

# System Focus

### Precision Medicine: Issues and Strategies for Healthcare Directors

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Precision medicine, also called personalized or individualized medicine, is a rapidly evolving field where physicians use results from a patient's genetic tests, advanced molecular diagnostics, and medical and history condition to determine which treatments will work best for that particular patient. Equally important with precision medicine is the development of a plan to prevent a disease or medical condition from occurring in the first place.<sup>1</sup>

This new medical frontier got a major boost from President Obama's Precision Medicine Initiative announced in 2015, which gained bipartisan support in 2016 when Congress passed the 21st Century Cures Act. Significant interest of Americans in their genetic makeup is further fueling precision medicine. Millions are using 23andMe and rival Ancestry.com to track their health information and build a personal genetic profile. Many people believe precision medicine to be the future of medicine.

#### **How Effective Is It?**

The correlation of precision medicine and improved patient outcomes is a strong one. For example, in a study at the University of California, San Diego School of Medicine, tumor shrinkage rates were 30.6 percent for patients whose treatment was selected based on their tumors' molecular characteristics, compared with 4.9 percent for other patients.<sup>2</sup> Precision medicine also holds major promise in reducing adverse patient outcomes and the total cost of healthcare by identifying through diagnostics the patients *unlikely* to respond to specific drugs or other therapeutics, thereby sparing them "the costs, false hopes, and potential side effects of undergoing an ineffective treatment," note experts.<sup>3</sup> For example, consider the implications of being able to identify an effective cancer or arthritis drug before treatment starts. Drugs traditionally prove ineffective in 75 percent and 50 percent of cancer and arthritic patients respectively.<sup>4</sup>

CRISPR-Cas9, a genome editing tool, might have a very significant effect on precision medicine in the near future. The tool could enable genetic defects to be edited out, resulting in the elimination of diseases with defined genetic abnormalities.<sup>5</sup>

Health insurers and employers are watching closely to see whether better outcomes can reduce costs at a time when it's not uncommon for a new genomic cancer treatment to cost \$2,000–\$5,000 per dose.

#### Health System Impact and Issues

For America's health systems, precision medicine raises major issues, including how it could change the economic and competitive landscape of healthcare.

<sup>&</sup>lt;sup>1</sup> The Personalized Medicine Coalition, "The Basics: What Is Personalized Medicine?" 2017 (available at <u>www.personalizedmedicinecoalition.org/Education/Th</u> <u>e Basics</u>).

<sup>&</sup>lt;sup>2</sup> American Society of Clinical Oncology, "Precision Medicine Yields Better Outcomes for Patients in

Phase 1 Clinical Trials" (News Release), May 18, 2016.

<sup>&</sup>lt;sup>3</sup> Jonathan Darrow, Aaron Kesselheim, and Jessica Lasky-Su, "The Future of Precision Medicine: Great Promise, Significant Challenges," *Health Affairs Blog,* February 28, 2017.

<sup>&</sup>lt;sup>4</sup> The Personalized Medicine Coalition, 2017.

<sup>&</sup>lt;sup>5</sup> Darrow, Kesselheim, and Lasky-Su, 2017.

Relatively few community-based health systems have the financial resources or human capital to afford the expenses that go along with building the ability to predict, prevent, and treat disease using an individual's DNA. Organizations that are involved with precision medicine typically are specialized cancer treatment centers, such as the Moffitt Cancer Center & Research Institute, or large well-capitalized health systems, such as Intermountain Healthcare, Inova Health System, UPMC, and Dignity Health and Catholic Health Initiatives, among others.

The latter two, which are considering a merger, launched the Precision Medicine Alliance, LLC in September 2016. It offers 12 million patients access to precision medicine through affiliated community physicians. "Conventional wisdom suggests patients suffering from the same condition should be treated with the same therapy. Science now tells us that the efficacy of one-size-fits-all for medications and therapies varies by patient because each person has a unique DNA profile that responds differently to prevailing treatments," said Kevin E. Lofton, CEO of Catholic Health Initiatives.<sup>6</sup>

With the high costs of precision medicine, community health systems likely will have to rely on specialized centers. For example, Moffitt works with community hospitals and physician practices that have the ability to take tissue samples and send them to reference labs, but that don't have the time, resources, or clinical expertise to develop algorithms or make a more precise diagnosis.

Another major issue is how health systems can best position themselves in a delivery world with two seemingly opposing trends: population healthcare and individualized healthcare.

Public health experts comment: "Pitting the health of individuals against the health of populations risks widening an unnecessary

divide between medicine and public health. Population health planning requires directing efficient use of resources towards those most at risk. Stratification of populations into risk groups for multiple chronic diseases could provide more efficient and effective prevention and treatment strategies, and potentially reduce cost of care."<sup>7</sup> Also raised for precision medicine is the possibility of equity of access issues and a widening gap between the haves and the have nots.

With both population health management and precision medicine, system boards should be thinking about the issues identified for the latter by a task force sponsored by the Personalized Medicine Coalition, namely:<sup>8</sup>

- How to build patient and provider awareness and education programs, such as through online information, collaborative forums, social media, CME programs, and pharmacist engagement
- Patient empowerment for decision making and use of the data, such as through use of patient representatives and counseling services
- How to demonstrate the value of the approach and build profitable delivery models, such as through payer forums and economic impact studies
- Leadership, infrastructure, and information management, such as ensuring the standardization and interoperability of medical data and outcomes information
- Ensuring access to care, such as developing incentives for payers to cover novel technologies with valuebased evidence

Health systems must be able to develop profitable business models to support and sustain both the delivery of personalized medicine and population health management.

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<sup>&</sup>lt;sup>6</sup> "Dignity Health and Catholic Health Initiatives Team Up to Launch the Largest Community-Based Precision Medicine Program in the U.S" (Press Release), September 19, 2016.

 <sup>&</sup>lt;sup>7</sup> Muin Khoury and Sandro Galea, "Will Precision Medicine Improve Population Health?" *JAMA*, October 4, 2016; pp. 1357–1358.
<sup>8</sup> Daryl Pritchard, et al., "Strategies for Integrating Personalized Medicine into Healthcare Practice," *Personalized Medicine*, January 19, 2017; pp. 141–

## Key Questions for Health System Boards

With precision medicine gaining traction among researchers, providers, payers, and consumers, boards should consider these key questions:

- How aware is organizational leadership of precision medicine?
- What are the community's expectations for incorporation of genetic test results into treatment?
- Given the organization's current payment models, what would the implications be of a shift from traditional protocols to precision medicine for high-volume, high-cost diagnoses?

- What are the implications of creating a sustainable competitive advantage in an era of precision medicine?
- Should the organization develop its own precision medicine program or partner with a specialized center?
- If a partner is needed, what form of partnership should be pursued?

The same questions can be considered related to population health management. The answers may not be clear or easy. But precision medicine and population health management are both here to stay, so directors and leadership teams should start thinking hard about the central issues, how the models interrelate, and the best way to position the health system for future success.

The Governance Institute thanks Mark E. Grube, Managing Director and National Strategy Leader, Kaufman, Hall & Associates, LLC, and Governance Institute Advisor, for contributing this article. He can be reached at <u>mgrube@kaufmanhall.com</u>.