

# The Origins and Promise of Medical Standards Of Care\*

**Standards of care in medicine have gone through many changes and developments over the course of its history.**

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In a 1990 report on medical standards of care, the Institute of Medicine established a taxonomy of standards that remains relevant today [3]. According to this taxonomy, the following types of medical standards are used currently in the United States:

*Standards of quality*: statements of the minimum acceptable level of performance or results, what constitutes excellent performance or results, and the range in between.

*Medical (or clinical) practice guidelines*: systematically developed statements to assist practitioners in their decision making in specific clinical settings.

*Medical review criteria*: statements used to assess the appropriateness of specific decisions, services, and outcomes in the delivery of health care.

*Performance measures*: specific measures of a quantitative nature that estimate or monitor compliance with medical quality standards, medical practice guidelines, and medical review criteria by health care professionals.

"Standards of care" should not be thought of as a single, uniform whole. Rather, the appreciation of the different types and their different functions facilitates more thoughtful discussion and may even reduce apparent conceptual disagreement.

## Standards from Within: The Medical Profession and Its Specialties and Societies

Medical specialists and their learned societies have been the major engine for the development of medical standards of care. After World War II, large-scale funding of biomedical research in academic medical centers and expanded third-party payment greatly enhanced the power and prestige of medical specialties. Medical specialties concomitantly became interested in the quality of clinical practice. In particular, the specialties wanted to maintain control over the definition of the quality and content of medical care. Of note, during this same period, medical specialists became more willing to testify for plaintiffs in medical malpractice cases, making medical liability an important phenomenon in American medicine.

The development of medical standards of care took off in the 1980s. Medical professional associations, specialty societies, and voluntary health organizations became involved in developing standards of care in an increasingly rigorous fashion. By the late 1980s, the American Medical Association, working with medical specialty societies, launched a major initiative that signaled the endorsement of medical standard-setting by the organized medical profession [4]. In 1987, the Council of Medical Specialty Societies announced that the American medical profession and American medical specialty societies should participate more in standard setting [5].

## **Standards from Without: Third-Party Payers and Health Services Research**

In part, the medical profession was responding to pressures from third-party payers, who looked to standards to reduce unnecessary health care services. In 1981, the American College of Physicians and the Blue Cross and Blue Shield Association launched the Clinical Efficacy Assessment Project to evaluate use of specific medical procedures and technologies [6,7]. By the late 1980s, the Health Care Financing Administration (HCFA), which administered the Medicare and Medicaid programs, was using medical standards of care to develop both national coverage policy and medical review criteria for its programs [8].

Health services research, financed primarily by the federal government and conducted chiefly in academic medical centers, has played a crucial role in the evolution of medical standards of care. Specifically, professionals in the field of health services research, which began in the 1960s, took on the study of the cost, quality, and accessibility of health care services using economic and other social science research methodologies. Much of this research focused on improving the quality of ever-more-expensive health care. Health services research identified wide geographic variations in medical practice and this, in particular, provided powerful evidence of the need for medical standards of care.

Health services researchers also adopted new theories of quality management, extolling the principles of Total Quality Management (TQM) and Continuous Quality Improvement (CQI), concepts they imported from industry and adapted to health care settings [9]. These quality principles strive to reduce variation in the production process through work standardization and continuous improvements in outcomes rather than on identification and elimination of defects in production. Many health care professionals and health plans adopted these principles, as did the Joint Commission on Accreditation of Healthcare Organizations and other accrediting bodies.

Further, the adoption of computerized patient record enabled a dramatic change in how medical standards of care could be used in the delivery of clinical care. This development also facilitated use of TQM and CQI in quality assessment and improvement—strategies that must have supportive performance data to be effective. Such data can best be collected through computerized medical records.

The movement toward integrated systems for delivery of care and managed care plans also fueled the development and use of medical standards. Medical standards became a critical tool for comparing managed care plans in a competitive environment—a phenomenon consistent with the best of managed competition theory, which emphasizes state-of-the-art quality measurement as a primary strategy for comparing competing health plans.

Having learned from experiences in the 1990s, when restrictions on access and preferences alienated health care consumers, sponsors of managed care plans now rely increasingly on medical standards of care to determine appropriate and cost-effective care. Only by applying medical standards of care and evidenced-based medicine can inappropriate care be identified in a manner that is credible to physicians and patients.

Finally, federal agencies have played a critical role in the development of medical standards of care. Specifically, the National Institutes of Health and the Veterans Administration fund research that has supported medical standards empirically (ie, provided its "evidence base"). Since 1989, Congress has maintained an agency within the Department of Health and Human Services that has direct responsibility for the promotion and management of medical standards of care. Today, the Agency for Healthcare Research and Quality funds and promotes the health services research that supports these standards and convenes experts to facilitate their development. More recently, this agency has had a leadership role in addressing patient safety issues that rely heavily on medical standards for resolution [10].

In sum, medical standards of care are here to stay as an important part of American medicine. Although many physicians decry the advent of standards as "cookbook" medicine, other physicians maintain that standard-setting is necessary for high quality medical care. There is now little debate about their validity and importance for the delivery of high quality medical care. The American health care sector has indeed moved from a paradigm of autonomous professional decision making to a paradigm of collective decision making based on empirically derived standards of care.

With this move, however, come increasingly difficult questions. Medical standards now come from a multitude of sources. How do these sources derive their authority? Are the processes used in setting standards open, transparent, and designed in a way to marshal the best information to guide clinical practice? Should standards from "within" the profession agree with standards from "without"—from the business office, for example—particularly when external standards have cost containment as the end being pursued rather than a patient's individual interest? How can differing standards from different sources be reconciled? While pluralism in the development of standards may be desirable and consistent with our cultural value that competition is important, such pluralism—an outcome of the historical development of medical standards of care—poses challenges today for the medical profession and the patients it serves.

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