

## HTA Board meeting, 19 September 2024

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Agenda item	<b>4.1 Duty to Report</b>
For information or decision?	Information
Decision making to date?	N/A
Recommendation	N/A for information only
Which strategic risks are relevant?	Risk 1: Regulation Risk 2: Sector
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
Committee oversight?	N/A
Finance and resource implications	N/A
Timescales	On-going throughout 2024-25
Communication(s) (internal/ external stakeholders)	N/A
Identified legislative implications	N/A

# Duty to Report

## Recommendation

1. The Board is asked to **note** the HTA's early experience of working under the new Regulations that impose a statutory duty on certain clinicians to report certain transplants or suspicions of transplant-related offences to the HTA.

## Background

2. The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024 (The Regulations), also referred to as 'Duty to Report', came into force on 1 April 2024.<sup>1</sup>
3. The 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 information to the HTA:
  - a) if they have a reasonable suspicion that an organ donation and transplantation-related offence may have been committed, or
  - b) if they are made aware that a patient has received an organ transplant outside the UK.
4. This paper provides an overview of reports received by the HTA since the new Regulations came into force, covering the period 1 April 2024 – 31 August 2024.

## Reports under the Supply of Information about Transplants Regulations

5. Between 1 April 2024 and 31 August 2024, the HTA received 12 reports.
6. Table 1 below shows the number and status of these reports.

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<sup>1</sup> <[The Human Tissue Act 2004 \(Supply of Information about Transplants\) Regulations 2024 \(legislation.gov.uk\)](https://www.legislation.gov.uk/uk/2004/2024/1/1)> [Link accessed 22 August 2024]

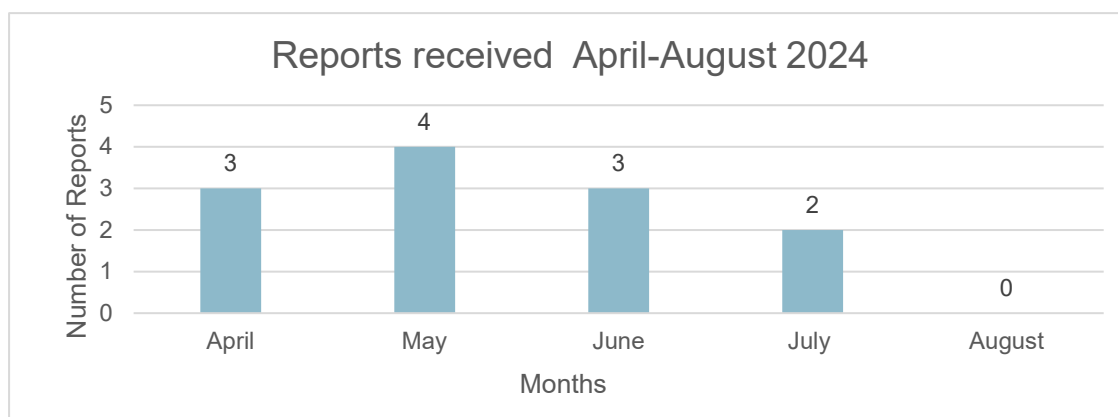
**Table 1:** Number of reports received by HTA in the period 1 April to 31 August 2024 and status at 31 August 2024 of HTA decision-making on those reports

Total reports received	Police referral decision considered by SMT	SMT decision to refer to Police	SMT decision not to refer to police	Status pending*
12	10	4	5	3

\*Note: ‘Status pending’ includes cases not yet considered for police referral by SMT or where SMT have considered the report and asked for further information to be provided before making a decision on referral.

7. Ten of the 12 reports have been considered for police referral by SMT. In almost all cases this has been once further information has been sought from the person or organisation who made the initial report.
8. Of the 12 reports received:
  - a) four were agreed to be referred to the police, which has either happened or is in progress;
  - b) five have been agreed not to be referred to the police;
  - c) a decision on one has been deferred pending the HTA seeking further information; and
  - d) two are being prepared for SMT consideration.
9. All reports to date have come from England and have been made under Regulation 4 (*Supply of information regarding organ transplants performed outside the United Kingdom*) rather than Regulation 3 (*Supply of information regarding specified offences*) of the Regulations.
10. Chart 1 below shows the number of reports received in each month since the introduction of the new Regulations.

**Chart 1:** Bar chart graph showing number of reports received by the HTA in each month from 1 April 2024 to 31 August 2024



## HTA22-24

11. The HTA received most reports (4) in May, dropping to 2 in July and none in August.<sup>2</sup> Following an initial higher level of reporting in the first two months after the Regulations came into force, numbers then reduced in the following three months. This may be caused by various factors unrelated to the underlying subject matter. It is too early to determine any long-term pattern or trend.
12. We can expect any referrals actively investigated by the police to be complex and to potentially involve international liaison. Hence the outcomes of any HTA referrals will not be known for some considerable time.
13. The HTA will not be able to provide updates on specific cases referred to the police for further investigation unless or until any information comes into the public domain through normal judicial processes.
14. In the long run, the HTA may be able to provide high level data summarising the outcome of cases referred to the police for further investigation.

### Next steps

15. The HTA will conduct a more in-depth evaluation of our experience of operating under these new Regulations after they have been in place for a full year.

### Recommendation

16. The Board is asked to **note** the HTA's early experience of working under the new Regulations that impose a statutory duty on certain clinicians to report certain transplants or suspicions of transplant-related offences to the HTA.

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<sup>2</sup> The HTA had been notified of two further potential cases in August, but formal submission of reports had not been made by 31 August.