BIOTECHNOLOGY

Genomics and us

Michael Rawlins examines a call for biotechnology to be geared towards public health.

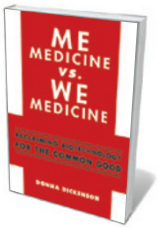
Personalized medicine has been a major ambition of clinical pharmacology for more than 40 years. The mantra of giving 'the right drug to the right patient, and at the right dose' has been accepted as the goal in seeking to maximize a drug's effectiveness and minimize its toxicity.

There have been modest successes. For example, in the 1970s researchers came up with the idea of using simple measurements of different patients' renal functions to tailor doses of drugs predominantly excreted unchanged in the urine — such as digoxin, the cardiac glycoside. And for the past three decades, the oestrogen antagonist and breast cancer treatment tamoxifen has been targeted solely at women with oestrogen-receptor-positive tumours.

Recent advances in genetics and genomics have shown that much more may be possible. We now know, for example, that there are important associations between mutations in human leukocyte antigen genes and the development of severe — sometimes lethal — adverse reactions to drugs such as abacavir (for HIV and AIDS) and carbamazepine (for epilepsy). It is now possible to identify patients who should avoid these drugs. Safe and effective warfarin doses can also be more reliably predicted by genotyping the enzymes involved in the drug's metabolism. And contemporary molecular genetics has become an important tool for monitoring the spread of infectious diseases and determining the antigenic components of influenza vaccines.

In *Me Medicine vs. We Medicine*, however, Donna Dickenson argues that the focus on personalized (me) medicine is eclipsing the focus on public health (we medicine). She is concerned that the personal-genomics revolution has yet to live up to the hype and that simple measures designed to maintain good health and prevent illness are being squeezed out by public and private funders, researchers, companies and health providers.

Dickenson is at her best when discussing the benefits of immunization in the context of public health. Taking a historical and sociological perspective, she provides a useful ethical analysis of the importance of herd immunity and the limitations of arguments that reject the concept of individual freedom among populations. She writes about the "free riders" who rely on herd immunity to avoid vaccination. She also reminds readers of mandatory US and UK vaccination programmes. In nineteenth-century England and Wales, for instance, the Poor Law Guardians were authorized to seek out and discipline non-compliers. Dickenson does not support the "vaccine sceptics", but places their concerns in this historical context.



Me Medicine vs. We Medicine: Reclaiming Biotechnology for the Common Good
DONNA DICKENSON
Columbia University Press: 2013. 304 pp. £19.95, $29.95

It is in her foray into personalized medicine that I feel her arguments become unsustainable. Dickenson writes that she has undertaken "a reality check" on the claims made for personalized medicine, and asserts that the evidence fails to support them. She also says that resources are preferentially given to personalized medicine, endangering public-health measures such as immunization. However, she provides no details on how she reviewed the literature or analysed the results.

Dickenson castigates Francis Collins, the geneticist who led the Human Genome Project, for describing personalized medicine as a "paradigm shift" in the way clinicians will be able to practise in future. She criticizes that project as "very generously funded, without having so far produced correspondingly weighty results for translational medicine".

She is not, of course, the only person to voice this opinion — Collins himself admitted in this journal that "those who somehow expected dramatic results overnight may be disappointed". But translating basic medicine into the clinic takes time. More than 40 years elapsed between the acceptance of the 'germ theory' of disease and the introduction of Salvarsan to treat syphilis; and 60 years passed between German physician Robert Koch's identification of the cause of tuberculosis and the discovery of streptomycin.

Dickenson devotes several chapters to the failings she perceives in direct-to-consumer genetic testing (such as that carried out by personal genetics company 23andMe, based in Mountain View, California) and private-cord-blood banking, which involves storing a baby's stem-cell-rich umbilical cord for its family's future medical use. However, in my view she does not fully explain how these procedures might have an adverse influence on personalized medicine.

Dickenson says that such 'retail' genetic analysis results in overwhelming additional demands on health-care systems. This is not necessarily true. For example, 23andMe tests for pseudocholinesterase deficiency, which affects about 1 in 1,000 people in some populations. The deficiency reduces the body's ability to metabolize some muscle-relaxant drugs used in anaesthesia, which can trigger temporary respiratory paralysis. Prior knowledge of a person's pseudocholinesterase status means an alternative agent can be used and resources can be saved.

Dickenson believes that for-profit commercial organizations largely support the development of personalized medicine. She cites the case of Herceptin (the brand name of the trastuzumab antibody), which is effective in the one-third of women with breast cancer whose tumours express the human epidermal growth factor receptor 2 (HER2) protein. Limiting use of the medicine to such women prevents use in those who would experience only its adverse effects, a particular concern given its potential to cause heart failure. However, because the manufacturer — Genentech of San Francisco, California — also holds the patent on the *HER2* gene, Dickenson says that other organizations are prevented from developing their own *HER2* antagonists. But this is not so — global health-care company GlaxoSmithKline has developed and marketed its own *HER2*-receptor antagonist, lapatinib (brand name Tykerb).

She also writes that Herceptin was only introduced in the UK National Health Service in response to public pressure. In fact, this happened as a result of guidance produced by London's National Institute for Health and Care Excellence during my time there as chairman, after taking careful account of its clinical- and cost-effectiveness.

Personalized medicine and public health are complementary approaches to maintaining the health of populations. And as most public-health measures are either cost-saving or cost-neutral in the long term, there is no cost-effectiveness conflict with personalized medicine. However effective our public-health measures, we all become sick. And when we do, the personalized medicine of the future offers great promise. ■

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