An exercise in fatuity: research governance and the emasculation of HSR

The ethical governance of health services research (HSR) is in a mess internationally. Policy-makers and research commissioners are unable to obtain prompt answers to their questions at reasonable and proportionate cost. Researchers adopt scientifically problematic methods, delivering less reliable and valid results, because of the ignorance and prejudices of ethics review committees ill equipped to deal with their projects. Excessive and inappropriate bureaucratic requirements soak up the expensive and valuable time of skilled investigators.

When such problems are encountered globally, we cannot attribute them to the incompetence or ill will of particular national systems – indeed the problem is, in many ways, one of good intentions. Ethics review was introduced for the best of motives: criticizing the protection of human subjects is like criticizing motherhood and apple pie. However, this concern for protection arises from a history of abuses in biomedical research that have no counterpart in the social sciences that underlie HSR. The ethical analysis of, and institutional responses to, these abuses are irrelevant to HSR.

Why has governance of ethics been established in biomedical research? The conventional story presents this as a simple response to the wartime medical experimentation of Nazi Germany. We often prefer not to recall exactly what this involved: dunking male prisoners in freezing water or strapping them to stretchers outdoors in sub-zero temperatures to induce hypothermia, and then warming them with intense sun lamps, internal irrigation with near-boiling water or sexual intercourse; twin studies involving forced gas inhalation to induce sputum, 2-L enemas preceding intestinal examination without anaesthetic and other procedures before the victims were killed by lethal injection and dissected. Other examples included sterilization with caustic substances injected into the uterus and deliberate infection with lethal diseases. However, historians have increasingly shown that Allied physicians did not have clean hands.[1,2] The 'moral consensus' against which Nazi doctors were judged was hastily fabricated just before the opening of the Nuremberg Trial. Similar atrocities by Japanese doctors were covered up in the interests of post-war reconstruction and some of the wartime and post-war experiments conducted by the Allies have not withstood subsequent scrutiny. Whistleblowers like Henry Beecher and Maurice Papworth questioned the routine assumptions of medical research in the 1950s and 1960s, challenges that led ultimately to the present regimes for the regulation of biomedical research.[3–5]

It is hardly surprizing, then, that suspicion attaches to biomedical research. Professional or commercial interests necessarily compromise investigators' motives and the potential for harm is significant. In this context, the desirability of a detailed independent review of research risks and benefits is understandable, as is the insistence on the voluntary informed consent of participants. However, what is it about either the past or present conduct of HSR that begins to compare with the hazards to which participants in biomedical studies have been, and are being, exposed? Where are the risks of death or serious, disabling and permanent injury? Clearly, there is potential for minor and transient emotional distress, for a degree of embarrassment and for some loss of privacy, although all are well-acknowledged problems with responses that do not depend on governance processes: if someone starts crying in an interview, then you suspend the questioning. HSR is not homeland security.

However, there is another crucial difference between biomedical research and HSR, and that is the nature of the obligation to participate. Although it has been argued that there is a general duty to participate in clinical research on communitarian grounds,[6] the obligation to take part in HSR derives from the basic conditions of illness as a social role. Half a century ago, the great American sociologist, Talcott Parsons, pointed out that sickness is essentially a dependency claim by those who are unable to perform normal social roles on those who can.[7] For this claim to succeed, claimants – the sick – must constantly demonstrate their commitment to limiting the burden on the well. As others, particularly Eliot Freidson,[8] have noted, this obligation presents difficult problems for the long-term or chronic sick. However, they do not escape it – Erving Goffman, for example, describes paralysed polio victims in iron lungs winking at medical and nursing staff to show that they are really trying to recover, to minimize their dependency claims, however desperate their situation.[9] Economic growth over the years since Parsons first published his analysis has blunted its impact, but it returns to haunt us as we confront the limits of the willingness of the well to pay taxes or insurance premiums for the care of the sick. The UK government has signalled its desire to shift to a 'something for something' approach in relation to the support of the long-term sick and disabled, and its reluctance to continue funding future increases in health care expenditure at current rates.[10] US national health expenditure is now 16% of gross domestic product and projected to rise to 18.7% by 2014,[11] and it is hard to imagine that similar considerations can long be avoided.

Medical sociology – and HSR in general – has developed as a dimension of this social compact. As understanding of the complexity of disease and its effects has increased, with a corresponding increase in the complexity of the institutions devised for its management, it has become ever harder to evaluate what constitutes a valid dependency claim and a convincing demonstration by claimants, sick people, of their co-operation with the expectations of the well. HSR is in part a tool by which institutions legitimize their receipt of funds from the tax or insurance-paying well, through demonstrating that they operate efficiently and effectively. However, it is also a tool by which the well can articulate and define their expectations of claimants to the sick role of what constitutes a reasonable effort to minimize the duration and cost of this claim. Because strict utilitarianism is not a viable principle of societal organization, as Parsons also demonstrated,[12] we may equally be concerned with principles of social solidarity expressed in a concern that the sick should receive equitable and humane treatment, in which HSR also has a critical role. Crucially, though, HSR exists to satisfy the expectations of the well that they are not being asked to write a blank cheque for the sick.

Once this is understood, the fatuity of most HSR research governance should become clear. Individual informed consent is not the founding principle that it is in biomedical research. The accountability of HSR is not to research participants but to its commissioners, to the agents of the well who wish to be assured that their material contributions to the care of the sick are being spent in a fit and proper way. The receipt of health and social care to which tax or insurance funds have contributed carries with it an obligation to be accountable for that benefit, and HSR is one of the means by which that accountability is documented. This is not an argument for the abuse of research participants – the self-interest of HSR researchers is a clear incentive to act in ways that encourage co-operation by seeking consent, building trust and the like. However, it is a strong argument against the uncritical transfer of a governance model, designed in the wake of real atrocities, to situations where the life and health of participants is not placed at serious risk. A new approach to governance is required, resting on the assumption that HSR will only be subject to external regulation in the few cases where there is a clear and compelling case for review because of exceptional vulnerability among those invited to participate.

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How might the way you look influence how well you are looked after?

In the current issue of the Journal, O'Reilly *et al.*[1]raise the question of whether the perceived attractiveness of patients might influence how they are treated by their General Practitioners (GPs). They are unable currently to answer that question since they have not looked at how patients who are more or less attractive are actually treated by their GPs; however, they show that in an experimental setting, GPs perceive differences in the average attractiveness of potential patients depending on the socioeconomic status of their area of residence – those from more affluent areas are rated as more attractive. (This observation is consistent with findings from the West of Scotland Twenty-07 Study that nurse interviewers rated adolescents from higher social classes and less-deprived neighbourhoods as more attractive than their more disadvantaged counterparts.[2,3]) O'Reilly *et al.*'s assumption that this might translate into different treatment is based both on the literature about socioeconomic status differences in the length and content of GP consultations and the literature (again, largely experimental) on the ways in which people perceived to be more attractive tend to be