

## Changes in this version

Update to include OTDT CARE approval.

Reference added with regards commissioned services.

## Policy

Defines how instances of non-compliance with Selection and Allocation Policies should be assessed and what actions should be taken when non-compliance does occur.

NHSBT has in place a process for reporting suspected and actual non-compliance with the Selection and Allocation Policies. Non-compliance is routinely reported at each Organ Advisory Group meeting.

The [Organ and Tissue Donation and Transplantation \(OTDT\)](#) Medical Director (or deputy in their absence or where there is a conflict of interest) will form a group of at least two other transplant clinicians (“the Compliance Group”) who will classify, investigate the incident and aim to report the outcome within 20 working days of the initial report of those incidents where there is potential cause for concern.

Incidents of non-compliance will be classified as minor or major, according to agreed criteria. If minor, then the clinician should identify what preventative actions have been taken to prevent recurrence where appropriate. If major and the clinician involved is not employed by NHSBT, then NHSBT will also report the incident to the clinician’s Medical Director, Director of Nursing and/or Chief Executive, and Commissioners as appropriate and, where relevant to the Human Tissue Authority. If the clinician is employed by NHSBT, the clinician will be subject, if appropriate, to the current disciplinary procedure and outcome reported to the NHSBT Board.

Depending on the outcome of the employer’s response, the NHSBT Board reserves the right to take additional action.

The [OTDT Medical Director](#) will be responsible for ensuring that the NHSBT Board is kept informed of major non-compliance, through the [OTDT Clinical Audit Risk and Effectiveness Group \(OTDT CARE\)](#).

## 1. Introduction

- 1.1. NHS Blood and Transplant (NHSBT) has a statutory responsibility for the development and implementation of policies for the selection of patients to the National Transplant List and for the allocation of organs donated by deceased donors in the NHS in the four nations of the UK.
- 1.2. These policies are developed by health care professionals under the auspices of the relevant Advisory Group after discussion with patients and patient groups and implemented by transplant centres after approval by [OTDT CARE](#).
- 1.3. Given the shortage of donors, non-compliance may result in inequity for those listed for transplantation.
- 1.4. With respect to selection of patients, transplant centres have the duty of ensuring that the potential transplant candidates meet the criteria as set out in the relevant Selection Policy. There are agreed processes to allow access to the transplant list for those patients who do not fulfil such criteria.
- 1.5. Organs donated by deceased donors may be allocated to an individual or a transplant centre for allocation, as outlined in the appropriate Allocation Policy.

## 2. Purpose

- 2.1. The purpose of this policy is to outline the process where individuals or teams either within NHSBT or at a transplant centre fail to comply with the current policies on selection and allocation.
- 2.2. It is accepted that non-compliance may be due to many different factors and, in exceptional cases there may be legitimate reasons why surgeons would not comply, such conduct being considered to be the appropriate course of action in the circumstances; so, the investigation and response to non-compliance must be considered and proportional. It should be noted that the instances of deliberate and inappropriate non-compliance are extremely rare.
- 2.3. Each transplant centre is responsible for ensuring compliance with Selection and Allocation Policies within the centre, including auditing its own compliance.

## 3. Action to be taken in the case of non-compliance

- 3.1. Incident Reporting
  - 3.1.1. All health care professionals and others (including NHSBT Hub Operations) involved in transplantation should report any instance of known or suspected clinically inappropriate non-compliance with the Selection and Allocation Policies to NHSBT.
  - 3.1.2. Such instances should be reported to NHSBT by accessing the NHSBT Incident reporting form via: <https://www.organdonation.nhs.uk/IncidentSubmission/> or via the Organ Donation website <http://www.odt.nhs.uk/>. In urgent cases, the reporter should

---

also contact [OTDT Medical Director](#) (or in their absence or where there may be a potential conflict of interest, their Deputy).

3.1.3. NHSBT Hub Operations gives a presentation on non-compliance with the Selection and Allocation Policies at each meeting of the Solid Organ Advisory Groups.

## 3.2. Investigation

3.2.1. Where concerns have been raised by clinicians, members of NHSBT or others or following receipt of a report of actual or suspected non-compliance with the Selection and Allocation Policies, the [OTDT Medical Director](#) (or in their absence or where there may be a potential conflict of interest, their Deputy) will contact the reporter and relevant clinicians to establish the circumstances around the non-compliance.

3.2.2. The [OTDT Medical Director](#) will convene a small group including at least two other transplant clinicians who are not clinicians at the relevant transplant centre (one of whom will normally be the Chair of the appropriate Advisory Group) (“the Compliance Group”) and will consult with other health care professionals as appropriate. This Compliance Group will classify the non-compliance (see 3.3), agree a course of action and complete a report at the end of the investigation.

## 3.3. Classification of non-compliance

3.3.1. Classification:

Minor includes inadvertent mistakes (such as resulting from a clerical error) or non-compliance mitigated by circumstances.

Major: intentional non-compliance or repeated non-compliance

## 3.4. Reporting

3.4.1. The [OTDT Medical Director](#) should provide a written report of the conclusions of the Compliance Group to the appropriate Advisory Group and [OTDT CARE](#). Major incidents will be escalated to the NHSBT Executive Board.

## 3.5. Action

3.5.1. Minor non-compliance: where appropriate, the relevant clinician will be asked to outline what actions have been taken to avoid repetition. The Advisory Group will review the relevant policy to determine whether modification is required.

3.5.2. Major:

3.5.2.1. In most cases, NHSBT will not be the employer. In such circumstances the [OTDT Medical Director](#) will report the incident to the Medical Director, Director of Nursing and/or Chief Executive of the employing centre for further investigation and action. The centre will be asked to provide a response in writing to NHSBT.

3.5.2.2. In the very rare cases where the action of the employing centre is considered inadequate, NHSBT may take further action, if the Board of NHSBT has given approval for such action.

3.5.2.3. Further action may include reporting the incident to the relevant Commissioners, and, in the case of serious professional misconduct (such as non-compliance for personal financial reward) to the appropriate regulatory body (such as the General Medical Council).

3.5.2.4. Where the non-compliance contravenes the licence held by the transplant centre under relevant legislation, NHSBT will inform the Human Tissue Authority.

3.5.2.5. Where NHSBT is the employer, this will be dealt with, if appropriate, according to current disciplinary guidelines and the Board of NHSBT informed

## 3.6. Repeated non-compliance

3.6.1. Should there be cases of repeated non-compliance, the NHSBT Board may recommend to the Commissioners that the Commissioners withdraw the commissioning of transplants and/or of transplantation of specific organs from that centre, or to the HTA that the licence of that transplant centre be withdrawn and/or NHSBT may decline to allocate deceased donor organs to that transplant centre, particularly where NHSBT has concerns around patient safety. It is recognised that this would be in very exceptional circumstances

## 3.7. Time lines

3.7.1. Incidences of possible non-compliance should be investigated and closed within 20 working days from the initial report, assuming full co-operation from the relevant transplant centre, although it is recognised that actions arising from the incidents may take longer to implement.

## Definitions

- Commissioners – The organisation, trust or health board that holds contracts with transplant centres.