HTA Board meeting, 26 June 2025

Agenda item	**3.1 – 12 Month Evaluation of the HTA 2004 (Supply of Information about Transplants) Regulations 2024**
For information or decision?	Information
Decision making to date?	N/A
Recommendation	The HTA Board is asked to note and comment by exception on the findings identified
Which strategic risks are relevant?	Risk 1: Operational
Strategic objective	Approach to Regulation
Core operations / Change activity	Core operations
Business Plan item	Regulation – fulfilling our licensing, inspection, incident management and approvals functions, providing technical advice and superintending compliance across the sector, including responding to the Fuller Independent inquiry and engaging with a review of our implementation of the Duty to Report regulations
Committee oversight?	N/A
Finance and resource implications	Business resource to implement the changes through revised processes
Timescales	2024-25
Communication(s) (internal/external stakeholders)	N/A
Identified legislative implications	The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024

12 Month Evaluation of the HTA 2004 (Supply of Information about Transplants) Regulations 2024

Ask

1. The Board is asked to **note** the findings from a 12 month review of the implementation of The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024, also referred to as 'Duty to Report'.

Background

2. The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024 (The Regulations) came into force on 1 April 2024. These Regulations place a statutory duty on relevant clinicians in England, Wales and Northern Ireland who work closely with patients that need, or have received, an organ transplant to report the following to the HTA:

   a) if they have a reasonable suspicion that an organ donation and transplantation-related offence may have been committed (Regulation 3)
   b) if they are made aware that a patient has received an organ transplant outside the UK (Regulation 4).

   Schedules one and two specify the information which must be reported.

3. As part of our regulatory function, to superintend compliance with the Human Tissue Act 2004 and associated Regulations, the HTA considers information reported by relevant clinicians under the Regulations. In instances where it believes an offence may have been committed, the HTA will refer the case to the police.

4. Relevant clinicians are classed as any of the following, whether practising in a transplant centre or a non-transplant centre:

   - a specialist nurse involved in living donor care;
   - a specialist nurse involved in recipient care;
   - a transplant surgeon;
   - a physician involved in living donor care; and
   - a physician involved in recipient care.

5. The Regulations were brought in at relatively short notice, and with a short gap between the Statutory Instrument being made (29 February 2024) and coming into force (1 April 2024).

6. At the outset, the HTA developed the essential infrastructure to support implementation of the new regulations using existing systems, which included developing a reporting system and supporting guidance. These processes were designed with the intention of reviewing and refining them after 12 months as activity levels and reporting patterns became clearer.

7. A preliminary “Pulse Check” conducted three months into implementation of the Regulations provided an early snapshot of progress, but it was not possible to draw conclusions on the process due to the low number of reports. At the September 2024 Board meeting, it was noted that a 12-month review would be required once more cases had been received. This paper fulfils the commitment to undertake a review of the first year of implementation.

8. The review considered how the HTA has implemented its responsibilities under the new Regulations. A proportionate, evidence-based approach was adopted, using both quantitative and qualitative insights. Key inputs included:

   - Quantitative analysis of report data over the 12-month period,
   - Structured discussion with the Living Organ Donation (LOD) team,
   - Qualitative data from a limited no. of clinicians and police forces, and
   - Qualitative data from all members of the HTA Senior Management Team.

Key findings

Reports received under the Supply of Information about Transplants Regulations during the business year April 2024/25

9. Between April 2024 and March 2025, the HTA received 39 reports under the Regulations, all from England.

10. Of these, 38 were submitted under Regulation 4 (transplants undertaken outside the UK) and just one under Regulation 3 (reasonable suspicion of an offence). 23 reports have been assessed, with 11 referred to the police for investigation due to concerns about the potential for a transplant-related offence to have been committed. For the remaining 15 cases awaiting assessment, information is still being gathered before a decision can be made.

11. With no previous statutory requirement for reporting (to the HTA or other body) of overseas transplants involving UK-based recipients, there was no baseline from which to estimate the likely scale of activity in Year 1. The first year of operation of ‘Duty to Report’ has therefore provided an effective and

informative baseline of levels of activity. In that context, it is interesting to note that the HTA has considered around half of the reports received, sometimes following further clarification, to warrant referral to the police for investigation.

12. This review has provided a valuable opportunity to reflect on the HTA's operational approach to implementing the Regulations, highlighting both strengths and areas for improvement. Key findings are outlined below, with further detail in **Annex 1**.

The process

Receiving the required information

13. The reporting form used to capture information mandated under Schedules 1 and 2 of the Regulations aligns with regulatory requirements. Operational insights suggest that improving the clarity and user-friendliness of the form's language could support more accurate and confident completion.

14. Extending the reporting deadline from three to seven days has improved submission quality while still meeting the duty to report.

Assessment of reports

15. The HTA assesses all submitted reports.

16. As per guidance "*the HTA may request additional information to assist them in processing or escalating reports".* Based on our experience we have found that additional information is often requested, such as, information about donor identity and relationship to the recipient. To further strengthen assessments and support proportionate, evidence-based decisions, we recommend clarifying what additional information is needed and considering informing clinicians earlier in the process that this may be requested.

17. The current reporting form provides for clinicians to refer cases on a factual basis (transplant overseas) or on the basis of a judgement (suspicion of a transplant related offence). Whilst both aspects can be completed, as noted above, during the first 12 months in all but one case, the form was completed on the factual basis that an overseas transplant had occurred. As the Regulations do allow for reporting under both heads, whilst not mandatory, we may wish to amend the form to make this clearer.

Decision to refer

18. In the first year of operation, the HTA decided that all DTR reports should be

considered by the Senior Management Team (SMT) for potential police referral, in line with the our internal policy for considering referral of potential offences under relevant human tissue legislation. However, in order to streamline our decision making, the HTA's Police Referral and Warrants Policy was changed, with Board agreement so that, with effect from April 2025, decisions on police referral are delegated to the Director of Regulation, unless exceptionally a referral to SMT is considered needed. However, the underlying process for considering police referrals will continue to be the same and the experience of these police referral considerations on DTR cases will continue to inform our evolving understanding of risk criteria and indicators.

Police referral

19. As noted above, 11 cases were referred to the police during the reporting period, contributing to a growing understanding of the circumstances in which people based in the UK are seeking or obtaining transplants overseas.

20. While the extraterritorial scope and the relatively new offences have presented some challenges, national guidance developed by the National Modern Slavery & Organised Immigration Crime Unit has been introduced to support police forces. Experience has shown the absence of requiring the recipient's home address can make it harder to allocate cases to the appropriate force in England, and the HTA is working with police partners to address this.

21. As of 31 March 2025, three cases have been closed by the police.

Enabling activities:

Awareness of reporting

22. Initial awareness was raised through targeted communications and attendance and presentations at events with relevant clinicians, supported by NHS Blood and Transplant (NHSBT). We note that there were no reports received from Wales and Northern Ireland during the first twelve months. The proposed introduction of a similar duty in Scotland from 1st July 2025 provides scope for the HTA to undertake a renewed UK-wide communication and engagement programme with relevant transplant clinicians.

Supporting public understanding

23. Given the significant preponderance of reports relating to travel overseas for transplants, some clinicians have identified a need for clearer communication on when and how to convey to patients the potential risks of travelling

overseas for transplants. However, there was a low response rate to the survey shared with relevant clinicians and we will wish to probe further when undertaking future engagement events. Some of the police who were surveyed also highlighted the importance of effective communication around the risks and the legal consequences. Again, this supports further exploring how communication can be improved.

Conclusions

22. The HTA has successfully managed the implementation of DTR, not least, given the level of uncertainty about the numbers and scope of reports likely to be received and the nature of activity this would reveal.

23. The HTA received no additional funding to resource the work needed to support and manage this work. As reported to the Board in December 2023, the HTA urgently reassessed and deprioritised some other commitments in the second half of the 2023/24 business year in order to free-up the resource required to implement DTR by 1st April 2024. The HTA continues to monitor resource usage and workload pressures in this area, which are kept under review through our business planning and monitoring processes.

24. The HTA remains committed to fulfilling its duties as part of the wider system in place and being further considered and developed nationally and internationally to supporting regulatory and law enforcement mechanisms aimed at identifying, managing and addressing the risks of people exploitation for organ transplantation.

25. The HTA understands that, set in an international context, these are novel regulations and there has been some interest expressed in our experiences by several other countries.

Next steps

26. The recommendations identified by this review are intended to support the LOD team by ensuring the process remains robust and responsive. Our next steps will focus on strengthening the existing processes and making refinements and enhancing clarity where needed, and ensuring the HTA is undertaking its statutory responsibilities effectively and efficiently.

27. The HTA will share this report and continue to share our learning from the implementation of the new regulations with our sponsorship team in DHSC.

28. To support continuous improvement, we will seek feedback from police and

clinicians from cases once they are closed.

29. In accordance with our statutory duties and commitment to transparency during 2025/26, we will add relevant data from our implementation of 'Duty to Report' to our corporate publication schedule. This will take into account activity levels and GDPR to ensure patient confidentiality is protected and ongoing investigations are safeguarded.

30. The Human Tissue (Supply of Information about Transplants) (Scotland) Regulations 2025 are expected to come into force on 1 July 2025, with the HTA being tasked by Scottish Government to fulfil a similar role for Scotland as it does under the existing Duty to Report Regulations for England, Wales and NI.

Recommendation

31. The Board is asked to **note** the findings from a 12 month review of the implementation of The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024, also referred to as 'Duty to Report'.

Annex 1 – Findings from the Review

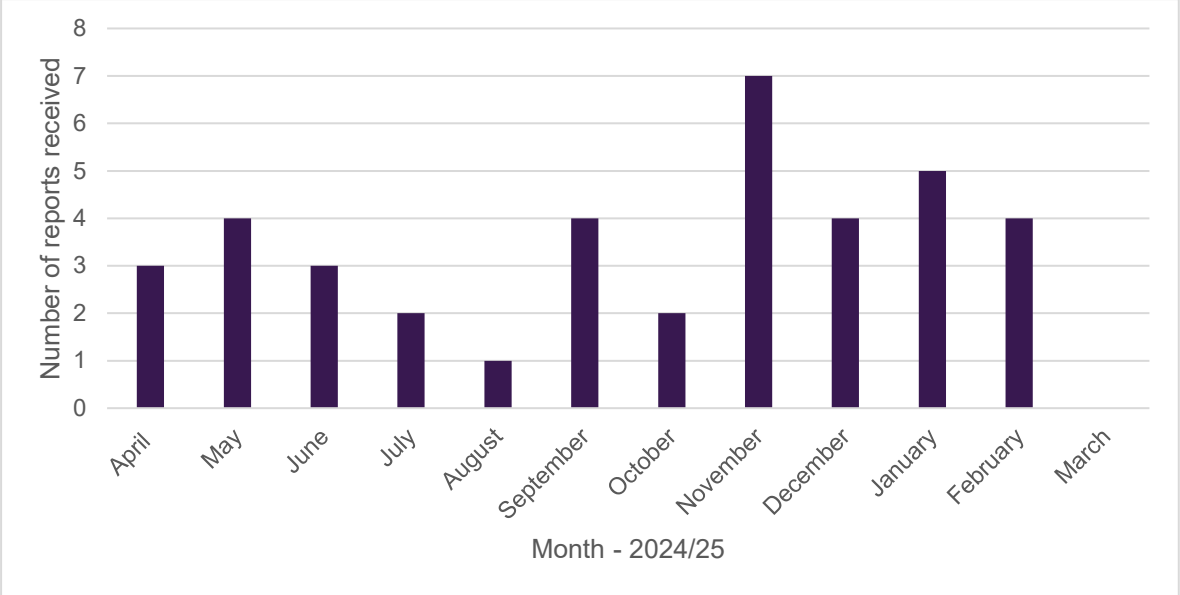
Data on reports from the first 12 months

1. As noted above, the HTA received 39 clinician reports between 1 April 2024 and 31 March 2025.

2. Chart 1 below provides the number of reports received each month since the introduction of the Regulations. There are some fluctuations however there is no set pattern, at this point to draw conclusions. One pattern that might have been assumed was that there could have been a flurry of activity, based on announcement of the new Regulations, and that the flow of cases would then reduce to a lower level.

3. That has not been the pattern in the first 12 months of reporting. Within a range of 1 to 7 cases per month, the mode is 4 per month and median is 3.25 cases per month, representing a fairly constant flow of a little under one case per week.

Chart 1: Number of reports received by HTA in the period 1 April 2024 to 31 March 2025 by month



4. As we are still at an early stage, the emphasis has not yet been on evaluating the data across each of the reports. However, at a high level, we can note that over the past year:

- We have received reports of patients undergoing transplants in 16 different countries out of the 39 cases.
- In several of these cases, the reports mentioned that the recipient has

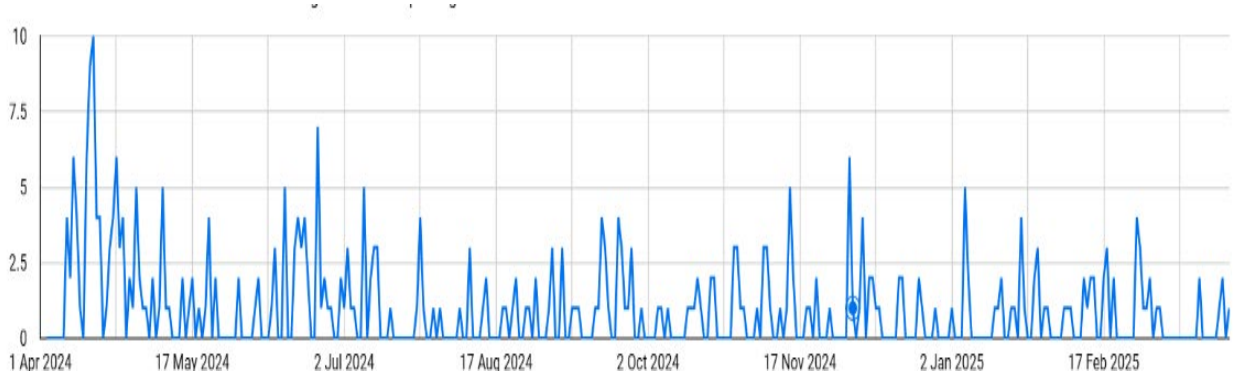
some form of prior family connection to the country to which they have travelled.

- The gender split for these patients was 17 males, 10 females and 2 not confirmed, at present.
- 31 patients had a kidney transplant and eight a liver transplant.

Guidance

5. Graph 1 shows the number of downloads of the professional guidance on our website between 1 April 2024 and 31 March 2025. Following an initial peak after the Regulations came into force, the data suggests that the guidance continues to be accessed and used throughout the year. The LOD team routinely includes a link to the guidance in their initial communications with clinicians.

Graph 1: Number of downloads of HTA's Professional guidance from 1 April 2024 to 31 March 2025



6. With regard to the HTA web pages which link to the guidance, there have been the following views for 2024/25:

- Supply of Information about Transplants Regulations 2024 | Human Tissue Authority – 753 views (which ranked no.5 of the HTA's top viewed news items in 24/25).
- Travelling outside the UK for organ transplantation | Human Tissue Authority – 630 views

7. It can be seen from Graph 1 that, perhaps unsurprisingly, the peak for downloading of the professional guidance was during April 2024, just after the new Regulations became operational but a regular beat of downloading the guidance has continued since that time.

Informal, qualitative feedback from relevant clinicians

8. An informal survey sent to relevant clinicians had a low response rate in the

time available and the views expressed may not be representative of all those involved. Nonetheless, as informal qualitative data they do help provide pointers for areas to explore more extensively with future engagement.

9. In relation to how clinicians had heard about the new Regulations, those who did respond highlighted three separate routes, which points to the value of having several vehicles to promote the change in the legislation with the advent of the new regulations. The routes cited were:

- Via their professional role (e.g. as a Living Donor Coordinator),
- Direct communication from HTA staff and email updates
- As a result of an incident at their hospital which brought the new Regulations to attention.

10. Some clinicians have also suggested more should be done to develop public-facing materials, such as posters or leaflets, to help patients understand the risks of travelling outside the UK for a transplant and what may be reported. This is something we will explore further with our system partners to determine the best way forward.

11. Feedback on the operational delivery of the new DTR scheme from relevant clinicians was also limited by a low response rate, however from a qualitative perspective, it is worth noting the following comments in relation to their experiences of working with the HTA:

“The prompt replies were helpful, as was liaising with only one person.”

“The communication was always prompt so I have no further suggestions”.
“Meetings were arranged virtually, which is always helpful to see the person you have been liaising with.”