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## Insourcing Health Care Innovation


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## Insourcing Health Care Innovation

### Abstract

Many health care professionals find it irritating when management gurus recommend solving health care's problems with approaches they would "copy and paste" from unrelated industries — a former chief executive of a manufacturing company claims that the same simple lessons that enabled him to transform his own industry can improve value in health care, or a business-school professor offers an eight-point leadership plan that she's translated into health care as easily as if she'd translated it into French. Many people who work in health care value outside perspectives and are open to new approaches — and yet bristle at facile recommendations emerging from these translations.

### Disciplines

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lenge manufacturers of products such as energy drinks who have determined themselves that caffeine is safe at much higher levels, and ultimately regulate the amount of caffeine permitted in products.

Whether states have authority on these issues is an important question. Federal law does not expressly preempt states from making their own determinations of GRAS status. However, a state taking such an action could place itself in conflict with federal law and be vulnerable to legal challenges based on arguments, for example, that state actions are preempted by federal law. States do have authority to use their police power to enact regulations directed at food-service establishments such as restaurants in order to support public health. States could, for example, require restaurants to reduce sodium levels in prepared foods, as New

York City did with trans fat, and could require warning labels for foods.

Over the past few decades, food-safety concerns have expanded from issues of foodborne illness and contaminants such as lead to include the effects food ingredients have on chronic diseases such as heart disease. The government's rightful role is to continue examining food ingredients to determine safe conditions for their use. The government has the authority and responsibility to regulate the unhealthful aspects of the food supply, and artificial trans fat is likely to be an important frontier. The fact that a regulatory arm of the U.S. government is now following the lead of other countries and some U.S. cities and states with regard to trans fat suggests that a watershed has been reached; regulatory reconsideration of ingredients such as

sugar, caffeine, and salt may well be next on the agenda.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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## Insourcing Health Care Innovation

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Many health care professionals find it irritating when management gurus recommend solving health care's problems with approaches they would "copy and paste" from unrelated industries — a former chief executive of a manufacturing company claims that the same simple lessons that enabled him to transform his own industry can improve value in health care, or a business-school professor offers an eight-point leadership plan that she's translated into health care as easily as if she'd trans-

lated it into French. Many people who work in health care value outside perspectives and are open to new approaches — and yet bristle at facile recommendations emerging from these translations.

At the same time, health care improvements can come from people who don't know the field asking, genuinely, "Couldn't you do it a different way?" — where insiders might be less able to imagine alternatives. Principles guiding high-impact innovation are evolving faster outside health care than inside. So it makes

sense not to give up on the management gurus entirely, but we can distinguish between those who follow good innovation practices and those who don't. Health care is not a single problem but thousands of problems, and rather than seeking a solution derived from other fields, we'd do better to find a solution *process* to use from within.

The challenge of health care innovation lies in combining contextual understanding with fresh perspectives. We — a physician, a business-school professor, a

hospital administrator, and an innovation executive — have found that a four-stage design process can produce that combination.<sup>1</sup> The four stages are contextual inquiry — immersion in the way things currently work; problem definition — reexamination of the challenge, to ensure that the right problem is being solved; divergence — exploration of alternatives to the first ideas; and rapid validation — moving quickly from prototyping to designing of focused experiments testing critical assumptions.

This process for high-impact innovation can be learned. It is informed by models from other settings, including the “plan–do–check–act” cycles credited to W. Edwards Deming and the design approaches of firms such as IDEO. The process need not be linear, but a willingness to immerse oneself in the real context as a first step distinguishes the external experts who will help from those who won’t. For the same reason, innovation from within has a potential advantage in health care settings. Whereas in many industries the thought leaders are secluded in corporate headquarters, physicians and nurses are situated right up front with the customers.

And yet as connected as clinicians are to their patients, in the first phase of the innovation process they can do more to embed themselves in their patients’ lives. For example, we have been working to improve medication adherence among patients discharged after myocardial infarction. The ways we gain insight about their experience — going to their homes and following them through their day — are not the stuff of everyday physician–

patient encounters, yet they provide knowledge that’s typically not learned in medical school. Experiencing the long commute without bathroom access that keeps someone from taking his diuretic exposes the inadequacy of better reminders. Noting the hand-drawn medication-tracking sheet on the refrigerator door of a patient now successfully staying out of the hospital (its size legible to a 72-year-old, with copies sent to her children) tells us something about the design and social component of effective adherence tools. William Osler said, “Listen to the patient. He is telling you the diagnosis.” Clinicians with established relationships are well positioned to get the one step closer required for meaningful innovations.

In the second phase, health systems too often converge on the wrong problem. Pursuing online self-scheduling when the need is new-patient access may merely make it easier to see how long it takes to get an appointment. In the 1980s, Hertz saw the need to address long lines at airport car-rental locations. Realizing that what customers wanted was not a shorter line but faster ways to get on their way, they were able to see past adding agents or changing customer paperwork to the invention of Hertz Gold, with no line at all.

Deliberate divergence, the third phase, rarely comes naturally in time-starved environments. Anchoring prematurely on a solution — perhaps one offered by a vendor promising magic elixirs for the pressing need — often results in large investments in projects that never meet expectations. Alternatively, rapid, lower-cost tests of multiple approaches, with ob-

servations about their advantages and disadvantages, can lead to surprises regarding the nature of the problem and what success looks like. In recent work on patient experience, we used a mobile app to elicit real-time patient feedback for timely course corrections, but concurrent experiments using pen and paper identified essential design elements that can now be incorporated into the more advanced technology.

Commercial entities have embraced the fourth phase, designing experiments to test key business assumptions in hours or days instead of discovering months or years later that they invested in the wrong strategy. In “vapor tests,” retailers sell products they haven’t yet created in order to assess demand. “Fake back ends” simulate automated solutions before an organization incurs the cost of real automation. Before we embarked on complex system changes to enable same-day orthopedic scheduling, an enterprising practice manager published his cell-phone number online to become an experimental call center for a 3-day test. This tiny pilot told us a lot about how to proceed and produced impressive data that convinced hospital leadership to act. Within health systems’ many constraints — from restrictions on handling of personal health information to regulations regarding human-subjects research — lie opportunities for quick experiments that staff are well positioned to conceive and execute. The best external experts take this approach, but most do not evolve big strategies through rapid, contextual tests.

Many organizations find it easier to spend larger sums on outsourced and shrink-wrapped

solutions than smaller sums on maintaining protected time for their staff to drive change. And yet clinicians know more than outsiders about health care's customers and context; they have street credibility and established trust relationships in an environment where those characteristics count; they can often reuse experiences in multiple projects; and they're usually mission-driven to improve outcomes. They also don't then resell the lessons learned; they give them away, in presentations and papers.

These insiders, however, often face three barriers to innovation. First, principles of rapid-cycle innovation are part of neither medical training nor clinicians' experience. Even in academic medical centers emphasizing research, clinicians who conduct controlled experiments in the laboratory often don't consider deploying them when seeking to improve care delivery. But just as operating-room "timeouts" introduced new discipline in clinical settings, we've seen care teams embrace rapid validation methods, testing and evaluating new ideas quickly.

Second, insiders' experience

can become constraining. Henry Ford is often credited with saying that had he asked his customers what they wanted, they would have said "faster horses." Though he apparently never said that, the story highlights the trap of envisioning incremental gain along established dimensions and the difficulty of envisioning the kind of change that replaces horses with cars. It's important to enforce divergent thinking, in part by using analogies when breakthroughs from outside health care can expand our vision.

Third, clinicians are busy. Health care organizations, operating on thin margins, rarely allow for slack in staff work. Many organizations say they simply cannot introduce time for stepping back and reimagining that work: it's too costly to take the workers who add the most value off the front lines. But it can be done with selected individuals and at strategic times. Companies that have begun insourcing innovation couldn't imagine doing so before they'd designed new time-allocation practices. Time for engagement is even more critical in health care: new ideas

create no value until they're implemented, and effective implementation in health care requires clinician acceptance.

Forward-thinking health systems understand the obligation to improve value. Health care can benefit from outside perspectives in this endeavor, but clinicians have the requisite drive, experience, and context to be productive innovators. If we adapt and internalize proven innovation principles from other fields, much effective innovation can come from within.

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## FDA Approval of Paroxetine for Menopausal Hot Flashes

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The recent approval by the Food and Drug Administration (FDA) of paroxetine (Brisdelle, Noven) for the treatment of moderate-to-severe vasomotor symptoms associated with menopause was distinctive for at least

two reasons. First, it offered the first nonhormonal option to women who cannot or do not want to use hormonal medications to treat their menopausal vasomotor symptoms. Second, the approval ran counter to the rec-

ommendation of the FDA Reproductive Health Drugs Advisory Committee, which had concluded, by a vote of 10 to 4, that the overall benefit-risk profile of Brisdelle did not support approval. The FDA always carefully