care physicians can cultivate the capability to deliver customer service and engage patients in coordinated care—thereby preventing crises and expensive costs—is still largely theory. Furthermore, given that most health care now requires very specialized expertise that PCPs don't offer, we should consider whether small physician groups are the best target for testing the value of primary care .

Let's examine the issues by evaluating Medicare's new Primary Care First (PCF)model.

Primary Care First: Doable in Today's Consolidated Health Care Environment?

Primary Care First is targeted to small but sophisticated practices, with 24/7 availability to patients, experience in risk-based reimbursements, use of certified EHR technology, and participation in data exchange. Practices are reimbursed for patient care by a population-based payment plus a flat fee per patient visit. In addition, there is an upside incentive potential of 50 percent of revenues and downside risk of 10 percent of revenues based on performance, a proposition that is attractive enough to induce physicians to keep costs in check to participate.

The key central factor that determines final revenues for the PCF primary care practice is based on the HEDIS Acute Hospital Utilization measure, with an algorithm that compares expected-to-actual utilization. Performance that is better than the

algorithm results is rewarded by degrees of improved performance, and performance that is poorer results in reimbursement to CMS.

Other Non-PCP Providers Drive Acute Hospitalization Outcome Performance

Here's a key concept for primary care practices trying to make sense of how to manage their risk in PCF: expected-to-actual hospital utilization is a performance indicator, but this is not actionable data. It is simply a measurement tool that has been introduced in PCF to minimize results that could be overly focused on historical levels of utilization by the group, or existing in the geographical region. In order to actually achieve performance on this measure, the primary care group will need to focus on how hospital admissions occur and what affects their length of stay.

The goal of PCF is to promote primary care and return to a primary-care-focused system as a mechanism of cost control and better patient service. But the reality is that only 2 percent of Medicare services are classified as true primary care. The remainder are specialty services, facility care, and post-acute services.

The harsh reality is this: To succeed in controlling hospital utilization under PCF, primary care physicians must be able to affect costs that are beyond the scope of their own services to patients, and in fact are provided by other physicians. These are:

- Specialty physicians who admit patients, perform procedures, and direct the patients' care plan, and

Hospitalists who oversee the inpatient course of care.

Successful practices under risk in the past required patients to get prior authorization before accessing specialty services, a policy enforced by the patients' HMO benefit plans. PCF Primary Care Physicians won't have these options because they are not allowed by Medicare's prohibition against curtailing beneficiaries' open access to providers.

Primary Care Physicians Must Choose Specialists and Hospitals

With revenues at stake, PCPs cannot afford to depend on old relationships and friendships to guide referrals to specialists. They also can't afford to remove themselves from the decision-making process once a patient is admitted and managed by a hospitalist. They will need data that compares specialty provider efficiency, quality and volume.

Unfortunately, the PCF model depends entirely on the primary care paradigm to deliver excellence and efficiency, but does not provide the necessary tools for PCPs to establish referral arrangements that are driven by patient results. By failing to ensure that PCPs can exert prudent purchasing power in specialty and institutional services, CMS has embedded a significant shortcoming in PCF that could leave PCPs vulnerable to revenue losses.

That said, primary care practices of the status envisioned by Primary Care First are not without resources. PCPs can implement methods to evaluate costs and quality of specialists by creating referral agreements with stipulations. These should include provision of per-episode costs for comparison with

other groups, adherence to customer service and PCP communication standards prior to finalizing referral arrangements. Cost per episode is emerging as the most reasonable methodology for comparing costs and aligning with clinical pathways for specialty care.

Health care vendors are currently developing episode and bundled payment packages to help specialists accommodate to risk and market their services. These same services can be dual-facing to create data that PCPs will need to evaluate multiple specialists. Primaries and specialists will both benefit by shared data that can be used to coordinate care and help patients make wise and cost-effective medical decisions.

Primary care physicians must also reengage in the hospital experience, rather than leaving patients fully in the hands of hospitalists and specialists while in inpatient settings. They should feel empowered to choose their preferred hospital and communicate this to their patients, while preserving their choices. There has been a long-standing impasse between primary care physicians and hospitals over PCP notification of their patients' admissions. Now is a time that PCPs can wield influence through their patient referrals to achieve their goals.

PCPs May Achieve Goals, but Infrastructure and Data Are Needed

Primary Care First is a model that harkens to times when patients trusted their primary care physicians and the physician-patient relationship was life-long. That has largely disappeared and is unlikely to make a strong comeback. It doesn't mean that the model is impossible, only that it is

lacking specific tools to help primary care physicians exert influence over costs.

The agenda is ambitious for PCF and for primary care as a means of central communication and coordination. That is a good development in a care system that is too often on autopilot.

With strategies that align all providers in a common quest to lower cost and raise outcomes, PCF can develop into a structure that will support a central role for primary care, as well as financial risk.

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Image: “Doctor and nurse with patient at the clinic of the FSA (Farm Security Administration) and farm labor camp. Caldwell, Idaho.” June 1941. Library of Congress

Here’s One Way to Do Better Science

written by Robert McNutt, M.D. | June 20, 2019

Clinical research with randomized trials (RTs), as opposed to basic or bench research, is the science of *comparison*. RTs ask a fundamental question: Is “x” better than “y”? They do more than observe how treatments work; they also require methods that control the research environment. Finding an independent contribution of one action over another demands *random,*

stratified populations in order to find truthful differences, as medical care advances on these differences. But the way that patients are typically recruited for RTs can undercut the validity of the study's findings. I propose we take a different approach, one I call "Gallup Research Medicine."

Current Study Recruitment Is Far From Systematic

First, let's look at how patients are often recruited for study. Physicians, recruited by researchers, ask patients to participate in trials. Having watched many physicians recruit, I find they ask patients they think will participate, excluding others for unsure reasons. They rarely recruit in a systematic manner (randomly or consecutive sampling). Sometimes physicians are busy and recruit patients only when they are not inundated. Sometimes they abdicate the responsibility of recruiting to others in their office. Physicians might even be paid to include patients. I know of one physician, offered more than $5,000 per patient to enter two patients in a trial of a device in the intensive care unit (ICU), who daily scoured the ICU looking for the perfect patients to include, while bypassing eligible patients.

For all these reasons, physicians should not choose who is in a study; they have other things to do. Sometimes, researchers recruit patients by getting lists of patients from a physician and, each day, contacting those coming for a visit. But visits are not random events, and recruiters are not always available when patients are. So, even bypassing physician recruitment is not good enough; a better way to recruit is needed.

Gallup Polls Offer Insight into a Better Recruitment Strategy

Here is an alternative approach for recruiting and studying more representative samples of patients in RTs. A little background: In the 1990s, I attended a lecture showing a new idea for an electronic health record at Harvard. Their system at the time included about 90 sites of care. Each time a person accessed care at a site, they were flagged as having a visit, and the visit (event) was stored in an event database. The data in this event database only included person, place, time and a "pointer" from the event database to the result database at that site. For example, if I went to site X for a test, the test result was housed in X's database, but my visit event was sent to a separate database.

Were I to see a physician, then, my event database would be queried and data from disparate sites loaded to a health record interface. Had I visited ten sites, the data from those would populate my record. When I left the visit, the interface would disappear, my visit would head to the event database, and, separately, the results of that event would head for the site database.

Now, let's turn to Gallup polls. Gallup's methodology is based on a similar conceptual idea to the electronic record I saw decades ago. They have an "event database" and use that event data to point to and gather further data from each of those events. The events are telephone numbers. The "stored data" on the other end of the phone number is a person. On a daily basis, 350 days per year, Gallup calls, *randomly*, 500 phones and asks for information.

These two experiences—(1) a virtual electronic health record informed by data housed at different sources but collated by an event database, and (2) poll data from a random sample of an entire population but collated by an event database—are essentially the same idea and suggest a way to produce better RTs. If my event and site-specific data can be collated, and if Gallup can randomize from full populations, then all women with breast cancer or heart disease, all men with prostate cancer, or any person with any defined illness can, likewise, be enrolled in disease-specific event databases. Should a study be needed, a random sample of diseased people could be queried.

How "Gallup Research Medicine" Could Work

Here's an example. Suppose I am uncertain if the woman discussed in a previous blog with triple positive (ER/PR/HER2) breast cancer should get the expensive, dangerous anti-HER2 drug. To answer this question, I would query a breast cancer event database at every health care site, produce a *nationwide breast cancer event registry*, and then call a random sample of women in this registry and ask for permission to gather their data for a research study.

If a woman agreed, we could then collate *disease specific data*, run an exclusion/inclusion algorithm to limit the population to triple positive women, for example, thereby creating a random, full population sample for study. At each site, remember, the event database points to data such as receptor status, stage, genetic markers and other data measured on all women. A research team would determine what data is needed.

The barriers for this idea are not technical. While I am not a computer wiz, I might start with an event database of person,

place, time and disease condition. Alternatively, the event database could just be a disease, a pointer to the person, places, times of their care, and another pointer to the site data.

What about calling a random sample? Gallup calls 500 people daily, 350 days per year. This means they contact 175,000 people a year. I am unsure how many people make calls, but if this single company can contact so many, imagine how many people could be contacted with a coordinated effort from a government research agency, or multiple polling companies. To give some research context, 242,476 women developed breast cancer in 2015, (last year analyzed). Of these, about 25 percent are triple positive, or about 60,000. It would be a straightforward task to contact this number of people, either in full or as a random sample.

Government Has the Research Infrastructure to Lead Such an Effort

While this may not be difficult to organize, I suggest government should lead. Government has the infrastructure for research with rules for human subject research. They can encourage each hospital or electronic record company to keep disease-specific event databases. In fact, our government is presently incentivizing the sharing of data; this research effort could be a pilot project.

The leadership for research planning might be best organized at a regional level, however. A present research organization model with 60 sites in the US is Clinical and Translational Research Centers (CTRC). These centers have recruitment offices, study design expertise, and management teams that

could keep the collated disease registries, perhaps educate patients and providers, present updates on outcomes via transparent measures, and revise if needed as studies progress. In addition, Institutional Review Board considerations, informing patients of research intent, and ethical considerations could be managed at the CTRC sites, as they now have those activities up and running.

These ideas are not the only potential ways to advance larger sample, appropriately stratified research studies. The idea behind an event database with pointers to on-site data is to limit problems with data conversions between disparate systems of care. Two systems would not have to share the same data structures, needing only to send targeted research data from their sites using their own data teams.

However, the first production version of Fast Healthcare Interoperability Resources (HL7 FHIR®) just launched in 2018; HL7 FHIR standardizes the structure of data for sharing. Already, disparate sites of care are developing uniform ways to transfer data using this software. Apps for HL7 FHIR could, without event databases, run queries of data at all electronic record sites to build disease registries. I am sure there are other ideas, but every effort should be made to advance the science of the RT.

Imagine a future of research using random samples of full populations for study, rather than haphazard samples and incomplete groups of prognostically different patients that are now the norm. While technical considerations are solvable, there are likely legal or political considerations, and current business models of conducting RTs may be upended. However,

doing high quality research should be such an important public health priority that we and our government should demand it.

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Image: Jacek Dylag

Can Provider Risk Cure High Medical Costs?

written by Theresa Hush | June 20, 2019

Fee-for-Service (FFS) has been on a slow march toward risk-based reimbursement for two decades. But FFS has proven to be remarkably resilient—until now. In the last six months, Medicare has doubled down on creating new provider risk models for ACOs, specialists and primary care physicians. All of them have methods to ensure that providers are held accountable for medical expenditure targets.

Wait. Haven’t we been here before?

What‘s different between now and the 1980s, when HMOs and provider risk first prevailed in the market—and then were purged as both ineffective and unpopular? Is provider risk a cure for high medical costs, or is it unfair to physicians? Will it drive physicians from participation in Medicare and commercial risk—or induce them to adopt it, then dump sicker patients and reduce access for consumers? Let’s examine

provider risk, its reasons and how providers are likely to react.

Why Now? Surging Health Care Costs Create New Urgency

We should look at provider risk reimbursement for what it is—a cap on medical expenses driven by services that physicians order or perform. These caps predominate in governmental programs because beneficiaries have open choice of providers, thus excluding options that are available to commercial health plans and employers, namely, narrow provider networks that limit choice.

After a period of low growth in Medicare costs, especially compared to commercial health plans, there is a projected surge coming. Significantly, the highest cost increase is expected in Medicare Part B, professional costs.

With only two percent of total Medicare spending attributed to direct primary care services, we should expect CMS to use models that control referrals and costs of specialty care. New downside risk provisions in ACOs and new primary care models affirm the concept of using gatekeeper models, as in the past, to control access to specialists. Since ACOs have had a difficult time proving successful in controlling referrals, CMS is betting that downside risk will create the internal leverage needed for ACOs to take these steps.

The use of risk reimbursement in multiple forms—ACOs, direct contracting, primary care risk and reward, Bundled Payment pilots and Medicare Advantage—allows CMS to test different organizational and reimbursement models that all include

expenditure targets. These models also either totally or partially eliminate FFS and its incentives for generating higher costs, which is the intended effect. In addition, they will surely affect income for some providers, and probably specialists.

Further, by using models that involve providers themselves as the guardian of costs, CMS avoids a political war over a simple change in the reimbursement system from FFS to something else.

The hesitancy to quickly change reimbursement is obvious with respect to bundled payments for specialty procedures. Despite the introduction of the Bundled Payment for Care Initiatives (BPCI) in 2013, Medicare tread slowly and carefully in implementing bundled payments based on time- and procedure-defined episodes of care. In fact, Medicare pulled back from mandatory bundled joint replacement procedures in the past few years in favor of voluntary measures, and scaled back testing of numerous specialty episodes. Now it is moving more deliberately forward with field-tested models that group payments together, but the models are still voluntary.

Good and Bad Incentives Exist in All Payment Methods

The positive aspect of FFS is that it directly relates to how many services physicians provide to patients. That same relationship, however, makes volume the primary indicator of productivity and value, and leaves the system vulnerable to excessive procedures motivated by physician-versus-patient decisions.

A system where physicians and not patients still govern choices

of treatment creates incentives for physicians to game FFS by performing unnecessary or borderline procedures rather than more conservative therapies. While such physician volume-boosting occurs, however, the larger problem now is that the newly consolidated health systems pressure physician, now employees, to meet higher volume goals and make more internal referrals. Those incentives are embedded in compensation plans as well as soft benefits like leadership appointments, access to operating room time and good space.

Capitation and bundled payments also have incentives, and these can also harm patients and de-activate cost control incentives. Under fixed cost models, these incentives can include:

> "Dumping" patients, especially patients with more restrictive coverage like Medicare and Medicaid;
> Delaying patient therapies where there are more questions about symptoms or efficacies, most likely to occur for patients with autoimmune diseases or where diagnoses and treatments are less clear-cut. Women and people of color, who have higher risk for these conditions, may be more vulnerable;
> Limiting scope of services or not referring patients for them; e.g., physical therapy, rehabilitation or home care, imaging and laboratory testing and other exclusions from the fixed fee. The more all-inclusive reimbursement models are designed to counter such incentives.

HMO history should have taught us that, although it is somewhat possible to control or lower the increase in costs, this approach can come at a high price: patient outrage and dissatisfaction.

What’s Different Now That Could Make Provider Risk Work for Providers and Patients?

Is it possible to put providers at risk successfully for both providers and their patients? That depends on the actions that providers take as payers implement these plans, as well as how transparent the changes are for patients. Four factors make it less likely for a transition to provider risk reimbursements to implode and to harm patients:

- Health care has become a political issue, and consumers are more aware and energized about health care than ever before. The constraints on Medicare and the safeguard of provider choice stems from political advocacy for beneficiaries. The ACA debate has seeded other groups. That political advocacy will need to mature beyond insurance, but it is easy to envision how health care access could become a larger consumer movement.
- Social media and journalism are highly focused on health care, and reporting on inequities and problems in health care is a common theme. There will be consumer and journalistic watchdogs on health care that can help popularize issues and push them into the political environment.
- Data is more available to identify problems in health care services, and there is more ability to obtain patient responses. What is not available now are good measures of quality. The system of quality reporting created by Medicare did not evolve, as industry experts hoped, into real measures of patient health and outcomes.
- Patients know they have options and are more educated about health. Spurred by health care providers, a growing

> alternative health care industry, and wearable devices, consumers are no longer waiting for providers to make decisions. The fact that patients want more involvement in choosing for themselves—and are also financially motivated to do so—will make them less likely to tolerate care that doesn't succeed (on their terms).

Physicians can protect themselves from undue risk in providing patient services and have many options for services to help them with population health, measuring cost and outcomes, and testing strategies. We have reported options for shadow testing of bundled payments and for navigating ACO arrangements, and have suggested how ACOs can create systems to select specialists.

This decade in health care is not the 1980s. Science is moving forward faster, and health care is more sophisticated. Both providers and patients need not feel helpless in a system that is changing and holding everyone more accountable. More technology focused on measuring patient outcomes and costs, better data, and transparency will all be required to accomplish a significant change in health care.

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Image: Rodion Kutsaev

How Providers Must Improve Value in Women's Health

written by Theresa Hush | June 20, 2019

Writing the Roji Health Intelligence® series on gender disparities and other women's health issues has been a

revelation. As a woman who has worked in so many parts of the health care industry, I was already aware of basic gender disparities, risk levels, incidence of disease, and economic issues that are predominant among women. Most women in health care have had their knowledge and judgment doubted as both patients and professionals. Women everywhere encounter the economic barriers associated with affordable health care, some much worse than others, and every woman who is a mother struggles with balancing the interests of children and income.

But here is what I was not prepared for: the cumulative weight and breadth of the problems—in disease after disease—that affect women and their search for good health. It is tragic that women die from heart attacks because the sex differences in cardiovascular disease are neither widely recognized nor understood, that women die after childbirth because risks are understated and urgent post-natal symptoms are ignored, and that women die from metastatic breast cancer because the money going to research focuses on prevention and early treatment. Devastating, as well, are the effects of pain and loss of functionality and independence experienced by women with progressive autoimmune diseases or who are simply old and alone.

The reasons that women struggle to get appropriate, quality health care may vary by disease, but there are common themes across all conditions. The most significant are these:

1. Under-participation of women in clinical research, trials, and basic science.
   Until 1987, the National Institutes of Health (NIH) and Federal Drug Administration (FDA) did not require the

participation of women in funded clinical research or trials. While both revised policies, studies show that women's participation still lags. Furthermore, basic science research has no requirement about the inclusion of female subjects that would then carry forth in clinical trial participation. As a result, the scientific basis to diagnose and treat women is often also absent. Cardiovascular disease provides a stark example, where protocols are based on male symptoms, but tests that are definitive or sensitive enough to identify heart attacks in women are still under study, even as heart disease is the number one cause of death in women.

Slowness of medical science to "catch up" to known, sex-specific biology and diseases.

There are big gaps in provider awareness about how diseases affect women—even when these differences are proven. For example, there is a baffling lack of protocols to investigate heart attacks in women presenting with heartburn, jaw or back pain, and other symptoms common to women. As happens with auto-immune diseases, endometriosis, and other conditions, the non-existence of specific protocols to ensure that women's health issues are investigated leaves providers open to cultural biases. This leads to the dismissal of certain symptoms even when the relevance of those symptoms, such as fatigue and pain, is supported by scientific findings.

Lack of women physicians and researchers in leadership.

More women health care leaders are needed to direct priorities for research and patient care, educate providers, and be advocates for women professionals and patients.

Five Strategies for Successful Improvement of Women's Health in VBHC

1. Engage women as patients and partners in change.

This apparently trivial suggestion is nothing but—because women distrust health care providers and insurers. They also make the vast majority of health care decisions, not only for themselves but for their families. Alienating women either as patients or partners to others will lead them to seek out-of-network services for ACOs, health systems, and practices that will be participating in risk-based reimbursement. Perception of provider expertise is interwoven with willingness to respectfully communicate and discuss care so that women are taken seriously.

Providers need to invest in a proactive strategy of engagement: Educate women about symptoms associated with at-risk conditions, and teach them how to talk to physicians, including questions to ask when considering treatments. We must communicate to women that it is not only acceptable, but essential to question their physicians, seek evidence associated with options, and push back when they don't get answers.

2. Establish measures and improvement activities for women's health.

Women make up the bulk of visits for many providers, both in number of visits and charges. Providers should expect more women patients with high-cost illnesses because of incidence of disease, along with associated higher cost overruns compared to

financial targets.

Yet measures of women's overall health are virtually absent, especially in areas where care has been deficient. Providers will need to focus on cohorts of women as distinct high-risk groups and establish specialized communication channels and care designs. Further, women-reported outcomes will be essential for measuring trust, diagnostic delays, and patient clinical factors as well as social determinants of health.

3. Reconsider the delivery system of services for women.

Providers should address the concept of dedicated women's health services and whether they fragment rather than help women receive the best health care. The bottom line: ask them. Women should participate in the development of services and have a voice in their care.

4. Address cultural biases in services to women patients through physician awareness and education.

The existence of cultural biases toward women, especially relative to their symptoms, has been frequently studied and documented. The Roji Health Intelligence women's health series points to the most obvious examples. As is true regarding racial biases, only concerted efforts by providers will change these attitudes over time. This will require creating educational programs for physicians that help them adjust to the changing culture of physicians in Value-Based Health Care (VBHC).

Physicians in VBHC, in order to be effective partners in cost reduction and outcome improvement, will have a very different role in the future system. They will spend more time in patient consultation and shared decision-making, charged with presenting options for treatment supported by evidence and review of patient circumstances. The paternalistic physician, who directs medical services and expects compliance from patients, will become a rarity under VBHC. Why? Because changes in health care finance and the culture are driving patients to have a larger voice.

5. Support women physicians and researchers in their clinical practice and research.

Improvement of women's health will require equity for women physicians and researchers. Removal of discriminatory pay, mentoring women into leadership, and support for women in the workplace will all be essential to changing expectations for women patients, as well. Actively seeking research proposals that improve women's health issues should be an expected part of an academic health center's directed research process.

Viewing these efforts as "reverse discrimination" is wrong. Like efforts in VBHC to identify and address social determinants of health, gender is a major component of disease as well as its treatment.

As health care providers implement Value-Based Health Care, it will be easy to let gender disappear into the fabric of strategies to mitigate financial risk. Based on ample science that shows sex-differences in disease and treatment results, addressing women's health proactively would be the wiser action. It is also a moral imperative to deliver care to women

that is backed by science and good medicine, not based on sex.

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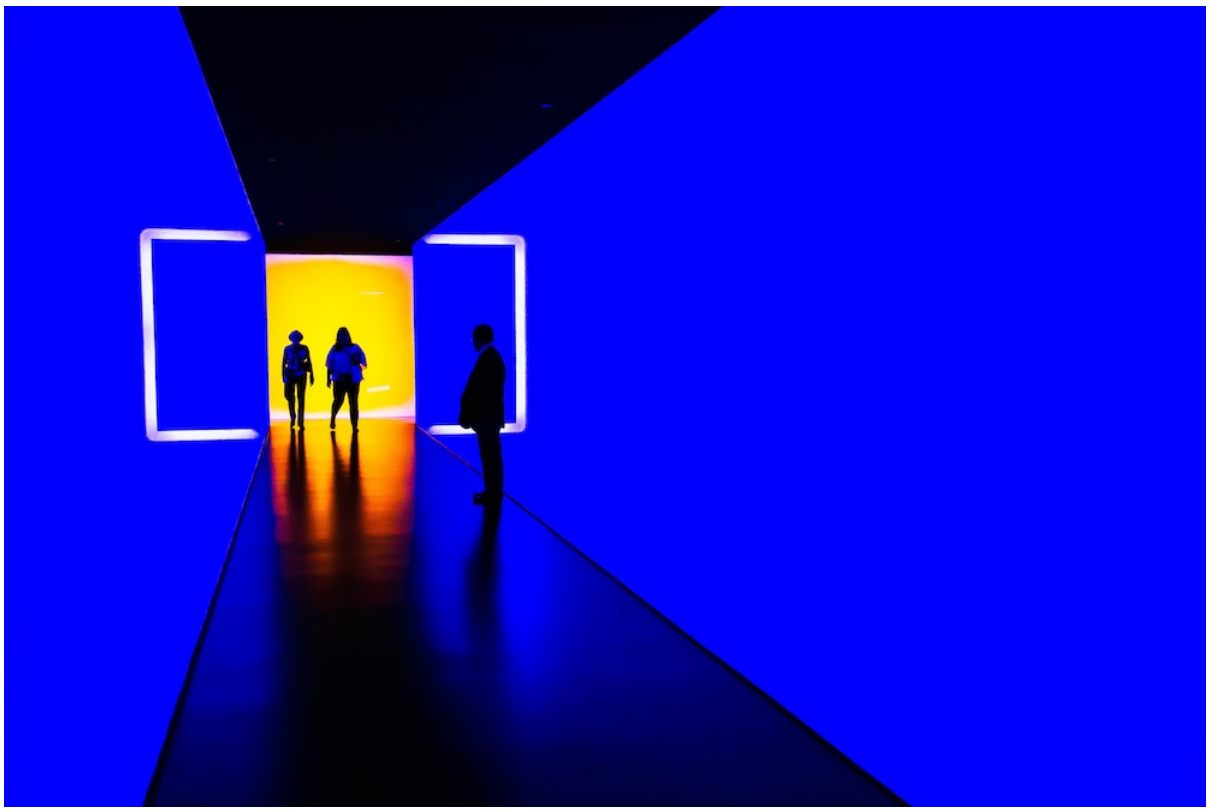
Image: Becca Tapert

How Will New Primary Care Models Affect Providers in VBHC?

written by Theresa Hush | June 20, 2019



Embraced by some provider groups and disparaged by others, CMS's five new payment models for practices focused on primary care include much to consider. All reflect a key departure of Medicare's Value-Based Health Care (VBHC) efforts to date: they are direct efforts by Medicare to transition physician practice revenues to risk without the necessity of ACO participation.

The primary care models will affect both providers and patients. In this article, we'll address the provider issues. How patient choice of care and outcomes for patients and patient populations will be affected deserves dedicated scrutiny in a future post.

No Surprise that CMS Actions May Sidestep ACOs

The non-ACO models should not be a surprise to providers. We predicted in a June 2018 blog post that CMS signals to ACOs should be taken seriously. CMS made its plan to move forward

with financial risk very clear, pushing for more growth of ACOs, higher provider participation, and more savings. They raised the possibility of direct contracting and showcased Medicare Advantage as a better deal. The agency repeatedly stressed the problems and incentives with Fee for Service (FFS).

Aside from the limited savings that many ACOs were able to achieve, CMS may have been influenced by ACOs to create the primary care models. When ACOs threatened to drop out of the program in reaction to the CMS downside risk, it was abundantly clear that ACOs' ability to convince their providers to adapt to financial risk had hit a limit.

How will Primary Care Models Affect Physician Practices?

Primary Care First

All five primary care models represent options that move practices in a step-wise fashion toward accepting financial risk for delivering care more efficiently, with adherence to quality standards (not yet specified).

The two payment models under Primary Care First (PCF and PCF High Needs) are very reminiscent of what existed under PQRS and the Value-Based Payment Modifier (VPM), and, most recently, CPC+ (which targets groups having infrastructure, so small practices will not be as familiar with this model). PCF and PCF High Needs are FFS models with some retrospective shared savings (incentive) and downside risk, calculated by an algorithm that targets metrics similar to the VPM. But these models, which are intended for smaller primary care practices,

also provide additional payments for the extra work involved, such as coordination of care.

PCF Models recognize that many small practices have neither the infrastructure nor the comfort level with risk that an ACO needs to meet its savings. So instead, CMS created a method to integrate them into VBHC and make it a positive step for practices. This new payment system enables CMS to incorporate a small amount of risk and provide practices with additional support, in the interests of leveraging primary care physicians. However, apart from the payments, how that primary care focus will be defined is currently somewhat vague..

Direct Contracting

The three Direct Contracting (DC) models are a much bigger departure from the current system than PCF. Aimed at large groups with existing infrastructure and experience in financial risk, the DC models recognize that many large multispecialty groups—especially in academic centers—can effectively participate in risk.

Clinically integrated networks or academic groups that have substantial technology and infrastructure have avoided expensive ACO architecture because of higher risk populations or provider attitudes. Under the DC models, because the groups will include primaries and multiple specialties under single governance, the capitated payment mechanism may be less a deterrent.

Academic groups with high concentration of Medicaid and dual eligible patients, in addition to more complex health issues, perceive the extra cost of upfront ACO investment and the

downside risk potential as too financially dangerous. But capitation can fix this perception by providing a stream of predictable revenues. The models' incentives to motivate patients to stay inside the group are beneficial financially to the group.

Are ACOs Hurt by the Primary Care Models?

Some ACOs have reacted with alarm to the models because ACOs depend on the motivation of primary care physicians to join their efforts. The models appear to be competing for primary care physicians at a time when there is scarcity of PCPs.

Confounding that issue are rule provisions that require physicians to make either/or decisions on joining an ACO. This is based on assignment of the physician practice Tax Identification Number (TIN) to the ACO along with the attribution of their patients—and costs, making it easier to account for costs, and upside /downside risk.

CMS will have to respond to two questions that affect the ACO bottom line and its ability to attract primary care physicians:

> Can primary care physicians participate in both a primary care model and in an ACO?
> If yes, how does this affect the incentive payments to primaries and the calculation of savings for ACOs?

The technical obstacle—dedication of the physician group's TIN to the ACO—is a simple fix, but leveling the playing field through incentive adjustments is not. And, the answers to these are likely to be different for PCF models and Direct Contracting.

PCF Can Help Both Primary Care Groups and ACOs

For small PCF physician groups, it is easier to blend the models and allow dual participation by primaries because both remain under FFS. The payment structure for PCF could actually benefit ACOs greatly by lowering primary care physicians' resistance to risk—and directly tying their actions to patient care costs and incentives.

There is a mutual benefit to both physician practices and ACOs by making it possible for PCF practices to participate. If small groups were concerned about their good efforts being offset by less efficient practices in an ACO network, CMS brings these primaries directly into the fold. They also get the infrastructure they need from the ACO to achieve their goals. For PCF, CMS could maintain separate incentive schemes for these primaries, adjust ACO shared savings and downside risk potential, or find a mechanism that blends the two accounting mechanisms.

Direct Contracting Will Compete with ACOs but Not Necessarily Disadvantage Them

Direct Contracting is an entirely different matter, yet from an ACO perspective it is hard to see a huge disadvantage. Such groups often already have the infrastructure to perform as accountable care practices or can afford them. Some have already used their market presence to establish ACOs that have drawn in other providers. But more are resistant and find the ACO model not to be nimble enough to address their unique needs.

Direct Contracting groups will be multi-specialty and, by CMS

design, large. The capitation payment is advantageous for them and will result in a stronger alignment within the group to get all providers onboard with improvements, from better data collection to adoption of interventions.

But the groups that will be directly contracting with CMS were never going to be part of an ACO, unless it was their own. Except for one model—the geographic attribution of patients within a region to the group, yet to be configured in detail—the patients are already likely to represent distinct populations. Even the geographic model is likely to be focused on patients that are dual-eligible and highly concentrated geographically.

ACOs Can Use the Opportunity Presented by Primary Care Models to Create Advantage

There is little doubt that if capitation models succeed and ACO risk mechanisms do not, capitation will find its way into the ACO arena. We should expect all of the models to morph along a continuum toward capitation with extra incentives and savings pools. A global capitation model like Medicare Advantage is easily imagined for ACOs.

But ACOs have the perfect opportunity to create the necessary sense of urgency in their groups to achieve better performance, and to distinguish their model by more innovation. Since the specter of capitation is now clearly in play, along with bundled payments, ACOs should move quickly to focus on their downstream patient costs, starting with specialty services. They can work with specialists now to create virtual episodes to examine variations in cost. They can focus on the collection of better data that will help them predict high-risk patients

and create interventions to change the arc of pre-diabetes and early hypertension.

The threat to ACOs is not external payment models; rather, the threat is underfunding of initiatives and a slow pace of change. Building internal strengths through better funding and infrastructure will create the opportunity for ACOs to achieve what a multi-specialty group can’t.

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Do “Women’s Health Centers” and Services Deliver on Value-Based Health Care?

written by Theresa Hush | June 20, 2019

Women make an astounding 80 percent of health care decisions for themselves and their families. But there's a disconnect between what women need and how providers have organized health care for them. While Value-Based Health Care (VBHC) is struggling to achieve more value for every health care dollar spent, providers are simultaneously sabotaging women in their customer base.

How? This might surprise you: through promotion of "women's health" services. While providers may have good intentions for offering a dedicated place for women's health needs, those services have actually fragmented care for women, especially those with more complex conditions.

Let's evaluate how dedicated women's health services can actually do a disservice for women as well as men, and can negatively affect the women that providers hope to reach.

Women’s Health Initiatives Focus Mainly on Women’s Reproductive Biology

To understand the limitations of how women’s health is defined, we’ll start with the World Health Organization (WHO). Among the top ten major health issues for women, half are directly related to sexuality, gender or reproduction: reproductive health, maternal health, HIV, sexually transmitted infections, and violence against women.

While these issues are important global status indicators for women’s health, note that cardiovascular disease, the leading cause of death for women in the U.S., is not even separately targeted as a women’s health issue—even though women often have a variant form of the disease with different symptoms that are harder to diagnose.

WHO identifies cancer as the top issue for women. Breast and lung cancer have the highest cancer incidence among women. And, indeed, breast health is commonly covered by providers who market women’s health, with mammogram screenings often part of the service mix. That’s because it falls into the classification scheme of gynecology and reproductive health.

WHO also calls out mental health and non-communicable diseases as important health priorities, along with “getting older” and “being young.” These catch-all categories may cover important conditions, such as women’s heart disease, but fail to identify or prioritize them.

By effectively equating women’s health to the status of reproductive organs, WHO sets the parameters for how women’s health is targeted globally. This affects funding, government

policy and grants, and how areas of research are delineated. We see the same set of priorities across the spectrum of public health and the health care industry. Because of this world-view, some women's health issues get showcased, while others—reflecting non-reproductive areas like cardiovascular or autoimmune diseases—get sidelined.

Like most organizations, the WHO women's health priorities were determined by health care members on the executive committee, only a handful of whom are women. A similar gender composition exists on boards and among decision-makers in health plans, health systems and their providers. Women themselves are not well represented in determining their most vital health needs.

Women Have Lost Trust in U.S. Health Care

In a recent survey of women's health care and health status, the Commonwealth Fund highlighted how women in the U.S. continue to lag behind women who live in other high income countries. American women have significant issues accessing and affording care, and less trust in the health care system.

Of 11 countries studied, American women also carry the heaviest burden of chronic disease, yet they have the highest rates of skipping needed care because of affordability. And they are the least satisfied with their care. The U.S. has the highest rate of maternal mortality among developed countries, and, potentially related, one of the highest rates of caesarean sections. Fewer women in the U.S. rate the quality of their health care as excellent or very good, compared to women in other countries studied. These findings are consistent with our examination of multiple clinical areas where both lack of clinical research supporting biological differences, coupled

with cultural biases toward women, stymie good health care for women.

Are Women's Health Care Centers Better or Worse for Value-Based Health Care?

Health care services can be organized for reasons of marketing, or in accord with the belief that specialization can deliver higher quality. From a marketing standpoint, a women's health center can deliver a few frequently sought-after features:

- Primary care, especially female physicians;
- One-stop shopping for primary plus reproductive services;
- A "storefront" with a more woman-friendly appearance.

However, early studies of women's health centers demonstrated unremarkable results regarding distinctive quality. Taking patient age, health risks, and outcome measures into account, results showed that women's health centers, in general, catered to younger women with fewer chronic conditions, with older and more complex patients receiving care at general medicine clinics instead. Also, while women at women's health centers were reported with higher mammography and cholesterol screenings, their rate of reported colorectal screening was lower. Patient satisfaction did not differ between the two settings.

Given their targeting of younger patients, women's health centers, as a rule, don't necessarily focus on post-reproductive-years risk factors, such as the increased cardiovascular risk caused by preeclampsia during pregnancy. Likewise, needs of women that emerge years after delivering children—such as uterine or vaginal prolapse or other pelvic

floor issues—affect as much as one-third of women and is a frequently neglected area of patient care. Many older women, typically not women's center patients, access services from different specialties to avoid associated incontinence, pain and infections. How health systems integrate protocols and processes across specialists is a significant issue that affects patient outcomes.

Fragmenting health care affects all patients. Some providers and advocates make a case for specializing women's services based on the fact that women have been victims of delay and experienced gender-disparate care, and that a jump-start is needed to correct the imbalance. A contradictory argument can be made for improving care for both men and women, recognizing unique biology and risks, and integrating, rather than dividing, resources. One thing is certain: for men and women to achieve their best health status will require more than most gender-specific programs can now provide.

How VBHC Should Reevaluate Women's Health Services

But in view of current Value-Based Health Care implementation, we should examine women's health services from a different set of expectations. Consideration of women's health centers should take place on a case-by-case basis, where the reasons and preferences (with women's input) are tallied against the downsides of gender-specific care. Here are key questions to ask when making those assessments:

> Do we need a women's health center to organize care for women, and how do we ensure that it addresses more than reproductive health as well as women of all ages? Or, are we

trying to isolate services for women because we haven't designed processes for identifying gender-specific conditions, treatments or care plans?
Are all providers included in efforts to appreciate gender-specific needs of women, biological differences, as well as to foster research?
Will a women's health center create better care for women through integration and coordination of services—and how is this different than what should happen for men or for all patients?
How do women's health centers fit into an accountable health care system design, for delivery of specialized services for women beyond reproductive health services and gynecology?
How do we address, for example, women's cardiovascular disease?
How do women of all ages fit into the model of women's health services?

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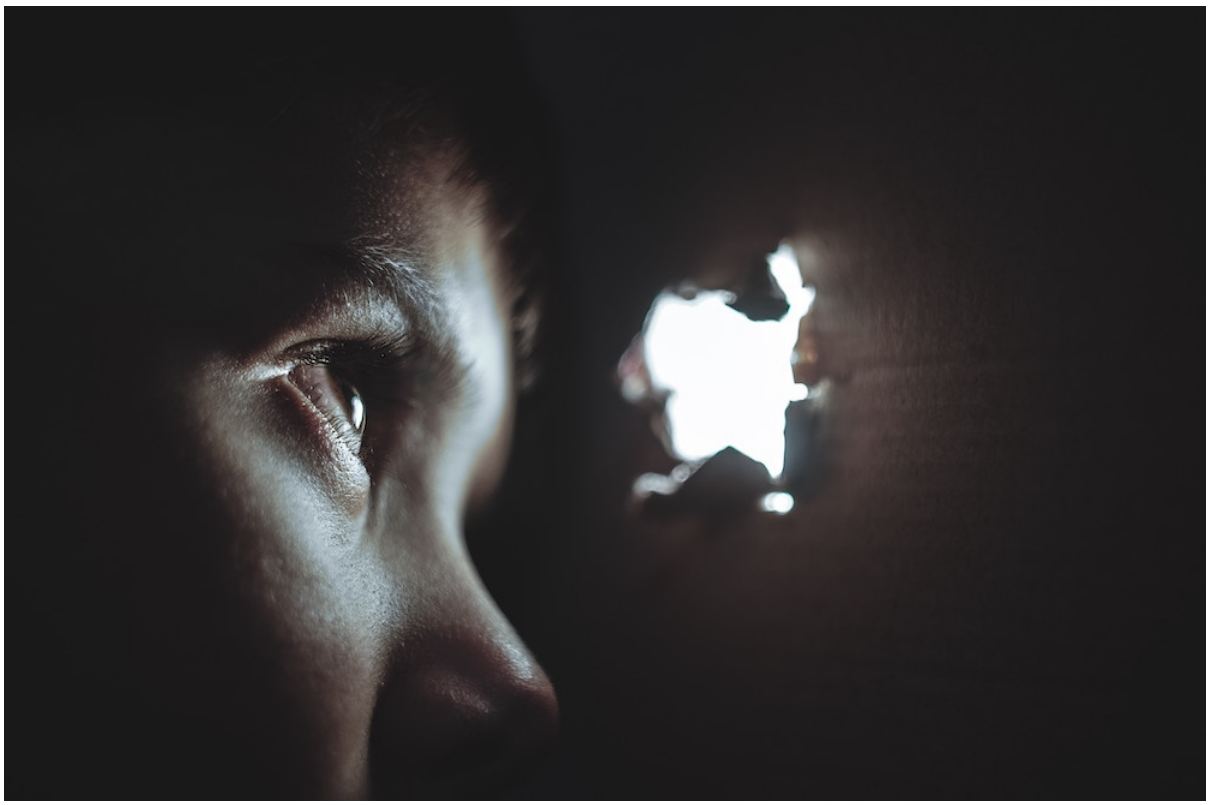
Image: Viktor Forgacs

If Not Now, It's Too Late: More Clinical Science Pitfalls and a Path to Improvement

written by Robert McNutt, M.D. | June 20, 2019



Let’s review three major vulnerabilities with how randomized trials (RTs) are conducted, as discussed so far in this series. Critically appraising a research study involves determining the “internal and external” validity. Internal validity deals with the conduct of the study, per se. External validity deals with whether the study’s findings can be generalized to others in the population. Here’s what can go wrong:

> Populations being studied in RTs are too often convenience samples of patients/subjects rather than random or systematic samples of subjects. This diminishes our ability to externalize findings from the RT to the population at large. This is a defect in external validity.
> After a population of people is gathered for study, simple randomization often fails to identify enough groups of individuals with variable and prognostically important characteristics that may alter the assessment of the value

of a treatment to them, rather than to the average. This is a defect in both the external and internal validity of the study.
Simple randomization does not assure that there will be adequate balancing of prognostically important clinical and personal characteristics. An imbalance may falsely support or refute the independent value of the treatment being tested. This is a defect in internal validity.

Why Masking Matters

There are other issues that diminish the value of information from RTs for patients. First, a tenet of a RT is that researchers, and those researched, must *not know* what they are getting, and, also, those assessing the measured outcomes must *not know* who got what. This is called "masking," and it is a crucial aspect of how a RT is conducted.

There are legions of studies showing that researchers and subjects change assessments and actions if they know what they are getting. I am a wine taster. I may love a brand of wine, but if I am presented that wine without knowing the brand, I often change my assessment. A group of expert wine tasters were given the same wine in bottles with different names and prices; when they scored the wine, they favored some bottle names, and, also, their assessments of quality tracked with price—more expensive, higher the score.

This "bias by knowing" is noted in clinical research; examples are many. One of my favorites was a RT comparing spine surgery versus no surgery for a herniated disc. Those people who accepted the RT, and who got spine surgery, rated outcomes *the same* as those who did not get surgery. However, a companion

observational study found that people getting surgery outside the RT rated outcomes *better* for surgery than those who did not have surgery.

Even though all those who had surgery knew it in both the RT and the observational study, their expectations were different and so were their assessments. Outside the RT, participants knew what they were getting, and, hence, their judgments were biased. If participants know what they are getting, *randomization is useless.*

Longitudinal RTs Take Too Long

Next, RTs, as practiced today, *take way too long*. For example, The National Lung Cancer Screening Trial (NLST), discussed throughout this series, started enrolling patients in 2002, but the study was not published until 2011, nine years later. Think about this a minute. Suppose the study definitively showed that CT scan screening saved lives (it does not, in my view); then, many people were denied potential better care while the study ran its course.

Why the long time period? The outcome they measured was infrequent, and it took time to accrue. When the baseline likelihood of an outcome is small, large numbers of patients are needed to see if one plan is better than another. Some think the 50,000+ in this study is a large number of subjects, *but it is not;* it is an inadequate number *for this question.* If outcome event rates are small, we need larger samples of patients so outcomes can be known in less than a few years.

The Problems with Observational Studies and the Language of Research

In my initial blog of this series, I raised issue with observational studies and how we report trials. First, observational trials are dangerous; some may be helpful, but only when the outcome event rates and differences between compared groups are huge. This is rare, and from a practical perspective, all observational trials may be ignored from the perspective of informing patients who must make choices. If there are many vulnerable aspects of RTs, imagine how many there are with observational research.

Second, research studies are written in a language useful to only a small number of people; those who do research. However, researchers should not work for researchers; they should work for patients. Absolute differences in outcomes for benefit and harm are the only things that a patient should see. It is up to better research than we have today to assure the numbers are good enough.

A Roadmap for Better Clinical Results

In summary, RTs, as conducted today, fall short of a standard for informing people of the consequences of choices. On my own scale of what makes a RT valuable, generalizability is most important; paying particular attention to groups of people with variable clinical and personal characteristics that may affect the measurement of differences in outcomes is close as 1A. Addressing these two issues at the beginning of a RT may nullify the third concern (unequal numbers of people in prognostic subgroups). I am ignoring unmasking, as an unmasked RT should be ignored, as should observational comparative data.

The following list assumes that RTs will be looking for small differences in outcomes. Clearly, it takes fewer people to detect a difference in outcomes when the efficacy is large (don’t need a RT to know you should have a parachute if you jump from a plane).

So, to achieve better clinical research:

- Study random samples of patients from full populations. Or, Study an entire sample or patients.
- Stratify, and oversample people with the greatest variations in prognostic variables.
- If you don’t stratify, use pre-randomization schemes to assure balanced numbers of people in prognostic subgroups.
- Choose to measure a single or, at most, two outcome variables that can be measured accurately.

In addition, future studies must follow these principles:

- Be less expensive than they are today.
- Be able to constantly refresh insights.
- Produce results in contemporary time periods.
- Focus on community/local catchment areas.
- Use just a few standardized, disease-specific and prognostic subgroup data, passively obtained.
- Be transparent; use a “ticker-tape” or stock market approach for presentation of outcomes over time and a standardized table presenting absolute differences in disease/harm outcomes.
- Incentivize and pay patients to participate.
- Inform patients and develop ways to coach them for choice.

How to do this? Future blog posts will present alternatives.

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Image: Dmitry Ratushny

Bootstrapped ACOs Facing Risk? Adopt Cost Strategies With Long Term RoI

written by Theresa Hush | June 20, 2019

The experimental phase of Medicare ACOs has been officially declared dead, per CMS. Going forward, ACOs must agree to take on financial risk for expenditures beyond their targets. That's sobering news for the majority of ACOs still struggling to succeed.

The reality is that most ACOs are bootstrapped—light on extra funding and dependent on existing tools to do more. In fact, about two-thirds of ACOs report that funding is their most significant challenge. And that is probably understated, since patient engagement problems (also reported by two-thirds of ACOs) and lack of data (reported by 40 percent) are remedied by solutions that require money.

ACOs that can save money over the long term, rather than count on one-time savings, will be better positioned under risk. While some investment in technology and data will be required,

it should not be formidably expensive. Beautiful analytics must drive conversation and processes for providers, in three critical areas:

- Variation in costs by episode of care.
- Examination of what is working or not to produce best individual outcomes and lowest costs.
- How physicians can speak so that patients can listen and engage.

Our eBook strategies can serve as the foundation for initiating long-term change and innovation.

Five Criteria for ACO Strategies to Achieve Return on Investment

ACOs must be selective in how they choose strategies for improvement, conserving precious resources for those initiatives with the highest likelihood of working. As payers turn to financial risk, ACOs have neither the time nor money to experiment without a good expectation of success. Using Return on Investment as a key criterion makes sense, because it directly relates the initiative to the end goal of efficiency.

Before adopting strategies, ACOs need to ensure that they are checking one or more of these boxes to deliver maximum results for patients and the organization. Ask whether each strategy or improvement program can meet these criteria:

- Test impact. Are patient volume and/or costs big enough to drive lower per-patient annual spending?
- Optimize specialty services. Does this initiative help ACOs to set up a network and services that optimize referrals and

prudent use of specialty services by patients?
Encourage physician growth. Does it create a positive learning process for physicians to lower costs of care through investigating patient experiences?
Improve medical decision-making. Does the initiative help physicians achieve motivational communication with patients that engages them in goal-setting and informed medical decisions based on benefits? Does it help patients become more skillful medical consumers?
Help patients at highest risk. Is it focused on patients with the greatest likelihood of long-term gains—such as patients with highest risk of admissions and emergency services; or patients who are economically disadvantaged, minorities or women; or with high cost chronic disease?

ACOs will fail the test of financial risk if they simply adopt the popular strategies of other ACOs or health systems. Instead, ACOs should innovate: establish core values and standards of care, then fit strategies to their goals. Since one of those goals will undoubtedly involve saving money, Return on Investment provides an excellent criterion for choosing how to start.

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