Scales that will evaluate whether paramedic-administered antibiotics, fluids, or both, improve sepsis survival compared with usual care. These trials could usher in a new approach for the diagnosis and treatment of sepsis that starts in the ambulance, not the ED.

Angus believes that in the future, randomized trials could be possible in a "Goldilocks" cohort of hospital patients with low or intermediate suspicion of infection and sepsis who might be harmed by aggressive treatment. "There may be an 'on-the-fence' group in whom clinicians would agree there is adequate equipoise" to conduct a trial, he said. However, he added that identifying these patients quickly will require more rapid diagnostics than are currently available—likely a combination of clinical tests and pathogen or host response biomarkers.

A Lifesaving Law?

The question of whether Rory's Regulations save lives isn't asked or answered in the recent study. Sepsis deaths were already decreasing in the United States before the mandate, and determining its contribution to the trend in New York will require a comparison with national data over the same time period.

Last year, Illinois passed Gabby's Law, requiring hospitals to adopt evidence-based sepsis protocols, and the Rory Staunton Foundation is seeking mandatory sepsis protocols in every state by 2020.

Yet "the certainty of evidence in what to do in sepsis has declined year over year," Howell said. In this climate of uncertainty, statewide mandates may be premature. Although public policies can create much-needed awareness around sepsis, experts say they may rob physicians of their clinical discretion at a time when best practices are still evolving and antibiotic stewardship is top of mind.

"It's really hard to simultaneously say, 'Give antibiotics as early as possible in patients before you even know if they're infected or not,' and at the same time, 'Please be judicious with the use of antibiotics so as not to promote antimicrobial resistance,'" Angus said. "That's sort of driving with a foot on the accelerator and the brake. It's really challenging."

In the end, physicians will err on the side of antibiotics, warned Emily Ko, MD, PhD, a hospitalist at Duke Regional Hospital who conducts research on biomarkers for sepsis and infectious disease at the Duke Center for Applied Genomics and Precision Medicine. "Protocol-driven care that mandates early antibiotic use will likely push physicians to prescribe antibiotics or face penalties even when a noninfectious or viral etiology is felt to be more likely the cause of symptoms," she said.

Mandating rapid sepsis treatment may also force ED staff to deprioritize other life-threatening conditions, Angus said: "If I put sepsis to the top of the list, what drops down on the list? This is where a lot of this contentiousness and controversy arises." ■

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The JAMA Forum

Rising Medical Costs Mean More Rough Times Ahead

David M. Cutler, PhD

Medical costs are rising again, after recent years of historic lows. As the figure shows, growth rates of real per person medical spending in the past 3 years have averaged 3.4% annually, up from 0.9% in 2011 to 2013. Although the current growth rate is low in a historical context, it exceeds the economy's growth as a whole. Thus, health costs are expected to reappear on the radar screen of governments, businesses, and households.

The issue of health care costs plays differently in the political arena than the issue of coverage. Politicians bicker endlessly about who should be covered and how generously, as the never-ending debate about the Affordable Care Act has demonstrated. In contrast, there is bipartisan agreement that policy action is needed to address rising medical costs.

That said, addressing costs in a meaningful way is difficult. The central difficulty is that medical spending increases apply to a mix of valuable services and less valuable ones. Spending more for drugs or surgeries that cure disease is worthwhile. But paying more for a medication because a pharmaceutical company has decided that the market will bear the cost is not.

The political arena is hunting for the equivalent of the perfect surgeon, one who can take out the diseased tissue without harming the intertwined vital organ. Sadly, no such policy exists.

The closest we come to the ideal policy is prevention. Disease prevented is both healthier for the individual and less expensive for the system. There have been major successes in prevention, such as new medications for hypertension and high cholesterol that have materially reduced the incidence of chronic cardiovascular disease in the past few decades. There is more to be done here, but prevention has its limits. Obesity accounts for a greater part of medical spending over time, and there are no widespread prevention strategies shown to reduce excessive weight. Furthermore, the risk factors for many high-cost conditions, such as Alzheimer disease and other forms of dementia, are not well understood.

David M. Cutler, PhD

As a result, when attention turns to action, the steps taken will necessarily involve difficult trade-offs. Three approaches that policy makers might take are cutting prices, charging people more in the form of cost sharing, or bundling payments.

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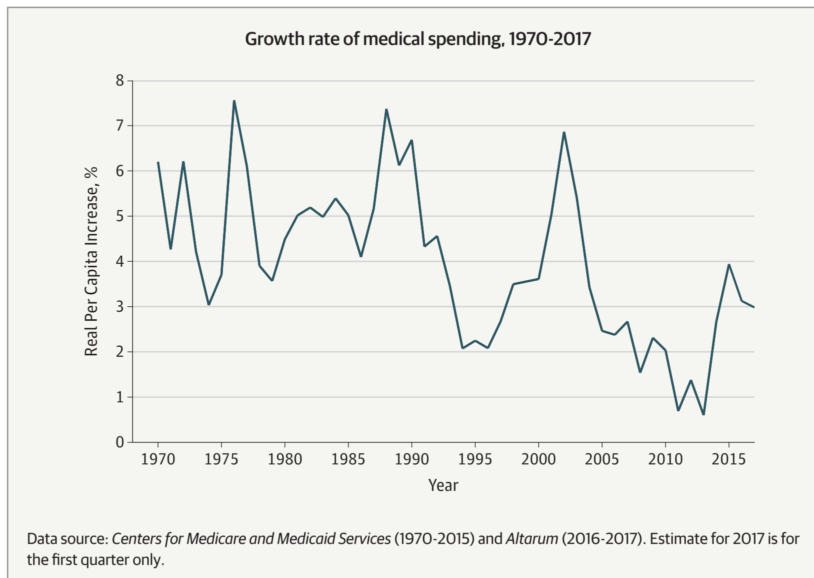

Data source: *Centers for Medicare and Medicaid Services* (1970-2015) and *Altarum* (2016-2017). Estimate for 2017 is for the first quarter only.

Cutting Prices

The time-honored way to reduce spending is to limit what is paid for each service. Both Medicare and Medicaid have responded to periodic budget crises by cutting prices paid.

The most obvious target for price-cutting is pharmaceuticals. Prices for pharmaceuticals vastly exceed production costs, as well as prices charged in other countries, so prices could be lowered without fear that existing drugs would become unprofitable. How lowering prices might affect pharmaceutical research and development is debated, which may limit action here.

But make no mistake: cost concerns will not be limited to pharmaceuticals. Physician and hospital prices are rising as well, and are also prominent targets for price cutting. The steps to lower prices are starting already. The Republican health care bill (the American Health Care Act, or AHCA), combined with President Trump's budget, proposes a 50% reduction in federal contributions to Medicaid. That would surely result in massive reductions in prices paid by Medicaid programs.

Charging People More

The strategy used by most businesses to address rising medical costs is to increase the amount that people have to pay to access care. Between 2006 and 2016, the proportion of people enrolled in a high-deductible health plan (a plan with a deducible higher than $1000 for an individual or $2000 for a family) rose from 4% to 29%.

People enrolled in high-deductible health plans use less care than people enrolled in plans with more modest cost sharing; savings are on the order of 10% to 15%. The difficulty is that the savings come from reductions in both more and less valuable care. People cut back on less-appropriate imaging but also on chronic medications for high cholesterol, diabetes, and hypertension. Unfortunately, even providing information about the cost and value of different therapies does not limit the damage from higher costs.

For physicians, there are other detrimental aspects of increased enrollment in plans with high cost sharing. When cost sharing is high, physician offices become bill collectors along with care providers. This complicates the doctor-patient relationship. Collecting all the money also adds to administrative expense. Nevertheless, businesses show no signs of wanting to slow down the push to high-deductible policies, so this conundrum is likely to get even bigger.

Bundled payments

Increasing cost sharing is more feasible in the private sector than in the public sector, where many people have lower incomes. The more common strategy in the public sector is to change the way that medical care is paid for, moving from volume-based payment to value-based payment. The Affordable Care Act created many such payment models, as did the Medicare Access and CHIP Reauthorization Act of 2015.

In practice, value-based payment often involves paying one amount for services that used to be reimbursed separately. Rather than pay separately for a hospitalization, the surgeon, and any post-acute care, there might be 1 bundled payment for the entire surgical episode. At a higher level, there might be a single payment for all care provided in an entire year, as in Medicare's accountable care organization program.

Theoretically, the shift to value-based payments may be either good or bad. It gives incentives for physicians to monitor care carefully because money not spent on medical care can be used for other purposes or added to take-home pay. But it also gives incentives to skimp on care or to select patients who are expected to cost less than the bundled payment.

Value-based payments are more recent than higher cost sharing, so information about the effects of such payments on care quality is much less developed. Generally, the literature shows some savings associated with value-based payments, but the savings are not enormous—5% or less—depending on the program. To date, there has been no evidence of adverse consequences. Indeed, many measures of quality are used to determine compensation, and by those metrics, quality seems to have improved.

The literature thus supports an expansion of value-based payments, but with a caveat: we have not yet figured out how to use bundled payments to save significant money.

It is difficult to predict how policy debates will evolve. But physicians should be aware that the difficult practice environment that they already face could become even more challenging as health care costs increase at faster rate. ■

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Published Online: June 23, 2017, at http//:newsatjama.jama.com/category/the-jama-forum/.

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