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The Strategic Defense of Physician Autonomy: State Public Health Agencies as Countervailing Powers

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Abstract

Advances in genetic testing and the aggressive marketing of genetic tests by commercial diagnostic laboratories have driven both consumer demand and the need for unbiased information about how tests should guide healthcare delivery. This paper uses the countervailing powers framework to explore the role of state public health agencies as arbiters of quality and safety, specifically through their efforts to encourage physicians to follow evidence-based recommendations for screening for hereditary cancers. Social scientists have often viewed actions by the state to regulate cost, quality, or safety as a threat to physician autonomy. This paper draws on case studies from two US states—Michigan and Connecticut—to better understand the specific role of state public health agencies, and especially whether their activities to encourage adherence to evidence-based recommendations bolster or subvert the interests of other parties in the healthcare arena. We find that lacking authority to compel provider to follow evidence-based recommendations, they improvised ways to foster compliance voluntarily, for example, by emphasizing the role of the physician as gatekeeper, thus affirming the importance of physician autonomy and clinical judgment. Both states also used public health surveillance data to make rare diseases visible and illustrate gaps between recommendations and practice. Finally, they both showed that following evidence-based recommendations could align the professional and market interests of healthcare stakeholders. Both states employed similar strategies with similar effects, despite substantial differences in the regulatory climate and organizational capacity. Taken as a whole, their activities orchestrated a countervailing response that checked the profit-seeking motives of commercial laboratories. Our findings demonstrate that rather than eroding physician autonomy, state action to monitor healthcare quality and encourage adherence to evidence-based recommendations can actually reinforce physician authority.

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Keywords

United States; health care quality; Evidence-based medicine; genetic testing; professional autonomy; countervailing powers; public health policy; public health organizations

Introduction

The high expectations for personalized medicine that dominate the post-genomic era and the aggressive marketing of genetic tests by commercial laboratories have created the need for unbiased information on how to use genetic tests to improve healthcare delivery. To promote healthcare quality and ensure the appropriate use of these genetic tests, expert panels have issued evidence-based recommendations on using genetic tests to identify patients who may be at especially high risk for disease. Efforts to direct healthcare quality—whether through issuance of evidence-based recommendations or alternative mechanisms—do not, however, influence healthcare delivery as rapidly as we might expect (Greenhalgh, Howick, & Maskrey, 2014; Timmermans, 2010). In the United States, federal and state public health agencies have launched educational programs, surveillance projects, and policy initiatives to monitor and promote appropriate use of genetic testing, viewing these projects as related to their mission of improving overall population health. In doing so, they have positioned themselves as an “honest broker,” to disseminate unbiased information about the appropriate use of genetic tests (Bowen, Kolor, Dotson, Ned, & Khoury, 2012; Khoury et al., 2011).

These efforts by federal and state health agencies provide a new vantage point for understanding how efforts to monitor healthcare quality may trigger conflict in the healthcare arena—especially longstanding tensions between physicians (who view themselves as professionals and who therefore expect autonomy and respect in their professional clinical judgment), and governmental regulatory agencies (who have, with increasing regularity, exercised state power to ensure healthcare quality and control costs). Medical sociologists and health policy scholars have drawn upon Light’s (1991) countervailing powers framework to understand both conflict and cooperation in the healthcare arena; this line of research has often viewed innovations such as evidence-based recommendations as mechanisms for curtailing professional autonomy. In this paper, we apply the countervailing powers framework to identify the strategies that public health agencies use in promoting healthcare quality. To date, medical sociologists have largely ignored the role of public health agencies in the healthcare arena. We argue that the countervailing powers framework could be applied to this phenomenon, and even be expanded in two ways. First, we argue that sociologists should view the state as a multi-faceted entity made up of organizations that occupy specific bureaucratic niches (e.g., agencies that license or regulate healthcare practitioners vs. others that monitor and promote public health). Specifically, sociologists should recognize that public health agencies generally wield less power in the healthcare arena than agencies that issue licenses or pay for healthcare services, and may therefore need to adopt a cooperative, rather than conflictual, stance in relations with physicians. Second, we argue that sociologists should examine variations in organizational capacity across states, which might produce variations in health policy and clinical practice in different regions of the US.

To address this gap, we present case studies of two state public health agencies—Michigan and Connecticut—and analyze the repertoire of activities they have developed to promote compliance with evidence-based recommendations for genetic testing, specifically for hereditary breast and ovarian cancers (HBOC). HBOC screening is an interesting application that straddles both the clinical and public health realms. Since the discovery of the BRCA1/2 genes in the mid 1990s, patients and providers have had to negotiate the utility of genetic testing in directing clinical care for individual women, i.e., whether a woman could benefit from early screening or surgical intervention. Over time, various professional societies have issued recommendations to regularize HBOC screening for high-risk women, at least for women with a family history of the disease (U.S. Preventive Services Task Force, 2013). Because early action on HBOC screening has preventive potential, however, it is also relevant to public health, and public health policymakers have begun to promote adherence to evidence-based recommendations for HBOC screening as a means of reducing overall breast cancer morbidity and mortality (Khoury et al., 2011; U.S. Preventive Services Task Force, 2013). This paper addresses three research questions: first, what strategies do public health agencies use to promote adherence to evidence-based recommendations; second, do variations in organizational capacity across states necessarily lead to different strategies to promote evidence-based practice; and third, how do state health agencies align their own interests with the interests of other stakeholders in these endeavors.

Background

The Countervailing Powers Framework

Medical historians and sociologists have documented the complex and variable relationship between the state (writ large) and the medical profession. These narratives often depict the early decades of the twentieth century as a ‘Golden Age of Medicine,’ when physicians exercised complete discretion over clinical decision-making (Freidson, 1970; Starr, 1982). During this era, the state played an essential role in enhancing medical professional authority by granting physicians an exclusive right to practice through licensure. The state also curbed competition by disreputable practitioners, regulated the patent medicine industry, and limited healthcare delivery in public health clinics (Starr, 1982). This endowed physicians with tremendous power and allowed the profession to pursue its professional and economic self-interests unchecked for decades, unfortunately resulting in variable healthcare quality and escalating healthcare costs (Light, 2000). These problems led to what Light and others have described as the ‘Buyer’s Revolt,’ or a rebalancing effort by other parties in the healthcare arena (especially purchasers such as the state or private insurers, most visibly with the passage of Medicare in the 1960s) to influence clinical decision-making and thus improve patient outcomes and curtail costs (Light, 1991, 2000).

In response to these fluctuations in physician autonomy, Light’s (1991) countervailing powers framework was developed to explain shifting power dynamics among actors in the healthcare arena. This framework has generally depicted physicians as increasingly embattled, with external actors—especially the state—posing escalating demands for accountability, cost effectiveness, and quality of care, potentially encroaching upon medical authority and eroding professional autonomy (Hafferty and Light, 1995; Light, 1991; Starr,

1982). Fields or arenas are, however, inherently dynamic. The healthcare arena has become populated by a growing number of organizational, professional, and institutional entities: not only healthcare professionals and state regulatory agencies, but also third-party payers, patient advocacy groups, and pharmaceutical or biotech companies.

A key element of the countervailing powers framework holds that as one party accumulates power, other actors will “muster their forces in an attempt to control the first” (Light, 1991, p. 500). The goals and interests of these actors sometimes meet and sometimes diverge, allowing for “significant alignments,” which may be coincidental or deliberate (Light, 2000, p. 203). For example, recent work has shown that various actors in the healthcare field, including physicians, state regulatory agencies, medical professional societies, medical schools, and medical journal editors have orchestrated a countervailing response to curb abuses by the pharmaceutical industry (e.g., influencing physician prescribing practices by offering commercial inducements or ghost-writing articles that position their products favorably in medical journals; Angell, 2000; Relman, 2007; Studdert et al., 2004). But although recent scholarship has applied the countervailing powers framework to study conflicts and allegiances between the medical profession and the pharmaceutical industry (e.g., Busfield 2010), medical sociologists have largely ignored the role of public health agencies in the healthcare arena. And because public health activities in the US are directed at the state level, we also do not know how state-level variations in public health policy may produce regional variations in healthcare quality.

Evidence-Based Guidelines as a Means of Promoting Healthcare Quality

In addition to understanding power relations within the healthcare arena, the countervailing powers framework may also be used to understand the types of systemic dysfunction that produce substandard care and lead to poor health outcomes, as well as the quality improvement initiatives that have sought to eliminate medical errors and improve healthcare quality (Zuiderent-Jerak & Berg, 2010). Quality improvement research has often examined efforts to standardize healthcare, sometimes through the imposition of specific performance metrics and other times by studying team-based learning and collaborative efforts to develop best practices. Another strand of this research has focused on designing reliable healthcare systems, and reducing the room for error. To date, however, this literature has been dominated by researchers within the healthcare profession, and has therefore ignored many interesting sociological questions, for example, about the division of labor in the healthcare field. Our paper specifically highlights the often-invisible work done by public health agencies. Public health agencies collect myriad data to monitor the health of the public and also provide important services by educating providers and the public about innovations in disease screening.

The sociological literature on evidence-based medicine (EBM) also provides a vantage point for understanding efforts to standardize healthcare delivery. EBM has sought to transform medical practice from a reliance on individual clinical judgment to decision-making based on a critical reading of the experimental literature (Timmermans, 2010). Policymakers find EBM appealing because it addresses pressing concerns in contemporary health policy, namely, variable quality and escalating costs (Institute of Medicine, 2001). Sociological

research has explored the epistemological battles that go into the formulation of clinical practice guidelines, the effects of EBM on medical training and physician authority, and the way EBM has influenced clinical practice (Timmermans, 2010). For example, critics have observed that EBM could erode medical professional authority and physician autonomy, resulting in the deprofessionalization of doctors, while others have suggested that evidence-based guidelines may have benefits for physicians' professional autonomy, by helping physicians claim jurisdictional authority over treatment of particular conditions, reinforcing the scientific basis of medicine, improving the quality of care delivered, and restoring public trust in physicians by discouraging physicians from pursuing economic self-interest (Broom, Adams, & Tovey, 2009; Mathews & Pronovost, 2008; Rappolt, 1997; Timmermans and Kolker, 2004; Timmermans, 2010). Alternatively, critics have expressed concerns that EBM will tie clinical decision-making to fiscal imperatives, diminishing practitioner discretion and reallocating power to healthcare administrators (Hafferty and Light, 1995; Rappolt, 1997). At least two significant gaps remain in this literature, however: first, what is the role of the state in promoting evidence-based guidelines, and second, how do different stakeholders assess the importance of evidence-based guidelines in advancing or protecting their own interests.

To explore the role of the state in promoting healthcare quality by encouraging physicians to comply with evidence-based recommendations, we focus on screening for hereditary breast and ovarian cancers (HBOC), because this is one of the few genetic tests that has accumulated enough evidence to show that it has both clinical and public health relevance. Although the proportion of women who are affected by HBOC is relatively small (about 5–10% of 240,000 cases annually), at-risk women can take steps to lessen their risk, such as earlier or more frequent surveillance, pharmacologic interventions, and prophylactic mastectomy (American Cancer Society, 2015). Because screening is clinically useful in guiding decision making for individual women, it is plausible that scaling screening up to identify more at-risk women could improve overall breast cancer morbidity and mortality rates. On the strength of this evidence, the U.S. Preventive Services Task Force (USPSTF) has recommended a campaign of targeted screening, i.e., offering genetic counseling to women with a family history of the disease (USPSTF, 2013).

These endorsements of targeted screening are especially important given the context surrounding breast cancer diagnosis, prevention, and treatment in the U.S. Public awareness about the toll of breast cancer on women's health is high because of decades of activism by patient advocacy groups (Kasper & Ferguson, 2002) and celebrity testimonials of illness. In 2013, the actress Angelina Jolie disclosed her decision to be tested for the *BRCA1/2* genes and to undergo prophylactic mastectomy. Jolie's announcement was widely covered in the media and cancer providers around the world reported huge increases in patient demands for genetic testing (e.g., Evans et al., 2014). Genetic testing laboratories have been only too happy to exploit public awareness of genetic testing and anxieties about a widely feared disease, and many laboratories have aggressively marketed genetic testing directly to consumers (Liu & Pearson, 2008). Notwithstanding the rapid growth of interest in genetic testing and concerns about potential overutilization, policymakers are still deeply concerned about underutilization, and that women who could legitimately benefit from testing may not be receiving it because of a multitude of barriers including lack of access to knowledgeable

providers, geographical barriers, and cost issues stemming from lack of insurance or inadequate insurance coverage (Forman & Hall, 2009). These barriers are especially problematic for minority populations, with African American women with a family history of breast or ovarian cancer significantly less likely to undergo genetic testing compared to white women (Armstrong et al., 2000).

In this context, then, HBOC screening is indeed a clinical concern, due to its role in guiding individual treatment plans, yet also holds potential to improve overall breast cancer morbidity and mortality, if it can be offered broadly enough to identify at-risk women. Therefore, public health agencies have an interest in encouraging targeted screening for HBOC, because of their interest in promoting population health. Educating providers and the public about appropriate screening techniques has long been a core part of public health's mission. In the case of HBOC, however, this mission is complicated by a rapidly evolving base of scientific evidence; the need to engage diverse stakeholders; the challenge of countering messaging campaigns by profit-driven clinical laboratories; and preparing providers to manage demands from anxious patients who may not meet the targeted screening criteria. We must therefore understand the contours of state power, and specifically, the capacities and limitations of state public health agencies to influence provider behavior. In this paper, we examine various strategies that two state public health agencies have used to encourage compliance with evidence-based recommendations. We also show how these activities aligned their own interests in promoting population health with the market and professional interests of providers, health insurers, and hospitals against commercial diagnostic laboratories.

Methods

We selected two states, Michigan and Connecticut, as case studies because they are leaders in integrating genomics in chronic disease prevention programming (Association of State and Territorial Health Officials, 2010). We describe two types of activities they undertook to encourage HBOC screening: (a) a mass media campaign directed at physicians and the public to counter aggressive advertising by genetic testing laboratories, and (b) several distinct projects using state surveillance data to document gaps in adherence to evidence-based guidelines. Their initiatives were similar, despite differences in their legal/regulatory climate (e.g., restrictions on use of public surveillance data) and organizational capacity (e.g., program staff, funding support).

This project is based on 55 semi-structured in-depth interviews, observations, and archival data. In developing the proposal, the first author approached the genomics program staff in each state to explain the purpose of the study and assess their interest in participating. Upon approval by the Northeastern University IRB and funding authorization, we interviewed the genomics program staff in each state. We then recruited interviewees via snowball sampling (Miles, Huberman, & Saldana, 2013). The genomics program staff introduced us via email to their internal collaborators (i.e., colleagues in the state health agencies) and external partners (e.g., clinicians, patient advocacy groups, third party payers, and academic researchers). We separately recruited key informants, also via email, based on their national leadership in public health genomics; they worked in federal agencies, non-profit patient

advocacy organizations, or academic institutions. The email introduction explained the purposes of the study, measures taken to protect both internal and external confidentiality, and invited interviewees to schedule a mutually convenient time for an interview (Tolich, 2004). Approximately 80% of the individuals contacted agreed to be interviewed. Interviews were conducted either in person or by telephone. After completing the informed consent protocol, the interview proceeded by seeking information on: the origins of genomics-related activities, barriers and challenges in integrating genomics in public health programming, and advantages and obstacles in partnership formation. This recruitment strategy elicited diverse perspectives on each agency's genomics activities. We conducted 26 interviews with staff members at the Michigan Department of Health and Human Services (MDHHS), 23 interviews with staff members of the Connecticut Department of Public Health (CDPH), and 6 key informant interviews. Interviews were conducted between November 2012, and October 2015, ranged from 30 to 90 minutes, and were recorded and transcribed verbatim. In addition to the interview transcripts, we reviewed archival data about genomics programs and observed 166 hours of meetings and events sponsored by both states. The archive included publicly available materials (e.g., publications, conference posters, and educational materials) as well as internal correspondence (e.g., grant applications, memos, and correspondence). Finally, we provided a draft manuscript to stakeholders in both states and conducted member validation interviews with 5 respondents (2 from Connecticut, 2 from Michigan, and 1 from CDC), to ensure the accuracy of our descriptions and interpretations of the states' activities (Miles et al., 2013).

We coded and analyzed all interview transcripts, archival material, and fieldnotes with QSR's NVivo 10, a qualitative analysis software package. Coding began with a pre-established set of codes drawn from themes in organizational and medical sociology, but using a grounded theory approach, new themes arose based on topics introduced by the interview subjects (Charmaz, 2006). Two authors coded interview transcripts, archival data, and field notes. The research team met regularly to review intercoder reliability, to resolve discrepancies, and to establish rules for coding practices.

Results

We first describe the types of activities Michigan and Connecticut undertook to promote HBOC screening. We then identify four ways these projects realigned the interests of stakeholders to facilitate compliance with evidence-based recommendations: first, they used public health surveillance data to demonstrate gaps between current practice and evidence-based recommendations; second, they strategically affirmed the role of the physician as gatekeeper to genetic services; and third, they showed how following evidence-based recommendations could also serve the professional and market interests of key partners. Our findings demonstrate that although the state health agencies' primary objective was to promote public health by reducing breast cancer morbidity and mortality, they implicitly and strategically bolstered physician professional authority. We also show, somewhat surprisingly, that variations in organizational capacity between states did not change the strategies they used. Finally, we show that despite the generally weak position of public health agencies in the healthcare arena, these projects aligned the interests of stakeholders in

the healthcare arena in a countervailing response to check the profit-seeking motives of the commercial testing laboratories.

Promoting HBOC Screening

Counter-Campaign against Myriad’s Direct-to-Consumer Advertising in New England—In 2007, state health officials in Connecticut, New York, and Massachusetts learned that Myriad, the company that at the time held exclusive patents on *BRCA1/2* testing, was launching a Direct-to-Consumer Advertising (DTCA) campaign in New England to increase awareness of the test and stimulate consumer demand (Hogarth, Javitt, & Melzer, 2008). Because *BRCA1/2* testing is appropriate for only the small minority of women with a strong family history of breast cancer, state health officials disagreed with this strategy. In response, the states collaborated on a counter-campaign to provide “accurate, up-to-date, and unbiased information” to physicians and the public about the appropriate use of *BRCA1/2* testing, including posters, websites, a hotline, and information packets mailed to more than 20,000 physicians throughout the region (Association of State and Territorial Health Officials, 2010, p. 45). The educational materials directed consumers with concerns about hereditary cancer to contact genetic professionals (either physicians who are board-certified in genetics or genetic counselors) in each state (Greendale, Dacus, Boddie-Willis, Negussie, & Burke, 2008).

Using Extant and Novel Surveillance Data—Both states used public health surveillance data to document gaps between current practice and evidence-based recommendations. They used these data to educate three constituencies—physicians, hospitals, and health insurance companies—about the benefits of following evidence-based recommendations. As we will show, these data sometimes illustrated the potential public health consequences of missed screening opportunities, and at other times identified specific barriers that women encounter in screening (e.g., lack of provider knowledge, inadequate insurance coverage).

Both states used data from their state cancer registries to estimate the number of women who might benefit from HBOC screening. All 50 states have cancer registries that collect data from hospitals on cancer cases diagnosed at their facility (National Cancer Registrars Association, 2014). In 2009, Michigan piloted a project to share cancer registry data with the reporting hospitals. Each Michigan hospital received a report showing the number of patients who might benefit from HBOC screening. The report facilitated compliance with current recommendations because it used each hospital’s own specific data to show how many women at that facility would have met the guidelines specified in the evidence-based screening recommendations. This illustrated the relevance of the recommendations for patient management, because hospitals could see how many young women with breast cancer they had seen at their facility, and who should have been screened under the evidence-based recommendations. The reports also contained informational resources that explained the evidence-based recommendations for HBOC screening, along with a directory of board-certified cancer genetics providers in the state and educational information that hospitals could share with providers and patients. After disseminating the reports, Michigan delivered grand rounds presentations at hospitals that requested additional education

(McLosky, Anderson, Duquette, & Fussman, 2012). Connecticut mimicked this project in 2011, with a few minor modifications (CDC Office of Public Health Genomics, 2015).

In addition, Michigan undertook three projects to assess compliance with and outcomes of HBOC screening practices. First, they surveyed 289 young female breast cancer survivors, i.e., Michigan residents diagnosed before age 50 (Anderson et al., 2012). Second, they established data collection partnerships with 10 of the 11 cancer genetics clinics in the state (Michigan Department of Community Health, 2012). These two projects captured more specific data than the state's cancer registry, such as quantifying how many women received genetic counseling for HBOC, which providers referred them, and reasons for not proceeding with testing, if applicable. Third, they collected policies from 25 insurance companies that offered coverage to Michigan residents and determined how many offered coverage that aligned with evidence-based recommendations. They partnered with the Michigan Association of Health Plans (MAHP), a statewide membership organization, to educate their members about best practices for HBOC screening. For example, they provided: an explanation of evidence-based recommendations, model language that insurers could include in policies, information about genetic counseling, and a directory of genetic providers in the state. They also gave presentations at annual meetings of the MAHP's membership and presented plaques to applaud insurers that had aligned their policies with evidence-based guidelines (D. Duquette, Lewis, McLosky, & Bach, 2012). Michigan used findings from these three projects to try to persuade physicians, hospitals, and insurance companies that adhering to evidence-based recommendations would meet the state's overarching goal of improving population health while also serving the partners' interests in delivering quality healthcare. As we will show, the public health agencies used data from each of these surveillance projects to promote HBOC screening without treading on physician authority.

Using Public Health Surveillance Data to Identify Gaps Between Recommendations and Practice

The state cancer registry reports demonstrated the gaps between evidence-based recommendations and current practice in four ways. First, they demonstrated the potential population health burden of HBOC on residents of each state, in an attempt to dispel misconceptions that hereditary cancers are a negligible public health burden simply because they are rarer than typical cancers. Although the state cancer registry is a vital source of public health data, physicians and hospital administrators often complain about mandatory reporting. As one Michigan staff member told us,

A lot of the time we hear physicians say, "Oh, we don't see those people." ... Because I think they enter the numbers and then there's just a cancer registrar that submits it to the state....You can get so caught up in your day-to-day job that you just enter them and the physicians especially don't see the numbers that are going to them. (MI Interview 5, March 2013)

The substantial numbers of patients who might benefit from HBOC screening surprised providers and hospital administrators. For example, Michigan found over 5,000 cancer cases

reported in 2006–2007 that might be appropriate for HBOC screening; Connecticut identified over 3,700 such cases diagnosed between 2008 and 2009.

Second, the reports demonstrated to hospital administrators and providers that they are already treating patients who could benefit from HBOC screening, and created an opportunity for those providers to recontact and screen those patients for HBOC, if they had not already done so. In Michigan, seven hospitals requested patient names so that they could contact them to offer appropriate follow-up (Trepanier 2012). In this way, the reports helped providers implement the evidence-based recommendations by screening women who currently had cancer, to see if they carried disease-specific variants in *BRCA1/2*. If so, they could make more informed recommendations about woman's future care (e.g., by discussing prophylactic mastectomy).

Third, and of greatest relevance to their public health mission, by illustrating the current disease burden of breast cancer, they illustrated a larger point about the potential consequences of missed screening opportunities. And because the reports contained information about the guidelines, a directory of qualified genetics professionals in each state, and materials they could share with patients, the reports helped train providers on how to follow the guidelines. In Connecticut, 70% of the hospitals requested grand rounds presentations to share this information with providers. The reports were paired with educational materials that sought to routinize screening of at-risk patients.

Fourth, the additional projects that Michigan undertook to collect novel surveillance data identified system-wide barriers in screening. For example, the survey of young breast cancer survivors revealed that 58% of women had not pursued HBOC screening because no one had ever recommended it. As another example, the review of health insurance policies showed that in 2009, most health plans in the state (21 out of 25) did not have written policies covering HBOC screening, even though evidence-based recommendations had been issued four years previously. Additionally, they showed that nearly 14% of women in Michigan (13.6% or 243 out of 1,611 women) who met the HBOC screening criteria were forced to decline testing because of insufficient insurance coverage. Finally, they illustrated that although some inappropriate testing was occurring in Michigan (approximately 40% of those tested between 2007 and 2011 did not meet screening criteria), it was less common than insurers might have feared (Hayden et al., 2017; MDHHS Cancer Genomics Program, 2012). As noted earlier, national statistics have shown both a recent surge in patient demand for testing (possibly owing to marketing practices of testing laboratories or celebrity disclosures), but also that at-risk women face barriers in accessing screening. Across multiple projects, Michigan leveraged their own surveillance data to illustrate how these problems of under- and over-utilization were playing out in Michigan.

Finally, it is worth noting that the state cancer registry reports supported physicians and providers in quality improvement projects by giving them a clear benchmark of their performance relative to evidence-based recommendations. In the current national health policy climate, physicians and hospital systems face increasing pressures to track quality and performance—both to comply with accreditation requirements and to advertise quality of care to consumers (Marshall, Shekelle, Davies, & Smith, 2003). Hospitals and providers

were not, however, systematically tracking compliance with HBOC screening recommendations. Sharing public health surveillance data allowed state health officials to support physicians and hospital administrators in quality improvement projects they should have been doing anyway.

Moreover, these projects showed that coordinated, system-wide action would be necessary by multiple stakeholders to lower barriers in access to care, and did not assign blame to any single actor in the system. Pointing out gaps between recommendations and practice identified new quality improvement targets for physicians and hospitals. Demonstrating the significance of lack of coverage as a barrier showed insurance companies the necessity of aligning their policies with current recommendations.

Reinforcing the Position of Physicians as Gatekeepers

Though neither state explicitly sought to promote physician autonomy, maintaining physicians in the role of gatekeeper was nevertheless an important strategy. For example, in the Myriad counter-campaign that Connecticut helped orchestrate in New England, outreach materials for both the public and providers stressed that consumers should seek genetic counseling from a qualified professional (either a physician or a genetic counselor) before pursuing genetic testing.¹ The counter-campaign thus discouraged consumers from working directly with a testing laboratory and channeled them back into the medical system. This had the effect of affirming the physician's clinical judgment in deciding whether genetic testing may be appropriate. This approach likely helped the state agencies secure the cooperation of the state chapters of medical professional societies, who agreed to disseminate outreach materials to their members (Association of State and Territorial Health Officials, 2010).

Both states viewed physicians as strategic allies in promoting *appropriate* screening, and a critical partner in a countervailing response to unnecessary, profit-driven testing. They believed that well-educated physicians would be better situated to discourage anxious patients who demanded unnecessary testing. For example, one Michigan public health argued,

“I think that if Sally goes into her doctor and her doctor gives her a message that we spoon fed the doctor, it's going to have a better effect... We've created a doctor who's going to be spreading that message more and more.” (MI Interview 8, March 2013)

They also believed that educated physicians would protect unsophisticated consumers from the negative effects of DTC advertising. Some research has suggested that lay consumers are especially vulnerable to the claims of testing companies, because they lack a nuanced understanding of genetics and the complex considerations in risk stratification (Gollust, Hull, & Wilfond, 2002). By emphasizing the importance of the physician as gatekeeper, the state agencies placed a buffer between commercial testing laboratories and naïve consumers.

¹Commercial laboratories do not invest in much DTCA activity in Michigan, possibly because Michigan has a stringent law requiring a physician to document the patient's informed consent before genetic testing can proceed (Interview with Michigan state health agency personnel, 1/5/16).

The importance of preserving the physician's role as gatekeeper was also evident in the ways that both states used data to demonstrate gaps between recommendations and practice. As described earlier, both states reported cancer registry data to hospitals and physicians, rather than notify patients directly. Both states anticipated a long-term benefit in educating physicians and hospitals about evidence-based recommendations—training providers in following the guidelines might help them identify at-risk women before disease onset. But they also chose not to contact patients directly because of concerns about data privacy and data quality. Connecticut could not have contacted patients directly, because of state-specific restrictions on use of their cancer registry data, but Michigan could have done so. But as with any public health surveillance database, both states realized that the cancer registry might have errors. As one state agency staffer explained:

“I tend to like [contacting the hospital/physician instead of patients] just because ... there are glitches and holes in the data at times. So when you write a doctor and tell him his patient is at risk and he knows that's wrong, then he just thinks you are stupid. But if you write a patient and tell her that [she needs to speak with a genetic counselor] when the data is wrong, you've created a problem.” (MI Interview 8, March 2013)

Health department staff recognized that not only are physicians the best gatekeepers at determining whether a patient is at risk and could benefit from screening, they are also best suited to safeguard patients from needless anxiety that might ensue if they were incorrectly identified as a cancer patient.

Michigan's review of health insurance policies similarly reinforced the role of physician as gatekeeper. Many health insurers, in Michigan and nationally, have viewed genetic testing as costly and have just routinely required pre-authorization for any genetic test (Carlson, 2005). By forcing patients and their providers to seek pre-authorization for HBOC screening (even though evidence-based recommendations exist attesting to its clinical utility), insurers were effectively usurping physicians' clinical judgment and erecting barriers to screening (Weldon, Trosman, Gradishar, Benson, & Schink, 2012). In their outreach, Michigan portrayed physicians who are knowledgeable about evidence-based guidelines as key partners in encouraging the *appropriate* use of genetic counseling and testing among patients who might legitimately benefit, while curbing the inappropriate use of those services. This initiative produced impressive results—the number of insurers covering HBOC screening in accordance with evidence-based recommendations increased from just 4 in 2008 to 14 in 2013 (MDHHS, 2013), thereby increasing the number of Michigan residents who could access these services without an onerous pre-authorization request by 74%.

Aligning the Professional and Market Concerns of Key Stakeholders

Both states showed how following evidence-based guidelines could align the economic and professional goals of three key stakeholders: physicians, hospital administrators, and health insurers.

Physicians and hospital administrators face pressures to mitigate malpractice claims that might arise if they fail to offer state of the art clinical care (Birbeck et al., 2004). Both states used state cancer registry data to demonstrate gaps between recommendations and practice,

and supplied easy-to-follow instructions to correct those deficiencies. Hospital administrators recognized that if they could demonstrate adherence to evidence-based recommendations, it would minimize likelihood of malpractice suits. Moreover, hospital administrators need to contain costs and identify new sources of revenue. The facility-specific reports showed substantial numbers of current patients who might be eligible for HBOC screening, and (depending on the outcome) might need further imaging, laboratory, radiologic, surgical, and inpatient services. Savvy hospital administrators could see that following evidence-based recommendations might help them capture downstream revenue (Litton et al. 2010; Ho 2004; Pirzadeh 2009). As one respondent explained:

This is a litigation opportunity for somebody. We might be sued if we don't do something about this. And I think that's the big fear. That's what gets people going, is either money missed in terms of billing or money averted in terms of lawsuits. (MI Interview 15, August 2013)

As noted above, seven hospitals in Michigan requested reports with patient identifiers, so that they could contact those patients and offer follow-up screening and diagnostic services.

Health insurers worried most deeply about cost containment. Michigan's data confirmed that while some inappropriate testing was occurring, it was a less substantial problem than underutilization of screening to identify at-risk women. Moreover, providing coverage for appropriate HBOC screening helps insurers control costs by identifying patients at an earlier stage of disease, therefore saving on long-term costs of treatment. One of Michigan's external collaborators argued:

We're finally getting the evidence that [HBOC screening] does lower mortality... And I think that we need to start embracing that. And figure out how we can save the most lives without wasting health care dollars...How can we start finding those people, how can we start getting them to experts and not just [be concerned with] selling tests. (MI Interview 22, February 2014)

Another described this as a win-win for health insurers and patients, saying, "I think those [health plans] who have implemented it have all realized some return on that investment ... it saves money for them and provides a potentially direct benefit to their members" (MI Interview 23, February 2014).

Both Michigan and Connecticut heeded the unique professional and economic concerns of primary care physicians. Primary care doctors have little time to stay current on how genetics affects adult-onset diseases, may not have had extensive training on genomics in medical school, and lack confidence in relatively simple tasks such as recording a complete family health history (Gramling, Nash, Siren, Eaton, & Culpepper, 2004). Both states developed outreach materials that made it easy to integrate HBOC screening into practice. For example, Connecticut developed a slide card that quickly helped providers determine if a patient met the family history screening criteria. Most significantly, all of the messaging stressed that physicians did not need to become genetics experts themselves, but just needed to know enough to identify a potentially at-risk patient and refer that patient to a genetic specialist. The states' efforts to raise awareness of evidence-based recommendations had the

effect of re-skilling primary care physicians, without requiring much time or effort on their part (Broom et al., 2009).

Finally, both states addressed the economic concerns of primary care doctors, especially their fear of competition. A key informant in Connecticut described the unscrupulous tactics Myriad had employed in New England, saying:

At the same time that they were doing [consumer] ads, they were doing [provider] marketing. They had armies of executives going into every single office saying things like, if you don't offer this BRCA testing to your patients, they're going to leave your practice and go down the road to [another OB/GYN office]. (CT Interview 17, July 2014)

Myriad was stoking the fears of primary care physicians, many of whom operate in low-margin practices, that if they did not order a genetic test for an anxious patient, that patient would find another physician willing to order it for them. A health plan representative in Michigan attested to the impact of the aggressive tactics of sales representatives on physicians' decisions:

"I know which lab is in town doing marketing to providers, when I start getting a flood of the same exact test coming from a certain region. Like oh, look who's in town marketing this week." (MI Interview 32, February 2015)

In this context, the state agencies' educational efforts implicitly reaffirmed the physicians' ethical professionalism and clinical judgment—arming them with accurate, unbiased information about best practices to counter the aggressive marketing tactics of the commercial laboratories. Recent commentaries in biomedical and social science journals have identified the entrance of profit-driven commercial actors into the healthcare arena as a potential threat to the altruistic motivations of physicians and as a potential explanation for declining levels of public trust in physicians (Mechanic, 1996; Relman, 2007). The outreach by Michigan and Connecticut prevented primary care physicians from becoming the unwitting handmaidens of testing laboratories.

Discussion

In response to our three research questions, we find the following; first, state health agencies pursued a variety of strategies to promote evidence-based screening for HBOC, but preserving the role of the physician as gatekeeper was a critically important element. Although the countervailing powers framework has conventionally emphasized the state's power to limit professional autonomy, we see that these projects affirmed physicians' clinical judgment. We attribute this to the fact that public health agencies wield less power in the healthcare arena than state agencies that license professionals or pay for clinical services. Lacking specific authority to compel physician adherence to evidence-based protocols, the state public health agencies needed to persuade physicians to embrace those guidelines voluntarily. Public health policymakers in both states believed that physicians who were knowledgeable about current recommendations would be well situated to identify patients who could legitimately benefit from screening, while discouraging anxious patients who demanded it without basis.

Second, despite variations in organizational capacity, both states pursued similar tactics with similar effects. Myriad halted their DTCA campaign in New England after less than a year. Although it is difficult to know whether or how Connecticut's counter-campaign contributed to Myriad's marketing plans, stakeholders in Connecticut consider the demise of Myriad's DTCA campaign a key accomplishment (CT Interview 4, March 2014). Both states also stimulated interest in HBOC screening among hospital administrators. Seven hospitals in Michigan requested patient identifiers and 70% of hospitals in Connecticut requested grand round training sessions after receiving their reports of cancer registry data (Centers for Disease Control and Prevention, 2014). Finally, Michigan used their unique surveillance resources to document impressive results in removing barriers in access to care. In addition to increasing the proportion of Michigan residents covered by an insurance plan that aligned with evidence-based recommendations, they also documented a steady growth in the proportion of patients receiving appropriate screening, and showed that the number of cancer clinics with board-certified genetic professionals increased substantially 2008 and 2013 (Duquette, 2014).

Third, both states employed a multi-pronged campaign that aligned their own interests with the professional and market interests of key partners, showing how adherence to screening recommendations could achieve shared goals around improving healthcare quality, promoting population health, and discouraging inappropriate, profit-driven testing. Aligning these interests coalesced in a countervailing response to commercial diagnostic laboratories, and helped rebalance power in the health care field back towards the state and physicians.

We selected Michigan and Connecticut as case studies because they are in the vanguard of integrating genomics into their chronic disease prevention programs. While these states may not be representative of all US states in their capacity to act on cutting-edge research translation projects, they are analytically useful as extreme cases, in identifying factors that make such projects successful (Ragin, 2004). Moreover, since Michigan and Connecticut initiated this work, other states have mimicked the practice of using state cancer registry data to illustrate deficiencies in practice.

Conclusions

Our findings clarify the parameters of state power in the countervailing powers framework and highlight the often-invisible work that public health agencies can do to support quality improvement. While medical sociologists have shown the heavy hand of the state sometimes protecting medical professional autonomy and sometimes curbing it (Hafferty & Light, 1995; Light, 2000; Starr, 1982), we should bear in mind that public health organizations, as a branch of the state, are much weaker in their ability to dictate physician behavior. Our findings show that public health agencies must improvise ways to promote voluntary compliance with evidence-based recommendations. They knew that the mere existence of such recommendations would be unlikely to influence medical care, unless they were paired with state-specific data that showed gaps between guidelines and practice and that quantified the potential population health burden of HBOC among residents of their state. They were especially diplomatic in using surveillance data to persuade physicians, hospitals, and health insurers that coordinated action was necessary on HBOC screening. In Michigan, for

example, they collected multiple sources of data to show how the low uptake of HBOC screening was driven not only by lack of insurance coverage but also by a failure on the part of providers to recommend screening. This formulation did not assign blame for practice deficiencies to any single party but portrayed it as a system failure that required coordinated action by multiple parties. Similarly, both states positioned the cancer registry reports as tools that physicians, hospital administrators, and health plans could use in quality improvement projects, to document their ability to deliver high quality care. And it is important to note that these projects yielded benefits both for individual patients (by helping providers identify current patients who could benefit from screening) but also for the at-risk public (by educating providers and hospitals and thus habituating them to screening).

This work also illustrates the dynamics of cooperation within the healthcare arena, and how different alliances of actors can check the power of unruly actors. The countervailing powers framework has previously been used to understand how healthcare actors have organized to curb the abuses and excesses of the pharmaceutical industry (Busfield, 2010). Coalitions that form to exercise countervailing powers need not always sort out cleanly into a divide between corporate/commercial interests and professional parties, however. In this instance, the state allied with one set of corporate interests, i.e., the health plans, in a countervailing response against the profit-seeking motives of a different group of corporate actors, i.e., the clinical laboratories.

Finally, our work holds practical significance for health policy experts, and shows that it is possible for policymakers to promote standardization if they are sensitive to the professional norms of key stakeholders. At the same time, policymakers need to be able to marshal resources and expertise to foster this type of organizational change. A key strength of agencies in both states was their ability to exploit state surveillance data to illustrate gaps between expert recommendations and practice. Efforts to leverage other surveillance databases to improve evidence-based screening for different chronic conditions would be subject to legal and regulatory limits on using those data sources. Moreover, while we know that other states have initiated similar projects, states vary widely in their capacity to analyze epidemiologic data (Council of State and Territorial Epidemiologists, 2014). Further research will be needed to determine whether these strategies developed by Michigan and Connecticut will promote adherence to evidence-based recommendations and eliminate barriers to access elsewhere. It would also be fruitful to explore how these policy activities influence providers' perspectives on evidence-based recommendations. Other scholars have commented on how often public health programs shift responsibility for health promotion to individuals (Petersen & Lupton, 1997); interviews with physicians would shed light on the expanding role of governmentality in public health, specifically whether efforts to promote adherence to evidence-based guidelines constitutes another form of "managerial encroachment" (Waring, 2007). On the whole, however, the story we tell in this paper shows public health officials stepping into the role of the "honest broker," providing unbiased information on cutting-edge diagnostic techniques and therapies to improve the health of the public (Bowen et al., 2012; Khoury et al., 2011).

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Research Highlights

Compares state public health agencies promotion of evidence-based recommendations.

Expands our understanding of how public health agencies shape healthcare quality.

Public health officials succeeded by strategically appealing to physician autonomy.

Public health agencies are important actors in the countervailing powers framework.