Boost(erism) for Personalized Medicine

Ross White, 04/04/2011
(Medicine) Permanent link

While the prospects of personalized medicine to help clinicians and patients better understand, manage, and treat illness as they affect individuals is highly commendable, this movement has recently been met by what I see as a troubling levels of boosterism. This was evident at the National Undergraduate Bioethics Conference, held at Duke University in March.

The student organizers did a tremendous job of cultivating stimulating conversations over three days of presentations, seminars, panels, and, my personal favorite to watch, Bioethics Bowl. I was disturbed, however, by the first plenary session, "Personalized Medicine: The Promise and Ethical Challenges," which turned out to be heavy on the promise and light on the ethical challenges.

Ralph Synderman, the James B. Duke Professor of Medicine at Duke University School of Medicine, provided a useful history of the development of medicine over the past two centuries, or as he called it a shift from "finding and fixing disease" to "predicting and personalizing disease." He asserted that personalized medicine would play an integral role in making treatment cheaper and more efficient by allowing prevention, intervention, and management of disease to start earlier than they can today. He predicted that 10 years from now doctors would focus primarily on personalization, prediction, prevention, and participation from patients.

But, he was concerned that the medical establishment, or as he called it, "the academy", was currently too embedded in the status quo; personalized medicine would need to be lead by entrepreneurs and startups. He acknowledged, with what seemed like little reservation, that physicians might need to be replaced by a health coach or other aggregator of information, such as computer software.

To my dismay, but not my surprise, the next speaker, David Ewing Duncan, chief correspondent of NPR's Biotech Nation and director of the Center of Life Science Policy at University of California, Berkeley, was just as eager for the wave of personalized medicine. His lecture was largely a discussion of his 2009 book, *Experimental Man: What One Man's Body Reveals About His Future, Your Health, and Our Toxic World*, in which he reflects on his decision to, among other things, be tested for 320 chemical

toxins and 7 to 10 million gene markers, spend 22 hours in an MRI, have 1.7 liters of blood drawn, and have over 100 gigabytes of data produced on his body.

After discussing how cool it was to have so many tests performed and learn things about himself, he attempted to offer some qualifications. He raised the prospect of not wanting to know all of the information discovered from genetic and other predictive tests, or the difficulties with incidental findings. Mr. Duncan also acknowledged that he received inconsistent test results from different companies, something the Government Accountability Office warned about in a report requested by Congress last year on direct-to-consumer genetic tests.

At the end of his lecture, Duncan urged that we must consider values about how and where increased health information is applied. While he was cautious about placing too much weight on the results from such tests, he did not suggest that those reasons should limit the progress of personalized medicine. In addition to promoting this work on his Web site and one for the Experimental Man Project, he encourages visitors to sign what he calls a Personalized Health Manifesto – "an old-fashioned call to arms and action plan for a new age of health care." At the conclusion of his talk, he asked the audience, "Are you ready?" I was the only person who responded "No." Upon hearing my disapproval, Mr. Duncan responded, "Too bad, it's happening anyway."

I walked away from session unsettled by the overall tone of the lectures. The wave of personalized medicine was imminent and should be heralded.

While Snyderman and Duncan provided a useful survey of what personalized medicine might mean for all of us, they failed to get at some of the most poignant ethical issues and concerns raised by the rapid onset of personalized medicine. Most, myself included, would argue that more and better information, diagnostic tools, and treatments are good things in the practice of medicine, but must we assume that personalized medicine is inevitable and thus does not require meaningful consideration of ethical, social, and practical concerns?

During the plenary session, we were told that personalized medicine would help us all make better health decisions and alter behavior to improve our lives. This assertion assumes that one has the financial resources needed to make these changes and lives in an environment conducive to a transformation of health behaviors. While it may be great for someone with a genetic predisposition to diabetes to eat healthier or get more exercise, that individual must have ready access to healthier food options, the financial means to change food purchasing habits, and live in a neighborhood where it is safe and possible to exercise.

Proponents of personalized medicine also assume that individuals will be more inclined to adopt healthier behaviors if they discover genetic or familial susceptibility to a particular illness, and some evidence suggests that this is so. But it's also possible that genetic findings might inadvertently reinforce the belief that our genes are our destiny. A belief of genetic determinism might lead some individuals to become cynical about being

able to do anything to alter their medical history; while others might feel overwhelmed by complex health information they cannot fully understand but are still expected to act upon.

Personalized medicine will only be successful if physicians are able to spend more time with their patients to ensure understanding of health information and take the time to create meaningful prevention and treatment plans in conjunction with their patients. The odds of this happening are discouraging, given that physicians are already spending less time with their patients and technology such as Watson is being infused into clinical practice, thereby reducing physician-patient face time.

Governments at both the state and federal level have already intervened in cases where personalized medicine appears to have gone too far. In early March, an FDA advisory panel urged federal regulators to disallow the sale of direct-to-consumer tests unless patients obtain a prescription from a physician who can help interpret results. These recommendations followed on the heels of other interventions last year to slow the availability of consumer genetic tests. Last May, after Walgreens announced plans to sell genetic testing kits, the FDA ordered the manufacturer to stop selling them, arguing that they qualified as medical devices and had not met the department's approval.

Months later, the California Department of Health forced U.C., Berkeley – an affiliation of David Ewing Duncan – to end its plan to offer genetic testing to incoming freshmen and transfer students and tell them the results. The Department of Health ruled that this plan constituted a clinical trial, which requires a physician recommendation for each patients and the gene analysis to occur at a licensed lab.

The fact that these attempts to bring direct-to-consumer genetic tests to the public have been stopped in their tracks suggests that the impending march of personalized medicine may be premature and inadequately regulated. While personalized medicine encompasses a wider range of interventions and methods than just genetic tests, the problems with such tests are a microcosm of some of the wider ethical and social issues raised by the expansion of personalized medicine: questions of affordability and access to personalized medical interventions, the ability of individuals to understand and act upon the findings, the uncertain role of physicians in the clinical experience as technology progresses and fills perceived voids in current practice, and the safety and effectiveness of personalized medical applications.

Moving forward, clinicians, patients, and those with a financial interest in the promotion of personalized medicine must remain vigilant to these concerns and continue to consider that perhaps the wave of personalized medicine should be, if not reconfigured, at least slowed to ensure we all reap the benefits of modern medicine in the most effective, meaningful, and compassionate way possible.

Ross White is a research assistant at The Hastings Center.