NHS
Blood and Transplant

Clinical Governance in ODT

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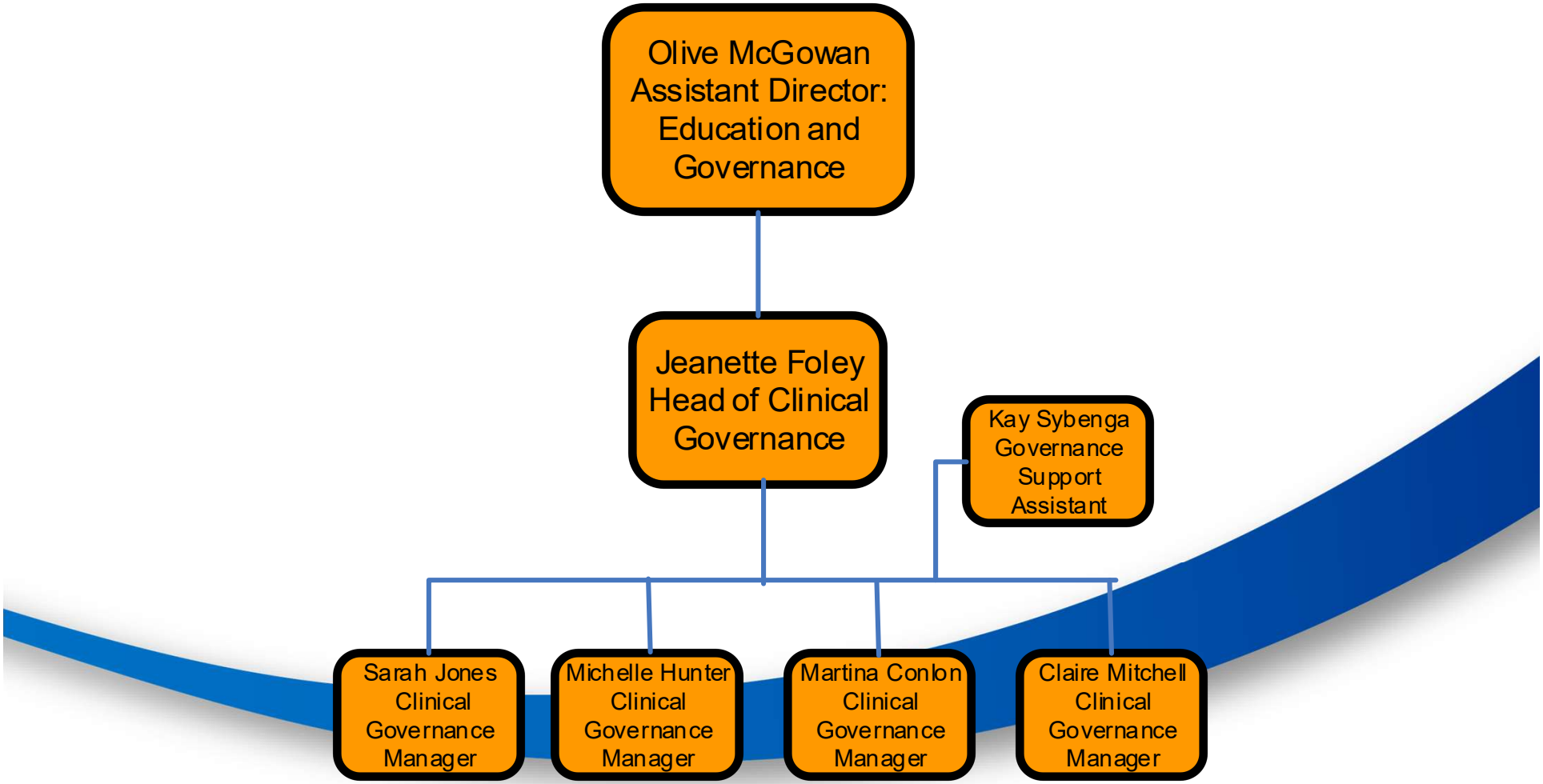
Who are we?



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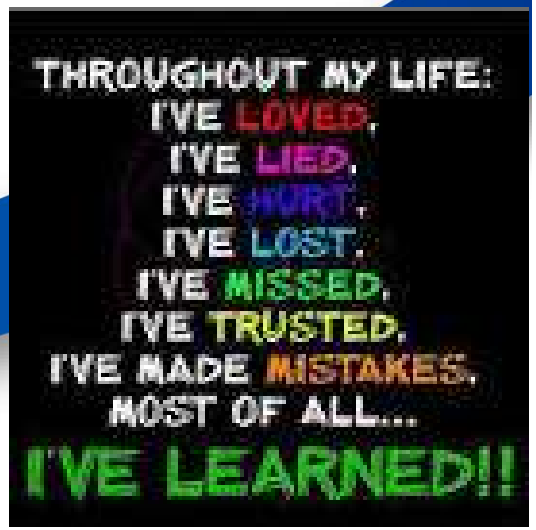
Clinical Governance

- Clinical Governance is a system through which NHS organisations are accountable for:
- Improving the quality of their services;
- Safeguarding high standards of care;
- Creating an environment in which excellence in clinical care will flourish
- Responsibility of every member of staff

Clinical Governance in ODT

NHS Blood and Transplant

- Making sure we deliver high standards of quality care to all, including recipients and donor families
- Continuously improving the safety and quality of what we do
- Ensuring a culture of shared learning within ODT to make processes more effective
- Ensuring things are open and transparent
- Ensuring a culture of shared learning within ODT and sharing outside of ODT
- Adherence to the regulations



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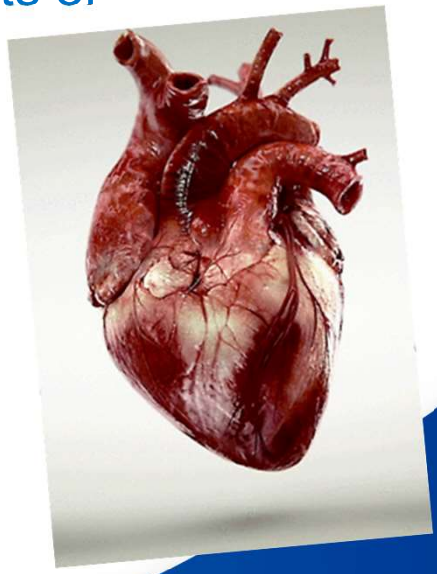
ODT - Clinical Incidents

- Any event that occurs during the chain from donation to transplantation, (deceased or living donation) that effects or has the potential to impact on the quality and safety of organs for transplantation.
- Any incident that may have national or wider learning
- Where there is a legal requirement to report under the regulations
- Incidents may be reported that relates to organs being sent/received from another EU country



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Incidents reported and requiring investigation

Month Reported	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20
Number of incidents	58	74	83	81	57	76	52	69	103	38	33	39

Number of incidents by responsibility and pathway – previous 6 months

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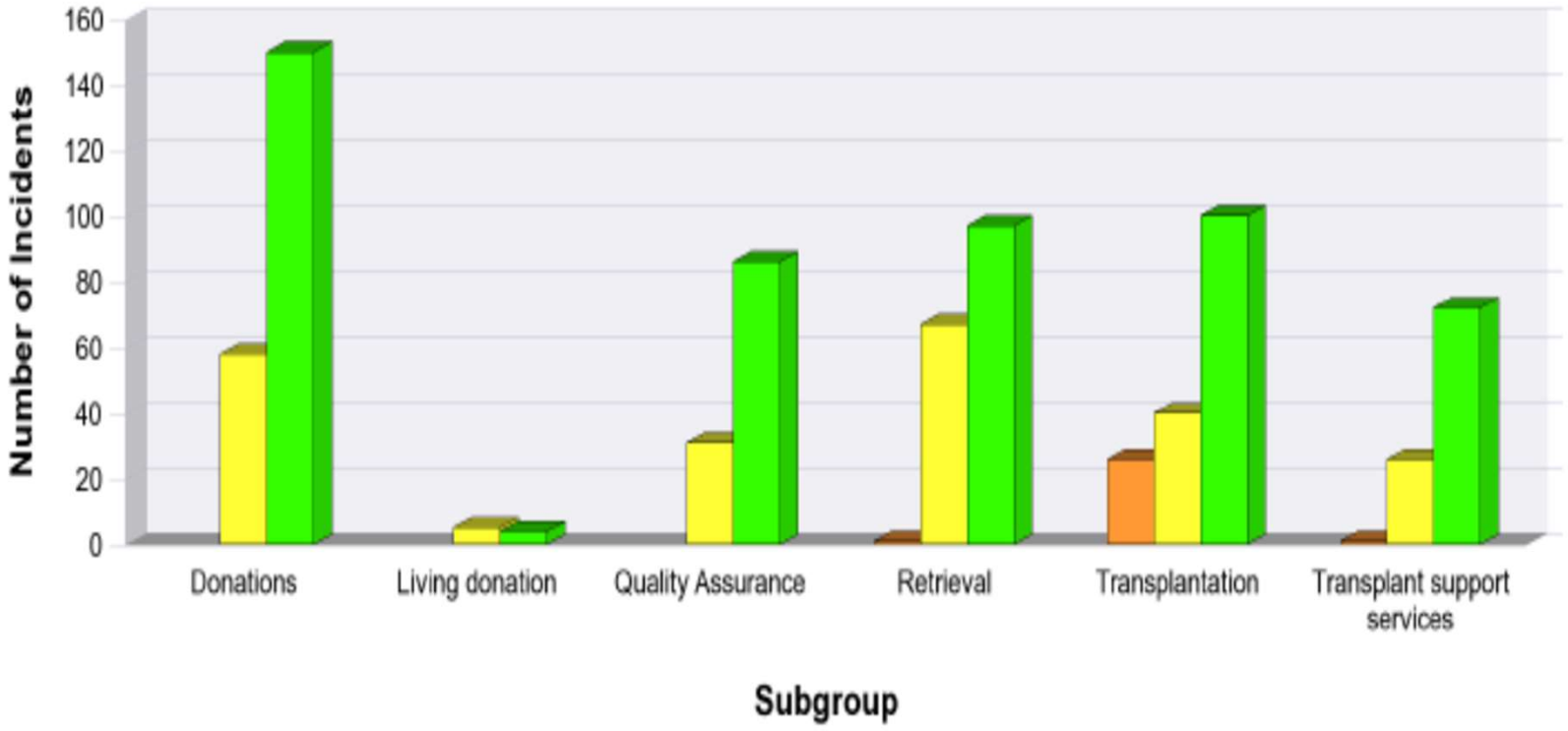
Number of Incidents by Responsibility and Pathway - Previous 6 Months

	Donations	Quality Assurance	Retrieval	Transplantation	Transplant support services
01. Donation	6			2	
02. Testing	2	5		3	3
03. Retrieval	11		15	1	
04. Transport		5			1
05. Transplant	1		1	2	
06. Post-Transplant	3	1		3	1
07. Recipient registration		1		4	
08. Offering	5			3	5
09. Tissue pathway	1				
11. Data/software process		2			1

Number of incidents by risk rating – rolling 12 months



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Human Factors

Clinical Governance embraces Human Factors. An organisation/ department is made up of three main aspects:

1. Hardware – the physical attributes, anything you can touch e.g. IT systems, the buildings equipment.

2. Software – how the organisation defines itself – the policies and procedures, guidelines and rules.

3. Humanware – the people within the organisation who make the business happen i.e. you!

Human Factors are how the people within the organisation interact with the hardware, software and each other.

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Incident Reporting...

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What to report?

- Be factual, stick to the point- bullet points
- Do not use emotion
- Say it in as few a words as possible
- Do not use identifiable data, names.
- Get someone not involved to check- do they understand it?
- Add attachments and time lines, if appropriate
- Summarise incident and ensure concerns are clear- e.g. number them.

NHSBT, ODT, clinical website *https://www.odt.nhs.uk/*

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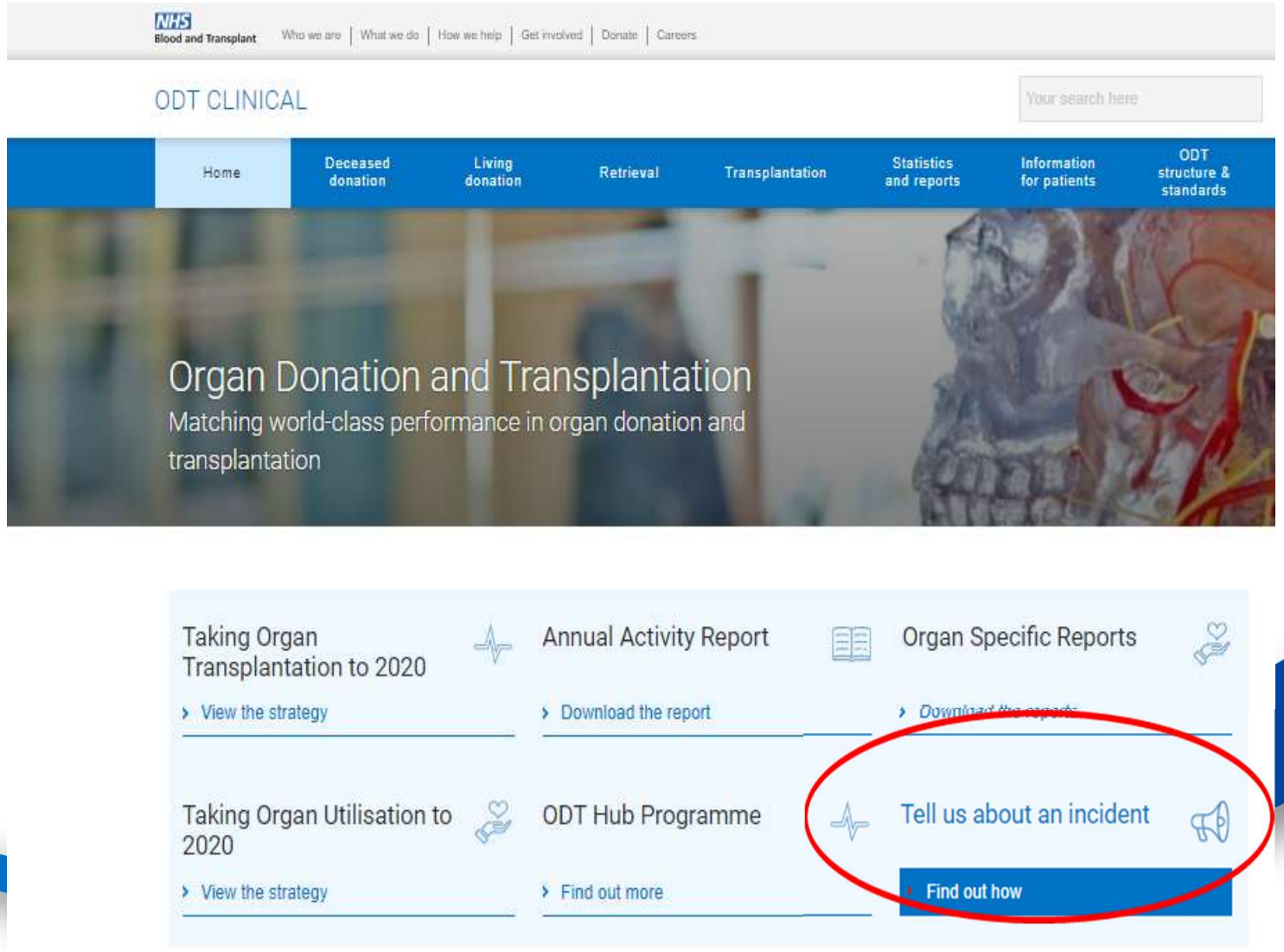

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Incident Reporting

Urgent incidents

Call ODT Hub Operations [illegible] if the incident is [illegible] and may affect the quality and safety of an organ for transplantation [illegible] treatment of recipients or potential recipients.

This call should be followed by completing this online form

Tell us about an incident

Tell us about an incident by completing this online form

Positive transport fluid results

Tell us about positive transport fluid results by downloading and completing the Rapid Alert – Positive transport fluid results form and emailing it to odthub.operations@nhsbt.nhs.uk

Why reporting incidents matters

Everyone involved in organ donation and transplantation wants to ensure that transplanted organs are as safe as possible for the recipient, and donor family care is provided to a high standard.

To achieve this, we need people to report all incidents and near misses.

Incidents, including near misses, will be evaluated and investigated where appropriate, practice strengthened to prevent recurrence and any future patient harm or donor family distress.

Everyone shares the responsibility to make things better for all involved. Often people think an incident or near miss is a one off or nothing to worry about. They feel there are no benefits to reporting or don't want to complain or tell tales. However, what may seem a small thing, may in fact be a wider issue.

In this section

Shared Learning

Incident Reporting

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INCIDENT SUBMISSION FORM

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Is incident deemed urgent and requires immediate action? No | Yes, not notified by phone | Yes, already notified by phone

You will be unable to complete the rest of this form until you answer the question above.

- Fields marked with * are mandatory, all other fields can be completed, if relevant, to provide information about the incident. For help completing fields, click on
- To avoid losing data, please be aware this form will time out after 30 minutes of inactivity and must be completed and submitted at the same time; it is not possible to partially complete the form and return to it later.
- In order to complete the form, please ensure that you have the relevant details and patient reference numbers to hand.

SUBMITTER DETAILS

First name | Job title

Last name | Email address

Phone number | Re-enter Email address

INCIDENT DETAILS

Date and time incident identified *

dd-mm-yyyy hh:mm

Details of incident and further action taken *

https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx

Details of incident and further action taken *

Max. 2000 characters

Attachments
Attachments are limited to a maximum of 10mb in size each. A maximum of 5 attachments may be added

Choose File | No file chosen

Donor ID status *

- ID not allocated
- Not related to an individual donor
- Donor ID

NHSBT donor ID number(s) and type(s) involved in this incident

Please Select

Recipient ID status *

- ID not allocated / not known
- Not related to an individual recipient
- Recipient ID

ID number(s) of the recipient involved in this incident?

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DETAILS OF THOSE INVOLVED

Organ Donation Services Team (ODST)
Please Select

Transplant Centre
Please Select

Retrieval Team
Please Select

Coroner / Procurator Fiscal jurisdiction
Enter Coroner / Procurator Fiscal jurisdiction name

Donating hospital – search by town / city
Please type town and select from list, if not listed enter name and town

Microbiology / Virology lab
Please type town and select from list, if not listed enter name and town

NHSBT site where incident occurred
Please Select

Haematology / Biochemistry lab
Please type town and select from list, if not listed enter name and town

H & I lab
Please Select

Histo-pathology lab
Please type town and select from list, if not listed enter name and town

ADDITIONAL INFORMATION

The incident has also been reported to these organisations
Select organisation(s)
Please Select

Reference numbers for reports to other organisations
One per line. Please list organisation reference number

- To print a copy of this form and the incident details please use the browser's print function BEFORE submitting the form
- Form data can be saved in pdf format AFTER the incident has been submitted
- As this form only recently went live we are interested in your feedback about how you found completing this form. Please send any feedback to NHSBT at clinicalgovernance.odt@nhsbt.nhs.uk

Submit

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How different can reports be?!?

Example 1 - Percutaneous catheter guidewire found at retrieval in the aorta

Example 2-

Consent XX/XX 18:30. Language support family no English. Spanish Nurses, hospital adm to BSD to donation very quick. Organs placed NORs mob~10:00hrs XX/XX.Met with Family ~12:00hrs XX/XX.Family very tired/confused.Support family overnight, further support required/confused unclear about donation process/BSD. Wife feeling pressured. All conversations with spanish speaking staff. We agreed to slow down process & give her some more time.NORs mobilised&organs accepted-updated both NORS & transplant centre-SOND dealing donation side, family support myself. Consent SNOD OC night/ SNOD TM relieving outgoing SNOD. Transplant centre had accepted urgent heart. Unsure of status of consent, weneed family to be given time. Necessary to slow process - teams understanding. Htransplant centre Rec Co-ord supportive. Comm continued Rec Co-ord spoken to transplant Cons. would not accept any further offers from this donor for both Urgent hearts. He believed consent invalid. RM updated. We explained speaking to family within 2 hours, likely to have definite confirmed consent, declined. Family decided to proceed with donation after further support. Heart accepted and transplanted further down urgent list.

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Report assessed...

Occurrence

Incident

The Incident System

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Investigation carried out and preventive actions identified

- Did any thing go wrong? If so what?
- Why did it go wrong?
- If there was no error, can practice still be improved and lessons learnt?
- Have any actions been taken following the investigation?

↓

Preventative actions, where appropriate, and shared learning

- Inform NHSBT what actions have been taken, or plan to be taken, with expected time frames

↓

Investigation, findings and any appropriate actions reviewed by NHSBT Incident Team and Sub Group Chairs

- Has the investigation addressed the concerns raised
- Will the findings mitigate recurrence where an error has occurred
- Should the findings be widely shared? AMD Comms, Cautionary Tales

↓

Outcome sent to reporter and investigator

↓

Incident closed

Trends- Transplantation, Retrieval and living donation

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- Communication breakdown
- Centres not accepting organs within agreed timeframes
- Requests for delays in retrieval – recipients/ multiple transplants/ resource
- Organs declined late after initial acceptance- resource/ recipients
- Discrepancies with microbiology/ HLA
- Delays to mobilising retrieval teams/ arriving on time and resource
- Any living donation that does not proceed or an error occurs in the pathway and has recipient impact – Lisa Burnapp

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Regulations and incidents

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Competent Authority

The Human Tissue Authority (HTA) has been appointed the Competent Authority for the EUODD in England, Wales, Northern Ireland and Scotland.

As the Competent Authority, the HTA is responsible for the regulatory framework that oversees that the quality and safety standards of the EUODD are being met.

HTA
Human Tissue Authority

The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (OQSR)

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- **Human Tissue Authority – CA**
- **Licensing – Framework – Audit - Enforcement**

NHS Blood and Transplant Procurement Organisation Licensed for:
Organ/donor characterisation
Preservation
Transportation

NHS Blood and Transplant Assisted Functions:
Investigation of SAE/SARs
Data Collection
Register of Living Donors
Annual Activity Reports
European Exchange

Commissioned Services
Transportation
NORS teams

Transplant Centres
Procurement and Transplant Licence
35-40 centres in UK
Licensed for:
Organ/donor characterisation
Retrieval
Preservation
Transportation
Implantation

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Assisted Function

In its role as the Competent Authority, the HTA have an agreement with NHSBT to provide an assisted function role. One aspect of this role is the management of a reporting system for serious adverse events and serious adverse reactions (SAEARs).

This requires NHSBT to:

- Manage a system to report, investigate, register and transmit information about SAEARs
- Notify the HTA of any SAEAR associated with organ donation and transplantation, the steps being taken to manage the SAEAR and confirmation that all actions associated with the SAEAR have been concluded.

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Serious Adverse Events/Reactions

The requirement to report SAEs and SARs applies to all UK establishments licensed under the Regulations, regardless of geographical location or whether they are a private or an NHS organisation. Includes areas such as:

- SNOD Characterisation
- NORS Teams
- Laboratories
- Transplant Centres
- Living Donation

Serious Adverse Events/Reactions

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- **SAR (Serious Adverse Reaction) -** Any unintended response, including a communicable disease, in the living donor or in the recipient that may be fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity. This may be associated with any stage of the chain from donation to transplantation.

- **SAE (Serious Adverse Event)** – Any untoward occurrence associated with the retrieval, testing, processing, storage or distribution of organs that might lead to death or life threatening, disabling or incapacitating conditions for patients (or which results in or prolongs hospitalisation or morbidity).

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Case studies

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Damage to an organ during retrieval

An organ was inadvertently damaged during retrieval. The damage associated with retrieval resulted in an otherwise transplantable organ rendered unsuitable for transplant

- SAE or SAR?

Transmission of a communicable disease

A CMV test result was reported incorrectly as negative when the actual test result was positive.

At the time of implantation in a CMV negative recipient the transplant surgeon was unaware that the donor test was CMV positive

- SAE or SAR?

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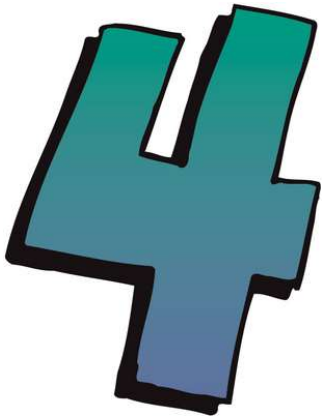
Donor has a previous history of malignancy which was known at the time of donation?

Past and present donor medical history was communicated to the implanting surgeon. The recipient was fully informed and the organ was accepted on the basis of a clinical risk and benefit analysis

- SAE or SAR?



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An unnecessary procedure performed on an organ recipient

An organ recipient was anesthetised in preparation for an organ transplant. On inspection of the organ, the surgeon following a risk and benefit analysis found the organ was unsuitable for transplantation and the procedure was aborted.

- SAE or SAR?

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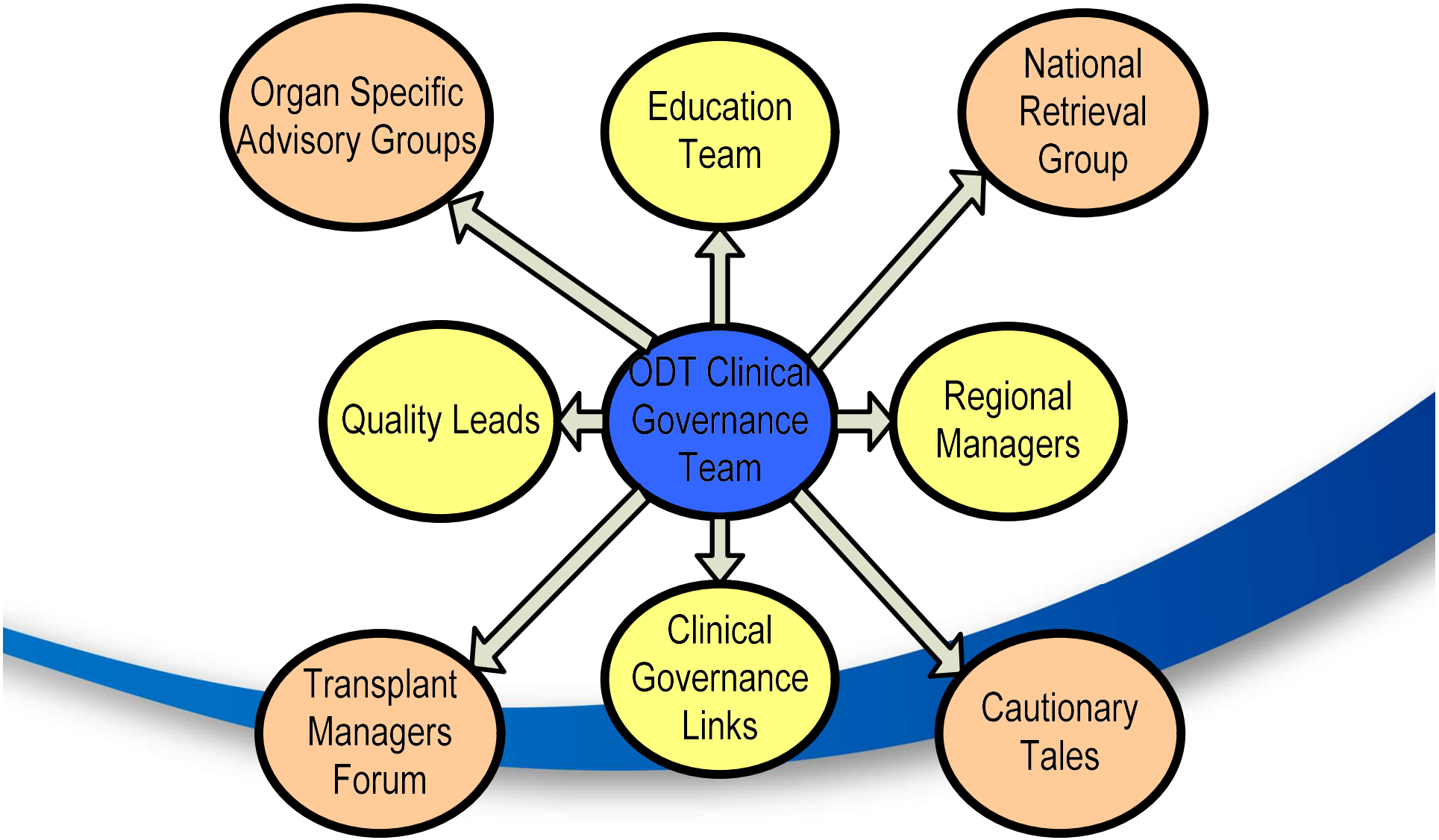
Shared Learning



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Summary – key points

- If you think its an incident - report it
- Be clear, concise and factual
- Ensure any immediate actions have been taken prior to submission of an incident
- When in doubt discuss with your managers
- Any questions give us a call or email us:

clinicalgovernace.ODT@nhsbt.nhs.uk

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Questions, Feedback, Suggestions?