

Red tape for clinical trial consent can be lethal: Experts

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Current rules requiring researchers to obtain consent for patients to take part in clinical trials in emergency situations are causing life-threatening delays to treatment, experts have argued.

They say that in severe trauma cases, waiting for a relative to give written permission is "unethical" because of the importance of prompt treatment.

Professor Ian Roberts, Dr Haleema Shakur and Dr David Prieto-Merino, from the Clinical Trials Unit of the London School of Hygiene & Tropical Medicine, make their point in a letter published in *The Lancet*.

It is co-signed by Sir Iain Chalmers, of the James Lind Initiative in Oxford, and Professor Jon Nicholl, from the University of Sheffield.

The researchers analysed data from a large international clinical trial in severe head injury and found that initiation of treatment is delayed by over an hour where written consent from relatives is required.

But when early treatment is vital – such as in the case of tranexamic acid for severe internal bleeding – this delay can prevent patients from benefiting and increase their risk of death.

The authors argue that about one sixth of patients in the CRASH-2 trial missed out on the chance to benefit from a life-saving treatment because of unethical application of what they call "consent rituals".

"The need for urgent treatment, even in patients who are conscious and whose relatives are available, excludes the possibility of fully informed consent," the letter states. "If consent rituals delay the start of a trial treatment such that the treatment effect could be reduced or obscured, we maintain that seeking consent is actually unethical."

It adds: "Informed consent procedures, like other well-intentioned public health interventions, should be assessed rigorously."

"The lethal effects we have shown might have been found decades ago had the research ethics community accepted a responsibility to provide robust evidence that its prescriptions are likely to do more good than harm."

Provided by London School of Hygiene & Tropical Medicine

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