Dissecting American Health Care
Commentaries on Health, Policy, and Politics

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For Americans involved in health care, the central issue of our time is our expensive, high-tech, infuriating health care system. As we approach spending 20 percent of our annual gross domestic product on health care, we somehow continue to exclude almost that percentage of residents from decent insurance coverage. Surveys show that we like our doctors but not anything else about our system.

After the election of 2008, it looked like the timing was perfect for change. Increasing costs and dissatisfaction with health care and a seemingly bullet-proof Democratic majority in Congress led many to think that the newly elected president could succeed where others had failed. Reform of health care delivery and coverage was just a matter of time and presidential leadership, we thought.

As it turned out, of course, the bullet-proof congressional majority was lost in an upset in a special election for a Massachusetts Senate seat. The road to a new health care system was full of ups and downs and alternating hope and despair. Almost everyone was dissatisfied with the result, signed into law in March of 2010. Since then, the struggle has continued, some trying to explain the new law and begin its implementation while others work to curtail its reach and repeal it.

This section of the book contains essays written while what Democrats call the “Affordable Care Act” and Republicans call “Obamacare” was created, debated, and passed. The commentaries cover many of the major questions that were being discussed: mandating coverage, managing costs, debating comprehensiveness, including preventive medicine, and increasing primary care. I have not re-edited columns in which my predictions turned out to be completely wrong, as I think they accurately represent the feelings of many at the time.
Two of the pieces focus on comparative effectiveness research (CER), which is intended to provide patients, policy makers, and clinicians with information about which drugs and procedures work for which patients. CER was portrayed by participants in the health care reform drama as either a panacea or the devil’s work. The truth, of course, is that it is neither. The controversy around it is, however, emblematic of the mix of serious debate and political posturing that has characterized much of this tumultuous period.
Our perfectly designed health care system

An interregnum thought experiment

The interregnum between a presidential election and the inauguration is a time of feverish activity, in which the president-elect and his staff decide who will help them govern and what they will try to do first. The press and pundits speculate breathlessly on who will be appointed and what they will do first. As I write this, for example, we have just learned that the new administration’s secretary of Health and Human Services is likely to be a respected former US senator, Tom Daschle. He has written a book about health care reform, which is likely to be his assignment when he starts in January.

I’ve been musing about the United States and how perfectly designed our current health care system is. Perfectly designed, of course, as every system is, to achieve exactly the results it gets, as quality improvement guru Don Berwick has famously said. In its own way, our system is really rather remarkable. Here’s a thought experiment to illustrate what I mean.

Suppose you have a big industrialized country that has lots of money to devote to health care: around $2 trillion a year. That is $6,400 per person, far more than any other country spends on health care. Let’s say, for the sake of the argument, that the country leads the world in technological advances, developing everything from computers to new scanners before anyone else. We’ll also give you a large and enormously profitable drug industry to develop and test new products. Throw in some of the world’s best health and health care researchers, well funded by the world’s richest health research institutes and foundations. To make sure that all this largesse is fairly distributed, we’ll even make this mythical country a democracy, where the voice of the people rules.

Your assignment, should you choose to accept it, is to take all of these resources and design a scenario (notice that I did not say a system) in which both health care process measures and health outcomes in the population

* This, of course, turned out not to be true; see page 79.
are paradoxically poor by international standards. So, despite the money, the technology, and the research talent, you have to find a way to keep neonatal mortality from falling and life expectancy from rising; a way to deliver suboptimal care for people with chronic diseases; and a way to keep delivery of appropriate preventive services uneven and inconsistent. In general, you have to ensure that you are getting poor value for your health care dollar.

This is not easy to do. Most countries would fail, but in the US we did it. The foundation of the scheme is disparity. First, deny health insurance to 47 million people to delay or prevent access to health care. Add another 16 million who are underinsured, so that a catastrophic health event bankrupts them. Create broad disparities in income, so that some people can’t afford to pay for insurance or health care. Make sure to tie most health insurance to employment, so that when people lose their jobs they also risk losing their insurance.

Second, make sure that there are no national systems of care or planning to allocate resources evenly across the population. This will allow every facility that wants a magnetic resonance imaging scanner to get one, even if the city already has dozens of MRIs, and it will lead to a high proportion of unnecessary scans, perhaps 20 percent to 30 percent. While we’re at it, let’s make sure that electronic health care records are adopted by fewer than 20 percent of doctors. That will ensure that medical records and health information are not transferred with the patient, which makes for many more needless tests and miscommunications. It will also impede improvements in continuity of care and patient safety.

Third, spend lots of money, say $300 billion or so a year, on drugs and devices, and allow drugs to be advertised directly to the consumer to keep demand high for new, expensive ones. The drug industry knows that every dollar spent on advertising to patients yields $4 in increased revenues.

Finally, none of this will work unless we make sure that no one is around to coordinate patients’ care, to serve as their medical “home,” and to deliver necessary preventive treatment and care for acute and chronic disease from cradle to grave. Most countries in the world entrust this job to primary care doctors, who generally make up about 60 percent of the medical workforce. In 1949, 59 percent of US doctors were general practitioners, so we really had to work hard to eliminate them if we were going to achieve our goals. Again, it wasn’t easy, but we did it. We made primary care less prestigious
than specialty practice. Our multiple payers ensured that most of doctors’
time would be spent on paperwork rather than on care of patients. We paid
primary care doctors less, a lot less, than subspecialists. And, in a recent
clever touch, we dramatically increased the cost of medical school, so that
students graduate with hundreds of thousands of dollars of debt, precluding
them from choosing a career in primary care. Bingo. Now we have a
situation where only 30 or 35 percent of doctors are generalists, and the
number is sinking fast.

So there you have it, Mr. Health Secretary-designate. That’s how we did
it. Good old American ingenuity. It’s a mess, for lots of reasons. But it’s our
mess. How to fix it? That’s your job.
How to waste a billion dollars

Comparative effectiveness research risks ineffectiveness if industry opposition to it succeeds

Comparative effectiveness research (CER) is all the rage in the United States right now. It seems that everywhere you turn, a conference or meeting or briefing on CER is being conducted. I knew it had gotten ridiculous when I saw an advertisement (and a website) for an upcoming “national summit” on CER sponsored by a for-profit medical conference company, “featuring a comparative effectiveness boot camp.” (Let’s see now, calculating quality-adjusted life years while wearing olive-drab fatigues?) I am not making this up.

The term “comparative effectiveness research” seems to be a relatively recent coinage, but the concept has been around forever. It is usually called technology assessment. The idea is to figure out which drug, device, treatment, or diagnostic test works best for a given condition in a given population. You do that by comparing active interventions with each other, not with placebos, to produce conclusions that are useful in real-world settings.

We have well-documented geographical variation in care in the US, in terms of rates of elective surgery, costs of procedures, practice patterns in caring for patients with specific diseases—you name it. Because there are few or no corresponding variations in health outcomes, everyone thinks there must be waste in there somewhere. If we could only find it and eliminate it, we should be able to decrease costs and improve quality of care. That is where CER comes in.

The theory is that doctors and patients don’t know whether talk therapy or drug treatment is better for attention deficit/hyperactivity disorder, or the best way to treat low back pain, or whether stents, surgery, or drugs are best for coronary artery disease. If only we had head-to-head trials or clever analyses of large clinical databases to compare them, we could figure this out, and the variation (and costs) would rapidly decrease. It is seen by some as no less than a panacea.
So, thought leaders have been promoting CER for the past several years, without much success. Then the huge stimulus package that Congress was considering early this year presented a golden opportunity. Finding $1.1 billion for CER was easy when the budget for the total bill was $787 billion.

Interestingly, however, there was a lot of opposition to the inclusion of funds for CER in the stimulus bill. Just before its final passage, lobbyists for drug and medical device manufacturers worked overtime to remove the funding. They ultimately failed and now deny that they were against CER. They say that they were only concerned that such research would stifle innovation and lead to government rationing of care, with the least expensive drugs and treatments being favored.

So they formed an instant grassroots organization, the Partnership to Improve Patient Care, to monitor how the CER funds are administered. Although the organization’s website lists as members dozens of medical societies and disease advocacy groups, the steering committee (and presumably the funding) is dominated by the powerful “big three”: the trade associations for the medical device, biotechnology, and drug manufacturers. At every CER forum I have attended they have all been there, testifying to the importance of individualized care and the need to exclude cost considerations from comparative effectiveness analyses.

It is not just the drug and device manufacturers who are against CER. Conservative commentators have accused it of denying freedom of choice to patients and coming between patients and their doctors. They see CER as the first step toward government controlled and rationed care, threatening personalized medicine.

It is no surprise that CER has become controversial. You only have to look at the history of technology assessment around the world to learn that when drugs and devices are compared, some win and some lose. The stakes are high, and no one likes to lose.

It seems to me that CER is neither the panacea that some proclaim nor the devil’s work that others decry. The variation in care across the US is not just a knowledge problem. It is driven in part by lack of knowledge, but also by local traditions, fear of lawsuits, physicians’ desire for personal gain, and the way our health care system is organized. Research alone will not fix all of these.
It would be a shame, though, if the constant lobbying by conservatives and the industry dilutes the focus and narrows the scope of the CER that the Department of Health and Human Services sponsors. While it won't fix everything, $1.1 billion could fund useful research and methodological advances if it is applied thoughtfully.

A committee on CER appointed by the Institute of Medicine is due to report at the end of this month. It is likely that it will come up with recommendations for specific studies and infrastructure, recommendations that should be heeded. I hope that the committee also points out that costs, when used to assess value, are an integral part of comparing the effectiveness of medical interventions. Also, they should say that none of this will make any difference unless the results of the research are actually incorporated into how we deliver care. We will not have gotten much for our billion dollars if the research is done but not applied.
Who will pay and who will say no?

Not everyone can get what they want from the US health care reforms

We are now in a difficult period in the attempt to reform the health care “system” in the United States. Initial optimism has waned, President Obama’s popularity has plummeted, and the doomsayers are hanging the burial crepe. Shades of 1994, the year of Hillary Clinton’s failed attempt at health care reform.

Earlier this year there was unprecedented cooperation not only between Democrats and (some) Republicans but also within the ruling Democratic party. This has now splintered. Most of the powerful special interest groups—doctors, hospitals, big pharma, and the insurance and health plan industry—were on board as well, falling over themselves to make public concessions so as to maintain a place at the negotiating table. Sadly, those days of bonhomie are gone.

The problem is that no one is willing to give up much. Further, no one is willing to admit that someone will have to say no to the sometimes extravagant ways of the past. The hard part is still ahead, and two related issues loom especially large: paying for the new coverage, and saying no to inappropriate care.

Given that the US already spends a larger percentage of its gross domestic product on health care than any other major country and that we have large disparities in costs with few differences in outcomes, it is tempting to assume that there must be waste in there somewhere. Simply find the waste, cut it out, and bingo—enough funding emerges to cover the previously uninsured. It is not that easy, though. We got where we are because no one wanted to be told what to do: not patients, not doctors, and not health systems. So it is no small matter to rein in the spending that has gotten out of control.

One widely chanted mantra for saving money to pay for reform is to invest in putative panaceas such as preventive medicine and health information technology. The sad truth is that appropriate preventive care, though a wise investment in health, rarely actually saves money. Also,
instituting electronic medical records will be enormously expensive in the short run, given our many different systems and massive need for electronic infrastructure in individual practices. There is not much money to be saved there, either. Which is why the independent Congressional Budget Office refuses to rate either prevention or health IT as offsetting the costs of new coverage.

Only tax money—such as the proposed tax increase on people with higher incomes or new taxes on health insurance benefits—will pay for the costs of covering the uninsured. Of course, both of these are risky politically.

The second issue is control. Part of the reason that US health care costs so much is that first, we don't always know the best way to treat problems and, second, when we do we don't always do it. Comparative effectiveness research is supposed to give us this kind of information, but those with special interests have worked hard to ensure that the results of such research won't have the force of law or regulation behind them. Doing this research and not enforcing the findings is silly and wasteful. Someone, some entity, has to have the power to say no.

What it all comes down to is incentives. Given our predominantly fee-for-service system, there is no getting around the fact that doing more, whether you are a doctor or a hospital, leads to more charges and thus more income. Until that basic equation is altered—by creating new systems of care and giving those systems overall responsibility for expenses for a population—we will never slow the growth of spending.

So what will we do? Some argue for smaller, piecemeal reforms that will fix a few of the obvious problems we have: tort reform to reduce malpractice lawsuits and the resulting practice of expensive “defensive medicine”; health insurance portability to ensure that people can take their coverage with them when they change jobs; better coverage of preventive care; and changes in tax policies to allow cheaper individual and group policies.

None of these, however, will change the basic incentive of do more, get more.

The dangers of the current course are that we may not get any reform at all, which would not only miss a real opportunity but ultimately bankrupt us. Or we could go part way and not get real reform that fundamentally changes the incentives and reorders the system. Or, finally, we could get “real” health care reform, which might not work, costing an enormous
amount of money and not yielding corresponding increases in coverage, outcomes, and satisfaction.

Republicans are seeing blood in the water and are now working hard to kill any reform. They have no real comprehensive alternative to offer, but the public is impatient and receptive to clever negative advertising comparing health care reform to irrelevant government fiascos such as the response to Hurricane Katrina.

It is pretty close to panic time. Will we have health care reform, will we have nothing, or will we go part way? It seems to me that unless we have enough reform to cover almost everyone, create an institution that will say no when the evidence is against treatments, and change the incentives so that they are aligned for appropriate rather than just more care, we will have accomplished nothing.
The gatekeeper and the wizard, redux
An Olde World fairy tale,* exported to America

Once upon a time, in a country far away, lived a great wizard with wondrous healing powers. He lived in a splendid castle on a hill overlooking the city. The wizard was clever. He knew how to use magic crystals to see inside people to find out what was wrong with them, and he had magic spells and potions to treat their illnesses. When sick people came to see the wizard, he often cured them or made them feel better and live longer. For his work he was paid handsomely.

Down the hill, in a nice big house, though not as grand as the wizard’s, lived a gatekeeper. An important part of her job was to decide who got to see the wizard. She was also clever, and she had magic potions as well. After all, she and the wizard had gone to the same school, though they had learned different sorts of magic after leaving it. All the people who felt poorly came to see her. For the most part the gatekeeper could tell who needed to see the wizard and who didn’t. She treated most of them herself and sent a few up the hill to see the wizard. She was paid well for her work, though not nearly as well as the wizard.

In olden days there were many more gatekeepers than wizards. This made sense, because most people who felt poorly were in fact not terribly ill and were treated extremely well by gatekeepers with their potions. And the few who were very ill got to see the wizard, who used his special crystals and spells on them to good effect.

But then two things happened. First, the costs of the school for wizards and gatekeepers were greatly increased. This led many students to finish school with enormous debts. More and more decided to become wizards rather than gatekeepers because the pay was better. But that meant that now there were too few gatekeepers and too many wizards.

* With apologies and homage to Nigel Mathers. This is an updated and Americanized version of a series of fairy tales he published in the BMJ about 20 years ago (see bibliography).
The second thing that happened was that the rules were changed. Anyone who felt poorly—or even those who didn’t—could go directly up the hill to see the wizard. They no longer had to stop and see the gatekeeper first. These two changes led to big trouble.

Even though wizards were excellent at treating very sick people, it turned out that gatekeepers were much better at telling who was sick and who was not. And gatekeepers charged much less for their magic. Almost everyone who saw a wizard ended up being viewed through magic crystals and treated with his spells and potions. And the wizard’s powerful crystals and spells not only cost a lot, but they didn’t really help people who weren’t very ill. Sometimes their side effects even made people worse. Also, there were now so few gatekeepers that many people couldn’t find one. Costs were out of control, lots of people couldn’t afford care when they were sick, and the countryside was in an uproar.

Then a new prince came to power, young but wise.

The young prince heard the concerns of the people and gave everyone hope. He promised that everyone who felt poorly could get help. He promised to improve the care that they received, and he also promised to reduce costs. These were difficult promises to keep.

One big problem was that the prince could not change the rules by himself. To make changes he had to convince the House of Gnomes that his ideas were the best. Everyone agreed that there was a problem, but they disagreed on how to fix it. It was hard work getting a consensus, especially because the gnomes had just agreed to smelt vast piles of gold for the kingdom’s coffers.

The prince and his courtiers spent most of their time and energy figuring out how to pay for more people to get care. Almost no one talked about who was delivering the care: gatekeepers or wizards. Part of their plan was to control the use of the expensive crystals and spells, and that meant sending everyone to gatekeepers first. But how were people supposed to see gatekeepers first when there weren’t enough of them around and when fewer and fewer students were becoming gatekeepers? No one talked about that.

The storyteller wishes he could tell you that this fable had a happy ending, but this complicated story is not finished. We do not know yet whether everyone ends up living happily ever after or not.
All or nothing at all?
If US health reform doesn’t change coverage, costs, and quality, will it matter?

As I write this, two health reform bills are moving through the US Senate and three are in the House of Representatives. Senate leadership is meeting to combine their two bills into something that will have a chance of getting through the more conservative of the two bodies. This is looking more and more likely to succeed. The House has a similar blending task for their more liberal bills, which probably shouldn’t prove too difficult.

Then the bills go to the floors of the respective chambers for passage. Finally, if they make it that far, comes the conference of all conferences: an attempt to craft a bill both houses can agree on.

Most observers feel that we are pretty close to a historic change. The question is, what would a final law look like? What reforms will remain and what will get compromised away? Will the new regulations make a difference? As Frank Sinatra famously sang, should it be all or nothing at all—or is half a love enough? Here are some thoughts on the major issues.

The problems to be addressed are well documented. We spend over $2.4 trillion annually on health care. We have more than 46 million uninsured Americans. Our population health outcomes lag the developed (and some of the developing) world. That’s bad.

All of the bills would require most Americans to have health insurance or pay a penalty. People with low income, and some with middle income, would get subsidies to help them afford insurance, though the subsidies are less in the Senate Finance Committee bill than they are in either the other Senate bill or the House bills. Insurance companies would be required to cover all applicants; they could no longer deny insurance because of pre-existing conditions. That’s good.

Different coverage estimates accompany the different bills. The Senate Finance Committee bill, which costs the least, leaves the most people uninsured, about 17 million after 10 years. This seems unacceptable, both for moral reasons and because ultimately it would probably lead to higher costs,
as people without insurance defer care and end up with more complicated and costly problems.

All the bills require a minimum level of benefits without annual or lifetime caps, including inpatient and outpatient services and preventive care. This is good. They do, however, vary in their requirements for out-of-pocket copayments for services. Again, the Senate Finance bill costs patients the most.

One of the major battles is whether or not there will be a so-called public option—a government-sponsored (presumably low-cost) plan to compete with the private plans to keep their charges—and profits—low. One of the Senate bills and all the House bills have such a public option. The Republicans and some Democrats, backed by the very strong insurance lobby, are against it, calling it unfair competition that will ultimately drive the private sector out of business, leaving a single plan: the one sponsored by the government.

It is not clear how this issue will be resolved, as liberals insist a public option will improve care and help keep costs down and conservatives see it as the road to—gasp—socialized medicine. Possible compromises include a trigger mechanism, which would provide a safety net public plan only in states without affordable private coverage, or allowing the states to sponsor public plans if they think it necessary.

How to raise the money to pay for the new system is another contentious issue. The president and Congress are committed to a “budget neutral” law, meaning that revenues have to be found to offset its cost over the first 10 years of its existence. The new system then would have to start decreasing the deficit in subsequent years. To raise the money, the House bills tax wealthy Americans and the Senate Finance bill taxes health care industries and expensive private health insurance plans. Conservatives howl that the Senate bill would really increase the financial burden on the middle class as the taxes are passed through as increased premiums. Not good.

None of this, of course, addresses the quality of health care and changing the incentives that currently pay doctors and hospitals more only when they deliver more care, rather than when they deliver better care. This is the third part of an interconnected triad with cost and access. Costs can never be controlled if there is no check on constantly delivering more care, especially if there are more people with insurance to pay for that care. The Senate
Finance bill begins to address this issue by creating a new Medicare center to test ways to improve quality and reduce costs. That is a start. None of the bills fundamentally change the current incentive structure.

In summary, my answer to the Frank Sinatra question is that, since the current system is both morally repugnant and financially unsustainable, “all or nothing at all” is a fool's choice for reform. Whatever emerges from the Congress is likely to be better than what we have now. If it is not perfect, we'll have time to improve it. Cover (many) more people, constrain costs, and begin to figure out ways to incentivize better quality. Might not make a catchy tune, but half a love is better than none.
US health care reform is in the waste can

Can one state’s senatorial election really scuttle the whole thing?

The first piece of conventional wisdom about the race for the late Edward Kennedy’s US Senate seat was that there was no chance that the Republican candidate, Scott Brown, could defeat the Massachusetts attorney general, the Democrat Martha Coakley. Massachusetts is a heavily Democratic state, it was Kennedy’s seat for almost 50 years, and it was crucial for the Democrats to maintain their 60–40 advantage in the US Senate.

As everyone now knows, this conventional wisdom was wrong. In the fading days of the campaign Coakley’s large lead evaporated and Brown won handily, with 53 percent of the vote.

The second bit of conventional wisdom about this race, explaining the amazing upset, was that it was a vote against President Obama’s policies, especially health care reform. A perfect storm, pundits said: a weak Democratic candidate, a poorly run campaign, and voters impatient for economic recovery, all in a state that already had passed its own universal health coverage law and thus “didn’t need” a new federal law.

As everyone may not know, however, the answer to whether this conventional wisdom is correct is—we don’t know. And we never will. Because the outcome of the race was a foregone conclusion for so long, none of the news organizations paid for the exit polling that would have told us what motivated a large number of independents to vote Republican. Was it health reform? Economic woes? Disaffection with the overwhelmingly Democratic governance in Massachusetts? An insider running in an outsider environment? Whatever caused it, the result of this one state race has had cataclysmic implications nationally.

If you have lost track of the health care reform saga over the holidays, here is where it stood on the eve of the Massachusetts election: both houses of Congress had passed different bills, either of which would have revolutionized the US health care system. To get a bill passed in the Senate, huge and unsavory compromises had been made that benefited unions, specific states, anti-abortion advocates, and others. Daily meetings were
taking place to come up with a compromise version of the two bills that would be acceptable to both houses of Congress and to the White House.

This was entirely a Democratic effort. Early attempts to involve at least a token number of Republicans failed, and both bills passed with no Republican votes. To get a final bill through the 100-member Senate the Democrats needed all 60 of their votes, because of arcane rules involving the so-called filibuster. As anyone who remembers Jimmy Stewart in *Mr. Smith Goes to Washington* knows, one senator can trump the majority by holding the floor and speaking forever. This has evolved from actually holding the floor to threatening to filibuster, and 60 votes are required to defeat it. Because any negotiated compromise on the health care bill would have to be ratified in both houses, the Massachusetts vote has had incredible repercussions.

So what happens now?

Initially some people suggested that the Democrats try to vote quickly on a compromise before the Senate seated its newest member. But even Democratic senators realized that such a move would be subverting the will of the people. Others proposed that the House of Representatives, dominated by Democrats and without a filibuster rule, should just adopt the Senate version and send it to the president for signature. Soon after the election, though, the Democratic speaker of the House, Nancy Pelosi, announced that she didn't have the votes to pass the more conservative Senate bill. A third procedural trick would use something called “reconciliation” rules to pass the bill. This strategy, which would require only a simple majority for passage, was abandoned because it only applies to matters affecting financial appropriations, and parts of the bills don't involve money.

President Obama immediately suggested that a bipartisan effort could start anew to focus on aspects of reform that all parties agreed on, such as insurance reform, cost reduction, and helping out small businesses. Cynics dubbed this proposal “health care lite,” and even the president conceded that it was unlikely to happen. Republicans, sensing victory, are not interested in coming to the negotiating table. Realistically, to get insurance reforms (no exclusions on the basis of pre-existing conditions, no lifetime maximums, and so on) you have to have universal coverage. That means subsidies for those people who cannot afford care, which breaks the budget. Suddenly it isn't health care lite any more.
US health care reform is in the waste can

So does this mean that the results of a single state's senatorial election will actually derail what looked until last week to be a reasonably good chance of a major change in the US health care system? Is there any way to salvage important reform from this mess?

I think it looks very unlikely indeed. Certainly the president can make some administrative reforms in the programs he controls, such as Medicare and Medicaid, to move them aggressively toward rewarding quality rather than quantity of care. He can encourage and help other states to follow Massachusetts' lead in covering more of their citizens. He can use his bully pulpit to try to gain support for a streamlined bill that doesn't have all the special interest provisions that made the current Senate bill so odious.

But I don't think anyone is optimistic that significant health care reform will emerge this year or any time soon. We had our opportunity and we squandered it.
Prevention and the new US health reform act

Important but overlooked benefits were snuck into the bill

Contrary to many predictions (including mine; see the previous essay), President Obama and the Democrats found the will and a tricky strategy to pass sweeping health care reform legislation. Now that the bill has been signed into law, everyone is discussing what will happen and when. Critics of all persuasions are no less active than they were before passage.

Critics from the right say that the program will do nothing to staunch the hemorrhaging of spending on health care and thus will only worsen our dire economic situation. Critics from the left say that the new law is like treating cancer with morphine: it will bring temporary relief but won’t alter the root cause of the problem, which they say is the private insurance system.

To some extent, both sets of critics are right. But at this point it seems to me that the only question remaining is the same one facing Congress last month when they voted: was this bill, imperfect as it was, better than doing nothing? There were only two choices at the end of the day: pass the bill, warts and all, or do nothing, probably for decades.

I come down on the side of passage for two big reasons. The first is what the projections showed things would look like in 10 years if the current system remained unchanged: an estimated 60 million uninsured people, health care spending of almost $5 trillion a year, family insurance premiums increasing to $30,000 annually, and a Medicare trust fund that runs out of money. Pretty grim.

Second, there are real, indisputable benefits to the new law. Some were much discussed and are known to all: a dramatic increase of coverage among the uninsured, portability of plans across jobs and states, and the prohibition of denial of coverage for pre-existing conditions. Some of the features of the law, however, are not well known. They were quietly inserted when everyone’s attention was diverted by “hot button” issues such as abortion, the need for a “public” plan, and individual pork-barrel provisions for the states of wavering senators.
Many of these unsung provisions are in the area of health promotion and disease prevention. Careful reading of the bill reveals a surprising and almost shockingly broad set of prevention-related changes and enhancements that span personal health care, public health, and community infrastructure.

From September 23, six months after the bill was signed, all new US health insurance policies must cover every evidence-based clinical preventive service—screening tests, immunizations, and counseling interventions—at no cost to beneficiaries. This eliminates deductibles and copayments, which have been shown to be disincentives to the delivery of preventive care. Services covered will include all preventive care recommended by the US Preventive Services Task Force. Many health plans already made these services available without charge, but this provision standardizes future coverage for everyone who is insured.

There is a loophole to this provision. Only “new” policies are covered. Are policies “new” when they are renewed each year? Probably not. It will be up to the regulators to define new, and this could lead to delays in implementation of the coverage. Medicare patients won’t face delays, however. Almost every American age 65 or older and younger people who are disabled will get this benefit without the loophole, starting January 1, 2011.

Another new Medicare benefit is the expansion of the single “welcome to Medicare” wellness visit to an annual preventive check-up. All Medicare patients will be entitled to a no-cost annual visit that includes a health risk assessment, creation of a personalized prevention plan, and appropriate screening tests and immunizations, effective from January 1.

Medicaid beneficiaries, whose number will be dramatically increased by the new law, will also see an increase in preventive care coverage. In addition, pregnant women with Medicaid will be entitled to coverage for smoking cessation programs from October 1. The states, which administer Medicaid, will also receive grants to provide incentives to Medicaid beneficiaries to enlist in comprehensive and proved wellness programs. Funds to evaluate these programs are provided.

Employers, who provide most health insurance in the US, are also included in the prevention benefits of the new law, especially relating to employee wellness programs. Many large companies already offer these, and
from 2011 small businesses can apply to a $200 million fund for grants to subsidize their wellness programs. The law also increases, from 20 percent to 30 percent, the allowable premium discount that employers may offer to employees who participate in wellness programs. A 10-state demonstration is authorized to evaluate employer wellness programs from 2014.

Finally, a $5 billion federal prevention and public health fund is created to pay for community infrastructure, such as bike paths, playgrounds, sidewalks, and hiking trails, to increase physical activity and build healthier communities. Also, chain restaurants will be required to provide full nutritional information on their menus to allow their customers to see just how many calories that Big Mac contains (540, if you’re wondering).

All in all, in addition to providing for health care coverage for more Americans, the health reform act should also result in improvements in health promotion and disease prevention. Even if costs are not cut, we will likely be purchasing improved health with the dollars we spend.
PCORI: odd name, important job, potential trouble

Research institute mandated by health reform begins work in the spotlight

In the last few years, there has been much debate in the US about comparative effectiveness research (CER), defined by the Institute of Medicine as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.” According to the IOM, the idea is “to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.”

CER first vaulted into the news here when Congress dedicated $1.1 billion to it as part of the fiscal stimulus package passed in 2009, at the height of the recession.* The Department of Health and Human Services, through NIH and the Agency for Healthcare Research and Quality, quickly disbursed those funds to sponsor research and research infrastructure development to improve medical decisions and clinical outcomes by comparing various drugs, treatments, and other interventions.

Some critics, often pharmaceutical or medical device manufacturers, warned that CER would disadvantage certain new and expensive treatments that head-to-head trials found were only marginally more effective than cheaper, currently available treatments. Other critics, mainly conservatives in the US, were worried that a slavish adherence to CER findings would lead to rationing, inhibiting “individual choice” and dooming individuals to receive only treatments that government bureaucrats chose for them.

Despite these concerns, the government role in CER did not end with the stimulus package. Thus was born the Patient-Centered Outcomes Research Institute. Affectionately known as PCORI, it was initially a little-noticed provision of the Affordable Care Act, the health reform legislation. It established PCORI as an independent research institute to sponsor CER.

* See page 102.
PCORI is funded generously, mainly from a tap on health insurance premiums. By 2013, it will have a budget of about half a billion dollars a year to spend on research and research dissemination.

This sounds great, right? A well-funded independent institute to do CER to improve care and reduce costs. But like most things in government, and certainly much in the Affordable Care Act, it is not quite that straightforward.

First, a search of the enabling legislation fails to find CER mentioned in it at all. Instead, it has been replaced by something called “comparative clinical effectiveness research.” This is meant to restrict PCORI-sponsored research to noneconomic assessments. In fact, PCORI-funded work is specifically proscribed from using quality-adjusted life years or other such measures common in cost-effectiveness analyses. Further, the HHS secretary cannot use the results of PCORI-funded research to determine or deny coverage or reimbursement for health care services.

Second, there is PCORI’s odd name. What is “patient-centered outcomes research,” anyway? Why not just call it the CER institute? This, it turns out, is a legacy of concerns that CER will only find “on average” what works best for most people in large trials, thereby discriminating against individuals, especially individuals with disabilities or guarded prognoses. Hence, patient-centered.

Organizations such as the Partnership to Improve Patient Care, an Astroturf (fake) grass-roots group whose steering committee includes the major lobbyists for drug and device manufacturers, show up at every board meeting to make sure PCORI is “communicating results rather than setting centralized coverage decisions, addressing the full range of information gaps that matter to patients, addressing differences in individual patient needs, and supporting continued medical advances.” Translation? Supporting expensive new drugs that extend life for a few months at huge cost.

Third, creating a new research organization the size of a small NIH institute out of nothing is not a trivial matter. Ask the people at the UK’s controversial National Institute for Health and Clinical Excellence (NICE). The Affordable Care Act only mandated the appointment of a governing board for PCORI, and they have had the immense job of creating a full-fledged research institute overnight in open view of a critical public. Not an easy task.
So far, the PCORI board has worked diligently to craft bylaws, hire a staff, and begin work. They first have to figure out what patient-centered outcomes research is. Then they have to decide what research to fund and how to go about it. While the board has not actually spent a dime yet on research, this hasn't stopped the *Wall Street Journal* and other conservative voices from sniping at them as part of their campaign against CER: “comparative effectiveness isn’t about informing choices. It’s really about taking away options.” Despite the posting of PCORI board member biographies on the web and the webcasting of their public meetings, the *Journal* demands to know “who these people are and what they favor.”

Partially crippled by its wacky name and its inability to sponsor cost-effectiveness research, PCORI is treading a treacherous road toward a noble goal. I hope they are not distracted by the special interest clamor and conservative clap-trap. CER is not a panacea, but it has real potential to improve care and decrease costs. If head-to-head trials help us compare treatments and treatment systems for common problems, we can improve quality and safety. If just a few of the expensive boondoggles we fervently believe in are exposed and expunged, CER can rationalize (not ration) care and pay for itself. It would be nice if everyone would just leave them alone and let them get on with it.