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Lean Healthcare: 6 Methodologies for Improvement from Dr. Brent James

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This report is a summary from a presentation at a regional healthcare conference by Brent James, M.D., clinical professor at Stanford University of Medicine and former vice president and chief quality officer at Intermountain Healthcare.

In 2018, the quality of patient care falls far short of its theoretical potential. Massive variation in clinical practices undermines the goal of good care for all patients. High rates of inappropriate care where the risk of harm is inherent in the treatment can outweigh any potential benefit. This leads to preventable care-associated patient injury and death due to a striking inability to do what we know works.

Additionally, variations in care generate huge amounts of waste across all segments of healthcare systems, leading to spiraling prices that can limit patient access to affordable care. This challenge has existed for decades, but lean healthcare management principles offer a solution.

Healthcare systems that adopt lean principles can reduce waste while improving the quality of care. By applying rigorous clinical data measurement methods to routine care delivery, these systems identify evidence-based best practice protocols and blend those into the clinical workflow. Data from these best practices are then fed back through a continuous-learning loop that enables healthcare teams across organizations to constantly update and improve the protocols, ultimately reducing waste, lowering costs, and improving access to care and patient outcomes.

The goal of this report is threefold:

1. Illustrate how lean healthcare principles can help improve quality of care.
2. Introduce the steps needed to create shared baseline protocols using embedded data systems to establish a continuous-learning loop.
3. To demonstrate the financial leverage a lean approach offers by eliminating waste and improving net operating margins and return on investment.

Healthcare's Need for Lean Methods: Five Factors

There are some basic tensions inherent in the business of healthcare. Clinicians often focus on patient outcomes, regardless of cost. The financial office, on the other hand, responds, "No money, no mission." Healthcare is still a business.

To resolve that dynamic tension, healthcare systems have tried several approaches. In the 1980s, healthcare organizations used Activity-Based Costing (ABC) systems that had been successful in other industries. At the same time, The Dartmouth Atlas, developed by Jack Wennberg, worked to measure and identify significant geographic variations in care.

In 1986, Intermountain Healthcare localized the otherwise broad approach of the Dartmouth Atlas within its own healthcare system, incorporating ABC principles along the way. Intermountain's Quality, Utilization and Efficiency (QUE) studies applied rigorous clinical research methods to routine care delivery performance in six clinical areas at the health system's inpatient facilities on a local level. And yet the QUE studies still identified massive variations among physicians and care teams, even though they all were following Intermountain's best care protocols.

Variations in care exist both on broad geographic scale and on more localized levels. Five factors contribute to this variation, and each provides opportunities for great improvement.

1. Significant variation in clinical practices. Standardization in care for every individual patient is still nearly impossible, given the variation in access to healthcare. The Affordable Care Act (ACA) was designed to increase access to care by theoretically guaranteeing care to everyone. But in reality, access to care varies across the spectrum. In fact, Wennberg made the compelling case that where a patient goes to receive care is more important than whether she has insurance—dramatically so. This implies that healthcare professionals don't necessarily agree on best practices.
2. High rates of inappropriate care. When the risk of harm inherent in a treatment outweighs the potential benefit, it can rightly be called inappropriate. A Rand study found that this was the case in an astounding 32 percent of patients who underwent carotid endarterectomy procedures. In another study, The Courage Trial of Cardiovascular Medicine, half of all cardiac stenting was identified as clinically inappropriate.
3. Unacceptable rates of preventable care-associated patient injuries and deaths. In a profession aiming to "First, do no harm," research shows 210,000 preventable deaths each year in the U.S. alone. Hospitals are truly a public health problem; medical errors are the third leading cause of death in the U.S.
4. An inability to follow best practices. Anything that is powerful enough to heal can also harm. In 2003, Elizabeth McGlynn of Kaiser Permanente took a list of recommended care processes

and evaluated if that care was provided to eligible patients in 12 major metropolitan areas. She found that adults surveyed received [only 54.9 percent of these recommended processes](). Healthcare professionals are constantly walking a very thin line between health and harm; there is a strong need to more accurately identify, then continuously implement proven methods.

5. Waste. All of this adds up to huge amounts of waste in healthcare, leading to spiraling prices that continue to limit access to care. According to the National Academy of Medicine, [between 35 and 50 percent of all money spent on care delivery today in the U.S. is technically waste](). Whether the waste results from building unusable products, providing unnecessary treatments, or simple inefficiency, it adds no value from a patient's perspective. With the U.S. spending $3.6 trillion annually on the delivery of healthcare, as much as $2 trillion of that amount may be quality-associated waste.

This last factor is critical to the survival of healthcare systems. In the average system, a net operating income drop below three percent can cause failure. The response of many healthcare systems is to build more hospitals, ambulatory surgical centers, imaging centers, etc. But the financial leverage that the "build mentality" can deliver via increased revenue is just a five to nine percent contribution for each case *added*. By contrast, the financial leverage from waste elimination is a 50 to 100 percent contribution to margin for each case *avoided*.

A lean healthcare approach helps organizations generate that financial leverage *and* improve the quality of care by emphasizing a clinical management method.

The Evolution from Craft-Style Models of Care to Guidelines

"The complexity of modern medicine exceeds the capacity of the unaided expert mind."
- David Eddy, Stanford University

At the start of the 20th century, medicine evolved into a craft-style model to address the complexity of care at that time. Physicians and nurses were experts, with all the evidence, experience, and memory stored in the human mind. When the craft model was introduced, it worked quite well, producing dramatic improvements in care.

More than a century later, advances in medical science have sparked a quantum leap in understanding of the human organism, health, and disease. The industry has generated petabytes of new evidence, processes, and procedures. But the sheer volume of new information exceeds the capacity of the unaided expert mind to quickly calculate all the variables in a clinical setting.

To address this evolution of medical knowledge beyond the craft stage, healthcare, like many other industries, turned to guidelines. The challenge with guidelines is always variation (in technology, patients, and caregivers). Demonstrating this concept, a [National Institutes of Health-funded (NIH) study in 1991]() identified large variations in ventilator settings across and within groups of expert pulmonologists. The challenge was the complexity within the lab; there are as many as 40 factors to consider when setting a ventilator. However, studies show that the maximum number of factors an expert clinician can consider at one time is nine.

When the NIH issued the study, the literature on ventilator settings offered evidence for a best practice in only about 20 percent of the cases. In the other 80 percent of cases, doctors and nurses had to determine what was best on their own, because there was no evidence and therefore no best practice. Even when expert consensus is achieved, success still depends on clinicians remembering that information correctly.

The Problem of Guidelines in Healthcare

That is the fallacy of guidelines. A one-size-fits-all approach is untenable when every patient, every doctor, every nurse, every clinical setting is different. This has been proven in many studies:

- Level 1, 2, or 3 evidence is available only about 15 to 25 percent of the time.
- Experts cannot accurately estimate rates relying on subjective recall.
- Best practice guidelines can vary based on the specialty or individual level of the providers.
- Systems that rely on human memory execute correctly only half the time *(McGlynn: 55 percent for adults, 46 percent for children)*
- No two patients are the same; therefore, no guideline perfectly fits any patient (with very rare exceptions).

Six Steps to Mass Customization in Healthcare

Rather than rely solely on guidelines, healthcare systems should use a clinical management method to develop shared baseline protocols. This is the healthcare-specific version of what is known in lean terminology as "mass customization." In other industries, mass customization combines the low unit costs of mass production processes with the flexibility of individual customization. In healthcare, there are six steps to this approach:

1. Identify a high-priority clinical process.
2. Build an evidence-based best practice protocol. It's important to note that this is always imperfect, due to poor evidence and the unreliability of a consensus approach to the best practice, but those issues are resolved later.
3. Blend the protocol into the clinical workflow to avoid dependence on human memory (often referred to as clinical decision support). This makes the idea of "best care" the lowest energy state for doctors and nurses, a default choice that happens automatically unless someone must modify it due to other factors.
4. Embed data systems to track both protocol variations and short and long-term patient results (i.e., intermediate and final clinical, cost and satisfaction outcomes).
5. Demand that clinicians vary their use of the protocol based on individual patient need. This is the customization element now that the mass production process for the guidelines has been established by Steps 1 through 4.
6. Feed data on variations and outcomes back in a lean-based continuous-learning loop that constantly updates and improves the protocol.

With this mass customization approach, it's important to have a "thinking mind" at the interface. This is someone who understands that no two individuals are alike and adjustments need to be made accordingly. Variation in and of itself is not bad, but the key to *effective* variation is standardization. Standards are established on the front end so people can vary around them, then

feed that information back through the learning loop to continuously improve the protocol. No longer a standard "best practice," the protocol becomes an iterative process that constantly improves and communicates the rationale for those improvements with other care team members.

The Continuous-Learning Loop and Developing New Insights

As teams use the mass customization approach to developing and sharing best protocols, team members must understand they will be scrutinized for applying a protocol too much compared to peers who are applying it too little. As the variation is examined in the continuous loop, for divergent team members, either the protocol has something to teach them, or they may have something to teach the rest of the team. It's amazing how often it is the latter, with team members developing new insights. That is how improvements are made.

When this iterative process is used, protocols may change fairly rapidly. This happened in a ventilator protocol compliance study in 16 large academic medical centers in the U.S. The original protocol, developed with input from those participants, was a flow chart over 40 pages long, with 20 decision nodes per page. Four months later, after applying the lean feedback loop, more than 125 changes were made in the best practice protocol without a single patient achieving full compliance. The chance of survival for the most serious patients increased from 9.5 percent to 44 percent–a startling improvement in clinical outcomes. This same protocol is now used in several hundred large intensive care units around the world, and to this day, not a single patient has achieved 100 percent compliance. Nor should they. Each patient is different. That's the value of a learning healthcare system. Clinicians can hold theory against reality and validate the best care through a true learning environment.

While delivering best care is the primary goal, the mass customization approach also impacts costs and productivity. In the case of the ventilator, using data to vary the use of the ventilator based on patient need resulted in cost savings of 25 percent. The structure helped decrease physician time to manage the composed cases while physician productivity increased by 50 percent.

Lean Lessons for Healthcare

Healthcare systems that adhere to a lean approach learn four crucial lessons:

1. They count their successes in lives. While the healthcare industry as a whole is still falling far short of the miracles within reach, with a lean approach to care delivery, patient outcomes can be dramatically better. This is a transformative approach to healthcare that is starting to drive the profession and industry ahead in dramatic ways.

2. There is nothing new here, except the idea that it takes a team and better process-aligned data systems. The healing professions have used a team-based lean healthcare approach for at least 60 years, without giving it a fancy name or trying to sell it as a consulting service. Healthcare professionals intuitively adopted the idea that agreed-upon standards enable effective customization based on patient need. What is different is the ability to use data systems to drive transparency so everyone can learn and benefit from others' effective variations. Moreover, the focus on patient-centered care requires organizations to think in terms of care processes. Quality improvement, the science of managing these processes more

effectively, allows a more robust approach to [population health](#) that emphasizes cost-effective preventive care over more expensive rescue care.

❸ Most often, better care is cheaper care. Quality, cost, and access make up [the Iron Triangle of healthcare delivery](#). In an industry with small margins, cheaper care means a better bottom line. But without access to care, quality care is meaningless. And, accessible doesn't just mean a patient can walk in the door; it also means that care is affordable for the people in an organization's communities.

❹ The long-term [organizational](#) viability of clinical quality improvement strategies requires aligned financial incentives. Consolidations, mergers and acquisitions, and vertical integration continues to dominate the healthcare business news. This is an unstoppable force, especially in an industry where there is as much as $2 trillion in waste left sitting on the table. There's always a consolidator that will extract that waste from the system, so it pays to be lean now, both for the long-term health of the organization and for the future of healthcare overall.

The Survival of Healthcare Organizations Depends on Applying Lean Principles

Systems that can leverage lean management principles to reduce waste while improving the quality of care will be better positioned to survive and thrive in healthcare going forward. The healthcare organizations that have leveraged lean systems have achieved success by applying rigorous clinical data measurement methods to routine care delivery performances. This iterative process not only improves protocols and quality of care, but also explains to other members of the care team the rationale for those improvements, so they can further improve.

It is through this dynamic, data-based learning loop that lean management offers the best opportunity for healthcare systems to shape a better future for their systems through waste reduction, lower costs, and improved access to care and patient outcomes.