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The infected blood scandal: lessons for clinical research

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Biographies

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Declaration of interests

Bobbie and Emma co-convened the Medical Ethics Expert Report for the Infected Blood Inquiry.

The Infected Blood Scandal: Lessons for Clinical Research

The six-year Infected Blood Inquiry investigated the causes and impacts of NHS treatment with infected blood products in the 1970s and 80s.¹ Thousands of adults and children were infected with HIV and Hepatitis C. The impacts of the biggest treatment disaster in the NHS are wide-ranging. Here we focus on research.

Patients were subject to research that is reminiscent of some of the worst cases of misconduct from the past. With echoes of the infamous Tuskegee trial,² adult and child patients and their parents were not given information on risks or alternatives and often were not even told they were part of a research programme. When results indicated they had been infected, some were not informed. They were not aware of a need to ask about their status, because they did not know they had been tested.

Volume II of the report is dedicated to what happened at Treloar's school, a school that offered therapy alongside learning for disabled children. In the 1970s and 80s there were around 50 children with bleeding disorders boarding there. A research centre was established to take advantage of this concentration. Given what we know about plasma products, the risk to these children of infection could not have been eliminated, but because of the research undertaken that risk was vastly elevated. Of 122 children with bleeding disorders attending in

¹ Infected Blood Inquiry. The Inquiry Report 2024, HC 569 Available at <https://www.infectedbloodinquiry.org.uk/reports/inquiry-report> accessed 29 May 2024.

² Jones, J. H. *Bad Blood: Tuskegee Syphilis Experiment*, Free Press: 1981.

that period only 30 have survived.³ The report damningly concludes that the children became ‘objects for research’.⁴

The Kantian principle that people must never be used as a ‘mere means to an end’ is reflected in the Hippocratic Oath, the physicians’ promise to make the care of patients their first concern. It remains central to ethical guidance today.⁵ The Declaration of Helsinki 1964 put the interests of the individual before those of society and made consent the cornerstone of ethical research. Furthermore, the 1975 version was clear that whatever the research objectives, participants had a right to the best proven treatment.

The Inquiry has revealed that people were mistreated, wronged and severely harmed, and the implications reach beyond the individuals involved. Scientifically robust research is important, particularly where children are concerned. Too many treatments have never been adequately researched in a paediatric setting.

Alongside children’s right not to be viewed as mere objects for research, they have a right to have any treatments evidenced by research. Children have become active participants in research, influencing how it is carried out and making decisions about their involvement.⁶ The RCPCH developed a Charter in 2016 to guide discussions about research involvement and the burdens and risks it inevitably involves.⁷

The Inquiry report acknowledges the harms that can flow from a failure to advance science. It admonishes the state for failing to resource and encourage research that could have led more swiftly to safer and more effective treatment:

It is central to fairness that where the risks of a treatment have been increased significantly by the actions (or failures to act) of those responsible for providing it, then the elimination or reduction of that risk should be fully resourced.⁸

Sir Brian Langstaff, chair of the Inquiry, asks that the report and evidence stand as an educational tool for future doctors. The Inquiry highlights the importance of embedding ethics in the training of our future clinical researchers. Alongside the imperative to conduct scientifically robust research is the stringent reminder that researchers are first and foremost doctors with the duty to put their patients first.

Going forward let us continue the conversation with those who have been so abused and whose rights were so patently disregarded. Let us work with those who face similar health challenges here and now. We must engage with them to discover what they may have considered a fair request, adequate protection and a successful outcome to help progress research into their conditions. Patients increasingly understand the value of an evidence-

³ Infected Blood Inquiry. The Report Volume II, 209.

⁴ Infected Blood Inquiry. The Report Volume II, 213.

⁵ GMC. Good Medical Practice 2024, 7 Available at <https://www.gmc-uk.org/-/media/documents/good-medical-practice-2024---english-102607294.pdf> accessed 29 May 2024.

⁶ Nuffield Council on Bioethics. *Children and Clinical Research: Ethical Issues* 2015 Available at <https://www.nuffieldbioethics.org/publications/children-and-clinical-research> accessed 29 May 2024.

⁷ RCPCH. *Research Charter for Infants', Children's and Young People's Child Health* 2016 Available at <https://www.rcpch.ac.uk/resources/research-charter-infants-childrens-young-peoples-child-health> accessed 29 May 2024.

⁸ Infected Blood Inquiry. The Report Volume III, 435.

based health service and patient groups are engaged with the research process in ways that were unknown in the 1970s and 80s. This progress must not be undermined.



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