

Health Reforms as Examples of Multilevel Interventions in Cancer Care

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To increase access and improve system quality and efficiency, President Obama signed the Patient Protection and Affordable Care Act with sweeping changes to the nation's health-care system. Although not intended to be specific to cancer, the act's implementation will profoundly impact cancer care. Its components will influence multiple levels of the health-care environment including states, communities, health-care organizations, and individuals seeking care. To illustrate these influences, two reforms are considered: 1) accountable care organizations and 2) insurance-based reforms to gather evidence about effectiveness. We discuss these reforms using three facets of multilevel interventions: 1) their intended and unintended consequences, 2) the importance of timing, and 3) their implications for cancer. The success of complex health reforms requires understanding the scientific basis and evidence for carrying out such multilevel interventions. Conversely and equally important, successful implementation of multilevel interventions depends on understanding the political setting and goals of health-care reform.

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There is growing recognition that research and implementation projects that focus narrowly on one level of cancer prevention (eg, comparing methods to help people stop smoking), or one facet of cancer care (eg, screening), or one organizational level (eg, in-hospital surgical treatment) are insufficient to fully explain how and why interventions fail to improve care, fail to be adopted into practice, or are adopted gradually or with poor fidelity. For example, efforts to get people to stop using tobacco may be thwarted by state efforts to raise revenue from the sale of tobacco. Successful demonstrations to help insurers improve mammogram screening in compliance with guidelines may be abandoned once the research is completed because an important motivation for the organization was the ability to claim participation in research. Organizational innovations in major academic medical centers that improve surgical outcomes may not be feasibly implemented in community hospitals or may depend on incentives not available in other settings.

These problems are not unique to cancer care and are far from easily resolved. Multilevel interventions may be able to address these shortcomings, but effective and sustainable solutions must build on an understanding of the scientific basis for those interventions. Many of these subjects are addressed elsewhere in this issue. Here, we argue that successful multilevel interventions importantly interact with and depend on the details and goals of major policy reforms of our health-care system.

The Patient Protection and Affordable Care Act (ACA), signed into law by President Obama on March 23, 2010, is an excellent example of such reforms. Although not intended to be specific to cancer and its treatment, its implementation will have far-ranging and profound impacts on cancer care. Its major provisions aim to increase access through insurance reform, improve the evidence and impact of care options, establish and promote innovation and quality improvement by such means as restructuring the Centers

for Medicare and Medicaid Services (CMS), and reform care delivery by establishing incentives to create and effectively use medical homes and integrated and collaborative delivery systems of care. Related federal reforms seek to use incentives to encourage meaningful use of electronic medical records for quality and cost monitoring as well as to gather data for evaluating effectiveness.

Much of the public's attention regarding the ACA has focused on its insurance-related reforms to increase access to health care broadly, especially for people formerly uninsured. These reforms are especially important for cancer patients, both because such access is crucial when expensive care is needed and because premiums cannot be set prohibitively high for people with a history of having been treated for cancer. While recognizing the importance of access reform, we focus on reforms that bear directly on care delivery—especially attempts to establish accountability for care outcomes and to structure payments to give the right level of care to the right people at the right time—as a way to illustrate the importance of improving our knowledge and understanding of cancer care and its multilevel environment.

Accordingly, this article focuses on two components of the ACA: accountable care organizations (ACOs) and insurance-based reforms to gather evidence of effectiveness. Our discussion explores three facets related to studying and implementing complex multilevel interventions within the context of the ACA: 1) the intended and unintended consequences of each reform at multiple levels, 2) the importance of time for their success, and 3) their implications for cancer care.

Example 1: ACOs

Fundamentally, the ACO concept couples simultaneous reform of provider payment and the delivery system with the goal of controlling

costs while maintaining or improving quality of care. Many argue that to bring costs under control while improving quality, we must first reform the provider payment system because it pays for services irrespective of high prices and rewards volume rather than value (1). Others hold that it is impossible to change the payment system to achieve these desired objectives unless reforms first change the delivery system. They point to the need for delivery reforms to create incentives for health-care professionals, who usually work in independent nonintegrated institutional settings, to work collaboratively and to demonstrate their capacity to handle new payment approaches (2). Therefore, ACOs' simultaneous reform of both payment and delivery systems is a deliberate attempt to avoid the "chicken and egg" conundrum of where to start (3,4).

The ACA has several provisions to reform provider payments, focused particularly on creating ACO models for Medicare beneficiaries. Therefore, while public and private networks will likely establish models of ACOs and influence their development, we focus on the Shared Saving Program. This Program authorizes CMS to pilot the creation of ACOs and make associated provider payment changes in Medicare by introducing mechanisms to reward ACOs that lower growth in health-care costs while meeting performance standards about quality.

In this program, ACOs are networks of local providers (eg, primary care physicians, specialists, and hospitals) that agree to be held accountable for the care of a defined set of Medicare beneficiaries. The principal way that CMS will hold ACOs accountable is by rewarding them financially if they meet defined targets for this set of beneficiaries that demonstrate slowing growth in the cost of care and meeting/exceeding performance measures related to quality. A secondary way uses public reporting of quality and cost information to influence public perception of an ACO's performance.

Proponents generally view three ACO characteristics as essential to meet these goals: 1) the ability to manage the continuum of care across different institutional settings, for example, ambulatory centers, hospitals, and post-acute care settings; 2) the capability to prospectively plan budgets and resource needs; and 3) sufficient size to support comprehensive, valid, and reliable performance measurement (5).

The notion of accountability, embodied in these characteristics, is not new. Accountability was an essential concept for the managed competition approach adopted in President Clinton's Health Security Act, even dubbing health maintenance organizations as "accountable health plans" (6).

What is new is the direct focus on holding health-care providers and the local delivery system accountable instead of insurers and health maintenance organizations (7). ACOs' focus on local providers and delivery systems stems from the desire to address a number of continuing problems, especially the lack of financial incentives to reduce cost and improve quality and the resulting uncoordinated care and unwarranted geographic variation in practice patterns and health spending. It is thus distinct and separate from the contracting that occurs in the Medicare Advantage (managed care) program. [See others (8,9) for these effects.]

After receiving more than 1300 comments on their proposed rules, including some severe criticism from the major players in health-care delivery (10), CMS issued its Final Rule in October

2011, making several major adjustments to improve the reception of the industry (11). One important change in the final rules was that CMS reduced its requirements for provider risk assumption, instead providing higher financial rewards for those that do assume risk and offering some opportunities for loans to make upfront changes that would be repaid in the form of future rewards for performance (12). Nonetheless, some are concerned that these reforms may subject ACOs to regulation at the state level, that is, because some forms of ACO would involve providers taking financial risk and would employ mild (dis-)incentives to channel beneficiaries to ACOs, the program might have to address complex insurance regulation issues and deal with concerns about solvency (13). Consequently, organizations contemplating becoming ACOs have continuing concerns about how well the program will properly take into account the up-front risks that participating organizations must make to transform themselves and build the necessary integrated system and measurement capability.

Returning to the implications for cancer care delivery, ACO reforms help illustrate that the effects of complex multilevel interventions are poorly understood and most likely will require large financial outlays to accomplish the transitional steps to reach the maturity needed to deliver integrated and accountable care. Issues regarding timing are crucial: If financial risk is imposed too soon, fewer may take the lead to participate and more may fail financially if they do. If financial gain for health-care organizations is the driving reason behind their integration and coordination, they may lack the political will to make multilevel interventions successful. [See Alexander et al. (14) on the importance of timing in organizational reforms.]

The emergence and expected diffusion of ACOs raises many potential consequences—intended and unintended—for cancer care and research. Intended impacts include improving care by improved coordination among providers, rewarding quality, and using evidence-based care. ACOs are also intended to reduce the total cost of care, which could benefit patients and the public by making insurance coverage and care more affordable and economically sustainable.

Cancer care was not included in the originally-proposed 65 measures of quality, presumably because of the original intent to focus on outcomes, which are particularly difficult to assess and collect as measures of quality in cancer care. The final rules defined 33 quality measures, mostly based on clinical processes and patient experience-of-care rather than outcomes; this set includes cancer screening but not cancer treatment. This omission could result in stinting on such care due to cancer's relatively complex and expensive treatments, especially without monitoring for quality or offering credit to entities that improve cancer treatment quality (15).

Within a network, it is not clear who will manage cancer patients' care or how primary care physicians and oncologists will work together within the ACO. Evidence-based treatment guidelines exist for cancer, but, if this area is not ultimately being assessed through quality measures, neither ACOs nor CMS can monitor adherence to these guidelines. Moreover, because fee-for-service remains the base payment mechanism for CMS's Shared Saving Program, providers will continue to benefit from holding onto patients or delivering care that maximizes their current

reimbursement. Moreover, consolidation of providers into networks may result in offering fewer treatment options or producing other unintended impacts such as raising prices through strengthened powers to negotiate (10).

Another potential consequence of implementing ACOs is that their providers may be tempted to keep patients within their own ACO network and not refer them for treatment to comprehensive cancer centers, such as academic medical centers or National Cancer Institute (NCI)-designated centers. Cancer care is relatively expensive in general but is even more expensive at such centers, and there are no guidelines for when patients should be offered referral or how or if appropriate referral would be rewarded.

A further potential impact of ACOs on cancer care is that many patients may not fully understand what an ACO is and how it may affect the kinds of treatment recommendations and referrals they do or do not receive. [Considerable evidence already indicates that beneficiaries are confused by Medicare Part D (16).]

Ideally, inclusion in an ACO should be transparent and voluntary. Right now both aspects are problematic. Medicare beneficiaries do not actively choose or enroll in an ACO and are technically free to go anywhere fee-for-service Medicare beneficiaries can go. CMS prospectively assigns beneficiaries to ACOs on a quarterly basis, adjusting assignment annually based on services. CMS informs the ACOs (not the beneficiaries) who is assigned. ACOs can contact beneficiaries about data sharing; beneficiaries can opt out of data sharing but cannot opt out of assignment. This loose definition of beneficiaries in an ACO, coupled with incentives for ACO providers, could lead to practices that influence beneficiaries to stay within the network—even though beneficiaries have no incentives or requirements to do so. It could lead to beneficiaries being disengaged or even hostile to data sharing or attempts to reduce costs of care. Finally, over time, ACOs may try to discourage some complex costly patients from being in their network through subtle means, for example, by not providing certain cancer care services.

The emergence of ACOs is a clear example of how change at one level—federal policy—can ripple through the system with far-ranging effects over time. Accountability as a concept has been prominent in past insurance and delivery system sectors. However, under the new reform creating Medicare ACO pilot projects, there is an increased possibility that they will be adopted, causing changes at multiple levels, for example, provider organizations, cancer care teams, and other networks, and thereby affect patient care throughout the cancer care continuum. Unlike expansion of Medicare demonstration projects that require legislative action, a pilot can be expanded at the discretion of the secretary of the health and human services without going back to Congress. So, if the secretary judges the pilots to be producing the desired federal-level goals (not necessarily as evaluated in the context of cancer care), they could be scaled up or diffused much more rapidly. In addition, parallel actions of private payers and providers may accelerate the pace of change, to the extent that they adopt similar ACO programs.

Example 2: Insurance-Based Reforms to Improve the Evidence for Care

ACA reforms also include a number of financial incentives to encourage system stakeholders at various levels, such as patients,

providers, and device and pharmaceutical companies, to fully engage in collecting evidence about the effectiveness of care. The diffusion of evidence-based medicine depends fundamentally on having a solid base of research about the comparative effectiveness of devices, procedures, drugs, and treatment regimens, whether new or already approved and in use.

Growing the evidence base requires attention to scientific issues about disease and treatments. It also depends on patients' agreement to participate in gathering evidence through clinical trials and allowing access to their health data for such purposes. Similarly, providers must be convinced to follow approved protocols for providing the health care as well as for collecting data to evaluate its effectiveness.

Building the evidence base undoubtedly involves multilevel stakeholders whose incentives require careful multilevel interventions. Although patients and providers may be unwilling to contribute to the evidence base for many reasons, one important strategy being addressed in current reforms is to remove perverse financial incentives that discourage participation in effectiveness research. Positive incentives, although aimed at providers and patients, must also embrace reforms involving third-party payers. Insurance reform is needed to provide appropriate mechanisms and circumstances to pay for participating in research trials and for evaluating care that needs a stronger evidence base.

Insurance-based reforms to create incentives for collecting effectiveness data differ depending upon which key stakeholder (ie, level in the system) is targeted. We briefly discuss three targets: incentives focused on providers, on patients, and on both.

Insurance Incentives Focused on Providers

For the past decade, private health insurers, encouraged by employers seeking to control costs for their employees' health care, have developed a variety of incentives to pay providers designed to increase efficiency and/or quality or otherwise add value to the services provided. Such strategies generally rely on purchaser power and are collectively known as pay-for-performance (P4P). There is a rich but mixed literature about their effectiveness (17,18). In practice, P4P incentives tend to measure performance, not on what happened to patients' health, but on easily measured easily verified quality indicators of appropriate care by providers. Of interest here are P4P strategies that reward providers and patients for participating in research to gather evidence about outcomes and to evaluate and monitor the effectiveness of care (19).

P4P programs could be expanded to define and reward "accountable care" as gathering evidence for comparative effectiveness. For example, New York State requires managed care organizations that contract to care for NY Medicaid patients to conduct Performance Improvement Projects, that is, approved research efforts to evaluate the care and health of its enrollees or research interventions designed to improve quality. The state then rewards managed care organizations with evidence of such performance by assigning them a higher percentage of new enrollees who do not designate a preferred insurer. Similar programs could be adapted to reward providers to participate in registries or otherwise gather evidence for research purposes as an indication of being a high-performing learning organization" (20). Besides direct payments to organizations based on performance, rewards

such as allowing billing for data collection and reporting or otherwise supporting research activities could also be used.

Pronovost et al. (21) discuss another model in the context of P4P and data reporting. They propose a new commission be established to be responsible for defining standards for measuring and reporting quality of care, including how to make transparent and reduce selection bias, measurement bias, analytic bias, confounding, and random error. The commission also would describe the optimal training and certification needed to measure and report data. It would design an auditing system to ensure that data reports are accurate and potential biases are transparent. Such an approach would be compatible with policies to encourage providers to convert to electronic medical records and enhanced by tying incentives to providers who collect and report standardized data.

P4P and research combinations share some potential unintended consequences. Three principal concerns identified in the P4P literature are particularly relevant: 1) avoiding or dumping patients whose behavior or health might compromise the organization's performance measure, 2) "teaching to the test", that is, focusing efforts to improve the ratings on measured performance rather than improving quality performance overall, and 3) increasing the discrepancy in interorganizational quality [especially if bonuses for high performance come from inflationary adjustments made for treatments by lower-quality providers (22–24)].

Insurance Incentives Focused on Patients

These incentives primarily target patients' out-of-pocket costs. Called "value-based" insurance or "tiered coverage," these incentives base reimbursement on the cost-effectiveness of the treatment and whether patients use the most cost-effective approach first and then progress to more expensive treatments only after failure of lower-cost equivalents. For example, the first tier of reimbursement might include the most cost-effective type(s) of treatments for which the patient pays no or the lowest out-of-pocket expenses. The second tier might include effective but higher-cost treatments for which the patient pays more out-of-pocket. The highest tier might include treatments that do not have a well-established evidence base. Here, the patient has some coverage (perhaps at the same rate as the first or second tier) but is expected to pay any difference entirely out-of-pocket (25,26).

Although many studies suggest that patients respond to out-of-pocket incentives, the consequences of such incentives could backfire for the purposes of evidence gathering. The three-tiered approach would reduce the use of treatments lacking evidence, thereby also discouraging identification of treatments needing more evidence. Tiered coverage could also inadvertently lead to recruiting a population suboptimal for testing treatment effectiveness. While coverage-for-evidence could provide access to innovative care, private insurers and employers may be more interested in getting value-based coverage for their employees and would not see benefits from supporting research or innovation.

Incentives That Focus on Both Providers and Patients

This group of incentives is best represented by CMS's Coverage for Evidence program. As a government-based insurance program, CMS has a major responsibility for evaluating relevant clinical evidence to decide if it is of sufficient quality to be covered for a

given diagnosis (27). Recognizing that evidence may sometimes be incomplete or ambiguous, CMS embarked on a "coverage-for-evidence-development" program in which its role is both to ensure the gathering of evidence to evaluate the service and allow some coverage while evidence is under development.

CMS recognizes two subtypes of Coverage for Evidence: 1) coverage conditioned on specific additional data collection (such as a registry with information beyond usual claims information), which is referred to as Coverage with Appropriateness Determination; and 2) coverage conditioned on care being delivered in a setting with a prespecified data collection process and additional protections in place such as are present in some research studies, referred to as Coverage with Study Participation. Unfortunately, CMS rarely uses either designation.

The United Kingdom's National Institute for Health and Clinical Excellence (NICE) has a similar program, Only in Research—used rarely, by design. NICE is an independent organization responsible for providing guidance on treatment cost-effectiveness, and its findings influence the coverage policy of the National Health Service (NHS). Under this designation, NHS covers the service only in approved research trials. NICE's Citizen Council explained (28) why coverage for evidence was designed to be used sparingly: If the experimental treatment were in fact a significant high-value advance of care but was denied the opportunity for coverage-with-evidence, then patients would be denied access to valuable treatment. Consequently, there would be delays in building an evidence base and innovation would be hampered. On the other hand, if the treatment is not an advance but was not included in a program with a requirement to evaluate it carefully, an ineffective treatment might still become widely used, research about its evidence would be hampered or slowed, a poor innovation would be encouraged, and treatment costs would be wasted.

An additional unintended consequence of programs like Coverage for Evidence relates to the ambiguity and lack of consensus regarding which treatments are already evidence-based and which are not. It is possible that true innovations in clinical practice could be discouraged or punished as a result of being labeled as non-evidence-based.

For cancer, the example of multidisciplinary team care (MDC) presents a particularly thorny problem in both developing an evidence base and ensuring that well-known and well-regarded care processes can be adopted and institutionalized within community-based cancer programs (the context within which most cancer patients are seen). Quality cancer care is complex and depends upon careful coordination between multiple treatments and providers and upon technical information exchange and regular communication flow among all those involved in treatment [including patients, specialist physicians, other specialty disciplines, primary care physicians, and support services (29)].

Advances in various medical and surgical procedures have led to an increase in multimodality therapy, which increases the number of interfaces among cancer specialists and other clinicians in patient treatment. Contemporary cancer care thus presents a paradox: The potential for sophisticated treatment of unparalleled quality is high, yet the number of potential failure events in the continuum of cancer treatment—due to the complexity of successfully

carrying them out—has multiplied significantly (30). The overall success of cancer treatment now depends on both the effective use of each treatment innovation and also on the effective coordination of various treatments within each stage of the care continuum, as well as transitions between stages. Each failure in communication between various physicians and care providers, and every transition and interface miscue, can result in delayed treatment planning and staging, unnecessary duplication of tests, incomplete follow-up, increased patient anxiety, decreased patient satisfaction, and declines in quality of life.

The MDC team has been identified as one method of ensuring the timely exchange of patient-related and technical information across all physicians and support services involved in a patient's care. The setting and format of MDC encourages active involvement of all actors (including the patient and family) in developing a care plan. The health-care management literature advocates for more frequent use of MDC teams, and the NCI has historically supported their development and diffusion, dating back to the cancer network demonstrations of the 1970s and 1980s (31,32) and through the NCI Community Cancer Center Programs more recently (33). However, little, if any, empiric evidence exists on the prevalence, efficacy, and diffusion of MDC teams in cancer treatment or on their effectiveness in smoothing transitions across stages of cancer care (34).

Beyond these issues in employing insurance-based reforms to create incentives for collecting evidence and sharing data is another problem. Few incentives help organizations address the multilevel problems that need to be solved before successful implementation can be accomplished. For example, even though much attention is paid to promoting medical homes and integrating care, no incentives actually reward integrated teams and systems for gathering evidence. Indeed, no incentive at any level in the system is designed to explicitly reimburse providers for carrying out the core activity around which multidisciplinary care is based: team discussions with multiple providers, whether face-to-face or virtual, that result in a jointly determined prospective care plan for the patient—let alone to collect evidence about the care plan or about the value added by using an integrated team approach.

This example raises another aspect of the importance of explicitly recognizing and valuing time in complex multilevel interventions. Current incentives and organizations are designed to promote provider productivity (often measured as “billable time”) with the resultant emphasis on faster throughput and using the fewest total person-hours to plan and deliver care. This becomes an important counterincentive for integrative services such as those needed for multidisciplinary care in cancer and other diseases. Unfortunately, although the effective operation of such teams depends upon the commitment of individual providers to coordinate and communicate, such time-intensive activities are either seen as “less-productive” cost-centers or depend upon the “good will” of the health-care organizations within which they practice to provide flexible time and organizational supports for operating MDC teams (such as team coordinators and information technology support).

Timeframes complicate the goals of achieving effective multilevel interventions and building the evidence in numerous ways. Timeframes span almost all of the layers represented by the onion model in Taplin (35): 1) disease-time (how do you define the

boundaries between stages of cancer when evidence should be gathered?); 2) the timeframe of the continuum of cancer care (what evidence should be used to evaluate care at each stage, including whether it is preventive, active, or palliative care?); 3) time associated with integrative efforts (incremental time spent by multidisciplinary teams to process, develop, and reformulate the care plans and gather evidence); 4) timing needed to build a multilevel intervention (time it takes to implement incentives for third-party payers, providers, and patients to engage in the process of data collection); 5) the timing associated with policy reforms (time needed and windows-of-opportunity to legislate and implement incentive reforms); and 6) the slow process of research, data collection, and knowledge accumulation once evidence is being collected. This multitude of timeframes is overwhelming, but at the same time absolutely necessary to understand the interplay between multilevel interventions, associated policy reforms, and building evidence and advancing cancer treatment.

Conclusions

The passage of the ACA in 2010 will significantly affect the provision of health services in general and cancer care in particular. In discussing the impact of multilevel reforms on cancer care, we limited our focus to two examples: ACOs and insurance-based reforms to improve the evidence of care. There are many more examples and facets we could have used to analyze why and how multilevel interventions implicit in health reform can have profound impacts on cancer care and how much we need to improve our understanding of them. Our particular focus in discussing these reforms was to underscore the urgent need and importance of understanding the scientific theories and evidence underlying the clinical and care management dimensions of complex interventions as well as the organizational and political ramifications of successful implementation. Other chapters in this monograph help refine these issues and ideas.

Equally critical for the success of multilevel research—as illustrated in this article—is the recognition that researchers, implementers, and policy-makers must take into account the changing political landscape within which the health system is operating and must design interventions that are aligned with and/or take advantage of the broader policy context of health reform. Too many unintended consequences flow from the failure to fully appreciate that policy landscape or to anticipate how proposed policy changes may affect the expected outcomes of an intervention.

Moreover, the broad goals of reform for improving the value of care and holding entities accountable for its delivery need to specifically focus on delivering the full continuum of care, for which cancer care is an especially appropriate model. Trying to deliver care across this continuum exemplifies how complex and varying the levels and roles are in any multilevel intervention. The players responsible for actions, payments, and consequences at multiple levels vary profoundly if the target of opportunity is focused on prevention or early screening stage of the continuum in contrast to active treatment, posttreatment maintenance of cured patients, and/or end-of-life care once the cancer's advancement cannot be stopped.

We have tried to clarify the importance to multilevel interventions of getting health reform's incentives and provisions correct—and vice versa. The synergy between them is vitally important to the

success of these complex interventions. Obviously, we still have a long way to go.

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