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Changing health care quality paradigms: The rise of clinical guidelines and quality measures in
American medicine

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Abstract: Clinical guidelines and quality measures are important new paradigms for conceptualizing and managing quality in the United States. Researchers have proposed that professional elites—including members of academic medicine—were an important cause of the shift to guidelines and measures. This paper draws on content analysis of abstracts focused on quality in major American medical journals between 1975 and 2009 to empirically assess whether and how paradigms for managing quality changed in academic medicine. The content analysis shows that guidelines- and measures-based approaches to quality increased in prominence. Individual expertise-based approaches to quality, however, remain important. Concurrent with changing paradigms in academic medicine, there was a reorientation of policy towards increased use of guidelines and measures the late 1980s and early 1990s in the United States. This policy reorientation was informed by earlier work by medical researchers proposing new approaches to quality. The policy reorientation was followed by an increase in the prominence of guidelines and measures in medical research.

Health care quality has been a central goal of both the medical profession and of health policy in the United States for over a century. The ability to deliver quality care is the primary basis for the professional authority of the medical profession and a core objective guiding health policy (Scott, Ruef, Mendel, & Caronna, 2000; Shortell, 2004; Starr, 1982).

While quality has persisted as an enduring goal in medicine and health policy, there has been a shift in intellectual paradigms for conceptualizing and managing quality (Goldenberg, 2006). From the early 20th century until recent decades, there was a widespread belief that individual expertise—grounded in the training and skills of physicians—was the most important determinant of quality. Given this belief, public policy focused on creating standards for medical education or increasing the skills of practicing physicians. In recent decades, clinical guidelines and quality measures have become increasingly important—reflecting emerging beliefs that the quality of care could be codified (Nigam, 2011; Timmermans & Kolker, 2004; Weisz, Cambrosio, Keating, Knaapen, Schlich, & Tournay, 2007). Guidelines are codified rules defining appropriate or high quality medical care. Quality measures are quantified indicators of care processes or outcomes that are believed to reflect the quality of care delivered. As tools for defining what constitutes high quality work, guidelines and measures reflect an important shift in how quality is understood and managed (Goldenberg, 2006; Timmermans & Kolker, 2004; Weisz et al., 2007).

Researchers have developed two explanations of the origins of clinical guidelines and quality measures. The first explanation proposes that powerful actors outside the medical profession—including the state and managed care organizations—imposed guidelines and measures on the medical profession in the effort to increase accountability and reduce costs (Armstrong, 2002; Wiener, 2000). The second account emphasizes that elites from within the

medical profession—including academic physicians and leaders of professional societies—created guidelines and measures as a form of professional self-regulation (Armstrong, 2002; Freidson, 1994). More recent work has begun to blend these two accounts, proposing that multiple actors were important in creating guidelines and measures in the context of a growing and increasingly complex health care system. This research shows that both professional elites and states were important in precipitating the growth in guidelines and measures in a range of national contexts (Armstrong, 2002; Weisz et al., 2007).

The goals of this paper are to empirically examine whether and how paradigms among the professional elite—specifically academic medicine—have changed in the United States, and to examine whether changing paradigms in academic medicine were accompanied by changing public policies for managing quality. I draw on content analysis of medical journal abstracts focused on health care quality between 1975 and 2009 to examine whether and how paradigms changed in academic medicine. I develop a case study of changing approaches to managing quality in the Medicare program to understand how changing paradigms in academic medicine were reflected in changes in public policy. I focus my research on the United States. While the emergence of guidelines and measures, and shift in paradigms and public policies for managing quality has been global in scope (Armstrong, 2002; de Jong, Groenewegen, Spreeuwenberg, Schellevis, & Westert, 2010; Exworthy, Wilkinson, McColl, Moore, Roderick, Smith et al., 2003), its history and timing in the United States has been unique (Weisz et al., 2007).

DATA AND METHODS

I used content analysis of abstracts published between 1975 and 2009 in three major medical journals in the United States—Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Annals of Internal Medicine (Annals)—to systematically track changing paradigms in academic medicine over time (Neuendorf, 2002). I

used the National Library of Medicine’s Medical Subject Heading (MeSH) indexing system to identify abstracts focused on health care quality (National Library of Medicine, 2003). I used Ovid’s Medline database to identify abstracts with a primary subject heading of “quality of health care” including all subheadings and all publication types (e.g. journal articles, editorials, clinical trials) other than letters to the editor—a total of 1731 abstracts. I analyzed 935 abstracts in JAMA, 224 in NEJM, and 572 in Annals.

As official journals of three major medical associations, the American Medical Association [JAMA], the Massachusetts Medical Association [NEJM], and the American College of Physicians [Annals], they represent important communication outlets for organized medicine in the United States. As the three leading medical research journals, they are read by physicians across medical specialties, important target journals for medical researchers, and critical outlets for the communication of innovations in medical research. While all three journals are global in scope, they best represent intellectual developments in American medicine.

I began by reading all of the abstracts and did an initial exploratory coding of themes. I grouped these first order codes into three themes that reflected distinct approaches to quality: (1) individual expertise-based approaches to quality, (2) rules-based approaches, and (3) measures-based approaches. Individual expertise-based approaches focus on physician training and skills. Rules-based approaches draw on clinical guidelines and other codified rules. Measures-based approaches use quantified indicators that represent quality.

I developed a formal coding framework to systematically track the prevalence of the three codes over time.¹ I trained a research assistant to use the coding framework. The RA and I went through an iterative process in which we independently coded a sample of texts, discussed why we coded each abstract the way we did, and talked through any differences until we were

confident about our consistency. We then split the work of coding the 1731 abstracts. We independently coded an oversample of 100 abstracts as a final reliability check. The Cohen's kappa—a measure of inter-rater reliability—for the three codes were all above 0.70, indicating good to excellent agreement beyond chance (Neuendorf, 2002).

I analyzed trends in the relative prevalence of different approaches to health care quality by using five-year time intervals. I use five-year periods because the small number of abstracts focused on quality in the first 15 years led to wide fluctuations between years. I used logistic regression to estimate changes over time, and to test for significant differences in the prevalence of individual paradigms across time periods. I estimated three logistic regressions using whether an abstract drew on individual expertise-, rule- and measure-based approaches to quality as the dependent variables. I used the dummy variables representing the five-year time periods as independent variables, using the time period from 1979-79 as the reference category. I used Wald tests to test for significant differences between time periods.

I used qualitative analysis of primary and secondary sources to develop a case study of changing public policies for managing quality in the Medicare program. Primary sources included contemporary accounts of quality assurance activities in Medicare, as well as oral history interviews with senior administrators in the Health Care Financing Administration (HCFA)—the federal agency that administers the Medicare program, which renamed the Center for Medicare Services (CMS) in 2001 (Berkowitz, 1996; Institute of Medicine, 1990; Jencks & Wilensky, 1992; Roper, Winkenwerder, Hackbarth, & Krakauer, 1988; Santangelo, 1995). I combined my case study analysis with qualitative analysis of the medical journal abstracts used in my content analysis to develop insight into the relationship between changing paradigms in academic medicine and changes in public policies for managing quality.

EMPIRICAL FINDINGS

Changing Healthcare Quality Paradigms in Academic Medicine

Figure 1 presents articles focused on health care quality, as a percentage of all articles in JAMA, NEJM, and Annals. It shows that quality became an increasingly important topic in academic medicine. The percentage of articles focused on quality increased from 1.8 percent in 1975-79 to 8.6 percent in 2005-09.

Figure 2 presents the results of my content analysis of abstracts focused on health care quality in the three journals. It depicts the prevalence of individual expertise-, rules- and measures-based approaches to health care quality, as a percentage of abstracts focused on quality, over time. I find a steady decline in the importance of individual expertise-based approaches to quality, from 32 percent of all abstracts in 1975-79 to 9.2 percent in 2005-09. The prominence of individual expertise-based approaches to quality is significantly lower than in 1975-79 for all subsequent periods. The sharpest decrease, and only statistically significant decrease between time periods, occurred between 1975-79 and 1980-85, when use of the individual expertise-based approach dropped from 32 percent to 18.5 percent of abstracts focused on quality.

INSERT FIGURES 1 & 2

I observe a corresponding increase in the prominence of rules- and measures-based approaches to quality. Rules-based approaches increase in prominence from 9.3 percent of abstracts focused on quality in 1975-79 to 25.3 percent in 2005-09. I find a statistically significant increase in the prominence of rules-based approaches to quality between 1980-84 and 1985-89, as well as between 1990-94 and 1995-99. Measures-based approaches increase in prominence from 1.3 percent in 1975-79 to 13.4 percent in 2005-09. I find statistically significant increases, from 2.7 percent in 1990-94 to 8.6 in 1995-99, and from 9.2 percent in 2000-04 to 14.4 percent in 2005-09.

Three Policy Regimes for Managing Quality in Medicare

Table 1 outlines major changes in policy for managing quality in the Medicare program. I identified three time periods, characterized by distinct policy regimes for managing quality in Medicare. An initial *peer review period* began in the early 1970s, and persisted until the late 1980s. A transitional *policy reorientation* period began in the late 1980s with the Congressional mandate for a study to define a new strategy for quality assurance in Medicare, and a concurrent shift in thinking in HCFA. In this period, the Medicare program developed and experimented with new quality management approaches that drew on the use of clinical guidelines and measures. A final *quality improvement* period began after the implementation of new approaches to quality assurance in Medicare in the mid-1990s, and persists to the present day.

INSERT TABLE 1 HERE

The Interplay between Quality Paradigms in Academic Medicine and Medicare Policy

Peer Review Period—Individual expertise-based approaches to quality were the most prevalent paradigm between 1975 and 1984. For example:

“In the setting of clinical medical education, feedback refers to information describing students' or house officers' performance in a given activity that is intended to guide their future performance in that same or in a related activity. It is a key step in the acquisition of clinical skills, yet feedback is often omitted or handled improperly in clinical training...Once the nature of the feedback process is appreciated, however... the educational benefit of feedback can be realized” (Ende, 1983).

In this example, physician learning in the context of their clinical education is essential to improving quality. Consistent with other examples in my content analysis, the focus on development of clinical skills highlights the need for both formal knowledge and more tacit skills. Overall, 24.4 percent of all abstracts between 1975 and 1984, a total of 42 abstracts, used

individual expertise-based approaches to quality. In the same time period 5.8 percent of abstracts, a total of 10 abstracts, used rules-based approaches to quality.

Medicare policy in this period relied primarily on retrospective peer review of medical records. Experimental Medical Care Review Organizations (ECMRO) were created in 1971 to pilot a method of utilization review in which physician reviewers examined medical records on a case-by-case basis and formed judgments about the appropriateness of hospitalization and quality of care. ECMROs formed the basis for PSROs, created in 1972. To the extent that either EMCROs or PSROs managed quality, they assessed whether the care delivered was consistent with community standards (Bhatia, Blackstock, Nelson, & Ng, 2000). PROs, created in 1982 in the effort to rationalize and improve the PSRO program, continued used community standards as a basis for quality assurance (Bhatia et al., 2000; Institute of Medicine, 1990; Milgate & Hackbarth, 2005).

Policy Reorientation Period—Individual expertise-based approaches to quality remained important between the mid-1980s and mid-1990s, with 57 abstracts (13.3 percent) drawing on an individual expertise-based approach to quality between 1985 and 1994. Rules-based approaches increased in importance to 11.5 percent of the abstracts. Three new themes in this period reflect new developments in the use of clinical rules to define and manage quality.

First, research by John Wennberg and colleagues documenting geographic variation in health care played an important role in motivating a shift towards rules-based approaches to health care quality (Wennberg, Freeman, Shelton, & Bubolz, 1989). Second, a group of researchers at the Rand Corporation, most notably Robert Brook, published a series of articles documenting the prevalence of inappropriate care – based on clinical standards defined by expert panels (Chassin, Kosecoff, Solomon, & Brook, 1987). Third, a number of abstracts reported on

efforts of guidelines development task forces to create clinical practice guidelines, or on whether and when physicians followed clinical practice guidelines. These abstracts most clearly exemplify the growing prominence of rules-based approaches to quality. For example one abstract described is objective to “assess internist’s familiarity with, confidence in, and attitudes about practice guidelines issued by various organizations” (Tunis, Hayward, Wilson, Rubin, Bass, Johnston et al., 1994).

A small, but increased percentage of abstracts, 2.8 percent or 12 abstracts, also drew on measures-based approaches to quality. Half of these consider efforts by HCFA or state governments to release hospital or physician mortality statistics. For example:

“Public release of operator-specific data for cardiovascular procedures has set a new precedent, introducing the ‘scorecard’ era. Justification exists for public disclosure, but the mechanics of appropriate data release are complex from a clinical, statistical, and logistic standpoint” (Topol & Califf, 1994).

These changes in how rules- and measures-based approaches to quality were discussed in medical journal abstracts were accompanied by a reorientation in policies for managing quality in Medicare in the late 1980s and early 1990s (Bhatia et al., 2000; Milgate & Hackbarth, 2005). In 1986, Congress commissioned an Institute of Medicine (IOM) study to “design a strategy for quality review and assurance in Medicare.” As part of this charge, Congress requested that the strategy develop prototype criteria for reviewing and measuring quality (Institute of Medicine, 1990: xiii). The same year, William Roper was appointed as the Administrator for HCFA. He identified quality as one of his priorities, and aimed to redefine and improve quality management in Medicare (Santangelo, 1995).

Two years later, Roper announced HCFA's effectiveness initiative in an article in NEJM. The effectiveness initiative aimed to produce information about the effectiveness of specific medical interventions. Roper and his colleagues at HCFA emphasized that this reorientation of policy was motivated by research documenting geographic variation and the prevalence of inappropriate care (Roper et al., 1988: 1197).

Through the late 1980s, and early 1990s, HCFA experimented with promoting the use of clinical guidelines as tools for quality management in PROs. In 1993, HCFA implemented its Health Care Quality Improvement Initiative (HCQII), which was informed by the findings of the IOM study discussed above as well as research documenting geographic variation and the prevalence of inappropriate care. HCQII reorganized quality management in PROs to use principles of continuous quality improvement (Bhatia et al., 2000; Jencks & Wilensky, 1992; Wiener, 2000). The initiative shifted the focus of quality management in PROs from the use of "essentially intuitive local criteria to find problems in individual cases" towards the use of "explicit, more nationally uniform criteria to examine patterns of care and patterns of outcomes" (Jencks & Wilensky, 1992: 900).

Quality Improvement Period—There was a statistically significant increase in the use of both rules- and measures-based approaches between 1990-94 and 1995-99. Between 1995 and 2009, 20.7 percent of all abstracts focused on quality used rules-based approaches, while 10.6 percent used measures-based approaches. Articles using measures-based approaches to quality increasingly discussed pay-for-performance initiatives to tie incentives to performance on quality measures. For example:

"Value-based purchasing, or pay-for-performance, is a major emerging theme in U.S. health care. Forces enhancing adoption of pay-for-performance programs include continued increases in

medical costs beyond overall economic growth, a body of evidence that the quality of health care provided to patients is not directly related to the volume of services received, increasing evidence to serve as a basis for the development of standards against which to measure clinical performance, and increasing acceptance by physician organizations and individual practitioners of the rationale underlying these efforts” (Rowe, 2006).

Policies for managing quality in Medicare continued to use rules and measures. In 2002, Congress disbanded the PROs and reorganized them as Quality Improvement Organizations, with a mandate to implement collaborative quality improvement projects. In 2003, CMS, the successor agency to HCFA, launched the Premier Hospital Quality Incentive Demonstration, a pilot pay-for-performance initiative. In 2005, Congress passed legislation calling on CMS to develop a plan for implementing pay-for-performance by 2009, which will be implemented Fall 2012 (Ryan & Blustein, 2012).

DISCUSSION & CONCLUSION

My research offers empirical evidence of change in paradigms for conceptualizing and managing quality in academic medicine. Health care quality became an increasingly important issue in academic medicine in the United States between the 1970s and the present, with an increasing percentage of abstracts focusing on quality in three leading American medical journals over time. Concurrent with this growing emphasis on quality, rules- and measures-based approaches to quality increased in prominence, as a proportion of all abstracts focused on quality, over time.

While rules- and measures-based approaches to quality increased in prominence, they did not eclipse traditional paradigms, as suggested by some prior research (Freidson, 1994; Timmermans & Kolker, 2004). While individual-expertise-based approaches to quality decreased in prominence as a proportion of abstracts focused on quality, they persist as an

important paradigm for understanding and managing quality among professional elites. Although the proportion of abstracts that draw on individual-expertise based approaches to quality decreases over time, the absolute number does not. In fact, the average number of abstracts per year that uses an individual-expertise-based approach to quality increases over time, from an average of 4.8 per year in 1975-79 to 6.4 per year in 2005-09.

Rules- and measures-based approaches to quality increased in prominence after the period of policy reorientation in Medicare. While rules-based approaches to quality increased in prominence in the late 1980s, concurrent with the reorientation of Medicare policy, the larger increase in both rules- and measures-based approaches to quality took place after 1995. By this time, the Medicare program had already shifted towards the use of clinical guidelines and quality measures, as a basis for its quality management efforts.

Nevertheless, the case analysis suggests a recursive relationship between changing paradigms in academic medicine and changing policies for managing quality, consistent with the idea that multiple actors were responsible for the growth in guidelines and measures (Weisz et al., 2007). Though the largest increase in rules- and measures-based approaches to quality followed changes in Medicare policy, research published in the 1980s documenting geographic variation in medicine, and the prevalence of inappropriate care was important in motivating changes in Medicare policy that unfolded in the late 1980s and early 1990s (Jencks & Wilensky, 1992; Roper et al., 1988). The reorientation of Medicare policy, furthermore, began with pilot projects and research demonstrations by or in collaboration with researchers in academic medicine. The results of these research demonstrations were subsequently published in major medical journals, contributing to ongoing evolution in quality paradigms within academic medicine (e.g. Mehta, Montoye, Gallogly, Baker, Blount, Faul et al., 2002).

Appendix. Supplementary data

¹ A copy of the coding framework and annotated examples of coded abstracts can be found as an appendix to the online version of this article at [INSERT LINK TO ONLINE FILES]

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Table 1: Changing Policies for Managing Quality in Medicare	
Year	Event
1965	Medicare program created
1971	Experimental Medical Care Review Organizations (ECMRO) as pilot project for utilization review of Medicare hospitalizations
1972	Professional Standards Review Organizations (PSRO) created
1977	Health Care Financing Administration (HCFA) created with a mandate to administer the Medicare and Medicaid programs
1982	PSROs reorganized as Peer Review Organizations (PROs)
1986	Congress commissions the Institute of Medicine (IOM) to conduct a study to define a quality assurance strategy for Medicare
1986	HCFA decides to publish hospital mortality statistics to allow patients to make judgments about hospital quality
1988	William Roper, HCFA Administrator, publishes an article in NEJM announcing the “effectiveness initiative” to reorganize quality assurance strategies in Medicare
1989	Congress, with support from HCFA, created the Agency for Health Care Policy and Research, later renamed the Agency for Health Care Research and Quality, with a mandate to develop clinical guidelines
1993	HCFA implements the Health Care Quality Improvement Initiative (HCQII) to pilot the use of the principles of continuous quality improvement to improve quality
2002	PROs reorganized as Quality Improvement Organizations (QIOs)
2003	Center for Medicare Services (CMS) launches Premier Hospital Quality Incentive Demonstration, a pilot pay-for-performance initiative
Sources: (Bhatia et al., 2000; Institute of Medicine, 1990; Jencks & Wilensky, 1992; Milgate & Hackbarth, 2005; Roper et al., 1988; Wiener, 2000)	

Figure 1: Percent of Articles Focused on Quality

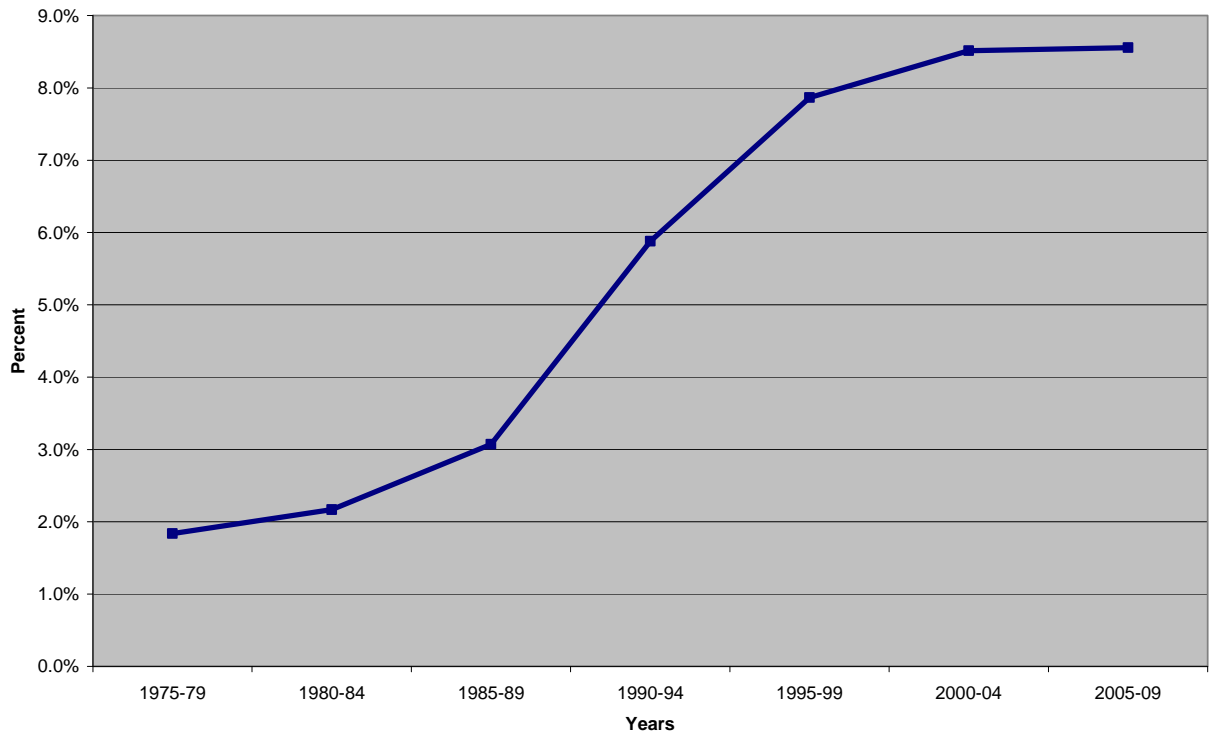


Figure 2: Changing Prominence of Health Care Quality Paradigms

