

Organ Damage Imaging Pilot Study Protocol

Authors: Organ Damage Imaging Working Group

1. Elijah Ablorsu - Chair
2. Afshin Tavakoli – Pancreas and kidney representative
3. Anand Jothidasan – CT Co-chair (Heart representative)
4. Mubassher Husain – CT Deputy
5. Derek Manas – MD and NHSBT representative
6. Richard Baker - NHSBT governance lead
7. Helen Bullock - SNOD representative
8. Julie Whitney - ODT HUB representative
9. Laura Ellis-Morgan - Head of Health Informatics for ODT
10. Rachel Hogg - Statistics and Clinical Research ODT
11. Shahid Farid - Liver surgeon representative

Background

Organ Damage Imaging Working group was set up to develop a guidance and process to provide more accurately photographic evidence of damage to retrieved organs at the time of retrieval and make it available to the accepting centre. We expect implementation of this program into daily practice will increase organ utilisation, shorten the process of organ acceptance, improve transplant outcomes and support governance process in case of clinical incident to damaged organ.

During WG meeting on 28th January 2022, all members of the group supported these objectives and agreed to conduct small-scale pilot study to assess feasibility of this initiative, process, identify potential problems and impact on NORS teams and SNODs.

Pilot Objectives

This pilot is designed to:

- assess the benefit of taking photographic evidence of every damage identified at the time of retrieval and impact on organs allocation process,
- assess benefit of introducing the checklist to guide surgeon to assess graft and help to detect any damage
- help to identify any potential issues

Length of the project

The length of this pilot study will be 3 months, with monthly review and full analysis at the end of this study. The start date will be set up once details of the pilot project are agreed by the group and logistics are in place.

Key stakeholders; roles and responsibilities

Running this pilot study requires involvement of several key stakeholders.

Four NORS teams will be involved in this pilot study (three abdominal – Manchester and Cardiff, Leeds and one cardiothoracic – Harefield) and pilot protocol will be triggered only during retrievals where these four teams attend at any donor hospital during pilot period.

Responsibility:

- to inform SNOD at donor hospital about this pilot study and plan to take photography of any damage to organ at the end of retrieval; and make SNOD familiar with the details of the pilot study and agrees process to deliver it.
- a NORS lead surgeon performs careful ex-situ assessment of every retrieved organ. If any damage is identified this protocol is initiated and followed.
- a NORS lead surgeon informs a SNOD about detected damage and assists with taking image(s)
- a NORS lead surgeon completes all required documentation and pilot's forms
- a NORS OPP will be responsible for completing "**Length of process**" form (attachment 2).

Every SNOD in donor hospital will be required to collaborate and support dedicated NORS team and follow process of this study

Responsibility:

- assist to NORS team to complete process of this plot in a case damage is identified
- takes image(s) of organ damage
- communicate and share images with accepting team/s and ODT Hub
- complete all required documentation and pilot's forms.

ODT Hub team plays key role in this study.

Responsibility:

- Inform accepting centre about available photographic documentation of damage to retrieved organ
- Gather contact details (e.g. e-mail address) from recipient centre that can be used to send images in a case of interest of recipient surgeon
- Share images with accepting centre.

Process

1. Dedicated NORS team informs a SNOD during initial handover about this pilot study and plan to take images of damage to retrieved organs identified during ex-situ inspection and make them available to accepting team at the time of offer.
2. A NORS surgeon performs careful inspection of every retrieved organ at the end of retrieval to identify any damage, pathology or abnormality. A surgeon follows "**Organ Damage Assessment Checklist**" specifically designed for this purpose. A hardcopy (attachment 1) of this form is completed by NORS OPP at the end of retrieval.

3. If NORS surgeon identifies any damage to retrieved organs process of this protocol is commenced and a surgeon must:
 - a. inform SNOD about damage
 - b. in details record damage on HOTA-A and RTI form
 - c. assist to SNOD to take image(s) (max 5 per damage)
4. A SNOD uses the “Genius” scan app (on a NHSBT registered iPad) to take a set of images of each retrieved organ. A SNOD will be guided by retrieval surgeon to take series of images of every damage for the best description.
5. A SNOD informs accepting team and ODT Hub about damage. If accepting teams has an interest and provides contact for secure image transfer (section 5.2. MPD1100/8 – Guidance and Principles - Donor Organ Photographs guidance) a SNOD sends images to accepting centre. In a case, an organ with damage is not allocated yet a SNOD sends images to ODT Hub to make them available to any centre.
6. A SNOD records information about available images of retrieved organs on “DonorPath > Pathway > Past medical History > Other General Comments”.
7. A NORS OPP will record length of time it takes to photograph of every retrieved organ on **“Length of Process” form** (attachment 2).
8. A lead NORS surgeon clearly records damage information with detailed description on HOTA-A and RTI form, as well as records information about taken images on these forms.
9. In a case of taking photography of organ damage, a NORS OPP asks a SNOD to complete **“Impact assessment” questionnaire** (attachment)

Project evaluation process

Study information will be collected progressively, and basic data evaluated on monthly bases (number of retrievals, number of injuries), and fully analysed after three months, at the end of pilot study.

Analysis

- Quantified length of imaging process:
 - Time to take set images of damage to retrieved organ. Source **“Length of Process” form** (attachment 2).
- Assess impact of organs imaging on retrieval process
 - Compare length of retrieval between historic (3 months pre-pilot period) sample and “pilot sample”.
 - Collected data:
 - Donor number
 - Donor type
 - Retrieved organs
 - Length of retrieval (time between start of “In-situ perfusion” and “Organ in a Box”)
 - Source NHSBT data
- Assess impact of available organs images on acceptance of Fast Track (FT) organs
 - Compare percentage of accepted FT organs between historic sample (3 months pre-pilot period) vs. “pilot” sample

- Collected data:
 - ODT number of FT organ
 - FT donor type
 - FT organ type
 - Organ accepted/declined
- Assess impact of action on team and service
 - Analyse data from **“Impact assessment” questionnaire** (attachment 3)
- Assess accuracy of recording of organ damage by retrieval surgeon
 - Compare incident/grade of damage between RTI and HOT-B form and compare it with historic sample.
- Core data collection required for analysis (NHSBT Dataset)
 - Donor Number
 - Date of retrieval
 - Donor Type
 - Donor Hospital
 - Retrieval Team
 - Retrieved organs
 - Time between start of “In-situ perfusion” and “Organ in a Box” (for each organ)
 - Pilot sample
 - Historic sample (sample of retrievals performed in 3 months prior study)
 - Organ Damage (RTI)
 - Incident
 - Grade
 - Organ Damage (HOT-B)
 - Incident
 - Grade

Outcomes and plan

Analysis report will be shared and discussed with WG members and recommendations presented to NHSBT.

Attachments:

1. Organ Damage Assessment Checklist
2. Length of Process form (link to online form)
 - Abdominal team: <https://forms.office.com/r/iMUmgV3fSF>
 - CT team: <https://forms.office.com/r/CFLtnGui4y>
3. Impact Assessment Questionnaire: (link to online form)
 - <https://forms.office.com/r/vyRw57XWbm>
3. MPD1100/8 – Guidance and Principles - Donor Organ Photographs

1. Organ Damage Assessment Checklist – abdominal team

Donor No	
Donor Hospital	
Date of retrieval	
Donor type	
NORS team	

Kidney		
Renal Artery	atheroma/atherosclerosis, damage, thrombus, orifice, aneurysm, accessory	
Aortic patch	atheroma/atherosclerosis	
Renal Vein	damage, thrombus,	
Ureter	damage, length	
Kidney Hilum	damage, haematoma	
Kidney capsule	location, length, depth	
Kidney parenchymal	appearance	
Biopsy side	location, size	
Any other pathology		

Pancreas		
Arterial/venous conduit	presence, atheroma/atherosclerosis, intimal dissection, damage	
Capsule and parenchyma	location, length, depth, underlying damage, subcapsular haematomas, mass lesions	
SMA	atheroma/atherosclerosis, damage, thrombus	
Splenic artery	course, damage, aneurysm, thrombus	
Portal & Splenic Vein	length, damage	
Duodenum	perfusion, perforation (DCD), diverticula, ulcers, intramural, haematomas	
Staple lines	on duodenum and mesentery	
Any Other Pathology		

Liver		
Edges	smooth, blunt	
Steatosis	mild, moderate, severe	
Weight	(g)	
Capsule injury	location, length	
Parenchymal injury	location, length, depth	
Liver Lesion		
Hepatic veins	intact orifices	
IVC		
Portal vein	injury/length	
Hepatic artery	anatomy, accessory, damage, arteries ligated quality	
Bile duct	flush	
Any Other Pathology		

DRAFT

1. Organ Damage Assessment Checklist – CT team

Donor No	
Donor Hospital	
Date of retrieval	
Donor type	
NORS team	

Heart	
<i>Pre-procurement assessment</i>	
Imaging	Echocardiogram, X-Ray, CT (coronary calcifications)
Cardiac output studies	screenshot
<i>In Situ Assessment</i>	
Inspection pic & video	Appearance, visible coronary plaques, contractility
<i>Back table Assessment</i>	
Aorta	Length
Pulmonary arteries	length
SVC	length
IVC	Distance from coronary sinus ostia
Atrial cuff	Distance from coronary sinus on the outside
Any Other Pathology	

Lung	
<i>Pre-procurement assessment</i>	
Radiology	X-Ray, CT
Bronchoscopy	anatomical anomalies, growths, infection/inflammation, aspiration, secretions
<i>In Situ Assessment</i>	
Inspection	Appearance, bulge, scarring, adhesions, signs of fat embolism, consolidation, necrotic areas, barotrauma
<i>Back table Assessment</i>	
Parenchymal damage	tearing around the infra-pulmonary ligament, tearing along the fissures
Deflation	
Atrial cuff	Small, injured, transected
Pulmonary Arteries	
Bronchus	
Any Other Pathology	

1. Length of Process Assessment form

Donor No	
Donor Hospital	
Date of retrieval	
Donor type	
NORS team	

Retrieved organ	Kidney left
Length of Process	
Type of images (photo/video)	
Number of images	

Retrieved organ	Kidney Right
Length of Process	
Type of images (photo/video)	
Number of images	

Retrieved organ	Liver
Length of Process	
Type of images (photo/video)	
Number of images	

Retrieved organ	Pancreas
Length of Process	
Type of images (photo/video)	
Number of images	

Retrieved organ	Heart
Length of Process	
Type of images (photo/video)	
Number of images	

Retrieved organ	Lungs
Length of Process	
Type of images (photo/video)	
Number of images	