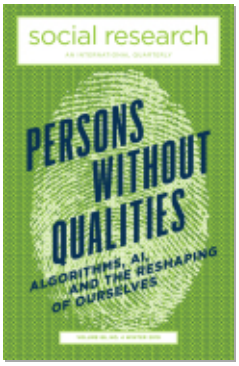
A New Stranger at the Bedside: Industrial Quality Management and the Erosion of Clinical Judgment in American Medicine



Justin B. Mutter

Social Research: An International Quarterly, Volume 86, Number 4, Winter 2019, pp. 931-954 (Article)

Published by Johns Hopkins University Press

Justin B. Mutter

A New Stranger at the Bedside: Industrial Quality Management and the Erosion of Clinical Judgment in American Medicine

INTRODUCTION: A NEW STRANGER

IN THE AUTUMN OF 2017, A PUBLIC DISPUTE BROKE OUT AMONG CERTAIN physician specialty societies in the United States. At issue was a new, more stringent definition of hypertension (high blood pressure), coupled with more exacting targets for control in both younger and older adults (Whelton et al. 2018). The new guidelines, from the American College of Cardiology and the American Heart Association, received widespread media attention. "Few risk factors are as important to health" as blood pressure, intoned an article in the *New York Times*, noting that approximately half of all adults would find themselves possible candidates for pharmacotherapy under the new recommendations (Kolata 2017). Generalist medical societies, however, which had published guidelines for older adults earlier in the year, expressed concern and declined to endorse the new standards. A representative from the American Academy of Family Physicians, for instance, claimed the scientific high ground, asserting, "With competing guide-

lines and recommendations, family physicians have an opportunity to be a guiding light in the darkness of confusion to deliver quality care that's grounded in science and is patient-centered" (Crawford 2017).

Disputes like this have long been fodder for historians, sociologists, and anthropologists studying the politics of defining disease. In many ways, this recent contest is a recapitulation of a common theme that historian Jeremy Greene identifies as "a state where the line between the normal and the pathological [is] a numerical abstraction" (2007, xi). Who gets to draw that line is, of course, a perennial question. Beyond the issue of definition, however, is a more pressing question of medical practice: How do the definitions become operational? Such public disputes are not abstract; they structure clinical judgment at the bedside, with sometimes dramatic consequences for good or for ill. Writing in a major medical journal, for instance, a physician in the Midwest describes the experience of a patient in his mid-eighties, whose fall resulting in a hip fracture spiraled into a nightmare. The author traces the patient's fall to the incorporation of hypertension and blood sugar targets in clinicians' performance expectations, a practice he characterizes as "tyranny." Such guidelines are not just suggestions; they are tools used to regulate clinician behavior and decisionmaking. As such, they powerfully condition what is and is not recommended in the provider-patient encounter. As the physician writes, "His doctor may have received a bonus for adhering to the guidelines, but [the patient] lost his home and independence" (Sarosi 2015, 562).

The political economy of medical guidelines is a relatively new phenomenon. While textbooks are as old as medicine itself, guidelines as an authoritative form of "regulatory objectivity" date only to the post–World War II era, and especially the late twentieth and early twenty-first centuries (Weisz et al. 2007; Cambrosio et al. 2006). By 1990, the number of available guidelines had approximately tripled to 70; by 2012, there were over 7,500 (Upshur 2014). Clinical guidelines are one spoke in the wheel of "quality management" in US health care that has been spinning for at least three decades. Another spoke

is comprised of quality metrics for medical providers and organizations. Their exponential growth mirrors the proliferation of clinical guidelines. These measures, numbering in the thousands, cost each individual provider at least $40,000 annually to manage (Casalino et al. 2016). In a fairly short time, quality management has become a substantial micro-industry within health care organizations, complete with ever-expanding authority over clinical practice.

This essay offers a critical account of how the quality management industry rose to prominence in health care, and examines its impact on the nature of clinical judgment. Borrowing David Rothman's apt concept of "strangers at the bedside" (1991), I argue that quality management is best understood as an integral feature of the "atomic unit of health care," the triad of providers, patients, and "information" (Nelson et al. 2011, 3–4). What comprises the third point on the triangle—"information"—has evolved over time. In Rothman's original formulation, the initial strangers were bioethicists and lawyers who organized in the 1960s and 1970s in response to medical research scandals and paternalistic health care services. They were motivated by the nearly "exclusive dedication of bioethics to the principle of patient autonomy" (Rothman 1991, 244). Yet, just as Rothman published his book, a powerful new stranger was emerging: a movement animated by serious concerns about medical error. Since then, "quality management" in medical care has exploded. Envisioned as a corrective to overuse and misuse of technological and clinical capacity, quality management claims to be the catalyst for both improved outcomes and reduced costs (Cutler 2014). Driven by this promise, medicine's latest interloper has become so essential, so commonplace, that a status of "close friend" is more accurate than "stranger." Although blood pressure guidelines may appear tyrannical to some, they are now widely viewed as a vital thread in the political and economic fabric of US health care.

How did this come about? And how have these "information" strangers transformed the experience of medical care for the two human elements (providers and patients) on health care's atomic tri-

ad? A historical account of the development clarifies what has been termed the "industrial model" of quality in US health care systems (Melo and Beck 2014). I use the term "industrial metaphor," rather than "model," to signify that quality management was more than a series of processes borrowed from manufacturing and engineering; it was also an *imaginative ethos* galvanizing social, political, and economic stakeholders. The architects of quality management reconstituted quality as the province of experts, who in turn epistemically aligned "quality" with illness biomarkers and medical procedures. These "process" measures could be easily collected and statistically aggregated. These changes have, in turn, transformed clinical judgment. Despite its many promises, the quality regime encourages a form of bedside judgment that is primarily algorithmic, jettisoning more classical conceptions of clinical care. "Information" now often overrides the contributions of providers and patients, eclipsing the autonomy of *both*.

THE ADVENT OF THE INDUSTRIAL METAPHOR

In 2016, Donald Berwick, writing in the *Milbank Quarterly* with medical historian Daniel M. Fox, celebrated the fiftieth anniversary of the publication of Avedis Donabedian's seminal essay, "Evaluating the Quality of Medical Care" (Berwick and Fox 2016; Donabedian [1966] 2005). Berwick was a natural choice for the task. Over the preceding two decades, he had become the national and international figurehead for the modern quality improvement movement in health care. Donabedian, widely considered to be the founder of quality assurance methodology in the postwar era, was a prolific analyst of health care systems and among the first to apply epidemiologic and other statistical approaches to formal assessments of medical quality. Berwick, in lauding Donabedian's many achievements, nonetheless highlighted three gaps in Donabedian's methodology. The most significant of these concerned a systems perspective:

> We cannot achieve real excellence without seeing and acting upon health care as a system. That raises, beyond anything Donabedian really anticipated, the value of better scientific understanding of health care as a system, of the importance of the continual design and redesign of processes of care, and of the crucial role of executives, clinical leaders, boards of trustees, and regulators in creating the culture and supports that allow continual improvement and innovation to thrive. (Berwick and Fox 2016, 240–41)

While Berwick embraced Donabedian's intensive focus on defining and measuring quality, he rejected the use of statistical methods to identify individual poor performers. This claim was a direct allusion to W. Edwards Deming's insistence that transformation must be managed into the whole system (Deming 1994).

In the 1980s, Berwick, as a young pediatrician and administrator, became increasingly concerned that the nascent quality movement was applying the insights of Donabedian and others in the wrong way. Early in his career, he had developed report cards of quality metrics for each physician under his administrative supervision, which some crumpled up and tossed back at him in disgust. It took an interaction with Deming for him to realize, "I'm doing this wrong" (Kenney 2008, 35). In 1989, Berwick published his own seminal essay, "Continuous Improvement as an Ideal in Health Care," delineating a new approach to quality assurance. Though his essay appeared in the prestigious *New England Journal of Medicine*, every book and article he cited was drawn from the industrial management and consulting literature. His argument was deceptively simple: "For the average doctor, quality fails when systems fail" (Berwick 1989, 56). In the aggregate, faulty systems contributed to poor medical decisionmaking far more than did individual providers. For all his rigorous attention to detail, Berwick held, Donabedian could not situate the parts of medical quality into its system whole. For this, the bedside needed a new stranger.

Berwick's essay was a catalyst in a larger sociopolitical reaction against what was commonly portrayed as traditional physician autonomy. Just as Rothman's strangers at the bedside worried about carefully guarded physician autonomy dispossessing patients of their rights, so too did Berwick's new stranger view industrial management techniques as methodologies for the triumph of systematic data over physicians' judgments. In contrast to battles over autonomy, however, quality management as "information" had the appearance of being apolitical. For Berwick, individually handing physicians their quality report cards was divisive; global data on an entire health system, on the other hand, could circumvent the question of authority. Noting the "ensuing fear" and distrust between providers and organizations that characterized the earliest years of managed care, Berwick and his colleagues claimed:

> Medicine and its clients have become aware that *neither* has the tools to accomplish the explicit assessment of quality of care. In the hands of the profession as the dominant authority, health care does not seem to need explicit quality measurement … [A] central tenet of quality improvement theory, that quality is made not by people but by processes, flies in the face of a central myth of health care—that quality is made by doctors…. We need knowledge. We need instruments for adaptation and change. We need theories. (Berwick, Godfrey, and Roessner 1990, 10, 15, 17)

Here "knowledge" is represented as a neutral, scientific salve for medicine's old wounds over the loss of physician independence. By focusing on the systems level—similar to how a foreman might review an entire assembly line's work (Berwick 1989)—new types of information will be collected that supersede providers and patients while still respecting their autonomy.

This call to "manage by facts" is at the root of the modern quality improvement movement (Berwick, Godfrey, and Roessner 1990,

49). The goal was never simply a matter of introducing checks and balances. The aim was to establish a new *foundation* for the science of good doctoring. In his first major address as president of the nascent Institute for Healthcare Improvement (IHI)—the organization that, more than any other, would evangelize the industrial metaphor—Berwick speaks of a young victim of medical error:

> It is our duty to help Kevin, yet we cannot help him without changing ourselves. There is a strong and inescapable line between the meeting of Kevin's needs, on the one hand, and the methods through which we manage ourselves, on the other. TQM [Total Quality Management], CQI [Continuous Quality Improvement], systems thinking, improvement … these are not buzzwords; they are answers to the question: How can we help him better? (Berwick 2004, 8)

In this view, managing by facts is neither an option nor even a "best practice." It is the key to genuine care.

It is hard to overstate the swiftness with which this view of quality management became standard among organizational leaders and policymakers alike in the late 1980s and 1990s. Its rapidly growing power was driven by the convergence of two major trends. The first and most intractable was the persistent inability of the health care sector—public or private—to contain costs. As medical expenditures per capita persistently rose faster than income, experts in health care financing began to use quality as a fulcrum for performance in their new models. The prominent economist Alain Enthoven, for example, made quality central to his widely adopted paradigm of managed competition. He wrote:

> Managed competition is a purchasing strategy to obtain maximum value for money…. It uses rules for competition, derived from rational microeconomic principles, to reward those health plans that do the best job of improving quality, cutting cost, and satisfying patients. (Enthoven 1993, 29)

If costs were to be contained without direct rationing, then there had to be some kind of administrative filter to accomplish the task, and quality assessment was assigned this role. Although discontent with managed competition increased in the early 2000s, quality management organizations remained at the epicenter of the fight against health care "waste" (Berwick and Hackbarth 2012). Quality and cost-containment had been joined.

The use of quality assessment to curb health care costs also aligned with growing demands to make government services more accountable. New appeals for "entrepreneurial" public management, exemplified in the international New Public Management movement in the 1990s (Borins 2002), found willing ears in the Clinton-Gore administration, with campaign advisors David Osbourne and Ted Gaebler calling for a "results-oriented" reform of the processes of agency management (Osbourne and Gaebler 1993). Together, these two trends, quality as cost-containment and as a tool for entrepreneurial accountability for public services, created fertile soil for the growth of the industrial metaphor. A final report from President Clinton's quality advisory commission, "Quality First: Better Health Care for All Americans," explicitly embraced industrial management techniques like total quality management and continuous quality improvement (President's Advisory Commission 1998). The Institute of Medicine (IOM) Committee on Quality of Health Care in America, which issued two landmark reports in the early 2000s, *To Err Is Human* and *Crossing the Quality Chasm*, formally endorsed the "human factors approach" from industrial engineering to better conceptualize medical error (IOM 2000; 2001). Berwick was a key contributor to both reports. They established the industrial metaphor as no longer a novel institutional idea but regulatory gospel.

The transposition of the industrial metaphor from fringe concept to foundational idea in US health systems had a dramatic impact. Among other effects, it led to the recasting of the definition of "quality" in ever-narrower and quantifiable biomedical terms.

DEFINING QUALITY DOWN: REGULATORY OBJECTIVITY IN MEDICAL MANAGEMENT

One of the common challenges identified in early work on quality assurance in US medical care was how to define quality. To ensure quality, one must be able to recognize accurately both its presence and its absence. Definitional concerns recur frequently in Donabedian's work, including in his foundational essay ([1966] 2005). In a later, 20-year review of quality research, he argued that one of the most important lingering tasks for quality assurance is to "look at the nature of quality itself, so that the conceptions we have of it are *socially more relevant and scientifically more valid*" (1985, 259, emphasis added). In a major report to what was then the Department of Health, Education, and Welfare, Donabedian cautioned:

> "Quality" is now a term perhaps too easily bandied about; and there is little hesitance in proposing that quality can be measured, or that it can be enforced as a matter of public and administrative policy. But this mood of almost belligerent confidence is perhaps premature, for there is much about the concept of quality that is elusive, undefined and unmeasured. (Donabedian 1978, vii)

While committed to the notion that quality must be assessed, Donabedian was consistently concerned about efforts to do this in a simplistic or reductionistic manner. Even at the end of his life and career—at the same time that Berwick was serving on the IOM's Committee on Quality of Health Care in America—Donabedian warned of the health care system's growing subservience to the technical aspects of quality (Mullan 2001).

His warning would go unheeded. The wholesale adoption of the industrial metaphor necessitated a reification of definitions of quality. Industrial management techniques, in the words of Berwick's close collaborator Paul Batalden, revolve around the following maxim: "To define quality, you have to measure it" (Kenney 2008, 47).

Notice that this is precisely the opposite epistemological approach from Donabedian's, for which the uncertain process of definition held primacy. With industrial quality management, the shop floor, even if chaotic, must be approached from a framework of rational organization if it is to be organized further. The measurement comes first—only then do we know what we are seeing. According to advocates of entrepreneurial public management, "What gets measured gets done" (Osbourne and Gaebler 1993, 146).

This reification leads to a process that I call "defining quality down," a process that has, in effect, two vectors. The first is a *powerfully hierarchical* trajectory that limits participatory engagement with the question of quality along all sides of medicine's atomic triangle. The second is an *epistemically constraining* trajectory that promotes measuring the most immanent, measurable, and actionable "results," rather than those that may be most important for good outcomes.

Let's start with the first vector. We have seen how the aim of neutrally "managing by facts" through quality assurance was meant to bypass claims to medical authority. However, as Christopher Hood notes, as industrial principles are translated into the public management of health care systems, they become markedly hierarchical in orientation. The definition of quality comes to be the near-exclusive province of groups of experts (Hood 1998). Accordingly, with the incorporation of the industrial metaphor, responsibility for quality improvement shifted from the province of local institutions and providers to that of authoritative institutions delineating national regulations.

The principal "pre-industrial" mechanism for quality assurance was peer review, and to a limited extent, regional organizations continue to play a role in quality management through the statutory mandates for quality improvement organizations (Marjoua and Bozic 2012). In the 1990s and early 2000s, however, the locus of authority shifted to national accreditation and standardization institutions, chiefly the National Committee for Quality Assurance (NCQA) and the National Quality Forum (NQF) (Burstin, Leatherman, and Goldmann

2016). The NCQA's development of the Healthcare Effectiveness Data and Information Set (HEDIS) in 1990, for example, rapidly became the prototype for private and public health plans to audit organizations for quality compliance (McIntyre, Rogers, and Heier 2001). HEDIS was a catalyst for the federal Health Care Financing Administration's goal of utilizing the "Total Quality Movement" to develop a set of fully "*external* quality-improvement programs" (Gagel 1995, 17, emphasis added).

By delineating extrinsic sets of quality metrics for the purposes of accreditation and performance assessment, medicine's new stranger ushered in an era of "coercive accountability" complete with new rules and hierarchies (Shore and Wright 2000). Though medical providers continued to play active roles in the *assurance* of quality at the bedside, they were no longer its main authors. Information about quality could only come from metrics. While Berwick and his colleagues never intended the quality management movement to become myopically focused on measurement (Berwick, James, and Coye 2003), the nine-member federal commission charged with developing a national quality measurement and reporting system envisioned that the "choice of measures and acquisition of data" would be "coordinated at the top end" of conceptual priorities for improvement (McGlynn 2003).

The intensive, hierarchical focus on metrics provided the *how* of industrial quality management, but not the *what*. Which metrics best reflected "quality" in medicine? Though many experts, including Berwick, were active in the development of measure sets during the early quality movement, the central figure arguably was Janet M. Corrigan, a nonclinician who held advanced degrees in health services, industrial engineering, and business. As executive director of President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, she would go on to play a major role in the IOM's two seminal reports. Corrigan was a natural choice to lead the NCQA in the 1990s, and she supervised the creation and development of HEDIS.

As the prototype for future iterations of measure sets, HEDIS relied on what sociologist Alberto Cambrosio and colleagues call "regulatory objectivity" (Cambrosio et al. 2006). This form of objectivity prioritizes standardization above all else. As Corrigan explained in 1994, it was critical that HEDIS be developed by a "neutral" entity, which, while recognizing that quality measurement was "[im] perfect," nonetheless could employ a method to "allow health plans to begin work on generating this kind of information and on establishing the infrastructure to create a standardized system of performance reporting" (Sinioris 1994, 83). In addition to its hierarchical orientation, such standardization required an epistemic simplification of what constitutes "quality" in health care. Donabedian's concern about the risks inherent in defining quality is absent from such plans. The new industrial techniques required discrete, quantifiable data points that could be statistically analyzed (Wadsworth, Stephens, and Godfrey 1986).

The regulatory preference for concrete, accessible quality information was reinforced by contemporary health services research, which highlighted the difficulty of accurately assessing quality using end-outcomes of medical care, such as mortality or major morbidity. Even sympathetic critics of the nascent quality management movement, for instance, worried that standardization of outcomes measurement without appropriate risk adjustment would be meaningless (Epstein 1995). Consider two individuals who each suffer a heart attack, are rushed to (two different) hospitals, and subsequently die from their condition. One of them received poor quality care that was nonetheless prompt and comprehensive, as she lived just five minutes from the hospital. The other individual received delayed care due to a two-hour trip to the hospital and was therefore in considerably worse condition upon arrival; despite receiving high quality evidence-based care, he could not be saved. In this scenario, to compare the care quality of the two hospitals using cardiovascular mortality rates, without accounting for geographic risk, would be misleading.

Berwick, Corrigan, and other key architects of the quality management movement were well aware of the inadequate statistical methods for risk-adjusting outcome measurements. Risk adjustment was, in fact, a major weakness of the managed care revolution in the 1990s. Therefore, HEDIS and other measure sets that followed predominantly—and purposefully—focused on process-oriented metrics (Corrigan and Nielsen 1993). Instead of measuring cardiovascular mortality, for example, metrics in the late 1990s and early 2000s captured disease-specific, strictly biomedical, and transactional features of health care delivery, such as whether or not a specific medication was administered to an individual experiencing a heart attack or whether an individual's blood pressure was adequately controlled to a standardized target. In addition to minimizing the need for risk adjustment, process-oriented measures were favored by experts *precisely because they allowed for industrial-style process control*. Outcomes-as-datapoints, experts noted, do not in and of themselves tell providers or administrators how to improve care. Processes, on the other hand, can both be readily measured and lead to discrete transformations in the delivery of care. As one quality management expert argued in 1997:

> Process-based measures of health care quality can be constructed as follows. First, experts combine evidence from many research studies to create evidence-based guidelines on clinical practices. These guidelines summarize recommendations for the care of patients with a given illness. Patients who are eligible to receive medical care on the basis of a specific guideline are then identified. A criterion for quality is also created to determine which patients actually received medical care as recommended by the guideline. The number of patients who received guideline-related care is divided by the number of patients who are eligible to receive that care. Rates that describe the extent to which patients receive processes of health care as recommended by evidence-based guidelines are then computed. (Palmer 1997, 733–34)

This description perfectly captures the work of industrial quality management as a stranger at the bedside. The methodical progression from "evidence" to "patients" to measurement and on to aggregate statistics is presented in assembly-line fashion. Notice the explicit symbiosis between the powerfully hierarchical and purposefully epistemically constraining natures of this activity. The work is pictured as expertly apolitical; the disease-based metrics embody their own discrete "rationality and morality" that are fully external to provider and patient judgment (Shore and Wright 2000, 57).

THE TRANSFORMATION OF CLINICAL JUDGMENT

In a recent essay for the *New England Journal of Medicine*, three authors from Google and Harvard Medical School ask expectantly, "What if every medical decision, whether made by an intensivist or a community health worker, was instantly reviewed by a team of experts who provided guidance if the decision seemed amiss?" Such expertise, they observe, available at the touch of a button, is the promise of "machine learning" in health care (Rajkomar, Dean, and Kohane 2019, 1347). Artificial intelligence is not just the next possible phase in industrial quality management; it may be inevitable, as one of the authors noted in an earlier paper, "as more control is ceded to algorithms" (Beam and Kohane 2018, 1318).

For medicine, Rajkomar, Dean, and Kohane's essay is a signpost not only of things to come, but also of the present state of clinical judgment at the bedside. The evangelization of the industrial metaphor through quality management's hierarchies and epistemic constraints has transformed clinicians' understanding of their healing function. Although there have been many contributors to statistical and technical reasoning's predominance in today's clinical activity—including the evidence-based medicine (EBM) movement—the primary mechanism by which such reasoning has been *enforced* is quality management. As quality management became coterminous with good doctoring, measurement and reporting systems began to play a critical role in the regulatory integration of EBM with daily clinical

practices. Patients and providers are important to the decisionmaking system only as sources of data. They are not independent sources of judgment. Information is all.

Where does this leave clinician judgment? The denotation of "clinical reasoning" in much of contemporary medical education literature is already reflective of a transition away from providers' judgment toward statistical and algorithmic computation. Granted, "clinical judgment" has long been fraught with competing definitions. Standard accounts, however, typically highlighted Aristotle's discussion of practical reasoning (*phronesis*), whereby clinicians "fit their knowledge and experience to the circumstances of each patient" (Montgomery 2006, 33; see also Braude 2012; Cassell 1997). That view is weakening.

The embrace of "dual process theory" from cognitive psychology provides the clearest evidence of this shift. Clinicians, according to the theory, operate using two separate but complementary faculties of reasoning: intuition and analysis. Intuition resides in the long-term memory and can be accessed rapidly as a series of "illness scripts" drawn from prior patient encounters and experiences of medical decisionmaking; these are "general representation[s] in the physician's mind of an illness" (ten Cate 2018, 5). When evaluating a patient's concern, the clinician's intuitive pattern recognition is active immediately, and then gradually engages in a dialogue with his or her analytic processing, such as interpreting lab test results and images, and utilizing scientific knowledge of pathophysiology. Especially significant for the question of judgment is how "intuition" in this dialogue is commonly construed.

Many dual process advocates view their theory as a corrective to the highly analytical reductionism of modern medical education, which elides the role of the individual clinician (Pelaccia et al. 2011). Illness scripts, however, are often depicted as a kind of repository of experience, a book that *already* has been written and that, one might say, the clinician knows by heart. As such, the work of intuition is to situate a patient's concerns into *existing* patterns, rather than to al-

low those concerns to inform emergent patterns in real time. Nearly all dual process advocates note the unreliability of intuition's work in this regard, and analytical processes are conceived as a "monitoring system" for intuition, saving it from errors in pattern recognition (Croskerry 2009). In dual process theory, the individual patient and provider are dwarfed by information, whether intuitive or analytic in nature.

This highly mechanical view of clinical judgment both minimizes and mischaracterizes the role of medical intuition. Not surprisingly, when machine learning advocates envision algorithms that "incorporate lessons from a collective experience" using "massive amounts of data" inaccessible to the human mind alone (Rajkomar, Dean, and Kohane 2019, 1347–48), this sounds a lot like a global library for individual clinicians' illness scripts according to the dual process model. As some hope that machine learning will one day serve as clinicians' collective intuition, we risk catastrophic erosion of a more relational, contextual clinical judgment. To illustrate what is at stake, I consider a hypothetical clinician-patient encounter, which, though common in its features, has real-world complexity.

A 78-year-old man, whom I will call Jerry, has resided at home alone for several years since the death of his wife. He is estranged from other family members and has limited social support. He is partially physically impaired from a prior stroke, and takes medications for diabetes, high blood pressure, gout, arthritis, and a series of other medical conditions. Jerry recently suffered a heart attack and was in the hospital for about a week. He comes to see his primary care physician after discharge from the hospital. This clinician, Susan, has known and cared for him for 10 years.

Among the customary quality metrics that are used to assess Susan's performance in the delivery of care are 1) percentage of patients receiving beta-blockers and ace-inhibitors after a heart attack and 2) percentage of patients achieving a certain biomarker level for diabetes control. Both of these are process-oriented measures strongly supported by the standards of evidence-based medicine. However,

Susan knows Jerry well and, in particular, she knows that the most important thing to him is how he feels each day. She also knows that he has a kidney condition that makes one of these medications potentially problematic. He wants to live as long as he can, but he does not wish to sacrifice his current quality of life at the altar of longevity alone. She also knows that he has limited support at home and is worried about the impact of his mounting medical conditions and medications on his safety. He has been feeling poorly since returning home from the hospital, and Susan is concerned, though by no means certain, that some of his medications may be contributing adversely to his symptoms. She and Jerry discuss these issues at length.

Susan's decisionmaking in this scenario may directly contradict expert quality management. In order to truly *care* for Jerry in this moment, she needs to be more epistemically open, and more engaged dialogically with Jerry than with regulatory hierarchies. She is also acutely aware of how much *context* matters for Jerry's conditions. For all its professed attention to "systems thinking," as it defines quality down, industrial quality management tends to ignore the larger context of medicine—the social, economic, and political forces that shape the experiences of health and illness, both at home and in medical settings. She and Jerry both, however, are attentive to the impact that his lack of psychosocial support may have on his quality of life and his longevity in the coming months. Finally, quality management's short timeline—the goal of achieving disease-based results measured by discrete data points in the near future—is at odds with Susan's and Jerry's approach to decisions that play out, and are perhaps continually revised, over a comparatively ill-defined time course. She may choose, for example, to continue one of his suspect medications for a few more weeks to see if his symptoms were from his hospitalization and heart attack or a side effect of the medications themselves. Though these choices are difficult, she is comfortable with this uncertainty because of her longstanding relationship with Jerry, marked by trust.

Now consider Susan's clinical reasoning compared with the dual process perspective. She no doubt draws "intuitively" upon her prior experiences taking care of patients like Jerry and may even engage in pattern recognition. And she certainly engages her "analytic" knowledge of the pathophysiology of heart disease and pharmacologic understanding of medications. But while both are necessary to her reasoning, they are by no means sufficient. Although she hopes to make the "right" decisions, it is more accurate to say that she aims to make "good" ones. Her decisions may not be right in the sense of conformity to expert standards or norms for diagnosis and treatment, yet they may very well be good in that they set Jerry on a trajectory commensurate with his life goals. Because dual process theory is preoccupied with whether intuition is right in this conforming sense, rather than good, it misses common and critical features of clinical judgment. The "patient's presentation" is not an original input into a methodical flow diagram for a single disease or collection of symptoms; it is the reason for the diagram itself. The patient-provider relationship is as much, if not more, of a "monitoring system" for the "information" as the reverse. In other words, it is not that her "intuition" overrides her analytic processing, but rather that *her assessment of the whole overrides both*. As physician-philosopher Hillel Braude has written, this is why any modern account of clinical judgment that neglects phenomenological and practical reasoning—no matter what its intent—will end up subservient to algorithmic judgment (2012).

CONCLUSION: REBALANCING THE ATOMIC UNIT OF HEALTH CARE

I have written elsewhere of the quality management movement's missteps and failure to reach its own goals (Mutter et al. 2018), and I am certainly not alone in this concern (Brook 2010; Berenson and Rice 2015). Berwick himself is critical of quality management's lackluster performance, though he does not specifically implicate industrial methodology as a culprit (Berwick 2016). But aside from weaknesses on its own terms, as a new stranger at the bedside, quality manage-

ment has markedly transformed the terms of clinical practice itself. Inspired by the industrial metaphor, its penchant for regulatory objectivity altered the political economy in which both institutions and individual practitioners operate, favoring statistical and probabilistic reasoning over classical conceptions of clinician judgment and intuition. Its influence remains not only profound and pervasive, but also—as calls to increase the role of artificial intelligence in medicine intensify—proliferative.

While there are some aspects of medicine for which industrial quality management is well suited—specifically its more procedural activities such as central line placement, cardiac resuscitation, and other highly technical processes—like most aspects of biomedicine, its usefulness tends to erode in the face of biological, cognitive, and contextual complexity. Although industrial management techniques do see "systems" as complex entities, the conceptualization of systems is dependent almost exclusively on simplistic, process-oriented measurements. The wheel matters only insofar as we can discretely identify its many cogs.

I have noted that this stranger is now a friend, but in reality, it has become a powerful master. It is collapsing the atomic unit of health care, with "information" increasingly eclipsing the phenomenological and practical contributions of patients and providers. Contrary to the industrial metaphor, medicine *can* thrive through practices that embrace uncertainty (Montgomery 2006, 189–207). In view of powerful forms of regulatory objectivity and professional education that teach a narrow view of clinician judgment, this will require a revitalization of the balance among human relationships in health care's triad: the provider, the patient, and clinical "information." It will also require encapsulating that triad in a larger circle of context, recognizing that all features of the unit are conditioned by their social, political, and economic environments.

REFERENCES

Beam, Andrew L., and Isaac S. Kohane. 2018. "Big Data and Machine Learning in Health Care." *JAMA* 319 (13): 1317–18.

Berenson, Robert A., and Thomas Rice. 2015. "Beyond Measurement and Reward: Methods of Motivating Quality Improvement and Accountability." *Health Services Research* 50 (S2): 2155–86.

Berwick, Donald M. 1989. "Continuous Improvement as an Ideal in Health Care." *New England Journal of Medicine* 320 (1): 53–56.

———. 2004. *Escape Fire: Designs for the Future of Health Care*. San Francisco: John Wiley & Sons, Inc.

———. 2016. "Era 3 for Medicine and Health Care." *JAMA* 315 (13): 1329–30.

Berwick, Donald M., and Daniel M. Fox. 2016. "Evaluating the Quality of Medical Care: Donabedian's Classic Article 50 Years Later." *Milbank Quarterly* 94 (2): 237–41.

Berwick, Donald M., A. Blanton Godfrey, and Jane Roessner. 1990. *Curing Health Care: New Strategies for Quality Improvement*. San Francisco: John Wiley & Sons, Inc.

Berwick, Donald M., and Andrew D. Hackbarth. 2012. "Eliminating Waste in US Health Care." *JAMA* 307 (14): 1513–16.

Berwick, Donald M., Brent James, and Molly J. Coye. 2003. "Connections between Quality Measurement and Improvement." *Medical Care* 41 (1 Sup.): I30–38.

Borins, Sanford. 2002. "New Public Management, North American Style." In *New Public Management: Current Trends and Future Prospects*, edited by Stephen P. Osbourne and Ewan Ferlie, 181–94. New York: Routledge.

Braude, Hillel D. 2012. *Intuition in Medicine: A Philosophical Defense of Clinical Reasoning*. Chicago: U. Chicago Press.

Brook, Robert H. 2010. "The End of the Quality Improvement Movement: Long Live Improving Value." *JAMA* 304 (16): 1831–32.

Burstin, Helen, Sheila Leatherman, and Donald Goldmann. 2016. "The Evolution of Healthcare Quality Measurement in the United States." *Journal of Internal Medicine* 279 (2): 154–59.

Cambrosio, Alberto, Peter Keating, Thomas Schlich, and George Weisz. 2006. "Regulatory Objectivity and the Generation and Management of Evidence in Medicine." *Social Science & Medicine* 63 (1): 189–99.

Casalino, Lawrence P., David Gans, Rachel Weber, Meagan Cea, Amber Tuchovsky, Tara F. Bishop, Yesenia Miranda, Brittany A. Frankel, Kristina B. Ziehler, Meghan M. Wong, and Todd B. Evenson. 2016. "US Physician Practices Spend More than $15.4 Billion Annually to Report Quality Measures." *Health Affairs* 35 (3): 401–6.

Cassell, Eric J. 1997. *Doctoring: The Nature of Primary Care Medicine*. New York: Oxford U. Press.

Corrigan, Janet M., and Don M. Nielsen. 1993. "Toward the Development of Uniform Reporting Standards for Managed Care Organizations: The Health Plan Employer Data and Information Set (Version 2.0)." *Joint Commission Journal on Quality Improvement* 19 (12): 566–75.

Crawford, Chris. 2017. "AAFP Decides to Not Endorse AHA/ACC Hypertension Guideline." *AAFP News*, Dec. 12. https://www.aafp.org/news/health-of-the-public/20171212notendorseaha-accgdlne.html.

Croskerry, Pat. 2009. "A Universal Model of Diagnostic Reasoning." *Academic Medicine* 84 (8): 1022–28.

Cutler, David. 2014. *The Quality Cure: How Focusing on Health Care Quality Can Save Your Life and Lower Spending Too*. Berkeley: U. California Press.

Deming, W. Edwards. 1994. *The New Economics for Industry, Government, Education*. Cambridge, MA: MIT, Center for Advanced Educational Services.

Donabedian, Avedis. 1978. "Needed Research in the Assessment and Monitoring of the Quality of Medical Care." Hyattsville, MD: US Dept. of Health, Education, and Welfare; Public Health Service; National Center for Health Services Research.

———. 1985. "Twenty Years of Research on the Quality of Medical Care: 1964–1984." *Evaluation & the Health Professions* 8 (3): 243–65.

———. [1966] 2005. "Evaluating the Quality of Medical Care." *Milbank Quarterly* 83 (4): 691–729.

Enthoven, Alain C. 1993. "The History and Principles of Managed Competition." *Health Affairs* 12 (Supplement): 24–48.

Epstein, Arnold. 1995. "Performance Reports on Quality: Prototypes, Problems, and Prospects." *New England Journal of Medicine* 333 (1): 57–61.

Gagel, Barbara J. 1995. "Health Care Quality Improvement Program: A New Approach." *Health Care Financing Review* 16 (4): 15–23.

Greene, Jeremy A. 2007. *Prescribing by Numbers: Drugs and the Definition of Disease*. Baltimore, MD: Johns Hopkins U. Press.

Hood, Christopher. 1998. *The Art of the State: Culture, Rhetoric, and Public Management*. New York: Oxford U. Press.

Institute of Medicine, Committee on Quality of Healthcare in America. 2000. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press.

———. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academies Press.

Kenney, Charles. 2008. *The Best Practice: How the New Quality Movement Is Transforming Medicine*. New York: Public Affairs.

Kolata, Gina. 2017. "Under New Guidelines, Millions More Americans Will Need to Lower Blood Pressure." *New York Times*, Nov. 13. https://www.nytimes.com/2017/11/13/health/blood-pressure-treatment-guidelines.html.

Marjoua, Youssra, and Kevin J. Bozic. 2012. "Brief History of Quality Movement in US Healthcare," *Current Reviews in Musculoskeletal Medicine* 5 (4): 265–73.

McGlynn, Elizabeth A. 2003. "Introduction and Overview of the Conceptual Framework for a National Quality Measurement and Reporting System." *Medical Care* 41 (1 Supplement): I1–7.

McIntyre, Dennis, Lisa Rogers, and Ellen J. Heier. 2001. "Overview, History, and Objectives of Performance Measurement." *Health Care Financing Review* 22 (3): 7–21.

Melo, Sara, and Matthias Beck. 2014. *Quality Management and Managerialism in Healthcare: A Critical Historical Survey*. New York: Palgrave Macmillan.

Montgomery, Kathryn. 2006. *How Doctors Think: Clinical Judgment and the Practice of Medicine*. New York: Oxford U. Press.

Mullan, Fitzhugh. 2001. "A Founder of Quality Assessment Encounters a Troubled System Firsthand." *Health Affairs* 20 (1): 137–41.

Mutter, Justin B., Winston Liaw, Miranda A. Moore, Rebecca S. Etz, Amanda Howe, and Andrew Bazemore. 2018. "Core Principles to Improve Primary Care Quality Management." *Journal of the American Board of Family Medicine* 31 (6): 931–40.

Nelson, Eugene C., Paul B. Batalden, Marjorie M. Godfrey, and Joel S. Lazar. 2011. "Introducing Clinical Microsystems." In *Value by Design: Developing Clinical Microsystems to Achieve Organizational Excellence*, edited by Nelson, Batalden, Godfrey, and Lazar, 1–28. San Francisco: Jossey-Bass.

Osbourne, David, and Ted Gaebler. 1993. *Reinventing Government: How the Entrepreneurial Spirit Is Transforming the Public Sector*. New York: Penguin Books.

Palmer, R. Heather. 1997. "Process-Based Measures of Quality: The Need for Detailed Clinical Data in Large Health Care Databases." *Annals of Internal Medicine* 127 (8 Part 2): 733–38.

Pelaccia, Thierry, Jacques Tardif, Emmanuel Triby, and Bernard Charlin. 2011. "An Analysis of Clinical Reasoning through a Recent and Comprehensive Approach: The Dual-Process Theory." *Medical Education Online* 16 (1).

President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. 1998. "Quality First: Better Health Care for All Americans." Washington, DC: The Commission. http://govinfo.library.unt.edu/hcquality/.

Rajkomar, Alvin, Jeffrey Dean, and Isaac Kohane. 2019. "Machine Learning in Medicine." *New England Journal of Medicine* 380 (14): 1347–58.

Rothman, David J. 1991. *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*. New Brunswick, NJ: AldineTransaction.

Sarosi, George A. 2015. "The Tyranny of Guidelines." *Annals of Internal Medicine* 163 (7): 562–63.

Shore, Chris, and Susan Wright. 2000. "Coercive Accountability: The Rise of Audit Culture in Higher Education." In *Audit Cultures: Anthropological Studies in Accountability, Ethics and the Academy*, edited by Marilyn Strathern, 57–89. New York: Routledge.

Sinioris, Marie E. 1994. "Janet M. Corrigan, PhD. Interview by Marie E. Sinioris." *Quality Management in Health Care* 2 (4): 82–89.

ten Cate, Olle. 2018. "Introduction." In *Principles and Practice of Case-Based Clinical Reasoning Education: A Method for Preclinical Students*, edited by Olle ten Cate, Eugene J. F. M. Custers, and Stephen J. Durning, 3–19. New York: Springer.

Upshur, Ross. 2014. "Do Clinical Guidelines Still Make Sense? No." *Annals of Family Medicine* 12 (3): 202–3.

Wadsworth, Harrison M., Kenneth S. Stephens, and A. Blanton Godfrey. 1986. *Modern Methods for Quality Control and Improvement*. San Francisco: John Wiley & Sons.

Weisz, George, Alberto Cambrosio, Peter Keating, Loes Knaapen, Thomas Schlich, and Virginie J. Tournay. 2007. "The Emergence of Clinical Practice Guidelines," *Milbank Quarterly* 85 (4): 691–727.

Whelton, Paul K., Robert M. Carey, Wilber S. Aronow, Donald E. Casey, Jr., Karen J. Collins, Cheryl Dennison Himmelfarb, Sondra M. DePalma, Samuel Gidding, Kenneth A. Jamerson, Daniel W. Jones, Eric J. MacLaughlin, et al. 2018. "2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines." *Hypertension* 71 (6): e13–e115.