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Changes in this version

Document updated to align new approval process via OTDT CARE. Flowcharts amended.

Clarity of assessment of policy interdependency for all reviews.

Policy

1. Background

NHSBT has the statutory responsibility of developing and implementing allocation policies of organs from deceased donors. Together with stakeholders NHSBT is jointly responsible for developing and implementing selection policies enabling patients to receive organs from deceased donors.

These policies should be clear and, as far as possible, evidence based and based on the principles of equity, fairness, benefit, and utility. All policies should be supported by clinicians and other relevant stakeholders. Criteria for assessment of these policies have been developed and agreed.

As clinical practice evolves and improves, and as both donor and recipient characteristics change, it is important that these policies are reviewed on a regular basis and revised as necessary.

Policies are developed and reviewed at minimum annually and on an as required basis by the relevant Advisory Group or the Allocation and Selection Policy Steering Committee (see Appendix A) and reviewed and approved by the *Organ and Tissue Donation and Transplantation Clinical Audit Risk and Effectiveness Group (OTDT CARE)* on behalf of the Board of NHSBT before being implemented by NHSBT and partners. This is to capture ad-hoc changes that happen as needed meeting service need.

2. Aim of policy

The selection and allocation policies are of relevance both for information and implementation by a large number of stakeholders, including patients and their families, clinicians who refer, assess and manage patients before and after transplant, those in organ donation, organ retrieval and other health care professionals, commissioners and regulators. These may work in different institutions other than NHSBT and in different countries of the UK. Furthermore, safe & effective implementation of some of these changes may take weeks or months, so agreement of changes to policies will not always immediately translate into action.

The purpose of this document is to define the stages not only when patient selection and organ allocation policies should be reviewed but how such changes are proposed, agreed, and implemented.

The stages are:

- Proposal for change
- Consultation
- Approval of change
- Assessment of policy interdependency

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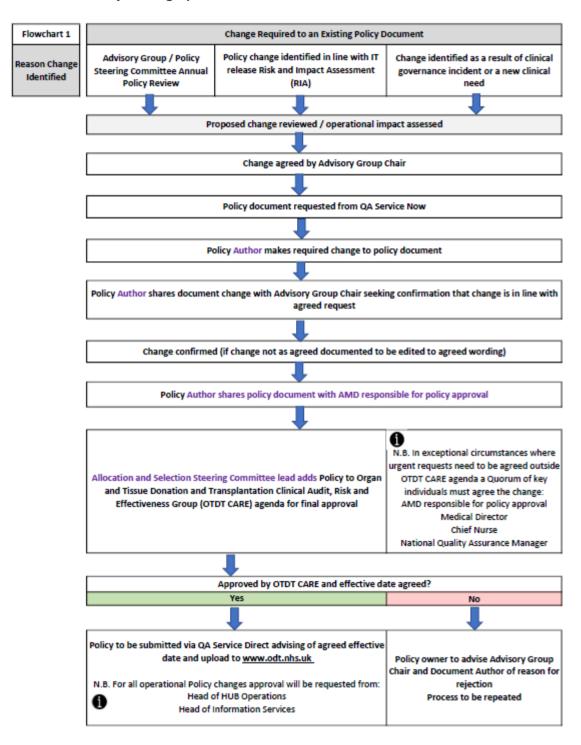
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- Implementation of changes
- Dissemination of changes

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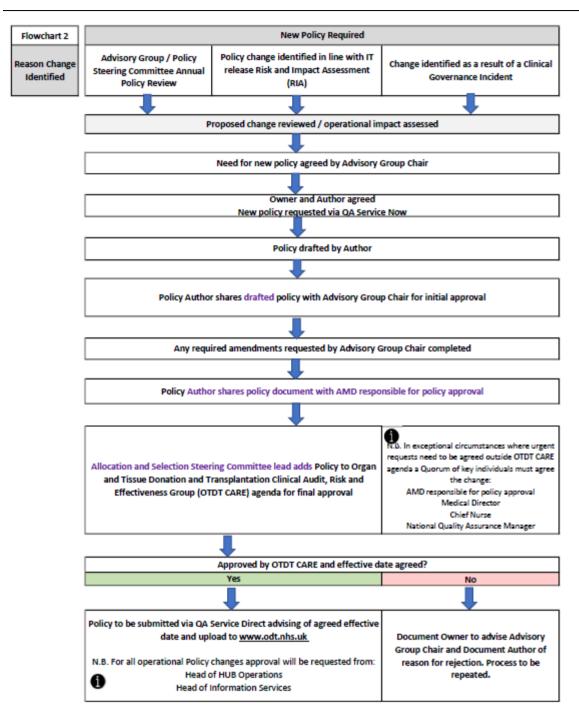
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3. Clinical Policy Change process





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4. Appendix A

Terms of Reference for Allocation and Selection Policies Steering Committee

The purpose of the Steering Committee is to meet to discuss the policies that support allocation and selection of deceased and living donors.

1.0 Membership

1.1 Chair: Head of Service Delivery - ODT Hub

Deputy Chair: Head of Service Delivery - Organ Donation & Nursing

1.2 Members

1.2.1 Stats and Clinical Research for Kidney

Stats and Clinical Research for Liver

Stats and Clinical Research for Cardiothoracic

Stats and Clinical Research for Pancreas

Stats and Clinical Research for Bowel Advisory Group

Stats and Clinical Research for Ocular Tissue

Stats and Clinical Research for Living Donation

ODT QA Manager

Head of Hub Operations (or representative)

Information Services Manager (or representative)

Lead Recipient Coordinator

ODT HUB Project Coordinator

1.2.2 Responsible Oversight and Approval:

OTDT Associate Medical Director - Transplant Medicine

- 1.2.3 The Chair, in discussion with members of the Group, may invite other appropriate members to join the group.
- 1.3 Members will be responsible for:
 - 1.3.1 Bringing to the Steering Committee any relevant concerns or suggestions arising from the meetings that are relevant to the work of the Committee.
 - 1.3.2 Responding to relevant items on the agenda.
 - 1.3.3 Attending at least 75% of meetings and, if unable to attend, nominating a deputy.
 - 1.3.4 Where unable to attend a colleague is nominated to update and make decisions on your behalf.
 - 1.3.5 Ensuring that all associated new change requests have been accepted or rejected in advance of the meeting.

1.4 Role of the Steering Committee

The role of the Steering Committee is primarily to discuss and advise on Allocation and Selection Policy updates taking into consideration any foreseen operational impacts and associated delivery.

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In particular, the Committee will:

Give full consideration to operational impact.

Identify any interdependencies across organ group policies.

Help ensure timely implementation of agreed policies.

Advise on development, recommend approval and publication externally of clinical policies.

Review and recommend approval of clinical policies which cover the work of more than one advisory group.

2.0 Frequency of meetings

The Steering Committee will meet monthly via Teams adhering to completion of policy actions in advance of OTDT Associate Medical Director – Transplant Medicine approval. Full details can be located within POL223 Patient Selection and Organ Allocation Policies Review and Approval.