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**How institutional change and individual researchers helped advance clinical guidelines in
American health care**

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ABSTRACT

Clinical guidelines are important tools for managing health care quality. Research on the origins of guidelines primarily focuses on the institutional causes of their emergence and growth. Individual medical researchers, however, have played important roles. This paper develops knowledge of the role of individual medical researchers in advancing guidelines, and of how researchers' efforts were enabled or constrained by broader institutional changes. Drawing on an analytical case study focused on the role of Kerr White, John Wennberg, and Robert Brook, it shows that guidelines were a product of the interplay between institutional change in the medical field and actions by individual researchers, acting as institutional entrepreneurs. Increased government involvement in the health care field triggered the involvement of a range of new actors in health care. These new organizations created a context that allowed individual researchers to advance guidelines by creating job opportunities, providing research funding, and creating opportunities for researchers to engage with the policy process. Individual researchers availed of this context to both advance their ideas, and to draw new actors into the field.

Clinical guidelines have emerged as important tools for managing health care quality over the past forty years. Guidelines reflect the emergence of rules-based approaches to quality, in which the quality of care is determined by codified standards. The growing prominence of guidelines in the United States reflects a fundamental transformation in the institutions of American medicine, involving the extension of ideas from the enlightenment, which were used to guide work in the domain of public health since the late 19th century, to the practice of medicine. Prior to the rise of clinical guidelines, policy focused on standardizing medical training, but refrained from defining rules that could standardize physicians' work (Stevens, 2000). Clinical guidelines represent a reconfiguration of medical knowledge, including paradigms for understanding what quality health care means as well as practices for conducting clinical research (Lambert, 2006; Timmermans & Kolker, 2004; Weisz, Cambrosio, Keating, Knaapen, Schlich, & Tournay, 2007). Guidelines have impacted managerial practices and policy approaches to managing quality (Nigam, 2012a), status and power dynamics within the profession (Freidson, 1994; Menchik & Meltzer, 2010), approaches to learning among medical residents (Timmermans & Angell, 2001), and the roles and relationships between the medical profession and other powerful actors, including the state and purchasers of health insurance (Porter, 1995; Timmermans & Berg, 2003; Weisz et al., 2007).

Research on the origins of guidelines largely emphasizes that they are a product of institutional changes in the social organization of health care. Researchers have proposed that members of the medical profession created guidelines in the effort to preserve professional authority in the face of external calls for accountability (Armstrong, 2002; Freidson, 1994), or that multiple actors promoted them in the effort to impose coherence and order onto a growing, and increasingly complex health care system (Weisz et al., 2007). A smaller body of research

proposes individual medical researchers played an important role in advancing guidelines—highlighting the roles of John Wennberg, Robert Brook, and others in the United States, as well as Archie Cochrane and David Sackett in the United Kingdom and Canada (Gray, 1992; Gray, Gusmano, & Collins, 2003; Timmermans & Berg, 2003). While individuals clearly played an important role, the health care system is vast, complex, and notoriously difficult to change (Ferlie & Shortell, 2001; Lockett, Currie, Waring, Finn, & Martin, 2012). A challenge for research focusing on the role of individual actors is to explain how individuals are able to precipitate change in large and complex systems.

This challenge of conceptualizing the roles of both individual actors and systemic factors in precipitating a fundamental change in American medicine echoes a broader challenge in organizational theory. Since the 1970s, a significant body of research in organizational theory has developed knowledge of effect of institutions on social action (DiMaggio & Powell, 1991; Meyer & Rowan, 1977; Scott, Ruef, Mendel, & Caronna, 2000). Institutions include rules that govern behavior, the set of actors involved in a social domain, and institutional logics—sets of cognitive paradigms and material practices that guide action (Scott et al., 2000). Institutions impact social action at the level of the *organizational field*—the set of interdependent actors that make up a distinctive social domain and share a common system of meaning, such as the health care system, education system, or system of organized religion (Scott, 2001; Wooten & Hoffman, 2008). Early work in institutional theory focused on how institutions constrained action by defining the cognitive frameworks that actors drew on as well as actors' identities and interests (Friedland & Alford, 1991; Meyer & Rowan, 1977). Subsequently, researchers have increasingly examined the agency of actors in altering institutional arrangements. This shift toward a focus on individual agents raised the paradox of embedded agency—the challenge of

explaining how individual actors are able to change institutional arrangements that define and constrain their cognition and interests (Holm, 1995; Seo & Creed, 2002).

To address this paradox, researchers have conceptualized the role of *institutional entrepreneurs*—actors who are embedded in an institutional environment who engage in deliberate action to alter institutional arrangements (DiMaggio, 1988; Hardy & Maguire, 2008; Lockett et al., 2012). There are two prevailing explanations of how institutional entrepreneurship is possible. The first explanation identifies enabling conditions for institutional entrepreneurship, proposing that it is more likely in emerging fields, mature fields destabilized by disruptive events, and fields with a multiplicity of institutional logics (Battilana, Leca, & Boxenbaum, 2009; Hardy & Maguire, 2008). The second focuses on the characteristics of institutional entrepreneurs. Much of this work proposes that institutional entrepreneurs have unusual abilities of reflection or extraordinary political skill. A smaller body of work proposes that institutional entrepreneurs occupy a social position in a field that allows them to question existing institutional arrangements and gives them access to resources that would enable them to bring about change (Hardy & Maguire, 2008). Two shortcomings of these two approaches are that they devote limited attention to the co-evolution of organizational fields and embedded agency, and that they run the risk of glorifying institutional entrepreneurs as actors with preternatural powers of imagination or persuasive skill.

A third approach, less developed in existing research, would conceptualize institutional entrepreneurship as a process. This approach would examine the dynamic relationship between changing field conditions and efforts by individual actors in order to conceptualize the process by which individual actions to transform existing institutional arrangements can emerge and succeed (Battilana et al., 2009; Hardy & Maguire, 2008).

Consistent with this third approach, I seek to understand the processes by which individual researchers came to advance new approaches to health care quality in American medicine, and by which their efforts resulted in the institutionalization of guidelines. I develop an analytical case study that focuses on the roles of three individuals: Kerr White, John Wennberg, and Robert Brook. Kerr White was one of the earliest researchers to apply epidemiological principles to medical research. He played a critical role in creating health services research as a research domain within American medicine. Health services research is a “multidisciplinary field of inquiry... that examines the use, costs, quality, accessibility, delivery, organization, financing, and outcomes of health care services” (Institute of Medicine, 1995:3). White helped create the context within which John Wennberg and Robert Brook were able to advance ideas that formed the intellectual foundations for guidelines in the 1980s and 1990s.

I find that the institutionalization of clinical guidelines was an outcome of a recursive relationship between changes in *field composition*—the set of actors involved in an organizational field and the actions of institutional entrepreneurs. Growing federal government involvement in health care after World War II changed field composition by drawing new federal agencies and private organizations into the organizational field of American medicine. This shift in field composition created a favorable context for institutional entrepreneurship by creating job opportunities, sources of research funding, and access to the political process that were critical in allowing White, Wennberg, and Brook to advance new paradigms. White, Wennberg and Brook worked to further alter field composition, by drawing new actors into the organizational field. These new actors played a critical role in institutionalizing clinical guidelines.

I examine the emergence and institutionalization of guidelines across three time periods. *A setting the stage* period began with growing involvement of the federal government in the

health care system after World War II, and persists until 1968, the year that the National Center for Health Services Research (NCHSR) was created as a unit within the federal government. This ushered in a period of *mobilization* in which Wennberg and Brook worked to advance clinical guidelines as frameworks for conceptualizing and managing quality. The mobilization period persists until 1989, when Congress created the Agency for Health Care Policy and Research (AHCPR)—later renamed the Agency for Health Care Research and Quality (AHRQ)—as a new federal agency, replacing NCHSR, with a specific mandate to develop clinical guidelines and fund health services research. This triggered a period of *institutionalization* in which clinical guidelines became established as widely accepted frameworks for thinking about, measuring, and managing quality.

DATA AND METHODS

I use case study methods (Yin, 2003), analyzing primary and secondary texts of the history of health services research, and of specific efforts to advance clinical guidelines to develop knowledge of how the interplay between organizational fields and individual researchers led to the growing importance of guidelines. I analyzed archived interviews with and memoirs by key figures in the history of health services research, including White, Wennberg, and Brook. I also analyzed a broad range of other primary texts, including published first-person accounts outlining the activities of key actors (Flook, 1969; Huntley, 1969; Roper, Winkenwerder, Hackbarth, & Krakauer, 1988), conference proceedings, published articles outlining new approaches to health care quality (Flook & Sanazaro, 1973; Iglehart, 1984), and Institute of Medicine (IOM) reports. Finally, I analyzed secondary histories of the field of health services research and the creation and histories of both AHCPR and the IOM.

In analyzing the primary and secondary texts, I sought to systematically identify examples of the effects of new or established actors in the health care system to assess the impact of changing field composition. I coded the texts for evidence highlighting the context for institutional entrepreneurship, including evidence of direct or indirect support for individuals' efforts to advance clinical guidelines specifically, or to promote health services research more generally. I identified examples of actions that played a role in drawing new actors into the organizational field to develop insight into how field composition changes.

CASE ANALYSIS

Setting the Stage, 1944-1968

The period after World War II was marked by growing federal involvement in the health care system, which facilitated the field's expansion and increased its complexity (Starr, 1982; Weisz et al., 2007). Prevailing beliefs in medicine emphasized that quality could best be produced by well-trained professionals exercising judgment about how to treat individual patients (Nigam, 2012b; Timmermans & Berg, 2003).

Field Composition. A series of laws expanded the federal government's role in American medicine between World War II and the 1960s. This legislation impacted field composition by mandating the creation of specific agencies or organizations within the U.S. government to play a role in the health care system. In 1944, the federal government substantially increased the size of the extra-mural grant programs—funding primarily university-based medical research—of the National Institutes of Health (NIH), expanding its role as an actor in the health care system (Dunn & Jones, 2010; Starr, 1982). In 1963, the Health Professions Educational Assistance Act financed expansion in medical schools, facilitating growth in academic medicine (Dunn & Jones, 2010; MacBride, 1973). In 1965, the federal government created Medicare and Medicaid,

offering government financing of health care for the elderly and poor, marking an unprecedented expansion in the federal government's involvement in health care (Starr, 1982; Stevens, 2000). The creation of Medicare expanded the role of the federal government's Department of Health, Education, and Welfare (HEW)—since renamed the Department of Health and Human Services (HHS)—in the healthcare field. In the same year, Congress created the Regional Medical Program (RMP) to promote rural access to the benefits of academic medicine and medical research. The RMP facilitated cooperative relations between medical schools, research institutions, and hospitals through its regional offices (U.S. Department of Health Education and Welfare, 1967; Wennberg, 2010).

As part of this expansion, the federal government began to finance health services research. Complementing its role in financing hospital construction, Congress designated \$1.2 million for “hospital research and demonstrations” in 1955 (Berkowitz, 1998d; Flook, 1969). The NIH created the “hospital facilities research” study section in 1955 to administer its funds, which were first distributed in 1956 (McCarthy & White, 2000). Subsequent legislation increased federal funding for health services research through the late 1950s and early 1960s (Flook, 1969; McCarthy & White, 2000).

Complementing the federal government's direct effects on field composition—including the involvement of the NIH, HEW, and fifty-four offices of the RMP—the government's increased role also had indirect effects on field composition. Financing of medical research and education promoted growth in academic medicine, including physician researchers with faculty positions at major medical schools and teaching hospitals (Berkowitz, 1998e; Dunn & Jones, 2010; Starr, 1982). Growth in medical schools and in federal financing for health services research was accompanied by the emergence of health services research departments. The

federal government's growing role in the medical field was also accompanied by increased funding and activity by major private foundations aimed at influencing policy (Berkowitz, 1998e; Flook & Sanazaro, 1973; Iglehart, 1983).

Context for Institutional Entrepreneurship. These changes in field composition helped create a context within which Kerr White was able to establish health services research as an area of research within the medical profession. Kerr White was one of the first researchers in the United States to use epidemiological principles to examine patterns of medical care. His work used epidemiological methods to look at patterns of patient care in order to develop knowledge of whether medical care was doing more harm than good, and whether physicians were responding to concerns expressed by patients. One important goal in his career was to put in place systems for systematically collecting data about what physicians did in caring for populations of patients in order to allow researchers to make empirical judgments about the quality of care in the system. His work represented a sharp break from existing clinical research, which focused on the mechanisms of disease, and represented a challenge to prevailing beliefs that medical professionals consistently provided the care that benefitted patients, and that the quality of care could best be judged by individual physicians (Berkowitz, 1998d).

White's interest in using epidemiological approaches to study medicine was informed by the influence of Jerry Morris, head of the United Kingdom Medical Research Council's Social Medicine Research Unit at the London Hospital. Morris was a pioneer in the use of epidemiological principals for understanding medical care in the U.K. White's interests were also shaped by his involvement with an interdisciplinary group of peers at the University of North Carolina, where he participated in a workshop that included physician researchers, public health scholars, and sociologists with an interest in health and medicine (Berkowitz, 1998d).

While various intellectual influences shaped White's desire to use epidemiological principals to examine patterns of medical care, changes in field compositions created job opportunities that allowed White to advance his ideas and establish a career as a health services researcher. After completing his training, White took his first faculty job as an assistant professor at the University of North Carolina (UNC) medical school in 1952. He described this job as a product of the expansion of medical education:

[University of North Carolina] was a two-year school and it became a four-year school in 1952-53; in fact it was the first new four-year school after World War II. There had been no clinical faculty before when it was a two-year school, so we were among the first clinical faculty there and it blossomed forth (Berkowitz, 1998d).

Ongoing changes in the field created a sequence of job opportunities that allowed White to develop a career. In 1962, White was offered a job in a newly created department of Epidemiology and Community Medicine at the University of Vermont, potentially the first medical school department using the word epidemiology. He viewed this job as an opportunity to pursue his intellectual interests—using epidemiological principals for examining population-level patterns of medical treatment. At Vermont, he attempted to put in place a system for collecting population-level data on physician practices, an effort that was unorthodox at the time. He described the opposition he faced:

It turned out to be a much more difficult task than I had envisaged. We had quite a time. I was called a communist by the medical society, and I was hauled up before the trustees of the medical society. I talked to rooms full of lawyers, hospital boards, and administrators (Berkowitz, 1998d).

Shortly after arriving in Vermont, he was offered a job as head of a newly created department of Public Health Administration at Johns Hopkins University, one of the most prestigious universities for medical and public health research in the country. Describing the

rationale for the new department, White said that “Medicare and Medicaid were just coming in and I think they hired me to give a course on how to fill out Medicare forms” (Berkowitz, 1998d). Describing his decision to leave Vermont, White recalled:

They offered me a substantial budget and prime real estate, originally in the hospital itself. I thought, “Well, you can probably say things from Hopkins that you can’t say from Vermont, or you can say the same sort of things but your colleagues pay more attention when you come from Hopkins” (Berkowitz, 1998d).

Changing field composition in American medicine also created new resources that allowed White to pursue his research. In 1956, while at UNC, White applied for and received a grant from the first batch of funds made available for “hospital facilities research” through the Hill-Burton Act. Through his time at UNC, he was also able to get funding from major foundations, including the Commonwealth Fund and the Rockefeller Foundation, to support his research. As head of a new department at the University of Vermont, he had a large research budget that he could use to do population-based studies. He also was able to get additional funding from the NIH.

Finally, changing field composition created opportunities for participation in the political system. In 1956, a year after receiving his first NIH grant, through the Hill-Burton act, White was appointed to the NIH’s Hospital Facilities Study Section, the first NIH study section dedicated to administering funds for health services research. He later became head of a reorganized “health services research” study section (McCarthy & White, 2000). He used this avenue to help establish health services research as a field of research within medicine, and create the NCHSR as an organization within the federal government to coordinate and fund health services research.

Practices of Institutional Entrepreneurs. Facilitated by the changing context for institutional entrepreneurship, White, in addition to advancing new ideas, further changed field composition by helping create NCHSR. He was able to do so, in part, because of his role as a member of the Hospital Facilities Research study section at NIH. Together with the section's executive secretary, Thomas McCarthy, he engaged in a multi-pronged effort to help establish health services research as a legitimate research domain. Among their efforts, they forged relationships with individuals representing different interest groups, including the American Hospital Association, the American Medical Association, and administrators in HEW. Through these meetings, they helped define a collective goal to work for the creation of a unit in the Office of the Assistant Secretary of HEW to coordinate and fund health services research (McCarthy & White, 2000). Given this collective goal, White recounted that a "loose coalition lobbied [the] Assistant Secretary of HEW and others in the federal government to get NCHSR established" (Berkowitz, 1998d). As an important new actor for coordinating and funding health services research, the NCHSR played an important role in facilitating subsequent efforts—by John Wennberg, Robert Brook, and others—to advance the intellectual foundations for guidelines.

Mobilization, 1969-1989

The growing federal government role in health care through the 1950s and 1960s set in motion processes that brought additional actors into the field in the 1970s, including the Institute of Medicine (IOM), the RAND Corporation, and the Health Care Financing Administration (HCFA). Within this context, John Wennberg and Robert Brook worked to advance ideas that formed the basis for guidelines development in the United States. John Wennberg published his research documenting geographic variations in patterns of medical treatment. He found that

geographic variation could not be explained by clinical factors, and that greater use of surgical procedures was not associated with better outcomes. Based on his findings, he concluded that there was limited scientific basis for much medical practice (Wennberg, 1984; Wennberg & Gittelsohn, 1973). Wennberg cites White and his research as a key intellectual influence, observing that White, a mentor, taught him “the importance of using the tools of epidemiology to study the health care system” (Wennberg, 2010: xi). Wennberg, like White, was also informed by an interdisciplinary background. In addition to his medical training, Wennberg got a degree in epidemiology, and enrolled in a Ph.D. program in Sociology. This interdisciplinary training helped motivate his early research looking at patterns of care across small areas first in Vermont, and later in Maine.

Robert Brook published his work on the appropriateness of care. This research used an expert-defined clinical standard defining appropriate care for particular medical diagnoses to document the prevalence of appropriate and inappropriate care. These expert derived standards of appropriateness were codified rules, similar to clinical guidelines, and an important precursor to more evidence-based standards (Chassin, Kosecoff, Park, Winslow, Kahn, Merrick et al., 1987). Like Wennberg, he also credits White’s intellectual influence as a mentor (Brook, 1997).

Building on and extending an earlier generation of work in the field of health services research, Wennberg and Brooks’ research created an intellectual foundation for clinical guidelines by emphasizing a need for a better grounding of medical practice in science. Their efforts were enabled both by earlier changes in field composition, and by the prior efforts of Kerr White to establish health services research as a legitimate field of research within medicine.

Field Composition. The growing federal government involvement in the health care system, combined with changes in field composition, drew additional actors into the medical

field. For example, the IOM was established in 1970 as an institute within the National Academies of Sciences. The IOM was created as a professional body of experts that would provide advice to the federal government and inform health policy. The IOM's creation was possible because of earlier changes in field composition, including the growth in academic medicine, the involvement of the National Institutes of Health, and the increased involvement by foundations in the field. (Berkowitz, 1998e).

The RAND Corporation's entry into the field of American medicine was similarly triggered by past changes in field composition. RAND was a policy research organization that did contract research for the Department of Defense. Motivated by President Lyndon Johnson's war on poverty, RAND became interested in adding programs focused on social policy in the mid-1960s. Partially in response to the creation of Medicare and Medicaid, it chose health as one of two social policy areas (Berkowitz, 1998a, b, c).

Finally, the Medicare and Medicaid programs led to the creation of additional government agencies that played a role in the medical field. In 1972, the government created Professional Standards Review Organizations (PSROs) to monitor the quality and utilization of care by Medicare patients (Bussmann & Davidson, 1981). The PSROs were modeled on Experimental Medical Care Review Organizations, which were created as a pilot project funded by NCHSR (Salive, Mayfield, & Weissman, 1990). As Medicare and Medicaid expenditures continued to rise, the Secretary of HEW in the Carter Administration created the Health Care Financing Administration (HCFA), a unit within HEW with a specific mandate to administer Medicare and Medicaid. HCFA became an additional source of research funding as well as an important source of data (Berkowitz, 1998e; Roper et al., 1988; Santangelo, 1995).

Context for Institutional Entrepreneurship. This growth and increased complexity in the medical field created a context in which John Wennberg and Robert Brook could both develop careers as medical and health services researchers, and advance new ideas. Changes in field composition created new sources of employment for both Wennberg and Brook. Wennberg, on finishing his training at Hopkins, took his first job as a faculty member at the University of Vermont, and as the director of Vermont's RMP. He described getting this job as the RMP director as a "lucky break" that gave him the resources to do his first work on geographic variation. (Wennberg, 2010:15).

Brook, on finishing his training, began his career as a research fellow at NCHSR. He then joined the first cohort of Robert Wood Johnson Foundation clinical scholars, a fellowship program created to give medical researchers experience with the policy process (Altman, 1995). After his fellowship, he moved to RAND, where he was hired as the clinical director for the health insurance experiment. It was at RAND that he was able to do his initial research documenting the prevalence of appropriate and inappropriate care (Berkowitz, 1998b, d).

Changing field composition also created new sources of research funding that allowed Wennberg and Brook to advance their ideas. Brook's work at the RAND corporation was funded by NCHSR (Berkowitz, 1998b). Wennberg recounts receiving critical funding from a number of sources. In addition to his budget as director of Vermont's RMP, Wennberg received funding for his early work on variations, first in Vermont and later in Maine, from NCHSR, the Robert Wood Johnson Foundation, the Commonwealth Fund, and the Hartford Foundation (Wennberg, 1984, 2010).

Finally, changing field composition created new opportunities for Wennberg and Brook to participate in the profession and the policy process, and to publicize their ideas. Brook was

able to participate in the medical profession as a member of several IOM study panels, starting with a study section examining efforts to manage quality in Medicare (Brook, 1995; Institute of Medicine, 1974). The IOM and foundations similarly helped give Wennberg critical access to the public policy process. Wennberg credits a 1983 conference on geographic variation, combined with a subsequent press conference in Washington, DC, with sparking policy interest in new approaches to health care quality (Mullan, 2004; Wennberg, 2010). The initial conference was convened by the IOM with the aim of bringing research on geographic variation and inappropriate care to the attention of a broader audience. It was accompanied by a press conference, as well as a policy forum, which gave Wennberg the opportunity to form relationships with both members of Congress as well as key Congressional staffers. The Hartford Foundation further publicized the ideas discussed in the conference by underwriting a special issue focused on geographic variation in the journal *Health Affairs*, in which Wennberg outlined his policy proposals for addressing the problem of geographic variation (Wennberg, 1984). His proposals formed the basis for a number of proposed pieces of legislation between 1985 and 1989 (Gray, 1992). The initial ties to policy audiences facilitated by the conferences and special issue helped guide Wennberg's efforts to advance new paradigms.

Practices of Institutional Entrepreneurs. Wennberg and Brook both helped draw new actors into the field. Both played important roles in creating the Association for Health Services Research (AHSR), a professional association for health services researchers, in 1981. Wennberg played a particularly critical role in creating the AHCPR as a new federal agency with a specific mandate to develop clinical guidelines. Gray (1992) underscores his role, noting "Wennberg was there at the beginning and the end and was the common denominator of everything that

happened in between. He testified at almost every relevant congressional hearing, and his name was invoked by almost every witness” (44).

Wennberg deliberately cultivated ties with policy makers. In alliance with AHSR, he worked to lobby for increased federal financing for health services research. He met Senator David Durenberger through the 1983 conference on geographic variation, and cultivated relationships with Durenberger and his staff in the following years. In 1987, Durenberger sponsored legislation that funded Patient Outcomes Research Teams to develop clinical guidelines for specific conditions. Wennberg continued to testify before Congress and lobby for the creation of a new federal agency for funding health services research. These efforts ultimately resulted in the creation of AHCPR with a mandate to finance health services research and create clinical guidelines in 1989 (Gray, 1992; Mullan, 2004; Wennberg, 2010).

Institutionalization, 1990—present

After the creation of AHCPR, clinical guidelines became institutionalized as a central approach towards managing and achieving health care quality (Milgate & Hackbarth, 2005; Nigam, 2012b). This consolidation of the importance of clinical guidelines was a product of past changes in field composition which created a group of actors—including the newly created AHCPR—that played a collective role in advancing guidelines as new approaches to managing quality. The impact of HCFA’s effectiveness initiative—a program to finance research that would improve the quality of care for Medicare patients—illustrates. William Roper, HCFA administrator during the Reagan administration, announced the effectiveness initiative in an editorial in the *New England Journal of Medicine* in 1988. Drawing on Wennberg’s ideas, he identified “wide variations in practice patterns” as a primary motivation for embarking on the initiative (Roper et al., 1988). After announcing the initiative, HCFA commissioned a report

from the IOM to define the clinical goals and organization for the initiative (Institute of Medicine, 1989). At the same time, Roper joined Wennberg and AHSR in advocating for the creation of AHCPR to Congress and the White House (Gray, 1992; Gray et al., 2003; Santangelo, 1995). Concurrent with the start of the initiative and the creation of AHCPR, HCFA commissioned the IOM to convene a study that would identify new approaches to quality assurance in Medicare (Berkowitz, 1998c; Institute of Medicine, 1990, 1991; Lohr, 1995). Two reports from the study recommended that Medicare quality assurance could adopt principles of total quality management, using clinical rules, quality data, and feedback of performance information to physicians and hospitals to continuously improve quality of care (Institute of Medicine, 1990, 1991). HCFA used these findings to fund pilot projects by teams of medical and health services researchers. Over time, it fully embraced the findings of the IOM report, reorganizing the Medicare PROs as Quality Improvement Organizations in 2002 (Milgate & Hackbarth, 2005).

Context for Institutional Entrepreneurship. At this time, both Wennberg and Brook were well established in their careers. Wennberg had left his position at the University of Vermont to take a faculty position at Harvard University's medical school. He moved to Dartmouth University in 1972, where he was hired as Associate Professor of Epidemiology. He was promoted to Full Professor in 1980. Brook remained at the RAND Corporation, where he became Director, and then Vice President of RAND's health programs.

Opportunities for Brook and Wennberg to participate in the profession and policy process also reflected their increased professional status and the embrace within academic medicine of the ideas that they advanced in their careers. There was a proliferation of IOM study panels dealing with issues relating to health care quality through the 1990s. Brook and his protégés were

regularly invited to serve on study panels. Both Brook and Wennberg were elected as members of the Institute of Medicine in the 1980s. In 1986, the IOM established the Gustav Lienhard Award to recognize career achievement in improving health care services in the United States. The IOM recognized Brook's work with the Lienhard award in 2005, and Wennberg in 2008.

DISCUSSION

I develop an account of the process by which the interplay between institutional change in health care and the actions of individual medical researchers led to the emergence and institutionalization of clinical guidelines in American medicine. My central argument is that growing government involvement in American health care after World War II brought about changes in field composition—the set of actors involved in the health care field—by drawing new federal agencies, private foundations, the Rand Corporation, and the IOM into the medical field. These new actors created a favorable context for institutional entrepreneurship, enabling Kerr White, John Wennberg, and Robert Brook to advance new paradigms that led, over time, to the institutionalization of clinical guidelines in American medicine.

My focus on the importance of changing field composition differs from prior research identifying systemic causes of the shift towards guidelines. Researchers develop two main arguments explaining how systemic change led to the shift towards guidelines. Freidson (1994) advances the first argument, proposing that escalating health care costs provoked the state and private purchasers of health insurance to increasingly hold medical professionals accountable for the cost and quality of health care. In response, elite members of the medical profession developed clinical guidelines as a way of demonstrating accountability and preserving professional authority or medical dominance. My account differs from Freidson in that it does not emphasize the idea that powerful actors placed new demands on the profession. Rather, it

focuses attention on opportunities for research created by the entry of new actors. Nor does my account suggest that guidelines were a product of efforts to maintain professional dominance. Rather it reflects the efforts of medical researchers to advance new ideas that they believe are important to improving quality.

The second argument proposes that states and other actors created guidelines as tools for regulating an increasingly fragmented and complex system. My work is broadly consistent with this argument. It differs, however, in two ways. First, I highlight the role of individual researchers in creating an intellectual foundation for clinical guidelines. These researchers played a critical role in defining the professional problem—the lack of a scientific basis for medical practice—that could be solved through the use of guidelines. It was only after medical researchers defined the problem to create an intellectual foundation for guidelines that state agencies used them to impose order on the health care system. Second, my work focuses attention on specific resources—job opportunities, research funding, and opportunities for participating in the political process—that allowed individual medical researchers to advance new ideas.

Finally, my work differs from research focused on the role of individual researchers in driving change. While White, Wennberg, and Brook played critical roles, as individual researchers, in advancing clinical guidelines, I focus attention on the role of systemic change in health care in making their careers possible, and in enabling their efforts to advance new paradigms.

CONCLUSIONS

My work has two broader implications for contemporary debates about embedded agency in organizational theory. First, distinct from prior work identifying enabling conditions for

institutional entrepreneurship, I show how ongoing changes in field composition—set in motion both by the federal government’s growing role in health care and by the efforts of institutional entrepreneurs—enabled and constrained efforts to advance clinical guidelines over time. This suggests that future work should more closely examine the dynamic relationship between organizational fields and embedded agency. While I focus on the importance of the changing set of actors in a field in enabling institutional entrepreneurship, future work could explore how other changing aspects of fields including the relational orientation of actors towards one another (Bourdieu & Wacquant, 1992), or the mix of institutional logics (Thornton & Ocasio, 2008) could shape the potential for embedded agency over time. Second, in focusing on the role of institutional entrepreneurs in drawing new actors into the medical field, my work suggests that future work could explore a broader range of practices of institutional entrepreneurship. Empirical work on institutional entrepreneurship has focused almost exclusively on their use of discursive practices (Battilana et al., 2009). I highlight the role of institutional entrepreneurs in altering field composition, a topic that has not been explored in prior work. This suggests the need for additional research, however, exploring other, non-discursive practices that institutional entrepreneurs can draw on to alter existing institutional arrangements.

My work also has implications for our knowledge of how policy can create a context that supports intellectual innovation in medicine. My work provides evidence suggesting that the present set of policies for managing quality, including the contemporary push towards pay-for-performance (Ryan & Blustein, 2012), is an outcome of both the expansion of the government’s role in health care post-World War II and the idiosyncratic paradigms advanced by individual institutional entrepreneurs. The emergence of health services research as an area of inquiry was in part an unintended outcome of federal policy choices that created relatively unconstrained

resources in support of medical research. Policies to expand medical education by creating new research oriented medical schools, or to create new funding sources for novel but loosely defined research areas such as “hospital facilities research,” created resources that individual researchers could appropriate to advance research programs that were not directly anticipated or intended by federal policy makers. These research paradigms were only subsequently embraced by policy makers.

The Accountable Care Act is a similar expansion in the federal government’s role that, in addition to expanding health insurance coverage and reforming health care delivery, will likely create new resources that could support intellectual change in academic medicine. How the act is implemented, including the types of organizations created under the act and the research resources created through it will influence the act’s impact on the generation of new paradigms and ideas in medical research. My work highlights that small pools of resources to create context that supports novel and unanticipated ideas can have significant effects. Legislation creating the Center for Healthcare Innovations as part of the Accountable Care Act in the United States suggests that policy makers are interested in creating a context in which new ideas about health care delivery can be developed and flourish (Grumbach K, 2009). It is unclear that the implementation of health care reform under the act will be accompanied by new extra-mural or peer reviewed funding that could further support the development of new ideas. Policy makers should be mindful of the effects that their choices in implementing major policy shifts can have indirect and unintended consequences on the context for intellectual innovation in medical research. Future work, however, is also needed to better understand how specific policies impact the potential for innovation in research examining how the health care delivery system can better achieve the goals of reduced cost and increased quality

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