To better integrate these technologies into disease detection and response, the CDC launched its Advanced Molecular Detection and Response to Infectious Disease Outbreaks (AMD) initiative in 2014 to expand its own capacity, as well as that of state and local health departments (http://www.cdc.gov/amd/). One goal of the initiative is to modernize PulseNet, the network of laboratories that work together to detect clusters of foodborne illness that signal an outbreak.

Cheaper sequencing and mushrooming volumes of sequencing data are outpacing the supply of bioinformatics experts who can provide clinically meaningful interpretations of sequencing data, and this supply-and-demand problem is limiting the expansion of genome sequencing technologies in clinical and public health settings. One of the goals of the CDC’s AMD initiative is to address this problem, explained Monroe. As a start, the agency has been working with the Association of Public Health Laboratories and nearby academic partners, primarily Emory University and Georgia Institute of Technology, to establish bioinformatics training fellowships.

Experts predict that genome sequencing may one day become routine in tertiary centers, but it’s likelier that for everyday care in the clinic, rapid PCR-based molecular diagnostic tests will play a greater role. “We could use the information from sequenced genomes to develop PCR-based molecular diagnostics that could give [clinicians] a better assessment of which antibiotic a patient’s infection will respond to,” said Segre. “We don’t need to do genome sequencing for a patient who comes in with an E coli urinary tract infection, but we do need it in the context of an ICU that cares for, say, a critically ill patient who has had a bone marrow transplant, to find out what [microbes] that person was colonized with.”

Caution Against Spurious Associations

Some experts add a cautionary note about problems posed by such factors as sample contamination or insufficient expertise in interpreting sequence data. Lipkin pointed to a recent metagenomics study in which researchers reported finding evidence of plague and anthrax bacteria in the New York City subways, a claim widely hyped by news outlets (http://bit.ly/IGXeIQO).

“These claims were made based on short fragments of information for sequences that are common to a wide range of bacteria, not specific to those pathogens,” Lipkin said.

Lipkin noted that the technology’s sensitivity boosts the risk that low-level contaminants may also be amplified. For example, in 2006, researchers claimed to have found a link between xenotropic murine leukemia virus-related virus (XMRV) and prostate cancer (Urisman A et al. PLoS Pathog. 2006;2[3]:e25). However, careful follow-up studies failed to detect XMRV in tissue samples from men with prostate cancer, and researchers subsequently determined that the presence of XMRV was the result of contaminated cell cultures (Lee D et al. PLoS One. 2012;7[9]:e44954).

As use of genomic tools continues to expand, it’s important to ensure that the validity of molecular discoveries is rigorously tested, Lipkin said. “Spurious associations undermine public confidence in the validity of science.”

Nonetheless, as genomic sequencing technology and other AMD tools are refined, their use in pathogen discovery, outbreak tracing, and diagnosis promises a new era in how the clinical and public health communities will identify and respond to microbial threats.

The JAMA Forum

Back to the Future: Volume as a Quality Metric

Ashish K. Jha, MD, MPH

Recently, a group of leading academic institutions asked all hospitals to pledge to minimize the number of patients who undergo certain surgeries performed by surgeons and hospitals who seldom do those procedures. The “Take the Volume Pledge” campaign, initiated by 2 of the most respected experts on quality and safety in the nation, John Birkmeyer, MD, of Dartmouth-Hitchcock health system, and Peter Pronovost, MD, PhD, of Johns Hopkins Medicine, makes a lot of clinical sense (http://bit.ly/1L3PvF1). We know that when patients receive these surgeries at low-volume institutions or in the hands of low-volume surgeons, they tend to fare worse.

What’s remarkable isn’t that these leaders asked hospitals to focus on volume as a way to improve patient outcomes, but that they are doing it in 2015. And herein lies a story of volume as a quality metric, long used because it was all we had, then falling out of favor, and now coming back again. This story also reminds us of the nation’s inadequate efforts to measure quality meaningfully and the price we pay in lives lost and patients harmed.

We have always known that volume matters. The notion is simple and intuitive: practice makes perfect; experience creates better physicians. Surely, a surgeon who performs a single esophagectomy a year will do the surgery less well and manage complications less effectively than a surgeon who does one every week or even every month. This is why surgical training is so long and why we value experts who have seen many cases similar to the one confronting them today.

And for more than 2 decades, work of leading scholars has shown clearly and convincingly that volume matters (http://bit.ly/1KIo7Lz). Mortality at low-volume centers for certain procedures is as much as 5 times higher than at the highest-volume centers (http://bit.ly/1KIo7Lz). Such evidence has prompted quality and safety organizations to encourage patients and providers to use high-volume centers (http://bit.ly/1B66Mdt).

But over the past decade, quality measurement efforts moved away from volume. Volume was obviously just a proxy. What we cared about was good outcomes, and if we could measure outcomes directly, why bother with volume? Although high-
volume centers may be, on average, better than low-volume centers, surely there are some poor-performing, high-volume centers and well-performing, low-volume ones. So the thinking was that we could dispense with volumes if we could directly measure outcomes such as mortality and complications.

But the journey toward measuring outcomes has not panned out as we had hoped. Although some programs, such as the National Surgical Quality Improvement Program (NSQIP), have been measuring outcomes for many kinds of surgeries, most of those data are not widely available. And for the 3% of US hospitals with publicly available NSQIP data, the information is difficult to comprehend.

For all other hospitals, Medicare has been measuring and reporting readmissions, a utilization measure that may be related to quality, using statistical models that ensure nearly every hospital—especially the ones that do only a few cases a year—looks average (http://bit.ly/1GhIjAT). In the most recent reports on Medicare's Hospital Compare, of 3495 hospitals that perform hip or knee surgery, only 32 (less than 1%) were labeled as being worse than expected on readmissions (http://1.usa.gov/IcqANBQ). If everyone is average, why bother improving? What’s worse is that for most of the complicated procedures (eg, colectomy, esophagectomy, or abdominal aortic aneurysm repair)—those with high rates of mortality, complications, and a substantial risk of disability) almost no national data exist. One reason for this is that most hospitals have too few cases to create statistically meaningful assessments.

But the problem with our current measurement approach is not only having many institutions with too few cases, but also that we haven’t measured many of the things that matter. For example, what outcomes might be important for a pancreatectomy to treat a resectable pancreatic cancer? Surviving the surgery and the first 30 days thereafter is paramount, but maintaining the ability to effectively respond to complications. For example, what should a high-volume center perform more effectively together, systems to identify complications early, and the ability to effectively respond to complications. They also may be more likely to have critical support programs, such as wound care, nutrition, and occupational therapy, to maximize patients’ abilities to return to their activities of daily living.

A few years ago, my colleagues and I found that when hospitals with few esophagectomy cases had more nurses, posiotom emission tomography scanners, and 3 clinically unrelated sets of services (lung transplant, complex oncology, and bariatric surgery) available, their outcomes were nearly as good as high-volume hospitals (http://1.usa.gov/1IJz3JL). And more than a decade ago, a remarkable study found that the volume of lung resections performed in a hospital was a better predictor of mortality after pancreateoduodenectomy than the volume of the pancreateoduodenectomies (http://bit.ly/1S8xExA). These and other studies suggest that the story is a bit more complicated than “practice makes perfect.”

So, in 2015, we’re back to volume as a surrogate for quality. Why have Birkmeyer, Pronovost, and others championed the volume pledge? They understand that it is possible to below volume and high-quality; I suspect they would even agree that if we could perfectly measure all the things that matter, we would not need volume as a surrogate. But, as practitioners and leaders, they have pushed the volume pledge because it will save lives today.

Implementing it will not be without challenges. For example, what should a high-volume hospital do with a newly minted surgeon who hasn’t yet met the volume threshold? And some will inevitably argue that the volume pledge may be self-serving because it creates monopolies for highly reimbursed, complex surgical services. The response to this objection is that the strength of the evidence for volume is clear and the pledge is being championed by 2 clinical leaders who are unmatched in their commitment to and effectiveness in improving patient outcomes.

So hospital leaders around the nation should absolutely take the volume pledge, but we still need to work to develop the measures that are meaningful to patients and clinicians and that are readily available in a way that is accessible and comprehensible. In 2015, we should expect nothing less.

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