

prominent role. Will registry data (or data coming from other digital sources, such as electronic health records) be of high enough quality? Will too many data fields be missing? How will we balance efficacy versus effectiveness? Can we transition single registries from efficacy to effectiveness, making it possible to assess external validity much more expeditiously than we do now? What are the best populations or subpopulations to study? How will we approach concerns about privacy and informed consent (particularly in the context of trials that compare acceptable standards of care and use cluster-randomization methods)? Is blinding possible? Will researchers be able to obtain long-term follow-up or measure composite outcomes? How will we standardize and adjudicate certain outcomes? Can we assure representativeness, given that even within a registry there may be systematic differences between patients who are and are not eligible for randomization or between those who do or do not consent?

These are only some of the problems we will have to address. The TASTE trial was performed in Scandinavia, where the health care and information technology environments are markedly different from those elsewhere in the world. Can randomized registry trials be undertaken outside

Scandinavia, in places where health care and clinical data are fragmented and of lower quality? Some American investigators are already using the approach (e.g., the Study of Access Site for Enhancement of Percutaneous Coronary Intervention for Women; NCT01406236). But even if we can perform many more randomized registry trials in the United States, we must recognize that the approach cannot solve all the problems we have with trials. For certain kinds of trials, such as metabolic efficacy studies that focus on complex physiologic and metabolic pathways hypothesized to respond to changes in diet or to experimental pharmacologic agents, current organizational structures would probably work much better with only minor modifications.

The randomized registry trial represents a disruptive technology, a technology that transforms existing standards, procedures, and cost structures. Will it be given serious consideration as a way to resolve the recognized limitations of current clinical-trial design? Theodore Roosevelt once said, "Do what you can, with what you have, where you are." Today we can no longer afford to undertake randomized effectiveness trials that cost tens or hundreds of millions of dollars. But today we also have registries and other powerful digital platforms. Today it may

be possible to design and conduct megatrials with what we have: bigger data and smaller budgets. Yet we must also recognize and acknowledge the daunting challenges that diverse groups of researchers and stakeholders must overcome to get there.

The views expressed in this article are those of the authors and do not necessarily represent the official positions of the National Heart, Lung, and Blood Institute. Dr. Lauer is the National Institutes of Health representative on the Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI); none of the views expressed here represent those of PCORI or its Methodology Committee.

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

From the Office of the Director, Division of Cardiovascular Sciences, the National Heart, Lung, and Blood Institute, Bethesda, MD (M.S.L.); and the Mathematics and Statistics Department, Boston University, and the Harvard Clinical Research Institute — both in Boston (R.B.D.).

This article was published on September 1, 2013, at NEJM.org.

1. Antman EM, Harrington RA. Transforming clinical trials in cardiovascular disease: mission critical for health and economic well-being. *JAMA* 2012;308:1743-4.
2. Pocock SJ, Elbourne DR. Randomized trials or observational tribulations? *N Engl J Med* 2000;342:1907-9.
3. Fröbert O, Lagerqvist B, Gudnason T, et al. Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia (TASTE trial): a multicenter, prospective, randomized, controlled clinical registry trial based on the Swedish Angiography and Angioplasty Registry (SCAAR) platform: study design and rationale. *Am Heart J* 2010;160:1042-8.

DOI: 10.1056/NEJMp1310102

Copyright © 2013 Massachusetts Medical Society.

Smoothing the Way to High Quality, Safety, and Economy

Eugene Litvak, Ph.D., and Harvey V. Fineberg, M.D., Ph.D.

In recent years, health care institutions have awakened to the need to provide safe, high-quality care at lower cost. The Centers for Medicare and Medic-

aid Services is implementing multiple incentives and penalties intended to help realize this goal. For example, innovations designed to reduce the rate of in-

fections associated with ventilators or central venous catheters have had demonstrated success. We believe that greater attention to a frequently overlooked param-

eter in health service design — patient load and flow — would accelerate progress toward reliable, safe, efficient care.

A reliable health system is one that functions properly in difficult and unanticipated circumstances as well as in normal or easy ones — indeed, difficult and unanticipated circumstances are par for the course in health care. Among the most common such conditions are periods of excess patient load that can overwhelm even the most conscientious physician or nurse and impair the quality of care. A growing body of evidence illuminates the adverse consequences of excessive patient load. Studies have shown that increased patient volume increases the likelihood of harm to patients, the rate of health care–associated infections, the average length of stay, and the odds of readmission.¹ Nearly 40% of hospitalists report experiencing an unsafe volume of patients at least monthly.¹

As patient demand fluctuates and the number of patients per nurse increases, delivery of high-quality, safe care becomes unreliable. Even the best protocols cannot be consistently followed when an organization is overwhelmed with patients and staff must take shortcuts or delay attending to some patients who need care. In addition, periodic stresses on the delivery system undermine clinicians' morale. Once providers and institutions adopt shortcuts and tolerate delays during peak days and hours, they may come to accept them as their usual standard of care even during valleys in patient load.

Periodic peaks in patient flow pressure hospitals to spend more on both physical and human resources. Because of the long-

standing tradition of cost-plus reimbursement, the readiest physical accommodation for a periodic imbalance between patient demand and delivery-system capacity has been to provide additional capacity (e.g., build more hospital beds at a capital cost alone of more than \$1 million each), so that peaks in demand can be met.²

Health systems have only three staffing choices for accommodating peaks in patient flow: having enough staff available at all times to meet the peaks, an option that is neither affordable to the system as a whole nor widely feasible in the face of the insufficient number of nurses; intentionally staffing for below-peak patient levels and tolerating periods of inadequate care; or establishing dynamic nursing pools to fill in during the peaks, a scheme that fails if bed occupancy changes every hour or two.

All these unsatisfactory options are based on the premise that peaks in patient demand are patient-driven — that is, primarily dependent on natural fluctuations in the occurrence of illness and injury that are beyond the control of health care professionals and institutional leaders. That supposition, however, is highly dubious.

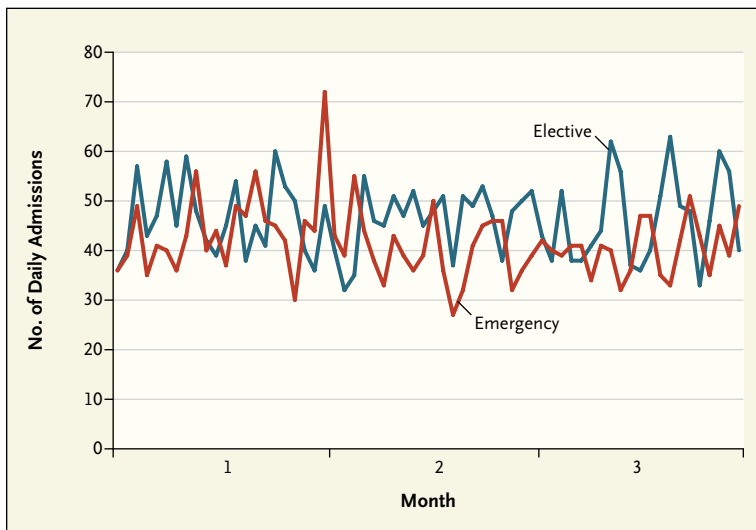
Overall, the average occupancy rate of U.S. hospital beds is 65 to 67% — substantially lower than that in many other industrialized countries, according to the Organization for Economic Cooperation and Development. Despite the fact that on average, one third of U.S. hospital-bed capacity is idle at any given time, utilized hospital capacity fluctuates daily even in individual hospitals (see graph), and hospitals are often overcrowded. Patients are fortunate

if they're admitted during a valley in patient demand and unfortunate if they arrive during a peak, when all hospital resources (beds, nurses, physicians, radiology equipment, etc.) are stretched thin.

Excess flow of patients is not simply a feature of natural disasters, pandemics, or tragic events. At every hospital examined by the Institute for Healthcare Optimization and others,³ the majority of variability in patient flow is attributable to scheduled admissions.

In many U.S. hospitals, it has become standard practice to perform as many planned surgeries each day as are requested by surgeons with admitting privileges. When many surgeries are scheduled for the same day, they create artificial peaks in "patient" demand. These peaks are truly driven not by patient needs, desire, or benefit but rather by a confluence of managerial inattention and deeply rooted professional prerogatives and institutional practices. These artificial peaks and valleys continue to foster health care delivery that endangers patients, reduces access to care, puts artificial pressure on clinicians during peaks, and results in underutilization of health care resources during valleys. They are a major impediment to building a safe and efficient delivery system.

Artificial peaks and valleys in patient flow can and should be analyzed and smoothed, by means of a practically proven method.^{3,4} This method requires first separating the hospital resources (e.g., operating rooms) used for elective and unscheduled procedures and then ensuring that similar numbers of elective admissions occur in different hospital wards each day.³ Hospitals such as Johns



Daily Fluctuations in One Hospital's Admissions for Emergency and Elective Surgery.
Data are for weekdays only and are from the Institute for Healthcare Optimization.

Hopkins, Cincinnati Children's, and the Mayo Clinic in Florida have applied this method successfully, through leadership commitment, engagement of physicians and especially surgeons, use of local data, and reliance on the principles of operations research. Applying this method over 1 to 2 years, these hospitals have achieved multimillion-dollar reductions in annual costs while simultaneously improving patient safety, quality of care, and satisfaction among patients, clinicians, and hospital managers alike.^{2,4,5} For example, by properly managing patient flow, Cincinnati Children's Hospital saved \$100 million

in capital costs and increased its margin by more than \$100 million annually while improving the quality of care.⁵ If each of the almost 6000 U.S. hospitals achieved only 10% of these financial results, it would mean about **\$60 billion in savings**, plus reduced overcrowding, complications, readmissions, and mortality.² If every hospital avoided adding just one extra bed for accommodating artificial influxes of patients, the health care system would save \$6 billion to \$12 billion in capital costs alone.

Direct and indirect savings from smoother patient flow could give Medicare a new lease on

life, underwrite biomedical research, reduce the national debt, support schools, and serve many other private and public purposes. At the same time, properly managed patient flow can reduce medical errors and enhance the quality of care. We owe these improvements to our patients, to the health care community, and to the next generation.

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

From the Institute for Healthcare Optimization, Newton, MA (E.L.); and the Institute of Medicine of the National Academies, Washington, DC (H.V.F.).

1. Studies of the effects of patient flow variability on healthcare quality and safety. Newton, MA: Institute for Healthcare Optimization, 2013 (<http://www.ihoptimize.org/what-we-do-methodology-quality-and-safety.htm>).
2. Litvak E, Bisognano M. More patients, less payment: increasing hospital efficiency in the aftermath of health reform. *Health Aff (Millwood)* 2011;30:76-80.
3. Litvak E, ed. *Managing patient flow: strategies and solutions*. 2nd ed. Oakbrook Terrace, IL: Joint Commission Resources, 2010.
4. Smith CD, Spackman T, Brommer K, et al. Re-engineering the operating room using variability methodology to improve health care value. *J Am Coll Surg* 2013;216:559-68. [Erratum, *J Am Coll Surg* 2013;216:1230.]
5. Ryckman F, Adler E, Anneken A, et al. Cincinnati Children's Hospital Medical Center: redesigning perioperative flow using operations management tools to improve access and safety. In: Litvak E, ed. *Managing patient flow in hospitals: strategies and solutions*. 2nd ed. Oakbrook Terrace, IL: Joint Commission Resources, 2010:97-111.

DOI: 10.1056/NEJMp1307699

Copyright © 2013 Massachusetts Medical Society.

The Debt of Life — Thai Lessons on a Process-Oriented Ethical Logic

Scott D. Stonington, M.D., Ph.D.

"We love him so much," said Ms. M., standing over her father as he lay on life support in a Boston ICU where I was an intern. "We want to do everything

— or at least I want to," she said tearfully, acknowledging the disagreement among her siblings about how to proceed. Later that morning, I presented her father's

case on rounds: after a failed bone marrow transplant, he'd had a myocardial infarction, which had led to heart failure, then renal failure, then pneumonia and