

NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE
POLICY FOR ACCESS TO DATA AND INFORMATION
THROUGH STATISTICS & CLINICAL AUDIT

1 Introduction and scope

In order to fulfil the 2005 Directions, NHS Blood and Transplant (NHSBT) is obliged to collect, record and analyse anonymised and personally identifiable and sensitive data concerning potential and actual organ donors, patients registered for transplant, transplant recipients including long-term follow-up information and individuals registering on the Organ Donor Register.

The national data collected enables NHSBT to fulfil its statutory obligations with regard to the effective use of organs, equitable organ allocation and performance monitoring of transplant centres in terms of patient outcomes. However, many requests for data on activity and outcomes are received to address questions of interest to colleagues engaged in transplantation, the media and other stakeholders.

This policy clarifies how data held by NHSBT can be accessed and used by individuals or groups within NHSBT, with advisory roles to NHSBT, within the wider NHS, from other organisations with an interest in organ donation and transplantation and by members of the public.

This policy does not cover

- data that are provided in order to allocate organs safely and appropriately for transplant
- data that are provided to inform care for patients on an individual basis
- data that are sent to other transplant registries as agreed with, and on behalf of, UK transplant centres
- analyses undertaken to support NHSBT's advisory groups and their sub-groups, where the work is part of an agreed programme of work
- requests for data or information that are solely handled by the Communications team; only published information will be provided by them without consulting others within NHSBT.

The policy relates to data concerning donation, transplantation and outcomes of all organs (kidney, pancreas, liver, heart, lung, small bowel) but additionally relates to pancreatic islet and cornea donation and transplantation and the use of Ventricular Assist Devices (VADs) as a bridge to heart transplantation. The policy will also apply to data collection anticipated for the future, eg that relating to hand, face and thymus transplantation.

2 Background

The data that are collected and held by NHSBT are provided in a number of paper and/or electronic formats by NHSBT's Specialist Nurses for Organ Donation, local transplant personnel (recipient transplant coordinators, transplant surgeons, H&I laboratory staff), NHSBT's data collection service or, in the case of the ODR, by members of the public either directly, or through one of the agencies who collect registrations and pass them on to NHSBT. Some of the data are provided as a statutory requirement as set out by the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006.

Data collected include personal and sensitive identifiable information, in addition to detailed clinical information which enables the objective evaluation of potential organ donors, the effective allocation of organs and detailed analyses of post-transplant outcomes.

The raw data and information derived from them provide a valuable source of reference for individuals or groups within and outside of NHSBT. Much information is made publicly available through the NHSBT Organ Donation and Transplantation (ODT) website (www.organdonation.nhs.uk), Advisory Group and NHSBT reports and scientific peer-reviewed journals. The provision of data and information relating to organ donation and transplantation needs to be carefully managed to ensure that data and analyses that are not publicly available are provided appropriately and within governance guidelines, and to ensure that resources are used effectively.

3 Purpose of the policy

This policy sets out the processes and agreements that apply to the requesting of raw data or summary information, access rights to data/information and the approval and prioritisation of such requests.

In determining levels of access and priority levels it is important to consider the following:

- The affiliation of the person/organisation asking for data/information
- The reason for the request and the intended use of the data
- The nature and detail of the data requested
- The level of resource required to respond to the request

All requests must comply with legal requirements and the NHSBT Information Governance Policy as detailed in **Appendix 1**. Confidentiality of information is paramount and consideration must be paid to the reporting of information based on small numbers such that it must not be possible to identify individuals (see Appendix 1). Anonymised data will be provided wherever possible.

4 Process for requesting data/information

Requests for data/information are generally dealt with by the NHSBT Statistics and Clinical Audit (SCA) team. Exceptions to this are where requests can be answered directly from publicly available information by the person or group receiving the request.

There are a number of routes by which requests can be made and the appropriate mechanism will depend on what is being requested. Usually, there is direct contact between the Enquiries Lead in SCA and the requester. In the case of media enquiries the request is always handled through the Communications Team. Enquiries may be passed on to SCA through the Information Manager, who handles enquiries that are made through the contact details that appear on the ODT website.

The following methods of requesting data/information from SCA are appropriate:

- Application form available on the ODT website for access to local data or information or for national published information (ODT Data Request Form, Appendix 2)
- An application form for data for multi-centre or national research studies by external researchers (ODT Research Data Application Form, Appendix 3)
- Email / phone call to the Enquiries Lead for Statistics and Clinical Audit (SCA).

Phone calls and emails may be followed up by a requirement to complete the appropriate form where the nature of the request or the level of complexity suggests that this is appropriate. Where the request relates to local data or to national published information, the Enquiries Lead for SCA will use their judgement as to whether a form is required to capture the detail of the request or whether the initial email or phone call will suffice.

People requesting data from NHSBT are required to apply for approval from local or national ethics committees where appropriate.

5 Access to data/information – approvals

Whether a request will be met and the timeliness of the response will depend on the affiliation of the person requesting the information and the nature of the request. To assist the Enquiries Lead for SCA, a Request Oversight Group will provide advice as required and will meet on a quarterly basis to review briefly the requests received and responded to in that quarter. The Request Oversight Group (ROG) will include the Associate Medical Director (AMD) for

ODT, the Associate Director of Statistics and Clinical Audit and the Head of Organ Donation and Transplantation Studies. It will usually suffice for one member of this group to provide advice on any one request.

Information relating to organ donation and transplantation is published in a variety of formats:

- Annual Activity Report
- ODT website
- NHSBT Advisory Group reports
- Publications in scientific journals
- Slides and abstracts from meetings and conferences

Wherever possible, these sources of published information are used to respond to those seeking information. Often an answer to a similar question can be provided from a published source that will satisfy their need.

Those requesting information include:

- NHSBT staff
 - Operational/statutory needs
 - Reporting of key performance indicators (KPI)
 - Governance purposes
 - Other purposes
- Advisory Groups
- Commissioners (including NCG, specialist commissioner groups)
- Departments of Health (England, Scotland, Wales, N Ireland)
- Other health bodies (the Human Tissue Authority, the Care Quality Commission, the National Institute for Health and Clinical Excellence)
- Transplant unit staff
- Other health care professionals
- Lay members and any others including
 - Patients and their families
 - Patient groups
 - Media and Journalists
 - Researchers

When a request is received, the following principles apply to the level of access to data, information and analysis and the priority with which it will be addressed:

5.1 NHSBT staff

5.1.1 Operational/statutory needs

Requests for data or information in support of NHSBT's operations will be acted upon as a priority. This includes data or information needed to fulfill requirements with regard to organ allocation and performance monitoring. Such requests should be made by a member of the ODT Senior Management Team or other Senior Managers within NHSBT.

5.1.2 Reporting of key performance indicators (KPI)

KPI data will be reported as a priority within the agreed timescales and to the agreed specification for the Executive Team report, the ODT Senior Management Team Scorecard and other supporting scorecards. Any changes in content must be requested by the relevant Associate Director within ODT and will be treated as high priority and implemented as soon as resources and availability of appropriate data permit.

5.1.3 Governance purposes

Data or information to support clinical governance, as agreed by the Medical and Research Director of NHSBT or an Associate Medical Director, will be treated as high priority and implemented as soon as resource limitations permit, with at least two members of ROG providing advice about any conflicting priorities.

5.1.4 Other purposes

Data or information requested for other purposes will be given a lower priority. Requests may be made by NHSBT staff on behalf of other organisations / Health Depts / media etc and these are considered below according to the origin of the request. The following principles apply to requests purely from within NHSBT:

- An appropriate request form must be completed if raw data are being requested for at least 20 patients or if the information requested will take more than an hour to provide (see ODT Data Request Form, Appendix 2).
- Requests from Specialist Nurses for Organ Donation (SNODs) must always be supported by Team Managers or Regional Managers – shown (at least) by inclusion of such an individual on an email request. Telephone requests directly from SNODs will not be acted upon without evidence of support from their Team Manager.

- Requests will be supported where resource permits, the request is deemed reasonable by the SCA Enquiries Lead and the work required does not exceed one hour. A member of ROG will be consulted for any advice required.
- The timescale for provision of data/information will be agreed between the SCA Enquiries Lead and the requester.
- For requests demanding more than one hour of resource, the SCA Enquiries Lead will seek advice from at least one member of the Request Oversight Group (ROG) as to whether the work should be done and to agree an appropriate deadline. At their discretion the Enquiries Lead may also seek advice about any request received.
- Any issues arising about the information that should be provided and the timescale will be referred to a member of the ROG for advice.

5.2 Advisory Groups

Annual work plans will be agreed between Advisory Group Chairs, the Associate Medical Director (AMD) for ODT, the Associate Director of Statistics and Clinical Audit and the Head of Organ Donation and Transplantation Studies. Any requests arising through Advisory Groups that are not part of the agreed work plan and that will require more than one hour of SCA resource will be reviewed by the ROG. The group will advise on the appropriateness and relative priority of the request. The decision must be agreed between at least two members of the group. The work will then be scheduled if appropriate. If considerable additional work is required (more than 10 working days) the ROG will refer the request to the Director of ODT for approval. Work requiring less than an hour's work may also be referred to the ROG at the discretion of the SCA Enquiries Lead or relevant statistician.

5.3 Commissioners (including NCG, specialist commissioner groups)

Any requests arising from Commissioning groups that are outwith the scope of the liver and cardiothoracic audits funded by National Specialised Commissioning Team (NSCT) or are not part of an agreed work plan and that will require more than one hour of SCA resource will be reviewed by the ROG. The group will advise on the appropriateness and relative priority of the request. The decision must be agreed between at least two members of the group. The work will then be scheduled if appropriate. If considerable work is required (more than 5 working days) the ROG will refer the request to the Director of ODT for approval. Work requiring less than an hour's work may also be referred to the ROG at the discretion of the SCA Enquiries Lead.

5.4 Departments of Health (England, Scotland, Wales, N Ireland)

Any requests arising from the health departments of England, Scotland, Wales and N Ireland that are not part of the agreed regular reports and that will require more than one hour of SCA resource will be reviewed by the ROG. The group will advise on the appropriateness and relative priority of the request. The decision must be agreed between at least two members of the group. The work will then be scheduled if appropriate. If considerable additional work is required (more than 5 working days) the ROG will refer the request to the Director of ODT for approval. Work requiring less than an hour's work may also be referred to the ROG at the discretion of the SCA Enquiries Lead. Information required for Parliamentary Questions will be given priority and ROG consulted only at the discretion of the Enquiries Lead.

5.5 Other health bodies

Any requests arising from other relevant health bodies (the Human Tissue Authority (HTA), the Care Quality Commission (CQC) and the National Institute for Health and Clinical Excellence (NICE) and others as appropriate) that will require more than one hour of SCA resource will be reviewed by the ROG. The group will advise on the appropriateness and relative priority of the request. The decision must be agreed between at least two members of the group. Advice may be sought from relevant Chairs of Advisory Groups as required. The work will then be scheduled if appropriate. If considerable additional work is required (more than 5 working days) the ROG will refer the request to the Director of ODT for approval. Work requiring less than an hour's work may also be referred to the ROG at the discretion of the SCA Enquiries Lead.

5.6 Transplant unit / Hospital Trust staff

5.6.1 Local transplant unit / Trust data and information

- Requests from transplant unit / Trust personnel must always be supported by someone at consultant level within the Trust – shown (at least) by inclusion of such an individual on an email request.
- An appropriate request form must be completed if raw data for at least 20 patients are being requested or if the information requested will take more than one hour to provide (see ODT Data Request Form, Appendix 2).
- Requests expected to take less than one hour will usually be supported provided that
 - SCA resource is available
 - It is agreed that it is not practicable to use data that should be available locally

- The timescale for provision of data/information will be agreed between the SCA Enquiries Lead and the requester.
- For requests necessitating more than one hour of resource, the SCA Enquiries Lead will seek advice from at least one member of the Request Oversight Group (ROG) as to whether the work should be done and to agree an appropriate deadline. For requests necessitating more than one day's work, at least two members of ROG must agree to the request.
- If the SCA Enquiries Lead has any doubts about any aspect of the request or if any issues arise about what information should be provided and to what timescale, a member of ROG will be consulted for advice.

In terms of transplant related data, local data are defined here as including donor data for local transplant patients provided that personally identifiable donor data are not included.

5.6.2 Data / information from a small number of other transplant units / Trusts

Where data/information are requested from a small number of other transplant units / Trusts (representing less than 50% of relevant national activity), consent for access to the data from these centres must be obtained from the Director of the Transplant Unit(s) or the Medical Director(s) of the Trust(s) concerned (as appropriate) and documentary evidence of this provided in support of the request. Only anonymised data will be provided wherever possible.

The same principles apply as per section 5.6.1.

5.6.3 Multi-centre and national data / information requests

Where data/information from a large number of other transplant units / Trusts (representing at least 50% of relevant national activity) or national data are requested, an appropriate request form must be completed (see ODT Research Data Application Form, Appendix 3).

All such requests will be reviewed by the ROG and if considered feasible (in terms of availability of data and resource) will be passed to the relevant Advisory Group's review group to determine the clinical value of the study. The resource needed from SCA may be for provision of data only, or for data and analytical input. These studies will not normally be regarded as having high priority and resources will be provided as and when available subject to agreement by the relevant review group. In each supported application, an agreement must be signed by the applicant and their Clinical Director to ensure that appropriate data sharing and publication principles are adhered to.

5.7 Other health care professionals

For all other requests from within the NHS (ie outside NHSBT, transplant centres and relevant Trusts) only published data will routinely be provided. Any exceptions to this must be agreed by at least two members of the ROG. If considerable work is required (more than 5 working days) the ROG will refer the request to the Director of ODT for approval.

5.8 Lay members and any others

- Patients and their families
- Patient groups
- Media and Journalists
- Researchers
- Pharmaceutical company representatives
- Others

All other, non-NHS, non-Governmental, organisations and personnel, including the media, can be provided only with published information concerning organ donation and transplantation. Any exceptions to this must be agreed by at least two members of the ROG. If considerable work would be required (more than 5 working days) the ROG will refer the request to the Director of ODT for approval.

Should this entail the use of substantial NHSBT resources then NHSBT reserves the right to make a charge.

Local information with regard to ODR registrations will also be provided to support local promotional campaigns provided that resource is available and the request does not require more than one hour's work. Exceptions to this will be referred to at least two members of ROG.

SCA staff will not liaise directly with the media, but will provide information indirectly through the appropriate Communications Team personnel.

6 Access to data/information – prioritisation

Requests that are deemed to be high priority, including agreed work plans and reports, will be delivered wherever possible. Areas of work that are considered high priority are identified below. All other requests will be deemed to be of a lower priority and ROG members will advise on relative priorities as required. Any unresolved issues will be referred to the Director of ODT.

High priority requests are as follows:

- NHSBT staff
 - Operational/statutory needs
 - Reporting of key performance indicators (KPI)
 - Governance purposes
 - Issues impacting on number of transplants achieved
 - Issues with a direct impact on patient care
- Advisory Groups
 - Organ allocation issues
 - Issues impacting on number of transplants achieved
 - Issues with a direct impact on patient care
- Commissioners (including NCG, specialist commissioner groups)
 - Issues impacting on number of transplants achieved
- Departments of Health (England, Scotland, Wales, N Ireland)
 - Parliamentary Questions
 - Agreed reports
 - Issues impacting on number of transplants achieved
- Other health bodies (eg HTA, CQC, NICE)
 - Issues impacting on number of transplants achieved
 - Issues with a direct impact on patient care
- Transplant unit / hospital Trust staff
 - Issues impacting on number of transplants achieved
 - Issues with a direct impact on patient care
- Other health care professionals
 - Issues impacting on number of transplants achieved
 - Issues with a direct impact on patient care
- Lay members and any others (patients and their families, patient groups etc)
 - Issues with a direct impact on patient care

7 Publication and authorship

Novel work undertaken on the basis of data held by NHSBT may be published in the peer-reviewed literature. The following guidelines should be followed:

- The guidelines set out by the International Committee of Medical Journal Editors should be followed¹
- Authorship should be agreed in advance and should recognise NHSBT staff and all others making a substantial contribution (a minimum of 2 hours) to the work
- For papers written on behalf of an Advisory Group or steering group, this should be stated
- For papers written as a result of a working group, all members should be acknowledged by name at the end of the article, with those making substantial contributions named in the authorship

- If papers are written on the basis of data from a limited number of transplant centres / Trusts, key individuals at all those centres/Trusts should be encouraged to contribute and then be named as co-authors
- The source of the data should always be acknowledged (eg UK Transplant Registry held by NHS Blood and Transplant)
- Papers on the basis of national data or multi-centre data should include the following acknowledgement – *‘The authors are grateful to all the transplant centres in the UK who contributed data on which this article is based’*.

Where possible and appropriate, printed figures and material displayed at meetings should carry the NHSBT logo and the source be acknowledged.

¹ ICMJE. Available at: www.icmje.org/ethical_1author. Accessed Jan 2011.

8 Summary

This policy clarifies how data held by ODT can be accessed and used by individuals or groups within ODT, those who act in an advisory capacity to ODT, staff within the wider NHS, staff from other organisations with an interest in organ donation and transplantation and by members of the public.

It also defines the process for obtaining guidance when resource is not sufficient to meet demand or requests are not deemed appropriate or when considerable resource is required.

However, it is not possible to legislate for all contingencies and in many instances there will be a judgement call by the relevant individuals or groups as described.

A report will be produced for the ODT SMT every six months, outlining the number of requests for data/information from the different sources, the number of requests met and turned down, and where appropriate, the time taken to obtain the relevant information.

These guidelines will be reviewed every 12 months.

Appendix 1 Legislation and confidentiality

1 Freedom of Information Act (2000)

NHSBT is subject to the Act, taking into consideration the requirements for NHS organisations to be open. Care must be taken and the exemptions should be noted (endangering an individual's health and safety or prejudicing the function of the authority) in addition to time spent (up to the equivalent of two and a half days work), charging (maximum of £450) and time scale (within 20 working days).

2 Data Protection Act (1998)

NHSBT is bound by the Act and must comply with the principles.

3 NHSBT Information Governance Policy

In line with the Cabinet Office Mandate, the policy requires that transmitting PID is to be avoided if possible. Where it is necessary, it must be done in a secure fashion eg. email file encryption , special delivery (50+) (post). Further advice can be requested regarding the send of information from the Information Governance Manager.

4 Duty of Confidence (applicable to the deceased)

NHSBT is bound by this duty.

5 Guidelines for working with small numbers

Problems with confidentiality arise when there are small denominators. In larger populations, it is more difficult to identify individuals from data released. For example, if there are 5,000 individuals in a specific age-race-sex group in a single county, the likelihood of identifying a single individual from data in a published table is quite small.

In smaller populations, it is more likely that an individual might be identifiable, if there are only one or two individuals with some special characteristics. For example, in a modest-sized community, it may be common knowledge that there is only one child who is frequently hospitalised, and a table showing that this community has one paediatric liver donor could unintentionally disclose confidential information. Rules should apply for privacy protection that consider both denominator and numerator size.

Prior to disseminating or publishing information that contains confidential information, agreement must be reached by first considering the size of the denominators and the population size represented against the data that will be published. Generally, tabular data based on denominators greater than 300 persons present minimal risk for individual identification but for smaller groups, data should be carefully reviewed.

The risk of violating confidentiality increases substantially when data are tabulated for small subgroups of the population within small geographic areas and potentially specific health issues. Caution is required if the population size is between 100 and 300, and extreme caution is warranted when the population is less than 100. In such cases data should be aggregated (e.g. >5 or <5).

There is also a need to review risks around group identification. If information is published about a group of individuals identifiable by their age, race, or other reported characteristics this should also be reviewed before final publication.

The Information Governance Manager will provide appropriate advice about data confidentiality issues.

Appendix 2

Organ Donation and Transplantation

Data/Information Request Form*Blood and Transplant*

REQUESTER DETAILS:	
Title:	<input type="text"/> Name: <input type="text"/>
Job title:	<input type="text"/>
Organisation:	<input type="text"/>
Address:	<input type="text"/>
Tel:	<input type="text"/>
Mobile:	<input type="text"/>
Fax:	<input type="text"/>
Email:	<input type="text"/>
Name of senior person supporting this request (Consultant, SN-OD Team Manager etc) <input type="text"/>	
INFORMATION REQUIRED:	
Requested by: (If different from above)	<input type="text"/>
Requested for:	<input type="text"/>
Data/information requirements: (where appropriate, please list all data required)	<input type="text"/>
Reason for request/ intended use of data:	<input type="text"/>
Date required by:	<input type="text"/> Is this deadline essential or desirable? <input type="text"/>
Please specify the impact that failure to provide this information would have (eg impact patient care): <input type="text"/>	

Appendix 3

NATIONAL TRANSPLANT DATABASE



Application for Data

REF No -

UK Transplant

APPLICANT DETAILS		Section 1
Title _____	Name _____	
Institution address	<div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; height: 15px;"></div>	
Postcode	<div style="display: flex; gap: 5px;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	
Co-authors and affiliation	<div style="border: 1px solid black; height: 20px;"></div>	
Study title	<div style="border: 1px solid black; height: 20px;"></div>	
Deadline <small>(Date the data are required)</small>	<div style="display: flex; gap: 5px;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">2</div> <div style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">0</div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	
STUDY DESCRIPTION		Section 2
Study summary <small>(Provide a brief summary of the proposed study in abstract form)</small>	<div style="border: 1px solid black; height: 120px;"></div>	
Study aims <small>(State the specific aims of the study)</small>	<div style="border: 1px solid black; height: 100px;"></div>	
Background information <small>(Explain how this study will benefit transplantation)</small>	<div style="border: 1px solid black; height: 120px;"></div>	

DATA AND ANALYSIS		Section 3
Study cohort		
Data requirements <i>(List all data required)</i>		
Statistical analysis <i>(Provide a brief outline of the proposed statistical analysis)</i>		
Publication <i>(State intentions for publishing study results eg name meetings, conferences and journals)</i>		

PATIENT CONSENT AND DATA PROTECTION		Section 4
Is any patient identifiable information required?		Yes / No? _____
If Yes,		
a) Do you have patient consent?		Yes / No? _____
b) If you do not have patient consent, have you got approval to use patient identifiable information for the study from the Patient Information Advisory Group and your local Ethics Committee?		Yes / No? _____
If Yes, please provide documentary evidence of this approval		
Data protection <i>(Indicate any safeguards set in place to limit use of, and access to, the data)</i>		

For UKT use only	UKT's Caldicott Guardian		UKT's Data Protection Officer			
	Application approved: Yes / No? _____ Date: _____	Name: _____	Application approved: Yes / No? _____ Date: _____	Name: _____		
If No, state why: _____						
Application approved:	AG Chair		AASG		Unit Directors	
	Yes / No / Not sought? _____ Date: _____	Yes / No / Not sought? _____ Date: _____	Yes / No / Not sought? _____ Date: _____	Yes / No / Not sought? _____ Date: _____	Yes / No / Not sought? _____ Date: _____	Yes / No / Not sought? _____ Date: _____
If No or Not sought, state why: _____						