HTA
Human Tissue Authority

The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024

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Guidance on reporting under the Regulations

Guidance at a glance

The Regulations

Relevant clinicians in England, Wales and Northern Ireland who work closely with patients that need, or have received, an organ transplant are required to report the following:

a. if they have a reasonable suspicion that an organ donation and transplantation-related offence may have been committed under the Human Tissue Act or Modern Slavery legislation (see paragraphs 14-18, for more information and paragraph 15 for examples of 'reasonable suspicion'), and

b. if they are made aware that a patient has received an organ transplant outside the UK (see paragraphs 19-22, for more information).

Reporting to the Human Tissue Authority

Clinicians must report a case to the HTA by emailing report@hta.gov.uk. See paragraphs 25-27, for more information.

Penalties for not reporting

Failing to report under the Regulations is an offence. Clinicians risk criminal charges amounting to a fine for failing to report, or an unlimited fine for providing false or misleading information. See paragraph 23, for more information.

Informing patients

Patients should be aware that clinicians are obliged to share information about any organ transplant that has taken place outside the UK, with the HTA. This is regardless of whether potentially unlawful activity is suspected. See paragraphs 32-34, for more information.

Purpose of this guidance

1. On 1 April 2024, the Supply of Information about Transplants Regulations 2024[1] ('Regulations') came into force under the Human Tissue Act 2004[2] ('HT Act').

2. This guidance document aims to support clinicians who are required to report information to the Human Tissue Authority (HTA) under the Regulations. In particular, it includes who is required to report, what information should be reported and how to submit a report. It also explains when and to whom the HTA will share the reported information, as well as the penalties for failing to report under the Regulations.

3. This guidance should be read in conjunction with the Regulations.

An overview of the Regulations

4. Prior to 1 April 2024, clinicians were not required to report suspicions of an organ donation and transplantation-related offence having been committed under the HT Act or an organ transplant having taken place outside the UK. Relying on powers in section 34 of the HT Act, the government has since introduced the Regulations, which require relevant clinicians to report this information.

5. As of 1 April 2024, the Regulations place a statutory duty on relevant clinicians (see regulation 2) in England, Wales and Northern Ireland who work closely with patients that need, or have received, an organ transplant. The duty requires clinicians 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 (see regulation 3), or

    b. if they are made aware that a patient has received an organ transplant outside the UK (see regulation 4).

6. The HTA will consider information reported by clinicians under the Regulations. In instances where it believes an offence may have been committed, the HTA will refer the case to the police.

The legal and regulatory background

[1] Legislation.gov.uk (2024) The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024: www.legislation.gov.uk/uksi/2024/262/contents/made
[2] Human Tissue Act 2004

7. The HT Act provides the legal framework for living organ donation in England, Wales and Northern Ireland, and the HTA approves organ and bone marrow donations from living people.

8. For the purposes of living donation, HTA approval is required for the removal of an organ, or part of an organ where the intention is that it will be transplanted into another person. Before the HTA can approve a living donation, it must be satisfied that no reward has been, or is to be, given. As a result, the HT Act sets out the following offences in relation to living organ donation, for which the maximum penalty is imprisonment and / or a fine:

    a. Section 32[3] makes it an offence to engage in commercial dealings in human material for transplantation. This includes paying for an organ transplant, supplying an organ for payment, or offering or arranging either of these acts. A full list of offences can be found at section 32.

    b. Section 32A[4] extends the offences set out in section 32 to acts carried out outside the UK, when the person committing them is a habitual resident of England and Wales or is a UK national not habitually resident in Northern Ireland. The HTA must also be notified of residents of Northern Ireland who have received an organ transplant outside the UK.

    c. Section 33[5] makes it an offence to conduct a transplant involving a living donor unless the requirements set out in the HT Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006[6] are met. This includes that the HTA is satisfied that no reward has been or is to be given (and that all other relevant conditions have been met).

9. Sections 2 and 3(4) of the Modern Slavery Act 2015[7] and the Human Trafficking and Exploitation (Criminal Justice and Support for Victims) Act (Northern Ireland) 2015[8] also make it an offence to arrange or facilitate the travel of an organ donor who is exploited in any part of the world.

Reporting requirements

Who is required to report information to the HTA?

[3] Section 32 of the HT Act
[4] Section 32A of the HT Act
[5] Section 33 of the HT Act
[6] The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006
[7] Section 2 of the Modern Slavery Act 2015
[8] Section 3(4) of the Human Trafficking and Exploitation (Criminal Justice and Support for Victims) Act (Northern Ireland) 2015

10. Under regulation 2, a statutory duty is placed on all 'relevant clinicians' ('clinicians') working in secondary and tertiary care settings in the NHS and independent sector across England, Wales and Northern Ireland. The term 'relevant clinicians' refers to any of the following whether in a transplant centre or a non-transplant centre:

    a. a specialist nurse involved in living donor care

    b. a specialist nurse involved in recipient care

    c. a transplant surgeon

    d. a physician involved in living donor care, and

    e. a physician involved in recipient care.

11. Clinicians who have a reasonable suspicion that an organ transplant-related offence may have been committed or have been made aware that a patient has received an organ transplant outside the UK are required to report this information to the HTA.

12. The reporting clinician should ensure other clinicians in the patient's pathway are aware that a report has been made under the Regulations to minimise the potential for duplicate reporting.

13. Clinicians are not expected to report to the HTA if they have reason to believe another clinician has already notified the HTA of the same suspected offence or an organ transplant has taken place outside the UK. However, if new or additional information comes to light about a particular case that has not already been reported to the HTA, this should be passed to the HTA (ideally by the original reporting clinician).

What and when do clinicians need to report if they have a reasonable suspicion that an organ transplant-related offence may have been committed?

14. Under regulation 3, clinicians must report to the HTA if they have a 'reasonable suspicion' that a person may have committed an organ transplant-related offence as set out in:

    a. sections 32, 32A or 33 of the HT Act

    b. section 2 of the Modern Slavery Act 2015, or

    c. section 2 of the Human Trafficking and Exploitation (Criminal Justice and Support for Victims) Act (Northern Ireland) 2015.

15. Clinicians do not have to be certain that an offence has been committed before reporting to the HTA. Grounds for a 'reasonable suspicion' may include:

    a. where the work up of a living donor is not progressed for non-clinical reasons (for example, due to there being a suspicion that a donor has, or will be, rewarded for their donation), and

    b. if the donor has a changing or conflicting account about their reasons for donating.

16. If a clinician has a reasonable suspicion that an organ transplant-related offence may have been committed, they must notify the HTA as soon as 'reasonably practicable' (i.e., within seven working days as a mark of best practice).

17. When reporting a reasonable suspicion, the clinician must share what they know about the information set out in schedule 1 of the Regulations. This information should be readily available to the clinician at the time of reporting and include:

    a. Information about the clinician submitting a report to the HTA:

        i. the full name, contact details, position and place of work.

    b. Information about the reasonable suspicion:

        i. that a report is being made due to the clinician having a reasonable suspicion that an offence may have been committed (and note which offence, if known)

        ii. a description of the indicator(s) that led to the clinician having a reasonable suspicion

        iii. a description of the organ believed to have been transplanted.

    c. Information about the individuals involved in the commission of the suspected offence:

        i. the full name, date of birth and gender of the donor (or potential donor)

        ii. the full name, date of birth and gender of the recipient (or intended recipient)

        iii. the full name, date of birth and gender of any other person(s) believed to have been involved in the commission of the suspected offence

iv. the relationship between the donor and recipient (or the potential donor and intended recipient), if one exists.

18. The HTA may request additional information to assist them in processing or escalating reports, such as the HTA licence number, if a clinician is reporting from a HTA-licensed establishment.

What and when do clinicians need to report if they are made aware that a patient has received an organ transplant outside the UK?

19. Habitual residents of England, Wales and Northern Ireland can and do have legitimate organ transplants outside the UK, within approved legal and ethical frameworks. This also applies to UK nationals who are not habitually resident in England, Wales and Northern Ireland.

20. Under regulation 4, clinicians must notify the HTA as soon as 'reasonably practicable' (i.e., within seven working days as a mark of best practice) if they are made aware that a patient has received an organ transplant outside the UK. This is regardless of whether clinicians consider it to have been a legitimate and lawful transplant.

21. When reporting an organ transplant that has taken place outside the UK, the clinician must share what they know about the information set out in schedule 2 of the Regulations. This information includes:

    a. Information about the clinician submitting a report to the HTA:

        i. the full name, contact details, position and place of work.

    b. Information about the recipient:

        i. the full name, date of birth, age (at time of organ transplantation), gender and country / countries of legal citizenship or residency

        ii. whether the recipient was treated at the clinician's centre before travelling outside the UK for an organ transplant

        iii. the status of the recipient on the UK organ transplant list when they travelled outside the UK for an organ transplant

        iv. whether the recipient was referred for an organ transplant outside the UK (and if so, the reason(s) for this).

    c. Information about the donor:

        i. the full name, date of birth, age (at time of organ donation), gender and country / countries of legal citizenship or residency

ii. whether the donor was living or deceased at the time of the organ donation.

d. Information about the transplant:

i. the relationship between the donor and recipient, if one exists

ii. description of the organ that is believed to have been transplanted

iii. the date that the organ transplant took place

iv. the country, city and centre where the organ transplant took place

v. whether the reporting clinician's centre has contact details for the clinician who performed the organ transplant or the centre where the organ transplant took place.

22. The HTA may request additional information to assist them in processing or escalating reports, such as the HTA licence number, if a clinician is reporting from a HTA-licensed establishment.

What are the penalties for failing to report under the Regulations?

23. Failure to comply with the Regulations is an offence. As set out in section 34 of the HT Act, a person found guilty is liable on summary conviction to:

a. a fine not exceeding level 3 on the standard scale (i.e., £1,000) for failing to comply without a reasonable excuse, or

b. a fine not exceeding level 5 on the standard scale (i.e., an unlimited fine) for knowingly or recklessly supplying information that is false or misleading.

Are there any exemptions under the Regulations?

24. Reporting requirements under the Regulations do not apply in the following scenarios:

a. if a clinician has reason to believe that another relevant clinician has previously supplied information to the HTA about the same suspected offence or organ transplant outside the UK, or

b. if a clinician learns about a suspected offence potentially having been committed or organ transplant that has taken place outside the UK, outside the course of their profession (e.g., by reading about it in the news).

Submitting information to the HTA

How should clinicians submit reports to the HTA?

25. Clinicians must report a reasonable suspicion that a person may have committed an offence or had an organ transplant outside the UK to the HTA as soon as reasonably practicable. In line with best practice, the HTA should receive reports within seven working days.

26. Clinicians must notify the HTA that they need to report a case by emailing report@hta.gov.uk. Once a report has been submitted, the HTA will confirm receipt of the report, assign the report a case number and ask the clinician to complete a form that enables them to provide the information required under the Regulations. Clinicians should complete and return the form as instructed within three working days.

27. As stated under regulation 5, reporting information under the Regulations does not breach any obligation of confidence that a clinician may owe. Should a clinician choose not to report, they risk failing to comply with the Regulations.

27. As best practice, clinicians should also notify the information governance team at their organisation that patient information has been shared with the HTA under the Regulations. In instances where there are immediate safeguarding concerns (such as cases involving potential human trafficking and child exploitation), clinicians must report to their respective safeguarding team in line with their organisation's safeguarding policies. Clinicians should call the police where there is immediate risk of harm or threat to life.

What should be expected of the HTA once a report has been submitted?

28. The HTA will consider all reports made by a clinician under the Regulations. The information within a report will be shared with the police for further investigation if the HTA considers the transplant to be associated with potentially unlawful activity. Should the HTA require additional information to assist its decision-making, its Living Organ Donation team will contact the reporting clinician directly.

29. If a police referral is made, the HTA will notify the reporting clinician via email of this decision, as well as which police force it has been referred. Once referred, the police will take responsibility for any subsequent investigation. This includes contacting the reporting clinician for additional information or evidence as appropriate, and ensuring the reporting clinician is kept updated on the progress of the investigation.

30. If no police referral is made, the HTA will notify the reporting clinician via email of this decision.

31. The HTA is not responsible for determining whether a criminal offence has taken place or any ongoing communication between the police and the reporting clinician regarding an investigation.

Informing patients and ongoing care

What should clinicians tell their patients?

32. Clinicians should inform patients that they are obliged to share information – including personal data – with the HTA if they travel outside the UK for an organ transplant. If patients express an interest or intent to travel outside the UK for an organ transplant, clinicians may choose to use the opportunity to help patients make an informed decision by outlining in general terms:

    a. the potential for patients to open themselves up to prosecution and be reported to the HTA for potential police referral where an offence may have been committed

    b. the potential health risks associated with the organ transplant, and

    c. the consequences of engaging in any unlawful activity relating to the transplant.

33. In instances where an organ transplant has taken place outside of the UK, the clinician should advise the patient that they are required under the Regulations to notify the HTA. This includes when the transplant is legitimate.

34. When reporting a reasonable suspicion, clinicians must not alert the person (be they donor or recipient) that a report has been submitted to the HTA as it may interfere with the detection and prevention of a crime.

END

Revision control		
Section	**Content change**	**Date revised**
Full guidance	Introducing new guidance	1 April 2024