

**HEALTH CARE**

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**QUALITY IMPROVEMENT:**

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**ETHICAL AND**

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**REGULATORY ISSUES**

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## Physician Ethics and Participation in Quality Improvement: Renewing a Professional Obligation<sup>1</sup>

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### Introduction

A central promise of modern medicine has been innovation to improve the quality of care and health outcomes.<sup>2</sup> Yet studies from the past several decades have shown that physicians use their innovative tools suboptimally. Quality of medical care in the United States lags behind the nation's scientific knowledge base, with evidence showing persistent overuse, underuse, and misuse of health-care services.<sup>3</sup>

While the literature on health-care quality improvement (QI) generally stresses the systemic nature of quality problems,<sup>4</sup> this chapter focuses on physicians. Given their central role in the health-care system, physicians must play a significant role in QI; yet many physicians seem strangely reluctant to take on this mission at the level of delivery.<sup>5</sup> In fact, physicians are often seen as obstacles to QI projects.<sup>6</sup> Michael Millenson notes both a silence of deed—"the repeated failure of physicians . . . to respond with corrective action to studies documenting severe and preventable quality problems"—and a silence of word—"the absence of a thorough discussion of the tragic consequences of that lack of response."<sup>7</sup>

But physician resistance to QI is inconsistent with professional ethical obligations to provide the best care possible, to learn from instances when care falls short of the ideal, and to seek opportunities to improve care.<sup>8</sup> In this chapter, we review the history of physicians' ethical obligations with regard to QI, making special note of recurrent issues that have prevented physicians from becoming fully engaged in QI.

We use "QI" to designate any activity that has an aim of improving quality, not merely the modern concept of QI, i.e., the use of a specific set of management tools to do so. However, as the history unfolds, this broader specification of what comprises QI will be an important theme.

### Quality Improvement: A Long-Standing Professional Duty

While the modern QI movement in health care—the industrial model, using data-driven, planned change projects to assess and improve quality<sup>9</sup>—has developed only in the past few

decades, physicians since antiquity have propounded methods and attitudes that acknowledged the possibility of error in medicine and have embraced opportunities to learn from the trials of everyday practice. At first, it may seem odd to posit a concern with quality in ancient times, when many medical practices, such as bleeding and purging, were frankly harmful, but our concern is not so much with the actual efficacy of medicine in the past as with doctors' perceived obligation to improve the care they provided, even if it was under misguided paradigms of medicine and disease.

In addition, efforts to improve quality of care have always existed in context with professional beliefs relating to, among other things, the nature of the patient-doctor relationship, physicians' obligations toward the community versus individual patients, the status of medical practice as both an "art" and a "science," and the challenges of collaboration with other health workers within systems of care. These beliefs have interfaced with the obligation to improve quality in complex ways. In the selective history presented here, we highlight a few dynamic periods when the practice environment shifted or knowledge and available technologies suddenly changed. At these times, physicians were forced to envision anew what quality means, how best to promote it, and whether to commit to QI despite significant barriers. These historic episodes portend contemporary professional challenges to QI; and understanding this history can help ground a renewed commitment.

### The Hippocratic Tradition: Linking Medical Science to Personal Ethics

Early conceptions of medical quality revolved, naturally, around competence, but also around humility in practice, recognition of the risks of medical treatments, and devotion to the welfare of patients. These conceptions were spelled out in the collection of approximately 60 treatises known as the Hippocratic corpus. Produced by the medical school associated with Hippocrates (c. 460 to c. 370 B.C.E.), these texts figure centrally in the origin of Western medicine's scientific and ethical orientation. Prior to the Hippocratic school, the same person often served as both sorcerer and healer; according to Margaret Mead, the Hippocratics first made the distinction between the two.<sup>10</sup> Also, unlike other practitioners of the healing arts who relied on ritual and magic, Hippocratic practitioners presumed a natural, causal origin of disease based on empirical observation, and they espoused crude theories of etiology and treatment that anticipated modern medical science.<sup>11</sup>

The Hippocratic texts intermingle clinical and ethical observations, underscoring their interdependence by stressing the danger inherent in the practice of medicine and the resultant need for judiciousness and humility on the part of the physician. For instance, the Hippocratic texts outlined diagnostic methods but also detailed treatment failures for the benefit of future physicians. Surgical texts focus on *mathema* (lessons learned), and "the frank discussion of malpractices . . . as a method of instruction . . . [was] incorporated into the teaching of the correct treatment of fractures and luxations [dislocations]. . . . [Because] describing a mistake with all its consequences makes it avoidable . . . safeguard[ing] against repeating it."<sup>12</sup> The most

famous surgical text in the Hippocratic corpus, *On Fractures*, opens with a promise to discuss medical mistakes: "I must therefore mention which of the physician's mistakes I want to teach you not to do (*apodidaxai*)."<sup>13</sup>

Throughout the corpus, the Hippocratics modestly and cautiously appraised physicians' powers. One of its most famous aphorisms is, "Life is short, the art is long, opportunity fleeting, experiment perilous, judgment difficult."<sup>14</sup> Moreover, the ancient Greek word for experiment, *experimentum*, denoted *any* attempted therapy, whether experimental or routine, underscoring two things: first, the degree to which medical treatment was unpredictable and risky, and second, the learning-oriented nature of the humility being advised.

In addition to humility, the other key Hippocratic QI theme is the recognition that since patients are vulnerable and treatment is often dangerous, medical practice entails both science and art and thus assumes explicit moral dimensions. By committing physicians to "follow that system of regimen which, according to [their] ability and judgment, [they] consider for the benefit of patients, and abstain[ing] from whatever is deleterious and mischievous," the Hippocratic Oath integrates ethical promises into the concept of medical competence.<sup>15</sup>

The personal nature of the oath demonstrates, however, that the Hippocratics were primarily interested in personal virtue rather than group or professional responsibilities.<sup>16</sup> For them, ensuring quality was an individual endeavor, best accomplished through personal competence, a learning-oriented humility, and devotion to their patients' well-being. The notion of QI as a *professional* responsibility had to wait upon the development of the concept of the physician as a professional.<sup>17</sup>

### **Moving Toward Professionalism: Science Becomes a Binding Ideal for all Physicians**

We now skip forward more than 1,000 years, to the Middle Ages. During this period, relations between medicine and the church were very important, and illnesses of body and of spirit were seen as connected, giving physicians and priests similar responsibilities to individuals and communities.<sup>18</sup> But with reverence for the ancients and God at the fore, a different version of humility—one might call it servant-oriented humility—became heavily emphasized, with the result that little progress was made in improving the effectiveness of medical practice. It was not until the Renaissance and burgeoning Enlightenment of the 18th century that significant advances were made in understanding illness and disease and in improving treatments. As we shall see, however, this progress ultimately came at the expense of medical humility, including, sadly, the learning-oriented humility of the Hippocratics.

Despite the personal promises in the Hippocratic Oath, by the 18th century, an enlightened John Gregory (1724–1773) perceived personal moral laxity on the part of the medical practitioners in England. At the time, the private market for medical services was unregulated and unscrupulous. To be a member of the medical "profession" meant only that a physician "had undertaken a university education in medicine [for which there was no standard curriculum, as there is now] and so should be the preferred practitioners for the well-to-do sick."<sup>19</sup> No single concept of health and disease dominated, and doctors offered competing theories

in hopes of attracting patients. To remedy this situation, Gregory proposed improving on the Hippocratic Oath by adopting a professionwide ethic of virtuous service to a greater scientific mission.

Influenced heavily by Scottish Enlightenment thinkers and the methods of Baconian science, Gregory gave the first body of systematic lectures in English on ethics for physicians. He called on physicians to humbly advance the curative mission of medicine. Most notably, he expanded on the learning-oriented humility of the Hippocratics (as distinct from the servant-oriented humility of the Middle Ages), calling this sort of humility "diffidence." He wrote that the "sense of the present imperfect state of our art, ought to incite us to improve it, not only from a love of the art itself, but from a principle of humanity."<sup>20</sup> Note the use of the plural, "our art." For Gregory, diffidence was essentially a personal virtue, part of what he called an "ethics of character." But shared service to humanity meant that acknowledging mistakes and advancing science were moral duties for all physicians:

I may reckon [that] among the moral duties incumbent on a physician, [is] . . . candor, which makes him open to conviction, and ready to acknowledge and rectify his mistakes. An obstinate adherence to an unsuccessful method of treating a disease, must be owing to a high degree of self-conceit, and a belief of the infallibility of a system. . . . It sometimes happens too, that this obstinacy proceeds from a defect in the heart. Such physicians see that they are wrong; but are too proud to acknowledge their error, especially if it be pointed out to them by one of the profession. To this species of pride, a pride compatible with true dignity and elevation of mind, have the lives of thousands been sacrificed.<sup>21</sup>

This devotion to science and the Gregorian ethics of character were both readily imported to the New World. America's first professor of clinical medicine, Thomas Bond, who had studied in Britain and France and, along with Benjamin Franklin, established Pennsylvania Hospital, the first incorporated hospital in the United States, argued that a physician's character is demonstrated in his willingness to admit mistakes and use science to improve quality. Arguing in favor of bedside training of medical students in a 1766 essay titled "The Utility of Clinical Lectures," Bond wrote:

If the Disease baffles the power of Art and the Patient falls a Sacrifice to it, he [the physician] then brings his Knowledge to the Test, and fixes Honour or discredit on his Reputation by exposing all the Morbid parts to View, and Demonstrates by what means it produced Death, and if perchance he finds something unexpected, which Betrays an Error in Judgment, he like a great and good man immediately acknowledges the mistake, and, for the benefit of survivors, points out other methods by which it might have been more happily treated.<sup>22</sup>

In 1769, Samuel Bard, who founded the Columbia College of Physicians and Surgeons, addressed the first medical graduates of Kings College (now Columbia University) with the following admonitions about their duty to continually improve upon their knowledge:

Your Labours will have no End. . . . Do not imagine, that from this Time your Studies are to cease; so far from it, you are to be considered as but just entering upon them; and unless your whole Lives, are one continued Series of Applications and Improvement, you will fall

short of your duty. . . . In a Profession then, like that you have embraced, where the Object is of so great Importance as the Life of a Man; you are accountable even for the Errors of Ignorance, unless you have embraced every opportunity for obtaining Knowledge.<sup>23</sup>

As a partisan of the Enlightenment, Bard also understood that improving medical knowledge came not merely from studying books, but also from studying patients, both alive and dead:

Whenever you shall be so unhappy as to fail, in your Endeavors to relieve; let it be your constant Aim to convert, particular Misfortunes into generally Blessings, by carefully inspecting the Bodies of the Dead, inquiring into the Causes of their Diseases, and thence improving your own Knowledge, and making further useful Discoveries in the healing Art.<sup>24</sup>

Benjamin Rush, perhaps the most famous American physician of the 18th century, gave similar advice a few years later, in 1789, when he recommended that students

open all the dead bodies you can, without doing violence to the feelings of your patients, or the prejudices of the common people. . . . record the epidemics of every season; their times of appearing and disappearing, and the connection of the weather with each of them. . . . Preserve, likewise, an account of chronic cases. Record the name, age, and occupation of your patient; describe his disease accurately, and the changes produced in it by your remedies; mention the doses of every medicine you administer to him. It is impossible to tell how much improvement facility in practice you will find from following these directions.<sup>25</sup>

Rush had signed the Declaration of Independence and served as physician to General George Washington's troops at Valley Forge. Writing in the year of the signing of the U.S. Constitution (1787), he told his students that if, as physicians, they combined Gregorian personal virtues of openness, honesty, and diffidence (humility) with empirical observation and a commitment to continually improving medicine, they could create a new medicine and a new era of human happiness:

Human misery of every kind is evidently on decline. Happiness, like truth, is a unit. While the world, from the progress of intellectual, moral, and political truth, is becoming a more safe and agreeable place for man, the votaries of medicine should not be idle. All the doors of the temple of nature have been thrown open, by the convulsions of the late American revolution. This is the time, therefore, to press upon her altars. We have already drawn from them discoveries in morals, philosophy, and government; all of which have human happiness for their object. Let us preserve truth and happiness, by drawing from the same source, in the present critical moment, a knowledge of antidotes to those diseases which are supposed to be incurable.<sup>26</sup>

Early American medical leaders, heirs to the Enlightenment views of Gregory, thus embraced ideals of continual medical improvement based on scientific observation and investigation, though still always in the context of personal, rather than group, or professional, moral

responsibility. These ideals of personal virtue were embraced in the charters and codes formulated by American medical societies in the early 19th century (e.g., the 1823 New York *System of Ethics* and the 1832 Baltimore *System of Medical Ethics*).<sup>27</sup>

Similar personal virtues were central to the Hippocratic corpus, but quality was also evolving, from a simple willingness to do one's best and be humble about what medicine can offer toward obligations to share information about errors and learn from one's colleagues. Quality was becoming a group responsibility.

### Professionalization: Quality Becomes a Group Responsibility

At the turn of the 19th century, Thomas Percival, a prominent physician and an author of moral parables in Manchester, England, profoundly transformed medical ethics by construing ethical duties as matters of professional standing rather than personal character. Percival recognized that the old ethic of individual character was insufficient for the new work environment of the hospital: Personal disputes could quickly affect the care of many patients. After several occasions in the late 1700s in which intercollegial disputes disrupted patient care at the Manchester Infirmary, Percival was charged with drafting a set of institutional regulations. In 1803, these were republished under the title *Medical Ethics*.<sup>28</sup> In this work, Percival proposed a distinct realm of group responsibilities which he called "professional ethics," marking the first use of that important phrase. Specifically, he proposed that the ethics governing hospital conduct derived not from individual character alone, but from physicians' fiduciary responsibility, *as a group*, to care for patients and the public's health. "Let the physician and surgeon never forget that their professions are public trusts," he wrote,<sup>29</sup> and he dealt in separate sections with duties to hospitals, conduct in private practice, relations with apothecaries, and duties related to the law.

As part of his recognition that hospital work demanded group responsibility, for example, Percival conceived of clinical rounds in which "the junior physician present should *deliver* his *opinion* first, and the others in the progressive order of their seniority," so that each level provided a check on the knowledge and proposed actions of those at lower levels.<sup>30</sup> Hence Percival moved medical ethics, "into the new world of complex social relationships between professionals with differing competencies working together in an institution within an urban industrial society."<sup>31</sup>

While solo general practitioners were still the norm, hospitals were becoming more important, and Percival's group ethics encouraged doctors to take advantage of the new collegial means of QI that hospital practice offered. Percival called for the creation of a hospitalwide "register" in which all doctors and surgeons could track interesting and extraordinary cases, in the hospital and in their private practices. The register would include tables indicating patients' demographic data, diagnoses, and outcomes. Through analyses of the register, he hoped, physicians would attain "a clearer insight into the comparative success of . . . their practice[s]; and would be incited to a diligent investigation of the causes of such differences."<sup>32</sup> He also recognized the value of collaborating with apothecaries, noting that "the apothecary will regard the free communication of the physician as a privilege and means of improvement" and that

both would be more effective in caring for patients if they cooperated.<sup>33</sup> However, in acknowledgment of physicians' concern that any admission of error could be professionally harmful (another recurring theme of QI in medicine), Percival recommended that the hospital register be open to physicians only.<sup>34</sup>

Despite his adamant belief in professional ethics, Percival still relied heavily on personal character to promote QI, recommending that

At the close of every interesting and important case, especially when it hath terminated fatally, a physician should trace back, in calm reflection, all the steps which he had taken in the treatment of it. This review of the origin, progress, and conclusion of the malady; of the whole curative plan pursued; and of the particular operation of the several remedies employed, as well as of the doses and periods of time in which they were administered, will furnish the most authentic documents, on which individual experience can be formed. But it is in a moral view that the practice is here recommended; and it should be performed with the most scrupulous impartiality. Let no self-deception be permitted in the retrospect; and if errors, either of omission or commission, are discovered, it behooves that they should be brought fairly and fully to the mental view. Regrets may follow, but criminality will thus be obviated.<sup>35</sup>

Though Percival's *Medical Ethics* was never adopted by the British medical establishment, his work is of landmark importance because his orientation of ethics around the profession rather than the individual, essentially creating the notion of medical professionalism, served as a basis for the American Medical Association's (AMA's) *Code of Medical Ethics*, published in 1847. In the "Introduction to the 1847 Code of Medical Ethics," John Bell (1796–1872) acknowledged the ideal Hippocrates had set forth ("The duties of a physician were never more beautifully exemplified"<sup>36</sup>) but strongly emphasized a Percivalian obligation of physicians to work together, especially to promote public health. He wrote, "On them [physicians] devolves, in a peculiar manner, the task of noting all the circumstances affecting the public health, and of displaying skill and ingenuity in devising the best means for its protection," and he called physicians "conservators of the public health"<sup>37</sup> and exhorted them to work with their "professional brethren" on health promotion and to promote "scientific logical medicine."<sup>38</sup>

### **The Social Contract: Standard-Setting and Professional Autonomy**

This new notion of medical professionalism was built on an explicit social contract. Physicians would agree to certain shared obligations, as written in the *Code of Medical Ethics*, and the public and patients would grant the profession a number of important privileges in return—most notably, the liberty to set professional standards, i.e., professional autonomy. But almost immediately upon the founding of the AMA around its code, tensions arose regarding what "professional autonomy" would mean. Would the profession issue quality standards binding on all practitioners, or would individual physicians be free to set their own standards?

Though shaky at first, the former view would hold considerable sway for many years. Throughout the Progressive Era (1890–1913), "professional autonomy" meant that the profes-



sion set and enforced shared standards for quality practice.<sup>39</sup> Within a year of its founding, the AMA had established committees to set standards on medical education, medical sciences, practical medicine, surgery, obstetrics, medical literature, and publications. Standing committees on anatomy, physiology, materia medica, chemistry, forensic medicine, vital statistics, hygiene, and sanitary measures soon followed.<sup>40</sup> The reciprocal arrangement was clear: Individual practitioners would benefit from professional social privileges garnered by the AMA, but in return, they were expected to follow the dictates of the profession, as set by AMA committees.

The AMA's work to impose uniform standards was sorely needed. Between 1840 and 1849, only 55 of 170 candidates for surgical appointments passed the Army Medical Board examination, which acting Surgeon General H. S. Heiskell, M.D., attributed to "insufficient preparatory education, a hurried course of pupilage, want of proficiency in practical anatomy, in pathology and in clinical medicine."<sup>41</sup> In 1848, one year after its founding, the AMA recommended that medical education be clinical and demonstrative, with cooperation between medical colleges and hospitals, and that hospitals appoint staff based on merit.

### Cabot's "Ethics of Competence"

A critical further shift away from an ethic of personal virtue toward group responsibilities was provided by Dr. Richard C. Cabot (1868–1939), a Professor of Clinical Medicine at Harvard Medical School and a Professor of Social Ethics at Harvard College.<sup>42</sup> Cabot was concerned both with humanism in medicine and with the changes it was undergoing at the end of the 19th century, including "the shift of care to the hospital, the use of ancillary professions such as social work in caring for the patient, and the increasing appreciation of science in understanding disease."<sup>43</sup> To Cabot, gentlemanly character was of little concern; what mattered ethically was a physician's ability to effectively treat disease, which often meant working with others, including non-physicians. He called this an "ethics of competence," and in an article titled "Medical Ethics in the Hospital," Cabot stressed the importance of cooperation among the many professionals caring for patients, accurate keeping and analysis of records, and the resolution by committee of disputes over clinical care. While similar ideas had been voiced earlier (including by Percival), Cabot joined his ethics of competence with the ideal of group responsibility and new methods of quantitative analysis to great effect. At Massachusetts General Hospital, he analyzed the autopsies of 1,000 patients and discovered a high rate of diagnostic error. Jonsen writes:

**His [Cabot's] publication of this analysis and a later similar study dismayed and angered many of his colleagues, who accused him of the ethical breach of "publicly advertising the faults of the general practitioner." But for Cabot, this *was* ethics: moral practice was competent; incompetent practice was unethical. Clinical competence had moved to the center of medical ethics.<sup>44</sup>**

## Standards for Medical Education

Cabot and others recognized that the ethic of group competence would ultimately require a complete overhaul of the education system. But while the AMA had had minor successes in its initial efforts to improve education standards, by 1900 there remained an abundance of poor-quality, for-profit medical schools, despite the growing need for more-sophisticated medical education. As King writes, "By 1900 the growth of science, no longer a matter of scholarly isolation, was actively affecting medical practice and medical education."<sup>45</sup> Yet at the beginning of the 20th century, the minimum requirement for entrance to medical school was only two years of high school, and even this was not always demanded by for-profit medical schools that were interested in filling as many seats as possible. Only 7 percent of medical students held an undergraduate degree prior to matriculation to medical school.<sup>46</sup> Furthermore, few medical schools were affiliated with universities or hospitals, so most lacked the means to provide a rigorous grounding in laboratory science and clinical medicine.<sup>47</sup>

In 1904, the AMA established its Council on Medical Education "to enhance and standardize requirements for medical schools."<sup>48</sup> But without broad public awareness of quality problems or support for a solution, it was unable to fulfill its mandate. In 1910, the council sought out the impartial and respected Carnegie Endowment for the Advancement of Teaching to produce a report on the state of medical education.<sup>49</sup> The resulting report, *Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching*, by Abraham Flexner, brought the shortcomings of medical education to wide public attention and, amid great fanfare, Flexner recommended the "drastic reduction in the number of schools from 155 to 31."<sup>50</sup>

## Art, Science, and New Organizations

In addition to retooling the educational system, realizing an ethic of competence at the turn of the century also involved a reconceptualization of clinical practice. Despite the efforts of pioneers like Bond, in the 1800s the "art of medicine" and the "science of medicine" largely remained separate, at least in America—practitioners focused on the art, researchers on the science. Observation was an important clinical skill, but formal physiologic and anatomic measurements were used little in the day-to-day practice of medicine. This changed with the advent of tools such as the ophthalmoscope, stethoscope, and laryngoscope, as well as techniques to monitor body temperature and hemoglobin levels. Physicians increasingly were becoming scientists, which seemed to conflict with the notion of medical practice as art. In a speech to the AMA titled "The Essentials of the Art of Medicine," Dr. John H. Musser, President of the AMA in 1904, remarked, "With the incoming of scientific precision there is the outgoing of so-called art. Diagnosis by intuition, by careless 'rule of thumb' . . . is as little trustworthy as the shifting sand of the Sahara."<sup>51</sup>

With these new scientific techniques, physicians were again asked to adopt an attitude of self-questioning and critical judgment; medicine was seeking the diffidence—humility—in medical practice that Gregory, Bond, and the Hippocratics had earlier endorsed. And again,

this was not passive, servant-oriented humility in the face of God's inscrutable ways, but rather a learning-oriented humility, aimed at improving medical science for society and all of humanity.

But, building on Cabot's earlier discovery of high rates of misdiagnosis in hospitals and his understanding of the importance of organizations, some were beginning to question whether doctors alone could fix quality problems in health care. In 1910, Ernest Codman (1869–1940) "noted the need to improve hospital conditions and to track patients to verify that their care had been effective."<sup>52</sup> Quality demanded the actions of organizations, and especially hospitals. Codman wrote, "Every hospital should follow every patient it treats long enough to determine whether the treatment has been successful, and then to inquire 'if not, why not' with a view to preventing similar failures in the future."<sup>53</sup> Like Cabot, Codman benefited in the early 1900s from statistical methods then becoming available in his pursuit of what he called the "end result idea." A onetime member of the Massachusetts General staff and the Harvard faculty, however, Codman eventually resigned from the hospital in protest of his colleagues' resistance toward using outcomes as the basis for professional advancement. Still, by 1918, his work led the American College of Surgeons to establish its Hospital Standardization Program. The program called, in part, for standards of staff organization and hiring, medical record-keeping, and supervised diagnosis and treatment within hospitals, including formal case reports of adverse outcomes.<sup>54</sup>

Though he built on a great tradition, following Gregory, Percival, Cabot, Bard, and others, Codman's work is often thought of as the beginning of a new paradigm for medicine: a greater focus on measured outcomes and, later, evidence-based medicine. In addition, Codman's legacy was to solidify the role of organizations in pursuing QI. In little more than 100 years (1803–1918), QI had clearly moved from an individual endeavor based on the personal virtues of doctors, to a shared professional obligation (i.e., a matter of professional ethics), to an organizational challenge for hospitals, albeit with doctors still playing a leading role in this larger scheme.

### **Great Leaps in Quality: Science Succeeds, Humility Fails**

One cannot discuss quality of care without noting that by the end of the 19th century, scientific discoveries had solidly established the germ theory of disease, opening the way for incalculable improvements in the quality of care physicians were able to deliver. It is difficult today even to imagine the impact medicine was seen to have on society during this time. The mid- to late 1800s saw the discovery of the agents of anthrax, tuberculosis, and childbed fever, along with early work on vaccines and antibiosis. And then, within only about 20 years, closing out the 1800s, the infectious agents of amoebic and bacillary dysentery, cholera, gonorrhea, diphtheria, typhoid fever, leprosy, malaria, glanders, and many more diseases were discovered. Early antibiotics provided medicine with miraculous cures, in addition to the profound public health benefits of better understanding of infectious diseases. Between 1900 and 1920—before the widespread use of antibiotics—deaths from the common killers typhoid, diphtheria, and gastritis were cut by more than half, and tuberculosis deaths dropped by one-third, through

physician-led public health interventions. By the 1940s, with the introduction of penicillin and streptomycin, influenza deaths dropped by more than one-half, and tuberculosis deaths were falling so rapidly that the disease was widely expected to be rapidly eliminated. At the beginning of the 1900s, all-cause mortality in the United States plummeted 60 percent, from more than 1,600/100,000/year to less than 1,000/100,000/year.<sup>55</sup> Within a generation—a mere 30 years—physicians had become miracle workers.

In 1926, in the wake of this success, a popular book, *The Microbe Hunters*, made heroes of physicians and microbiologists.<sup>56</sup> With research continuing to yield one medical miracle after another, the United States dramatically increased federal and state funding for hospitals and research,<sup>57</sup> and, as Sullivan writes, “Medicine came to link its reputation ever more closely to its claims to be scientific.”<sup>58</sup>

On the basis of clear, demonstrable improvements in quality, medicine in the early 20th century attained “unquestioned authority.”<sup>59</sup> Patients trusted physicians’ commitment to patient welfare, believed in the miraculous efficacy of new medical treatments, and allowed physicians tremendous discretion. This authority was often well-used, but it also manifested as increasing paternalism and retrenchment from the long-sought-after diffidence in medical practice.

### New Organizations for QI

In parallel with this increasing paternalism, changes in medical practice also brought along wider recognition, as Percival and Codman had implied, that full responsibility for quality lay beyond individual physicians’ immediate reach, requiring organizational action. Medical leaders were coming to recognize that QI was moving beyond the purview of doctors as a group and needed to encompass many other professional stakeholders.

As medicine became more scientific, complex, and hospital-based, entirely new organizations became necessary to monitor quality. The Hospital Quality Program and efforts to reform medical education, noted above, were early examples. As another example, at the turn of the century, drug quality was a limiting factor in quality of care, but Congress had repeatedly declined to exert federal control over the manufacture of drugs, so the AMA waged a campaign to better regulate drug quality.<sup>60</sup> So-called “nostrums” were seen as “an evil that existed within the medical profession itself,” and in 1900, in a series of articles in the *Journal of the American Medical Association*, the AMA vowed to undertake an examination of patent medicines.<sup>61</sup> In 1905, it established the Council on Pharmacy and Chemistry to standardize drug manufacturing and advertising. The next year, the AMA established a laboratory to evaluate substances submitted for approval. Then, in part through the workings of the AMA’s political machinery and its Committee on National Legislation, Congress passed The Pure Foods and Drug Act in 1906, establishing the Food and Drug Administration (FDA) and requiring drug makers to disclose certain of the ingredients of drugs they marketed. The AMA would continue to investigate and publicize information on drug composition through most of the 20th century, in a series of books, *Nostrums and Quackery*, which went through three editions into the 1940s.<sup>62</sup>

Later examples increasingly show the complex interplay of government, the private sector, and the profession to monitor and improve quality. Most notably, in 1952, the American College of Surgeons joined with the American College of Physicians, the American Hospital Association, the AMA, and the Canadian Medical Association to form the Joint Commission on Accreditation of Hospitals (JCAH, now the Joint Commission on Accreditation of Healthcare Organizations, JCAHO). With power derived from both professional and governmental authority (ultimately, Medicare payments hinged on JCAHO accreditation, for example), the Joint Commission's focus on quality assurance evolved rapidly to QI; initially, it surveyed hospitals on a set of minimum standards, but in 1966 it opted for "optimal achievable standards," in recognition of the advances in techniques to measure and improve quality.<sup>63</sup>

### Modern Outcomes Movement, Ancient Conflicts

In the 1970s, the "outcomes movement" gained substantial momentum both from rising health-care costs and from new research on health-care utilization that "cast doubt on the existing knowledge base for medical practice,"<sup>64</sup> including unaccounted-for variations in medical-practice patterns in similar populations.<sup>65</sup> The basis of the movement, derived from Gregory, Cabot, Codman, and others, was the idea that "probabilistic studies are the best evidence of what works, and that better medical practice will result from the direct application of research findings by individual physicians."<sup>66</sup> As statistical evidence showing correlations between procedures and outcomes amassed, modern evidence-based medicine (EBM) was born. Outcomes studies were designed to serve as the basis for practice guidelines, which could provide explicit, statistically sound treatment recommendations for specific conditions.

In 1986, Congress created the Agency for Health Care Policy and Research (AHCPR, now the Agency for Healthcare Research and Quality, AHRQ), in part to create clinical practice guidelines that could guide physician decisionmaking, standardize practice, and improve health-care quality. Evidence- and population-based medicine would also become the cornerstones of managed care, with its emphasis on cost-containment and access to voluminous patient data.<sup>67</sup> The notion, as Chervenak and McCullough put it, was that "large institutions can . . . [assume] responsibility for patient care and can collect and analyze data in ways not feasible in the now passing, decentralized, cottage-industry world of medical practice."<sup>68</sup>

AHCPR almost immediately ran into difficulty over its guidelines program, however, which has subsequently been transformed into a clearinghouse rather than having a standard-setting function.<sup>69</sup> Likewise, managed care continues to struggle with implementation of clinical practice guidelines.<sup>70</sup>

Considering the history of QI, it was virtually inevitable that the outcomes movement, at least as manifested in guidelines, would meet with resistance among physicians; not because physicians are uninterested in improving quality, but because of the way guidelines challenge what and how physicians know. The conflict is clear and long-standing, if not intractable. The "art" of medicine values physicians for their ability to treat each patient individually based

on the accretion of clinical judgment, not simply the ability to follow instructions provided by massive clinical studies.<sup>71</sup> But—as a founder of the EBM movement, David Sackett, put it when asked to speak to the effect of artfulness in medicine—according to EBM, “Art kills.”<sup>72</sup>

### The Guidelines Rebellion

Doctors were not alone in seeking to retain the art in clinical care and pushing back against population-based guidelines, which became widely referred to as “cookbook medicine.” Concomitant with the growth of the outcomes and EBM movements, which sought to prescribe optimal treatment programs for individuals based on data from populations, three interrelated opposing movements arose; taken together, they comprised a widespread rebellion against the use of guidelines to improve quality.

The first driver of the guidelines rebellion was the conflation of QI and cost control. Dramatic increases in health-care costs had led to the strong need to curtail expenditures, and guidelines can be used to constrain unnecessary care and thus reduce costs. Of course, guidelines could also lead to increased use of effective care, which might cost more, but this was rarely noted, as guidelines were sold to payers and policymakers almost solely on the promise of reducing costs. Unfortunately, this led inevitably to the conflation of the cost-control and QI movements, which greatly heightened physician and patient wariness about QI and whether its proponents were really interested in raising quality or whether reducing costs was the primary objective.

Second, following the Vietnam War and Watergate, many individuals had begun to question authority—including medical scientific authority—and to place tremendous value on individual autonomy.

For patients, this trend took form in the bioethics revolution, laws and regulations enforcing the ideals of shared decisionmaking and informed consent, and the growth of medical consumerism. Paternalism, whether on the part of individual doctors or of large systems of care, was under assault. Some patients questioned doctors’ authority as it became clear that some “scientific medicine” was not really based on science. But many patients also wanted something beyond science; they wanted their individual desires and health beliefs to inform their medical care. Of course, respecting individual autonomy can be a driver of QI, insofar as patients want scientific information to inform their decisions, but unfettered consumerism in health care also leads to the use of alternative and unorthodox therapies—as was seen in England in Gregory’s time and in America at the time of the founding of the AMA, and is seen to a certain extent today. More broadly, individualism naturally rebels against the standardized, population-based decisionmaking that EBM represents.

For physicians—who, based on their history of paternalistic ethics since 1847, might have argued for standardized scientific decisionmaking—the increasing importance of patient autonomy as an ethical principle meant that medical ethics became increasingly associated with strict advocacy for individual patients’ needs and desires. In 1984, Dr. Norman Levinsky wrote, “Physicians are required to do everything that they believe may benefit each patient, without regard to costs or other societal considerations.”<sup>73</sup> Concerns about inappropriate cor-

porate or state controls over medical care played neatly into this trend, the end result of which was that many physicians came to believe they were obliged to reject nearly any social role (and especially a cost-containment role) if doing so would help a patient obtain a health benefit—as defined by the patient.

Finally, and perhaps most important among physicians, an old tension within the profession reappeared, but this time the individualists came to prominence. “Medical professionalism” mutated from entailing the right of the profession as a group to set and enforce standards for practice (which could have supported the movements toward professionally created practice guidelines) to being construed as conferring on individual physicians the right to choose what therapies to offer each patient. In effect, “professional autonomy” came to be understood as a license to practice without meaningful oversight, even by one’s peers.<sup>74</sup> This reading of professionalism might be an understandable reaction to the surge in autonomy as a primary ethical principle and to wariness of the corporate cost-control mandate. But it could hardly be more different from the initial understanding of professionalism as requiring groupwide standard-setting, which, not coincidentally, is how physicians won the right to professional self-regulation to begin with.

Thus, both patients and physicians have been involved in rebelling against the perceived interference of QI projects, or at least those that result in enforceable guidelines for clinical practice. Yet these ethical, practical, and professional qualms over QI would ultimately need to succumb to mounting scientific evidence of significant, avoidable problems with quality of care in the United States.

### Quality at the Crossroads: Adopting a Systems Approach to QI

In 1996, the Institute of Medicine (IOM) unveiled a massive Quality Initiative to assess and improve the nation’s health-care quality, and in 2000, it released *To Err Is Human: Building a Safer Health System*,<sup>75</sup> which summarized earlier findings regarding medical errors in detail (noting, most famously, that as many as 98,000 Americans might die each year as a result of medical errors) and dramatically brought health-care quality problems to public attention.<sup>76</sup> The week the report was released, editorial pages took note: *The New York Times* pointed out that, according to the report, the casualties from medical errors were the same as if “three jumbo jets filled with patients crash every two days,”<sup>77</sup> and *The Washington Post* reported that “the sheer scale of the loss of life should act as a spur across the system.”<sup>78</sup>

Indeed, the “system” has been spurred. Numerous professional organizations have now formally embraced systematic approaches to QI. For example, in 1999, the Accreditation Council for Graduate Medical Education issued six core competencies that all residency training programs must teach young physicians.<sup>79</sup> Among these are *professionalism*, which is to be related to “practice-based learning and improvement.” Residents must be able to “analyze practice experience and perform practice-based improvement activities using a systematic methodology” and “obtain and use information about their own population of patients and the larger population from which their patients are drawn and specifically included.”<sup>80</sup> In 2002, the American Board of Internal Medicine (ABIM), the American College of Physicians—American

Society of Internal Medicine, and the European Federation of Internal Medicine issued "The Charter on Medical Professionalism." Among its nine professional responsibilities were the following:

Physicians must be dedicated to continuous improvement in the quality of health care. This commitment entails not only maintaining clinical competence but also working collectively with other professionals to reduce medical error, increase patient safety, minimize overuse of health care resources, and optimize the outcomes of care. Physicians must actively participate in the development of better measures of quality of care and application of quality measures to assess routinely the performance of individuals, institutions, and systems responsible for health care delivery. Physicians, both individually and through their professional associations, must take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.<sup>81</sup>

The AMA's Principles of Medical Ethics (the nine core statements on which the Code is based) were revised in 2000 to include the statement, "A physician shall continue to study, apply and advance scientific knowledge, maintain a commitment to medical education . . . and participate in activities contributing to the improvement of the community and the betterment of public health." Similar statements appear throughout the Code and in many other professional-association policies, documenting the commitment among the profession's leaders to modern systems-based methods of QI. And these documents are being followed with action, such as the Physician Consortium for Performance Improvement, which is led by professional associations and dedicated to developing and implementing quality measures for medical practice.<sup>82</sup>

Such recognition of QI as a professional social obligation holds great promise for physicians as professionals. Writing about the Physician Charter, Brennan notes, "The principles underlying civic medical professionalism [shared obligations toward communities] derive from traditional professional values, but they extend the accountability of the profession from dutiful action on behalf of individual patients to the social contract with the public."<sup>83</sup> In fact, although "civic medical professionalism" is a relatively new term, it reflects a concept of professionalism dating at least to 1847. Indeed, it is this concept on which physicians' social status largely rests, even though it was neglected for several decades. And its reemergence has coincided with a new appreciation of the fact that individual physicians cannot improve health care working alone. Like Percival, Cabot, Codman, and the AMA's 1847 Code, the American College of Physicians' Physician Charter and similar documents, including the *Declaration of Professional Responsibility* (AMA Code, p. xx) are intended to mobilize physicians, in aggregate and working with other stakeholders, to fulfill their end of the compact between medicine and the public.



## Bringing All Stakeholders into QI

Before closing, we must note an important counternarrative to the theme of an evolving civic-minded, professional teamwork approach to improving health-care quality: that of the market as the primary driver of quality. According to this alternative—but very commonly held—view, the putative professional is understood fundamentally to be an interchangeable purveyor of expert skills and services. The norm that it advocates is one of sophisticated technicians working in groups and overseen in some fashion by managers who can harness market forces to drive quality. Physicians are seen foremost as “providers” who should compete on parameters such as hospital days per thousand patients, formulary use, and rate of immunizations.<sup>84</sup> By monitoring performance, and assuming a good supply, poor-quality providers can rapidly be swapped out for better performers.

The influence of this market-driven model is reflected, for example, in efforts at public reporting on individual physician performance and in many of the most common pay-for-performance programs. Tensions between these two potential drivers of QI—professional collegial action and market-based competition—are important. Scholars of the professions note that selling technical expertise (even if it is sold within a well-functioning market, which is far from assured in health care) is insufficient grounds for maintaining some of physicians’ current social prerogatives. Dr. William Sullivan writes, “Historically, the legitimacy, authority, and legal privileges of the most prestigious professions have depended heavily on their claims (and finally their demonstration) of civic performance, especially social leadership in the public interest.”<sup>85</sup> It is partly in recognition of this fact that some are now calling for a revival of civic, or “social-trustee,” professionalism in medicine.<sup>86</sup>

We raise the market approach here not to discuss these tensions,<sup>87</sup> but rather to note that the market model, in fact, tends often to be in alignment with professionals on the goals of QI. As a result, some private purchasers have shown great interest in supporting QI initiatives. The Leapfrog Group, for example, has organized more than 150 organizations that provide health-care benefits and is working to identify patient-safety problems in hospitals and reward players in the health industry for coming up with solutions.<sup>88</sup>

Government purchasers are also aligning toward QI. Medicare, for example, works with peer review organizations (PROs), now known as quality-improvement organizations (QIOs), throughout the United States “to make sure patients get the right care at the right time.”<sup>89</sup> And multi-stakeholder efforts such as the National Quality Foundation (NQF) and the Ethical Force program have joined older players, including JCAHO, the AMA, and the American Hospital Association, in bringing organizations together to address QI across the health-care system.

## Conclusion

QI in medicine has evolved from an individual concern based on personal virtue and duties toward patients to a collective (professional) concern driven by a shared devotion to science, and finally to a systemic concern involving many stakeholders.

Considering the long, evolutionary history of physicians' ethical commitment to improving the quality of care patients receive, the tremendous accomplishments derived from this commitment, and the numerous current statements of support by professional organizations, it is disappointing that physicians are still too frequently seen as obstacles to implementing QI projects. Yet, given the history we have reviewed, it should not be surprising.

Understanding the evolution of QI from an individual to a professional to a systemic activity is important to understanding that certain recurrent factors will continue to pose challenges to full physician participation in QI. The profession must grapple with ongoing tensions between humility (Gregory's "diffidence") and pride in meaningful accomplishments. Admitting to quality problems is the first step in QI, but barriers to such admissions (including both the threat of lawsuits and personal shame) are pervasive. Questions remain about how to balance professional social obligations and obligations toward individual patients. In fact, some physicians do not see or admit to a social role for the profession, and many do not belong to the professional associations that should establish quality standards. Wariness of cost-control masquerading as QI remains common. And medical practice continues to become increasingly complex, demanding greater and greater teamwork, even though physicians are often poorly trained in how to work within a team.

We have shown, however, that despite these barriers, there is ample historical precedent for physician leadership in QI. This is an especially crucial time for physicians to step up to the challenge. Both ethical and prudential arguments favor doing so. Ethical arguments are reflected in numerous statements, dating as far back as the Hippocratic era, that physicians must admit errors and engage in QI as fundamental duties. Pragmatically, the social promise to promote QI lies at the base of the public's trust in physicians and thus physicians' authority, as a group, to self-regulate and enjoy other social privileges.<sup>90</sup> By taking this promise seriously, physicians can improve their patients' care and simultaneously regain some of the autonomy they have recently lost to the government and to managed care.<sup>91</sup>

Capitalizing on this opportunity will require reciprocal changes in some physicians' wary attitudes toward QI *and* in certain top-down-management, "cookbook" approaches to QI. Physicians in all settings should be leading QI as an integral part of routine patient care, rather than having QI initiatives imposed upon them as external, burdensome, irrelevant, or even risky tasks. Recognizing that health care today is complex and team-oriented, physician leadership in QI does not mean that physicians bear the full burden of solving all the problems. But it does mean that physicians must show clear resolve and renewed leadership in their endeavors.

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