INTRODUCTION: THE DRIVE TO REDUCE VARIABILITY IN OUR LIVES

Consider the route you took when you drove to work today. Are you going to take a significantly different route tomorrow? How comfortable would you be flying on a plane for which all pre-flight safety evaluations were based solely on the pilot’s intuition or experience? Perhaps the pilot doesn’t feel that the fuel level needs to be checked. Or the landing gear. Or the engines. Would you board that plane?

Across virtually all the activities and processes that make up our daily lives, we attempt to reduce variability. You likely take the same basic route to and from work each day because it is the most time-efficient. And requiring all pilots and flight engineers (even the most experienced) to follow pre-flight checklists has reduced the variability in the safety of air travel so greatly that it is now far safer to fly commercially across an ocean than to drive to the airport (0.07 vs. 7.28 passenger deaths per billion passenger miles, respectively). The mandatory processes and guidelines used by the airlines also significantly reduce financial waste by standardizing fuel requirements calculations.

Variability often wastes time. Variability often wastes money. Variability often increases the risk of injury or death. And nowhere is the damaging impact of variability on value (quality over cost) more apparent than in the world of health and healthcare delivery.

THE DIFFERENT FACES OF HARMFUL VARIABILITY IN HEALTHCARE

Variability in health and healthcare appears across all sites of care delivery, including non-traditional points of care such as the patient home, and results in a dramatic reduction in the value of clinical care (both quality and cost). Variability in care delivery means a subset of patients (often a large subset) experience poorer clinical outcomes. Variability in care delivery also leads to spending without benefit, that is, waste. While variability in healthcare takes many forms, it can be segregated broadly into three major categories: operational, knowledge, and ownership. In actuality, much of the value reduction in health and healthcare represents a combination of these three types of variability.
“Operational Variability” in Healthcare

Operational variability in the care delivered by doctors, nurses, pharmacists, and other clinicians can harm patients, often significantly. As the term implies, operational variability can often be traced to a basic provider activity or inactivity. While damaging, operational variability may be easily identifiable and addressed. For instance, consider a once common example of clearly dangerous and costly operational variability: physician handwriting.

Fortunately, the risks associated with variable physician handwriting were rapidly addressed through relatively uncomplicated technological solution: Computerized Physician Order Entry.

Unfortunately, the complexity of today’s U.S. healthcare system means that not all operational variability is so easily countered. As healthcare reform drives us from acute, reactive, inpatient care toward proactive, non-hospital maintenance and preventative care, operational variability – and the clinical and financial risk it generates – metastasizes.

Care itself is rapidly moving out of traditional settings, such as hospitals and physician offices, to lay commercial facilities (i.e. large retail pharmacy chains), places of employment, and patient homes. And the roles and responsibilities of providers are expanding, with greater clinical care responsibilities shifting to nurses and to patients themselves, along with their loved ones. Such a rapidly changing, multiple-setting, numerous-provider system is fertile soil for operational variability and subsequent patient risk and cost inefficiency. Within traditional care settings, integrated Electronic Health Records (EHR) systems can reduce some operational variability. But to truly address new challenges appearing as our entire healthcare delivery model morphs requires broader solutions that cross care transition gaps among sites and providers.

One such conceptual approach gaining popularity today is clinical pathways. While definitions and approaches to development are numerous, a commonly shared goal of clinical pathways is the longitudinal reduction of operational variability as patients move from care setting to care setting and from provider to provider.

“Knowledge Variability” in Healthcare

This form of variability, which poses the greatest threat to the quality and cost efficiency of health and healthcare delivery, is more challenging to identify and address. And ironically, this most dangerous form of variability results from one of our most impressive scientific achievements: the warp-speed expansion in our understanding of genomics, human physiology, and human pathophysiology. Knowledge variability is the natural consequence of the unparalleled and explosive rate at which we are gaining new insights into ourselves.

Consider the time it takes for medical knowledge to double1: Today, everything we know about health and healthcare doubles in less time than it takes to complete medical school. By 2020, the entire world’s medical knowledge will double every 73 days!

Even those physicians who most strongly deny the need for technological support in patient care delivery, even the most self-confident of “expert, experienced” physicians, cannot reasonably refute the obvious implications of this explosive rate in our understanding of genomics, pathophysiology, and physiology.

The fact is that it is no longer acceptable for clinicians to solely rely on their training, medical intuition, and experience when it comes to health and healthcare delivery.

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ADDRESSING KNOWLEDGE VARIABILITY IN HEALTHCARE

A common erroneous belief is that knowledge variability in health and care delivery can be significantly reduced solely through the implementation of an EHR. No doubt some harmful and financially wasteful aspects of care delivery are improved through basic EHR alerts and functions. But does the presence of an EHR ensure that a cancer patient gets the best oncologic care? Have we eliminated incorrect drug doses or the performance of unnecessary radiologic procedures simply because an EHR has been implemented? Of course not.

Technology itself is not the answer to the dangers and waste resulting from knowledge variability. The solution to the quality and cost-efficiency harm caused by knowledge variability is found in current, credible, evidence-based information. And while an EHR definitely serves as a powerful vehicle through which such information can be delivered in the form of Clinical Decision Support (CDS), that guidance also can be provided via cloud-based internet solutions or even via faxed or scanned documents or over the phone.

Thus, regardless of how and where providers and patients access the information, current, credible, evidence-based CDS solutions offer the greatest opportunity to realize the enormous potential of healthcare reform. Two simple, real-world examples easily demonstrate the power of CDS to significantly reduce knowledge variability and dramatically impact the clinical quality and cost-efficiency of health and care delivery.

Effective CDS reduces variability but leaves room for physician training and experience when planning and implementing patient care.

Example 1: Physician Knowledge Variability and Financial Waste

Since the 1980s, ICUs all over the world have routinely irradiated the chests of patients on a daily basis despite evidence-based studies that demonstrate that such daily imaging provides a significant subset of patients with no clinical benefit while wasting large amounts of money. CDS solutions delivering current, credible, evidence-based information and guidelines can immediately put a halt to such wasteful knowledge variability.

Most powerful when delivered within order sets that push evidence-based guidelines to the physician, but also valuable when made available within reference solutions, care plans, and/or clinical pathways, CDS solutions empower providers to safely reduce financial waste resulting from knowledge variability.

Example 2: Physician Knowledge Variability and Patient Harm

A general surgeon in a suburban practice prepares to operate on a 49-year-old man with a cancer of the right colon. The surgeon operates on colon cancer about once a month, and he plans to perform his standard operation, a partial colon resection, for a large bowel malignancy. In this situation, however, that is the wrong surgical procedure.

Variable knowledge means that a different surgeon with greater knowledge might correctly suspect, based on the patient’s young age and tumor location, that he suffers from a genetic condition called Lynch Syndrome (Hereditary Nonpolyposis Colorectal Cancer). The etiology in an estimated 6 percent of all colorectal cancer patients, Lynch Syndrome should be suspected in younger patients, especially those with right-sided tumors.
Such variability in genomic and surgical knowledge has several potentially disastrous impacts not only on the quality and cost of the patient’s care, but on the health and healthcare of the patient’s first-degree relatives. The performance of the incorrect partial colon resection leaves the patient at significant risk (as high as 19 percent chance over 10 years) of a second, future, large intestinal cancer, one that may not be curable even with aggressive treatment. In addition, the patient will not be appropriately screened for additional malignancies associated with the genetic syndrome. Finally, the patient’s family members won’t be tested, resulting in the failure to screen similarly affected individuals for colon, ovarian, gastric, hepatobiliary, and other malignancies.

KNOWLEDGE VARIABILITY AMONG NURSES AND OTHER HEALTH PROFESSIONALS
The healthcare reform revolution can alternatively be called, “The Dawn of Nursing.” As the healthcare sector shifts to value-based, non-hospital, maintenance and preventive care, the roles and responsibilities of traditional non-physician providers (nurses, therapists, pharmacists, etc.) are expanding dramatically. Nurses have significantly increased clinical responsibilities, as outpatient offices increase their patient populations and hours of operation and the demands on home health and skilled nursing facility personnel rise. The advent and increasing popularity of retail clinics adds yet another layer of complexity as a growing number of patients seek healthcare in these venues.

Even within the hospital, activities aimed at reducing over-staffing routinely send nurses to “float” to patient care areas where they are less familiar with optimal care delivery. In addition, nursing turnover, traveling nurses, and other nurse staffing realities regularly demand rapid orientation of new staff to individual hospital and healthcare system care and administrative policies and procedures. The result is that nursing in particular is at great risk of harming patients and wasting resources due to knowledge variability in our drive to improve the value of patient health and healthcare.

Again, EHRs offer a beneficial but limited opportunity to reduce knowledge variability, and such solutions are currently found only in hospitals and a subset of outpatient offices. Fortunately, as with physician knowledge variability, CDS solutions empower nurses and nurse administrators with current, credible, evidence-based solutions to address nurse knowledge variability in real time at all points of patient care delivery. Videos, print, and high-definition images that rapidly and clearly provide synoptic instructions, demonstrate clinical skills, and offer rapid access to evidence-based guidance at any point of care provide “floating,” traveling, and new nurses with the current, credible, evidence-based (and institution-specific) information needed to reduce knowledge variability, patient risk, and financial waste. Even for experienced nurses, the availability of such quick “refreshers” can decrease the risks and costs of hospital-acquired conditions and preventable medical errors, while supporting nurse re-certification and advancement.

KNOWLEDGE VARIABILITY IN THE ULTIMATE PROVIDER: THE PATIENT
Maximizing the success of health and healthcare reform demands that patients themselves serve as healthcare providers, along with their families and friends. This reality is based on the simple fact that patients spend virtually no time under the direct care of a physician. Americans visit doctors an average of four times annually with physician visits most commonly lasting only 13-16 minutes, for a grand total of just over one hour each year. And this doesn’t include the significant population of patients who see their physicians fewer times or not at all. Even assuming that a seismic shift in our cultural view results in patients accepting “ownership” of their health, the health and healthcare knowledge variability among our general population is profound.

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2 Here’s how many minutes the average doctor actually spends with each patient, Business Insider, April 6, 2016, http://www.businessinsider.com/how-long-is-average-doctors-visit-2016-4
And once again, our best opportunity to address this vast, wasteful, and dangerous variability is through CDS solutions delivered anytime, anywhere, on any device – but targeted to patients. However, while healthcare professionals such as physicians and nurses are relatively homogeneous in their language, educational, and cultural capabilities, the patient population is widely diverse. Thus to be successful in reducing knowledge variability, CDS solutions for patients must be offered in a variety of formats that take into account patient sub-population language skills, educational levels, cultural perspectives, and most effective presentation platforms (print, video, and/or images).

Even after receiving seemingly clear care instructions from their physicians, nurses, and therapists, patients often demonstrate significant knowledge variability, which places their health at risk. The same applies to the patient’s support network of family and friends. This potentially harmful reality is frequently unsuspected by the patient’s clinicians, who assume that their instructions were understood. Here, too, CDS solutions, appropriately localized for language, educational level, culture, and presentation platform, can dramatically reduce patient risk. Such current, credible, thoughtfully presented information can be repeatedly reviewed by patients and their support network, allowing both simple and more complicated care instructions to be understood and reinforced during even prolonged treatment periods.

**OWNERSHIP VARIABILITY: THE GREATEST CHALLENGE**

CDS solutions clearly empower clinicians to deliver the best care. As noted, however, the key to ultimately realizing the potential of high-value health and healthcare lies with the patients themselves. Unfortunately, it’s a far greater challenge to empower patients than it is providers via current, credible, evidence-based CDS solutions. It is counter-intuitive, yet true, that many patients are less engaged in their own health and healthcare than their providers. And while some, perhaps much, of the failure of patients to truly own their health is the result of knowledge variability, their failure to seek out readily available, credible clinical guidance stems from a more complex cultural and psychological reality: ownership variability.

Examples of variability in patient ownership are abundant. In the United States, at least half of all patients fail to take their prescription medications as instructed. The result? Medication non-compliance leads to 125,000 deaths annually and is implicated in 10 to 25 percent of all hospitalizations and nursing home admissions at an annual cost of $100 billion to $300 billion. Other variabilities include the failure to undergo evidence-based cancer screening, receive evidence-proven vaccines, regularly test blood glucose levels (diabetics) and take a few seconds daily to check body weight (heart failure patients).

While the complex topic of Patient Engagement is not the focus of this work, it must be accomplished if we are to truly reform healthcare worldwide. To do this, we must overcome the multi-factorial causes of ownership variability.

In summary, variability in physician, nurse, pharmacist, other provider and patient knowledge is, unfortunately, the rule, not the exception, especially in today’s exploding world of genomics and “personalized” (“precision”) medicine. And the damage caused by such variability, both in terms of clinical outcomes for patients and costs of care for payers, are dramatic and far-reaching.

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ADDRESSING PHYSICIAN OBJECTIONS TO CDS

Physicians routinely object to attempts at “standardizing” the care they provide. Having trained and practiced for years, many experienced physicians are both fearful of and angered by processes they perceive as removing their voice in the delivery of care and forcing them to deliver “cook book” medicine.

But “reducing variability” and “standardization” are not the same. The goal of variability reduction in healthcare is to eliminate potentially dangerous and/or wasteful activities and processes based on current, credible evidence. Thus, effective CDS reduces variability but leaves room for physician training and experience when planning and implementing patient care.

In fact, it is essential that we continue to rely heavily on physicians’ training and experience to deliver the best healthcare. For example, there is evidence supporting differing approaches to thromboembolism prevention in surgical patients, the treatment of infections, the evaluation of generalized abdominal pain, and even the surgical treatment of colon cancer in our example of the patient suffering from Lynch Syndrome (total or subtotal colectomy). Meaningful incorporation of CDS enables physicians and other providers to avoid actions that are of little or no benefit to patients, waste valuable financial resources and time and unnecessarily place patients at risk.

For example, a physician may select the blood thinner to prescribe for a patient based on his or her training and experience. That is acceptable, even favorable variability. Yet it is remarkable how many physicians prescribe warfarin (the most frequently prescribed anticoagulant), without considering the nearly two dozen commonly found genetic mutations that impact the body’s metabolism of the drug. This oversight can translate to significant clinical implications for patients, simply because those physicians lack the required knowledge. This is unacceptable variability in care delivery.

Thus it should be apparent to every physician, nurse, or other provider that, given the reality that the world’s medical knowledge soon will be doubling every 10 to 12 weeks, consistent, high-quality healthcare can be achieved only through the use of current, credible, evidence-based CDS solutions.

ADDRESSING VARIABILITY THROUGH “PULL” AND “PUSH” CDS SOLUTIONS

There are numerous commercially available CDS solutions aimed at empowering clinicians and their patients. Before plunging into the healthcare reform pool and buying every CDS solution in sight, it is critical to understand some basics. First and foremost, it is essential to appreciate that CDS solutions fall broadly into two categories. Using an automotive safety analogy, these categories can be thought of in terms of seat belts and airbags.

Order sets and other push CDS solutions solve the huge “you don’t know what you don’t know” challenge faced by providers. And, just like the safest cars, healthcare systems with both push and pull technologies will be the most effective in reducing risk and costs.
“Pull” CDS Solutions

Every car sold in the United States is required to have functional seat belts, and many states require all drivers and passengers to wear them while the car is moving. Such mandates have dramatically reduced the number of deaths and injuries due to auto accidents. And yet, every year, more than half of the 30,000-plus motor vehicle deaths and a significant percentage of the 2 million-plus injuries are attributed to the failure of people to “buckle up.”

Seat belts are classic “pull” solutions. That is, they are highly effective in reducing risk, but only when actively used. Many types of CDS solutions are similar, requiring the user to pull current, credible, evidence-based information if seeking to provide the highest-value healthcare. Clinical reference solutions are likely the most widely utilized pull CDS solutions today. Indeed, rapid access to evidence-based knowledge, guidelines, and images is extremely powerful in supporting appropriate clinical decisions for all users. But how can you search for (pull) information that you don’t know you don’t know? How can the general surgeon in our previous example search for information on inherited colon cancer if he doesn’t know that he should search for it? In other words, reference and other pull CDS solutions are extremely valuable, but they require the user to “buckle up.”

“Push” solutions, on the other hand, are the airbags of CDS. When you get into your car, the airbag is ready. When you rear-end the car in front of you, the airbag automatically deploys to protect you. You are the passive recipient of this risk-reducing technology. There are a limited number of push CDS solutions, but these offer the greatest opportunity to dramatically impact the value of healthcare delivery. Order sets are the most obvious example.

It should be apparent to every physician, nurse, or other provider that, faced with the reality that the entire world’s medical knowledge soon will be doubling every 10 to 12 weeks, consistent, high-quality healthcare can be achieved only through the use of current, credible, evidence-based CDS solutions.

Going back to our colon-cancer patient: When he was admitted to the hospital or seen in the office, order sets would immediately push current, credible, evidence-based guidance to the surgeon, suggesting (based on the patient’s age, tumor location, etc.) that the surgeon consider the likelihood of inherited colon cancer syndrome and recommending the blood test that identifies the known DNA mismatch repair genetic mutations. And should the blood test confirm Lynch Syndrome, order sets would push information guiding the surgeon to perform the correct operative procedure. They also would provide guidance for the testing of the patient’s first-degree relatives for the syndrome, as well as the evidence-based lifelong screening guidelines for any who test positive. In addition, the physician could click on hyperlinks embedded within the pushed orders to immediately access the guidelines and studies on which the recommendations are based.

Order sets and other push CDS solutions solve the huge “you don’t know what you don’t know” challenge faced by providers. And, just like the safest cars, healthcare systems with both push and pull technologies will be the most effective in reducing risk and costs.
CONCLUSION
A limited amount of variability in any process can actually be valuable, even significantly valuable. Take humanity itself: While the vast majority of spontaneous genetic mutations are of no survival advantage, and many confer a disadvantage, the evolutionary variability in DNA replication has resulted in the favorable organismal changes that brought about our very existence.

In health and healthcare, variability has resulted in amazing advances and dramatic improvements in longevity and the quality of life across the globe. But such variability is safest when evaluated via well-designed, scientifically rigorous clinical trials. Outside of this evidence-based scope of investigation and evaluation, variability in how healthcare professionals make diagnostic and therapeutic decisions and in how patients choose to tend to their care carries with it the very real risk of injury or death, reduced quality of life, and excessive financial waste.

By focusing on reducing variability in how we care for ourselves, our loved ones, and our populations, we are changing the dynamic of health and healthcare around the world for the better.

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Thought Leadership:
Addressing the Greatest Threat to Healthcare
By: Peter Edelstein, MD, FACS, FASCRS
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