Introduction to Personalized Medicine

Readers may have noticed a new healthcare catchphrase gracing magazine covers and even the front page of the *New York Times*: “personalized medicine.” But what does it mean and how will it change healthcare? According to the President’s Council of Advisors on Science and Technology, “Personalized medicine refers to the tailoring of medical treatment to the individual characteristics of each patient.” Personalized medicine is important because of several emerging clinical and financial trends in healthcare. As a result, there is a strong impetus for personalized medicine, which can succeed if we can find a way to break down the silos that have traditionally separated clinical and financial world views.

The clinical trends important to personalized medicine are evidence-based medicine, the genomic revolution, and big data. Evidence-based medicine is behind the push to reduce variation in care, making providers accountable for delivering treatments that are grounded in scientific evidence. The genomic revolution refers to our ability to quickly and cheaply sequence the human genome and to determine the biological basis of behavior and disease. Big data refers to our ability to create large data sets and implement automated systems, like IBM’s Watson, to sort through and make sense of all the information we collect.

Personalized medicine also capitalizes on emerging financial trends in healthcare—pay for performance, bundled payments, and expansion of affordable care. Pay for performance is where the rubber meets the road for evidence based healthcare—no outcome, no income. Bundled payments refer to the recognition that medical care, like a hospitalization for a heart attack, should be paid for in a lump sum rather than as separate line item bills for the hospital stay, EKGs, and aspirin. The need to deliver affordable care is at the heart of Affordable Care Act, which aims to expand health insurance coverage to the uninsured by finding savings in other parts of the healthcare system.

Personalized medicine ties together the clinical trends of evidence-based medicine, the genomic revolution, and big data with the financial trends of pay for performance, bundled payments, and expansion of affordable care. Evidence-based medicine gives payers reassurance that individuals are getting the most appropriate treatment based on published guidelines. Payment rates for the expected cost of an entire course of care should be as personalized as the treatments they finance, to ensure that provider compensation is adequate and provides the correct incentives—that will require smart bundled payments. Providers will collect data on their patients, compare outcomes to those in the published literature to benchmark their performance, and researchers can use the same data to refine the published literature on outcomes and costs for this population, i.e. big data. Payers could use the same data to provide extra incentives for high-performance care as demonstrated through superior outcomes, which is the goal of pay for performance. This process will ultimately save costs for patients and allow us to sustainably cover the entire population with health insurance, the essence of affordable care.

So what’s the problem? In our current fragmented, fee-for-service medical system, the vision I outlined has yet to become a reality. Personalized medicine is a bundled product. However, payers often pay for each diagnostic, drug, and device separately. We all know that the informatics needed to connect a diagnostic to the therapy regimen and outcomes just doesn’t exist in most healthcare environments. Finally, payers are wary of the idea of paying more upfront for a new technology that promises savings in the future—they are more comfortable focusing on the cost savings in the here and now by denying reimbursement for a new test outright, requiring prior authorizations, or a high degree of patient cost sharing in order to contain costs.

So what’s the solution? Well, we could wait for the integrated, affordable healthcare system of our dreams. If we are talking about today, however, and not the year 2100, the answer is to take a more integrated perspective. What will get payers to agree to pay for a new technology when technology has been at the heart of our cost containment crisis? Data that shows that personalized medicine can save costs by avoiding treatments that will not work. What will get providers to order those tests, and then actually use the results? Properly designed incentives that compare the expected outcomes and costs of care with patients’ actual experience. Patients will also need to be convinced of the need to become involved in personalized treatment decisions. High-deductible cost sharing and opaque prices mean that patients are getting tired of being surprised with large bills for care that they consider necessary. The promise of personalized medicine rests on the ability of scientists and financial analysts to collaborate to deliver this critical information in an impactful way.

I have seen these issues play out on the ground level in my own research. In one recent study, funded by MDxHealth, I was part of a team that investigated the potential cost savings from a new technology for the problem of unnecessary prostate biopsies. MDxHealth’s product, ConfirmDx for prostate cancer, is designed
to reduce the cost associated with repeat biopsies to diagnose prostate cancer. Using a budget impact model, we found that there was the potential for the test to be cost saving when accounting for the costs of repeated biopsies and the costs of the side effects of this invasive diagnostic procedure. However, the potential for cost savings were limited by the need to conform to the one-year time horizon common in U.S. managed care. In addition, prospective trials that collect clinical and financial data on the outcomes and cost of care will be needed to convince payers and providers that our results are credible. New payment models are needed to correctly align the incentives of patients, providers, and payers so that the individual responsible for the cost of care shares in the benefits of any cost savings.

While there are barriers to studying and implementing personalized medicine, the underlying forces motivating this new platform for healthcare are even stronger. The questions of how much technology should cost, who should pay, and the value of any new technology have taken on a heightened significance in the age of tighter budgets. Personalized medicine holds the promise of moving from a world of reducing waste on average to reducing waste on a patient-by-patient basis, which means a much greater potential for savings. In order to realize this vision, it will be necessary to collect both clinical and financial evidence in order to make the case for personalized medicine. We can then achieve our goals of treating patients as individuals, and doing so at a price we can afford.

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REFERENCES