



## Lying awake worrying about asteroids

*Medical research in the UK is gripped by an anti-intellectual winter*

During the last British winter, a moderately well-off elderly couple in London somehow failed to pay their gas bill. After the routine warnings, the gas company turned off their supply. Interpreting the Data Protection Act of 1998 as prohibiting the divulgence of personal information to a third party without consent, the gas company failed to notify the local social services department that its former customers were now at risk. Eventually, one of the pensioners died quietly of hypothermia and the other of a cardiac event.

This true story highlights a national community that collectively has lost sight of reasonable balances between risk and benefit in regard to information and, by extension, the same equation as it applies to the systematic collection of data as it occurs in academic research. Somehow, the paediatric cardiac surgery scandal at Bristol Royal Infirmary and the murders committed by Shipman have, in the minds of tabloid editors and health bureaucrats, become conflated with the Alder Hey matter. The latter involved paediatric pathologists retaining tissue samples and body parts of deceased children “for research”, without obtaining the consent of their parents. A further ingredient is several infamous cases (mostly outside the United Kingdom) of research investigators being caught fabricating data. Throw in a typically prescriptive directive from the European Union regarding clinical trials of new drugs, and the results are a burgeoning “industry” regulating research, and paperwork that is multiplying faster than maggots in a dunghill.

The UK Government has only added to the momentum. Its Research Management and Governance Framework obliges every National Health Service Trust, be it in primary care, a general hospital or the mental health services, to develop systems to ensure that it is aware of all research taking place on its “patch”, and that each project meets all relevant standards of ethical, intellectual, scientific and fiscal propriety. At first glance, this appears entirely reasonable, but the reality is that investigators now have to prepare and submit multiple copies not only of grant applications, and then ethics applications, but also of new forms for research governance. Every piece of research involving users or staff of health and social care services, or the data such organisations hold, requires approval using a nationally standardised ethics form that potentially runs to 73 pages. This also applies to research projects undertaken in these settings by students, including undergraduates. The disincentives to initiating research are clearly massive, and the burdens are becoming unsustainable, especially those on supervisors of trainees who need skills and experience in doing and interpreting research to practise their professions properly. In primary care, in particular, it may well be impossible for the responsible Trust to know

which of its dozens of affiliated general practitioners are trying a new drug on a few patients at the behest of some larger or smaller pharmaceutical company, perhaps based at the other end of the country or even overseas. But if something goes wrong, it is the CEO of that Trust whose neck will be on the block.

Should these individuals be lying awake worrying about that possibility? If we can disentangle Bristol and Shipman from research, because hopefully both were exceptional episodes of exceptionally bad clinical practice, then the truth is probably that the Alder Heys of this world are also rare and are likely becoming progressively rarer. Attitudes do change, and the kind of paternalism represented by the actions of the Alder Hey pathologists is generally on the wane. Indeed, several Australian jurisdictions revised their coroners acts about a decade before

Alder Hey “broke”, because of a rising tide of concern that bodies had been released to grieving relatives with no indication that significant elements or even complete organs had been retained. The transition was not without pain, and pathology staff were obliged to brush up their skills for dealing with the living, but we fairly

quickly reached a new level of respect for all of the parties in the forensic triangle. Certainly, Australian researchers were spared the chore faced by all British medical academics post-Alder Hey of having to account for every last histology slide up and down the country.

In a highly competitive, publish-or-perish environment, the temptation to bend or break the rules of scientific and intellectual integrity may never be eliminated. And peer review is demonstrably not a foolproof defence against fraudsters. While instances of ingenious invention of interesting findings clearly do come along more frequently than transits of Venus, and therefore are more common than collisions of asteroids with the Earth, any scientifically literate member of an ethics committee will tell you that we face far greater problems in the shape of poorly designed and ethically and scientifically inadequate research protocols. At the very least, it takes the average medical student around 4 years to lose completely the capacity to describe any piece of research in terms that a potential lay participant can understand. Added to this is the problem posed by powerful computers that readily reanalyse any given set of data until at least one “statistically significant” (and therefore publishable) result emerges.

Perhaps worst of all is the tendency for authoritative individuals and organisations to recommend clinical and public health policies that go well beyond the available evidence. In the UK, for example, the major diabetes charity has run a “missing million” campaign, advocating screening the population for undiagnosed diabetes. And all because rigorous controlled trials

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have shown that tight control of blood glucose level and blood pressure in people with clinically evident diabetes reduces vascular and renal complications.<sup>1,2</sup>

Research and its reputation are not without their problems, but breaches of the Data Protection Act, pathological paternalism, and the imminence of a cosmic collision are not chief among them. Greater clarity in thinking and improved scientific and ethical literacy in the population at large, in the community of investigators, and among policymakers and politicians would shorten the anti-intellectual winter now gripping much of medical research in the UK.

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1 UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). *Lancet* 1998; 352: 854-865.

2 UK Prospective Diabetes Study Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. *BMJ* 1998; 317: 703-713. □