Current controversies

Who needs health care—the well or the sick?

Iona Heath

Shifting drug spending from the worried well in developed countries to those with treatable disease in poorer nations will benefit the health of everyone

Caversham Group Practice, London NW5 2UP
Iona Heath
general practitioner
iona.heath@dsl.pipex.com

BMJ 2005;330:954–6

Investment in health care, especially when it is driven by the interests of pharmaceutical companies, seems to produce a J curve. For most of the curve, the more money spent, the better the health outcomes, but after a certain point, the more spending and the more emphasis on health at the expense of other areas of human activity and achievement, the worse overall health becomes. Many poorer countries are trapped high on the long arm of the curve while richer countries seem intent on exploring the upper end of the short arm through the excessive self confidence of preventive medicine.[1] The emphasis on preventive care damages patients in rich countries by tipping them towards misery. This process is built on a foundation of fear and is fanned by economic and political pressures.

Health and wealth

Amartya Sen has compared people living in Bihar, Kerala, and the United States.[2] Bihar is the poorest state in India, and Kerala is the state that has invested most heavily in education and achieved the highest rates of literacy. Predictably, life expectancy is lowest in Bihar and highest in the United States, with Kerala's falling between the two but much closer to the United States. However, the rates of self reported illness are paradoxical: low in Bihar, where the low expectations of health are disturbing, and enormously high in the United States, which is equally disturbing but for different reasons. Kerala combines the greatest longevity and the highest rate of self reported illness of all the Indian states. It seems that the more people are exposed to doctors and contemporary health care, including the rhetoric of preventive care, the sicker they feel. What is happening to these different communities and why? What is the relation between perceived and observed health—between resignation, contentment, anxiety, and distress? George Eliot thought these questions the core of research and, describing the young Dr Lydgate in *Middlemarch*, she wrote:

> He wanted to pierce the obscurity of those minute processes which prepare human misery and joy . . . that delicate poise and transition that determine the growth of happy and unhappy consciousness.[3]

A fraction of the spending on preventive medicine in rich countries could make a huge difference to the health of poorer nations

Prolonging life

Health has become the over-riding contemporary virtue, and the measure of health care in rich countries has become, to a great extent, the simple prolongation of life. Doctors are exhorted to use preventive technologies to try to ensure that everyone lives as long as possible. The danger is that the achievement of longer and, by all objective measures, healthier lives, may result in those lives being increasingly dominated by feelings of illness and fear.

The political and financial power of the multinational pharmaceutical conglomerates continues to grow, and they supply money and resources to both clinicians and researchers. At the same time, developments in information technology drive the rigorous standardisation of the diagnosis and treatment of illness and disease so that care is increasingly directed by protocols that minimise uncertainties. Contemporary complexity science shows the lack of a linear relation between cause and effect, but doctors and healthcare systems persist in purveying a simplistic rhetoric: "If you do this, this will follow." How many patients really understand the numbers needed to treat they are caught up in? How hard do doctors try to explain?

The critic Lionel Trilling believed that stating any proposition without at least a hint of doubt about its validity is a form of bullying.[4] We urgently need to move away from bullying of patients by doctors, of doctors by politicians and, I suspect, of politicians by multinational corporations.[5] We must foster doubt and acknowledge and discuss our uncertainty and the limits of our knowledge. Science can help only if research is interpreted with a degree of scepticism and distrust and its application accommodates Trilling's view that, pending further thought, all claims ought to be provisional. Each generation looks back on the science of earlier generations and sees the extent of ignorance but each, in turn, seems blind to its own ignorance.

The three trends of the industrialisation of health, the medicalisation of life, and the politicisation of medicine are intertwined and mutually reinforcing, and each depends on the pretence that we know much more than we do. The fears of politicians, practitioners, and the public combined with the enduring human craving for a predictable future are making us all into willing participants. Managers and politicians collude with the "need to create images of control in the face of risk"[6] and attempt to regulate clinical practice more closely through increasingly rigid and burdensome systems of audit and inspection.[7] The dangers of this approach are illustrated by the current situation within which, after a succession of media scandals, beleaguered histologists and cytologists are now so afraid of missing malignancy that they are beginning to err on the side of excessive caution, triggering unnecessary intervention and mutilation and the illusion of increased survival.[8]

Medicalising healthy populations

The waning of professional power is portrayed as being in the interests of patient autonomy, but its replacement by corporate power may compromise patient autonomy even more. Only a minority of most populations are sick at any one time; the majority are healthy. It is clearly in the interest of the pharmaceutical industry that this majority should be persuaded that they need to take action to remain healthy by being screened and taking preventive medicine. Seventy per cent of the UK population is taking medicines to treat or prevent ill health or to enhance wellbeing. How can this level of medicine taking be appropriate in a population which, by all objective measures, is healthier than ever before in history? Excessive prescribing drives iatrogenesis, with adverse drug reactions estimated to account for 4% of bed capacity within the NHS at a projected annual cost of £466m (€674m, $890m).[9]

As the overall health of a population increases, more money can be made from selling healthcare interventions for the healthy majority than for the sick minority. In rich countries, more money is now invested in research into the prevention of disease than into its treatment.[10] It is instructive, in the UK context, to weigh the huge amount invested in the vast bureaucracy of health promotion against the waiting times for interventions of proved effectiveness and the neglect of the care of frail elderly people, particularly those with Alzheimer's disease and other forms of dementia.

Summary points

The more people are exposed to contemporary health care, the sicker they feel

We do not understand the effects of being labelled at risk

More money can be made from selling healthcare interventions for the healthy majority than for the sick minority

A tax on preventive drugs sold in rich countries could be used to fund drugs in poor countries

An increasingly common tactic is to portray a risk factor as a disease. Raised blood pressure and osteopenia provide just two examples. Each is a biological continuum with symptomatic disease at one extreme. It is always difficult to draw a line and dichotomise a continuous variable into normal and abnormal categories, but it is in the interests of the pharmaceutical industry to draw a line that includes as large a population as possible within the range of abnormality. But is it in the interests of the rest of us, either as patients or as citizens?

Linn Getz and colleagues have drawn attention to our limited understanding of the effect of being labelled at risk.[11] Information about risk is widely presumed to increase people's sense of control over their lives and ultimately their quality of life, but risk information also casts shadows of doubt and insecurity over people's lives and undermines their experience of integrity and health. The more that preventive healthcare initiatives emphasise risk and instruct people about the many ways in which it is possible to die, the more uncertain the future may seem and the more fearful people may become.

As doctors, are we simply interested in postponing death? Should we not also be interested in reducing rather than fanning the human burden of fear and in emphasising rather than undermining health. Are we sure that the balance sheet of preventive activity really offers more good than harm? It is contingency—chance, fate, uncertainty—that makes life beautiful.[12] It is the enduring truth that we can never know what will happen tomorrow, whether or not we have taken our aspirin and our statin, which makes life thrilling. As doctors, we need to relocate our engagement with our patients more in the present of their lives and their immediate concerns and, in so doing, we can hope to ensure a better future on both limbs of the health expenditure J curve.

In 1978, James Tobin the economist who went on to win the Nobel Prize in 1981, proposed a worldwide tax on all foreign exchange transactions.[13] He argued that it would reduce exchange rate volatility, thereby improve macroeconomic performance and generate revenue that could be used to support peace and sustainable development. A modest 0.25% tax would generate over $300bn (£157bn, €227bn) a year (the total UN annual budget is about $10bn). A variation of this proposal could be a pharmaceutical Tobin tax on

preventive drugs sold in rich countries that would be used to fund treatment pharmaceuticals in poor countries. This could help to flatten both arms of the J curve and thereby benefit people in both rich and poor countries.

Contributors and sources: IH has been a general practitioner in the same inner city practice in London for nearly 30 years. The ideas in this article arose from thinking and reading around the experience of caring for patients in this context and were first presented at the 31st Annual Meeting of the North American Primary Care Research Group in October 2003.

Competing interests: None declared.

1 Sackett DL. The arrogance of preventive medicine. *CMAJ* 2002;167:363-4.
2 Sen A. Health: perception versus observation. *BMJ* 2002;324:860-1.
3 Eliot G. *Middlemarch*. London: Penguin Classics, 1994 (first published 1871-2).
4 Delbanco A. Night vision [review of Trilling L, *The moral obligation to be intelligent: selected essays*]. *N Y Rev Books* 2001;48(1).
5 Abraham J. The pharmaceutical industry as a political player. *Lancet* 2002;360:1498-502.
6 Power M. *The audit society: rituals of verification*. Oxford: Oxford University Press, 1997.
7 Fitzpatrick M. *The tyranny of health: doctors and the regulation of lifestyle*. London: Routledge, 2001.
8 Ernster VL, Ballard-Barbash R, Barlow WE, Zheng Y, Weaver DL, Cutter G, et al. Detection of ductal carcinoma in situ in women undergoing screening mammography. *J Natl Cancer Inst* 2002:94:1546-54.
9 Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *BMJ* 2004;329:15-9.
10 Freemantle N, Hill S. Medicalisation, limits to medicine, or never enough money to go around? *BMJ* 2002;324:864-5.
11 Getz L Sigurdsson JA, Hetlevik I. Is opportunistic disease prevention in the consultation ethically justifiable? *BMJ* 2003;327:498- 500.
12 Nussbaum MC. *The fragility of goodness*. Cambridge: Cambridge University Press, 1986.
13 Tobin tax network. www.tobintax.org.uk/?lid=1443 (accessed 9 Feb 2005).

(Accepted 2 February 2005)

Principles for international registration of protocol information and results from human trials of health related interventions: Ottawa statement (part 1)

Karmela Krleža-Jerić, An-Wen Chan, Kay Dickersin, Ida Sim, Jeremy Grimshaw, Christian Gluud for the Ottawa Group

Registering of trials is essential to make sure all results are publicly available and that ethical obligations to participants are met

Randomised Controlled Trials Unit, Canadian Institutes of Health Research, Ottawa, 160 Elgin Street, Ottawa ON, K1A 0W9, Canada
Karmela Krleža-Jerić *clinical research officer*
An-Wen Chan *special advisor*
Department of Community Health, Brown University, Providence, USA
Kay Dickersin *professor*
Department of Medicine, University of California, San Francisco, USA
Ida Sim *associate professor of medicine*
Clinical Epidemiology Program, Ottawa Health Research Institute, Ottawa, Canada
Jeremy Grimshaw *director*

continued over

BMJ 2005;330:956–9

Recent evidence of selective reporting of results has eroded public and academic confidence in publications of clinical trials, leading to renewed calls for trial registration.[1–5] The dangers of non-disclosure of trial results, although described for years, sparked an international furore last spring after the publication of two systematic reviews on the effects of selective serotonin reuptake inhibitors for childhood depression.[1 6] Subsequent legal proceedings[7] and policy statements by journal editors,[8 9] medical associations,[10] and industry[11] have recognised the importance of trial registration. The rationale for registering trials is well known (box 1).[12 13] Most importantly, the contribution to social good that justifies research on human participants is not realised when resulting knowledge remains invisible.

As an interested and neutral party that has been registering the trials that it funds,[14] the Canadian Institutes of Health Research hosted an open meeting on 4 October 2004 in Ottawa, Canada, to foster international consensus on trial registration. The resulting Ottawa statement aims to establish internationally recognised principles for registration (box 2). The full statement is on bmj.com, but here we highlight and discuss some of the key principles. A statement on how to implement these principles (part 2) is still in development.

Box 1: Rationale for registration of clinical trials

Ethical

- Respect the investigator-participant covenant to contribute to biomedical knowledge by making trial methods and results public
- Provide global open access to information
- Reduce unnecessary duplication of invested research resources through awareness of existing trials
- Assure accountability with regard to global standards for ethical research
- Enable monitoring of adherence to ethical principles and process

Scientific

- Increase the reliability and availability of evidence on which healthcare decisions are based
- Improve trial participation
- Increase opportunities for collaboration
- Ensure transparency of trial design and methods
- Provide open review of protocols to improve trial quality and refine methods
- Provide means for identification and prevention of biased under-reporting or over-reporting of research
- Accelerate knowledge creation

Summary of principles

The mandatory registration of all trials has three components:

- Obtaining an internationally unique identification number (unique ID)
- Registering the original protocol along with subsequent amendments
- Registering the trial results.

P+ *Members of the Ottawa Group and the full statement are on bmj.com*