Data Access Policy

Policy for Access to Data and Information through Statistics & Clinical Studies

Key Points

- This policy clarifies how data held by NHS Blood and Transplant (NHSBT) Organ Donation and Transplantation (ODT) directorate 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,
    - members of the public.

- 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 ocular tissue donation and transplantation and the use of Ventricular Assist Devices (VADs) as a bridge to heart transplantation. The policy will also apply to data collected relating to potential donation, organ retrieval, registration, transplantation and outcome of solid and vascular composite allografts.

- This policy describes the process of how to access local and national data and the priority given to those requests. 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.

- Much information is already made publicly available through the NHSBT Organ Donation and Transplantation (ODT) website (http://www.odt.nhs.uk/), including Advisory Group and NHSBT reports and scientific peer-reviewed journals.

- Details of standard national organ and ocular tissue datasets available to applicants from transplant units in the UK for a consultant led study are available on the website https://www.odt.nhs.uk/statistics-and-reports/access-data/

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1. Introduction and scope

In order to fulfil the 2005 Directions, NHS Blood and Transplant (NHSBT) collects, records and analyses data that can be anonymised and/or personally identifiable or sensitive concerning potential and actual organ donors, patients registered for transplant, transplant recipients including long-term follow-up information and individuals registering on the NHS Organ Donor Register (ODR).

Data collected nationally enables NHSBT to fulfil its statutory obligations with regard to the effective use of organs, equitable organ offering and performance monitoring of transplant centres in terms of patient and graft outcomes as well as support patients and the public with relevant information in a timely and transparent manner. NHSBT receives many requests for data on activity and outcomes to address questions of interest to colleagues engaged in transplantation, the media and other stakeholders.

NHSBT is keen to make data available and support the public and health care professionals to access data in a timely and appropriate manner. 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 in line with NHSBT's legal obligations.

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 (AG) 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 Directorate; only published information will be provided by them without necessarily 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 ocular tissue donation and transplantation and the use of Ventricular Assist Devices (VADs) as a bridge to heart transplantation. The policy will also apply to data collected relating to potential donation, organ retrieval, registration, transplantation and outcome of solid and vascular composite allografts.

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 and other regulatory acts.

Data collected include personal and sensitive identifiable information, in addition to detailed clinical information which enables the objective evaluation of potential organ donors, validated criteria for listing of transplant candidates, the effective offering 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 (http://www.odt.nhs.uk/), including Annual Organ Specific Reports, Advisory Group and NHSBT reports, and scientific peer-reviewed journals.

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
- The use for which it is intended to use and share the data

All requests must comply with legal requirements and the NHSBT Information Governance Policy as detailed in Appendix 1. Confidentiality of information is paramount and in addition to consideration of the security of the data, consideration must be also given to the possibility of 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 unless there is explicit agreement for patient identifiable data to be released.

4. Process for requesting data/information

Requests for data/information are generally dealt with by the NHSBT Statistics and Clinical Studies (SCS) team, unless the requests can be answered directly from publicly available information.

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 SCS and the requester. Media enquiries should be handled through the Media and PR Team and requests for Parliamentary Questions/Departments of Health through the External Affairs Team. Enquiries may be passed on to SCS through the Information Manager.

The following methods of requesting data/information from SCS 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)

- Contact with the Enquiries Lead for Statistics and Clinical Studies (SCS) via email statistical.enquiries@nhsbt.nhs.uk or phone: 0117 9757472.

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 SCS 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 may be required to apply for approval from local or national ethics committees where patient identifiable data are needed, or where this is required for their study.

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 SCS, advice may be obtained from the Associate Medical Director (AMD) for ODT, the Associate Director of SCS or the Head of Organ Donation and Transplantation Studies (the Request Oversight Group (ROG)).

Requests for data come from many sources, including:

- NHSBT staff
  - Operational/statutory/commissioning needs
  - Reporting of key performance indicators (KPI)
  - Governance purposes
  - Other purposes
- NHSBT Advisory Groups
  - Organ and Ocular Tissue Advisory Groups
  - National Organ Donation Committee (NODC)
  - National Retrieval Group (NRG)
  - Research, Innovation and Novel Technologies Advisory Group (RINTAG)
- Commissioners
- Departments of Health (England, Scotland, Wales, N Ireland)
- Other health bodies (the Human Tissue Authority, the Care Quality Commission, Public Health England, the National Institute for Health and Care Excellence)
- Transplant unit /hospital 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/commissioning 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 fulfil requirements with regard to organ donation, retrieval and offering, 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) and Quality Dashboard information

KPI and other quality 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 ODT 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 Departments, media and others 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 (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 SCS Enquiries Lead and the work required does not exceed one hour.
- The timescale for provision of data/information will be agreed between the SCS Enquiries Lead and the requester.
- For requests demanding more than one hour of resource, the SCS Enquiries Lead will seek advice 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. NHSBT Advisory Groups

5.2.1. Annual work plans will be agreed between NHSBT Advisory Group Chairs, the Associate Medical Director (AMD) for ODT, the Associate Director of SCS and the Head of Organ Donation and Transplantation Studies.

5.2.2. Any requests arising through NHSBT Advisory Groups and Sub-groups that are not part of the agreed work plan and that will require more than one hour of SCS resource will be reviewed in regular meetings between the Chair and the relevant Data Lead.

5.2.3. It is not the role of the NHSBT Advisory Group (or relevant Sub-group) to comment on the academic quality of the proposed work (although the quality of proposed analysis will impact on the priority).
5.2.4. If agreed, the work will then be scheduled as appropriate.

5.3. Commissioners

Any requests arising from Commissioning groups that are out with the scope of the transplant audits funded by NHS England or are not part of an agreed work plan and that will require more than one hour of SCS resource will be reviewed by the ROG. 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 SCS 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 SCS 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 SCS Enquiries Lead. Information required for Parliamentary Questions will be given priority and ROG consulted only at the discretion of the Enquiries Lead.

SCS staff will not liaise directly with the health departments, but will provide information indirectly through the appropriate External Affairs Team personnel.

5.5. Other health bodies

Any requests arising from other relevant health bodies (the Human Tissue Authority (HTA), the Care Quality Commission (CQC), Public Health England (PHE), the National Institute for Health and Care Excellence (NICE) and others as appropriate) that will require more than one hour of SCS 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 NHSBT 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 SCS Enquiries Lead.

5.6. Transplant unit / Hospital staff

5.6.1. Local transplant unit / hospital data and information

- Requests from transplant unit / hospital personnel must always be supported by someone at consultant level within the hospital – 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).

- In some circumstances, patient identifiable data for patients under the care of the transplant unit / hospital in question may be provided.
- Requests expected to take less than one hour will usually be supported provided that
    - SCS 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 SCS Enquiries Lead and the requester.
- For requests necessitating more than one hour of resource, the SCS Enquiries Lead will seek advice from at least one member of the ROG as to whether the work should be done and to agree an appropriate deadline. If the work is to be done by the Data Lead, then the request must be agreed also by the Chair of the AG or ODT Clinical Audit, Risk and Effectiveness (CARE) group. For requests necessitating more than one day's work, at least two members of ROG must agree to the request.
- If the SCS 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 / hospitals

Where data/information are requested from a small number of other transplant units / hospitals (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 hospital(s) concerned (as appropriate) and documentary evidence of this provided in support of the request, unless the ROG recommend otherwise. 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 / hospitals (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 members of the ROG and if considered feasible (in terms of availability of data and resource) will be passed to the relevant NHSBT Advisory Group's review group to determine the clinical value of the study. The resource needed from SCS 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 and/or ODT CARE. 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 (see Data Release Agreement, Appendix 4).

Details of standard national organ and ocular tissue datasets available to applicants from transplant units in the UK for a consultant led study are available on the website https://www.odt.nhs.uk/statistics-and-reports/access-data/.

5.7. Other health care professionals

For all other requests from within the NHS (i.e. outside NHSBT, transplant centres, commissioners and relevant hospitals) 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 to cover costs.

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.

SCS staff will not liaise directly with the media, but will provide information indirectly through the appropriate Media and PR 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
- NHSBT Advisory Groups
  - Organ offering issues
  - Issues impacting on number of transplants achieved
  - Issues with a direct impact on patient care
- Commissioners
  - 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 (e.g. HTA, CQC, NICE)
    - Issues impacting on number of transplants achieved
    - Issues with a direct impact on patient care
- Transplant unit / hospital 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 followed[1]
- Authorship should be agreed in advance and should recognise NHSBT staff and all others making a substantial contribution to the work as recommended by international and national editorial guidelines. Others who make a contribution should be identified in the Acknowledgements.
- 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 / hospital, key individuals at all those centres/Hospital should be encouraged to contribute and then be named as co-authors.
- The source of the data should always be acknowledged (e.g. 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'.
- NHSBT encourages authors to make publications readily accessible (open access) wherever possible.
- 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: http://www.icmje.org/icmje-recommendations.pdf Accessed January 2019.

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.

These guidelines will be reviewed every 12 months.

9. Appendices

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). All requests received should be sent to NHSBT Customer Services for logging.

2. Data Protection Act (2018) and General Data Protection Regulations (2018)

NHSBT is bound by both the Data Protection Act (DPA) 2018 and the General Data Protection Regulation (GDPR) 2018. The DPA does not prohibit the disclosure of personal data, but any disclosure has to be fair, lawful and in compliance with the principles.

3. NHSBT Information Governance Policy

In line with the Cabinet Office Mandate, the policy requires that transmitting patient identifiable data is to be avoided if possible. Where it is necessary, it must be done in a secure fashion such as email file encryption, special delivery when details of more than 50 people are included. Further advice can be requested regarding the sending 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 recipient 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.

6. The Legal basis for using data and effective anonymisation

Using data that do not identify an individual is the easiest way to protect confidentiality. Whenever possible, anonymised data should be used for all purposes other than direct care.

The following list details a list of unique identifiers:

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, postcode, and their equivalent geographical codes, except for the initial four digits of a postcode if, according to the current publicly available data from the Office for National Statistics and/or the Information Commissioner's Office:
    a) The geographic unit formed by combining all postcodes with the same four initial digits contains more than 20,000 people.
    b) The initial three digits of a postcode for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. National Insurance numbers.
8. NHS number and medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/licence numbers.
12. Vehicle identifiers and serial numbers, including licence plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Information Commissioners Officer.

There is a requirement to ensure the anonymisation of data is effective so the risk of breaking the law is minimised.

Appendix 2 – ODT Data Request form

Appendix 3 – ODT Research Data Application form

Appendix 4 – ODT Data Release Agreement form