



## editorial

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### Ethics in research: a box of tissues

'Our revolution in accountability has not reduced attitudes of mistrust, but rather reinforced a culture of suspicion. Instead of working towards intelligent accountability based on good governance, independent inspection and careful reporting, we are galloping towards central planning by performance indicators, reinforced by obsessions with blame and compensation. This is pretty miserable both for those who feel suspicious and for those who are suspected of untrustworthy action – sometimes with little evidence'

Onora O'Neill, The Reith Lectures, BBC, 2002

Recently while applying for research and development approval for a Multi-Centre Research Ethics Committee (MREC) approved study, our research team spent some time and effort discussing the merits of adding a sentence in the ethics section: 'a box of tissues will be made available for any participants who become distressed during the interview'. We had received conflicting advice about the merits of including or excluding the sentence, based on previous experience with R&D committees. Our application already emphasised that the subject matter of the interview was not in itself distressing, that the interviews would be conducted on willing and well-informed participants, that the researchers would be supervised and trained in conducting interviews in an empathic and sensitive manner, and the interviews would be terminated if participants so wished. But we had not considered a box of tissues.

Regardless of the merits of this particular sentence, the episode highlights two emerging trends in medical research: a belief in the power of documented procedural detail in controlling unexpected outcomes, and the implicit (and often overt) attack on the presumption of trust in medical professionals and researchers.

The Helsinki Declaration (available at <http://www.wma.net/e/policy/b3.htm>) states that every precaution should be taken to minimise the impact of the study on the participant's physical and mental integrity. It further states that 'the research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with'. From this demand for a clear statement of ethical considerations, how did we arrive at a situation where the availability of a box of tissues has to be specified? And what might omission of the box in an application mean? Is it an

ethical transgression? Is it symptomatic of the researchers' insensitivity to the harm they might cause? Does it reflect entrenched stigma that people with mental illness are non-autonomous and psychiatric researchers ethically compromised? Or does it simply mean that scrutiny committees are not free from the temptation of nitpicking as self-justification? After all, the perfect application would make the committee's scrutiny redundant; it is perhaps a form of survival instinct to make a comment, any comment, rather than allow things to proceed unhindered; and prohibition is so much easier than facilitation.

Ethical guidelines are presumably written by well-meaning and concerned individuals who make finely balanced judgements after serious moral deliberations. The history of medicine is littered with examples of research misconduct and callousness towards participants (Gillon, 2005). Research must be conducted ethically and research governance requires a clear ethical framework. Guidelines are an integral and necessary part of any such framework. However, faced with the need for specifying procedural detail down to the availability of a box of tissues, one cannot help wonder: Are these guidelines surveillance masquerading as procedures? Is the committee which considers specification of such detail genuinely concerned with anticipating and minimising harm or in attributing blame should there be a complaint?

Some research procedures might put all participants at a low level of risk, whereas others might be very low risk overall but selectively risky in some participants. Where such probabilities are known, committees are entitled to expect researchers to have considered differential aspects of risk and harm prevention. In thinking about the right course of action, we can only appeal to general principles. Moral practice cannot always be reduced to specific actions, since all possible outcomes of any intervention cannot be predicted. This becomes even more difficult when we move from controlling risks of interventions to controlling human interactions.

High-profile and well-publicised adverse events, in medicine in particular and public services in general, lead to inquiries which recommend mechanisms to ensure better future protection of the public. Illuminated by the brilliance of hindsight and seduced by expert testimonies that unpredictable and unforeseen events should have



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been predicted and foreseen, such inquiries confidently assert that similar tragedies should never happen again. Research administrators and academic institutes become cautious and preoccupied with the thought: what can we do to avoid being in that situation? Increasing attention is paid to every possible outcome, no matter how trivial or remote, safeguards are implemented and all actions documented. However, whether this attention to minutia necessarily achieves safety, prevents low probability events, minimises harm or makes the research more ethical is open to question (Gunsalus, 2004).

The standard response to anyone questioning this regulatory prodding and overzealous control is likely to be 'but what if it were your child/spouse/relative?' Truth however is harsh and uncaring; the honest answer to the question: 'why did it happen to me?' might be 'bad things happen in life. Why not to you?' We could state in applications: 'we recognise that during this project we might make a mistake. We hope not to but if we do, we have tried to ensure mechanisms that identify these mistakes early and minimise risk'. However, honesty is no recompense, we seek legal protections.

It is an illusion that the law can fully protect us; law can only intrude more and more into every aspect of our life, including relationships, and where law intrudes, commerce follows. Legalisation of human interactions is followed by commercialisation of human emotions. Financial value is placed upon distress, the magnitude of which is argued in learned discourses, requiring further

laws. Law in the West now intrudes into the most intimate of relationships. In non-Western societies, human interactions are governed by cultural values and are not dependent upon legislation. We consider many such societies to be lawless. Not surprisingly, those societies consider our relationships to be devoid of values.

I can offer no solutions to these problems. All I can say to junior colleagues embarking upon research is that no matter how noble your intent, no matter how keen your enthusiasm, no matter how compassionate your approach, don't forget the box of tissues.

## Declaration of interest

S.S. routinely deals with research and development and ethics committees.

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