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OP-ED CONTRIBUTOR

A Lifesaving Checklist

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IN Bethesda, Md., in a squat building off a suburban parkway, sits a small federal agency called the Office for Human Research Protections. Its aim is to protect people. But lately you have to wonder. Consider this recent case.

A year ago, researchers at Johns Hopkins University published the results of a program that instituted in nearly every intensive care unit in Michigan a simple five-step checklist designed to prevent certain hospital infections. It reminds doctors to make sure, for example, that before putting large intravenous lines into patients, they actually wash their hands and don a sterile gown and gloves.

The results were stunning. Within three months, the rate of bloodstream infections from these I.V. lines fell by two-thirds. The average I.C.U. cut its infection rate from 4 percent to zero. Over 18 months, the program saved more than 1,500 lives and nearly $200 million.

Yet this past month, the Office for Human Research Protections shut the program down. The agency issued notice to the researchers and the Michigan Health and Hospital Association that, by introducing a checklist and tracking the results without written, informed consent from each patient and health-care provider, they had violated scientific ethics regulations. Johns Hopkins had to halt not only the program in Michigan but also its plans to extend it to hospitals in New Jersey and Rhode Island.

The government's decision was bizarre and dangerous. But there was a certain blinkered logic to it, which went like this: A checklist is an alteration in medical care no less than an experimental drug is. Studying an experimental drug in people without federal monitoring and explicit written permission from each patient is unethical and illegal. Therefore it is no less unethical and illegal to do the same with a checklist. Indeed, a checklist may require even more stringent oversight, the administration ruled, because the data gathered in testing it could put not only the patients but also the doctors at risk — by exposing how poorly some of them follow basic infection-prevention procedures.

The need for safeguards in medical experimentation has been evident since before the Nazi physician trials at Nuremberg. Testing a checklist for infection prevention, however, is not the same as testing an experimental drug — and neither are like-minded efforts now under way to reduce pneumonia in hospitals,

improve the consistency of stroke and heart attack treatment and increase flu vaccination rates. Such organizational research work, new to medicine, aims to cement minimum standards and ensure they are followed, not to discover new therapies. This work is different from drug testing not merely because it poses lower risks, but because a failure to carry it out poses a vastly greater risk to people's lives.

A large body of evidence gathered in recent years has revealed a profound failure by health-care professionals to follow basic steps proven to stop infection and other major complications. We now know that hundreds of thousands of Americans suffer serious complications or die as a result. It's not for lack of effort. People in health care work long, hard hours. They are struggling, however, to provide increasingly complex care in the absence of effective systematization.

Excellent clinical care is no longer possible without doctors and nurses routinely using checklists and other organizational strategies and studying their results. There need to be as few barriers to such efforts as possible. Instead, the endeavor itself is treated as the danger.

If the government's ruling were applied more widely, whole swaths of critical work to ensure safe and effective care would either halt or shrink: efforts by the Centers for Disease Control and Prevention to examine responses to outbreaks of infectious disease; the military's program to track the care of wounded soldiers; the Five Million Lives campaign, by the nonprofit Institute for Healthcare Improvement, to reduce avoidable complications in 3,700 hospitals nationwide.

I work with the World Health Organization on a new effort to introduce surgical safety checklists worldwide. It aims to ensure that a dozen basic safety steps are actually followed in operating rooms here and abroad — that the operating team gives an antibiotic before making an incision, for example, and reviews how much blood loss to prepare for. A critical component of the program involves tracking successes and failures and learning from them. If each of the hundreds of hospitals we're trying to draw into the program were required to obtain permissions for this, even just from research regulators, few could join.

Scientific research regulations had previously exempted efforts to improve medical quality and public health — because they hadn't been scientific. Now that the work is becoming more systematic (and effective), the authorities have stepped in. And they're in danger of putting ethics bureaucracy in the way of actual ethical medical care. The agency should allow this research to continue unencumbered. If it won't, then Congress will have to.

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