Health Practice Patterns and Wasted Resources

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Executive Summary

Prices are only part of the problem of high US health costs. A review of research for CAHC on U.S. health costs indicates that unexplained variation in health care delivery – unnecessary or inefficient care – accounts for much of the waste in Medicare spending and nearly half of excess private health care costs.

Our goal is to shed light on the contribution medical practices make to the crisis in American health care costs. This review of the literature highlights evidence that the utilization of care is responsible for almost all cost variation under the Medicare program and roughly half of variation in commercial markets. It also reviews the track records of delivery models designed to curb waste, such as Medicare's Hospital Value-Based Purchasing incentives and Oregon's Coordinated Care Organizations.

The literature review indicates that unnecessary and inappropriate medications and procedures account for a large share of the nation's health bill. This, in part, is because medical professionals and organizations are financially incentivized to do so.

Findings:

- Medicare costs vary widely due to quantity of services, not price or demographics
- Half of regional variation in costs under private insurance is due to practice patterns -- price variations account for the other half of regional variations in costs
- Excess supply tends to create demand for health care products and services
- Best practice evidence is too slowly developed and widely ignored
- Government efforts to control the price of health care items and services alone will not fix the problem

Using a variety of examples including C-Section rates, blood pressure medications, cardiac stents and opioids, the evidence shows health care delivery in the U.S. wastes enormous resources, regardless of prices charged.

Recommendations:

1. **Establish a Joint Center for Best Practices.** The National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) need to establish a Joint Center for Best Practices to discover, summarize, and disseminate information on the best practices known to science.

2. **Give Medical Specialty Societies a Role, If They Insist on Effectiveness.** Guidelines established by medical specialty societies can be very influential in helping physicians update their practice patterns as new evidence is introduced and when best practice guidelines are established. However, medical professional associations should base

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practice guidelines on empirical evidence of beneficial treatments, not on economic pressures from their members.

3. **Pay for Effective Services, Not Volume or Traditional Fee-for-Service.** Incentives that reward providers for providing more health care than is effective, should be eliminated from the system. This is a problem in Medicare's traditional Fee-for-Service program, some state Medicaid programs, and many private insurance plans. The Centers for Medicare and Medicaid Services (CMS), which administers Medicare and Medicaid, should make the replacement of fee-for-service reimbursement with value-based payments its highest policy priority.

4. **Encourage Value-Based Payment Arrangements for Prescription Medications.** Value-based payment arrangements (sometimes known as outcomes-based contracts) for prescription medications are contracts between payers and biopharmaceutical manufacturers in which the manufacturer is reimbursed based on their product's performance and the patient's clinical outcome(s). Value-based payment arrangements are most often used for the highest-cost medications; they have the potential to reduce overall health costs by coupling payment to patient outcomes, altering current incentives. However, there are several legal and regulatory impediments to creating value-based payments for high-cost prescription drugs.

5. **Make Data Collection and Dissemination a Federal Priority.** The federal government should be more proactive in collecting and disseminating data and supporting empirical analysis to document the efficacy of medical practices. This is particularly true for practices that come under question based on small-scale studies. The federal government could also be more proactive in providing information consumers can use to identify high-quality providers.

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Introduction

There is a school of thought that the high cost of the U.S. health system is a pricing issue—that our problem is that we simply pay a lot more for health goods and services than people in other countries. Those who believe U.S. healthcare is expensive because of high prices often cite studies showing that consumers in the United States generally do not receive more treatment, or better treatment than those in other developed countries.

However, this report shows that focusing on price alone potentially misses enormous opportunities to improve the delivery of health care services received by Americans. We may not be going to the doctor as often as people living in other developed countries and may spend fewer days on average in the hospital when admitted, but that does not refute evidence that we often receive more from our healthcare providers than we need or is good for us.

Most health spending in the U.S. is concentrated among the highest cost cases. High-cost consumers are often swarmed by specialists, each treating some different ailment, often with little sense of how the various treatments might interact. Lack of coordination, mismanagement, inadequate and counterproductive services are often to blame for high-cost consumers lack proper care.

And while the high-cost cases demand attention, they are not the only source of misapplied resources. For example, C-section births often cost two or three times a normal delivery. In Utah, the rate of C-section deliveries is roughly 21% of all births. By comparison, Broward and Miami-Dade counties have C-section rates nearly twice that of Utah with no evidence to justify the disparity.

Moreover, research on the U.S. delivery system has lagged. For decades, the U.S. health delivery system has been badly served by inadequate efficacy trials, leading to widespread use of products and procedures that are ineffective or worse. For example, we now know that treating stable coronary artery disease with balloon angioplasty and stent insertions is frequently no more effective than optimal drug treatment. The billions of dollars spent on these surgeries cries out for an explanation of why it took so long for a definitive study to be accepted by the American College of Cardiology. Making matters worse, there are now reports of vascular surgeons and other physicians recruiting older people at church fairs for unnecessary stenting for peripheral artery disease (Makary 2019).

We begin by presenting examples, ranging from childbirth to cardiac surgery to drug treatments to show how ineffective or inefficient care remains widespread. Finally, we briefly describe some evolving models to rationalize care delivery with the potential to improve the health of high-cost patients, even those with multiple chronic conditions, on a more holistic and cost-effective basis.

High Cost of Healthcare Is Caused by More Than Prices

Why Do Medicare's Costs Vary from Place to Place?

In 2009, Dr. Atul Gawande wrote an article in the *New Yorker* describing the difference in Medicare costs per enrollee in McAllen and El Paso, Texas, two cities with demographically similar populations. In his article, he wrote:

> Between 2001 and 2005, critically ill Medicare patients received almost fifty percent more specialist visits in McAllen than in El Paso, and were two-thirds more likely to see ten or more specialists in a six-month period. In 2005 and 2006, patients in McAllen received twenty percent more echocardiography, two hundred percent more nerve-conduction studies to diagnose carpal-tunnel syndrome, and five hundred and fifty percent more urine flow studies to diagnose prostate troubles. They received one-fifth to two-thirds more gallbladder operations, knee replacements, breast biopsies, and bladder scopes. They also received two to three times as many pacemakers, implantable defibrillators, cardiac-bypass operations, carotid endarterectomies, and coronary-artery stents. And Medicare paid for five times as many home-nurse visits. The primary cause of McAllen's extreme costs was, very simply, the across-the-board overuse of medicine (Gawande 2009).

For the nation as a whole, Cooper et al. (2019) analyzed the relative contribution of price and quantity of services for all Medicare patients in 2011. Cooper et al. broke down the discrepancy in spending per beneficiary at the diagnostic related group (DRG) level into three components: (1) share of variance in spending attributable to differences in prices across hospital referral regions (HRRs);[1] (2) share of variance in spending attributable to differences in quantity of services delivered across HRRs; and (3) differences in quantity of services attributable to the covariance of price and quantity. The results for the top-10 DRGs are shown in Table 1, with the bottom row showing results for the spending samples averaged across the DRGs where each is weighted by spending.

According to Cooper and his colleagues' results, 95.3% of the variation in Medicare spending is attributable to variations in quantity across the HRRs and 12.7% is attributable to price variation with an -8.1% covariance.

In a different approach, Fisher et al. (2003a, b) estimated how total risk-adjusted spending per elderly Medicare beneficiary varied across 306 HRRs based on variations in treatment levels. They found greater than twofold differences in age-, sex- and race-adjusted spending across

[1] The HRRs developed by the Dartmouth Atlas Project team are geographic units of analysis that are widely used in research into health delivery and costs. These regions are composed of zip code areas with a minimum population of 120,000 grouped together based on referral patterns for highly specialized, tertiary care for Medicare beneficiaries. The residents of each HRR had to receive at least 65% of their hospitalizations within the HRR.

regions primarily due to the quantity of services provided and the predominance of internists and other specialists in the high-cost regions. For those covered under Medicare where DRG prices are set with some variation across geographic areas based on general differences in costs, it is not surprising that variations in treatment costs are driven by the level of services delivered rather than prices.

Table 1: Price-quantity decomposition of Medicare spending in 2011

Procedures	Share price	Share quantity	Share co-variance
Respiratory system diagnosis with ventilator support 96+ hours	0.102	0.771	0.217
Percutaneous cardiovascular procedure with drug-eluting stent without MCC	0.153	1.113	-0.265
Major small & large bowel procedure with MCC	0.213	0.888	-0.101
Major small & large bowel procedure with CC	0.193	0.811	-0.005
Esophagitis, gastroenteritis & miscellaneous digestive disorders without MCC	0.164	1.028	-0.192
Spinal fusion except cervical without MCC	0.085	1.067	-0.152
Major joint replacement or reattachment of lower extremity without MCC	0.213	0.973	-0.186
Infectious & parasitic diseases with operating room procedure with MCC	0.112	0.769	0.119
Septicemia without MV 96+ hours w MCC	0.12	0.815	0.064
Rehabilitation with CC/MCC	0.056	1.164	-0.219
Average shares (weighted by spending)	0.127	0.953	-0.081

Source: Cooper et al. (2019), Table II.

Note: CC in the procedure labels is an abbreviation for "complication or comorbidity;" MCC is an abbreviation for "major complication morbidity."

Added delivery of medical goods and services at higher costs might be warranted if it resulted in demonstrably better outcomes. Medicare patients in the highest-spending regions spent 69% more days in the hospital than those in the lowest-spending regions, had 154% more physician visits and, in the last six months of life, were 153% more likely to have 10 or more treating physicians (Wennberg 2005, pp. 26-27). Fisher et al. (2003a, b) used mortality rates, changes in functional status and reported satisfaction to determine whether higher-cost treatment yielded better results than lower-cost treatment and found no differences in outcomes or satisfaction levels.

Private Insurance Costs Vary Widely

Cooper et al. (2019b) also developed an analysis of spending by individuals covered by private health insurance plans under Aetna, Humana and United Healthcare using data compiled by the Health Care Cost Institute (HCCI). Their data include claims for healthcare services delivered to 27.6% of individuals in the United States covered by employer-sponsored health insurance between 2007 and 2011. Cooper and his colleagues used the HCCI data to develop a companion set of calculations to those in Table 1 for private patients who were ages 55 to 64 and covered

under employer-sponsored insurance. As shown in Table 2, 49.6% of variations in spending are attributable to variations in prices across the HRRs, and 49.5% is attributable to variations in quantity with the covariance nearly zero.

The differences between the results in Tables 1 and 2 suggest that variations in both prices and healthcare delivery play important roles in explaining health costs for those covered under employer-sponsored health insurance. Although some researchers are convinced that it is our high prices that make our health costs so much higher than those in other countries, Cooper et al. (2009b, pp. 70-72) found that the quantities of services delivered under Medicare and the private insurance arrangements were more correlated than the pricing under the two forms of insurance. This result suggests that the research findings that more intensive delivery of health services across market areas does not improve health outcomes for those covered under Medicare is also an issue that should be considered for those covered under employer-sponsored insurance plans. High prices charged for services delivered under health insurance plans covering most workers are important but not the only thing driving the high costs they incur.

Table 2: Price-quantity decomposition of HCCI private, employer-sponsored insurance spending on patients ages 55 to 64 in 2011

Procedures	Share price	Share quantity	Share co-variance
Respiratory system diagnosis with ventilator support 96+ hours	0.650	0.415	-0.064
Percutaneous cardiovascular procedure with drug-eluting stent without MCC	0.465	0.681	-0.146
Major small & large bowel procedure with MCC	0.676	0.299	0.025
Major small & large bowel procedure with CC	0.474	0.453	0.073
Esophagitis, gastroenteritis & miscellaneous digestive disorders without MCC	0.387	0.637	-0.024
Spinal fusion except cervical without MCC	0.334	0.512	0.154
Major joint replacement or reattachment of lower extremity without MCC	0.381	0.645	-0.026
Infectious & parasitic diseases with O.R. procedure with MCC	0.701	0.360	-0.061
Septicemia without MV 96+ hours w MCC	0.536	0.365	0.099
Rehabilitation with CC/MCC	0.460	0.430	0.109
Average Shares (weighted by spending)	0.496	0.495	0.009

Source: Cooper et al. (2019), Table II.

Note: CC in the procedure labels is an abbreviation for “complication or comorbidity,” and MCC is an abbreviation for “major complication morbidity.”

Healthcare Supply Creates Its Own Demand

Dr. Milton Roemer (1961) wrote in *Hospitals* magazine that, “A built bed is a filled bed.” Feldstein (1971) refined Roemer’s observation by asking whether more hospital beds increased

demand by making hospital care cheaper or whether added beds shifted the demand curve, creating a "pure availability effect." Feldstein (1971, p. 865) estimated an elasticity of demand effect, suggesting that a 1% increase in beds resulted in a 0.53% increase in hospitalization. Roemer's observations are known as "Roemer's Law," and subsequent research has suggested it applies to many other aspects of health care delivery as well.

The aforementioned Dartmouth Atlas Project documents variations in the distribution of medical resources among the Medicare and Medicaid populations. Using data on 306 hospital referral regions in 1996, they showed a strong association between the number of hospital beds available per 1,000 people in each region and the number of Medicare discharges per 1,000 Medicare enrollees during 1995 and 1996. They found a close relationship between the number of cardiologists in each hospital region and the number of visits to cardiologists per Medicare enrollee (Arora and True 2012).

In assessing variations in the provision of health services, the Dartmouth Atlas researchers classify care into three broad categories: effective care, preference-sensitive care and supply-sensitive care. Effective care includes interventions whose efficacy has been proven on the basis of outcomes where the benefits outweigh the risks. Examples of such treatments include prescribing beta blockers for heart-attack patients and screening diabetics for retinal disease.

Preference-sensitive care includes treatments that present multiple options and tradeoffs for using one approach versus another. Dr. John Wennberg at Dartmouth (2005) points to variations in the numbers of knee and hip replacements and back surgeries in communities with similar populations, and argues that variations cannot be explained by differences in illness rates or patient preferences. In these cases, he says physicians should inform patients of their options and tradeoffs and involve them in making treatment decisions.

The third type of care is supply-sensitive care, which is what Roemer's law is all about—more hospital beds for a given population means more treatment. Feldstein (1971, p. 870) found that a higher prevalence of specialty-practice doctors increased both demand for admissions and duration of hospital stays. Wennberg showed that supply-sensitive care spending was 66% higher across the highest-cost HRRs than the lowest-cost regions, while spending was essentially the same for effective and preference-sensitive care.

A number of studies have attempted to evaluate whether variations in treatment levels reflect patient characteristics or behavior. Anthony et al. (2009) used a national sample of Medicare beneficiaries to assess care-seeking preferences by asking how they would respond to (1) noticing a new chest pain while walking up steps, or (2) dealing with a residual cough after having the flu. They matched the responses to Medicare utilization records over a two-year period and found considerable variation in respondents' desire for medical help and that the preferences were predictive of physician visits. But the researchers also concluded the patients' preferences had little influence on regional usage patterns. Thus, differences in treatment patterns were more strongly linked to providers' motivations than to patient preferences.

Mandelblatt et al. (2012) studied a group of women ages 65 and older who were diagnosed with breast cancer to assess the decision-making styles of patients and their treating physicians, and the interactions between them in deciding whether to undergo chemotherapy. Those who communicated more with their doctors were more likely to undergo chemotherapy. Those who made their own decisions on the treatment they received tended to rate their communication with their physicians more highly than those who relied more heavily on their doctors' input.

Finkelstein, Gentzkow and Williams (2016) used a random sample of Medicare beneficiaries from 1998 through 2008 to look at variations in health care use, excluding beneficiaries who moved multiple times. The analysis found that about 40% to 50% of variation of utilization was due to patient characteristics and 50% to 60% was due to regional factors.

Cutler et al. (2019) used vignettes in surveys of 598 cardiologists to characterize their treatment patterns across the 306 HRRs developed by the Dartmouth Atlas Project and conducted a parallel survey of primary care physicians. They also surveyed 2,882 Medicare beneficiaries to assess regional demand characteristics. Two of the questions were about tests and specialist referrals following a new chest pain, even if the patient's primary physician thought it unnecessary. The other three questions related to patients' preferences for end-of-life care: Would they want to be put on a respirator if it would extend their life by a week? What about if it extended it for a month? Would they want drugs to eliminate constant pain even if it would shorten their lives?

These measures of demand-and-supply characteristics were used to analyze variations in Medicare expenditures for enrollees 65 or older during their last two years of life. The analysts concluded patient demand was relatively unimportant in explaining variations in treatment patterns. The most important factor was physicians' belief about treatment; and 35% of spending for end-of-life care and 12% of care after a heart attack resulted from physicians' beliefs that were unsupported by clinical evidence.

A more recent study by Moscone et al. (2019) found that total spending on heart attack patients had little effect on outcomes—what mattered more was how the money was spent. Patients who received a stent the day of the attack benefitted from the treatment, but those treated more intensively with home health care services in the six months after the heart attack generally did worse.

Doctors Wennberg and Fisher have developed a number of analyses with other colleagues at Dartmouth measuring variations in the use of health resources on patients with specific ailments. In one study, they looked at highly rated academic medical centers and their treatment of patients with hip fractures, colorectal cancer and acute myocardial infarction during the first six months of follow-up after initial treatment.

Patients with hip fractures in the highest-intensity hospitals had 82% more physician visits, 90% more diagnostic tests and 46% more minor surgeries than those in the lowest-intensity hospitals. Among those with cancer, patients in the highest-intensity hospitals had 61% more

physician visits, 94% more diagnostic tests and 28% more minor surgeries. Heart attack patients in the high-intensity setting had 56% more physician visits, 73% more diagnostic tests and 54% more minor surgeries. The patients in the high-intensity setting being treated for colorectal cancer or heart attacks had slightly higher mortality rates than those in the low-intensity setting (Fisher et al. 2004). They found similar variations in treatment patterns for patients during their last six months of life (Wennberg et al. 2004).

Inside the Delivery Room: A Case Study in Labor Management

Dr. Marty Makary (2019) describes an afternoon in the life of an on-call Florida hospital obstetrician he dubs "Dr. Dinner," who regularly finished his office visits at 2:00 p.m. and then proceeded to the hospital where he performed a C-section on any woman in labor, whether she needed it or not. This schedule enabled the doctor to leave the hospital by five and be home in time for dinner. Makary also summarizes the reasons why natural childbirth is generally better for the baby—as the baby moves through the birth canal, the contractions squeeze fluid out of its lungs and promote healthy breathing—and reduces recovery time for the mother.

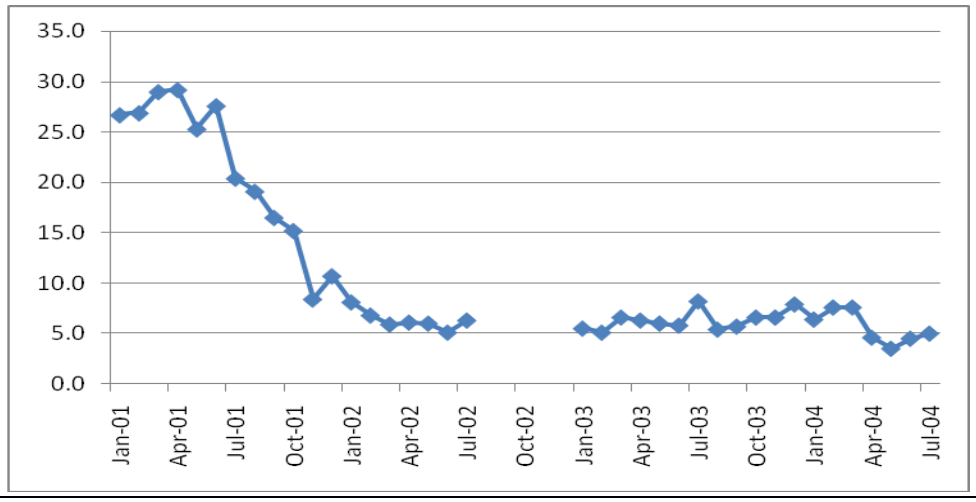
For years, the World Health Organization has recommended that C-section births should not exceed 10% to 15% of all births (WHO, 1985). These procedures are medically warranted where complications in the pregnancy or during labor necessitate early or immediate delivery. Unnecessary C-sections "pose avoidable risks, including longer maternal recovery, neonatal respiratory problems and potentially severe complications in subsequent pregnancies" (Child Health USA, 2013).

In the United States, slightly less than one-third of all babies were delivered by C-section in 2016, ranging from 38.2% in Mississippi to 22.3% in Utah (CDC, 2018). Utah offers an interesting example of using data and analysis to improve outcomes and reduce costs. The largest health care provider in Utah is Intermountain Healthcare, which is based in Salt Lake City and operates in Utah and Idaho. It provides hospital services and offers integrated managed care services under Select Health insurance. A number of years ago, the Institute for Healthcare Delivery Research at Intermountain Healthcare undertook a systematic evaluation of some of its highest-revenue service delivery areas including maternity services. One area of focus was the timing of induced labor for expectant mothers and the incidence of medical complications related to gestational age at the time of induction. They empirically documented that medical complications increased significantly for inductions before 39 weeks. For mothers induced at 37 weeks, 6.66% of their infants were admitted to the neonatal intensive care unit. The admittance rate dropped to 3.36% at 38 weeks and to 2.47% at 39 weeks.

Based on its analysis, Intermountain Healthcare hospitals restricted induced labor before 39 weeks to cases of medical necessity. Initially physicians were resistant to the changes, but administrators instructed nurses not to begin medications to induce labor on patients less than 39 weeks pregnant without medical justification, even if the doctor ordered it. While the doctors themselves could administer such medications, doing so meant they had to wait a considerable time for the medication to take effect and the patient to give birth. The new criteria effectively eliminated early inductions that were medically unnecessary. Figure 2 shows

the change in treatment patterns as the new policy was implemented, which dramatically reduced both complications and the cost of childbirth. The C-section rate, which had been close to the national average of roughly 32% , dropped to 12% for first births and to 21% overall.

Figure 2. Percentage of live births by inducing labor before 39 weeks of pregnancy at Intermountain Healthcare System



Source: Intermountain Healthcare System, Salt Lake City, Utah.

Childbirth practices in south Florida followed a different path. Table 3 shows the total births and C-section rates at several hospitals in Miami-Dade and Broward counties between July 2007 and June 2008 and then eight or so years later. In the 2007-2008 period, C-section rates varied from a high of 70.4% of births at Kendall Regional to a low of 34.2% at Jackson South, with all hospitals above the national average of 31.8%.

The Miami Herald article "More S. Florida Babies Born by an Appointment," which provided the 2006-2007 data in Table 3, suggested that these high C-section rates were not driven by medical considerations (Dorschner 2009). From a health perspective, a doctor quoted in the article noted "that babies born without labor tend to have more respiratory problems." Cost differentials were also cited as another good reason for fewer C-sections. At the time, C-sections in the area cost between $11,000 and $30,000 compared with $5,000 to $16,000 per natural birth, according to the Florida Agency for Health Care Administration. Reducing the C-section rates in these two counties even to the still-high national rates would have saved between $0.5 billion and $1 billion a year. The two-right hand columns in Table 2 update the deliveries and C-section rates in the Miami-Dade and Broward County hospitals to 2015 or 2016. While the rates increased slightly at some hospitals and fell at others, the patterns of C-section deliveries in these hospitals over the intervening eight or nine years remained essentially the same.

Table 3: South Florida birth rates and C-section rates for specified hospitals for July 2007 through June 2008 and in 2015 or 2016

	July 2007-June 2008		2015 or 2016	
	Total births	Percentage C-sections	Total births	Percentage C-sections
Miami-Dade				
Kendall Regional	2,180	70.4%	1,948	62.0% [a]
Hialeah	1,657	52.6%	1,500	68.0% [b]
South Miami	4,145	59.9%	4,097	53.4% [b]
Baptist	4,416	50.3%	3,867	36.4% [b]
Mercy	1,384	58.0%	1,884	55.0% [a]
Mount Sinai	1,944	48.6%	2,678	45.0% [a]
North Shore	2,016	42.0%	1,995	31.6% [b]
Palmetto General	2,005	47.8%	NA	38.0% [b]
Homestead	1,522	49.8%	1,573	44.7% [b]
Jackson Memorial	5,524	50.4%	4,021	49.2% [a]
Jackson North	1,704	36.7%	1,950	34.5% [a]
Jackson South	1,472	34.2%	951	38.4% [a]
Broward				
Plantation General	3,254	47.4%	2,436	45.0% [a]
Northwest Medical	1,855	40.2%	1,955	44.8% [a]
Holy Cross	1,211	51.6%	871	49.0% [a]
Memorial Regional	4,153	41.7%	5,176	45.0% [a]
Memorial West	4,758	40.9%	3,900	39.0% [a]
Memorial Miramar	2,992	47.2%	3,665	43.0% [a]
Broward General	3,550	41.7%	3,436	41.0% [a]
Coral Springs	2,214	37.8%	2,115	41.0% [a]

Sources: John Dorschner, "More S. Florida babies born by an appointment," *The Miami Herald* 10 (May 2009, Early Edition), Health and Medicine Section, Page 1; *Sun-Sentinel*, "Compare: Tri-County Hospitals and Birthing Centers" (17 April 2017), found on 5 March 2018 at: http://www.sun-sentinel.com/features/south-florida-parenting/sfp-tri-county-hospitals-and-birthing-centers-story.html. Sammy Mack, "C-Section Rates Extremely High in Florida (13 April 2016), *WUSF.usf.edu*, found on 5 March 2018 at: http://health.wusf.usf.edu/post/c-section-rates-extremely-high-florida#stream/0.

[a] Rate comes from *Sun-Sentinel*.
[b] Rate comes from Mack.

There are several reasons that some women might prefer an elective C-section, including resolving scheduling conflicts, averting possible undesirable outcomes of natural birth, such as urinary incontinence or impaired sexual function, and avoiding the pain of labor. After a C-section, new mothers usually stay in the hospital longer than those who delivered naturally.

As noted earlier, C-sections increase the risk of undesirable outcomes for mothers and infants. MacDorman et al. (2006) linked U.S. live birth records (5,762,037) and death records (11,897) for births from 1998 through 2001 to assess the risk of infant and neonatal deaths (i.e., death in the first 28 days of life) by delivery method among women without indicated risks. Neonatal mortality rates for children born by C-section were 1.77 per 1,000 births versus 0.62 per 1,000 births for children delivered vaginally. Controlling for demographics, medical factors, congenital malfunctions and Apgar scores[2] of less than four reduced the differences only marginally.

Reducing premature births was an important reason that Intermountain Healthcare set 39 weeks as the baseline for inducing labor. Babies born by elective C-section are four times more likely than those delivered vaginally to have persistent pulmonary hypertension, which is when the baby does not switch from fetal to normal blood circulation and does not get an adequate blood supply to the lungs. Recent studies in the Netherlands and Norway have found that C-section babies are also at higher risk of developing asthma. A U.S. survey of new mothers' childbearing experiences found that only 14% of those giving birth by C-section held their children immediately after birth compared with 43% of mothers who delivered vaginally. This is important because the immediate contact is found to sooth the crying baby and fosters the initiation and a longer duration of breastfeeding (VBAC, 2016).

The Matter of the Heart Points to the Heart of the Matter

On 16 November 2019, a headline in the *New York Times* announced, "Surgery for Blocked Arteries is often Unwarranted, Researchers Find" (Kolata 2019). That same day, a *Washington Post* headline declared, "Stents and Bypass Surgery Are No More Effective than Drugs for Stable Heart Disease, Highly Anticipated Trial Results Show." The story following the latter headline explained:

> The new study was designed to finally settle the question of whether stents are better for patients with stable heart disease—and some physicians said it could change how tens of thousands of people are treated in hospitals, transform how cardiologists talk with patients about their options and save hundreds of millions of dollars in health care spending each year.
>
> About 500,000 heart stent procedures are performed each year in the United States, and the researchers estimate that about a fifth of those are for people with stable heart disease. Of those, about a quarter—or an estimated 23,000 procedures—are for people without any chest pain. If just those procedures are avoided, researchers estimated, it could save about $570 million each year. But the researchers think that is a conservative estimate, and that as doctors and patients discuss options, even more procedures might

[2] The Apgar score is the result of a quick test given newborn infants at one and five minutes after birth. It is the sum of individual assessment scores on heart rate, respiratory effort, muscle tone, response to stimulation and skin color. Each component of the score battery is rated 0, 1 or 2 so 10 is a perfect score.

be delayed or skipped depending on each patient's circumstances, preferences and activity level (Johnson 2019).

The *Ischemia Trial* was a multiyear, cross-national study of alternative treatments for patients with stable ischemic heart disease and moderate to severe ischemia. Ischemia is a restriction in blood supply. The study included 5,179 people determined to have ischemia on a stress test. Certain high-risk individuals were excluded—e.g., those with unprotected left artery disease, advanced kidney disease, recent heart attack, unacceptable angina at baseline, prior stent or coronary artery bypass graft (CABG) in the past year. At the baseline, 34% reported no angina, 44% reported suffering from angina several times a month and 22% said they had angina either daily or weekly (ACC 2019).

The participants were randomly assigned to one of two treatment groups: one group underwent a percutaneous coronary intervention (PCI)—angioplasty with a stent—or a CABG procedure; the second group was treated with drug therapy. The participants were followed for 3.3 years after the initial treatment. There were 2,588 individuals assigned to the invasive therapy group and 2,591 to the drug therapy group. Patients in the intensive therapy group received coronary angioplasty and PCI or CABG as determined by the treating physician. Participants in the drug therapy group only received angioplasty if the medical therapy was unsuccessful. Over the follow-up period, 96% of the invasive group received catheterization versus 23% of the drug group. Coronary revascularization—the insertion of a stent or CABG—was performed in 80% of the invasive group and 23% of the medical therapy group (ACC 2019). The summary interpretation of the results was:

> Among patients with stable ischemic heart disease and moderate to severe ischemia on noninvasive stress testing, routine invasive therapy failed to reduce major cardiac events compared with optimal medical therapy. There was also no benefit from invasive therapy regarding all-cause mortality or cardiovascular mortality/myocardial infarction. One-third of subjects reported no angina symptoms at baseline. Routine invasive therapy was associated with harm at 6 months (increase in periprocedural myocardial infarctions) and associated with benefit at 4 years (reduction in spontaneous myocardial infarction). These results do not apply to patients with current/recent acute coronary syndrome, highly symptomatic patients, left main stenosis, or left ventricular ejection fraction <35% (ACC 2019).

The *Washington Post* article about the study indicated that, "Kirk Garratt, past president of the Society for Cardiovascular Angioplasty and Interventions, said the results were unsurprising and were in line with current practice" (Johnson 2019). That assessment would likely be challenged by some because the use of PCI and CABG operations has been criticized for decades by some physicians who have cited prior studies to support their opposition.

There has been general agreement for some time that PCI reduces deaths for heart attack victims, but using it for stable coronary artery disease has been more controversial. Beyond that, Hadler (2004) contends that these procedures often fit the criteria for Type II Medical

Malpractice. He writes that, “Type I Medical Malpractice is familiar: medical or surgical performance that is unacceptable. Type II Medical Malpractice is doing something to patients very well that was not needed in the first place.” According to Hadler, compelling scientific evidence suggests that much of the cardiovascular surgery done for years to treat heart disease resulting from atherosclerosis amounts to Type II Medical Malpractice (Hadler 2004, p. 20).

By the 1970s, cardiac surgeons were performing CABG surgeries to detour blood flow around clogged heart arteries in people suffering from stable coronary artery disease. Partly in response to the critics of these surgeries, three large random trials compared equal numbers of patients who received the coronary artery bypass surgery with those who received the optimal drug therapy of the day. According to the results, which were published in the mid-1980s, 97% of those who underwent the CABG surgery were no better off than those treated with the appropriate drugs. For the other 3% of patients with plaques involving the left main coronary artery, the five-year survival rate was 65% for those who received medical therapy versus 85% for those who had CABGs (Hadler 2004).

Dr. Hadler concluded the CABG procedure should have been abandoned for most heart patients 15 years earlier. But 500,000 of these surgeries were performed in 2005. He noted that surgical practitioners continued to trumpet the 20% survival benefit without mentioning that it only applied to the 3% of patients with clogged left main arteries. According to Hadler, advocates for the surgery also conveniently left out that 2% to 8% of those who had the surgery died either on the operating table or during the post-operative recovery period, and that 50% of surviving patients suffered emotional distress during the six months after the procedure and that 40% suffered memory loss a year later.

In 1974, Andreas Grüntzig used a balloon-tipped catheter to open a blocked leg artery at the Medical Policlinic of the University of Zürich. Grüntzig had hit upon the idea a few years earlier when a patient asked him if, instead of using drug treatment or complex coronary bypass surgery, it was possible to clean his obstructed arteries the way a plumber used wire brushes to clean pipes. By 1977, Grüntzig was ready to apply his technique to a human coronary artery, but cardiac surgeons at Zürich were worried about potential complications, so the first such surgery was performed at St. Mary’s Hospital in San Francisco on May 9, 1977. For the first few patients, the balloon angioplasties were done on anesthetized patients during coronary bypass surgery with the dilations performed before the aorta-coronary bypass (Barton et al., 2014).

As the balloon angioplasty procedures became popular, doctors learned that after opening an artery and then withdrawing the catheter, the artery often reclosed fairly quickly, so they started inserting metal stents to keep the artery open and the blood flowing freely. Then doctors discovered that plaques would build up around the stent, resulting in further occlusion at the site, so “drug-eluting stents” were introduced to dispense drugs to prevent further blockages. By the 1990s, cardiologists were using PCI regularly, largely because it was less invasive than bypass surgery.

Hadler noted that heart surgeons welcomed the new procedure, in part, because if angioplasty with a stent had an unfavorable outcome, "CABG is the fallback. And if the CABG 'fails,' another CABG is the fallback" (Hadler, 2004, p. 26). Hadler noted that, while there had been many trials of angioplasty, they usually compared outcomes from one form of the procedure against another or against CABG. The trials found that angioplasty was both gentler and as effective as CABG. But since CABG was no more effective at keeping 97% of angina sufferers alive (those whose plaques did not involve the left main coronary artery) than medical therapy, Hadler suspected that angioplasty was not superior to medical therapy either.

Many studies have assessed the relative effectiveness of PCI compared to optimal drug therapy over the years. The documented benefits of angioplasty with stents during acute myocardial infarction events were noted above. But the window for its maximum benefit is relatively small, only a few hours after the event. Hochman et al. (2006) evaluated the relative merits of angioplasty versus medication for stable patients with total blockage of an infarct-related artery three to 28 days after a heart attack. The objective measures included aggregate death rates, rates of subsequent heart attacks or rates of Class IV heart failure.[3] This was a randomized controlled trial funded by the National Heart, Lung, and Blood Institute. Known as the Occluded Artery Trial (OAT), the study included 2,166 patients, 1,082 of whom were assigned to a routine angioplasty and stenting treatment combined with an optimal medical therapy regimen, and 1,084 who received optimal medical therapy treatment alone. According to the evaluation, an angioplasty with stent performed three to 28 days after a heart attack was no more effective than optimal medical therapy alone in reducing deaths, another heart attack or heart failure during four years of follow-up.

These random-controlled studies are intended to accumulate scientific evidence that informs clinical practice. After completion of the OAT study, the Task Force on Practice Guidelines of the American College of Cardiology and the American Heart Association updated their practice guidelines (Anderson et al., 2007) on treating patients with unstable angina[4] and non-ST-elevation myocardial infarction (NSTEMI).[5] Summarizing the results of the OAT study, the task force concluded:

> Percutaneous coronary intervention did not reduce death, reinfarction, or HF [heart failure], and there was a trend toward excess reinfarction during 4 years follow-up. Findings in the 295-patient NSTEMI subgroup were similar to those in the overall group

[3] Class IV heart failure renders a person unable to undertake any physical activity without discomfort and the presence of heart failure while the person is at rest.

[4] Unstable angina is a condition in which the heart gets inadequate blood flow or oxygen. It is considered unstable because it can occur at any time, whereas "stable angina" occurs when a person is under exertion.

[5] An NSTEMI is a heart attack without complete blockage of a major coronary artery. This form of heart attack is typically somewhat less serious than an ST-segment elevation myocardial infarction (STEMI), which involves a complete blockage of a coronary artery. While the NSTEMI may not cause as much immediate damage as the STEMI, it is a serious medical event and requires prompt treatment to prevent unnecessary injury.

(n = 2,166) and the larger STEMI groups. Thus, a routine PCI strategy in OAT-type patients with persistently occluded infarct-related coronary arteries after NSTEMI is not indicated (Anderson et al., 2007, p. e233).

The task force indicated that PCI and CABG usage for the unstable angina/non-ST-elevation myocardial infarction cases was similar to usage for stable angina. Patients with severe left ventricle systolic dysfunction (which often leads to heart failure), diabetes, multiple vessel disease and left anterior descending artery (typically supplying more than half the blood to the heart) involvement should be considered for CABG. "Compared with high-risk patients, low-risk patients will have negligibly increased chances of long-term survival with CABG (or PCI) and therefore should be managed medically" (Anderson et al., 2007, p. e236). The task force's recommendations were developed in collaboration with the American College of Emergency Physicians, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons, and were endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation and the Society of Academic Emergency Medicine.

A year later, the same task force updated guidelines for management of patients with ST-elevation myocardial infarction (STEMI). The earlier update had dealt with unstable angina and NSTEMI. Once again, the task force looked to the OAT study in proposing updated guidelines for treating heart attack patients. "These studies demonstrate that elective PCI of an occluded infarct artery 1 to 28 days after MI in stable patients had no incremental benefit beyond optimal medical therapy with aspirin, beta blockers, ACE inhibitors, and statins in preserving LV function and preventing subsequent cardiovascular events" (Antman et al. 2008).

A year after publication of the OAT study, another study was released evaluating the relative efficacy of medical treatments for stable coronary artery disease in patients who had not had a heart attack (Boden et al., 2007). This latter study, known as Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE), set out to determine whether PCI coupled with optimal medical therapy (OMT) reduced the risks of death or non-fatal heart attack in patients with stable coronary artery disease relative to patients who received only optimal medical therapy. The study population of 2,287 patients with evidence of myocardial ischemia—inadequate blood flow to the heart—and significant coronary artery disease were randomly assigned to one of two treatment groups: 1,149 patients received PCI treatment combined with optimal medical therapy, and 1,138 received optimal medical therapy alone. Study participants were drawn from 50 U.S. and Canadian treatment centers from 1999 through 2004, and were tracked from 2.7 to 7.0 years. Between the two groups (PCI versus OMT), there were no significant differences in the composite of death, myocardial infarction or stroke (20.0 versus 19.5%); hospitalization for acute coronary syndrome (12.4% versus 11.8%); or myocardial infarction (13.2% versus 12.3%). The overall conclusion was that angioplasty treatment coupled with medical therapy was no better than optimal medical therapy alone for patients with stable coronary artery disease (Boden et al. 2007).

Shortly after the COURAGE results were published, a group of 14 physicians published a critical evaluation (Kereiakes et al. 2007) of the study. In summary, they argued that the goal of

reducing death and myocardial infarction rates was unrealistic because the stable artery disease patients had already received aggressive medical therapy. The study did show that the patients initially treated with PCI achieved better angina-free status and a reduced rate of required subsequent revascularization relative to patients assigned to medical treatment only. These added benefits for the PCI treatment group were achieved without higher death rates or heart attacks. Second, the trial showed that patients with multiple vessel blockages who were not treated for each blockage were less likely to realize the full benefits of the initial PCI treatment and more frequently required further revascularization. Third, 32% of patients receiving medical therapy ended up receiving revascularization treatment to relieve severe or progressive angina symptoms. Fourth, many of the PCI procedures had used the bare-metal stents, and the results would likely have been better if the drug-eluting stents had been used along with more complete vascularization in cases with multiple blockages. Fifth, all study participants already had received coronary angiography and "those with severe and/or complex stenosis may not have been included, and investigator bias in patient selection toward lower angiographic risk could not be excluded. This premise (lower-risk patients enrolled) would appear to be supported by the relatively low (0.4%) annual cardiac mortality observed in the entire study cohort" (Kereiakes et al. 2007, pp. 1599-1600). Finally, the medical and catheter-based approaches play a complementary or synergistic role in treating coronary artery disease and the choice of therapy should reflect each patient's lifestyle, functional capacity, symptoms and ability to take prescribed medications. Outside their list of concerns about the methodology of the COURAGE study and interpretation of the results, the critics observed that the study group had been unusually compliant with prescription schedules during the trial.

Ten of the 14 authors who penned the critique of the COURAGE results were affiliated with other organizations that had some financial interest in the outcome.[6]

By the end of the first decade of the new millennium, a number of studies had concluded that drug treatment was as effective as popular surgical interventions for most people suffering

[6] Dr. David J. Kereiakes has received research grants from Pfizer, Conor Medsystems, Boston Scientific, Medtronic, Danchi Sanyko and Cordis Corp., and consulting fees from Conor Medsystems, Cordis Corp., Core Valve, Eli Lilly & Co., Boston Scientific and Abbott/Bioabsorbable Vascular Solutions. Dr. Paul S. Teirstein has received research grants from Cordis, Boston Scientific, Abbott and Conor Medsystems and royalties from Boston Scientific. Dr. Mitchell W. Krucoff is a consultant for Abbott, Biosensors, Boston Scientific, Cordis J&J, Conor Medsystems, Medtronic and Terumo and has received research grants from Abbott, Biosensors, Boston Scientific, Cordis J&J, Conor Medsystems, Medtronic and Terumo. Dr. Ron Waksman is a consultant and has received speaker fees from Biotronik, Medtronic and Boston Scientific, and research grants from Biotronik, Boston Scientific, Medicines Co., GlaxoSmithKline, Schering-Plough and Sanofi-Aventis. Dr. David O. Williams is a consultant for Cordis and Abbot Vascular and has received research support from Cordis, Abbott Vascular and Boston Scientific. Dr. Jeffrey J. Pompa has received research grants from Cordis, Boston Scientific, Medtronic, Abbott, ev3 and Biosensors; is on the advisory boards of Cordis, Boston Scientific, Medtronic and Abbott; and is on the Speakers' Bureau of Pfizer, Medicines Co., Bristol-Myers Squibb and Sanofi-Aventis. Dr. Maurice Buchbinder has received consultant/research grants from Boston Scientific and Cordis. Dr. Roxana Mehran has received grants from Medicines Co., Boston Scientific and Cordis. Dr. Jeffrey W. Moses is a consultant for Cordis. Dr. Gregg W. Stone has received grants from Boston Scientific and Abbott; consulting fees from Xtent, St. Jude Medical and Medicines Co.; honoraria from Boston Scientific, Abbott, Medicines Co., Nycomed and Medtronic; has equity interests in Devax and Xtent; and is on the Board of Directors of Devax.

from stable coronary artery disease. For post-incident treatment of heart attack patients, the evidence was strong enough that the major medical societies recommended drug treatment as the preferred option over revascularization.

But did all the research and revised medical guidelines make any difference? Deyell et al. (2011) suggest that the effect on practice patterns was negligible. They assessed the clinical response to the revised guidelines published by the American College of Cardiology and American Heart Association in response to the OAT study. They used the National Cardiovascular Data Registry to identify patients admitted for STEMI or NSTEMI from January 1, 2005 through December 31, 2008, which included 28,780 patients from 896 hospitals. The researchers considered three periods: one before the OAT study was published (January 1, 2005 through November 30, 2006); the second from publication until the revised guidelines were published (December 1, 2006 through November 30, 2007); and the period after the updated guidelines were released (December 1, 2007 through December 30, 2008).

Before the OAT report was published in November 2006, the rate of PCI operations for occlusions was 54.2%. The rate dropped to 52.8% between the release of the study and the publication of new guidelines, and to 51.9% after the revised guidelines were released. Looking back over the periods, the researchers realized that PCI procedures peaked in March 2006 and then declined significantly up to publication of the OAT results. After the OAT results came out in November, the rate of procedures was significantly lower than it was in March but not much lower than the April-to-November rate. While it is not clear why, the rate clearly dropped before the OAT results were released, and why the rates before and after the new guidelines were issued did not differ significantly.

Deyell et al. (2011) concluded that two years after their release, the revised guidelines based on the OAT study had not been widely incorporated into clinical practice in most U.S. hospitals. Trying to explain these results, they offered:

> Analysis of physician behaviors suggest a wide spectrum of factors contributing to this clinical inertia, including lack of agreement regarding interpretation of data especially when it contradicts long-held beliefs and external influences, such as conflicting patient expectations and financial incentives to perform the unindicated procedure and fear of litigation (Deyell et al., 2011, p. 1641).

A year after Deyell and his colleagues documented that the OAT results and revisions to practice guidelines had no effect on practice patterns, a meta-analysis developed by Stergiopoulos and Brown pooled the results of eight clinical trials, including the OAT and COURAGE studies, and concluded that “initial stent implantation for stable CAD [coronary artery disease] shows no evidence of benefit compared with initial medical therapy for prevention of death, nonfatal MI, unplanned revascularization, or angina” (Stergiopoulos and Brown, 2012, p.312). The results of this meta-analysis were criticized as adding nothing new to the debate over PCI treatment for stable coronary artery disease, and for ignoring the primary reason many doctors were still using the procedure. Dr. Kirk Garratt of Lenox Hill Hospital in

New York City said that he and other doctors continued to use stenting because of "the improved functional capacity it offers" in reducing angina (Smith [Michael] 2012).

Deyell and his colleagues considered the clinical response to changing practice guidelines on PCI procedures through 2008. In 2009, the American College of Cardiology published new appropriateness criteria for coronary revascularization that could entail either PCI or CABG procedures (Patel et al., 2009). In this case, they developed roughly 180 clinical scenarios and asked technical panels to score them for appropriateness of revascularization. Scores of seven to nine were deemed appropriate for an operation, scores of one to three were inappropriate, and scores of four to six were considered uncertain. For objectivity, the panels were constrained "not to include a majority of individuals whose livelihood is tied to the technology under study."

To summarize, the development of the new care standards for the use of PCI and CABG procedures, the American College of Cardiology used the "Delphi approach"—they asked the Oracles—to assess the range of real-life circumstances clinicians would face and to postulate when these treatments were appropriate, inappropriate or iffy.[7] The reason given for this approach was the "paucity of large randomized clinical trials" on which to base guidelines for clinical practice that would achieve more consistent and appropriate treatment patterns (Patel et al. 2009, p.1332).

Even had this rationalization been reasonable, the approach is astounding on its face. Hadler (2004) had pointed to trials from the mid-1980s demonstrating the ineffectiveness of these procedures and raising doubts about the efficacy of CABG in patients with stable coronary artery disease. Then other trials concluded that PCI procedures were no more beneficial than drug treatment for many patients with even more serious heart and circulatory problems. For 25 years, billions of dollars had been spent year-in and year-out on hundreds of thousands of operations, yet the surgeons' premier professional organization claimed there was insufficient empirical evidence for developing standards of practice. If the studies were not adequate, why didn't the professional societies demand a definitive trial or set of trials?

[7] Daniel Kahneman, the behavioral psychologist who had studied the thought and decision processes of individuals, including professionals, for years, suggests the Delphi approach taken here is flawed: The experts may not know the limits of their expertise. An experienced psychotherapist knows that she is skilled in working out what is going on in her patient's mind and that she has good intuitions about what the patient will say next. It is tempting for her to conclude that she can also anticipate how well the patient will do next year, but this conclusion is not equally justified. Short-term anticipation and long-term forecasting are different tasks, and the therapist has had adequate opportunity to learn one but not the other (Kahneman, 2011, p. 242). It is important to remember that Kahneman was referring to "experts" who were exercising their best professional judgments. One has to wonder what the implications are of staffing the Delphi panels with "experts" "whose livelihood is tied to the technology under study."

Desai et al. (2015) evaluated the implications of the new Appropriateness of Care Criteria over the five years following their release. Tracking PCI procedures from 766 hospitals, they estimated that the number of "nonacute PCIs" decreased from 89,704 procedures in 2010 to 59,375 in 2014. The percentage of these classified as inappropriate declined from 26.2% to 13.3% over the period, a decline in absolute terms from 21,781 to 7,921 cases. The authors said they could not rule out the possibility that the decline in inappropriate PCI procedures might be due to changes in documentation of symptoms or "even intentional up-coding particularly of subjective data elements such as symptom severity" (Desai et al., 2015, p. 2049). Specifically, they noted that the percentage of patients with reportedly more severe angina was higher although there was little change in the extent of coronary artery disease.

Of the 648,150 PCI procedures reported in 2014, including all cases with and without acute coronary syndrome, 92.4% of them were considered appropriate under the new guidelines, 5.5% were judged uncertain, and 2.1% or 13,464 cases were considered inappropriate. Given the volume of PCI cases, having only 2.1% considered inappropriate suggests that, by that time, these procedures were seldom performed without good reason. But it is not clear whether the resolution was due to fewer inappropriate PCIs or the new measures of appropriate care.

Steven Nissen, chairman of cardiovascular medicine at the Cleveland Clinic and a former president of the American College of Cardiology, was an influential player in the development of the new grading system for PCI and CABG. Epstein (2017) quotes Nissen as saying that treatment patterns "have gotten better, but they're not where they need to be," an implicit indication that the new measurement of inappropriate procedures should be regarded with caution.

In 2014, *Bloomberg News* reported that emergency room doctors at Mount Sinai Hospital in New York City were seeing incoming patients reporting acute symptoms of heart disease who already had same-day appointments with the catheterization lab. Three of the emergency room doctors who talked to reporters said that the "hospital's cath lab has regularly scheduled such emergencies-by-appointment." A couple of patients said they had been coached to say they were having acute symptoms of heart disease.

It might be that emergency treatments would trigger insurance benefits otherwise not available to patients. Whatever the explanation, the hospital had been aggressive in increasing catheterizations. The annual report from the prior year had characterized the growth as "remarkable," "substantial," "significant" and "tremendous," according to the reporters. The annual report also noted that fewer than 4% of the stent procedures the hospital had performed on stable cardiac patients in 2010 were considered inappropriate. The report also stated that compensation for lab physicians was based on incentives linked to procedures (Armstrong, Waldman and Putka, 2014).

It is not clear whether this sort of practice or other means of changing the measurements rather than the reality were widespread, but Epstein (2017) quoted Dr. Nissen, the chairman of cardiology at the Cleveland Clinic, as believing that eliminating financial incentives for doing

cardiac procedures would help eliminate unnecessary surgeries. Nissen told Epstein, "I have a dozen or so cardiologists, and they get the exact same salary whether they put in a stent or don't and I think that's made a difference and kept our rates of unnecessary procedures low."

Epstein (2017) also reported that Nissen and David Holmes, a Mayo Clinic cardiologist who was also a former president of the American College of Cardiology, made the case that PCI was appropriate for some patients with stable coronary artery disease to reduce their pain. As evidence mounted that, for many patients, angioplasty and stenting did not save lives, some doctors began justifying them by claiming that they reduced angina pain more effectively than drug treatment.

In Europe, the COURAGE trial results and meta-analyses led to treatment guidelines that called for medical treatment as the first line of therapy for stable coronary artery disease and recommended PCI only in patients with continuing angina (Windecker et al., 2014). The guideline recommendation that angina relief justified the use of PCI on patients with stable coronary artery disease was developed without medical evidence of the efficacy of PCI for this purpose (Al-Lamee et al., 2018).

The lack of supporting evidence prompted a group of clinicians in the United Kingdom to undertake a blinded, randomized trial of PCI versus a placebo procedure for angina relief in patients with "severe (≥70%) single-vessel stenosis." All participants spent the first six weeks in a medical therapy optimization phase and in assessments of symptom burden, functional capacity, myocardial ischemic burden and quality of life. After randomization, members of the PCI treatment group were administered drug-eluting stents to treat all "angiographically significant" lesions. Members of the placebo group were sedated for at least 15 minutes on the operating table and then the coronary catheters were withdrawn with no intervention. Six weeks after the procedures, all trial subjects were retested with the same instruments used in the pre-randomization assessment.

The two groups were compared on the basis of their pre- and post-procedure electrocardiograms taken during exercise treadmill tests, angina severity measures and overall health status. The results indicated that "PCI did not improve exercise time beyond the effect of the placebo … There was also no improvement beyond placebo in the other exercise and patient-centered endpoints" (Al-Lamee 2018, p. 37). In other words, there was no evidence to support the contention that PCI was any more effective than a placebo in relieving angina pain. It is likely that the *Ischemia Trial* results will be considered as the American College of Cardiology develops new care standards for using PCI and CABG procedures, but a recent article in a magazine targeted to cardiologists and catheterization labs is also relevant. In the article, Kim and Zamanian (2018) observed:

> With the volume of PCI procedures in the United States estimated at more than 950,000 per year and rising, there will be positive growth in many associated device markets, such as interventional catheters, interventional guidewires and various other devices used per procedure. This is good news, considering that PCI procedures, as well as

coronary balloon and stent sales, have experienced substantial declines for several years following multiple clinical studies that presented evidence of over-stenting. However, procedure volume has recently stabilized, and growth is expected to continue, due to the emergence of a new area of opportunity – complex PCI cases (Kim and Zamanian 2018).

Stents: Old problem, New Opportunity

Makary (2019) describes another way that some physician practices responded to declining PCI rates—they went to church. As Makary was researching questionable practices among health providers for his recent book, he met with Dr. Sridhar Chatrathi, a cardiologist working in the Maryland suburbs of Washington, D.C., who was concerned about some physicians who were redirecting their stenting abilities from the heart to a new malady—poor leg circulation.

Chatrathi took Makary to a health fair run by a local church with a predominantly African American congregation, where a woman from a local cardiology group was comparing blood flow in people's arms with the flow in their legs. It turns out that differences in blood flow in the legs and arms of older people is common—the femoral leg artery is long and narrowing is normal, but the body usually adapts. At the health fair, the screener was telling folks with different flow rates in their legs and arms that they needed to get it checked out. "Endovascular procedures" on these patients are so easy, and it is not only cardiologists who are at the table. Chatrathi explained that many vascular clinics in the Washington, D.C., area were lining up new patients and raking in lots of money.

According to Makary, finding an old person without leg pain is akin to finding a penguin in the desert. But those who complain of leg pain at one of these clinics receive an ankle-brachial index test, whose results often lead to an ultrasound test. The next step is a Doppler study and then a diagnostic catheterization where a small blockage is discovered – ultimately Grandpa goes home with a stent in his leg and Medicare receives a $10,000 bill.

Makary and his research team at Johns Hopkins in Baltimore identified nearly 1,100 churches across the country that were serving as vascular screening centers. The researchers searched county-level Medicare data to see where the rates of these procedures were highest and put dots on a continental U.S. map to show them. The map of the southeast and middle third of the country looked like it has a bad case of measles. The researchers overlaid shading on the counties to show income levels, and these procedures were concentrated in lower-income counties. If nothing else, the concentration of this new treatment phenomenon cries out for structured studies to determine the relative benefits and risks of these procedures or whether they are simply another of what Dr. Nortin Hadler has labeled Type-II Malpractice.

Take Two Pills and Call Me in the Morning

Sam Quinones' widely acclaimed book, *Dreamland: The True Tale of America's Opiate Epidemic*, gives a good picture of the carnage that overuse of opioid painkillers led to in the United States. Possibly the most amazing aspect of the opioid story is not only how flimsy the evidence behind

these drugs was, but also how pervasively they were embraced by medical providers. In a short letter in the 10 January 1980 edition of the *New England Journal of Medicine*, Porter and Jick wrote:

> Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were merepridine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction (Porter and Jick, 1980).

Six years later, an article in the *Journal of the International Association for the Study of Pain* by Portenoy and Foley reported on their analysis of 38 patients who had been maintained on opioid analgesics for non-malignant pain and evaluation of their safety and efficacy. They concluded that "… opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of abuse" (Portenoy and Foley, 1986).

The President's Commission on Combating Drug Addiction and the Opioid Crisis concluded that these two reports served as a motivating force for the widespread use and abuse of opioids. The Porter and Jick letter was cited in more than 600 subsequent articles, often as evidence of the beneficial effects and potentially low risks of opioids. The President's Commission report concluded that the articles "eroded the historical evidence" of the addictive nature of opioids and that the poor-quality evidence cited "was unfortunately accepted by federal agencies and other oversight organizations" (President's Commission, 2017, p. 20).

The report from the President's Commission also cited a number of other contributing factors in today's opioid crisis, such as advocacy by both patients and physicians for using opioids for pain management. In 1995, the American Pain Society started a campaign to treat pain as the "fifth vital sign." In his presidential address at a pain forum, the head of the society said that "If pain were assessed with the same zeal" as body temperature, blood pressure, heart rate and respiratory rate, it would have a much better chance of being treated properly." Subsequently the Veterans Administration and the Joint Commission on Accreditation of Healthcare Organizations designated pain as the fifth vital sign. The President's Commission concluded, "This designation set in motion a growing compulsion to detect and treat pain, especially to prescribe opioids beyond traditional boundaries of treating acute, postoperative, procedural pain and end-of-life care" (President's Commission, 2017, p. 21).

Opioid drug manufacturers marketed their products aggressively, and the supply-chain industry claimed that the drugs were highly effective in managing pain while the risk of addiction was low. There were "rogue pharmacies and unethical physicians prescribing and distributing" the

drugs, and patients whose prescriptions were diverted or who sold their drugs illegally. Quinones' (2015) book chronicles the evolution of the opioid crisis and the role played by manufacturers and marketers.

In 2001, the Joint Commission on Accreditation of Healthcare Organizations introduced pain assessment and treatment standards, and many providers started using treatment guidelines linking opioids to the patient's grade on the pain scale. Measured on a scale of one to five, an early study found that patient satisfaction with their pain management rose from 4.13 to 4.38, a statistically significant improvement. But the incidence of opioid-linked adverse drug reactions per 100,000 inpatient hospital days increased from 11.0 before the numerical scale guidelines were introduced to 24.5 afterwards (Vila 2005). In 2008, poisoning became the leading cause of injury death in the United States, and 90% of these were drug related, according to the CDC. Opioids were linked to 40% of drug poisonings in 2008 (Bakalar 2011). From 1999 to 2008, the number of opioid-related deaths in the United States grew from 4,000 to 14,800. Opioids were involved in 40% of drug-related deaths in 2008 compared to 25% in 1999 (Warner et al. 2011).

Makary said that he stumbled into the realization that opioids were being over-prescribed when his father was recovering from an operation similar to the ones he regularly performed. Although Makary regularly prescribed 60 opioid tablets for pain after these operations, his father only needed one ibuprofen tablet for pain the night after his surgery. Makary observed that, "it directly contradicted my residency training, in which I was taught to give every patient a boatload of opioid tablets upon discharge. The medical community at large ingrained in all of us that opioids were not addictive and urged us to prescribe generously. And that's exactly what we all did" (Makary 2019, p. 127).

All states now have Prescription Drug Monitoring Programs or PDMPs which are accessible databases of controlled substance prescriptions dispensed to individuals. A Congressional Research Service review of these programs suggests several limitations of their effectiveness. The programs are organized and operated at the state level and have established varying requirements on what substances have to be reported, which dispensaries are required to submit information and frequency of data collection. They also vary in terms of who has access to the data, the conditions under which it may be accessed and the mechanisms available to enforce compliance. There are also varying standards for sharing information across state borders (Sacco, Duff and Sarata, 2018)—a potential problem in many urban areas.

Another challenge is the information is not in a prescriber or pharmacist's workflow, meaning they must log out of their system and log into the state database to check, an action that takes between 2 to 6 minutes per script. That doesn't sound like much, but most of the US population lives near a state boarder, meaning a clinician must check multiple state databases. For example, in the Washington DC area, it is possible for a patient to travel from Virginia, to DC and onto Maryland within a 30-minute period. As a result, pharmacies in the DMV area regularly check all three state databases, taking up to 18 minutes per patient, largely because the state databases don't normally interface with each other because they are not

interoperable. For a patient addicted to opioids, this creates opportunities to shop for doctors willing to write multiple prescriptions (and make money) and pharmacies willing to dispense them (Makary 2019).

The National Council for Prescription Drug Programs has called for the establishment of real-time interfacing databases across PDMPs with standardized data elements, values and patient matching criteria that can be accessed by clinicians in real time before prescribing medications (NCPDP 2020). Development of such a system has the potential to dramatically reduce prescription abuse and may have other applications as well.

It's Everywhere

This discussion about healthcare treatment patterns has shone a spotlight on intensive cases, childbirth and clogged arteries, which represent a fraction of the pantheon of modern health practices. So, do the excess C-sections, CABG and PCI procedures reflect relatively isolated cases or a widespread problem? Some recent empirical evidence provides a strong clue.

Ioannidis (2005) reviewed articles published from 1990 to 2003 in three of the most respected medical journals—*New England Journal of Medicine, Journal of the American Medical Association* and *Lancet*—along with 10 other highly respected specialty journals. He focused specifically on articles that "addressed the efficacy of therapeutic or preventative interventions and pertained to primary data," and he limited the selection to articles that were cited 1,000 or more times within three years of their publication in subsequent articles in the medical literature. After evaluating 45 reviews that found medical interventions to be effective, Ioannidis discovered that seven or 16% of the articles were contradicted by subsequent studies, and another seven were found to be less effective than the original article had claimed. Twenty of the studies (44%) were confirmed by subsequent studies, and 11 (24%) were not reconsidered in subsequent articles. Among these widely cited studies, nearly a third were proved wrong or exaggerated.

A similar analysis reviewed all the original articles—which excluded letters, comments, and editorials—published in the *New England Journal of Medicine* in 2009. In this case, the authors looked at 35 reviews of existing standards of care. In 16 of these studies (46%), the existing standard of care was found to be ineffective (Prasad, Gall and Cifu, 2011). Given these results, the research was expanded to include articles from 2001 through 2010 in the *New England Journal of Medicine*. Here the authors reviewed 363 articles reporting on the efficacy of standards of medical practice. When the reviews were tallied, 146 (40.2%) of the articles found the standard of practice to be ineffective, 138 articles (38.0%) found current practice to be effective, and 79 articles (22%) were inconclusive (Prasad et al., 2013). Prasad and Cifu (2015, p. 84) would later comment: "Forty percent is a lot. Nearly half of what doctors do. If that much of medical practice is ineffective, it is pretty scary and it's not hard to see why the United States spends 2 to 3 times more per capita on health care each year than other nations."

Nevertheless, these reviews questioning the efficacy of practices once hailed in the medical literature do not quite capture the breadth of the problem. Prasad and Cifu (2015) wrote a

book citing examples of documented problems that span the spectrum of medical treatments—including common procedures, devices and drug therapies. The following three examples present a small part of the story that Prasad and Cifu tell.

Arthroscopic knee surgery has been done for years to repair degenerative meniscal tears. The authors estimated that 700,000 of these operations are performed annually, costing $4 billion a year. A 2013 study found that surgery followed by physical therapy was no more effective than physical therapy alone. A second study found that the surgery was no more effective than a sham procedure, where the surgeons simply inserted their scopes and looked around, pretending to repair the meniscus. There was no difference in pain level or functioning at two, six or 12 months after the surgery between people whose meniscal tear had been repaired and those whose tears were left alone (Prasad and Cifu, 2015, p. 22).

Another example involves intra-aortic balloon pumps that surgeons use to respond to cardiogenic shock—when the heart stops pumping normally after a massive heart attack. The surgeon inserts the balloon pump into the aorta on the tip of a catheter, where it is inflated and deflated in rhythm with the heart's beating. It is supposed to improve the functioning of the left ventricle, the heart chamber that pumps blood into the aorta, and lighten the heart's workload.[8] In 2012, a trial was conducted on 600 patients suffering cardiogenic shock caused by a heart attack. All were given the best possible care for their heart attacks, but half the patients received the intra-aortic balloon pump and half did not. 40% of participants died within 30 days of their major heart attacks, but mortality rates were the same for those with and without the balloon pumps. Moreover, the pumps did not reduce the incidence of second heart attacks while the patients were hospitalized, strokes or complications in procedures to open the blocked arteries that had caused the original heart attacks (Prasad and Cifu, 2015, pp.39-40).

The third example addresses atenolol, a beta blocker widely prescribed for hypertension. First introduced in 1976, the drug was considered so effective at reducing blood pressure that it became a "trial standard," the bar that new drugs had to meet or beat for approval (Prasad and Cifu, 2015, p. 19). In a 1997 trial in Sweden, more than 9,000 patients with high blood pressure were randomly assigned to use either atenolol or a competitor drug, losartan, for four years. Not only did both drugs reduce blood pressure by the same amount, the group using the competitor drug suffered fewer deaths and strokes. Until this trial, the evidence had clearly indicated that atenolol was effective at reducing blood pressure, and clinicians had presumed that it must also reduce heart attacks, strokes and deaths. After the Swedish trial, a number of follow-on trials tested the effectiveness of atenolol against placebos or other anti-hypertension drugs.

[8] When the left ventricle of the heart begins to contract, the balloon deflates creating a vacuum causing the blood from the heart to flow more forcefully into the aorta, and out to the body. When the left ventricle contraction is finished and the heart is at rest, the balloon inflates, helping the blood to flow through the coronary arteries to the heart muscle.

Carlberg, Samuelsson and Lindholm (2004) summarized the results from two sets of trials. Their meta-analysis of four trials that followed 6,825 patients over an average of 4.6 years compared atenolol to a placebo. They found a significant difference in the effects on blood pressure but no variance in all-cause mortality, cardiovascular mortality or heart attacks. The risk of stroke tended to be lower for patients being treated with atenolol, but the differences were not statistically significant. The meta-analysis of five trials that followed 17,671 patients for an average of 4.6 years, comparing atenolol to other blood-pressure-reducing drugs, found no major differences in blood pressure reductions between the two groups, but all-cause mortality, cardiovascular mortality and strokes were significantly higher with atenolol versus the alternative. According to Carlberg et al., their "results cast doubts on atenolol as a suitable drug for hypertension patients. Moreover, they challenged the use of atenolol as a reference drug in outcome trials in hypertension" (Carlberg, Samuelsson and Lindholm, 2004, p. 1684).

When Carlberg and his colleagues published their results, 45 million prescriptions for atenolol were written in the United States. One might think the new evidence would mark the end for atenolol. Yet in 2015, 30 million atenolol prescriptions were written (ClinCalc, 2018). By 2017, the prescription rate had dropped to 20 million for the year, but it was still the 36th most frequently prescribed drug in the country (ClinCalc 2020). Epstein (2017) wrote about asking a family practitioner who dispensed 1,100 prescriptions for atenolol in 2014 to patients 65 and older why he continued prescribing a medication that had performed poorly in randomized control trials. The physician responded that, "I read a lot of medical magazines, but I didn't see that." He said his patients were doing just fine on the medication and asked that any relevant journal articles be sent to him.

Controlling the Overuse of Health Care

Identifying the Low-Hanging Fruit

Excluding medical research, capital investments and the like, personal health care expenditures were slightly less than $3.09 trillion for medical goods and service during 2018. Average per capita spending on personal health care in 2018 was $9,430, but one must dig deeper for meaningful numbers. Among those in the bottom half of the distribution, average per capita spending was only $528. People in the 50th to 80th percentile of the distribution averaged $4,620, while those in the 80th to 90th percentile averaged $14,804. Average costs rose to $30,175 for people in the 90th to 95th percentile, to $66,714 for those in the 95th to 99th percentile and, finally, to $212,165 for individuals in the top 1%.

If there is a pattern of over treating patients, a good place to look for potential savings is where the big bucks are spent. Figure 1 shows the concentration of U.S. health expenditures in 2015. The dashed line shows what health expenditures would be if they were evenly distributed across the population; the solid line shows actual cumulative expenditures. The year makes little difference, as the spending pattern has hardly changed over the last couple of decades. More than half the population spent less than 3% of health dollars in 2015, and 70% spent 9.7%. The top 10% spent two-thirds, the top 5% spent 51% of the money, and nearly one quarter of all health care dollars were spent by the top 1%.

Big Costs Present Big Potential

We should explore all avenues to rein in excessive health spending. The concentration of spending on such a small group suggests that a targeted approach would have an outsized impact. No doubt, some of the most expensive patients in Figure 3 suffer from hepatitis-C or similarly treatable diseases, which might be cured with drug therapy that costs $100,000 or more, but many incur high costs through a much more diversified portfolio of treatments. The health problems faced by this latter group are generally multifaceted and complex. Moreover, they receive treatment from a health system plagued by both high prices and poor management of service delivery.

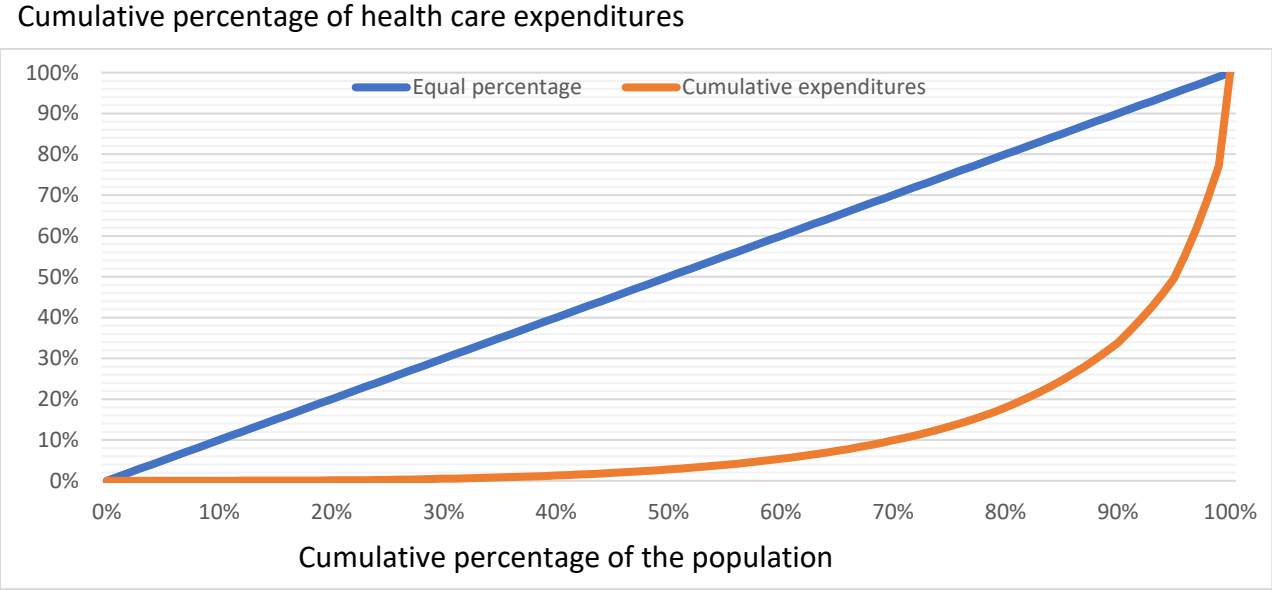
Jauhar (2014) cited a 50-year-old patient with shortness of breath who had been admitted to the hospital where Dr. Jauhar and a colleague were on staff. Dr. Jauhar summarized:

> *During his month-long stay, which probably cost upward of $200,000, he was seen by a hematologist; an endocrinologist; a kidney specialist; a podiatrist; two cardiologists; a cardiac electrophysiologist; an infectious-disease specialist; a pulmonologist; an ear, nose and throat specialist; a urologist; a gastroenterologist; a neurologist; a nutritionist; a general surgeon; a thoracic surgeon; and a pain specialist. The man underwent 12 procedures, including cardiac catheterization, a pacemaker implant and a bone-marrow biopsy (to work up mild chronic anemia). Every day he was in the hospital, his insurance company probably got billed nearly $1,000 for doctor visits alone. Despite this wearying schedule, he maintained an*

upbeat manner, walking the corridors daily with assistance to chat with nurses and physician's assistants. When he was discharged (with only minimal improvement in his shortness of breath), follow-up visits were scheduled for him with seven specialists.

This case, in which expert consultations sprouted with little rhyme, reason or coordination, reinforced a lesson I learned many times in my first year as an attending [physician]: In our health care system, if you have a slew of physicians and a willing patient, almost any sort of terrible excess can occur (Jauhar, 2014, p. 94).

Figure 1: Concentration of U.S. health care expenditures for civilian noninstitutionalized population in 2015



Source: Agency for Healthcare Research and Quality, *Medical Expenditure Panel Survey*, Household Component, 2015.

Hayes et al. (2016) analyzed health care expenditures from the 2009-2011 Medical Expenditure Panel Survey (MEPS)-Household Component[9] to understand which illnesses and conditions lead to high health care use. Of the 94% adults whose expenditures fell in the top 10% over the two-year period reported having three or more chronic diseases, and 39% also had a functional impairment that limited their ability to perform activities of daily living or instrumental activities. Looking at expenditures in a single year, 76% had three or more chronic diseases, and 19% also had a functional impairment.

[9] MEPS is a set of large-scale surveys of families and individuals, their medical providers and employers across the United States. MEPS is the most complete source of data on the cost and use of health care and health insurance coverage.

In the fee-for-service model, Dr. Jauhar's example explains the potentially very high-cost outcome. Jauhar (2014, p. 94) observes, "There are many downsides to having too many doctors on a case. The specialists' recommendations are often at cross purposes. The kidney doctor advises 'careful hydration'; the cardiologist, discontinuation of intravenous fluid. Because specialists aren't paid to confer with one another or coordinate … they often leave primary attending(s) [physicians] without a clear direction as to what to do."

Value-Based Care

In recent years, there has been growing interest in shifting away from the fee-for-service model to "value-based" care, where the goal is to coordinate the services patients need to get better and stay better. At least in theory, providers are reimbursed for value—which means delivering services and treatments that improve health, reduce or at least manage the effects of chronic ailments, and help patients attain healthier lifestyles. A crucial element of value-based care is using periodic assessments as the basis for continuing program improvements. While the primary goal is to help patients get healthier, the expectation is that value-based delivery of services will reduce costs as well. To encourage experimentation and development of these models, the Affordable Care Act (ACA) encouraged groups of physicians to contract with the government as "accountable-care organizations" that would deliver care to Medicare beneficiaries more effectively and efficiently. When accountable care organizations save money, a share of the savings is rebated back to the group.

At the hospital level, CMS introduced a hospital value-based purchasing (HVBP) program in 2011 using Medicare reimbursement incentives to reward high-performing hospitals. The goal was to increase patient safety and satisfaction using incentives based on quality of care rather than fees for services. The program combined bonuses and penalties, together worth 2% of total Medicare payments to hospitals, based on how well the hospitals met quality measures or improved their performance over time. After two years, an evaluation compared 30-day risk-adjusted mortality rates for acute myocardial infarction, heart failure and pneumonia between 2,919 hospitals participating in the HVBP program and a nonparticipating control group of 1,348 hospitals. The evaluation concluded that the differences in mortality trends were small and statistically non-significant. The researchers did not find better outcomes in any subgroups of hospitals in the HVBP group relative to the control hospitals (Figueroa et al., 2016).

A companion study measured the effects of the HVBP program on patient satisfaction as measured by a CMS survey, the Hospital Consumer Assessment of Healthcare Providers and Systems. The assessment period ran from 2008—before the HVBP program started—through 2014, and again included participating and nonparticipating hospitals. Overall, patient experience ratings improved by 6.1 percentage points over the six-year period, but most of the improvement occurred before the program was implemented, and there was no evidence that patients treated in HVBP hospitals were any more satisfied than those in other hospitals (Papanicolas et al., 2017).

The Commonwealth Fund recently reviewed the operations of CareMore, a Medicare Advantage plan that started in 1993 as a small regional medical practice in southern California

and now serves 160,000 patients across nine states and the District of Columbia.[10] Its business model aims to identify high-risk patients and coordinate their services. The plan partners with primary physicians who refer high-risk patients to CareMore Care Centers for treatment. Some patients use the centers for a single episode and then transition back to their primary physician for ongoing health needs, while those with major continuing ailments might receive care from the centers for years. The partnering primary physicians are paid on a capitated basis so there is no penalty for handing off a patient to CareMore, and doing so might free up time and resources for additional patients. Nurse practitioners, medical assistants and other non-physician staff are responsible for delivering much of the care that would typically be dispensed by physicians, thus freeing up doctors to oversee care provided in hospitals and skilled nursing facilities.

Individual cases in the hospital setting are managed by physicians, generally internists, known as "extensivists" in the CareMore environment, who provide general medical treatment and oversee the work of specialists to ensure that the combined package of services is appropriate for the patient's needs and quality of life. Overall case management is handled by nurses who meet regularly with the extensivists to keep abreast of treatment progress, handle preparations for the post-discharge period, and facilitate communications with patients and their families. Part of the task of these case managers is to assess patients' nonmedical needs and link them with local service agencies that can help. In 2015, CareMore had 20% fewer hospital admissions, 23% fewer bed days and 4% shorter stays than fee-for-service Medicare, and its costs were estimated to be 1% to 8% less than those incurred by comparable plans in 2014 (Hostetter, Klein and McCarthy, 2017).

At a recent *Journal of the American Medical Association* forum, Jha argued that for the value-based model to work in hospitals, financial incentives must be large enough to make it worth hospitals' while to invest the money and time necessary to restructure their systems, motivate clinicians to change their practice patterns, and enable clinical and organizational leaders to develop appropriate evaluation instruments (Jha, 2017).

In 2012, Oregon reformed its Medicaid system. Medicaid services had been provided through managed care arrangements. The new system enrolled 90% of the Medicaid population in 16 coordinated care organizations (CCOs) which offered or linked to a broader range of services including physical health, dental, mental health and addiction services, with other social services as necessary. The CCOs worked under a global budget, risk-adjusted for the covered population and financed prospectively by the state. They had spending flexibility and could cover services outside the traditional constraints of "medical necessity." Given their fixed budget, the organizations risked financial losses—and also had the potential for upside gains. McConnell et al. (2017) described how the CCOs prepared for their role:

[10] CareMore has been growing in recent years. The data reported here were based on their website description of their business as of 17 March 2020.

> CCOs have engaged in a variety of innovative efforts to change the delivery of care for their Medicaid patients. These strategies include incentives to enroll patients in primary care homes; the use of data in new ways to target high-risk patients; the integration of behavioral health services in primary care sites; care transition programs for emergency department (ED) patients admitted to inpatient settings; increased training and employment of community health workers; pilot programs designed to test new ways to care for high-risk groups; and the use of flexible funds to support special services that are intended to improve health and reduce the use of the medical care system (McConnell et al., 2017, p. 451).

To measure the outcomes, claims data for 2013 and 2014 were used to compare access, appropriateness of care, utilization and spending for evaluation and management, imaging, procedures, tests and inpatient facility care between Medicaid populations in Oregon and Washington. Over the two-year comparison period, Oregon spent 7% less than Washington on the measured services, had fewer avoidable emergency department visits and realized improvements in appropriateness of care. One potential concern was a decline in primary care visits (McConnell et al., 2017).

Rethinking Health Care: The Federal Role

Establish a Joint Center for Best Practices.

The National Institutes of Health (NIH), the Centers for Disease Control (CDC) and Food and Drug Administration (FDA) need to establish a Joint Center for Best Practices to discover, summarize, and disseminate information and examples on the best practices known to science.

Within the federal Department of Health and Human Services, the Agency for Healthcare Research and Quality (AHRQ) focuses mainly on health care quality and safety, studying and providing data on subjects including hospital acquired conditions and readmissions. However, AHRQ is not well suited for the more controversial mission of exposing low-value treatments or care patterns more broadly, even if that care is performed at a high-quality level. Likewise, public/private organizations like the Patient-Centered Outcomes Research Institute (PCORI) that fund effectiveness research studies may not also have the stature or ability to synthesize research and make broader recommendations on the most appropriate practice patterns.[11]

The best practices mission should be infused throughout the federal healthcare research agencies, including the CDC, FDA, NIH, and AHRQ. These agencies would have the joint credibility to bring together research from many perspectives and the joint power to withstand politization of the results. We believe a joint task force with regular reporting on consensus findings, areas that need more research, and consensus best practice recommendations would

[11] See www.pcori.org.

have the greatest impact.

Give Medical Specialty Societies a Role.

Guidelines established by medical specialty societies can be very influential in helping physicians update their practice patterns as new evidence is introduced and when best practice guidelines are established. Medical professional associations should base practice guidelines on empirical evidence of beneficial treatments.

During the evolution of the COVID-19 pandemic in the United States, the Infectious Disease Society of America has developed evolving and "frequently updated evidence-based guidelines to support patients, clinicians and other health-care professionals in their decisions about treatment and management of patients with COVID-19" (IDSociety 2021). The first version of their guidelines was published on 11 April 2020 and the fourth edition on 5 March 2021.

The guidelines include recommendations for specific treatments and indications of whether they are strong or conditional based on the evidence available. In cases where the existing evidence is judged to be insufficient to support promising interventions, the guidelines recommend their use in clinical trials.

In response to the pandemic, there has been a great deal of discussion in the news media, on cable-TV shows and in social media about the role of science in how members of the public should comport themselves and on appropriate treatments for those who are stricken with the virus should be treated. The statements that have been made by the nationally recognized leaders of the NIH, the CDC, the FDA and other relevant government agencies have aligned closely with the evolving guidelines that have been published by the Infectious Disease Society of America.

What has largely been missing from the public discussions about the evolving scientific knowledge about appropriate treatment of COVID-19 patients is the extent to which practitioners in the health delivery system are keeping abreast of the developments and adopting them in their treatment regimens. There is clearly evidence to suggest that changing guidelines from the medical societies regarding the treatment for heart disease have not been universally adopted by physicians delivering services to patients. Without some form of monitoring compliance with evolving guidelines, it impossible to judge their effectiveness.

Pay for Effective Services, Not Volume; Phase-Out Traditional Fee-for-Service (FFS) Payment Methods.

Financial incentives that reward providers for delivering more health care than indicated by effectiveness guidelines should be eliminated from the system. This is a problem in Medicare's traditional Fee-for-Service program, some state Medicaid programs, and many private insurance plans. The Centers for Medicare and Medicaid Services (CMS), which administers Medicare and Medicaid, should make the replacement of fee-for-service reimbursement with

value-based payments its highest policy priority.

Historically, Medicare's traditional program has set a backward-facing standard of sorts on fee-for-service reimbursement. Because of Medicare's large and high-utilizing enrollees, the program has tremendous influence on the overall health sector. Medicare's FFS program can be a very large share of many providers' revenues and, because of that, can be a potent force in driving organization changes in the delivery system that will result in increased efficiency.

Dr. Kevin Schulman (2018) who studies and publishes research on hospital innovation concluded that large fee-for-service hospital systems were not committing the talent and resources necessary to transform the quality of care and reduce costs. Medicare has a value incentive program for hospitals whereby it sets aside 2% of reimbursements that are awarded to hospitals who score relatively high on its quality measures or make significant gains over time. But 2% reimbursements for quality awards and penalties has not motivated hospitals to reconstruct their organizational culture and structure along the lines that Jha (2017) has suggested would make restructuring worthwhile in recent congressional testimony.

Because the FFS program reimburses providers without adjusting for quality or appropriateness of services to more than a marginal extent, it makes it difficult for private insurers and state Medicaid programs to insist on effectiveness-based, or better yet, value-based reimbursement systems. Expanding the Medicare value incentive program would provide hospital systems with the economic motivations to undertake changes that have potential spillover effects for the other major public and private insurance programs.

Encourage Value-Based Payment Arrangements for Prescription Medications.

Value-based payment arrangements (sometimes known as outcomes-based contracts) for prescription medications are contracts between payers and biopharmaceutical manufacturers in which the manufacturer is reimbursed based on their product's performance and the patient's clinical outcome(s). Value-based payment arrangements are most often used for the highest-cost medications; they have the potential to reduce overall health costs by matching the right drug to the right patient and targeting payment to what works. However, there are several legal and regulatory impediments to making value-based payments for high-cost prescription drugs. First, Congress should reform the laws that restrict or prevent the use of value-based payment arrangements in federal programs such as Medicare and Medicaid. Second, the federal government should ensure that its rules don't inadvertently prevent the creation of value-based payment arrangements between private insurance plans and pharmaceutical manufacturers. In particular, certain federal anti-kickback statutes and so-called "best price" rules can interfere with value-based arrangements that reward healthcare providers when treatments work optimally or reduce payments when the drug therapy does not work. Modifying these laws will ensure that government rules don't inadvertently prevent contracting based on outcomes between both private and public insurance plans and biopharmaceutical manufacturers.

Make Data Collection and Dissemination a Federal Priority.

Many of the studies cited throughout this discussion have had access to prices of health service delivery in one setting or another. Few would dispute the tremendous value of the Dartmouth Atlas project's documentation of health services financed by Medicare and Medicaid, and the same can be said about the research performed by the Health Care Cost Institute and those using its data.

The federal government should be more proactive in collecting and disseminating data and supporting empirical analysis to document the efficacy of medical practices that come under question based on small-scale studies and in providing information consumers can use to identify high-quality providers.

Building databases that enable people to compare prices and quality of healthcare goods and services is critical if we want consumers to make better decisions, regulators to better manage costs and researchers to assess the success of these efforts. A number of states have passed legislation to establish all-payer-claims databases, often referred to APCDs. The data in these systems have been used to allow consumers to review price and quality measures for procedures delivered by specific providers and for assessing the price implications of public policy initiatives and potential provider mergers (Freedman, Green and Landon 2016). The states face a variety of challenges in putting these data systems together, a major one being that self-insured plans are regulated under ERISA and exempt from state reporting laws. Building the databases at the state level limits the utility of these databases, especially for analyzing health care delivery markets that span state lines.

The federal government is best positioned to summarize data on trends in regional patterns and on improvements over time in broader measures of health outcomes, such as hospital readmissions or potentially avoidable admissions and complications, which can be identified from continuously collected data on health insuance claims from both public and private sources.

Public concerns about protecting privacy of health information has been cited as a reason not to develop data of the sort suggested at the federal level. These same concerns led to passage of the Health Insurance Portability and Accountability Act (HIPAA) but, since the passage of that legislation, the federal government has continued to support valuable research efforts like the Dartmouth Atlas Project and the many research initiatives based on its data without significant breach of HIPAA's privacy regulations or disclosure of other non-health information. Wherever such data might reside within the government, protections that have already been developed for Medicare data could be extended to the larger database.

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