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

Amit Nigam*

Cass Business School, City University London, 106 Bunhill Row, London EC1Y 8TZ, UK

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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.

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Introduction

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 et al., 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

* Tel.: +44 (0)20 7040 8747; fax: +44 (0)20 7040 8328.
E-mail address: amit.nigam@city.ac.uk.

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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

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