NHS Ethics: Shoe-bombers and why 'less needs to be more'

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Neuropsychological research poses several challenges. Some of these, such as developing new ideas and conducting innovative studies, are approached with great enthusiasm, and are an integral and motivating part of academic research. By contrast, other challenges feel like gruelling, near-impossible tasks, designed to test the will of would-be researchers. For many, the process of obtaining UK National Health Service (NHS) ethics approval is the archetypal example of such a task. Baron (this issue) highlights several of the difficulties concerning the ethical review of research involving human subjects, identifying flaws in the current system, and their negative impact on the research process. In this commentary we further reflect on the current system for gaining ethics approval to work with brain-injured patients in the UK, and its implications for neuropsychology research in the UK and beyond.

What is the Declaration of Helsinki for and why was it devised?

The Declaration of Helsinki was originally developed for the medical community by the World Medical Association (WMA) in June 1964 in Helsinki, Finland as a set of ethical principles regarding human experimentation. Since 1964, it has undergone seven revisions expanding in length from 11 paragraphs to 37 in the 2013 version, reflecting both continual developments as well as clarifications that are needed.

Why is this Declaration important to neuropsychologists?

As neuropsychologists, we work with brain-injured patients for a variety of reasons including (but not exclusively) to gain a better understanding of intact functions, to improve assessment of other patients, and finally to develop rehabilitation to allow post-injury readjustment. To allow us to perform these various aspects of our work, having a trusting relationship with our patients (who to all intents and purposes are highly vulnerable due to their neurological limitations such aphasia, confusion, and information processing difficulties) is of paramount importance.We are bound by the same duty of care as medical staff and this duty is a vital aspect of our practice both by training and by professional registration. Furthermore, patients and their relatives have the right to be correctly informed about all relevant aspects of the research, possible implications for their health (if any) and right to decline participation. Therefore,having clear Ethics rules is not just a mandatory aspect for modern research, it is also a useful support to reach better research outcomes and protect patients from any form of possible abuse.

How do we feel about the NHS's interpretation of the Declaration of Helsinki?

There is a consensus that, while the neuropsychology community firmly believes in protecting the rights of our research patients, the processes required to gain NHS approval have become more and more complex over the years, as a consequence of historical events that may have little to do with neuropsychology. For example, it was discovered in 1999 that Alder Hey Hospital in Liverpool had been systematically harvesting the organs of deceased babies without the knowledge or consent of the bereaved parents. This appalling scandal resulted in a number of recommendations for research within the NHS. Despite this completely understandable response, it may have led to a knee-jerk reaction to anything involving 'patients'. An analogous situation can be found in the domain of aviation safety: following the discovery that would-be terrorist and suicide-bomber Richard Reid had

attempted to take liquid explosives onto a plane inside his shoe, millions of people around the world are now barred from taking liquids onto planes unless they are in very small bottles. Although these regulations may not actually prevent harm, airline security is seen to be doing *something*. Quite possibly medical research ethics is similarly driven by *being seen to do something/anything*, without being quite clear in its purpose. A culture has developed in which we busy ourselves with being seen to protect patients from opportunistic, misguided and misleading scientists who are in fact operating with great integrity in line with their codes of practice. As a result, neuropsychologists have been saddled with working within a system that is largely irrelevant and unnecessary. Most of the work that we do is non-invasive, mainly consisting of behavioural studies with paper-and-pencil or computer tasks. Apart from the length of time spent completing these largely innocuous assessments, which constitute minimal (everyday) risk (similar to that which could happen by watching TV), there is negligible risk to the patient's well-being. On the contrary, several patients are genuinely interested in taking part in our studies, as their participation allows them to reframe their difficulties into a new scientific perspective, and to consider their condition as a potential resource for themselves and the community. However, NHS ethics review tend to adopt the most stringent criterion, without discriminating between high- and minimal-risky methodology. This approach typically involves elaborate justification of the minutia of a proposed study, which then needs to be assessed and evaluated on its merit. Researchers are burdened with endless requests of compliance to the rules of the game, even if quite removed from its actual purpose. A myriad of communication difficulties between the different disciplines makes the process protracted and demanding. All this time we are not actually producing anything at all - no novel insight, no scientific progression, and quite possibly not even safer research conditions. This is no self-assessment process for responsible professionals. This is a culture of imposing scrutiny and standing guard.

What are the implications of the 'more is ridiculous' in the current framework for getting NHS approval?

There are a number of implications of what we feel is a misplaced ethical procedure that has been imposed upon neuropsychologists in the name of protecting patients. The procedures are extremely lengthy and often require documentation that has little relevance to the patient and the care with which we work with them. These lengthy processes have financial implications because of the sheer time that it takes to complete, review, and administrate the extensive documentation. Furthermore, despite having one national medical research ethics procedure that in its draconian format covers all practices and all eventualities, significant fragmentation and duplication persists around research governance when recruiting clinical populations from different regional health trusts. This non-harmonised layer of bureaucracy results in much duplication and wildly varying governance requirements as different sites seem to have different local policies about a large variety of issues from recruitment modality to format of the information sheets, forcing further amendments of largely redundant documentation. This incredible amount of redundancy, repeating the same lengthy procedure multiple times, has financial implications again for the time of the researchers, and therefore for the Universities, NHS, administrators and review panel members. At some levels, the analogy with the implications of the lone-wolf shoe-bomber is complete, because one man's act has resulted in an unnecessarily lengthy and complicated procedure for research which has minimal (if any) risk. Just as flying to a destination has been made more difficult, alternative methods of transport (e.g. Eurostar to Paris) have become more attractive, in a parallel manner, despite firmly believing in the Declaration of Helsinki, many neuropsychologists feel that the NHS system is a **disincentive** to conducting the research that they are passionate about.

How do other countries do things?

As one of the working groups tasked by the British Neuropsychological Society to consider the challenges of neuropsychological research ethics, we surveyed the challenges faced by colleagues in other countries. We communicated with neuropsychological researchers from Belgium, France, Germany, The Netherlands, Sweden, Italy, Greece, Israel, the USA, India, Japan, New Zealand and South Africa. What was strikingly evident from this exercise was that all struggled with many of the same issues. All researchers' productivity seemed to be burdened by ethics procedures that were not designed for the nature of our research. Some seem to have it easier than their colleagues in other countries, while others considered moving their research across the border to countries where procedures appeared to them to be more light-touch. The general themes of dissatisfaction were around insurance or indemnity, poor fit of neuropsychological research with medical research ethical procedures, needing to reapply or notify when making small changes to the research that do not actually affect the ethical principles, and seemingly incommensurable differences in understanding between disciplines.

It occurred to us that it is the unusual open-ended nature of neuropsychological research that may make these challenges so universal. Our research is often data-driven. The fact that our methods do not actually vary much, and therefore the ethical issues hardly requiring constant re-examining, does not seem to satisfy those who stand guard. Details, in the name of protocol, need to be spelled out even before they are known. Our need for flexibility is regarded with much suspicion due to a lack of trust which seems to run across international borders. In summary, it was sadly not possible to identify one country or ethics system that could be taken as a best-practice model. Neuropsychologists internationally struggle with the same issues.

What do we propose as a way forward? A case of when 'less is more'….

As a community within the British Neuropsychological Society, we have Fellows of the Royal Society, members of major research panels, and medical doctors. Within our community therefore, there is a plethora of expertise that can be used to police our ethical procedures. At the moment, the Research Ethical Committees (REC) process in the UK offers the possibility of considering applications for a short process called 'proportionate review'. However, often neuropsychological studies are not considered eligible for this fast-track process as the panels consider that our studies present medical issues. It would be useful to resolve any perceived differences in what constitutes 'minimal (everyday) risk', most likely covering a large proportion of neuropsychological research. Once such understanding has been established, this would allow for more proportional ethical review that could be more local and furthermore make insurance of risk much more straightforward.

We mentioned above the lack of fit between the nature of neuropsychological research and medical ethics practice. In our non-interventionist basic behavioural research, we tend to use a very specific set of methodologies that does not actually vary much between the different research projects which nevertheless require individual ethical approval. A disconnect arises from patient ethics that is designed for medical trials. In ourbasic science work we generally have no set protocol with outcome measures assessed at fixed time points In contrast to group studies where all aspects of the research are planned, (multiple) single case studies are more open-ended and lists of tests and experimental tasks cannot be predefined a priori. This is data-driven research where the next step in the research process is based on what we find patient can and cannot do on tasks that have been designed to answer each question in turn, making minor procedural adjustment to address the next questions. . But importantly with regards to ethics, our methods do not change much as we progress in research programmes and patients' right of informed consent is not undermined. What would be very useful therefore is and alternative ethical approval path for basic science for group and single case studies in

neuropsychology. The often generic methods used in a research programme would be described (the things participating patients would do, and the things they would *never* do) and the scientific merit of a number of broader basic research questions would be clearly demonstrated. This would then form a generic approval for a broad research programme that would be awarded ethical approval for a period of, say, ten years. This would be a real cost-saving, and would aid publically funded research productivity in neuropsychology; the Declaration of Helsinki would be firmly adhered whilst benefitting both patients and society's understanding of the brain.