

# EDITORIALS



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## Self experimentation and the Nuremberg Code

Ethics review is needed only when other people are subjects too

The Nuremberg Code is the cornerstone of human experimentation law and ethics.<sup>1</sup> Nonetheless, the suggested exception of self experimentation in its article 5 has never been persuasive: no experiment should be conducted if there is an a priori reason to believe that death or disabling injury will occur, except, perhaps, in experiments where the experimental physicians also serve as subjects.

The judges should have stopped at the word “occur.” Why is the exception there, and is it justifiable to put the lives of others at risk because the investigator is willing to risk his or her own life? The answer is that the prosecution at Nuremberg (and apparently the judges as well) thought that this exception was necessary to prevent the Nazi doctors from arguing that previous US government military experiments—most notably the Walter Reed yellow fever experiment—had also knowingly risked the lives of subjects.

This explanation is supported by the originally suggested wording of article 5 by each of the two principal doctors who worked for the prosecution at Nuremberg, Leo Alexander and Andrew Ivy. Alexander suggested adding yet another clause: “such as was done in the case of Walter Reed’s yellow fever experiments.”<sup>2</sup> Ivy would have replaced the existing clause with: “except in such experiments as those on yellow fever where the experimenters serve as subjects along with non-scientific personnel.”<sup>3</sup>

As Alexander and Ivy had anticipated, the 1900-1 yellow fever experiments did come up in the cross examination of Andrew Ivy.

Ultimately, however, the studies did not play a crucial role because Ivy testified that he could not recall their details. Instead, he made a different point, that unlike the Nazi experiments, these were not performed under government or military orders. Because of the common equation of Walter Reed with self experimentation, it is of interest that Walter Reed himself, unlike his research team, was not a subject in the experiments. Similarly, although the yellow fever experiments made an appearance at Nuremberg, nothing in the testimony suggested that the willingness of an investigator to be a subject could serve as an ethical justification to put other humans at risk of death.

Neither of these historical footnotes has much relevance today, not least because few, if any, contemporary researchers are willing to risk their own lives to prove the value or safety of their research.<sup>4</sup> In the rare contemporary cases of self experimentation (an experiment done by the investigator on himself or herself only) must be reviewed and approved by an ethics committee before it is conducted.<sup>4</sup> Three linked articles help clarify the ethics review question.

Groves studied his bicycle riding and only his bicycle riding, and he has no plans to conduct bicycle riding research. He justifies not having his “n=1” bicycle riding study reviewed because he is the “sole investigator and subject” of the study and that it was “conducted . . . using his normal mode of transport.”<sup>5</sup> This misses the central point. Groves was not doing research at all—he was not seeking generalisable knowledge by testing a hypothesis. He was simply trying to decide which of two bicycles to ride to work. The fact that he wrote up his “findings” in the form of a journal article does not make his decision making process a research project. It is a single anecdote that makes interesting reading, but it is much more suited to a cycling magazine or the newspapers than to a medical journal.<sup>6</sup> Of course ethics review committees do not and should not review consumer product choice procedures (although someone might caution Groves about the dangers of cycling in the rain and snow).

The Danish research team doesn’t say why it didn’t seek ethics committee review for its study on whether alcohol can be absorbed through the feet, although it was probably because all three investigators were physicians in good health, they understood the study, and they reasonably believed that it carried no risk, except perhaps of embarrassment.<sup>7</sup> This is responsible. But it is also responsible for an institution (and a medical journal) to require that the “no risk” determination be made by an ethics committee. As the Danish team acknowledges, a slight modification to the protocol, such as including “eyeball drinking,” could radically alter the risks of the research.<sup>7</sup>

The PARCHED investigators did seek and obtain ethics committee approval for their investigator subject study. This is appropriate because their group contained more than one investigator subject (no plural exists for self experimentation), and because they recognised the risk of death posed by compromises to renal function.<sup>8</sup> The ethics committee was overly cautious in its requirement of a data monitoring committee, but it curiously did not require documentation of fluid intake by the subjects, suggesting a cursory review at best. The investigators properly note this failure as a limitation of their study, but this simply makes their recommendation to drink more water while on shift all the more puzzling.

Where does this leave us? The reasonable conclusion is that, contrary to article 5 of the Nuremberg Code, for life threatening research the participation of the researcher as a subject adds nothing to the ethical analysis of whether the research can be justified at all. The Walter Reed studies should have been characterised as unethical at Nuremberg (because they predictably would cause the

deaths of non-investigator subjects), rather than weakly defended, and they certainly provide no ethical basis for their repetition today. Informed consent is a necessary, but not sufficient, condition of ethical experimentation. Self experimentation is neither necessary nor sufficient. Even where risks are minimal, prior ethics committee review of research in which investigators are subjects should be sought, if only to confirm the reasonableness of the risk assessment. If, on the other hand, an investigator proposes to experiment only on him or herself, that activity is not properly categorised as research at all, but as self indulgence (or, some may say, self abuse). Nuremberg continues to teach us serious ethical lessons. Trivial interventions masquerading as research studies are primarily a source of amusement.

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▶ PFI: perfidious financial idiocy. A “free lunch” that could destroy the NHS (*BMJ* 1999;319:2)

## The private finance initiative: the gift that goes on taking

Its genius is how it diverts public resources to private interests

Perfidious financial idiocy was how the *BMJ's* editor described the private finance initiative (PFI) in 1999.<sup>1</sup> Under the policy, NHS hospitals and land are sold off and new hospitals built using private loans instead of public loans or grants. We argued at the time that this would result in bed closures because hospitals had not been funded to pay the full costs of the loans, which are paid back over the 30-60 year contract period.<sup>2-3</sup> And that's what happened: English NHS hospital capacity fell by 73 882 beds (almost a third) between 1992-3 and 2009-10, and occupancy rates rose to unsafe levels of more than 85% during the period when the PFI system of loan financing was introduced.<sup>4-5</sup> In 2000, as controversy grew over PFI related bed reductions, the government's National Bed Inquiry found that further acute sector closures were unlikely to be safely attainable without more intermediate and community service beds, and it recommended reversal of bed closures.<sup>6</sup> The wasteful £4bn (€4.8bn; \$6.3bn) independent sector treatment centre programme was introduced as a stop gap,<sup>7</sup> and hospital reconfiguration continued.

Last week the Public Accounts Committee revealed that PFI is even less affordable.<sup>8</sup> Banks lending to PFI projects have increased their interest rates by 20-30% since the financial crisis. But, as Audit Scotland has shown, private finance interest rates were already 2.5-4% above public borrowing rates before the government bail out.<sup>9</sup> Higher charges for interest rates mean higher annual repayments by the NHS, as much as £200m a year for every 0.01% to 0.03% increase in lending rate.<sup>10</sup> The Public Accounts Committee calculates that the increased bank charges “added £1 billion to the contract price, payable over 30 years, for the 35 projects financed in 2009.”<sup>8</sup>

But the problem of higher interest rate charges is not confined to new PFI deals. The PFI's annual charges rise each year because annual payments are linked to the retail price index. This policy requires large injections of taxpayers' money to support it. The funding freeze and ring fenced PFI debt payments that are index linked provide the ingredients for a perfect economic storm.

The scale of the problem for the UK is formidable. By

December 2009, 159 PFI projects, worth £13.2bn in terms of building costs, had been signed to the NHS, and total debt to be repaid had reached £43bn. This year alone (2010-11) all PFI payments across the public sector will reach £8.6bn. The commitment over the next 25 years is projected to be £210bn.<sup>8</sup>

What stands out is the disparity between the original cost of a building and the final bill—a consequence of higher interest and returns to investors. Is the bill worth it?

The government says it is. It argues that we are buying cost efficiency and that contractors have an incentive to be more efficient because it is their own money, not taxpayers' money, that is at risk. According to the treasury, when “risk transfer” of this kind is taken into account, private finance is no more expensive than public finance.<sup>11</sup>

The UK parliament has repeatedly questioned the lack of evidence in support of risk transfer and value for money claims. In July 2010, a National Audit Office paper to a House of Lords committee described value for money as “subjective judgements of risk, which can easily be adjusted to show private finance as cheaper.”<sup>12</sup> The chairman of the Public Accounts Committee described PFI as “probably the most secure projects to which the banks could lend.”<sup>12</sup> The committee previously expressed concern over high interest rates, returns that contractors earn from PFI projects, and the risks they actually bear.<sup>13</sup>

To restore confidence in the financial markets and to free up lending, the UK government increased public borrowing to support the banking sector. It is this increased borrowing that lies behind the austerity drive across the public sector. In 2008-9, the government recapitalised the Royal Bank of Scotland Group (RBS) and the Lloyds Banking Group at a total cost of £37bn to become the major shareholder in both banks, holding 70% of RBS shares and 43.5% of Lloyds shares.<sup>14</sup> The government also agreed to protect RBS from losses on risky assets up to £282bn.<sup>15</sup> The effect of government rescue is to transfer the risks, completely or in part, from the private sector back to the taxpayer.

These same banks provide loans to and take equity shares

in many PFI schemes; it is ironical that they are currently using high PFI interest rates to rebuild their balance sheet after the financial collapse. In other words, the public sector is making PFI payments to banks it partially owns, at a higher cost of borrowing than traditional public borrowing. This means that investment risks have now been transferred back to the tax paying public, negating the rationale for the policy. The rewards to PFI investors and shareholders are shrouded in secrecy, but an analysis of the financial projections for three hospital projects at the time the contracts were signed has shown that pure equity investors expected to receive £168m for £0.5m of equity invested in the Royal Infirmary of Edinburgh, equity of £100 in Hairmyres PFI hospital was expected to generate £89.14m for investors, and for Hereford hospital equity of £1000 was expected to generate £55.7m.<sup>16</sup> These high rewards are contractually protected and underwritten by government.

The genius of PFI is the way it diverts public resources from public to private interests, providing guaranteed profits to its backers in a time of austerity. But the shiny “new builds” will be cold comfort for the thousands of NHS staff now being served “at risk of redundancy notices” and millions of patients who face withdrawal of much needed entitlements and public services. A public enquiry and full publication of all contracts are long overdue.

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▶ The knowledge disease (*BMJ* 1993;307:1578)

## Strategies for coping with information overload

You need a machine to help you

Fraser and Dunstan show that even within a narrow specialty it is impossible to keep up with published medical reports.<sup>1</sup> Trainees in cardiac imaging reading 40 papers a day five days a week would take over 11 years to bring themselves up to date with the specialty. But by the time they had completed that task, another 82 000 relevant papers would have been published, requiring another eight years’ reading. And this analysis assumes that trainees need to know about cardiac imaging only, whereas they surely need to keep up with other areas of medicine and healthcare. The authors conclude that it is impossible to be an expert.

This problem is not new. Dave Sackett, the “father” of evidence based medicine, found some 20 years ago that to keep up to date in internal medicine it was necessary to read 17 articles a day 365 days a year.<sup>2</sup> He also found that the median time spent reading by newly graduated doctors was zero, while for senior consultants it was 30 minutes, with 40% reading nothing.<sup>2</sup>

Some 10 years ago I asked around 100 doctors how much of what they should read to do their job better they actually read. About 80% said less than 50%, and 10% said less than 1%.<sup>3</sup> More than half felt guilty about this, and when asked to describe in one word how they felt about their information supply it was mostly negative (impossible, overwhelmed, crushed, despairing, depressed), with just a few answering “challenged.”<sup>3</sup>

One of the best known responses to information overload was the founding of the Cochrane Collaboration, named after the epidemiologist Archie Cochrane who called for a “critical

summary . . . adapted periodically, of all relevant randomised controlled trials.”<sup>4</sup> He knew that most of the new information was of poor quality, and Brian Haynes showed later that less than 1% of studies in most medical journals reach stringent scientific standards.<sup>5</sup> John Ioannidis has argued in the best read paper in *PLoS Medicine* that most research findings are false.<sup>6</sup> So it makes no sense for doctors to try and read everything: rather, argued Cochrane, they should rely on critical summaries.

But 20 years after the launch of the Cochrane Collaboration a review has found progress to be poor.<sup>7</sup> Around 75 clinical trials and 11 systematic reviews are published every day, with no sign of abating. Yet many clinical topics have no Cochrane Library systematic reviews, and perhaps three quarters of interventions lack a firm evidence base. We have what Muir Gray, once director of the National Library for Health, calls an information paradox—we are overwhelmed by new information yet have many unanswered questions. The average 10 minute consultation between a doctor and patient will throw up at least one question that cannot be answered.<sup>8</sup> The box lists the possible strategies for dealing with the problem, but the only one that might bring success is to use a machine.

Several years ago after conducting a semi-systematic review of the information needs of doctors I tried to identify the characteristics of the machine that would finally solve the seemingly impossible problem of answering all the questions that arise in medicine with the very latest research.<sup>8</sup> Here are the characteristics:



W HEATH ROBINSON

**Strategies for dealing with information overload**

**The ostrich strategy**

With this strategy doctors simply ignore the torrent of new information. If Sackett's data are right, many doctors adopt this strategy, especially as they get older.<sup>9</sup>

**The pigeon strategy**

Perhaps the most common strategy is to hang around with other doctors and pick up tidbits of information. You attend grand rounds and the occasional postgraduate meeting, follow some guidelines, and rely on drug company representatives to tell you about new treatments. When you have a tricky question about a patient you consult a colleague—the most common way to get an answer.<sup>8</sup> You sometimes flick through journals, but you learn more from the mass media. The most annoying way that you learn new things is from patients who bring newspaper clippings, garbled stories about something on the television, or long printouts from the internet.

**The owl strategy**

Probably the rarest strategy is that proposed by the originators of evidence based medicine. You build your knowledge patient by patient by identifying questions that arise during interactions. You refine the questions to one that can be answered, search for all relevant evidence, and systematically analyse it, abandoning the large amount that is of poor quality and combining, preferably numerically, that of high quality. The advantage of this strategy is that your information relates directly to your patients. Unfortunately, almost nobody has the time and very few the skills to pursue such a strategy.

**The Jackdaw strategy**

Doctors who pursue this strategy follow the pigeon strategy but also regularly search for highly refined evidence—from perhaps the Cochrane Library, Clinical Evidence, guidelines, or other

sources of evidence based reviews. Unfortunately these sources are full of holes (because the evidence simply doesn't exist), and the evidence is not useful—and may even be harmful—for patients with comorbidity (who now constitute most patients).<sup>10</sup>

**The inhuman strategy**

John Fox, once director of the Advanced Computing Laboratory, said that practising medicine is an inhuman activity, meaning that it's absurd for doctors to practise without the help of machines. Individual doctors have no chance of keeping up with new research, but teams of people can process new information and feed it into machines that doctors (and patients) can use. The most popular of these machines is UptoDate, which has 400 000 users, but there is also *BMJ* Point of Care, the Map of Medicine, and more.

- Part of the information system that doctors use as they see patients
- Able to answer highly complex questions
- Connected to a large valid database
- Electronic
- Fast (answers within five seconds)
- Easy to use (as easy as a car)
- Portable
- Prompts doctors in a way that is helpful not demeaning
- Connected to the patient record
- Gives evidence related to individual patients
- A servant of patients as well as doctors
- Provides psychological support.

Some of these characteristics may never be achieved. For example, it is impossible to give evidence related to individual patients because evidence is gathered on populations. It would also be hard for machines to provide psychological support, but many of the questions that doctors ask themselves, such as, "Did I do the right thing by that young woman who died of breast cancer last week?", are really a request for psychological support.<sup>8</sup>

And will doctors be willing to use such machines? De Dombal showed that computers are better at diagnosing acute abdominal pain than doctors, but his strategies were never widely adopted.<sup>11</sup> My father resented my mother buying a dishwasher because he feared it would replace his role, and

perhaps doctors are worried that machines might precipitate the reformation, described so beautifully by Joanne Shaw, where priestly doctors with their Latin bibles will have to give way to plebeians speaking the vernacular.<sup>12</sup>

"Will we ever solve the problem of information overload?" I imagine myself asking God as I arrive in heaven. "Sure," he'll answer, "but not in my lifetime."

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