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Decision Making on Medical Innovations in a Changing Health Care Environment: Insights from Accountable Care Organizations and Payers on Personalized Medicine and Other Technologies

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ABSTRACT

Background: New payment and care organization approaches, such as those of accountable care organizations (ACOs), are reshaping accountability and shifting risk, as well as decision making, from payers to providers, within the Triple Aim context of health reform. The Triple Aim calls for improving experience of care, improving health of populations, and reducing health care costs. **Objectives:** To understand how the transition to the ACO model impacts decision making on adoption and use of innovative technologies in the era of accelerating scientific advancement of personalized medicine and other innovations. **Methods:** We interviewed representatives from 10 private payers and 6 provider institutions involved in implementing the ACO model (i.e., ACOs) to understand changes, challenges, and facilitators of decision making on medical innovations, including personalized medicine. We used the framework approach of qualitative research for study design and thematic analysis. **Results:** We found that representatives from the participating payer companies and ACOs perceive similar challenges to ACOs' decision making in

terms of achieving a balance between the components of the Triple Aim—improving care experience, improving population health, and reducing costs. The challenges include the prevalence of cost over care quality considerations in ACOs' decisions and ACOs' insufficient analytical and technology assessment capacity to evaluate complex innovations such as personalized medicine. Decision-making facilitators included increased competition across ACOs and patients' interest in personalized medicine. **Conclusions:** As new payment models evolve, payers, ACOs, and other stakeholders should address challenges and leverage opportunities to arm ACOs with robust, consistent, rigorous, and transparent approaches to decision making on medical innovations.

Keywords: accountable care organizations, coverage policy, decision making, personalized medicine.

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Introduction

In a 2008 seminal article, Berwick et al. [1] proposed the Triple Aim for US health care: improving the experience of care, improving the health of populations, and reducing health costs. The Triple Aim became an overarching objective of the US 2010 health reform and precipitated the rise of new payment and care organization models [2,3]. The accountable care organization (ACO) model, first introduced in 2006 as a means to shift accountability from the individual provider to the organization level [4], emerged in the health reform era as a mechanism for achieving the Triple Aim and health system transformation [3,5]. An ACO is a provider-led organization with a strong base of primary care, collectively accountable for quality and per capita

costs across the full continuum of care [6]. In 2012, the Centers for Medicare & Medicaid Services launched two ACO initiatives—the Pioneer ACO Model and the Medicare Shared Savings Program [7]. Early results have been promising in the overall cost savings and quality improvement, but showed modest cost impact, some patient attrition, as well as variability in results across participating ACOs [8–13]. All along, experts viewed the ACO model as work in process and highlighted the necessity to continue its evolution and enhancement [14–18]. Nevertheless, adoption of the ACO model by payers and health systems continues to gain momentum [5,19–21].

An ACO's accountability for the Triple Aim inherently entails assuming a higher degree of financial risk, previously carried by health care payers [7,18], as well as increased responsibility for

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decision making on how to achieve the Triple Aim [15,20,22]. Berwick et al. [1] argued that this decision making is “an exercise in balance” because some actions could advance one aim but counter other aims. They noted that the adoption of innovative medical technologies was a critical example of the necessity to balance decisions in the Triple Aim context because some technologies could improve the health of individuals and certain populations but raise costs. Furthermore, a simulation of ACO results showed that use of guideline-recommended tests and drugs improves quality but reduces cost savings or increases costs [23]. As scientific progress produces new diagnostics, therapeutics, and digital health technologies, it becomes crucial to understand how and by whom decisions on medical innovations are made in the era of the Triple Aim and ACOs.

The importance of ACO decision making has been described in the literature, with the focus on decisions about whether a provider organization should form an ACO [24], agreeing how to structure ACO governance and risk [15,22], engaging physicians in key aspects of ACO decision making, including clinical protocols [20,25,26], and determining what care to refer to outside providers [27]. Nevertheless, ACO decision making on adoption of innovative medical technologies does not appear to have received attention: we found only two commentaries highlighting this topic and expressing concerns about disincentives for ACOs to adopt medical technology innovations [28,29].

To address this gap, we undertook a study with ACOs and private payers on aspects relevant to decision making. In the non-ACO environment, payers evaluate an innovative technology, and whether it is medically necessary, and then convey this decision in a coverage policy [30–32]. A payer’s positive coverage decision determines whether the technology is reimbursed for the payer’s enrollees (subject to benefit design) and has considerable influence on providers’ decisions to adopt and use this technology [33–37]. To examine whether or how decision making is changing in the ACO environment, it was important to include both sides of the ACO arrangement—ACOs and payers. We focused on private payers because they cover two-third of the US insured population [38], increasingly participate in ACO arrangements [16,19,39], and their participation is considered key to the long-term success of the ACO movement [8,26,40,41].

To examine decision making on innovative technologies, we focused on personalized medicine (also referred to as precision or genomic medicine)—an important field with accelerating scientific and technological development and substantial promise for health, health care, and prevention [42–45]. Payers have reported challenges to their coverage decisions on personalized medicine, including the fast-paced scientific development, rapid proliferation of tests, as well as the lack of evidence on the validity and utility of many tests [30–32,46–50]. These challenges may also be relevant in ACO decision making on personalized medicine. We used a specific example of innovative cancer genomic panels that identify a variety of an individual’s cancer germline (cancer risk) or somatic (tumor) mutations in one test. These panels are often expensive [51,52], not yet consistently covered by payers [50,51,53–56], and their use in clinical practice is controversial and hotly debated [57–68]. Thus, they present an opportunity to explore decision making on innovative technologies in the ACO setting.

Methods

Study Cohort and Methods

The study was conducted in accordance with the protocol approved by the University of California, San Francisco Institutional Review Board. We used qualitative research methodology,

specifically the framework approach [69,70], to design and conduct the study. This method uses semistructured interviews and thematic analysis and has been effectively used in our and others’ research to examine payer and provider decision making on medical innovations [31,46,47,49,50,71–74].

The interview cohort was assembled using purposive sampling [75]. To identify and recruit payer representatives, we leveraged our University of California, San Francisco Center for Translational and Policy Research on Personalized Medicine (TRANSPERS) Evidence and Reimbursement Policy Advisory Council. The cohort included 10 senior executives from 10 private payers, including six major national and four regional plans. Together, the 10 payers cover more than 125,000,000 enrollees [76], which comprises approximately 44% of all covered lives in the United States [77]. The executives were responsible for, and knowledgeable of, technology decision making and the ACO arrangements in their respective organizations.

The cohort also included six executives from six ACOs. We identified and recruited these representatives through a Chicago-based collaboration of medical centers and other stakeholders on personalized medicine in oncology. All six ACOs were located in the Midwest, but represented a range of characteristics. They varied in 1) academic affiliation (one academic and five non-academic organizations); 2) size (two large systems [10 or more hospitals], two medium-sized systems [4 or more hospitals], and two single-hospital systems); and 3) experience with the ACO model (two ACOs with 3 years or more since implementation; one with 1 year since implementation; and three in the beginning stages of implementation). All recruited ACO representatives had knowledge of their respective ACO arrangements.

On the basis of the goal and topics of our study, we developed an interview questionnaire (Table 1) and provided it to the cohort members ahead of the interviews. We started the payer interviews with the topics of the landscape, arrangement structures, and future direction of ACOs in their respective provider bases. These topics were beneficial to include because they provided important context for the understanding of ACO decision making and related challenges and facilitators conveyed by interviewees. The topic of ACO landscape was relevant only to payer interviewees because they work with multiple ACOs in their network, whereas ACO interviewees provided perspectives from one ACO. All other interview topics were included in both payers’ and providers’ questionnaires and focused on their perspectives on the shift of decision making between payers and ACOs and factors impacting ACO decisions on medical technologies, using the example of cancer genomic panels.

The interviews were conducted between January and July 2015, took 30 to 45 minutes each, and were taped and transcribed. Two investigators independently performed thematic analyses and coding according to the framework approach of qualitative research [69,70]. Disagreement was resolved by discussing differences and reaching consensus. Analysis showed saturation of themes, that is, repetition of themes across interviewees, and thus sufficiency of the interview cohort for the purposes of this study [78].

Cancer Genomic Panels

Cancer genomic panels are defined here as innovative genomic tests interrogating multiple cancer genes and/or syndromes that use next-generation sequencing and contain well-studied and less-studied genes. These panels could test for somatic mutations (tumor genetic testing) and/or germline mutations (for hereditary cancers). Cancer genomic panels are available commercially [51,52] and offer important benefits to patient and providers, compared with traditional single-gene/single-syndrome tests, for example, faster testing, more comprehensive genetic picture,

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