

'Consent rituals' in evaluation of coercive care

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Medical research is a pre-requisite for maintaining good clinical care and advancing our knowledge base. Before new interventions can be introduced into clinical practice, their effects have to be tested in research settings, often involving patients. Ethics committees, among other things, are concerned with protecting the interests of patients participating in research.¹ This is particularly acute for evaluation of treatments and especially sensitive when participants have mental health issues.

In psychiatry emergency situations, the levels of patient violence are high. Violent behaviour occurs in up to 30% of those who attend or are brought to psychiatric services for the first time,² and these acute violent situations represent a risk for the patients themselves, for other patients and for the staff.³ Guidelines recommend, first line, to calm the situation using words and reassurance, to acquire a diagnostic history and to complete physical and laboratory tests before starting drug treatment. Yet, if these techniques fail, effective and urgent alternative interventions are necessary to ensure the safety of everyone involved. To date, some of these interventions in psychiatric care remain coercive,^{4 5} but many of these approaches have not been subject to fair evaluation within trials despite calls from national bodies^{6 7} as well as grieving relatives.⁸

Where trials of treatments given under coercion have been undertaken, they have frequently necessitated informed consent from participants. These procedures generate a delay in the enrolment of participants and make results difficult to apply to everyday care. For those interested in research in this area, the issue of informed consent has dogged progress.⁹

In routine care, often out of urgent necessity, consent may not be gained before action has to be taken. We argue that the same should apply more commonly in experimental conditions in *emergency care where routine but undervalued treatments are used*. Consent should not necessarily be gained before random allocation and management.⁹ It is understood that trials of treatments used in acute emergency services are both important and ethical, including those in situations relevant to emergency mental healthcare (section 29, Declaration of Helsinki).¹⁰ However, few trials relevant to mental

healthcare take place in these circumstances, and almost none in Europe.

Persuasive evidence from the CRASH trial—a large international randomised study evaluating the effects of intravenous corticosteroids on death in people with serious head injury—has wide implications across specialties, not least ours.¹¹ To run CRASH, many centres had to be involved: 239 hospitals from 49 countries. All collaborating investigators were required to secure local ethics or research committee approval before starting recruitment. Some hospitals waived the need for consent, whereas others did not. If consent was required from relatives, initiation of treatment was delayed by a little over 1 h (1.2 h, 95% CI 0.7 to 1.8).¹¹ In normal practice, this sort of delay would not have occurred. Because of different practices of ethics requirements within the same trial and because the dataset was large, Roberts *et al*¹² could show how the delay brought about by stipulation of the local ethics committee for the researchers to gain informed consent in this trial increased mortality. Well-meaning 'consent rituals', as Roberts *et al*¹² put it, were lethal.

In every emergency setting, care decisions must be made in a short period of time, and the more time wasted, the more the risk of death or severe damage increases. Stipulating the need for consent in situations that delay urgent care may actually not be ethical. Researchers in this area need the help of thoughtful and confident ethics committees to truly protect the patient's interests by supporting evaluative research in this area—choices exist. Consent from others, some provision for waiver of consent, consent given in advance or no consent at all may be ethical options as long as procedures are in place to maximally protect patient rights.

Examples of pragmatic trials in this area come from the experience of authors working outside of Europe and the USA.^{13 14} These studies—carried out in Brazil and in India—were randomised evaluations comparing intervention strategies (physical restraints versus seclusion room; or pharmacological treatments) for management of people with acute aggression or agitation owing to serious mental illness. Trials were undertaken in

emergency conditions, administering treatments already used in clinical practice and in situations where there was a genuine doubt about which intervention would be best for each patient. In these studies, no informed consent was asked for from participants before randomisation. Because of the nature of these trials, the committees requested additional procedures from the researchers, but these procedures did not interfere with a trial design that dovetailed into routine care.^{13 15} These ethics committees understood the limited nature of the evidence upon which people in their region were being treated. They also understood that this well-meaning care, built on foundations of such limited evidence, left their institution vulnerable to criticism. They decided that, in the light of limited or almost inapplicable evidence, patients' rights were even best served by randomisation without consent. Put another way, these committees supported the view that these vulnerable—albeit violent—psychotic people had a right to be randomised under highly monitored conditions that did not detract from routine care, and required careful evaluation and control. In this way, treatments in their hospitals would be fairly administered as well as fairly evaluated.

Another pragmatic approach is to conduct cluster randomised trials, where the unit of random allocation is a group or a cluster (such as a clinical unit or a hospital ward), not the single participant.¹⁶ In these trials, all patients are treated according to an experimental or control protocol approved by the ethics committee before the trial starts, but informed consent may not be required from each patient involved. One example is Van de Sande *et al*'s¹⁷ cluster randomised trial conducted in four psychiatric wards located in Rotterdam, the Netherlands. This study evaluated the effect of risk assessment on the number of aggression incidents and the use of seclusion in psychiatric settings. Four wards were divided into two experimental and control clusters, and all patients admitted during the study period (nearly 600 involuntary patients) were included. This study protocol was approved by the regional ethics committee, but no consent procedures were completed before enrolment.

Although guidelines used in Europe¹⁸ are happy to consider evidence from trials from Brazil and India, noting the two trials that were available at the time of the guideline's publication¹⁹ to be "unlike most of the other studies [...], both were

large studies of a high methodological quality” (p. 77), more local trials are needed. We hope European ethics committees will also promote high-level research in this undervalued area of care and not delay or put unnecessary barriers in the way of evaluation. Patients and their carers need good applicable evidence of the effects of treatments—especially those given under conditions of coercion. Large trials, even from care cultures far from home, may, because of persuasive results,²⁰ change local practice²¹—but this is rare. Having been set a standard by the committees of Brazil and India, we think these models could be imported into Europe. We are pleased to see this beginning to happen through the Netherlands, but barriers which preclude routine care being fairly tested as well as procrastination are not only unethical, but may also be lethal.

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Competing interests None.

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