Quality Improvement Opportunities in Health Care—Making It Easy to Do It Right

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What has been accomplished is only an earnest of what shall be done in the future. Upon our heels a fresh perfection must tread, born of us, fated to excel us. We have but served and but seen a beginning.

—Sir William Osler, commenting on the contributions he had made to medical professionalism

At the turn of the last century, William Osler, Harvey Cushing, and other clinical leaders redefined the caring professions and their role in modern society. They restructured hospital organization, established scientific research as the foundation for clinical practice, formalized and standardized clinical education, and set and enforced high ethical and personal performance standards among those who would claim to be physicians or nurses. Their era marked a major turning point in health care delivery.

Prior to 1900, seeking a physician's help for a serious illness did little to change a patient's final result, but since that time, Americans' life expectancy has almost doubled. A child born in the United States in 1998 can expect to live almost 78 years, while 100 years ago, half of all Americans died before the age of 49.5

Early advances in life expectancy derived mostly from public health. Sanitation, clean water, safe food, increasingly effective immunization against epidemic infectious disease, and other similar preventive measures drove massive declines in mortality. The last 30 years have seen an increasing role for disease treatment as a source of life expectancy. For example, since 1970, age-adjusted mortality from heart disease and stroke, the first and third most common causes of death in the United States, have fallen by 56% and 70%, respectively.5 Continuing advances in pharmaceuticals, genomics, and other clinical sciences presage even better clinical tools to prevent, detect, arrest, and reverse disease. Current health care is demonstrably the best that the world has ever seen.

Despite those impressive accomplishments, current clinical performance still falls far short of its theoretic potential. The Institute of Medicine's (IOMs) Roundtable on Quality catalogued a startlingly broad array of failures in applying extant knowledge to routine care.6 Other reports extended that list.7 For example, Schuster et al. found that across all care delivery settings, only 52% of eligible adults older than 65 years received recommended yearly influenza vaccination, and only 28% received indicated pneumococcal vaccination. Overall, just 50% of Americans receive appropriate preventive care, 70% of patients suffering acute disease receive indicated acute care, 30% receive contraindicated therapies, 60% of those treated for chronic conditions received recommended care, and 20% received contraindicated treatments.8

More recently, the IOMs Committee on Quality of Health Care in America described the wide scope of care-related injuries patients suffer in U.S. hospitals9 and, in a second report, Crossing the Quality Chasm: A New Health System for the 21st Century, called for massive redesign of the health care delivery system to address system-wide failures of execution.10

For example, Allison et al. recently compared treatment and outcomes for acute myocardial infarction across U.S. major teaching, minor teaching, and nonteaching hospitals.11 They tracked myocardial reperfusion on admission, use of aspirin during hospitalization, and prescription of angiotensin-converting enzyme (ACE) inhibitors and beta-blockers at discharge as key treatment factors, and 30-day, 60-day, 90-day, and 2-year mortality as major outcomes. The study concluded that "admission to a teaching hospital was associated with better quality of care . . . and lower mortality," and traced most of the mortality difference to more appropriate use of beta-blockers and ACE inhibitors in teaching hospitals. That made the actual rates of appropriate administration of those drugs even more striking: Major teaching hospitals prescribed beta-blockers at discharge to "ideal candidates" only 48.8% of the time. They prescribed ACE inhibitors to "ideal candidates" only 63.7% of the time. That was still sufficient to significantly outperform nonteaching hospitals, which achieved only 36.4% and 58.0%, respectively, on the same measures.

The present gap between the good that health care professionals do achieve for patients, and the benefits we can and should achieve for patients, arises from the collision of 2 potent factors. The first factor is a set of core, subconscious beliefs about how care is best delivered and how professionals should interact. The second is the rapidly increasing complexity of evidence-based best clinical practice.
The Craft of Medicine

While many complementary principles fully define clinical professionalism,12,13 3 core ideas lie at their heart and distinguish the healing professions from others who claim professional status.

First, health professionals honor a fiduciary trust that places patients’ health care needs before any other end or goal.

Second, health professionals use and maintain a shared base of knowledge that is not comprehensively available to those who seek their help. (Beyond applying specialized clinical knowledge in order to practice, health professionals also commit to transmit their knowledge to others who are entering their profession, extending their profession through time; and to improve their shared knowledge while it is under their control. Hence the triumvirate that defines any good academic clinical program, of practice, teaching, and research.)

Finally, acting on behalf of patients as a group (that is, society), health professionals hold one another accountable for clinical performance. No other group can perform that critical function, because no other group is in a position to accurately judge how well a professional meets commitments to fiduciary patient trust and properly knows and applies the professionals’ specialized knowledge (which leads to the original definition of professional autonomy; which functions at a professional group, not an individual, level13).

As they rebuilt the health care licensing, education, and delivery system at the turn of the last century, Osler, Cushing, and their colleagues implemented the continuing principles that define the health professions in terms of professional crafts-manship. The fundamental idea was this: An individual physician, placing his patients’ health care needs before any other end or goal, drawing upon a vast body of clinical knowledge gained through formal education and ongoing practice experience, could devise a unique diagnostic and treatment regimen for each particular patient. The profession’s promise was that this approach would produce the best possible health care result for each patient, and for society as a whole.

Under such an understanding of professional role, the physician-patient relationship is hermetic and sacrosanct. Nothing can be allowed to intrude between physicians and their understanding of a particular patient’s disease, diagnostic and therapeutic needs, resources, local circumstances, preferences, and values. Most important, under the craft of medicine, care is defined, one patient at a time, as unique, individual cases with unique, individual solutions.

Clinicians transfer learning between patients through subjective recall of previous, similar cases. Within the craft of medicine, skilled clinical craftsmen define their own preferred understanding and approach. The health care delivery system is expected to adapt and accommodate, creating an environment within which each such skilled professional craftsman can use “what works for me.”

Osler et al. further sought to insulate physicians from the financial demands that accompany clinical practice and might pervert physicians’ fiduciary trust to patients. They created hospitals in which a separate group took responsibility for facility maintenance and financial performance, which eventually evolved into a second chasm that separates hospital administration and medical staff today.

Health Care Delivery and Complexity

One hallmark of the craft of medicine is variation in clinical practice, with failures in execution and outcomes that become obvious upon careful measurement across groups of patients. Wennberg’s Dartmouth Atlas of Health Care, updated roughly every 2 years, summarizes a massive literature demonstrating large variations in clinical practice based on geographic location, and documents ongoing significant variation within the federal Medicare program.14 Wennberg concludes that “geography is destiny”—the single largest determinant of the clinical treatment that will be selected for many medical conditions is geographic location, reflecting the views and beliefs of local clinicians acting within the craft of medicine. A more recent review found 2-fold differences in total Medicare health care costs across regions but no resultant differences in health outcomes.15 Chassin links the health system’s current gap in quality performance directly to variation in clinical practice, citing the mechanisms of underuse, overuse, and misuse of clinical treatments.17

In 1992, James and Horn drew a convenience sample containing 90 major peer-reviewed articles on variation in clinical practice.16 They reviewed each study’s discussion section and catalogued more than 70 different possible sources of variation hypothesized by the studies’ authors. The 3 most common causes of variation, in order of frequency of citation, related to knowledge and information flow are: (1) the complexity of clinical practice, (2) a lack of valid information identifying best care across a range of choices, and (3) physicians’ continued reliance upon subjective recall in making clinical judgments.

Lack of Valid Clinical Information

In 1979, Williamson et al. identified common treatment choices within 3 subspecialties of internal medicine, asked prominent internists to use their clinical expertise to identify best practices in each instance, then sought documented, best practice in the peer-reviewed medical literature. Using observational studies as a minimum evidence standard, Williamson’s team was able to find published evidence for best practice less than 10% of the time.17 In 1985, the U.S. Office of Technology Assessment asked experts to estimate how often the evidence base identified best practice for common treatment choices. Consensus opinion put the figure at less than 20%.18 In 1991, the National Institute of Health’s Office of Medical Applications of Research reviewed how often structured scientific literature searches had “made a substantive contribution” to assessments of best medical treatment performed at the request of the Health Care Financing Administration. They found that the peer-reviewed scientific literature contributed significantly in less than 20% of the assessments performed.19

Sackett described the formal use of clinical science to guide routine clinical practice as evidence-based medicine.20 Arguing in
support of evidence-based medicine, Ellis et al.'s companion paper asked a fundamentally different question about the evidence base than that posed in the studies listed above: In a London teaching hospital's internal medicine service, house officers could identify direct evidence of efficacy for 53% of the treatments they applied to patients. For another 29% of treatments, the team agreed that there was convincing nonexperimental evidence.21 Evidence to support selection of the best choice for a particular patient, among competing treatment alternatives, is much more limited.

**Complexity**

In counterpoint, Chassin found that the evidence base represented by randomized controlled trials is increasing exponentially. More than half of the randomized controlled trials performed since 1954, the date of the first such trial, were completed between 1990 and 1995. During 1995 alone, more than 10,000 new randomized controlled trials were reported in the peer-reviewed literature. Because the breadth and depth of medical science is also expanding (e.g., secondary to new pharmaceuticals and human genomics), it is difficult to assess the growth rate of the evidence base for existing clinical practices.

In 2000, the National Institute of Health's MEDLINE service added more than 8,000 articles to its reference database each week, representing about 40% of all peer-reviewed biomedical articles published worldwide.12 The rapid expansion of new medical knowledge highlights a more significant challenge: Eddy argues that even the current evidence base, despite its limitations, is so large and complex that clinicians operating within the traditional craft of medicine cannot properly apply it consistently during routine patient care.23 Shanefelt estimates that to remain current in their specialty, a general internist would need to read 20 articles per day, 365 days per year—“an impossible task.” He found that 3 to 4 years after board certification, both generalist and subspecialist internists begin to show significant declines in general medical knowledge and that 14 to 15 years postcertification, more than two thirds of practicing internists could not pass the American Board of Internal Medicine's qualifying examination.24

Other investigations have called the root premise of the craft of medicine into question. In 1956, Miller estimated that the human mind can evaluate a maximum of 9 factors at one time.25 Obviously, the effect of a disease process on a patient's anatomy and physiology, the many diagnostic and therapeutic alternatives that are commonly available, the likely outcomes of each choice, and the patient's personal resources and preferences will grossly exceed that limit in all but the simplest cases. How is a skilled clinical craftsman to choose?

**Reliance on Subjective Judgment**

Under the craft of medicine, skilled craftsman clinicians routinely rely upon subjective recall—their personal “clinical experience”—as the foundation for the recommendations they make to patients. But such subjective recall is significantly biased.26-27 When forced to rely upon clinical experience, clinicians consistently overestimate their successes and underestimate their failures, or overreact to striking failures. Clinicians may also read the scientific literature selectively, ignoring obvious failings in studies that support the practices they favor, and magnifying minor problems in other, better studies that contradict their desired result.28 Chassin described the resulting practice style as “enthusiasm for unproven methods”29 and linked it to fee-for-service payment and pleasure arising from technical expertise.30 Eddy describes the same phenomenon through a commonly accepted practice rubric, “if it might help, do it,”29-31 which defines clinical quality as “spare no expense.”

As long ago as 1982, Wennberg used the term “clinical uncertainty” to describe the combined effect of complexity, lack of valid scientific knowledge, and reliance on subjective judgment and linked it to the massive practice variation that typifies the craft of medicine.31 The problem of clinical uncertainty still hounds health care delivery today.32

**Solving the Complexity Problem: Profession-based Practice**

In response to clinical uncertainty and daunting evidence of a true chasm between actual care delivery performance versus best care delivery performance, the clinical professions are changing. That change is widespread and foundational, bringing together many complementary methods, including evidence-based medicine, clinical quality improvement, and evidence-based and consensus-based best practice—guidelines developed by subspecialty medical societies.34 The change is more in the manner in which clinicians understand and implement core professional values than in changes in the values themselves. At its heart, American care delivery is shifting from craft-based to “profession-based” clinical practice.

While addressing a wide array of related health systems issues, the Institute of Medicine's recent call for major reform in health care delivery, *Crossing the Quality Chasm: A New Health System for the 21st Century,*10 is a primer for profession-based practice. Profession-based practice addresses health care's inherent complexity and uncertainty through shared professional activity. The idea is this: Rather than focusing on patients one at a time, as lone professional craftsmen, a group of clinical colleagues come together to identify high-priority care delivery processes that apply to large populations of patients with similar needs. Working as a multidisciplinary professional team, they design an evidence-based best care guideline. They weave the resulting guideline into frontline care delivery flow, creating a common baseline with standardized staffing, training, supplies, physical layout, and other shared factors that define the care delivery environment. Finally, they add process management methods (i.e., quality improvement) to measure patient results and to systematically improve the guideline and their shared care environment, while leaving individual
clinicians free to vary from the common baseline based upon their professional judgment of unique patient needs.35-37 Profession-based practice aims to learn from and reduce (inappropriate) variation arising among clinicians while retaining (appropriate) variation arising from patients.

Profession-based practice is sometimes called “mass customization.” It blends the best of 2 worlds, harvesting the efficiencies and error reduction that come from standardization and simplification, while respecting the fact that no 2 patients are ever quite the same, so that clinical judgment continues to play a significant role. Some also describe it as “make it easy to do it right.” In an increasingly complex clinical care delivery environment, structure care delivery systems so that the evidence-based best practice is the default course—automatic, requiring no extra thought or work. That frees the clinical enterprise’s most valuable resource—the creative thought of highly trained professionals—to focus on those areas of special need and adjust care to each individual patient.

Experience from other fields, and early experience from within health care itself, suggest that such an approach can reduce error rates and improve patient outcomes while generating efficiencies that reduce the cost, complexity, and burden of health care delivery.38 For example, clinical leaders at Intermountain Health Care (a system of 22 hospitals plus more than 90 outpatient clinics, located in Utah, Idaho, and Nevada) identified appropriate discharge medications for patients hospitalized with heart disease as a high-priority area for clinical management and improvement. They developed an evidenced-based best practice guideline that contained indications and contraindications for 5 such medications: antiplatelet therapy (usually aspirin) for patients with ischemic heart disease; HMG-CoA reductase inhibitors (statins) for patients with ischemic heart disease; ACE or ARB inhibitors for patients with congestive heart failure or left ventricular systolic dysfunction; beta-blocker therapy for patients with a history of myocardial infarction; and warfarin for patients suffering from chronic atrial fibrillation.

They blended the guideline into the flow of clinical care by including it within a standardized packet of nursing discharge forms: As part of their routine discharge process, nurses complete a simple check sheet, detailing indications and contraindications for each medication. If a patient meets indications for any of the medications and has no contraindications, the nurse places a corresponding order on the discharge medications sheet. Physicians must countersign the order, and so still retain full control of final clinical decisions.

Figure 1 shows appropriate use rates for beta-blockers at discharge among ideal candidates (patients who had indications but no contraindications), as the guideline was implemented. Table 1 details performance across all 5 medications.

Follow-up studies showed that, once started at an initial hospital discharge, the vast majority of patients continued to receive appropriate medications in an outpatient setting. All-cause, one-year mortality rates for such patients fell significantly (from 22.7% to 17.8% for patients with congestive heart failure, and from 4.5% to 3.5% for patients with ischemic heart disease), representing a decrease of more than 450 deaths per year. All-cause rates for rehospitalization within one year also fell significantly, from 46.5 to 38.5% for congestive heart failure, and from 20.4 to 17.7% for ischemic heart disease, representing a total of almost 900 fewer hospitalizations per year.

Summary

The American health care system’s shift to profession-based practice is happening on a very wide scale, at a fundamental level, under a variety of different names and initiatives. It embodies a massive force, as the health professions respond to the burgeoning complexity that confronts all aspects of health care delivery. It also represents a profound redefinition of what it means to be a caring professional: The principles that define our professions will remain the same, but the way in which we implement those principles are changing to reflect a new reality, requiring new knowledge and new methods.

Such change carries significant implications for the practice of pharmacy. For example, the single largest area of preventable injuries faced by patients in American hospitals involves the appropriate selection and delivery of medications (adverse drug events). Pharmacists can move beyond their traditional roles, move out of the pharmacy, and contribute to multidisciplinary care teams as they identify, measure, and monitor critical medication delivery processes.

New pharmaceuticals have been identified as a major contributor to exploding health care costs. While federal regulation requires that every new medication receive careful scientific study to establish clinical efficacy, evidence directly comparing new to existing medications is usually lacking. Pharmacists help patients, physicians, and health care policy makers understand the cost-effectiveness of new products relative to existing choices.
Many pharmaceutical companies now advertise direct to consumers, recommending that patients “ask their physician” whether a new drug might be beneficial. Yet the process of establishing the level of potential benefit that a new medication offers to a particular patient is hugely complex, extending well beyond the capacity of most practicing physicians. Questions of side effects, lifestyle changes required for appropriate use, alternative treatment strategies, and costs complicate the question even further. Pharmacists can help patients understand the total impact that a new medication might have on their life. Pharmacists can help physicians as they advise patients.

At the end of his career, speaking at the dedication of the Phipps Clinic in England, Sir William Osler reflected on the similar, massive change that had defined his own professional life:

I am sorry for you, young men of this generation. You will do great things. You will have great victories, and standing on our shoulders, you will see far, but you can never have our sensations. To have lived through a revolution, to have seen a new birth of science, a new dispensation of health, reorganized medical schools, remodeled hospitals, a new outlook for humanity, is not given to every generation.

We live in interesting times. Those who succeed in the health care delivery system of the 21st century will be those who can best understand, harness, and direct the forces that are remodeling our professional landscape.

Outcomes measure(s): Among “ideal” patients (those who met indications, but had no drug-specific contraindications), proportion discharged on the indicated medication.

Sampling scheme: Baseline rates established through random sample chart review of all eligible patients, January-June 1999. All eligible patients tracked and recorded using manual data sheets, completed by a nurse at the time of discharge, from July 1999 on. Manual data collection sheets were compared to cases identified by examining ICD-9 diagnosis and procedure codes in hospital case-mix files, to insure that no eligible patients were missed.

Interventions:
1. Introduction of a standing order set, containing indication and contraindication check-off boxes for cardiac medications, placed in chart by nurses, with physician override. Tear-off copy for data collection.
2. Three additional hospitals added to original intervention site.
3. Repeat inservice of nurses, with introduction of regular performance feedback.

Aim: Improve to more than 90% the proportion of CV patients, without specific contraindications, receiving appropriate discharge medications:
- Post MI beta-blocker
- CHF / LV systolic dysfunction ACE inhibitor
- Ischemic heart disease aspirin + HMG-CoA reductase inhibitor (statin)
- Chronic atrial fibillation warfarin
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DISCLOSURES

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