Crossing the classroom–clinical practice divide in palliative care by using quality improvement methods

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Palliative care has come of age. It is an established specialty with standards of practice and mechanisms to deliver them. Nonetheless, a gap continues to exist between the standards to which palliative care aspires and those that are achieved in practice. Education dissemination has "spread the word" effectively. The proportion of clinicians who have not been exposed to classroom learning about palliative care is rapidly shrinking. However, crossing the divide from the classroom to the practice setting has been harder. The following describes how the standards to which palliative care aspires have taken root; and it goes on to propose a mechanism, using quality improvement (QI) methods, to cross the divide so that all patients can have full and fair benefit of palliative care.

1. Palliative care has come of age

Palliative care was an unrecognized term in medicine 30 years ago. Now it is a commonplace part of every medical person's vocabulary and for many outside medicine as well. "Hospice" and "palliative care" started out as parallel, like-purposed terms some three decades ago when Dame Cicely Saunders championed the former in England and Dr. Balfour Mount championed the latter in Canada. The first hospices began in the United States in Connecticut and Illinois and then spread nationwide. A turning point came when hospice services became part of the Medicare entitlement, and the term began to denote a type of health care (comprehensive, whole-person centered with the focus on symptom management and quality of life) for people with a prognosis of 6 months or less. The services could be provided in the home or a nursing home and, if necessary to control symptoms, in the hospital. In the last decade, the quality of care provided by hospice has come to be seen as desirable for all people with serious illness, and is now understood to be an important goal of care that should run hand in hand with curative therapy.

1.i. Establishing palliative care's scope and specialty standing

Important to the establishment of palliative care as a standard discipline in medicine was the identification of both core competencies and specialty level capacities that the field provides expertise in. Originally premised in the pioneering conceptual framework,[1] and then in research,[2,3] and national guidelines,[4] eventually curriculum materials (for physicians at a nonspecialty[5] and specialty level[6] and for nurses[7]) defined a de facto scope for the emerging field. Then a national consensus document emerged to establish these areas: the National Consensus Project for Quality Palliative Care. It provided guidelines describing the core and uniquely defining precepts and structures of clinical palliative care programs in eight domains: structure and processes, physical aspects, psychological and psychiatric, social aspects, spiritual aspects, cultural aspects, care of the imminently dying patient, and ethical and legal aspects of care.[8] More recently, the discipline has been accepted as a board-certifiable specialty by the American Board of Medical Specialties, and standard fellowship requirements for board eligibility have been established. Starting this year and running till about 2012, physicians with substantial experience in hospice and palliative medicine may be eligible on the basis of their experience. After 2012, completion of an Accreditation Council for Graduate Medical Education (ACGME)-accredited hospice and palliative medicine fellowship will be necessary for certification as a specialist.[9]

1.ii. Establishing standards of practice in palliative care

Development of palliative care practices in the symptom management realm has largely been based on biomedical evidence. Practices that address the psychosocial realm initially grew out of conviction and accepted social understandings, but more recently have begun to establish an empirical basis. Guidelines

for palliative care as identified in the National Comprehensive Cancer Network guidelines are, like other disciplines in medicine, mostly in the 2a category of evidence level; that is, they are based on uniform expert consensus and have some empirical basis.[10] The evidence base for palliative care is rapidly developing;[11] its progress has been aided by the establishment of research funding through the National Palliative Care Research Center[12] and by some funding mechanisms within the National Institutes of Health (NIH) that include a focus on palliative care.

1.iii. Establishing service infrastructure for palliative care

Also important, hospice and palliative care are now establishing standards of service organization and delivery. Most health care delivery organizations directly or indirectly provide for some or all of the following: home hospice, hospice care at a dedicated facility, hospice care within a long-term care facility or in a dedicated in-patient unit, and palliative care through a consult service. These are now options for most insurance plans as well.

2. The gap between established and practiced norms

Despite established standards, practices lag. The following areas in palliative care illustrate the significant gap that still exists between the established and actual norms of practice. Examples are taken from symptom management and communicative/cognitive aspects of palliative care.

2.i. Symptom management

Pain control

Pain is a frequent problem in any practice, whether the patients have advanced illness or other acute or chronic conditions.[13,14] It is a condition that patients and families fear greatly. A practical approach to pain management for cancer was developed by the World Health Organization (WHO),[15] and its use is relevant for pain of noncancer etiology as well. Step 1 analgesics involve use of acetaminophen and nonsteroidal anti-inflammatory agents. Step 2 and 3 analgesics include opioids and coanalgesics. Neuropathic pain, also responsive to step 2 and 3 analgesics, often requires use of anticonvulsants or antidepressants.[16,17] Other adjuvant agents such as alpha-2 adrenergic agonists, anxiolytics, and steroids can be helpful.[18] Specific types of pain etiology carry specific recommendations for treatment, such as use of biphosphonates for bony metastasis related pain.[19] Although very substantial evidence undergirds recommended practices and treatments are available, pain remains poorly assessed and treated.[20]

Depression, anxiety, fatigue

Depressive symptoms, anxiety, and fatigue are common problems in patients with advanced illness.[21] They often occur among patients with pain, and each may feed into the other.[22] A number of reviews and guidelines underscore the large evidence base that establishes standards of care,[23–25] yet, these conditions remain underrecognized and undertreated, with rates of depression being up to 40% in palliative care populations.[26]

Other symptom control

Other symptoms in patients needing palliative care are numerous. Common symptoms include dyspnea, nausea and vomiting, constipation, diarrhea, insomnia, skin breakdown, discomfort due to edema and effusions, and delirium. Management approaches to all these symptoms have been established,[27,28] but many clinicians are not trained in the implementation of these approaches and patients go without adequate care.

2.ii. Cognitive aspects of care

Advance care planning

Advance care planning emerged as a movement to right the balance of unbridled enthusiasm to "cure people of death." Patients, families, and clinicians alike found themselves caught in the dilemma of wanting to live, having life-sustaining interventions available, and knowing they would likely not work. For those who found the prospect of a dying period defined more by technology than by peace or human meaning, advance care planning offered hope.

As the field evolved, options for advance care planning divided into the general categories of either designating a proxy or writing down instructions, and all states now have statutes and the Constitution generally protects both mechanisms. Most experts now recommend a combined approach: it is difficult and burdensome to be a proxy, so it helps to have written instructions; on the other hand, writing instructions is difficult (few really know what they would want in a future life-sustaining intervention scenario), so it helps to have someone who can judge in real time. Research provided validated worksheets so that people could be guided to articulate their wishes in helpful ways.[29–31] Although far from a panacea, advance care planning is better than none. Emerging practices of selecting levels of care for identified scenarios and a cluster of orders for life-sustaining intervention[32] and identifying a person's threshold beyond which palliative care would be the primary goal are becoming standards of care.[33] Empirical evidence indicates that the process of advance care planning is helpful.[11] It is important to note that advance care planning is not solely for avoiding excesses of intervention but for expressing all relevant desires, including intervention. The emergence of a debate about futile intervention prompted articulation of a process approach to reaching resolution if requests for treatment are divergent among members of the patient-family-clinical team.[34,35]

Despite the progress made, advance care planning remains underused.[36]

Delivering serious information and discernment of goals of care

Additional areas in cognitive and relational aspects of palliative care are also supported by empirical evidence and expert consensus. Buckman's six-step Setting Perception Invitation Knowledge Emotion Strategy and Summary (SPIKES) protocol for breaking bad news, for example, can be readily learned and taught.[37] It provides what patients want from communication about important information.[38,39] And still, patients often do not have the information they need.

Goals of care underlie patients' desired care plan.[40] Disparities in goals for care lead to conflict.[41] Insufficient information about poor prognosis leads to suboptimal use of palliative care.[42] Patients consider that quality care includes understanding their goals for care.[43] A seven-step protocol for negotiating goals for care exists.[44] And yet, many patients are not asked about their goals of care.

2.iii. Six steps in norms improvement: stuck at step 3?

A time-honored approach to changing clinical practice is through research, with dissemination of findings through publication and continuing education. The sequence of six steps sought by education as identified by Davis and colleagues and by Dixon are attitude change, knowledge acquisition, skills acquisition, practice change, patient outcome improvement, and establishment of improved norms of practice.

Unfortunately, many studies have established that, as currently practiced, continuing education in medicine, which is mostly limited to the lecture hall and classroom and is based primarily on didactic lectures, does not result in significant changes to practice.[45,46] The transition from the classroom to the point of practice seems to fail. Some educators emphasize the need to think in terms of systems.[47] Recent models in education programs seek to improve impact and dissemination but they also have limitations.[48,49] The chasm between classroom learning and clinical practice change remains large. To close all the above gaps, this gap in norms improvement also needs to be closed.

3. Can quality improvement close the gap?

Quality improvement (also known as clinical practice improvement) offers a mechanism to help cross that chasm. In health care, QI methods have yielded dramatic improvements in some efforts,[50,51] including in palliative care,[52,53] but variable improvements in others, including some in the Centers for Medicare and Medicaid Services (CMS) Quality Improvement Organization Program.[54–56] Variations in application of QI methods such as selection of measures, systems redesign, gaining leadership and follow-through support, working with institutional culture, providing concrete direction in what to do, and an absence of control groups even in large initiatives have made assessment of the impact of QI as a standards dissemination method difficult.[57–61] Consequently, critics have found QI methods less rigorous than accepted health services research methods.[62] QI is designed to tailor implementation to the specific systems, including their unique features, of individual sites; it is not designed to generalize. Broad initiatives are therefore hard-pressed to have comparison groups with equivalent measures. Further, good QI demands sophistication and sustained resources and effort.

Nonetheless, efforts to establish common measures or at least a framework for them are gathering momentum.[63–65] And broadly applied, rigorous efforts in specific care areas such as geriatrics and palliative care are also underway, for instance through the Palliative Care Quality Improvement Collaborative (PCQuIC) in New York.[53,66,67] When used well, QI methods are impressive. Hence the question: Can the power of QI to effect change be captured without losing the ability of interventions to be generalizable and used in controlled trials?

3.i. What exactly is quality improvement?

QI uses methods derived primarily from industrial engineering. Health care has been adopting its methods more cautiously than other sectors where high-reliability organizations make extensive use of them.[68] QI uses a framework of understanding that sees health care delivery as a system of interacting elements that can be categorized into structures, processes, and outcomes,[69] the functioning of which is determined by its design, its components, and its culture.[70,71] QI uses principles of design research to identify barriers and optimize the fit of the improvement intervention with the specific system within which it must function. Then it uses cycles of testing, observation, adjusting, retesting, observing again, and so on until the implementation is sufficiently refined; then it is implemented and studied in its full scale.[72] Its primary evaluation is through comparison of pre- versus postintervention measures that are set out in "run charts."

History

The pioneers of continuous improvement theory were Walter Shewhart in the 1920s, who invented "statistical process control," and W. Edwards Deming (1900–1993), who developed the define, measure, analyze, improve and control (DMAIC) process that is used in quality management in many industries. Work in the 1970s by Joseph Juran, Armand Feigenbaum, and Kaoru Ishikawa resulted in an approach called total quality management. It two key notions for QI—quality requires attention to the design of systems and the improvement change itself—yields knowledge about how to improve the system to achieve desired ends.

Epistemological claim

Deming described four components of understanding that underpin design improvement. He named this four-component body of knowledge "a system of profound knowledge." The components are appreciation of a system, knowledge of variation and how it can point to design flaws, theory of knowledge or seeing the results of change as a source of information, and psychology.

Deming's theory of knowledge (using change as a source of information) makes an epistemological claim to understanding a system that is as strong as the claim to scientific knowledge as articulated by Karl Popper and other philosophers of science.[73] Comparing the two, it is remarkable how similar "change" is to

"intervention" in bench research and other clinical studies. In both paradigms, a well-chosen change or intervention is crucial to making an advance, and outliers provide important information. Indeed, Popper later published with Neil McIntyre a call for medicine to use error (variance, in Shewhart's and Deming's terminology) as a source of learning.[74]

The key point for QI and medicine is that Deming's approach provides for the understanding of a system that also results in change. Can QI close the type of gaps this paper has outlined?

Methods

Clinical practice improvement (CPI) methodology is developed from and is a variant of QI methodology. It is used to improve processes and outcomes in clinical care. Its purpose is to close exactly the type of gaps this paper has outlined. CPI has the following five recognized phases: project, diagnostic, intervention, impact and implementation, and sustaining improvement.

In the project phase, four actions occur: decide on the area of work or process that needs improving, form teams, write an aims statement, and consider appropriate measurements.

The diagnostic phase focuses on developing theories to explain why a particular problem or situation exists and what might solve it.

In the intervention phase, the selected changes are tested. The CPI testing method is based on the cycles of trial and learning process noted above; for CPI, the cycles are known as plan-do-study-act (PDSA) cycles. These cycles are the central component of CPI.

Achieving success in a set of PDSA cycles does not guarantee sustained improvement. The successful interventions then need to be formally implemented. Implementing a change means making it a part of normal business. It usually involves training and education of staff.

Finally, a process to sustain the improvement is necessary. This usually involves standardization of existing processes, documentation of relevant policy procedure protocols, and measurement and review to enable the change to become routine.

Comparing it with research

QI in medicine, or CPI, is essentially a purpose-designed combination of local research and improvement. The key distinction between QI and clinical research is that the former focuses on the individual system, whereas the latter seeks generalizable knowledge that can be used in any system. It is possible to share success stories, and organizations with this purpose such as the University HealthCare Consortium exist,[75] but scientific generalizability is not claimed by QI methods. In this sense, CPI has its own gap—the absence of generalizability.

3.ii. What is missing in clinical process improvement?

The need for clinicians' and all others' involvement

After QI methods arose in engineering, they migrated mostly to business through the influence of Deming. Engineering programs do exist that focus on health care.[76] However, until recently, QI remained the province of health care administrators. A critical stakeholder had been missing in many efforts to make improvements—the doctor. Fortunately, this is changing. In medical education, patient safety education is developing rapidly—the new ACGME curriculum requirements for medical schools include patient safety[77]—and these programs tend to include some training in QI methods. Residency training programs are beginning to offer rotations in QI.[78] Masters programs in patient safety are becoming available.[79] Currently about one-third of the medical schools in the United States offer combined MD-MBA programs; presumably QI methods are well covered in business administration programs.[80] Increasingly, health care organizations hire QI officers and patient safety officers; some have full institutes. Recently a fledgling

patient safety officer association has arisen, reflecting the growing trend.[81] A growing proportion of such QI leaders are physicians.

A remaining gap that still needs closure is to provide core education in CPI to all the clinicians already in practice who did not get it in their training. The culture of medicine is finally becoming supportive, and the time is now ripe for efforts such as the Patient Safety Education Project (PSEP), which offers immersion training to safety trainer teams in the methods of patient safety, including QI/CPI and their application to specific improvement projects. These teams can then return to their institutions, equipped to provide curriculum and central office supported education and project improvement activities.[82]

Allowing for generalizability: the tailored implementation of practice improvement approach

The new proposal in this paper is that the "gap" in CPI (the lack of generalizability) can be closed in the following way. A hybrid approach that combines into one package intervention: evidence-based clinical protocols with a ready-to-use tailored QI kit that offers flexibility among a limited number of possible actions and measurement options. This means that much of the labor intensity is removed for local application, and eventual comparison between QI efforts and assessment of generalizable impact is possible. Such a package intervention creates a tailored implementation of practice standards (TIPS) kit. The capacity for generalizability will come from TIPS' in-common, preprepared QI steps and valid measures. The (limited) flexibility is also an in common, essential feature, although it also limits generalizability. The idea is that it does not undermine generalizability entirely, but rather presents an inherent, modest limitation that, like all study limitations, must be taken into account. The TIPS approach also meets criteria for success that have been outlined in the literature, including procedures to get physician, leadership, and other buy-in; concrete guides on how to fix the problem including systems redesign; provision of explanatory theory, common definitions, measures, and data collection systems; use of suitable study design; and attention to economics.[60,61]

Getting the ethics right: a new mandate for data safety monitoring boards

Recently, controversy erupted over whether QI activities should be held to standards of clinical research for the purpose of human subjects' protection. In particular, should patients be asked for informed consent for projects that seek to implement practices that are already supported by empirical data? Commentators have repeatedly answered, "no."[83–85]

At the same time, a data safety monitoring board role (DSMB) and public information on hospital practices does become more important. A DSMB role to establish balanced measures as part of continuous quality improvement (CQI) that allow for the interaction between different CPI projects becomes essential. The health care system has finally been understood as such—a system. Systems cannot be affected by multiple changes without those changes interacting. For instance, imagine being a patient in the emergency department of a hospital that has been using TIPS to improve palliative care, but imagine too that you do not know whether you need palliative care or urgent surgery. The patient would certainly want to be sure that the hospital was not only monitoring data from all the palliative care TIPS projects, but also the surgical quality TIPS projects, and that it had balanced measures in place to ensure that some CPI projects were not undermining the others.

Similarly, imagine being a patient on the way to the hospital in an ambulance. The ambulance has the option of going to one hospital that uses the recently studied QI bundle for ventilator-associated pneumonia prevention,[86] or one that does not. The patient would almost certainly want to know about the choice and be able to choose the former.

A future policy in which summary information from hospitals' DSMB allows for the Joint Commission on Healthcare Organization (JCAHO) or other accreditation bodies to ensure adequate standards among all hospitals for implementation of established process improvement approaches may be necessary.

4. What medical professionals and organizations can do

If QI/CPI methodology can be applied in the above described fashion with a TIPS approach, and if QI/CPI is indeed a method that can cross the classroom–clinical practice divide in palliative care (and beyond), what should medical professionals and organizations now be doing? The forgoing indicates that the medical world needs to finish acquiring competencies at a classroom level in palliative care, acquire the competences in QI/CPI, set about implementing TIPS kits for key, specific areas of palliative care, and establish a central data monitoring system to allow for gathering generalizable knowledge and to allow for balance and stability in the system.

High impact, high dissemination training in palliative care is available for all disciplines in medicine—doctors, nurses, pharmacists, nonclinicians—through programs such as the Education in Palliative and End-of-life Care (EPEC) Project, which provides core education to physicians and other clinicians, the End-of-life/Palliative Education Resource Center (EPERC), which targets specialty-level clinicians, the End-of-life Nursing Education Consortium (ELNEC), which targets nurses, the Center to Advance Palliative Care (CAPC), which targets administrators, and others.[5–7] The exceptional capacity of these programs to disseminate core education is well established.[87,88]

Similar high-impact, high-dissemination programming is available for patient safety, and this includes training in CPI. Alternatively, and more directly, EPEC programming is increasingly including EPEC-TIPS training with the provision of kits for improving the areas taught in the EPEC core curriculum.[5] Institutions seeking to close gaps in palliative care should be sure to have a critical mass of people who are equipped to make EPEC-TIPS or similar CPI projects work. For this reason, it is advisable to train in groups that can return to the institution with deliverable projects in hand.

Whether it is a trainer team such as that just described or an existing QI team that works with a palliative care expert group, the health care facility can move to the next steps. It can select areas for improvement, connect the leadership and project implementation portions of the team, implement the improvement using PDSA methodology with balanced measures, and finally establish the improvements in a permanent CQI mechanism.

The equipment for dramatic, sustainable, balanced, panoramic improvement in palliative care is now available. The time to move forward is now.

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