

Findings Requiring Additional Action

*This Management Process Description replaces
MPD881/1.1*

Copy Number

Effective

22/01/18

Summary of Significant Changes

The addition of SOP5352 (Findings Requiring Histopathology Assessment) and FRM5867 (Histopathology Request Form). Change to Hub Operations from Duty Office, and also removed EOS/donor file and replaced with Donor Path.

Policy

To reduce associated risks with organ transplantation, it is necessary to consider certain provisions concerning transplantation. In particular, provisions aimed at addressing those unintended and unexpected findings occurring during the donation process. Findings requiring additional action may affect the quality and safety of organs.

If an unexpected or previously unknown finding is identified prior to transplantation, an organ may still be accepted based on the risk benefit analysis undertaken by the implanting surgeon.

Purpose

To inform and guide the Specialist Nurse – Organ Donation (SN-OD) on action to be taken in the event of an unintended or unexpected finding identified at any point during the donation process.

Responsibilities

Specialist Nurse – Organ Donation

This MPD is to be utilised by a qualified and trained SN-OD. If the SN-OD is in training, this MPD is to be utilised under supervision.

To communicate, report and document any finding requiring additional action that is identified during the organ donation process to the **Hub Operations**, Recipient Centre Points of Contact (RCPoC) and/or Eye/Tissue Establishments as necessary.

Hub Operations

To communicate with the appropriate SN-OD/RCPoC/Eye/Tissue Establishment once informed of the finding and document their actions on NTxD.

Team Manager/Geographical Regional Manager/on-call Regional Manager

Support the SN-OD as required in the event of a finding requiring additional action.

Definitions

SN-OD – for the purposes of this document the term “SN-OD” will apply to either Specialist Nurse or Specialist Practitioner in Organ Donation with the relevant knowledge, skills and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST).

TM–Team Manager/**RM** – Regional Manager-

To provide support to the SN-OD, as required, and to determine if clinical governance processes need to be followed. To investigate any cases where clinical governance forms have been completed.

Findings Requiring Additional Action

Findings requiring additional action are defined as any untoward and unexpected/or unanticipated finding that is discovered during the donation process and results in the potential failure to satisfy safe and effective donation and/or transplantation. For example:

1. Adverse outcomes for the recipients that are **not anticipated**, for example donor-derived malignancy or some donor-derived infections.
2. Donor information established post donation/transplantation which may have consequences for recipients.
3. Adverse incidents resulting in the non-transplantation of suitable donor organ(s) or reduction in the quality of organ(s) **except** in circumstances where the organ(s) were offered but not successfully allocated. Serious injury to the organs, such as major vascular injury or physical damage to the organ.
4. Suboptimal organ packing, compromising cold storage, for example lack of ice, insufficient packing solution, inappropriate organ containers or defects.
5. Statutory Notifiable Disease*.

***Statutory Notifiable Disease** - is any disease that is required by law to be reported to an expert practitioner in public health at the relevant local authority. The collation of information allows the authorities to monitor the disease, and provides early warning of possible outbreaks. Registered Medical Practitioners have a statutory responsibility to notify if they suspect one of their patients has an infectious disease from the list detailed in the Statutory Notifiable Diseases [INF958](#) (England & Wales), [INF960](#) (Scotland) and [INF961](#) (Northern Ireland)..

Expert Practitioner in Public Health—Trained healthcare professionals with an expertise in public health protection.

Medical Practitioner – To confirm finding (s) requiring additional action with the SN-OD and to facilitate expert practitioner advice, where required.

The escalation sequence for management support:

1. Team Manager
2. Geographical Regional Manager (if available)
3. On call Regional Manager (out of hours or if geographical RM not available)

ODT - Organ Donation Transplantation

ODST - Organ Donation Services Team

Recipient Centre Point of Contact (RCPoC) –

Inform the transplanting surgeon (following the processes defined in their local centre) of the finding (s) requiring additional action and information provided by the SN-OD.

Lead Surgeon - Is responsible for reporting any finding (s) requiring additional action during the retrieval procedure to the SN-OD.

Implanting Surgeon - Is ultimately responsible for the decision to accept and transplant a donated organ.

Procurator Fiscal – Public prosecutor in Scotland, investigating all sudden and suspicious deaths (similar to a Coroner).

Patient - This term refers to the donor/potential donor.

Patient family – For the purposes of this document “patient family” refers to the family, friends and significant others of the patient.

Donor Path - secure electronic system used by SNODs to upload clinical patient information. Data is shared with EOS and is accessible to RCPoCs to enable decisions about suitability of organs for transplantation.

NTxD - National Transplant Database includes details of all donors and patients who are waiting for, or who have received, a transplant.

TE - Tissue Establishments.

Eye Banks - responsible for the retrieval, processing, storage and allocation of eye tissue.

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Applicable Documents

ODT Clinical Governance Incident Notification System- NHSBT's reporting system to ensure analysis of the type, frequency and severity of adverse events and then use that information to inform changes and improve the service.

INF958 - Statutory Notifiable Diseases (England & Wales)

INF960 - Statutory Notifiable Diseases (Scotland)

INF961 - Statutory Notifiable Diseases (Northern Ireland)

POL180

Management of Positive Microbiological Blood Results in Deceased Organ or Tissue Donors

POL162 – Donor Characterisation

MPD882 - Communication with Family about Adverse Findings

MPD867 – Patient Information to be Communicated to Recipient Centre Points of Contact

MPD872-Diagnostics-Infections

MPD884-Organising Solid Organ retrieval

MPD385- Guidance on Good Documentation

SOP3649- Voice recording of organ donor clinical conversations

SOP5352- Findings Requiring Histopathology Assessment

FRM5867- Histopathology Request Form

INF135-Examples of Good Documentation

NHSBT: Donor contraindications to organ donation

NHSBT Guidance on Handling Person Identifiable Information:

<http://nhsbtweb/userfiles/22474%20Guidance%20of%20Confidential%20Comms%206pp%20DL.pdf>

<http://nhsbtweb/userfiles/final%206%20IG%20proofs.pdf>

Quality and Safety of Organs Intended for Transplantation Regulations 2012 No 1501
<http://www.legislation.gov.uk/ukxi/2012/1501/contents/made>

SaBTO guidance on the microbiological safety of human organs, tissues and cells used in transplantation
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121497

NHSBT - British Transplantation Society: Guidelines on the responsibilities of clinicians and the acceptance of organs from deceased donors

Diseases notifiable (to Local Authority Proper Officers) under the Health Protection (Notification) Regulations 2010 (England and Wales)

<http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/NotificationsOfInfectiousDiseases/ListOfNotifiableDiseases/>

Public health (SCOTLAND) ACT 2008

http://www.legislation.gov.uk/asp/2008/5/pdfs/as_p_20080005_en.pdf

<http://www.scotland.gov.uk/Topics/Health/NHS-Scotland/publicact>

Confidentiality - NHS Code of Practice:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253

Findings Requiring Additional Action

1. INTRODUCTION

- 1.1. Findings requiring additional action are classified as any untoward and unexpected occurrence associated with a donor, donor organs or tissue, which has the potential to result in the failure to satisfy safe and effective donation and/or transplantation.
- 1.2. Findings requiring additional action are a non-anticipated discovery that may be identified before, during or after the donation process. The finding/s must be reported and documented, so that relevant parties are informed to ensure appropriate action is taken to ensure the safety of the donation/transplantation process.

2. STATUTORY NOTIFIABLE DISEASES

- 2.1. The SN-OD should communicate with the Medical Practitioner in the donor hospital and confirm if the finding is a suspected/confirmed **statutory notifiable disease/infection** and therefore, potentially transmissible.
- 2.2. The Medical Practitioner must report a suspected/confirmed statutory notifiable disease/infection to an Expert Practitioner in Public Health.
- 2.3. It is the ultimate responsibility of the Medical Practitioner in the donating hospital to prompt local investigation and appropriate action to control the disease as part of their professional duties.
- 2.4. The SN-OD should contact the ODT Team Manager/geographical Regional Manager/on call Regional Manager for advice and support, as required.
- 2.5. The SN-OD must work closely with the Medical Practitioner in determining any potential risk to the patient's family members. If needed, expert advice must be sought from an Expert Practitioner in Public Health to advise on the correct course of action to take.
- 2.6. The SN-OD should assist the Medical Practitioners, if appropriate, in providing any information they have gained during the consent/authorisation and patient assessment process. This information could include new information regarding close relationships that determine any potential transmission/infection risk from the patient to others.
- 2.7. Medical Practitioners have a statutory duty to report a suspected/confirmed statutory notifiable disease/infection to an Expert Practitioner in Public Health, the reporting process differs dependant on the jurisdiction the patient is in:
 - 2.7.1. In England and Wales the statutory notifiable disease [INF958](#) must be reported to a Proper Officer of the Local Authority-Health Protection Unit, who in turn report to the Health Protection Agency.
 - 2.7.2. In Scotland the statutory notifiable disease [INF960](#) must be reported to the Health Boards, who in turn report to Health Protection Scotland (HPS).
 - 2.7.3. In Northern Ireland the statutory notifiable disease [INF961](#) must be reported to the Consultant in Communicable Disease Control (CCDC) or Duty Public Health Doctor and the Infection Control Team.
- 2.8. The attending Medical Practitioner should fill out a notification certificate immediately on diagnosis of a suspected statutory notifiable disease and should not wait for laboratory confirmation of the suspected infection or contamination before notification. The certificate should be sent to appropriate Expert Practitioner in Public Health within three days or verbally within 24 hours if the case is considered urgent.

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- 2.9. It is permissible to breach patient confidentiality by reporting statutory notifiable disease/s to the relevant authority where there is an overriding public interest. This is confirmed in the NHS Code of Practice: Confidentiality (DoH, 2003).

"There are exceptions to the duty of confidence that may make the use or disclosure of confidential information appropriate. Statute law requires or permits the disclosure of confidential information in certain circumstances.....Case law has also established that confidentiality can be breached where there is an overriding public interest"

3. FINDINGS REQUIRING ADDITIONAL ACTION POST CONSENT/AUTHORISATION AND PRE DONATION

- 3.1. If, following consent/authorisation, and during the donor characterisation process the SN-OD identifies a potential finding requiring additional action, they must communicate with the treating Medical Practitioner to discuss their findings and assess the potential implications in ensuring the safety and quality of the donation/transplantation process.
- 3.2. The SN-OD must ascertain from the Medical Practitioner if expert advice is required and/or if there are further medical records held that may identify any additional medical history that has not been disclosed by the patient's family.
- 3.3. The SN-OD should **only** stop the donation process from proceeding if, in conjunction with the treating Medical Practitioner, an **absolute contraindication** to donation is identified and confirmed as per NHSBT Donor Contraindications to Organ Donation.
- 3.4. If an absolute contraindication to donation is identified and confirmed, the SN-OD should utilise the relevant procedural document to guide communication with the patient's family. The SN-OD should use the escalation if required, for management support.
- 3.5. The ODT geographical RM/on call RM, may seek advice from NHSBT's Associate Medical Director or their Deputy as required, for advice and support.
- 3.6. As soon as possible, the SN-OD must document, as reported, all the information regarding the finding in the patient's medical records and photocopy the information for entry into the donor file.
- 3.7. The SN-OD should also document all relevant conversations held with the patient's family, medical and specialist practitioner(s) and recorded on to Donor Path.
- 3.8. A summary of events should also be recorded into Donor Path Where the Coroner/Procurator Fiscal is involved the SN-OD should contact them to inform them of the decision not to proceed with donation, as per local Coroner/Procurator Fiscal policy agreements with regional Organ Donation Services Teams (ODST).
- 3.9. The SN-OD **must** also document clearly the sequence of events on Donor Path, and EOS via the Referral/PDA forms, giving clear detail of the adverse finding/reasons why donation could not proceed.
- 3.10. If it is not possible to record all the relevant information on Donor Path and EOS, the SN-OD should put a note in the general comments section stating further information is available from the SN-OD/Hub Operations.
- 3.11. If there are **no** absolute contraindications to donation then the SN-OD should record all the information regarding the finding onto EOS and communicate this information to the Hub Operations/RCPoCs/Implanting surgeons.
- 3.12. Organ offering should continue as per national policy.

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- 3.13. In the event that all transplant centres decline the organ and/or tissue for transplantation then the SN-OD **must** communicate to **Hub Operations**/laboratories/RCPoCs/NORS teams that the donation process has been stood down.
- 3.14. In the event that the donor process is stood down, the SN-OD should utilise NHSBT [MPD882](#) in Communicating with Families about Findings requiring additional Action to guide their practice in communicating the rationale for this decision to the patient's family. This communication with the family should be held in collaboration with the donating hospital staff. The SN-OD should contact their ODS Team/Regional or duty Regional Manager, if required, for advice and support.
- 3.15. If appropriate, the SN-OD must complete an NHSBT Clinical Governance Form at the earliest opportunity, so that the nature of the finding is recorded and appropriately managed. The SN-OD should attach any additional background documentation which may help the investigation.
- 3.16. The SN-OD should document clearly all communication with the **Hub Operations**/RCPoCs/Implanting Surgeons regarding the reasons for non acceptance of an organ on Donor Path.

4. FINDINGS REQUIRING ADDITIONAL ACTION DURING THE RETRIEVAL PROCESS

- 4.1. In the event of a finding requiring additional action being discovered during the retrieval process **if** histopathology assessment is required the Lead Surgeon should follow [SOP5352](#) (Findings Requiring Histopathology Assessment). If other blood/specimen tests are required, the Lead Surgeon should inform the SN-OD of this requirement.
- 4.2. The SN-OD should facilitate histopathology assessment as per [SOP5352](#) (Findings Requiring Histopathology Assessment) and complete [FRM5867](#) (Histopathology Request Form).
- 4.3. The SN-OD should document the date and time the specimen/s were obtained, which department they were sent to for testing and anticipated timescales of the results. The SN-OD must communicate the nature of the finding to the **Hub Operations** and agree dissemination of information to RCPoC/Tissue Establishments/Eye Banks as per [SOP5352](#).
- 4.4. The SN-OD must follow [SOP5352](#) regarding follow up of results and gain hard copies via fax/email where possible. The SN-OD should confirm up the test results obtaining hard copies via fax/email where possible. The SN-OD should confirm receipt of the fax via the agreed method and document the communication on **Donor Path** as per NHSBT Guidance on Handling Person Identifiable Information.
- 4.5. The SN-OD should **only** stop the donation process from proceeding if they have identified and confirmed, in conjunction with the Lead Surgeon, an **absolute contraindication** to donation as per NHSBT: Donor contraindications to organ donation.
- 4.6. If results are received and assessed by the Lead Surgeon, the SN-OD should communicate the confirmed finding/s to the **Hub Operations** and agree dissemination of information to RCPoC/Tissue Establishments/Eye Banks.
- 4.7. The SN-OD should ensure the Lead Surgeon documents in the patient's medical record the details of the finding/s, any implication (if known) for the safety and quality of the organ and potential implications for the recipient.
- 4.8. The SN-OD should document clearly on **Donor Path** all information regarding the nature of the finding, the tests requested, the name of the Lead Surgeon, outcome of the investigation and all relevant communication.
- 4.9. If necessary, the SN-OD should escalate concerns regarding the finding/s using the escalation sequence for management support.

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- 4.10. If appropriate, the SN-OD should report the finding electronically to Clinical Governance at the earliest opportunity, so that the nature of the finding is recorded and appropriately managed. The SN-OD should attach any additional background documentation which may help the investigation.
- 4.11. The SN-OD should also contact the Coroner/Procurator Fiscal's office if required; to inform them of the finding, as per local Coroner/Procurator Fiscal policy agreements with regional ODST.
- 4.12. In this event, the SN-OD should utilise the [MPD882](#): Communicating with Families about findings requiring additional action to help guide their practice in communicating to the patient's family. The SN-OD should contact their ODST TM/geographical RM/on call RM, if required, for advice and support.

5. ADVERSE FINDING IDENTIFIED POST DONATION

Note:

The Hub Operations has a facilitative role in communicating findings requiring additional action to the Recipient Centre Points of Contact. The NHSBT Hub Operations staff is not clinically trained. It is the SN-OD's ultimate responsibility to ensure the correct information has been relayed to the Hub Operations/RCPoC/Tissue Establishment/Eye Bank and that any discussions are documented on Donor Path.

- 5.1. The SN-OD must report to Hub Operations, once notified, of any finding/s requiring additional action post donation and agree dissemination of information to RCPoC/Tissue Establishments/Eye Bank. Document the communication on Donor Path.
- 5.2. The SN-OD should follow Section 2 of this MPD to guide their practice in the event that the finding requiring additional action has been identified as a statutory notifiable disease.
- 5.3. The SN-OD should detail any outcomes awaited and likely timescales for the return of these outcomes for example frozen section, biopsy, histopathology or confirmatory blood/specimen results in sequence of events section on Donor Path.
- 5.4. The SN-OD should record, as reported, all the information relating to the finding/s requiring additional action within Donor Path.
- 5.5. The SN-OD should request a faxed/emailed hard copy of any blood results/reports confirming the finding for inclusion in the donor file and to support discussion with the Medical Practitioner when assessing any implications for the donor/patient family.
- 5.6. All communication with the person reporting the finding/s requiring additional action i.e. Hub Operations/RCPoC/Tissue Establishments/Eye Banks must be clearly documented on Donor Path, detailing the date, time, name of person communicated to, the nature of the conversation and any further action to be taken.
- 5.7. If necessary, the SN-OD should escalate concerns regarding the finding/s using the escalation sequence for management support.
- 5.8. If appropriate, the SN-OD must complete an NHSBT Clinical Governance Form at the earliest opportunity, so that the nature of the finding is recorded and appropriately managed. The SN-OD should attach any additional background documentation which may help the investigation.

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- 5.9. If an investigation has been requested at the donating hospital the SN-OD must follow up the pending results. The SN-OD must communicate the results/findings to the [Hub Operations/RCPoC/Tissue Establishments/Eyes Banks](#), obtaining and faxing/emailing hard copies of the results where possible, confirming receipt of the fax via agreed method and documenting communication [on Donor Path](#), as per NHSBT Guidance on Handling Person Identifiable Information.
- 5.10. In the event the finding/s requiring additional action has an implication for the patient's family the SN-OD should utilise [MPD882](#) for Communicating with Families about finding/s requiring additional action to help guide their practice in communicating with the patient's family. The SN-OD should seek support if necessary, using the escalation sequence for management support. The SN-OD must always communicate with the donating hospital staff to work in collaboration when discussing such information with a patient's family.
- 5.11. Where the Coroner/Procurator Fiscal is involved, the SN-OD should contact them to advise of the adverse finding, as per local Coroner/Procurator Fiscal policy agreements with regional ODST.

6. RECORDING OF INFORMATION

- 6.1. The SN-OD must record details of all relevant conversations with the Medical Practitioner, Expert Practitioner in Public Health and other Healthcare Professionals. These details must be located in the patient's medical records and [on Donor Path](#). All documented entries must be signed and dated. Guidance on good documentation can be found in [MPD385](#) and examples of good documentation in [INF135](#).