If Not Now, It's Too Late: Clinical Science Needs Fixing

written by Robert McNutt, M.D. | February 14, 2019

In 1967, the year I graduated from high school, my family's television required "rabbit ear" antennae with perched aluminum foil. Our farming family had little time to watch TV, but when

we did, the ritual included a side trip to reset the antennae's angle to ensure good reception. Today, I watch a clear picture on myriad devices, no antennae needed.

In the 1980s, my trips to a library to find medical literature were few. A single trip to the library would take hours and net only a small number of papers. Now, I obtain articles on any topic in a manner of minutes.

In the late 1980s and early1990s, when I returned to school to learn decision-analysis and health services research, my decision models were simple due to constraints imposed by computing power. Only when I completed the laborious number-crunching process could I slowly fashion insights about care. Today, models are complex, sophisticated instruments running at light-speed.

These remarkable advances in technology are obvious. But, has the science of caring for people mirrored the same meteoric advances?

Clinical Science Is Regressing

I think, actually, our ability to help patients with the technology of clinical science is regressing. The tools of science don't impede; it is the data we study and weaknesses in our study designs that thwart.

This may seem a specious claim if one just superficially notes the number of resources for medical information. PubMed claims 29 million citations; 6,000 biomedical journals are indexed, but tens of thousands more journals are produced. How can it be that we are stagnant or even backtracking, given this treasure

trove of information?

First, the fact there are so many publications is a symptom of the problem, not a solution. Nearly any sort of paper will see the light of day in some journal, somewhere. Researchers can, even now, pay to be published. The mass of information is so unstructured and scientifically unsound that it would take an act of a computing God to find importance floating in the mess.

The biggest problem, in my view, then, is the quality of clinical science foisted upon us. A faster way to garner superior clinical knowledge is desperately needed; once that remedy is found, as a byproduct, the number of poor insights and publications will decline.

How Clinical Science Must Improve to Be Relevant to the Patient

The weakest components of the way we presently conduct the scientific method are under-emphasized and under-appreciated. My opinion is informed by assessing scientific studies for more than 25 years as a medical editor, as a teacher of evidence-based-medicine, as a researcher and writer. Usually critiques of evidence focus on the "internal validity" of the study (how well the study was carried out). However, applying what we learn from a study to help patients is the problem, in my view, and present studies are limited in their ability to inform the vagaries of individuals.

To refine how insights from studies may be accurately generalized, the following components need improving. (I hint at the deficiency. Future blog posts will explore these in depth.)

Studying the wrong populations in the first place. Our penchant to publish leads to research done with convenience, using non-random samples of patients. This leaves us uncertain if study results are generalizable.
Lack of incorporating important variations in clinical/personal characteristics of studied populations. We flatten our insights by failing to include and plan for variations in individuals being studied. Hence, it is difficult to extrapolate study results to inform individuals whose characteristics, or combinations of characteristics, are unstudied.
Failure to mask intervention and outcome. If a participant or researcher knows the treatment/plans for care and, second, if the outcome variable is subjective in nature, randomization is a waste and no insight is possible.
Failed randomization when researchers are looking for small effect sizes. Random imbalances in numbers of patients in prognostic subgroups can negate insights, especially when small numbers of patients differ in outcome event rates for studied options.
Inappropriately using data from comparative observational studies to inform patients. Observational comparative data, including big data, are either wrong or un-provable; acting on them is dangerous.
Poor presentation of medical evidence to patients. Obfuscation is the norm.

Our present models of information management are outdated, slow and expensive, and information is often irrelevant by the time it reaches the patient’s bedside. We need a better approach to clinical science.

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Higher Risks, Worse Disease, Fewer Choices: Health Care Fails African American Women the Most

written by Theresa Hush | February 14, 2019

No matter how we measure disparity in health care for women in the U.S, African American women stand out. Across the board, they have higher risk factors for disease and poorer outcomes, including much higher mortality for many conditions. African American women contract cardiac disease and cancer at a younger age and, often, in worse forms. Their risk of maternal death after giving birth is three or four times greater.

Health care for African American women is complicated by racial and gender prejudices as well as by poverty and inadequate insurance coverage. But even among African American women who are not living below the poverty line, the disparities remain the same.

These poor outcomes are not “caused” by the health care system or by African American women. Pointing fingers is not useful. There are multiple factors involved, and no simple solutions. The popular tactic of offering incentives for modifying

lifestyle won't work, absent other interventions, such as providing better information about risk factors in conjunction with hands-on coaching. That's because genetics that influence disease incidence and type, along with social determinants of health, contribute to the problem.

Value-Based Health Care cannot be successful—and providers will fail in financial risk—if the highest risk patient populations are not acknowledged and their needs, addressed. Let's examine the problems and potential solutions through just a few of the clinical areas for which African American women have demonstrably worse outcomes and even higher mortality: chronic disease such as diabetes, hypertension, cardiovascular disease and their risk factors; maternal death; and breast cancer. These are just the most prevalent in a long list of disease categories that kill African American women at a higher rate, including additional cancers, autoimmune disease and asthma.

For African American Women, Social Determinants Create Chronic Disease Risks

Diabetes and hypertension are widespread in the African American population. According to the Third National Health and Nutrition Examination Survey, the prevalence of these diseases among African American women (but not men) is strongly associated with the poverty-to-income ratio. Adult African American women are also more likely to have co-morbidities, including hypertension, hyperlipidemia, diabetic neuropathy, retinopathy and End Stage Renal Disease (ESRD).

This is not surprising. With lower income also comes poorer nutrition, lack of access to food sources, and inability to find good health care in communities or to afford medication.

While there has been a belief system in health care that genes play a role in explaining predisposition to diabetes hypertension, this is not only unproven, but suspect—it is based on using skin color as a proxy for genetics, contributing to racial theories that African American genetics are different than white. Genetic research does not support this. The human genome is remarkably consistent, and while inherited genes can be specific to respond to environmental factors, these are not based on race but tied to regional ancestry.

These theories play out in how the health care industry views and treats serious chronic conditions in the Black community. A common belief among some physicians is that the high rate and severity of hypertension in African Americans stems from genetic salt sensitivity. This is an unproven theory. Instead, it is more likely that the 352 percent greater risk of mortality for Black women over white women (with stroke, alone, accounting for a 54 percent difference between African American and white women) is caused by later diagnosis, less ability to change risk factors, and poverty that influences life style options. Attempting to explain medical incidence with racial theories only serves to delay action at the real sources of inequities that prevent access to health care, nutritional diets, and exercise that are known foundations of preventing cardiovascular disease and diabetes.

Weight also plays a role in higher risk of hypertension. African American women over age 20 are more obese when compared to other populations of women and compared to men, and 77 percent of African American women are overweight or obese. In addition to smoking, obesity is now recognized as the second most significant risk factor in heart disease, stroke,

diabetes, some cancers and mental health.

When cardiovascular disease (CVD) occurs, it strikes African American women at a younger age and is more deadly. African American women with CVD have a universally higher mortality rate, inclusive of coronary artery disease, hypertension, stroke and congestive heart failure.

African American Women Get Less Information, Fewer Services and Referrals than White Women

According to the American Heart Association, African American Women lack awareness of their risks of major diseases and associated risk factors. Across six sequential national surveys of heart disease awareness as well as risk management and trust in providers, African American women were much less likely than white women to know that cardiovascular disease was their primary cause of death. They also expressed numerous barriers to management of disease and risk factors.

At least some of the information gap is due to lack of access to appropriate resources. African American women report that they get more information about cardiovascular disease from television than from providers. Studies also indicate that they receive less counseling from physicians, fewer referrals to specialists, and even less genetic testing for breast cancer.

Reducing obesity has proven challenging in all populations, and African American women are no exception. However, a comparison of programs points to some elements that might drive better results: participant goal-setting in an active discovery process, team participation, incorporation of exercise as well as dietary changes, and stronger links to community supports.

The U.S. Has the Worst Maternal Death Rate in the Developed World—With African American Women at Greatest Risk

No discussion of health care for African American women would be complete without underscoring the tragedy of the U.S. maternal death rate, the highest among developed countries. The factors are varied and cut across all American women.

But African American women are four times more likely to die than white women. Pregnancy-related deaths included CVD, stroke and other diseases, but also specific pregnancy risk, such as hemorrhage, cardiomyopathy, and pregnancy-related hypertension. Further, their higher mortality rate is not associated with education or socioeconomic status.

Experts attribute the cause to high risk coupled with low access to care. Advocates add that the high degree of racial segregation in health care experienced by African American women results in deliveries at lower quality facilities that cannot handle high-risk pregnancies. For poorer women, the later start to prenatal care and lack of community support or consistent medical care may contribute to unnecessary maternal deaths.

California has been able to dramatically reverse the trend, cutting the maternal death rate in half. Focusing on educating providers and developing protocols to address problems that arise in labor and delivery, the state helped improve the management of high-risk pregnant women.

Breast Cancer Is Even More Deadly for African American Women

Breast cancer is more complicated than previously understood (even twenty years ago); biology of the disease differs by type of tumor and each woman's individual genetics. Among all women with breast cancer, African-American women fare the worst—again, by far. Although white and African American women develop the disease in relatively equal proportions, African American women are 41 percent more likely to die.

Despite the fact that they have a slightly higher screening rate than all other women, African American women are diagnosed with breast cancer at a later stage of the disease than white women, but are younger at disease onset. Their tumors are also more likely to be aggressive, triple-negative breast cancer with poorer prognoses and more challenging treatment. The higher incidence rate of this deadly form of the disease among African American women has been associated with risk factors such as lower rates of breastfeeding and tendency to carry excess abdominal weight.

Disease characteristics are not the sole issue for African American women with breast cancer, however. They also face barriers associated with poverty, race and social injustice that limit access to primary care, quality screening and treatment. Over ten years, the disparity in care between African American and other women has become worse, with higher mortality rates and evidence of strong regional differences that reveal how differences in quality among providers and facilities can impact results.

In addition, African American women have significant gaps in

insurance coverage. More than 12 percent lack health insurance coverage compared to eight percent of white women. One in five low-income African American women lack health insurance, with the coverage disparity greatest for African American women of reproductive age. Complicating the issue further, 25 percent of African American women receive their coverage through Medicaid, which is now more vulnerable to cutbacks.

Cultural perceptions about breast cancer may also play a role in how women elect treatment and follow-up. However, there is evidence that African American women get less information and services than white women. In a limited study at Ohio State University last year, conducted through interviews of women high breast cancer risk, African American women were less likely to have access to adequate information about the disease. Only 15 per cent had seen a risk-relevant specialist, compared to 70 per cent of white women; less than a third received risk-related information from a primary care physician; and less than half were aware of three or four risk factors associated with breast cancer.

All of these issues are propelling the creation of organizations and resources to educate and support African American women. Survivorship organizations such as Sisters Network and the African American Breast Cancer Alliance are working to improve awareness of breast cancer among African American women and support those who are diagnosed. The Black Women's Health Imperative promotes health initiatives for both women and girls, but also a much-needed policy and political agenda for correcting health care disparity.

Three Ways VBHC Can Help Improve Outcomes for African American Women

The tragic lesson that African American women are imparting is the horrendous personal cost—as well as the cost to society—of our failure to address high risk populations. A collective willingness to ignore rising mortality across multiple diseases does not speak well for accountable care.

Race and poverty increase inequities for African American women. So, too, does gender, but it is very clear from current research that race accounts for even higher risk factors. Solutions to improving health care for women cannot assume that all women are the same. Culturally appropriate programs, developed with recognition of social injustice and economic deprivation, are essential.

While ACOs and other organizations on the front line of VBHC cannot resolve the socioeconomic barriers to care, nor address most social inequities, they can adopt three overarching goals:

- Implement VBHC cost-outcome improvement activities designed to reduce costs and improve quality that solicit inclusion of African American women as participants.
    - Adopt focused provider educational programs to ensure understanding of risk factors associated with conditions in African American women;
    - Establish broad patient education programs to help educate African American women about their risk factors and associated lifestyle, medication and other choices to reduce those risks;
    - Establish intake and follow-up processes to identify

barriers to treatments for African American women, along with community and family resources that could remove these obstacles to care;
Implement protocols for providers to assess high-risk patients and segue into more intensive management of their conditions.

Participate in advocacy efforts by community organizations and other entities to raise awareness of risk factors, and transition those at risk into behavior modification.
Educate providers in behavioral motivation and cultural sensitivities.

Addressing these inequities for African American women and all women is a massive and necessary undertaking. Where to begin? With the basics: generate awareness among fellow providers about health care disparities and their life-and-death consequences.

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Image: Eye for Ebony

Lessons in Health Care Empowerment from Women With Breast Cancer

written by Theresa Hush | February 14, 2019

For the one in eight women who will get breast cancer—more than 242,000 new cases were reported in 2015, alone, according to

the CDC's most recent data—the treatment is bad enough. Even more frightening is the uncertainty of what lies ahead. Will the cancer recur? And if so, when, and what's next?

Breast cancer kills 40,000 American women each year. Fear is a powerful motivator, because many women experience a recurrence of disease years after they were declared "cancer free." Nonetheless, women with breast cancer have created an extraordinary movement that has changed how people see the disease and how physicians and hospitals treat it.

They have built a broad support network, pushed for advancements in cancer science, and raised hundreds of millions of dollars for research. They are activists for environmental change to reduce risks of developing the disease, and are demanding social justice and better health care access.

Health care organizations and ACOs that are trying to get patients more involved in their conditions and treatments should pay attention, for many women with breast cancer have become experts and active in their own care. How did they do it? First by forming groups to access information, then by informing themselves. With the support of other women and knowledge of medical research, many women have been able to achieve better decisions and control over their lives, within their own medical constraints. In so doing, they have pushed the boundaries of what can be available for everyone.

Breast Cancer Activism is About Transparency and Better Treatment

This movement is gaining momentum for a reason: Breast cancer, despite a plethora of pink ribbons and annual walks for the

“cure,” is far from solved. Early optimism about cancer, in general, and breast cancer, in particular, has waned with a deepening understanding that genetic factors, environment, lifestyle and barriers to care all affect both the incidence of disease and survival rates. Aggressive, high-dose chemotherapy treatments have subjected women to unnecessary toxicity and misery in the failed hope of a cure.

While incidence of the disease has plateaued, survivorship has barely budged. Women are frustrated by stories of breast cancer heroines who braved the disease and still died, and charge that we “pinkwash” breast cancer while not seriously reducing risk and improving survival. They want transparency and action.

Let’s examine the issues from the vantage point of one particularly important population: women with metastatic breast cancer.

Women With Metastatic Breast Cancer Demand Better Research and Accessible, Flexible Health Care

Underfunded Research for Metastatic Disease

Women with metastatic breast cancer (MBC) face daunting risks. Between 20 to 30 percent of women with breast cancer will have a recurrence at some point in their lives, and the average survival rate after diagnosis of metastatic disease is two to four years. In response, women with MBC have mobilized to influence the direction of cancer research, increase knowledge of breast cancer realities, lead advocacy efforts, and organize patient-supplied databases to support research.

And with good reason. Of the estimated billion dollars spent on breast cancer research each year, virtually all goes toward prevention and early detection. Less than seven per cent of $15 billion invested in breast cancer funding between 2000 and 2013 in North America and the United Kingdom went toward MBC. Annually, less than five per cent of $6.2 billion in National Cancer Institute funding goes to increase scientific understanding of how cancer spreads—the key question in all metastatic disease and, by definition, how to go about treatment. The misallocation of funding is even more severe than perceived, because the total volume of women with MBC is not actually known. Only women with new diagnoses of MBC are included in the numbers; women who develop metastases—a much larger number—are not counted.

Why is breast cancer research so unbalanced, especially when the results of mammography and early detection have been unsuccessful? Some attribute the over-financing of prevention and detection studies to marketing strategies. As Siddhartha Mukherjee so eloquently explains in *The Emperor of All Maladies*, fear of potential cancer and the powerful desire to avoid the disease altogether have been leveraged to raise funds disproportionately for prevention and detection.

For women with MBC, whose lives are at stake, however, the lack of research on advanced stage disease is more than an indignity. It is fueling their activism. The Metastatic Breast Cancer Network and other groups are pressuring researchers to refocus attention on this most virulent form of the disease. They want studies that result in therapies that do more than extend survival by a few months and subject patients to side-effects that make quality of life impossible.

The Push for Insurance Authorization for Individualized Plans of Treatment

Women with MBC know that survival depends on understanding more of the science of breast cancer and individual biology, and that each woman's disease is unique. One person's response to drug therapies will differ completely from another's, and these differences are determined by the woman's genetic attributes as well as the tumor biology and behavior.

That is why these women are uniting against insurance efforts that require "step therapy" for MBC patients in Medicare Advantage plans. In step therapy, MBC patients must fail at one therapy before proceeding to the next in a given protocol. Step therapy assumes all cancers and patients respond the same to interventions, rather than individually. It erects further barriers for patients who can't afford to waste time on failing therapies—particularly when cancer researchers have yet to reach consensus regarding the correct "sequence" of treatments within an adopted a protocol, as demonstrated by a recent study of MBC patients on advanced drug therapy with and without endocrine therapy.

Women's Advocacy and Awareness in MBC Pave the Way for Better Patient Decision-Making

The vast number and range of groups supporting women with breast cancer reveal what can happen when patients actually do get involved in understanding their disease, learn to read the research and discuss plans of treatment with their physicians. Indeed, many of the groups in this coalition are brand new.

Two organizations, in particular, reflect this trend of women

seeking both knowledge and contribution. The MBC Alliance, which promotes multiple entities involved in breast cancer support, research and activism, has a program to help women become advocates for breast cancer causes. Count Me In is a recently formed nonprofit organization seeking to accelerate all cancer research through partnering of patient-supplied data and cancer researchers. The Metastatic Breast Cancer Project is participating in Count Me In and promoting enrollment by women with breast cancer.

How Providers Can Be More Responsive and Involved

While women with MBC have mobilized and begun to exert influence on the direction of research and treatment, the fact remains that each woman is still dependent on the information and guidance offered by her oncologist and health care team. She can read research to be better informed about treatment options, but ultimately will require her health care providers to meet specific minimum criteria:

- Diligent attention to her symptoms, investigating them for signs that current treatment has stopped being effective, and that the disease has progressed;
- Truthful information about new alternative treatments, with research results on effectiveness and side effects;
- Compassion and understanding.

These criteria may seem obvious, but stories abound regarding overlooked symptoms, overaggressive treatment, information withheld from the patient or family, recommendations for treatments that are too aggressive and not backed by good research, and an overly clinical and detached approach to the

patient. To effectively address the health needs of women with MBC—and build trust and loyalty between patient and provider organization—here are some basic steps:

- Health systems specializing in cancer care must place special emphasis on the patient experience as well as well as clinical excellence. Patients and family members should be asked to evaluate patient experiences with all members of the team on a regular basis, and those results should be used to assist providers.
- Protocols used by health care providers—including information on how and when they were developed—should be shared with patients and family members. The protocols should include not only the regimens recommended for metastatic breast cancer treatments, but also state which regimens are not being provided or considered. In addition, providers should clarify other aspects of concern: how women get access to clinical trials, assurance of transparency in providing research results and side effects, monitoring of quality of life during treatment, and respect for end-of-life wishes.
- Finally, research support for MBC should be a high priority for the many health care providers specializing in cancer care that are also research institutions creating proposals and studying the disease. Support for metastatic breast cancer studies is imperative and will go a long way toward winning the loyalty of women whose lives are at risk. These institutions have the potential to shift the course of breast cancer research nationally.

Women with MBC have shown they are willing and able to challenge the status quo about the course of this disease and

create a different experience of living with and fighting cancer. It is inspiring to witness.

At the same time, we must also acknowledge that these women in the vanguard are exhausted by the continual battle against not only their disease, but also the medical system that has stacked the deck against them. Their hard-won achievements will be even more uplifting if they succeed because providers join forces with their life-saving effort.

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Image: Sarah Cervantes

Silent, Deadly Heart Disease in Women: How Population Health Can Help

written by Theresa Hush | February 14, 2019

Cardiovascular disease (CVD) is the leading cause of death among women. But we hardly talk about it.

Indeed, CVD offers a remarkable lesson about complex, broad-based gender disparity that contributes to poorer health care for women. For acute myocardial infarctions (AMI or heart attacks) in particular, sex-specific health risk factors, disease variants tied to gender biology, limited medical research on sex differences in CVD, and cultural attitudes all contribute to the prevalence of heart disease among women—and increased mortality risk.

CVD Affects Women Differently Than Men

Cardiovascular disease was once assumed to occur predominantly in men rather than women. But the assumption that women are at lower risk of CVD is not, in fact, true. Although men contract heart diseases a few years earlier, on average, than women, the risk in later years is relatively even. When women do have CVD, however, they fare worse than men.

CVD among women has a different, sex-specific pathophysiology. In heart attacks, plaque in women acts differently than in men, resulting in more plaque erosion and microvascular disease. Women experience more angina. They have longer admissions, more complications, higher rates of readmissions, and greater mortality after the first cardiac event than men.

Another little-known fact: women have a higher 30-day mortality risk if they experience a heart attack; 23 percent die within a year compared to 18 percent of men. Among younger women, that heightened risk extends for a longer period of time after the event. Further, two-thirds of women who die suddenly from coronary events had no previous symptoms, compared to half of men who experience no symptoms.

Heart attacks in young women under 55 are of particular concern. Emerging data reveals an increase of coronary heart disease and deaths among women between the ages of 45 and 54. Growing awareness of sex-specific presentation of symptoms and biology is helping women as a whole to have better outcomes; however, younger women are not improving. They have higher risk factors, higher mortality and poorer prognoses following a first heart attack.

Women Have Different Symptoms for Heart Attacks—and Delay Seeking Help

Complicating outcome risks, the warning signs of an impending heart attack are not the same for women as for men. The crushing chest pain experienced by most men having a heart attack—symptoms well-publicized through public health outreach—is often absent in women. Rather, women are more likely to have unrelated symptoms that could easily be overlooked or attributed to a lesser medical concern, such as:

- Pain in upper back, shoulder, neck or jaw
- Pain in one or both arms
- Shortness of breath
- Nausea, vomiting
- Lightheadedness or dizziness
- Fatigue
- Sweating

The difference in symptoms may be caused by the differential pathology of microvascular disease in women. Also, women experience symptoms while resting, not just while active, which may lead them to dismiss the association with cardiac events.

Heart attack symptoms can also be intermittent. Women often overlook both intermittent and serious symptoms, and delay seeking treatment. In one study, home-to-hospital delays took up to three days, with delays greater than 60 minutes occurring for 70.3 percent of women versus 29.7 percent of men. Resultant treatment delays in women, in excess of the standard of less than twelve hours, caused more fatalities, specifically due to a lag in placement of stents and other reperfusion treatments.

There is little data on why this occurs, although those who have studied behavior conclude that women "are scared and put their families first." This may be just an assumption; it is also possible that women's vague presentations of symptoms—often easily dismissed— encourages them to wait.

Women Have Generally More Complex and Higher Risk Profiles for AMIs

Lifestyle choices and the prevalence of certain diseases also increase risk for women. In addition, some treatment complications can increase mortality or create poorer outcomes among women with CVD:

- Pregnancy complications such as pre-eclampsia or diabetes during pregnancy may increase risk of CVD for women.
- Some chemotherapy drugs for breast cancer increase risk for CVD.
- Menopause-induced low estrogen levels are a significant risk factor for microvascular disease.
- Some studies show that women tend to be more physically inactive, increasing risk.
- Type II diabetes and hypertension in women appear to present a higher risk for women than men.

    Smoking is the most preventable risk factor in CVD. The prevalence of smoking is lower in older women but, unfortunately, a major risk factor among younger women with CVD.
    Women often present with a combination of three or more risk factors for CVD, as opposed to men, whose presentation is typically less complex.

Women also have a higher risk associated with treatments, especially those that increase bleeding. Because most clinical trials do not include gender-specific results and the treatment standard is geared toward men, the safety and validity of treatments and dosing for women is sorely lacking.

Among women, race also complicates outcomes. For every finding of high CVD risk, black women, in particular, have much more severe risk factors than white women, and have higher mortality, as a result.

Gender Disparity in Health Care Is Present—but Indirect

According to several studies, women receive the same care as men once they present to providers with a heart attack. In one study, time from hospital arrival to actual treatment was the same for men and women.

However, this obscures the reality of women's cardiac care. At stake:

    Women who present with non-classic symptoms of heart attacks are not always correctly diagnosed, because . . .
    Tests and traditional diagnostic methods are geared toward

determining the pathophysiology of men with CVD, and do not capture microvascular and other forms of CVD prevalent in women.

Women—especially young women—are less likely to receive protocol-based care and, if they receive it at all, typically receive reperfusion therapy after a heart attack much later than indicated by protocol.

Clinical trials are rarely gender-specific or gender-analyzed, so that efficacy and risks are not adequately known for drugs and other reperfusion therapy. While women appear to do better with a PCI (stent) than thrombolytic drugs, which involve higher risk of bleeding for women, sound evidence is needed to show whether dosage issues or other factors improve results for women under these and various other therapies.

Can Population Health Approaches Help Improve AMI Outcomes for Women?

The disparity in care and outcomes for women are multi-factoral, and so, too, must be the solutions. Providers and provider organizations offer the best pathway for kick-starting improvement in women's heart care. Why? Because they are now implementing systemic processes to close gaps in care and improve problematic outcomes among patient populations.

Population health, alone, cannot resolve gender disparity in care, but it can be used in concert with a provider education strategy to focus on outcomes-improvement initiatives. Provider strategies begin with developing risk-based registries of women with various heart risk factors, most of which can be created using data already present. With this foundation, providers can

develop multiple strategies:

- Targeted patient education about heart attack symptoms, for subsets of women, such as young women who smoke and are more at risk for delay in seeking treatment;
- Patient reporting of additional risk factors not captured by data, such as pregnancy-related outcomes, for development of targeted outreach initiatives aimed at increasing activity, reducing obesity, and making other heart-healthy lifestyle choices;
- Partnership with research entities and academic centers to improve representation of women in studies based on risk factors;
- Measurement and improvement activities associated with treatment designed to ensure that providers are following protocols to test women appropriately who present with symptoms.

Helping women patients recognize their risk factors and improve response time to signs of trouble are essential to their positive outcomes. But providers will also need to be more responsive to women’s less dramatic symptoms, and less likely to dismiss their concerns as psychosomatic or hysterical. In short, any focus on patient improvement must be matched by equally strong efforts by providers to help correct biases against women. In particular, women presenting with pain or diffuse symptoms, women who are obese, and black women are vulnerable to such biases.

The value of culture- and gender-focused education could be enhanced by the inclusion of both providers and patients in learning experiences. Conversations in small groups to address

heart disease and obstacles to seeking care (or improving lifestyle)—facilitated by inviting patients based on registry criteria—can be used to engage patients in positive experiences and literacy-building. Similarly, population health improvement projects aimed at decision-making between physicians and patients could build rapport between individual physicians and their patients.

Accountability for patient health under Value-Based Health Care will require providers to envision new ways of connecting with their patients to resolve health issues. Women at risk of heart attacks is an ideal starting point, because the sex differences are not only clear in pathology, but also have a huge impact on outcomes and cost.

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Image: Christian Newman

The Real Trend to Watch in 2019: #MeToo for Health Care

written by Theresa Hush | February 14, 2019

Health care pundits need to sharpen their game. Year-end trend predictions are mostly old news. Growth of Artificial Intelligence and other technologies, entry of non-traditional business in health care, and pressure on the bottom line from

Value-Based Health Care—all have been well underway for several years. Further, these developments only reinforce health care providers' inward focus on managing internal machinery and health care financing, instead of real health care.

But consider this underreported trend that promises to reshape demand and shake up the supply of health care services: We are in the midst of a dramatic transformation of health care attitudes, services and organization by women acting as both health care consumers and professionals.

There's a lot to unpack here. Let's address women patient and consumer perspectives first, the motivating force that is generating momentum. In a future article, we'll evaluate the impact of women physicians and other professionals on the industry.

The #MeToo movement that gave voice to women who have experienced sexual harassment has empowered them to speak out about other forms of victimization, including sexual violence, unequal treatment in workplace opportunities and income, and more recently, discrimination in health care. Women have led the resistance to the ACA repeal and rallied against pre-existing conditions during recent mid-term elections.

Our prediction: These protests and political organizing will encompass the inequities women face by health care providers and payers, as well as directly challenge those institutions. Called the #MeToo movement in health care by one physician leader, the trend was recently highlighted by the American Public Health Association at its 2018 annual meeting. Providers should begin developing strategies now, because there is a lot

to address.

Concern Over Inequality in Health Care Benefits Is Going Mainstream

As women learn more about health care gender inequities, frustration is growing. While differences between men and women's health care benefits were recognized on a limited basis (e.g. reporting on discrepancy that Viagra is covered by insurance but not certain contraceptives), there was no political forum until benefits and sources of care used by women came under attack by efforts to repeal the ACA. With the progressive dismantling of ACA provisions, women have had key protections curtailed. Limited benefit plans that exclude pregnancy coverage outside the ACA requirements, for example, is transforming frustration into anger.

Restrictions and de-funding of Planned Parenthood's broad range of women's health care services, narrowing of Medicaid, and proposals for coverage that re-instate pre-existing conditions (which used to include pregnancy) have all reduced affordable health care options for women or made their health care more expensive. Not only do women earn less than men on average, but their economic buying power is further restricted by limited benefit plans and other efforts to reduce benefits that disproportionally hurt women, particularly minorities. A recent poll illuminated the somber reality of women's ability to afford basic health supplies. Two-thirds of low-income women surveyed revealed that they could not afford to purchase tampons and menstrual products and had to resort to home-made alternatives, such as toilet paper and rags.

Providers Fail Women By Treating Them Unequally

Gender discrimination in cardiovascular disease (CVD) offers a compelling example of how women face dire consequences of health care inequities. Women with heart disease have higher risks in terms of known differential risk factors and treatment efficacies, and poorer outcomes as a result. All of this has been known for the last decade. Although CVD is the leading cause of mortality among women, however, little has been done to address it. Women-specific research and physician education regarding effective and ineffective treatment modalities and protocols for women are woefully lacking, even after the data revealed that women experience cardiovascular disease very differently from men.

But heart disease is just one aspect of a much larger issue. Women are taken less seriously about pain symptoms, wait longer for pain medication in the emergency room and post coronary by-pass surgery, are seven times more likely to be misdiagnosed in the middle of having a heart attack than men, and are more frequently prescribed sedatives than appropriate pain treatment. Women also receive less effective medicine to relieve abdominal pain than men.

In daily life, women are not taken seriously when reporting severe menstrual pain, nor adequately diagnosed and treated, despite the risks of debilitating endometriosis.

Women are less likely to receive timely diagnoses for autoimmune and connective tissue diseases. When they present with eating disorders, underlying biological factors are less likely to be investigated and the disorder more likely to be associated only with behavioral problems (which are often

under-covered or not covered at all). As with CVD, these and other diseases that are predominant among women lack research funding—some say because they do primarily affect women. Maya Dusenbery, in her recently released book *Doing Harm*, claims that medicine doesn't just ignore women, it harms them.

Without a unifying sense of maltreatment based on gender, each case can be dismissed—even by women—as someone else's problem. As more stories emerge, however, detailing discrimination against women's access to quality health care, the tide is turning. Coupled with #MeToo momentum and the politicization of health care benefit issues, the preponderance of evidence may well catalyze a #MeToo health care movement that demands change from health care providers and payers.

Catalyst to Activism: Women Devalued

#MeToo gained momentum because it focused on how powerful men abused their power, using sexual harassment or violence to gain advantage over women. How those power dynamics are defined has broadened to include related issues—domestic violence as well as, for many, reproductive rights.

It is no accident that *The Handmaid's Tale* captured the zeitgeist of this cultural transition. We see a growing volume of articles documenting various practices that are now understood as acts of violence. A recent article about the "husband stitch" practice during childbirth, to cite just one egregious example, has been trending on social media among women.

Trending also are accounts of women prosecuted because they miscarried babies as a result of car accidents or other events,

referenced in this *New York Times* opinion piece. New reporting reveals how women who miscarry are denied effective drugs during this heartbreaking time, due to distrust about how they might use the drugs.

As women begin to understand these actions as a departure from the previous, pernicious disparity, and declare them to be hostile attacks, we are reaching a tipping point. With every story—U.S. maternal death rate is highest in the developed world, lack of urgency to address women's health issues such as metastatic breast cancer, and curtailment of women's health benefits like pregnancy care—it is only a matter of time before women, who demonstrated their political power in the 2018 midterms, will respond to this devaluation of women in health care as an abridgment of rights.

Providers Should Proactively Address Women

Young women are already steering clear of the traditional health system as much as possible, a trend that is beginning to impact revenue and delivery of health care. Older women with fewer options or more traditional habits regarding health care services will instead use pressure and politics to change the system.

For long term economic survival, let alone ethical principles, health care providers should begin to develop proactive strategies to minimize gender-based discrimination in all their clinical operations. Creating women-specific protocols for CVD diagnosis and intervention is essential, but similar actions should be taken to eliminate the biases in diagnostics and interventions for other illnesses, especially those that involve pain and any suspected behavioral components.

Education of physicians, residents and all medical personnel will be essential to both diminish disparate treatment of women and help create new communication mechanisms to ensure that women's symptoms are neither dismissed nor suppressed.

Beyond individual organizations, health care provider organizations should collectively lobby for legislative and policy positions as advocates for best women's health outcomes. In their research, they should propose and undertake studies that correctly take into account the separate biological makeup and response of women, and propose both research targeted to women and separate gender evaluation of results for all research studies.

As this trend evolves into #MeToo for health care, providers will have no option to sit on the sidelines. Their choices are either to remain divisive through inaction and fail, or to become collaborative and succeed. Count on women to find or create systems that will treat them fairly and serve them well.

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: Alexa Mazzarello

Pathways to Success: How CMS is Encouraging ACO Participation Despite Impending Financial Risk

written by Dave Halpert | February 14, 2019

CMS closed 2018 with a farewell to upside-only ACOs. Perhaps the biggest surprise in the "Pathways to Success" Final ACO Rule is its consistency with the Proposed Rule, which floated the revamped ACO Track back in August.

Citing superior performance among two-sided participants, as well as the belief that upside-only tracks reduce patient choice and increase costs, CMS has finalized its proposal to push all ACOs into two-sided arrangements. Not coincidentally, this rule was simultaneously released with NextGen ACO model results, which showed that these 44 downside-risk ACOs saved $164 million.

The rule, which will go into effect on July 1, 2019, establishes a framework that requires an ACO entering a new agreement (whether a new or existing ACO) to proceed on a defined path toward financial risk. There are two Tracks: BASIC and ENHANCED. BASIC consolidates (and subsequently eliminates)

Track 1, Track 1+, and Track 2 ACOs; the ENHANCED Track is the next iteration of Track 3.

The BASIC track begins with a period of upside-only (non-risk) performance years, transitioning to an APM-level of financial risk (two-sided). The ENHANCED track offers only a risk-based payment structure, with higher levels of risk and reward. Participation options are determined by provider makeup and previous experience. Regardless of starting point, the agreements have increased from three to five years, which is significant, as the longer period allows for time to implement processes for patient care and technology, and to measure results.

The bottom line is, well, all about the bottom line: CMS has not backed down on its promise to hold ACOs accountable for costs. Nevertheless, they have also made provisions that foster ACO development and facilitate success. In other words, despite mandating financial risk, CMS is continuing to encourage ACO participation through provisions within the Pathways to Success rule.

Five Ways CMS is Encouraging ACO Participation

1. Tying the “Glide Path” for financial risk to Advanced APM Status.

The Glide Path is the transition from one-sided risk to significant two-sided risk. In the BASIC Track, each year corresponds to a specific level, although previous participation and experience with risk may mean that an ACO begins BASIC at a more advanced stage. The first two levels (A and B) are one-sided, while the next three levels mandate

continually increasing levels of risk. Of those three, the top level (E) requires the necessary financial risk to be considered an Advanced Alternate Payment Model (APM) under the Quality Payment Program.

APM status is critical, as it means that Qualified Participants (QPs) will earn a 5 percent incentive payment automatically, on top of whatever Shared Savings are earned through the ACO. While it's true that there is a potential to incur shared losses as an ACO, exiting the ACO market simply shifts risk into MIPS. In the BASIC Track, shared losses are capped at 4 percent of expected expenditures, which (all things equal) is less than the potential penalty for MIPS.

2. Offering flexibility for physician-led ACOs.

The Rule lays out slightly different Pathways, depending on whether the ACO is considered a Low-Revenue or High-Revenue ACO. An ACO is considered Low-Revenue if its ACO providers' total A and B Fee For Service revenue is less than 35 percent of the total expenditures for assigned beneficiaries' ACOs. These are traditionally physician-led ACOs, rather than hospital-led, as an ACO with a hospital's TIN will account for a much greater portion of the total ACO population's Parts A and B expenditures.

Without as much capital compared to a hospital-owned ACO, these physician-led groups traditionally tend to avoid risks. Their concerns are mitigated through an option to add an additional performance year (based on comments to the Proposed Rule) without downside risk. This will necessitate jumping into a slightly higher level of risk the following year, but still

gives the ACO additional time to measure the results of its improvement efforts and to make changes prior to taking on financial risk.

Low-Revenue ACOs also have the option to enter into a second BASIC agreement, as this will help them prepare for the comparatively large jump in risk from BASIC Track Level E (capped at 4 percent of the updated benchmark) to ENHANCED Track (capped at 15 percent of the updated benchmark).

3. Offering higher shared savings rates for BASIC Track than initially proposed.

Originally, CMS had proposed a 25 percent Shared Savings rate for upside-only ACOs. In other words, if an ACO spent $1 million beyond the benchmark and Minimum Savings Rate, that ACO would recoup $250,000 in Shared Savings. In the Final Rule, Shared Savings for upside-only can be worth up to 40 percent. In the moderate risk years (Levels C and D), the Shared Savings Rate increases to 50 percent, with only 1 percent and 2 percent of total costs at risk, respectively. The possibility of a larger payout in the initial years may entice the risk-averse who might otherwise have dropped out of the program or declined to participate.

This is particularly critical for Low-Revenue ACOs. Consider an ACO whose Part A and B revenue for its ACO patients totals $10 million, but whose projected expenditures are $100 million. The ACO is considered low-volume, as it only receives 10 percent of the A and B revenue from its ACO population. If this ACO achieves 3 percent savings at a 40 percent share rate, that represents $1.2 million in Shared Savings—a 12 percent increase in revenue! For a High-Revenue ACO whose Part A and B revenue

for its ACO patients equals its projected expenditures, the same Shared Savings result in a more modest 1.2 percent incentive, but that's still preferable to an increase of 0.75 percent.

4. Encouraging patients to engage with ACOs.

CMS took MedPac's recommendation to allow entities to provide financial incentives to patients. The Final Rule allows ACOs to offer up to $20 per patient for each qualifying primary care service, along with "in-kind" incentives, which must be connected to a beneficiary's care and are either preventive care-related or advance a clinical goal (e.g. adherence to a specific regime). ACOs cannot incentivize patients for obtaining other services from inside the ACO (e.g. $20 for getting an MRI at the hospital, rather than an open imaging facility), but the ability to legally offer a reward for obtaining preventive care services gives ACOs a useful tool to facilitate adherence and/or treatment protocols. However, the program must be approved by CMS, and all patients must be notified—it cannot be "by invitation only," or started at an arbitrary point during the year.

Beneficiaries must also be notified at their initial visit that the provider is participating in an ACO, including goals and responsibilities. This may be accomplished with signs posted in the office, along with documentation available on request. Patients are to be notified that they have the opportunity to decline data sharing, and—most importantly—that they may choose to be attributed to a different ACO through a different provider, even if that provider is not considered a "primary care provider." While these provisions certainly don't guarantee "engagement" among providers or patients, they

provide a framework for a relationship between a patient and integrated care network.

5. Updating cost benchmarking methodology while adjusting allowed costs and services.

One of the challenges of the CMS benchmarking methodology was that it was based on the ACO's historic costs. Unfortunately, as a result, when an ACO reduced spending, it became more challenging to demonstrate savings compared to the new benchmark. Those who improved were locked into an untenable cycle of continuing cost reduction. This Final Rule addresses that issue by rapidly expanding the rate at which "regional benchmarking" will be factored into the overall benchmarking score. This enables CMS to compare the ACO to the area in which it resides, in addition to the ACO alone. These changes, along with updates to risk-adjustment, align the ACO and Medicare Advantage benchmarking methodologies. Of note, alignment between the ACO and Medicare Advantage models is a theme discussed frequently in the Final Rule.

Juxtaposed with the changes to benchmarking methodology are updates to the ways in which ACOs may deliver (and be reimbursed for) services, including Skilled Nursing Facility (SNF) care and telehealth services. The SNF provisions are related to the SNF 3-Day Rule Waiver (sometimes called the SNF Waiver or 3-Day Waiver). An ACO with downside risk has the opportunity to waive the 3-day hospital stay required before the patient may be discharged to a skilled nursing facility. While SNF care drives costs on its own, for patients who require SNF care—but may not require three days in the hospital—the SNF waiver can particularly benefit ACOs. On the

other side of the spectrum, telehealth services are easier to provide, as the rule removes restrictions related to the patient's location. As a result, ACOs may receive reimbursement for telehealth services that were previously not covered. This enables ACOs to proactively coordinate care without an office visit, potentially avoiding more substantial costs down the road.

The Show Goes On

With only 18 percent of the 561 ACOs in a two-sided risk model, the proposed Pathways to Success rule was a harsh jolt for the ACO world. A 2018 industry-led survey predicted that the majority of upside-only ACOs would drop out if risk became mandatory. Nevertheless, CMS expects to lose only three ACOs in 2019, while expecting to gain 10 in 2020, 12 in 2021, and 43 in 2022.

CMS has offered to extend existing agreements that would have terminated at the end of 2018 through June 30, 2019, and 90 percent of those ACOs have opted in. ACOs whose agreements last beyond July 1, 2019 (the starting point of any new ACO agreement) can finish out the remainder of their existing agreement. New ACO agreements taking effect on or after July 1, 2019, are on track for financial risk. Those who choose to exit the ACO arena may avoid the provisions outlined in the Pathways Rule, but with steadily increasing weight applied to the cost component of MIPS and the increasing number of Medicare Advantage plans, there is no escaping: Financial risk is here.

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their value and succeed in Risk. Roji Health Intelligence is a CMS Qualified Clinical Data Registry.

Image Credit: Fancycrave

There's More to be Learned from Good Results than Bad—and Why It Matters

written by Thomas Dent, M.D. | February 14, 2019

Becoming a physician requires passing many tests, beginning with premed studies, all the way through residency and, ultimately, board certification. You spend countless hours focused on passing examinations or rotations and learning to avoid pitfalls.

As a residency program director, I and my colleagues invested considerable effort to determine which residents were struggling and to develop strategies to help them. We focused on finding deficiencies that would impede them from being excellent physicians.

A fellow faculty member ran a Morbidity and Mortality conference that he nicknamed the “boo-boo” conference. This process of identifying and analyzing medical errors produced competitive physicians, but also ones who were tired and avoided the measurement process. Physicians who train this way

are very attuned to looking for where things have gone wrong—an attitude also fostered by our medical-legal system, which focuses on avoiding mistakes. When lives are at risk, this is essential. A physician must “stand tall” and acknowledge a mistake in order to maintain professionalism and integrity. Mistakes are best addressed in the long run by creating a process of continuous improvement. This process requires physician buy-in and cooperation.

Now I work in a company that assists in measuring clinician performance. Most of the time this measurement is based on quality measures developed by different groups for CMS. Reimbursement is tied to these measures. Clinicians and organizations are scored and compared to others. Not surprisingly, physicians have reported concern and anxiety over being “dinged” by poor scores. Conditioned by competitive medical training, they do not want to appear professionally inadequate and may focus disproportionate attention on those things that might contribute to an appearance of incompetence.

How Measurement Is Communicated and Evaluated Is as Important as the Data

All of this measuring in medicine is essential to evaluating outcomes and improving performance to achieve quality, affordable care. But how the measurements are communicated and interpreted makes all the difference in physicians’ ability and willingness to lead and participate in needed change in our health care system.

Now the emphasis in performance measurement is shifting from quality outcomes to cost of care. Physicians will be measured and compared to their peers based on the cost of care for

specific episodes of care. While this measurement isn't as threatening to professionalism, it can present an economic threat, particularly with the advent of narrow networks.

For example, there are many caveats to cost measures, based on differences in patients and resultant costs. But these costs may be beyond the purview of the physician. Although patients are "risk-adjusted" to make these measurements more meaningful, risk adjustment hasn't been as accurate at capturing causes of variance based on social or environmental factors, such as social support.

In working with providers to improve performance, it is neither inspiring nor helpful to focus on negative results. The response is often avoidance, hostility and hiding data. Who can blame them? Clinicians who perform procedures on or assume care of high-risk patients should not be compared to clinicians caring for lower risk populations. Even when the data is correct, the denial process can be extreme enough to mirror the five stages of grief described by Kubler-Ross.

Appreciative Inquiry Shifts the Emphasis from Blame to What Works

I propose an alternative approach—a management tool called "appreciative inquiry". Rather than seeking to identify and correct or avoid unexpected poor results, appreciative inquiry explores positive outcomes to discover operational improvements. In so doing, this approach changes relationship dynamics among administrators, providers and office staff.

Punitive challenges are replaced by aspirational goals. This invites providers to study why some things work well and to

identify existing best practices. Collaboration among providers is enhanced because it is much easier to share successes than failures.

To be of real value, appreciative inquiry must lead to measurable improvement. Rather than presenting actions and interventions that are part of improvement activities in the context of a negative situation, interventions are recommended based on success. This avoids stigmatizing the provider for not providing high quality and efficient care and places the emphasis on what works and has been done well.

An additional benefit: training in appreciative inquiry (along with mindfulness and narrative medicine) can help to prevent physician burnout.

Four Steps to a Positive Process of Performance Improvement

Here are four steps toward performance improvement actions and interventions that build off positive results (based on the Appreciative inquiry 4-D cycle of Discovery, Dream, Design, and Destiny):

> Make it real. Use data and examples from the practice. Whatever is done must be measurable. Look for positive change. Good or even average results in challenging patients (because of multiple or serious co-morbidities, unhealthy lifestyles, or personal circumstances) are unexpectedly positive outcomes and need to be recognized and investigated.
> Capture more information. Avoid the evasiveness of stressed and suspicious clinicians. This action is the antithesis of

rolling out poor results and demanding plans for improvement. Hiding or just not reporting unfavorable results is human nature, especially when there may be liability associated with poor outcomes. When things go well, the default is to assume that's just how things should be, but root causes need to be explored (for which it's much easier to get buy-in). Specifically ask what went well and what the clinicians aspire to that will make them proud of their work.

Generate reasons (hypotheses) for what caused positive results. These reasons should be tested in applications with future patients. The practice will need to be creative and approach this evaluation process with curiosity and inspiration.

Implement or deploy actions or interventions based on the hypotheses. Measure the impact and modify as needed.

Appreciative inquiry has been likened to an organizational placebo effect. A placebo is an intervention that produces positive results based upon the patient or physician believing it will. Appreciative inquiry builds on a solid research base and has been implemented in numerous organizations of all different sizes. Exploring why there is an unexpectedly good outcome creates energy and pride within the practice. It is best to take the high road to reach goals, a path that provides the greatest opportunity for inclusion and success.

Image: Darko Pribeg

Conflict of Interest in Medical Practice Is Hardwired: Unless We Acknowledge It, Nothing Will Change

written by Robert McNutt, M.D. | February 14, 2019

In philosophy class, we were asked to choose which of two children falling out of a boat, unable to swim, should we save. Kant believed all people share the same moral equivalency, and a choice cannot be made to save one or the other based on morality. They must be treated the same. This question was paired with a second question forcing a choice between sacrificing one to save others, or many to save one. Tough moral questions.

However, both questions were moot if the one being saved or sacrificed was your child. No matter what moral principle studied, whether in the context of absolute morality or trade-offs, we decided for our child. These philosophical questions become mere child's play when subjugated to my personal conflict of interest (COI). COI kills philosophical principles.

COI also obscures medical decision-making. How can a patient

make an informed choice among treatment options when her physician is making recommendations—wittingly or unwittingly—favoring vested interests that are hard-wired into the health care system? How can a patient evaluate cost of care and value received when the actual costs are distorted by an incentive system that favors internal referrals, extra tests and procedures that boost the provider's bottom line?

Medicine as Practiced in the U.S. Invites Conflict of Interest

Reams of papers describe COI in medicine. Governing boards at CMS include business leaders who stand to benefit from favorable rules; guideline committee members receive payments from industry for the industry's interventions being proposed in guidelines; billions of industry dollars are paid to physicians, as disclosed on government websites; physicians plead mea culpa for prescribing treatments and tests to avoid legal actions. These proclamations alone should make every medical decision-maker take pause when considering a medical intervention.

These examples, however, fail to lay bare a greater COI; COI is the practice of medicine. For example:

> A large practice group, sharing profits, refers to specialists in their practice.
> A specialty physician, paid for the number of tests performed, opines that a simple stress test is needed or an echocardiogram should be added.
> A patient sees a primary care physician and specialty physicians; but, due to competing financial interests, one specialist provides primary care services, such as injecting

a joint, instead of sending the patient back to the primary care physician.
A radiologist suggests at the end of a note that an MRI should be added to the CT scan.
An orthopedic specialist suggests physical therapy and sends their patient to their physical therapy staff.
A hospital assigns a “hospitalist” to assure early-as-possible discharge and hires a “utilization manager” to monitor the hospitalist, all to benefit the hospital and support, financially, the staff they hired.
A dying patient with cancer gets hospice, a palliative care team, a care-coordination team, a primary care doctor, an oncologist and a visiting nurse, all ordered from the same system of care, without questioning redundancies or the patient’s desires.

There are Stark Law regulations that are supposed to protect patients from COI for referrals to sites owned by physicians. The examples above, though, don’t necessarily involve ownership to create a COI. I do not know if those laws have helped patients, but I doubt it. The reason I doubt it is that unfettered decisions are still made by physicians and system leaders, owned or not. Even if Stark Law has protected patients, and I am wrong, there are no similar protections for other types of COI practiced today.

COI Adds to the High Cost of Health Care

Fee-for-service has been blamed for COI. However, many of the COI care processes above arose to reduce costs imposed by fee-for-service by paying lump sums. Hospitals and physician groups have financial risk if readmission rates are high, for example, so hospitals are building relationships with entities to keep

patients out of the hospital. Care-coordination, adding others to the delivery chain due to expanding cohabitation with networked groups, is being imbedded in quality payment systems. It is hard to show that more complex systems work better than simple systems, and coordination is a synonym of complexity

I propose that anytime a payment scheme includes an arrangement of people in order to reduce the cost of care, without patient input, COI is at play. How are these disparate teams to be managed? Who will be paid what amount under fee-for-service, or if capitated? Which of the tasks does the patient want or need? Jockeying for tasks is bound to occur. Someone in charge will have to make trade-offs between services. Trade-offs for management creates COI among those providing service. Making money reducing or increasing services creates COI with patients. How care is paid for does not assuage COI; it just changes who gets paid—not necessarily what happens to sick people.

In a study comparing the costs of care between countries to examine why medical care in the United States is so costly, researchers found that differences in costs were not due to wide ranging differences in the services provided. This is crucial. Our disjointed, costly insurance system, a universal system or an "alternative payment system" can change nothing if the totality of health care decisions are already "rubber stamped" in the supply chain. Case in point: I once reviewed the distribution of orders and consultations over a year for patients admitted to a hospital. I asked to see the distributions for 10 common diagnoses. The distribution of orders and consultations were nearly identical for all diagnoses. Medical care does what medical care does.

If these cost models were drugs, they would be equivalent in terms of value, but not cost. Unit cost reduction may be a worthy goal, but it is insufficient.

Patients Must Be the Final Arbiters of Medical Decisions

If a payment system is to help patients, it must be able to show marginal differences in the totality of choices made, not just the cost of a unit of care. Since we can't presently see marginal differences in goods and services, or medical decisions being made for patients, we can't fancy that one system of payment is better. The problem that needs to be solved before thinking about how to pay is how to change the hardwired, conflicted decisions being made in the first place.

There are two main reasons why patients should make medical decisions. First, the consequences of a choice are experienced only by the patient, not the physician. This reason is undeniable.

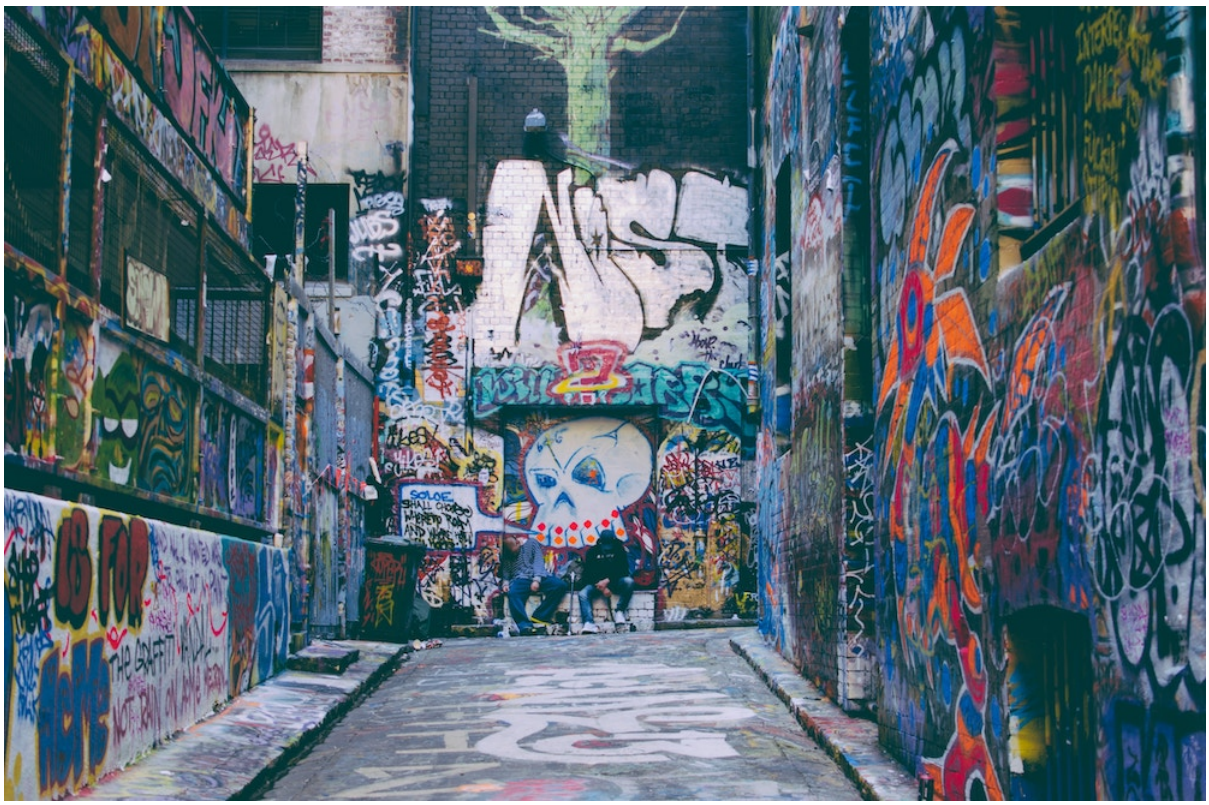
Second, the patient is the only one in the medical care supply chain with fully appropriate incentives. Patients don't have COI. They just want to get better, on their terms. Getting better requires being informed of marginal benefits and harms, and making a choice. Once informed, they will know how to value the choice. They will even be better at telling us what it should cost. There is no other way to better care than to put the patient in charge. That is the only system of care we need.

Kant was right. To be a useful system of care, the absolute morality of a sick person, rather than the system, must prevail.

Image: Pawel Szvmanski

Should Value-Based Health Care Help Improve Life Expectancy?

written by Theresa Hush | February 14, 2019



As Americans in a highly developed and prosperous economy, we have ascribed a value to our highly sophisticated, expensive health care system—that it should enable us to achieve better health. If we didn't believe in the value of our health care system, we would not support health coverage, most people would not visit health care providers, and the public health system would not get be funded.

This may sound all too obvious, but it isn't. Whether our health care system actually achieves that ascribed value of improving health status is now in question. Given last week's release of Center for Disease Control (CDC) statistics on life expectancy in the U.S., American health care gets a C-, at best. For the third year in a row, life expectancy in the U.S. has declined—a trend not recorded since World War I and the 1918 influenza pandemic.

This raises an interesting question about all the resources we are pouring into Value-Based Health Care (VBHC). How can we create VBHC solutions that really do achieve the value we want in health care?

One Test of Value: Our Collective Health Status

The CDC reported that an American born in 2017 could expect to live 78.6 years, a tenth of a year less than a 2016 estimate. Men's life expectancy declined by the same amount, to 76.1 years; life span for women remained the same at 81.1 years. This alarmed public health experts, in part because increased death rates among younger adults are reducing average life expectancy for the population as a whole. Since a society's health is associated with a nation's economic development status, the downturn raises the concern that Americans are not faring as well as they should.

The annual statistics released by the CDC highlighted a worrisome trend of higher death rates reported among young people due to unintended injuries—more specifically, death from drug overdoses. OD deaths rose 9.6 percent between 2016 and 2017, according to the CDC, to 70,237. That is many thousands more lives lost to drugs than to federal disaster emergencies during that same time period.

While the opioid crisis may be the biggest explanation for the statistics, particularly due to the increase in fentanyl deaths, it is not the only issue. Sharply increasing suicide rates among both women and men also contribute to concerns about our collective mental health status. Between 1999 and 2017, suicide rates jumped by a third, from 17.8 to 22.4 deaths per 100,000 among men and 4 to 6.1 per 100,000 among women; in

addition, the rate of suicides in rural areas is now twice that in cities.

More bad news from other recent studies—escalating death rates in young people from liver cirrhosis due to alcohol abuse—add to the grim picture of our national health.

Individual patients may not be concerned with whether the health care system as a whole improves health status and prevents untimely deaths, given that these are values derived from a social or public health perspective. At the same time, patients may take for granted that the job of health care is to heal and may articulate other values as higher priorities, such as access to coverage or affordability.

Another Test of Value: Value-Based Health Care

Value-Based Health Care responds to the latter concern that Americans are not getting value for their health care dollars by focusing reforms on economics rather than health status. The fact that we spend more on health care than any other developed country has been the driving force for changes in the health care system. VBHC's primary goal is to make our health care system affordable—for Medicare and Medicaid, business and health care consumers.

What about the role of quality measures, such as the five in MIPS that specifically address processes aimed to stem opioid overprescribing? Quality measures—including episodes that combine both quality and cost—have made positive contributions to VBHC and to better health value. However, many providers remain exempt from reporting, and those who participate need only report one outcome measure out of a total of six quality

measures and are therefore effectively exempt.

In short, Value-Based Health Care is mostly about economics, not health status. Value is defined primarily as cost, assuming a general standard of quality delivered by providers.

Any changes taking place under VBHC primarily affect payment models and reimbursements. While there are improvements intended for consumers, such as new Medicare requirements for access to digitalized health records and price transparency, these improvements are designed to help consumers be better *purchasers* of health care, emphasizing economic over medical decisions.

The end result of VBHC will be risk-based reimbursement for providers, starting with Medicare. Providers will be driven by reimbursements to participate in Medicare Advantage or ACOs, and specialists will agree to bundled payments with a fixed price. Without providers, the public health community or government pressing for change, it is unlikely that VBHC will also emphasize values such as protecting consumers from harm or preventing untimely death.

Three Actions that Providers Should Take to Provide Health Care of True Value

This values discrepancy matters, because cost and affordability are intertwined with health status; poor health status will ultimately affect costs. If VBHC maintains its current path, the deficiencies of being too cost-centric will become clear as costs continue to escalate while life expectancy declines further. Then a “new” solution will be suggested to replace VBHC, much the way that narrow PPO networks replaced HMOs—which

previously replaced free choice of provider. Each solution had a similar flaw: failure to properly balance the quality product of the system with its cost.

Can we afford more health care failures, economically or societally? Not if we want to avoid the collapse of our current system under financial risk, overstressed providers and costs that exceed the means of most consumers.

The sustainability of the health care system will require that providers take the lead to ensure that health care's real value is defined by health improvement and protection, not just cost cutting. To do so, they should incorporate values of improved health status and prevention of patient harm into their own VBHC initiatives. Here are three critical areas:

1. Measure the occurrence of health system failures and establish interventions. This should include:
    - Infections or illnesses that occur as a result of facility stays, procedures, use of antibiotics or other drugs;
    - Unexpected mortality of all kinds, including drug overdoses; and
    - Unintended consequences of treatment that result in secondary illnesses.
2. Improve provider screening and management of

behavioral health issues, including the development of an appropriate referral system if behavioral health or addiction treatment is not internally provided.

Focus VBHC initiatives on gaining improvements in patient health status and outcomes, rather than only patient visits or filling gaps in care. There are a number of preferred approaches to population health that could achieve better value for patients.

The health care system deserves champions who safeguard its real value. While we can't monetize health status, providers can ensure that the system they steward under VBHC creates better results for society. Whether those values are expressed in regulatory policies of Medicare or health plan reimbursements is beside the point, because payment vehicles cannot create good health—only providers and patients can.

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Image: Linda Xu

Can ACO Population Health Solve Patient Engagement?

written by Theresa Hush | February 14, 2019

Personal attitudes inform our strategies for improving patient health. As ACOs move forward in Value-Based Health Care, attitudes about patients and providers set the stage for collaboration or conflict. And with ACOs taking on financial risk for patients, those attitudes and strategies can make the difference between success and failure.

As we discussed in a previous post on the importance of involving physicians effectively in population health initiatives, alliances with physicians start with building trust and clinical leadership. Failure to do so will ultimately undercut both the ACO and their patients. So, too, must we be responsive to patients' needs—not just clinical, but in all aspects of health care.

Here are some common attitudes about patients and how they might inform ACO strategies. Do any of these ring true for you?

> Providers say they want to help patients achieve better health status, but they can't get patients to engage in meeting that goal.
> If only patients would adhere to the regimens designed for their care, providers say. If only they did what they were told to do, like stop smoking or lose weight or take their medicines, they would get better. But many patients simply don't pay attention.
> Population health targets specific patients for follow-up. Providers say that those delinquent patients will comply with instructions under the pressure of reminders and provider follow-up.

You can see here how the attitudes (and frustrations) drive the

population health strategy, such as it is. But we need to dig deeper: How do these attitudes impact the way we engage patients, for better or worse?

Population Health Should be Dialogue—Not Management—To Help Patients Succeed

The above characterization of patients and the need for adherence to goals is certainly not surprising. It's an attitude common to physicians, health plan and provider professionals, employers and many policymakers. But it is also a paternalistic attitude towards patients. It essentially means that patients should behave and not ask questions. It's an attitude that does not acknowledge the new realities facing health care consumers.

Many patients, especially young adults, do not agree with traditional roles. They want information, and they want to make their own decisions. Further, they want to make those decisions based on their own values. And many of them—often appropriately—question the science and cost-benefit for various screenings, treatment advice and other outcome assumptions. This is *not* non-compliance. It's self-advocacy.

There are many reasons that patients don't follow through with treatment regimens. They simply may not agree with the goals. Even if they do agree, they may need help from family or other support for fulfilling the goals, or can't because of financial or other issues.

Rather than use population health as a club for compliance, ACOs must redeploy these initiatives in an effort to communicate. Patients should feel comfortable articulating what

they want. How providers ask questions and recommend treatment is important, as is the information provided to patients for decisions. If ACOs fail to support a positive inquiry process with patients and belittle them with reminders instead, they lay the groundwork for disengagement.

Patient-centric Physicians Get Better Engagement

Here's the bottom line: alignment of physician and patient attitudes about their roles results in greater patient adherence. Patient-centric discussions, as opposed to one-sided and physician-directed monologues, are increasingly regarded as the first step toward achieving patient agreement and cooperation.

What this means for population health and other Value-Based Health Care strategies is a culture shift to change the roles—and the conversation—between physicians and patients. The time is past where ACO physicians can afford to be directive and removed from patients' issues.

Instead, tools such as motivational interviewing and counseling-style discussions with patients must inform the physician-patient relationship. ACOs, for their part, can ensure that practicing physicians are given the time and training to develop such skills. Medical schools and residency programs likewise must incorporate this transition in their classes and preparation. Future physicians will need expertise to help engineer change, sharing their clinical knowledge in decision-making processes that enable patients to determine benefits of treatment goals and alternatives.

Shift Focus of ACO Population Health to Disparate Populations

ACOs are responsible for the health of their entire enrolled patient population; naturally, however, they set population health priorities for groups that are generating poorer results and greater costs. One of those priority groups certainly should be patients with socio-economic issues coupled with severe medical issues. Lowering costs will ultimately require addressing these patients who have higher risk, unmanaged outcomes, and possibly also lack support systems to ensure treatment maintenance.

Compare these two approaches to management of high risk patients with diabetes:

> In Group 1, the ACO uses a patient registry with recent lab values to identify patients with unmanaged HgA1C control values. The patient is contacted by phone or mail and asked to return to the office for follow-up. At the appointment, the physician discusses diet and other concerns with the patient, who arrived alone, and reviews medication options. The patient says he will do better with diet but wants to remain on the same medication. A follow-up appointment is scheduled.
>
> In Group 2, the ACO establishes a population health project to address patients with poor and unmanaged HgA1C control values. The population health project is designed to evaluate patients with financial and support issues, for which predetermined processes have been arranged for patient help.
>
> The ACO uses a patient registry with recent lab values to

identify patients with unmanaged HgA1C control values. The care team member assigned to the physician calls the patient and expresses the physician's concern about the consistently poor results, and asks that the patient come to the office to talk over options. In the phone call, the care team member explores financial, family and other obstacles that the patient may be having that are affecting her health, and documents these in the record for the physician to review. The patient reveals that she is living alone and has financial pressures along with poor insurance coverage. A patient visit for the physician is scheduled, and the patient is asked to bring a family member or friend who can be available to support her. The care team ensures that enough time is allowed to meet with the physician as well as with a care team coordinator.

The patient is then designated by the ACO population health project to be queued for a discussion of support options after the physician appointment.

The physician reviews the chart, discusses the patient's difficulties and explores whether the patient is agreeable to participating in one or more of the additional support options, which can be discussed with the care team coordinator following the visit. They review medications and financial obstacles. The patient and family member leave the clinic after working with the care team coordinator on a supported diet program and reviewing financial options for medication assistance. The care team works with the family member to arrange for ongoing support.

While population health will inadvertently capture patients

needing extra support and services in data for these initiatives, some ACOs will have to address disparity in care specifically because it reflects needs in their patient population. For example, ACOs serving patients who are more susceptible to various diseases because of race or circumstances need to address those issues head-on. Provider biases against poverty, race and other factors are well documented and researched, and result in suboptimal care, if not outright abandonment of patients because of their challenges.

ACOs have an opportunity to succeed with a fresh perspective on population health, one focused on optimizing their patient diversity. The most positive financial reward under risk arrangements will result from improving care in moderately ill patients, preventing them from falling into a steep decline by providing better support and relatively simple interventions. To make gains with such patients, ACOs must develop effective, appropriate ways of eliciting accurate information about patient preferences and support issues, such that the patient can provide an adequate foundation for establishing plans of care. Second, ACOs or their participating organizations should work with clinical and non-clinical staff to remove biases in the medical decision-making process. Access to community resources will be essential to supplement the gap in the patient's resources, and ACOs will need to organize these in advance.

Prerequisite to Patient Engagement Is ACO Responsiveness to Consumer Needs

ACOs face another obstacle in gaining patient engagement:

patient trust. Many surveys have revealed that trust in health care providers has declined. Patients believe that providers care more about generating revenues than delivering good patient care, a reflection of their frustration with high cost and lack of price transparency, coupled with physician-driven decision-making. Even when patients give high marks to their physicians, they complain that their time with them is inadequate to discuss all their concerns.

To generate loyalty and cooperation, ACOs have the advantageous position to insist on changes in their participating provider processes. These include supporting a medical decision-making process that embraces clinical alternatives and research results, price transparency, conveniences in scheduling and more time for discussion.

To take on these challenges, the ACO must set the standards for its participating providers in fundamental ways that go beyond quality measures and cost variances. ACO population health efforts cannot be expected to realize their full potential through patient engagement without changing the way patients are engaged. That means identifying best practices for the physician-patient relationship, which many ACOs may feel is outside their scope of operations. Since the ACO must also help its provider organizations better collaborate with physicians and ensure that physicians receive value from their own ACO engagements, however, this approach is instead a natural outgrowth.

The catalyst to change may be Value-Based Health Care reimbursement, but the ACO is the vehicle to create the changes throughout its provider network as well as its patient

populations.

Can Population Health Help Patient Engagement?

Typical population health initiatives can result in returning patients to physicians for services, for some prevention of emergency room use, improvement in vaccinations and screenings, and identification of patients for more complex case management services. We don't discount their value.

But as a rule, these efforts cannot fully succeed unless they fit seamlessly into a changed patient care culture where both physicians and patients have new and respected roles. ACOs fight an uphill battle with reminder and outreach systems, trying to convince patients to do what they may not always be able to do, with communications often operating outside patient relationships with their physicians.

By contrast, ACOs can create population health efforts that attract patient participation. They can start by changing attitudes toward patients. By first assisting physicians with time and counseling skills to work with patients, and identifying patients' health goals and obstacles, ACOs can start a constructive dialogue about how to meet patient health goals. With that foundation, patients would be more eager to participate in initiatives that fit their interests, time and issues, such as:

- Group education, diet support groups, recipe exchanges and exercise competitions;
- Webinars with coaching calls established by the care team;
- Tracking and submission of personal data;
- Focus groups.

Population health is often understood by ACOs and their providers as a data exercise, since data is used to establish patient populations. But data is just the facilitator in population health. To cast the initiatives as technical and administrative undercuts its impact.

Population health is a human interchange, started through groups, but with improvements executed at the individual patient level between patients—with their support network—and the care team. Patient support networks, in particular, are an essential component of effective population health initiatives, for patient recovery and health improvement are usually dependent on help provided by relatives. Population health initiatives can indeed effectively engage patients in improvement activities. They can be geared to meeting goals established by those two parties, employing methods that work for individual patients.

ACOs, if they assume leadership, can become population health powerhouses.

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