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Update on Unethical Research Awards

This factsheet follows the factsheet sent on 5 December 2024 which set out the background for the additional autonomy award for victims of unethical research available via the supplementary route.

Introduction

Following Sir Robert Francis' report of August 2024 which recommended an uplift to the Autonomy Award in recognition of unethical research practices, the Minister for the Cabinet Office was keen to seek the views of the community 'as to the identity and dates of such projects'. In December, the Government therefore asked community representatives to provide feedback in response to the following two questions:

A. **Are you aware of any studies mentioned in the Infected Blood Inquiry Report that happened before or after the proposed date range (1974-1984) that should be considered in scope for the award, according to the eligibility criteria in this factsheet?**

B. **The Government has identified treatment centres where unethical research took place (see the table at the end of this document). Are you aware of any additional centres where unethical research took place that are mentioned in the Infected Blood Inquiry Report, and should therefore be considered in scope under the eligibility criteria?**

Each submission was considered with careful attention, and each piece of evidence was reviewed in line with the Inquiry's report to ensure all updates to the scope of the award made as a result of the engagement process were backed up by evidence found in the Infected Blood Inquiry (IBI). This is in line with Sir Robert's recommendation following his own engagement with the community last summer.

This factsheet explains the Government's updated position for the additional autonomy award to infected people who were victims of unethical research following engagement in December. The award for those who attended Treloar School and College remains unchanged.

The Government was grateful for the feedback and help of the community in outlining additional centres that the Government had not provided. When assessing the feedback we consulted Inquiry documents, and the evidence provided before taking a decision. If more evidence is provided in the future on additional centres the Government is committed to assessing any new evidence to ensure the full eligible list reflects where unethical research took place. Any changes would require additional new laws.

Changes to the award

Updates to the proposed date range (1974-1984), as per Question A:

The date range of 1974-1984 will remain unchanged. This is because we have not received any further evidence to suggest unethical research - as the Inquiry described it - occurred outside this period of time.

Updates to the eligible treatment centres where unethical research took place, as per Question B:

Upon reviewing the submissions, we are expanding the list of eligible centres to include a further four centres, bringing the total to nine. The centres added are:

- St. Thomas Haemophilia Centre
- Cardiff Haemophilia Centre
- Manchester Haemophilia Centre
- Sheffield Haemophilia Centre.

These centres are in addition to the following previously identified centres and eligibility criteria:

- Evidence of being part of one of Dr Craske's studies
- Treatment at Oxford Haemophilia Centre
- Treatment at Edinburgh Haemophilia Centre
- Treatment at Newcastle Haemophilia Centre
- Treatment at Royal Free Haemophilia Centre
- Treatment at Glasgow Haemophilia Centre

Reasons for changes to the award

Submissions received from the engagement highlighted a number of key research projects that are now included, and have therefore increased the number of eligible Haemophilia centres as follows:

Sheffield Haemophilia Centre:
Several submissions highlighted research studies conducted at Sheffield Haemophilia Centre. There is evidence of at least one study ('Percutaneous Liver Biopsy and Chronic Liver Disease in Haemophiliacs - 16 Sep 1978') that involved additional invasive tests that were not part of someone's normal treatment. We have therefore added Sheffield Haemophilia Centre to the list of eligible centres.

St. Thomas Haemophilia Centre:

There is limited evidence of unethical studies conducted at St Thomas Haemophilia Centre. However, it is clear that St Thomas Haemophilia Centre was very active in research. There is some evidence (pg 123, Volume 4 of the IBI Report) to suggest that a study of home therapy in 1975, in conjunction with Oxford Haemophilia Centre, altered patients' treatment. We have therefore added St Thomas Haemophilia Centre to the list of eligible centres.

Cardiff Haemopihilia Centre:
We received many submissions which questioned the ethical basis of the work of Professor Bloom at Cardiff Haemophilia Centre. It is well known that Professor Bloom's approach to treatment frequently involved innovative methods. However, this refers to the methods in which people received treatment and this was not part of research projects. Much of the material in the IBI refers to this approach and does not focus on research projects in great detail. However, there is sufficient evidence of research conducted by Professor Bloom at Cardiff Haemophilia Centre in his publications to suggest that Cardiff should be added to the list of eligible centres.

Manchester Haemophilia Centre:
We received submissions that indicated Manchester Haemophilia Centre was conducting research projects with unethical practices. There is limited evidence that this is the case in the Presentation to counsel on Haemophilia Centres. However, a reference to a study conducted at Manchester Haemophilia Centre published in the British Journal of Haematology indicates that patients were recruited for studies which could have impacted their treatment. For these reasons, we have included Manchester Haemophilia Centre.

The below issues were raised in multiple submissions and have not altered the date range or number of Centres for the following reasons:

Belfast Haemophilia Centre:
The Inquiry Report states that one of the functions of the Haemophilia Reference Centres was to 'coordinate meetings and research programmes'. We have found evidence of research that was undertaken with unethical practices at all reference centres, with the exception of Belfast. Belfast was added as a reference centre at a later date and neither the Inquiry Report, nor any presentation notes on the centre, refer to any unethical research being conducted at this centre.

Great Ormond Street Hospital:
Several submissions asserted that unethical research was conducted at Great Ormond Street Hospital (GOSH). GOSH was not identified by the Inquiry as raising concerns about unethical research. Neither the main report of the Inquiry nor the Presentation note on Haemophilia Centres mention unethical research being conducted at GOSH.

In Volume 4 of the Inquiry Report, the only reference to research to GOSH is (a) in relation to Professor Hardisty's ethical objection to a research protocol (p 329 fn 1857), implying that he would not have allowed his patients to participate, and (b) in his being added as an investigator to an Armour trial exemption. In the Presentation note on haemophilia centres it is noted that routine data from GOSH was contributed to three surveillance studies (where researchers observe people or data without trying to influence the outcome) undertaken between 1969 and 1980. However, this would not bring the participants within the scope of the proposed unethical research award.

We understand that there are missing records from GOSH. We have therefore expanded our search beyond the IBI Report in this specific circumstance and have searched for scientific publications where Professor Hardisty was an author. We have been unable to find any evidence of any relevant research projects.

HPVII/Liberate Trials:
We have examined the evidence on the clinical trials discussed in Volume 4 pages 303-4, to which our attention was drawn by respondents. After that review we have concluded that they should remain out of the scope of unethical research supplementary autonomy awards for at least one of the following reasons:

- The clinical trial recognised the need for a higher level of consent for participation and participants were made fully aware that the process was research.
- There was clear evidence of rigorous regulatory and ethics committee oversight that is not present in some of the research studies that are within scope of the unethical research award.
- The clinical trial was to establish the safety for new products where the risks of viral transmission were no greater than in standard clinical care and the clinical trials submitted did not increase this risk. Criticisms of the trials made by Sir Brian Langstaff on pages 304 of Volume 4 of the Inquiry's report were about the lack of transparency over risks of viral transmission, which was equally true of the products used in standard clinical practice.

Post-Mortem:
Several submissions raised cases concerning post-mortem practices and the consent standards for such practices. Whilst understandably distressing, these concerns do not fall within the scope of this additional award for unethical research projects and have not been highlighted as such by the IBI. Similar practices were highlighted in the Redfern Inquiry into Alder Hey and Bristol Royal Infirmary Inquiry. This led to the introduction of reformed legislation and guidance through the Human Tissue Act 2004, meaning that the current process of acquiring consent to undertake a post-mortem is significantly more comprehensive.

Treatments with Factor Concentrate:
Several submissions discussed unethical *treatment* practices, but as these were not unethical *research* practices, they have not resulted in a change in the eligibility criteria. We acknowledge that many people will have been subjected to treatment that did not meet proper ethical standards. This violation of people's personal autonomy is recognised by the core Autonomy award.

Dr Rosemary Biggs' Surveillance Research:
A study named 'Jaundice and Antibodies Directed against Factors VIII and IX in Patients Treated for Haemophilia or Christmas Disease in the United Kingdom - 05 Sep 1973' conducted by Dr Rosemary Biggs was submitted as evidence of unethical research. This is a large surveillance study (where researchers observe people or data without trying to influence the outcome), that was carried out across multiple Haemophilia Centres over a long time period.

We have excluded this study from the scope of the award because it was a surveillance study that looked at the incidence of jaundice and antibodies in patients. This collection of this data did not change patients' care and was not criticised by Sir Brian Langstaff in the Inquiry Report.

Some submissions noted that this research did not appear to differ much from the work of Dr Craske, which is included in the scope of the award. We have included all of Dr Craske's research as there is evidence that Dr Craske led interventional studies (a study that tests a potential treatment or intervention on people, often leading to patients' treatment being altered) - this goes beyond what would take place in a surveillance study, as was conducted by Dr Biggs. Dr Craske's work is also poorly documented, meaning that it is very difficult to differentiate between his studies and to determine the dates and centres at which they were carried out. We believe that in the light of this uncertainty, it is better to be inclusive than to risk excluding people who should be eligible but where evidence is lacking.

Note on individual medical records submitted as evidence:
Across the submissions, a wide range of documentation was included for our consideration. However, some of this could not be used to consider the scope, as it wasn't in line with the Inquiry Report, which remains the basis for the award. In other cases, people shared personal stories or offered documents that didn't necessarily provide evidence of unethical research in the way that Sir Brian Langstaff defined it.