

# Virtual Mentor

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## FROM THE EDITOR

### Getting Personal: The Promises and Potential Pitfalls of Personalized Medicine

The potential of personalized medicine, a technology and method of medical reasoning that hinges closely upon an individual's genetic make-up, is just starting to be explored. About a decade has gone by since the complete sequencing of human DNA in the Human Genome Project, which promised new understanding of disease and new cures. Since then, further discoveries have revolutionized the medical sciences, and we are already starting to see the technology catch up to the promise. Advancements in disease and genome detection technologies, as well as the development of tailored therapies based upon genetic make-up, are appearing in research studies, early clinical trials, and even, in some cases, in clinical practice. With new technologies and new knowledge come unique challenges and ethical dilemmas. We can know more about an individual than we ever have before, and we must be certain that we are good stewards of this information, as clinicians, as patients, as policy makers, and as world citizens.

In our first case discussion, Rachel A. Mills, MS, Susanne B. Haga, PhD, and Geoffrey S. Ginsburg, MD, PhD, a founding director of the Institute for Genome Sciences & Policy at Duke University, explore a variation on a common ethical theme: namely, how much information a patient is entitled to accept or ignore about his or her health, particularly when the patient has dependents to consider and when personalized medical technology makes it possible to detect a health problem before it becomes symptomatic. The concepts of autonomy and beneficence come to the fore when personalized medicine offers clinicians the ability to predict disease and help patients and their families plan accordingly.

Our second case highlights a real-life dilemma encountered by several undergraduate programs and medical schools attempting to educate their students about personalized medicine. In these instances, schools are offering genetic testing for the students to give them a personal experience as a platform for discussing not only the technology but also its implications and counseling demands. Dr. John Mahoney, MD, addresses questions of coercion, privacy, and the responsibilities that come with using students' genomes for education purposes. Although this activity serves as an interesting and informative exercise, it is essential to ask whether the benefits outweigh the potential risks.

The final case, addressed by Jeffrey R. Botkin, MD, MPH, tackles a rising trend at research and academic hospitals regarding the collection and biobanking of tissue and blood samples for genetic research purposes. Personalized medicine benefits greatly from the creation of biobanks that store a wide array of genetic material for

researchers to sequence and correlate to disease activity. These correlations can then be used in attempts to generate potential treatments for the associated diseases. Some hospitals have elected to use leftover tissue samples and blood draws from their hospitalized patients, automatically enrolling them in biobanks rather than obtaining consent for enrollment by the traditional method. This “opt-out” strategy works well for gathering a large data set, but not without ethical controversy.

The contribution to *Virtual Mentor*'s medical education section takes its cue from the ethical dilemmas raised in these cases. Bruce Korf, MD, draws upon his experiences as a clinician and educator to highlight strategies used to teach medical students and residents about the integration of genomics and personalized medicine into clinical practice. He stresses in particular the necessity of learning resource management and the conceptual competencies needed to stay abreast of clinical utilities as the field continues to develop.

Two articles in this edition also discuss the paradox of using personalized medicine, a technology ostensibly developed to tailor therapies to the individual, to potentially derive conclusions about cultural and ethnic groups. First, MD-PhD candidate Tim Chang reviews a 2009 journal article investigating whether genetic factors in the disease course of systemic sclerosis could be correlated with psychological and behavioral measures and, subsequently, patients' perceived functioning. The second article, by Ramya Rajagopalan, PhD, and Joan Hideko Fujimura, PhD, uncovers the errors that can occur when racial or ethnic group membership is used to guide treatment decisions.

In the state of the art and science section, Aaron M. Lowe, PhD, reviews a central aspect of personalized medicine: technologies involved in the rapid and reliable detection of genetic sequences and mutations. Starting from the sequencing of the human genome, the article highlights some of the technologies in the pipeline, what their current limitations are, and their medicolegal implications.

The health law section extends the discussion introduced in the first case discussion. Shawneequa Callier, JD, MA, and graduate student Rachel Simpson examine the medicolegal protections and ramifications of the communication of genetic risk to the families of those with disease. Legal precedents, the authors say, are insufficient guides for clinicians about their duty to inform family members of genetic risk.

Because personalized medicine is still a developing discipline, policy makers must consider whether legal and ethical regulations will be needed as the field evolves. In the first of this issue's policy articles, Dov Greenbaum, JD, PhD, relates research on personalized medicine therapeutics to past policy on developing therapeutics for orphan diseases. His contribution delineates how government and private business can work together on regulation, privacy laws, and governmental incentives that will allow industry to grow responsibly and cost-effectively.

In the second policy contribution, Wendy Foth, Carol Waudby, and Murray Brilliant, PhD expound on the topic of biobanking that was brought up in case 3. Using their combined experience with the Marshfield Clinic's Personalized Medicine Research Project, they discuss Department of Health and Human Services-issued certificates of confidentiality that biobanking organizations are encouraged to obtain prior to amassing large collections of personal genomic information. This article highlights the ethical and practical advantages these certificates offer to patient and researcher alike.

Finally, Sara Wainscott, MFA closes out this issue on personalized medicine with a poem. In a ghazal, she traces the historical, political, scientific, and metaphorical aspects of the genome, weaving together a scientific fabric that touches upon important contributions and advancements in the field that are transforming personalized medicine from dream to reality.

This month's issue faced a unique challenge of commenting on the ethics of a field that is in its infancy and only starting to appear in clinical practice. Although some might consider the treatment premature, we consider it essential to subject the emerging concerns to scrutiny and incorporate our answers into medical decision making. We consider this the beginning of an ongoing discussion about using genomes to explore disease and define—or redefine—the individual.

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