LIFE AND DEATH Iona Heath

The road to hell . . .

Clinical trial evidence is shamelessly extrapolated across time, population subgroup, and condition

The quality improvement movement within medicine is awash with good intentions. The trouble is that those in the driving seat are often in a hurry and have an unfortunate tendency to cut important corners. If, as a result, the principles and methods of science are ignored, the good intentions become self defeating, unrealisable, and dangerous. This is sadly what seems to be happening. Good intentions are being enacted through interventions that begin to represent something of a nadir in the ways in which research is translated into practice.

We are witnessing a degradation of knowledge, which results from its bureaucratic application to whole populations. Too often, evidence from clinical trials is being shamelessly extrapolated across time, across population subgroup, and across condition. Again and again, efforts are concentrated on crude process measures, while clinical outcomes that are genuinely significant for patients because they reduce or delay suffering or prolong life are ignored. Thirdly, the present state of clinical evidence systematically neglects the reporting of harms (www.aemg.cochrane.org/).

Let us examine these trends in relation to the care of type 2 diabetes in those belonging to that rapidly increasing proportion of the population who are aged over 80. Within the Quality and Outcomes Framework of the UK general practice contract and within similar systems in an increasing number of countries, doctors are incentivised to reduce patients' blood levels of glycosylated haemoglobin below 7.5%, whatever their age. The application of this target to the older people exemplifies every stage of the perversion of knowledge that I am trying to describe. There is almost no trial information available which is directly relevant to the care of those who are more than 80 years old. The deficit is glossed over by applying information gained from trials involving much younger people to a completely different population subgroup. Yet older

people, because of their necessarily more limited life expectancy, have much less opportunity to benefit from interventions aimed at reducing the risk of future complications. On the other hand, because of increasing physical frailty and being much more subject to multiple and compounding conditions, older patients are at greater risk of the adverse effects of polypharmacy and these risks, unlike the potential benefits, are incurred immediately.

An even more fundamental problem is that the level of glycosylated haemoglobin is a reductive and simplistic process measure which correlates poorly with clinically significant complications of type 2 diabetes in any age group and not at all for people over 80. The emphasis on these levels seems to derive from an extrapolation across conditions. In 1993, the results of the Diabetes Control and Complications Trial (DCCT) documented the potential and substantial benefits of tight control of blood glucose levels in patients with type 1 diabetes. The authors warned explicitly against using their findings in the care of those with type 2 diabetes, but that is precisely what has happened in the intervening years. Any use of the DCCT findings in the care of older people is particularly shocking given that the average age of the trial participants was 27 years.

The results of the United Kingdom Prospective Diabetes Study (UKPDS), published in 1998, have been used to support the emphasis on tight control of blood glucose levels in type 2 diabetes. However, as McCormack and Greenhalgh have so carefully argued (*BMJ* 2000;320:1720-3), the study in fact showed no clinically important benefit from the control of blood glucose with sulphonylureas and insulin over more than 10 years. Differences were detected in process measures such as albuminuria and the progression of retinopathy, but there were no differences in the outcomes that are important to patients: renal failure, blindness, and loss of visual

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acuity. The only effective agent was metformin, which is undoubtedly beneficial through mechanisms that seem poorly understood and are not completely explained by the effect on blood glucose levels.

Many treatment trials underemphasise the possibility of harm. To take the UKPDS as a single example, harms were recorded per year, whereas benefits were expressed over 10 years. The effect of this kind of reporting is to imply that harms are minimal in comparison to potential benefits. This is not always the case. The most frequent harm caused by intensive treatment of blood glucose levels is hypoglycaemia and some degree of hypoglycaemia was noted in 37% of those receiving the most intensive treatment. This is likely to be particularly devastating in older people because of their already increased vulnerability to falls, and the exclusion of older people from trials means that harms which are relevant to them may be significantly underestimated.

There seems little doubt that the treatment of type 2 diabetes in very old people should be carefully adjusted to their individual circumstances and preferences and not dictated by a futile insistence on ever tighter control of blood glucose. Every working day, thoughtful clinicians, subject to crudely implemented programmes of quality improvement or payment by results, are being confronted not only by the mismatch between the imperatives of such programmes and the needs and preoccupations of their patients, but also by the disturbing possibility that they may actively be harming their oldest and frailest patients. Maybe, if we as doctors have the courage to learn from our mistakes, the Quality and Outcomes Framework will, in the end, provoke a reaction sufficient to make it the cause of positive change and more integrity in the ways in which research is applied in clinical practice. Good intentions are not enough.

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ETHICS MAN **Daniel K Sokol**

A perforated education

Surely every medical student worth their stethoscope should be familiar with the bare bones of the profession's history?

If asked to name famous doctors in medicine's long and tempestuous history, what would you say? Hippocrates, Galen, Avicenna, Maimonides, Vesalius, Harvey, Lister, Osler, Cushing, Salk?

When I recently put this question to a class of third year medical students, I was disheartened to hear their first answer: Harold Shipman, the British general practitioner who murdered more than 200 patients and hanged himself in prison in 2003. The next most popular answer was Gregory House, a brilliant though mischievous, cynical, and quite fictional character of the popular American television series *House*.

A few days ago, I attended a surgical conference in London. A distinguished professor of surgery, who qualified in the first half of the 20th century, showed a chest x ray to the audience. "We used to see a lot of this in the 1940s, when I was a house surgeon," he reminisced. With an austere nod of the head, he asked an unsuspecting junior doctor for a diagnosis.

Junior doc: "I guess it could be..."

Surgeon: "Don't guess, boy!"

Junior doc (startled): "Is it a diaphragmatic hernia?"

Surgeon: "I discard you like a perforated condom."

As I heard "Harold Shipman" and "House" leave the lips of those medical students, the surgeon's colourful dismissal seemed apposite. How I wished consultants would use Osler's method of asking students on ward rounds for some historical background:

A case of exophthalmic goitre comes in—the question at once is put, "Who was Graves? Who was Parry? Who was Basedow?" Of course the student does not know; he is told to bring, on another day, the original article, and he is given five or 10 minutes in which to read a brief historical note.

It is perhaps unrealistic to expect

students to know more than the basics of the profession's history, but surely every medical student worth their stethoscope should be familiar with the bare bones of the subject. Aside from history's intrinsic interest, it can foster a sense of perspective and continuity, and a spirit of reflective inquiry. Physician-historians have written about how knowledge of medical history has improved their clinical practice, from preventing hubris to aiding diagnosis. Even a single session would benefit the student, and in answer to the obvious rejoinder "If history creeps into the curriculum, what goes out?" I suggest medical ethics, whose lessons can easily be incorporated into a history lecture. Medical history is replete with ethical issues. In fact, it is through studying the history of medicine that I became interested in medical ethics.

So I spent the next 30 minutes of the class discussing key moments in medical history: the transition from a supernatural to a rational model of disease, Galen's humoral theory, vaccination, antiseptics, the germ theory of disease, and so on.

For the last part of the hour, we dissected William Osler's essay *Teacher and Student*, in which Osler reflects on the characteristics of a good medical student and doctor. He writes of the art of detachment, the virtue of method, the quality of thoroughness, and the grace of humility. I asked the students about the importance of these qualities. We discussed the meaning of humility and the benefits of the virtue: the ability to identify and learn from our mistakes, to learn from others, to gauge our abilities, and make more balanced judgments about others. And inevitably, when the time came to discuss witnessed instances—or notable absences—of humility, the students invoked the cold hearted surgeon as the antithesis of humility. Where, in our hospitals, is

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the sensitive surgeon of TS Eliot's *East Coker*?

The wounded surgeon plies the steel

That questions the distempered part;

Beneath the bleeding hands we feel
The sharp compassion of the
healer's art

Resolving the enigma of the fever
chart.

Jotted down on a post-it note, a quote from the surgeon Richard Selzer dangles precariously on my computer:

"The surgeon must remain anesthetized to the philosophical, the literary, even the human implications of his work, in order to be able to carry it out dispassionately, at the proper remove from the white heat of the event."

How, if at all, can we reconcile these two extracts? I'll ask the students next time.

After the class ends, I bump into one of the students on the underground. "How did you find the class?" I ask, aware that any positive answer would be borne out of politeness. "It was thought provoking, but the guy next to me didn't see how it could help in exams."

I discard you like...

Call me naive, but is there not something amiss about contemporary medical education when frequent examinations stifle the intellectual meanderings so essential for an expanded mind? In 1954, a 12-year-old boy in the United States wrote to Mr Justice Frankfurter, an eminent Supreme Court judge, requesting advice for a career in law. The judge recommended that the boy read widely for "no one can be a truly competent lawyer unless he is a cultivated man." Is that, I wonder, also true of medicine? **Daniel K Sokol is lecturer in medical ethics and law, St George's, University of London**
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