

Postcards: race and medicine in the 21st century

ON 20 July 2004, it was reported that BiDil®, a drug aimed specifically at African Americans to treat heart failure, has proven so successful in a clinical trial conducted in the US that it was ended early.¹ The pharmaceutical company sponsoring the development of BiDil and the clinical trial to assess its efficacy, NitroMed Pharmaceuticals, hope that this will now lead the US Food and Drug Administration (FDA) to approve BiDil for prescription. BiDil could be the first of several 'ethnically-tailored' drugs to appear in the near future, with implications for the way drugs are prescribed by GPs and other clinicians.

The case of BiDil appears at a time when there has been extensive debate in the pages of medical and scientific journals regarding the vexed issue of whether race has any place in 21st century medicine and science. Questions regularly debated concern whether race actually exists. Is it a matter of biology or merely a social phenomenon, or maybe a little of both? Is ethnicity a better, more accurate term to use than race? Should patients and research subjects be categorised according to their race/ethnicity? If so, for what purpose and who should define these categories — the patients or the clinicians? Can the medical and scientific community agree on a set of common guidelines when using race or ethnicity to undertake and report on their research?

This debate flows from two not entirely separate issues. The first concerns continuing inequalities in access to health care by minority groups and disparities in health outcomes among different sections in society.² Few would argue with the need to ensure equity in health and health care, and the very pressing issues of racism have been recognised by past contributors to this journal.³ The other issue is the emphasis given now to the study of genetic variation as being key to investigating the aetiology of common disease and differential drug response. Increasingly, researchers in these fields are claiming that racial or ethnic differences (and their language varies in this way) are important to understanding both of these areas.

The example of BiDil illustrates both of these issues. The case for BiDil rests on the argument that African Americans and white Americans not only react differently to drugs used to treat heart failure, but that they also have specific biological differences that

mean taking different drugs will be of greater benefit to them. Medical guidelines recommend that most patients with heart failure be treated with drugs, such as enalapril, that contain an angiotensin-converting enzyme (ACE) inhibitor. However, some cardiologists argue that using enalapril to treat African Americans is less effective than is the case with white patients because they respond less favourably to the ACE inhibitor, with higher incidences of angioedema reported. By contrast, BiDil is a combination of hydralazine and isosorbide dinitrate and works to increase nitric oxide levels in the blood, which has been shown to be beneficial for people with heart failure. Moreover, research has indicated that African Americans could have lower levels of nitric oxide compared with other populations.⁴ So, on both counts, African Americans are seen to benefit from taking BiDil and the results of the recent clinical trial would seem to bear this out. It is therefore on the basis of these supposed biological — and perhaps genetic — differences between African and white Americans, that the supporters of BiDil claim that disparities in health outcomes can be reduced by the targeted prescription of this drug.

The case of BiDil highlights one dilemma that may face GPs and other clinicians when it comes to making decisions about prescribing such 'ethnically-tailored' drugs: the task of selecting their patients by racial or ethnic categories. Understandably, some may be unwilling to do so, as they are likely to be aware that assigning people into racial or ethnic categories is a socially and politically sensitive practice. Those who are willing to do so may rely on any number of ways of assessing patients' racial or ethnic background, such as skin pigmentation, physiognomic characteristics, language, religion, names, or place of birth. Some may ask patients to put themselves into categories, and these may or may not correspond to those used in the research to develop the drugs in the first place.

Anderson *et al* have warned against using race to describe patients as if it were an easily discernable objective fact.⁵ But others, such as Sally Satel, who calls herself a 'racially profiling doctor', have argued, as a 'rough marker' of underlying genetic differences, race is useful for diagnosis and prescription.⁶ She gives the example of how she prescribes a lower dose of Prozac to

References

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African American patients compared with Caucasians and Asians, based partly on her clinical experience and on the findings of current research. However, Satel's approach is slightly troubling because she does not say how she goes about identifying someone as African American. This is pertinent, given that she says less than half of the African American population are recognised to be slow metabolisers of antidepressants, who therefore need a lower dose.

This highlights the problem of 'racially' prescribing BiDil: research does not show that all people who might identify themselves, or be identified by others, as African American will have the same reaction to enalapril or will share the genetic variation that means they have lower levels of nitric oxide in their blood. The company and the researchers behind BiDil acknowledge this and say that race is just a proxy here until researchers can identify the specific genetic variations involved.¹ They are also quite precise in their language, using the expression 'African American', but newspaper reports are less so and use what journalists may regard as synonyms, such as 'black'. Patients outside of the US, who may identify themselves as black, or as having African or Afro Caribbean ancestry, may come to hear of this drug and consider that it may be more appropriate for them. Given that geneticists have shown African populations to be the most genetically diverse, without clinical trials in other countries, the question of whether BiDil is a drug that is equally effective in all 'black' people is an unresolved question, and this will need to be explained to patients.

The case of BiDil, perhaps as the first of several 'ethnically-tailored' drugs to appear, highlights some of the dilemmas and problems that GPs could face as race and ethnicity begin to feature in novel ways in the area of medicine and drug prescription. Currently, the debate about race, ethnicity, genetics, medicine and health features the voices of epidemiologists, health service researchers, and geneticists, as well as anthropologists, sociologists, and ethicists. The voices of GPs have been heard less often. As health professionals who have daily contact with patients from all parts of society, it is important that GPs make a much needed contribution to the debate.

Richard Tutton

Code is king

Why does every damn thing have to be tied down by a protocol? When a group of 15-year-olds wanted to help out in a local home for people with dementia the project was stopped because, since there were children involved, the old folk needed criminal review board checks. How is it that, as sensible people, we have constructed so many individually defensible, but collectively fetishistic, systems? A large part of the answer goes back to the recent explosion in our understanding of basic codes.

In this month's Postcard Tutton explores whether racially determined differences in genetic code justify the marketing of 'ethnically tailored' drugs. But it is not just DNA that increasingly orders our lives — code, its metaphors and its prescriptions, is everywhere.

There is currently an international battle going on to decide who can control the code that runs the Internet. Governments, together with assorted software and media behemoths are, for a variety of good and bad reasons, trying to seize control of the pipes and protocols that deliver the Net to your desktop. Meanwhile opponents argue that ensuring that Microsoft® or the government can not influence what heads up your Google searches is as fundamental as free speech. Whoever wins this battle, code is the new law since it is code that will increasingly determine what we can and can not do.

In the messier world of medicine our work is also becoming rapidly codified. If evidence based medicine is the genetic code for the practice of medicine, then the quality and outcomes framework is the institutional cytoplasm that turns our practices into busy little factories churning out low cholesterol citizens.

So why has code become so important? For the first time ubiquitous computers make it possible to track and collate numerous interlocking activities. Thirty years ago we depended on judgement. Today in principle, (and quite often in practice) computers render large sections of our interactions visible. Within medicine, not only has the evidence-based code been massively extended, computers now order the institutional cytoplasm, making it possible to schedule, order and deliver much more consistent practice. Add lawyers and litigation to the mix and you have a cultural code that promotes consistency, risk reduction and the primacy of safety. And a system that insists 85-year-olds need their trivially elevated diastolic controlled. Or their criminal record inspected before they can have tea with a 15-year-old.

Paul Hodgkin