

Introduction

The Politics of Standardization

IN 1991, leading international emergency medicine researchers gathered in the beautifully restored, 800-year-old Utstein Abbey on Mösterey, a small island off the southwestern Norwegian coast. In this breathtaking setting of green hills surrounded by wild seas, the international task force engaged in the very basic work of defining what counts as first aid life-saving behavior and how it should be recorded. Since the early 1960s, cardiopulmonary resuscitation (CPR) has been the principal first aid method of reviving victims of sudden death in the Western world. Whenever somebody suddenly collapsed, CPR gave any stranger the license to engage in prescribed actions to reverse the dying process. The rescuer should check the victim's breathing and, if no breathing can be detected, secure an open airway by tilting the victim's head back, and start mouth-to-mouth ventilation. Next, the rescuer should feel for a pulse, and, if lacking, begin chest compressions. From its establishment as the dominant resuscitation technique in the early 1970s, the efficiency of CPR has rarely been questioned and resources have been poured into constructing a community-wide "chain of survival"¹ that links every failing heart to the most advanced life-saving care possible in emergency departments.

While resuscitation techniques gained acceptance, an annoying problem remained unresolved: nobody could say how effective CPR was in saving human lives. The only data available were regional survival rates, but those varied widely—from less than one percent to 33 percent.² In most places, including big cities such as Chicago and New York, only one person in 100 would be saved on average while in Seattle about a third of resuscitative efforts would end up with a saved life. What explained such broad variation? Epidemiological researchers looking at the different survival rates could not compare them because no consensus existed about what counted as a true resuscitative effort (is every

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attempt at reviving a resuscitation, or should only the cases with the best chance for survival be counted?), and how one should define survival (does survival mean that the patient walked out of the hospital, or does it include merely breathing?). The difference between one percent and 33 percent could be explained by varying methodological approaches, terminological and conceptual inconsistencies, the different emergency medical systems, demographic variations, the efficiency of CPR administration, or the quality of the resuscitative efforts. There was no conclusive way to tell why resuscitating in Seattle seemed vastly more successful than saving lives in Chicago.

In order to fix the confusing Tower of Babel that plagued emergency medicine,³ international researchers gathered in the Utstein Abbey to propose a set of uniform guidelines to report outcome data for resuscitative interventions. Inspired by the International Committee of Medical Journal Editors, which recommended uniform requirements for articles submitted to biomedical journals, the researchers provided a glossary of terms, definitions for time points and intervals, a template for reporting data from resuscitation studies, definitions of outcomes, and recommendations for the description of emergency medical resuscitation systems. They published these standards aimed at “simplicity, conciseness, and practicality”⁴ in the leading emergency medicine journals and requested the collaboration of journal editors and National Institute of Health peer reviewers to check for conformity to the Utstein guidelines. If every researcher gathers the data points suggested by the template and then uses the appropriate formula, policy analysts can now assess the efficacy of resuscitative efforts within and between emergency systems and better understand cardiac mortality. Recognizing that in the past “the cart was put in front of the horse,”⁵ researchers will finally know after about thirty years of national education campaigns whether the point of diminished return is quickly reached in CPR, or whether more lives can be saved with, for example, automatic defibrillators.

The Utstein consensus conference is not an isolated instance of standardization in medicine. Over the past decades, a cottage industry of thousands of consensus conferences has emerged in the health care field, with psychiatrists attempting to standardize the assessment criteria for panic disorder,⁶ transplant centers trying to reach consensus about national criteria for heart organ donation,⁷ and manufacturers and users of ultrasound determining safety criteria of new devices.⁸ In

addition, national organizations, such as the American Heart Association, and international bodies, including the World Health Organization, regularly meet in umbrella conferences to update standard and safety guidelines related to the therapeutic use of biological products.⁹ Standardization has penetrated every corner of contemporary medicine: it forms the foundation of collaborative international research protocols, medical information technologies, and reimbursement procedures.

Of particular interest in the current standardization movement is the emphasis on *evidence-based medicine* (EBM), or “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”¹⁰ Although evidence-based medicine means different things (including an orientation toward critical self-evaluation, the production of evidence through research and scientific review, and/or the ability to scrutinize presented evidence for its validity and clinical applicability), in common medical parlance it mainly denotes the use of *clinical practice guidelines* to disseminate proven diagnostic and therapeutic knowledge. The U.S. Institute of Medicine defines clinical guidelines as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”¹¹ Such guidelines offer instructions on which diagnostic or screening tests to order, when to provide medical or surgical services, how long patients should stay in the hospital, and other details of clinical practice. Typically, a group of experts evaluates the scientific literature according to set criteria and then offers recommendations based on the strength of the evidence aimed at the practicing clinician.

According to the ideals of evidence-based medicine, clinical practice guidelines should be based on scientific evidence—preferably a meta-analysis of randomized clinical trials offering probability estimates of each outcome. Proponents of evidence-based medicine are wary of reasoning from basic principles or experience; they distrust claims based on expertise or pathophysiological models. They prefer to remain agnostic as to the reason why something should or should not work—rather, they objectively measure whether or not it works in real-life settings.

Yet such evidence is only rarely available to cover all the decision moments of a guideline. To fill in the blanks and to interpret conflicting statements that might exist in the literature, additional, less objec-

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tive steps are necessary to create a guideline. A preferred method is the consensus meeting, in which experts, such as the Utstein resuscitation researchers, come together to discuss the contested issues and work toward a practically feasible recommendation. Such meetings have been criticized for the lack of transparency in decision making and the suspicion that the resulting guidelines are often as much the result of group dynamics during the meeting as of the scientific literature. Woolf et al. note that “the fact that a group of individuals think that a practice is beneficial does not ensure that it actually is.”¹²

In response to such critiques, more systematic methodologies to develop practice guidelines emerged. Hierarchies to rate the scientific quality of the evidence upon which the guideline was based were developed, and statistical meta-analyses were used to aggregate critically the results of multiple clinical trials. In addition, cost-benefit data are increasingly being included in the evidence upon which the guideline is based. Relying on formal analytic methods and drawing from clinical epidemiology, guideline developers evaluate the benefits, harms, and costs of interventions and often derive explicit estimates of the probability of each outcome. Most guideline panels are comprised of health care professionals but occasionally also include methodologists, health economists, and patient and consumer representatives. Their task is to define a focus and an audience for the guideline; retrieve, evaluate, and synthesize the evidence; summarize the benefits and harms; and determine the appropriateness of the intervention.

For example, consider the guideline addressing the question whether screening for genital herpes should be part of a routine health care exam (see Figure I.1). Medical researchers estimate that 50 to 80 percent of American adults have type 1 herpes (HSV-1) while 21 percent have the second type (HSV-2). Yet the majority of people do not have a history of symptoms or outbreaks; the virus only shows up in blood tests.¹³ Genital herpes is considered dangerous in people with weakened immune systems and for women giving birth. According to some obstetricians, an active outbreak during delivery might generate fatal complications and constitutes an indication for caesarean-section and preventive drug treatment (with acyclovir). Sometimes pregnant women with partners who have a history of herpes are counseled to use condoms or abstain from intercourse during pregnancy. The guideline addresses whether those preventive measures are indicated by the evidence of the scien-

Figure I.1. U.S. herpes screening guideline.

Screening for genital herpes simplex.

RELEASE DATE: 1996

MAJOR RECOMMENDATIONS:

The **strength of the recommendation** for or against a preventive intervention was graded as follows:

A: There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.

B: There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.

C: There is insufficient evidence to recommend for or against the inclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.

D: There is fair evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

E: There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

CLINICAL INTERVENTION:

Routine screening for genital herpes simplex in asymptomatic persons, using culture, serology, or other tests, is not recommended ("**D**" recommendation).

Routine screening for genital herpes simplex infection in asymptomatic pregnant women, by surveillance cultures or serology, is also not recommended ("**D**" recommendation). Clinicians should take a complete sexual history on all adolescent and adult patients.

As part of the sexual history, clinicians should consider asking all pregnant women at the first prenatal visit whether they or their sex partner(s) have had genital herpetic lesions. There is insufficient evidence to recommend for or against routine counseling of women who have no history of genital herpes, but whose partners do have a positive history, to use condoms or abstain from intercourse during pregnancy ("**C**" recommendation); such counseling may be recommended, however, on other grounds, such as the lack of health risk and potential benefits of such behavior.

(Continued)

Figure I.1. (*Continued*)

There is also insufficient evidence to recommend for or against the examination of all pregnant women for signs of active genital HSV lesions during labor and the performance of cesarean delivery on those with lesions ("**C" recommendation**); recommendations to do so may be made on other grounds, such as the results of decision analyses and expert opinion. There is not yet sufficient evidence to recommend for or against routine use of systemic acyclovir in pregnant women with recurrent herpes to prevent reactivations near term ("**C" recommendation**).

DEVELOPER(S):

United States Preventive Services Task Force (USPSTF)—Federal Government Agency (U.S.)

Source: www.guideline.gov. Based on U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services*, 2d ed. (Baltimore: Williams & Wilkins, 1996), 335–346. Used with permission.

tific literature. Its intended audience consists of health care practitioners wondering whether they need to screen for genital herpes.

The guideline first reiterates the criteria for evidence and then offers recommendations with varying degrees of certainty based on a review of the research literature by federal health researchers. The researchers found "fair" evidence to recommend against routine screening for herpes in asymptomatic people and pregnant women while there is insufficient evidence for any other more specific recommendations. Thus the available scientific literature was insufficient to suggest caesarean-section, counseling, or preventive drug treatment as standard interventions. But the makers of the guideline acknowledged that other factors, including consultation with experts in the field, might result in taking these preventive measures.

Evidence-based medicine has become a powerful movement that promises to change the content and structure of medicine and its allied professions. Indications of the impact of this movement are new institutions, such as the Cochrane Collaboration, the National Institute for Clinical Excellence (NICE) for England and Wales, and the U.S. Agency for Healthcare Research and Quality (AHRQ) (formerly the Agency for Health Care Policy and Research [AHCPR]); new journals, such as *Evidence-Based Medicine*, *Clinical Practice Guidelines Update*, *Best*

Evidence (a CD ROM), *POEMs* (*Patient-Oriented Evidence that Matters*),¹⁴ *Bandolier*, *Effectiveness Matters*, and *The ACP Journal Club*; recurring editorials in top medical journals such as the *British Medical Journal*, the *Journal of the American Medical Association*, *Annals of Internal Medicine*, and the *New England Journal of Medicine*; classical medical and nursing textbooks discussing the importance of evidence-based medicine; innovations in methodologies and criteria to gather and evaluate data; the surge of randomized clinical trials in medical research; and the rise of “causal pathways,” “care plans,” and “outcome research” to streamline and evaluate every aspect of health care. Even critics of evidence-based medicine have their own journal: *Journal of Evaluation in Clinical Practice*.¹⁵

Outside of the spotlight, other standardization processes continue, often interlocking with and being reinforced by the drive toward evidence-based medicine. For medical data to become comparable, for example, terminologies and communication routes need to be standardized, and technical standards have to be implemented so that the information systems of all these different parties can communicate smoothly.

Particularly in the past five years, the development of clinical practice guidelines has boomed: in the United Kingdom an estimated 2,000 guidelines are in varying stages of proposal and implementation.¹⁶ In the United States, early estimates put the number of guidelines between 1,400 and 4,000, with currently about 1,000 new guidelines constructed annually.¹⁷ The web-based U.S. National Guideline Clearinghouse (www.guideline.gov), produced by the Agency for Healthcare Research and Quality, in partnership with the American Medical Association and the American Association of Health Plans, currently contains 921 guideline summaries.¹⁸ All throughout the Western world (and increasingly in third world countries as well), professional societies, public-sector agencies, research organizations, health care insurers, health maintenance organizations, and individual health care institutions are constructing and implementing guidelines.¹⁹ In fact, the number of guidelines being produced by all these different bodies, in all these different countries, leads to a bewildering situation, in which there may be dozens of often overlapping and contradictory guidelines for any given condition or decision problem.²⁰

To create some order, the U.S. National Guideline Clearinghouse includes only recently made or modified guidelines, authored by rec-

ognized medical bodies, government agencies, or plans. In the United Kingdom, NICE plays a similar role, creating new guidelines and improving relevant existing guidelines so that they “fulfill the NICE criteria for quality and content” (www.nice.org.uk). Besides physicians, nurses, insurers, physiotherapists, and dental assistants have all discovered the bandwagon of evidence-based medicine, nursing, physiotherapy, and so on. This raises the question of why there is such a great interest in standardizing medical care at this historical moment.

HISTORICAL ROOTS OF STANDARDIZATION

Evidence-based medicine is part of a wider movement to generate uniformity and quality control by streamlining processes. In the broader historical context, standardization forms a powerful vestige of modernism lingering in an increasingly postmodern world. The notion that predictability, accountability, and objectivity will follow uniformity belongs to the Enlightenment master narratives promising progress through increased rationality and control. “Modernity can be viewed as a process of emphasizing technological standardization and eliminating other established or culture-based standards. . . . Modern standard setting is characterized not by a change of *type* of standards, but rather by the specificity of the processes created to prescribe them, and by the multiplicity of standards, their ubiquity, and their formality.”²¹ Indeed, ever since Max Weber singled out the bureaucracy as the ideal typical organizational structure of the modern capitalist state, standards emerged as one of the hallmarks of rationalization. Through the abstract, written rules of standards, efficiency and control could be documented across diverse organizations. Standards specify how we work, how our technologies interact; they hold our sociotechnical societies together. Even military conflicts cannot be waged without basic standards: when American troops first landed in Kuwait, for example, before they did anything, they had to install the standard Volt.²²

The rudimentary principles of the current standardization movement were articulated in the shifting economical field of the late nineteenth to the beginning twentieth century. Economic historians argue that the need for standards emerged when production processes and goods crossed geographical boundaries and business and scientific methods were counterposed to faith in community and tradition.²³ The

classic example of the need for standardization is the integration of the railroad system. Two U.S. trade organizations, the American Railway Association and the Master Car Builders Association, adapted the standard gauge track in 1886 and standardized automatic couplers and air brakes in 1893.²⁴ Another impetus toward the standardization movement of the late nineteenth and early twentieth centuries was a preoccupation with safety. An early government-sponsored study of steam boiler explosions showed that many were due to a lack of standardization of the boilers and their parts.²⁵ While some of the early standardization efforts remained contested (e.g., the battle against the metric system at the beginning of the twentieth century), a consensus developed among engineers and entrepreneurs that not standardizing hurt business by generating waste, duplicating efforts, and creating bottlenecks in production. The standardization efforts took off when antitrust activists demanded that monopolistic firms increase their efficiency. In addition, the First World War legitimized standardization efforts when the government, with the support of President Herbert Hoover, issued mandatory specifications for war-related purchases. Hoover also organized the "Division of Simplified Practice," which developed procedures for cutting down on various sizes, varieties, and grades of commodities.²⁶ Efficiency through standardization became a national preoccupation in the prewar United States.²⁷

While the industrial standardization movement of the early twentieth century took place, the U.S. medical profession reformed the medical schools and their curricula, and the *hospital standardization movement* tried to create a set of minimal requirements to which every hospital should adhere. The impetus for standardizing hospitals came from the realization that patients would no longer be cared for by their trusted primary physician but by a diverse team of consulting and referring medical specialists relying on the recently developed laboratory sciences and diagnostic technologies such as clinical pathology and radiology. Such an interdisciplinary approach implied that patients would need to be cared for in hospitals instead of at home, in turn requiring hospitals to relinquish the stigma of pauper, welfare institutions and reach out to middle-class patients. This standardization movement also fed off the fear that if physicians did not establish efficiency standards themselves, public officials might do it for them. An extra impetus was the desire and necessity to make hospitals financially responsible in-

stitutions.²⁸ The American College of Surgeons specified a number of standard hospital criteria needed for the proper care of patients, including specific case records, clinical laboratories, payment schedules, postmortem investigations, training procedures, and safety measures. Not every reformist proposal made it into the standardization movement. The parts of early reform proposals dropped included all efforts to evaluate doctors or limit the autonomy of individual hospitals. The parts that survived were well-organized medical records (see Chapter 1 for a detailed discussion), some form of staff organization, and access to X-ray facilities and a clinical laboratory. The American College of Surgeons began accrediting hospitals in 1919. "Control of the hospital was in the hands of medical men, and the method of control was standardization."²⁹

A controversial outgrowth of the early standardization movement was Taylorism, or scientific management. Taylorism took a production process and improved the efficiency of the workers through time-motion analyses and a differential piece-rate system of payment. Evidence-based medicine is often (critically) compared to scientific management because of its focus on behavioral change with scientific underpinnings.³⁰ With a stopwatch in hand, engineer and former machinist Frederick W. Taylor would measure how long it took to perform the elementary movements of a job. For example, smoothing a wooden surface would be subdivided into smaller tasks: lift the piece from the floor to the planer table, level and set the piece, put on the stops and bolts, handle the mechanical planer, remove stops and bolts, remove piece to floor, and clean the machine.³¹ Adding up the time units, including time for "unavoidable delays," generated a standard time in which to complete the job. This time could be improved if the manager eliminated the false, useless, and slow movements and used the standard time to calculate an incentive wage instead of paying workers a daily rate. For some kinds of work, the studies showed that regular rests and a shortened workday might increase productivity. Managers then taught the standard best method to employees and made sure that every worker could do the tasks of the person below and above him or her in the hierarchy.

Taylor's goal was to increase the productivity process while providing increased prosperity for management and workers, promising an

increase in productivity and wages of 30 to 100 percent (the productivity increased more than the wages so that the average production cost went down).³² But at the same time, he hoped to create a scientific base for managing employees by discovering the laws and principles of working. Taylor's vision of science was one of unsophisticated positivism mixed with engineering pragmatism: through rigorous observations engineer/scientists could discover laws of human behavior and then optimize them through modifications and incentives.

While one of Taylor's four principles of scientific management was to obtain "intimate friendly cooperation between the management and the workers,"³³ scientific management was largely perceived as a solution for labor problems. Taylorism subscribed to the notion that antagonistic management-worker relationships could be solved through crude early behaviorism. The problem was called "soldiering," or workers' ability to pace the work rate. According to David Noble, workers engaged in pacing to "keep time to themselves, to avoid exhaustion, to exercise authority over their job, to avoid killing so-called gravy piece-rate jobs by overproducing and risking a rate cut, to stretch out available work for fear of layoffs, to exercise their creativity, and, last but not least, to express their solidarity and their hostility to management."³⁴ Scientific management was an attempt to transfer skills from machinists to the slide rules and instruction cards of management, changing rule-of-thumb management into its scientific counterpart.

This transfer did not materialize as expected by the corporate reformers. "No absolute science of metal cutting could be developed—there were simply too many stubborn variables to contend with."³⁵ Indeed, scientific management only caught on because large businesses, afraid that antitrust legislation would cripple them, considered novel means to become more cost-effective. When the railroad companies requested an increase in ticket rates, Louis Brandeis argued instead in a landmark legal case that the railroad's mismanagement had retarded their profits. Scientific management proponents testified that their methods could have saved the railroads \$1 million per day. The court ruled in their favor. As a consequence of extensive publicity, "scientific management" became a household term³⁶ and under the efforts of Lillian Gilbreth it literally entered the household with scientific management cooking, house cleaning, and home economics. For example, she wrote:

Like factory workers, children will be inclined to cooperate once they realize that their individual interests and skills have been taken into account in the management process. A household survey might reveal, for example, that one child is much more interested in washing dishes if she receives a new apron to wear while doing this task. Simple and low-cost adjustments such as this can be made to improve the cooperative spirit among family members and to make the home a happier place.³⁷

After the momentum of scientific management slowed down with changed labor relationships and management procedures in the aftermath of the First World War, standardization lost its broad ideological appeal and disappeared from the public's attention. It became a mundane, practical matter of ensuring that fire hoses fit fire trucks, or that a spare part for a car would match the original product's design. It was nothing spectacular, and nothing that would arouse interest outside of the backrooms where technicians elaborated their "minute specifications."³⁸ With the growth of international trade organizations after the Second World War, however, standardization reemerged in the public picture. Standardization appeared to be a highly useful means to avoid direct political conflicts about barriers, inequities, and asymmetries in international trade, and so a focus on standardization reemerged as the "product of a global economy":

If goods and services are to be freely exchanged across boundaries, given the complexities of multiple legal systems, the nature of the transaction [including what the purchaser can expect of the product] must be precisely identified.³⁹

Whereas scientific and technological progress provided the ideological luster that was associated with standardization at the beginning of the twentieth century, Krislov concludes, now standardization's appeal lies in the ideology of the free, global market: standardization is viewed as a necessity due to changes in the scale and complexity of commerce. Over the past decades, the European Union has made standardization of basically everything tradable a top priority. Economist Peter Grindley puts standards central to a successful business strategy, offering advice on how to "win with standards."⁴⁰ He argues that in order to take advantage of standardization, businesses need to adopt counterintuitive economic practices, such as sharing proprietary technology, encouraging standard adoption even if it generates more competition, and adopting a technically unexciting design to increase the total size of the market.

The standard is here viewed as the base to accumulate complementary products and lock in customers. In order to gain a competitive advantage, consumer protection groups have seized the standardization process as a means to increase safety of products⁴¹ while some government reformers have used their leverage in standard setting to force policies that would have little chance of succeeding via traditional legislative routes. California's air resources board, for example, has been a leader in setting fuel emission standards, requiring manufacturers to come up with cleaner cars.

In medicine, the overall interest in standardization similarly petered out after the first decades of the twentieth century. With the fading belief in the high hopes of scientific management, and with professional worries about the side effects of the standardization recipe (not the least of which was the never-ending threat of tight government control), it lost much of its original appearance. The licensing bodies continued their control of medical education and hospitals, but such developments were now no longer in the spotlight of the public's and the profession's attention.

In the late 1980s, standardization gradually reemerged as a focal point of interest in the health care field. In medicine, however, this did not initially take the connotation of globalization, strategic advantage, and free information exchange. Here other drives were at work. Whereas at the beginning of the twentieth century, standardization stopped short of prescribing the content of medical work, now this aim was at the heart of the increasing number of guidelines and guideline-creating agencies. Evidence-based medicine advocates wanted to intervene at the moment of a health care provider's special expertise: medical decision making. Earlier standardization attempts were almost always restricted to the skills, tools, and facilities required for that work: the required training, the required ancillary personnel, the design of the surgical theater, and so forth. The content of the work itself was left unaddressed: to decide the proper course of action for a given solution was the unique prerogative of the individual professional. Faced with a patient in situations that were never identical, the application of scientific knowledge was the art that only an experienced, true professional could master. Now, however, evidence-based medicine is foremost about delineating what sequence of activities constitutes a professional response to a given situation. Guidelines elaborate how scientific knowledge

should be applied. Of all the kinds of standardization attempts that have affected medicine in the twentieth century, evidence-based guidelines represent the farthest-reaching and most direct attempt to prescribe and preset the actions of health care professionals. At the same time, evidence-based medicine also enlarges a conceptual space for other forms of standardization in medicine. Dovetailing on the success of evidence-based medicine, drug corporations have attempted to standardize drug delivery in novel ways, researchers have engaged in complex standardized international collaborative research, and government agencies implement welfare policies by streamlining standardized protocols to assess disability and workers' compensations.

The recent rise of guidelines has been championed by several major figures. In Britain, Archie Cochrane was captured by the Germans during World War II and became the medical officer to 20,000 prisoners of war. Because Cochrane had access only to the most basic medical tools to treat the starved and diseased patients, he expected many of his patients to die. To his surprise only a handful of prisoners died, mostly from gunshot wounds. During a later prisoner-of-war experience, Cochrane had more modern medical procedures at his disposal. Because mortality rates were much higher in the second camp, Cochrane feared that inappropriate interventions caused unnecessary deaths. In 1972, Cochrane published *Effectiveness and Efficiency*, arguing against medical overuse of techniques with questionable evidence. He made a plea for investigating medical interventions with randomized clinical trials. Services that were harmful, not effective, or overly expensive could then be replaced by underutilized better techniques.⁴² Likewise, he argued for the urgency of systematic reviews of randomized controlled trials on a given topic, so that professionals would have quick access to high-quality summary information about the evidence for or against a certain intervention. The Cochrane Collaboration, named after him, now performs and collects such reviews, using state-of-the-art statistical techniques (www.cochrane.org).

In the United States, the work of epidemiologist John Wennberg made the need for more scientifically supported medical care blatantly apparent. For several decades Wennberg has been publishing the *Dartmouth Atlas of Health Care*.⁴³ This book maps the frequency of a variety of medical interventions by geographical area. The results confirmed an astonishing variability of medical practices depending on where the

patient happened to reside. For example, the researchers found that a Medicare patient in early stages of prostate cancer was eight times as likely to have his prostate gland removed if he lived in Baton Rouge, Louisiana, than if he lived in Tuscaloosa, Alabama. In some parts of the country radical breast cancer surgery was performed thirty-three times as often as breast-saving lumpectomies. Higher surgical rates were almost perfectly correlated with the availability of surgeons and diagnostic tests; thus people who underwent angiograms (diagnostic tests for heart and artery blockages) were much more likely to undergo bypass surgery.

The great variation for almost any intervention could not be explained by chance but was born out of inadequate medical knowledge, physician practice styles, patient preferences, over-reliance on inadequately verified diagnostic tools, and basic inequities in the health care system. One of the proposed solutions to counter over-reliance on surgical fads was to provide a scientific evidence basis for hysterectomy, mastectomy, carotid endarterectomy, and other interventions in the form of clinical practice guidelines. Wennberg's retrospective studies of patterns of care helped establish optimal treatment levels. Particularly, government agencies (but also medical professional organizations) were interested in this research since it provided them with tools to check outcomes and allocate financial resources. Already in 1984, Wennberg urged a greater place for clinical epidemiology in academic medicine.⁴⁴

A third figure associated with evidence-based medicine is David Sackett, who was born and educated in the United States but who built a career in Canada and the United Kingdom. As a clinical epidemiologist, Sackett developed research methods for testing medical innovations, for evaluating the scientific validity and clinical merit of medical interventions, and for educating physicians in applying the "current best evidence" from research. Together with Cochrane and Alvan Feinstein of the United States, Sackett made many methodological contributions to analyzing data gathered in the randomized clinical trial and legitimated clinical epidemiology as the foundation of evidence-based medicine. Sackett was instrumental in coining and promoting the term *evidence-based medicine* and articulating its principles.

These three major figures together with others have become identified as the founding fathers of the evidence-based movement, laying the groundwork for clinical practice guidelines as the solution for the

lack of scientific working habits in the health care field. Yet why did the evidence-based medicine movement take off so strongly in the 1980s? Comparable ideas, guidelines, and tools had been around for a long time, but only in the late 1980s did they suddenly come center stage. Put briefly, the recourse to guidelines and the strain that this placed on the cherished individual autonomy of health care professionals has become necessary to legitimate the professional's claim to exclusive expertise in health care (see Chapter 3). Whereas 100 years ago the profession was at a position of newly established, unprecedented strength, after the second half of the twentieth century, its position had come under increased pressure. With spiraling health care costs, more emancipated patients/consumers, increasing attention to medical practice variations, an information overload, and an overall critical scrutiny of the role of experts and professionals in society, the medical profession felt it had to take unprecedented action to maintain its position as exclusive safe-keeper and wielder of medical knowledge. "Unexamined reliance on professional judgment," it is argued, will no longer do. "More structured support and accountability for such judgment," in the form of evidence-based guidelines, is required to ensure the trust in the medical profession.⁴⁵ The crucial importance of taking the lead in these developments is framed as a matter of professional survival: "What changes are implemented and how successful they are will depend on who takes the leadership role in developing guidelines: the profession, business, the government, or insurance companies."⁴⁶

On the whole, these other parties all enthusiastically underwrite the importance of evidence-based medicine, creating a powerful network of allies and funding agencies propelling the movement. For governments and insurers, evidence-based guidelines promise more insight into and openness about medical decision making, affording an increased grip on the primary care process and, concurrently, opening up a new means to achieve cost control. The same guidelines that explicate optimal decision-making procedures can of course be used to regulate those processes (to delineate reimbursable from nonreimbursable actions, for example). For these parties, a promising option is to add economic evaluations to the evidence written into the guideline. Whereas evidence-based guidelines usually limit themselves to stating what diagnostic and therapeutic actions are effective, with the help of health economics they can also provide evidence of the efficiency of these ac-

tions. Through cost-effectiveness analysis, for example, the costs of different interventions can be compared and weighed against their effects. In this way, by only underwriting interventions that are both effective and efficient, many policy makers hope guidelines can become a means to counter the never-ending increase in health care spending. Yet, it is not only cost containment that guides third parties. Nick Manning discusses how the U.K. government was instrumental in generating the research evidence and guidelines of a new personality disorder in order to allow preemptive incarceration.⁴⁷

Patients and other health care professionals similarly tend to welcome the openness that comes with explicating decision procedures through guidelines. It allows them to be more informed partners in the interaction with physicians, and it brings the existing uncertainties in the medical knowledge base to the fore. In addition, other health care professionals see the creation of guidelines as a crucial strategy in their own professionalization process. By showing that they have a solid knowledge base, just like the medical profession, and that they are self-critical and scientific in their approach, these professionals hope to obtain high professional status.

Another development that weaves its course into the further growth of evidence-based medicine is the emergence of information technology in medicine. Dickersin and Manheimer note that “although science has long been acknowledged as the backbone of medicine, the actual practice of evidence-based healthcare may not have been possible before information systems technology advanced to its current state.”⁴⁸ More specifically, the development of guidelines will merge with what has been labeled the “next major change” in medical record keeping after the introduction of the patient-centered record:⁴⁹ the replacement of the paper patient record by an electronic patient record. This development has taken off full force since the early 1990s, stimulated by national and international funding both in the United States and in Europe,⁵⁰ and driven by the same ideology that has driven international standardization after World War II: the notions of globalization and free information flow.

The diverse drives, developments, and parties involved make for a fascinating yet volatile mixture. The different aims are not easily reconciled: enhancing the patient’s position might not be the most cost-effective option, and enhancing the payers’ insight and control

(through standardizing fixed courses of action, or through channeling information flows from the primary care process to the insurer's offices) may threaten the profession's position. These potential conflicts are real, and the further development and implementation of evidence-based guidelines will be the playing field on which these tensions will be played out. Although standardization in medicine has not become equated with the aims of globalization and free information exchange, as in the larger societal context, it has taken over the thoroughly depoliticized focus on technical measures that made standardization such a powerful phenomenon on the international political scene. In medicine as well, standards and guidelines can be discussed with regard to their scientific qualities or their technical adequacy, but to speak of their political nature seems almost to commit a category mistake.

RATIONALIZATION VERSUS REGULATION

Evidence-based medicine is portrayed as an alternative to medicine based on authority, tradition, and the physician's personal experience. The role of politics is rarely mentioned. When discussed, politics is portrayed as what evidence-based medicine will avoid. . . . Changing medical practice requires the development of political, legal, and medical institutions that oversee medical care. Promoting medical practice based on evidence will therefore necessitate more, not less politics.⁵¹

The high hopes and pervasive skepticism surrounding standards indicate the contested nature of standardization. Some proponents of evidence-based medicine have gone as far as to label the recent standardization efforts in health care and evidence-based medicine a paradigm shift in health care⁵² or even a new social movement.⁵³ Critics, on the other hand, have referred to evidence-based medicine proponents as "aerobic children vaulting through the statistical stratosphere"⁵⁴—emphasizing the theoretical void⁵⁵—and have characterized evidence-based medicine as a "fundamentalist cult with evangelical tendencies."⁵⁶

For supporters, the cost-benefit analysis of standardization is straightforward. Rigorous evidence-based medicine offers a tight link between medicine and scientific evidence, leading to better and more efficient care, improved health outcomes, better educated patients and clinicians, a scientific base for public policy, a higher quality of clinical

decisions, and better coordinated research activities. It provides every interested party with accessible and simple information to evaluate the necessity, benefits, indications, harms, costs, and risks of a particular intervention. Because evidence-based medicine integrates clinical acumen with current best evidence, it makes the competent clinician even more competent and less likely to become blinded by experience or theorizing. Following Max Weber, advocates of standardization argue that the process is a *sine qua non* for effective communication and collaboration because it facilitates a transparent medical practice. Standards bring order to a modern world and facilitate coordination between diverse entities (medical specialties, hospitals, industries, and countries) without a centralized legal authority. Advocates argue that some level of standardization is necessary and inevitable for rational social action. The evidence-based medicine movement helps to move the health care field in the direction of an “exact science.”⁵⁷

Critics, on the other hand, charge that evidence-based health care turns clinical practice into bland and unsavory “cookbook” medicine. This overused metaphor suggests that health care providers would merely follow recipes, executing what others have decided, and would stop consulting their own intuition and experience. Behind a negative assessment of standardization lies the accusation that standards lead to watered-down competition, innovation, autonomy, and creativity, concocting a world of increasing and empty sameness. This “McDonaldization” of medicine resides in the standard approach to health care problems advocated by the guidelines, in which every patient problem would be addressed generically, as one more instance of the same.⁵⁸ In this way, it is argued, evidence-based medicine is bound to repeat the mistakes of scientific management. In medical education, clinical uncertainty might be managed by simple rule following, undermining the role of expertise and charismatic teachers. In medical practice, a clinician’s prized autonomy might become secondary to what others have decided is best, resulting in the loss of individualized treatment. Standards, in this view, may become the unfair advantage that the powerful outsiders—managers, insurers, governments, and/or other professionals—impose on the powerless insiders. Worse, the traditional health care professions might be invaded and replaced by cheaper, less educated auxiliary occupations. Within medical subdisciplines, different professional groups formulating opposing guidelines or no-

menclatures might create divisive internal strife and undermine the public's trust in health care. Critics also point to examples of "inefficient" standards, including a guideline for sleep apnea that because of its over-reliance on randomized controlled trials provided the wrong perspective on the disease, even missing the reason why it was treated.⁵⁹ Critics note that the goal of uniformity is undermined by the abundance of competing standards. Finally, critics have assailed the conceptualization of medical practice at the heart of evidence-based medicine, listed methodological problems in clinical trial research and in postulating from epidemiological data to clinical situations, and allege authoritarian motives under the guise of anti-authoritarianism.

The contested nature of standardization centers on its politics. The political heritage of standards is apparent in Taylor's promotion of scientific management as a behaviorist tool to solve labor problems, standardization as an alternative tool for governmental and legal antitrust actions, the deliberate positioning of private industry bodies, action groups, and government organizations to seize the standard-setting process, and the emergence of evidence-based medicine against the threat of third parties to regulate health care. Critics and supporters agree that standards emerge out of political concerns and can be used to implement or thwart regulation. But they disagree on the need for such regulation and the usefulness of standards as policy tools. The most often heard critique is that standards over-regulate. Standards undermine the expertise of professionals, constituting an unnecessary and harmful intrusion into a world of autonomous experts. Comparing evidence-based medicine to a "rationalistic dictatorship based upon simplistic and incomplete analysis," one critic states, "my cards are on the table. I see EBM, in its present form, as a dangerous delusion; erroneous in both rationale and conclusions, and a potentially lethal weapon in the hands of misguided regulators and reformers."⁶⁰ This critic reiterates a widespread fear that the payers in the health care system, governments and insurers, might regulate the health care field and hold it accountable using evidence-based parameters formulated by the professions.

Supporters point out that standards are necessary to safeguard professional autonomy and exclusive expertise because they constitute a form of self-regulation. While third parties might try to enforce standards through sanctions, a distinguishing characteristic of standards is that, in comparison to laws and directives, they remain impersonal and