

# Boston Business Journal

## Medicines that treat patients, one genome at a time

### Personalized medicine

*is becoming a commonly heard phrase, but has it been fully studied?*

After many raised hopes, some false starts and the usual hype that accompanies any major technology innovation, the phenomenon of personalized medicine is becoming widely acknowledged as a major potential force for the transformation of health care.

Also known as molecular medicine or pharmacogenomics, personalized medicine uses genome-derived data, including human genetic variation, RNA and protein-expression differences, to predict the safety and efficacy of drugs in individual patients or groups of patients.

Following the mapping of the human genome in 2001, it is becoming practical to identify an individual's molecular makeup and thereby know his or her particular susceptibility to certain diseases, the probable progression of those diseases and their likely response to certain therapeutics. Thus, medicine will soon have the tools to differentiate between patients and patient groups to tailor and individualize treatment appropriately.

Doctors have always attempted to "individualize" treatment of their patients, of course. But their knowledge has been derived from prototypical population means and averages gathered to compose a prototypical person. The individualization traditionally performed, either intuitively or using biochemical measurements of one patient's profile, now has an added dimension of understanding.

Like a medieval painting — two-dimensional and flat — suddenly transformed with depth and texture into Renaissance art, diagnostics and therapeutics will now have the molecular perspective to "see" each individual. Thus physicians will have the tools to customize treatment based on the specificity of one person's genes, on the molecular signature of a disease as it unfolds in one person's body, and on the personal idiosyncrasies of one person's drug absorption and metabolism.

The scientific and medical communities

are increasingly focused on this subject. The *New England Journal of Medicine* has published a special series on genomic medicine and its clinical and ethical implications. Observers of our health care system are already noting that once patients have their drug-response genotype determined before prescription of a drug, drugs that would be unsafe or ineffective for them would not be prescribed, with the potential benefit of lowering health costs. Other thinkers caution that we are still uncertain how much such advances will improve care or what costs will be incurred.



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FDA will then draft its first industry guidelines. The bar will be raised for drug development, a definitive event in the progression to personalized medicine.

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While personalized medicine is becoming a reality, its potential to affect health care and the public have not been fully appreciated or considered. For example, patients may not understand why they are being selected for, or barred from, certain therapeutic options based on a "genomic profile." Drug developers may find that their blockbuster economic model for R&D investment is no longer viable. Regulators may find that traditional ways of measuring safety and efficacy are outmoded. Physicians may be required to learn an entirely new lexicon of disease and treatment modalities. Health care providers may have to confront issues surrounding best practices and insurance reimbursement. Last but not least, there is the potential to move the technology into our daily lives to enhance our lifestyles based on diet, exercise, leisure, learning and culture.

We consumers — all of whom will sooner or later in our lives be patients — are about to enter a fascinating era in which whom we are at the molecular level will be as important as what we have and how we feel. The opportunities are enormous to be diagnosed earlier and more accurately, and to receive a treatment that is appropriately efficacious and without unnecessary, adverse side effects. The challenges — of physician education, consumer education, medical ethics, health insurance and our entire health care delivery system — are equally large and already facing us.

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