

# Clinical Governance – Why it's important to report

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National Co-Lead for Governance NHSBT OTDT and Jane Rowlands, Clinical Governance Manager Recipient and Live Donor Coordinator Workshop 1<sup>st</sup> October 2021



The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary1984–1995 "....paediatric cardiac surgery services at Bristol were "simply not up to the task", because of shortages of key surgeons and nurses, and a lack of leadership, accountability, and teamwork"

# Learning from Bristol

Clinical governance is the system through which NHS organisations are accountable CULTURE for continuously improving the quality of their services and safeguarding high HIGH standards of care by creating an environment in which clinical excellence **STANDARDS** will flourish (Department of Health).

Clinical governance encompasses quality assurance, quality improvement and risk and incident management.

PPV Involvement	Opt out Involement ODR PREMs
IT/Information	Data & statistics ODT Hub NTxD
Risk Management	<i>Incident Reporting</i> HTA SAEARs SUI
Audit	Audit Programme CUSUM Organ specific Reports
Training/education	QA and CG Team – policies, Cautionary Tales, BTS, Courses
Effectiveness/Research	Scout, Normothermic perfusion, RINTAG
Staff	Culture and stakeholder engagement Leadership





Maintaining an environment which facilitates equitable distribution of a finite and limited resource ensuring the best possible outcomes by adherence to highest professional standards





NHS Blood and Transplant

Leadership Team work Support Patient focused Good data Pathway analysis Innovation

Low quality

High quality

# Why do you need Clinical Governance?



# Areas of responsibility



- Donor Characterisation
- Allocation and the NTXD
- Team Mobilisation
- Retrieval
- Transport
- Operation
- Disease Transmission
- Outcome monitoring







### https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/



### Incident Reporting

### Urgent incidents

Call ODT Hub Operations on 0117 975 7580 if the incident is urgent and may affect the quality and safety of an organ for transplantation or the 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 <u>Rapid Alert – Positive transport fluid results</u> form and emailing it to <u>odthub.operations@nhsbt.nhs.uk</u>

### In this section

Shared Learning

Incident Reporting

Learning from excellence

#### INCIDENT SUBMISSION FORM



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	э.		

• 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.	reports whereby photographs would provide further information, such as organ assessme	ent or damage, please attach	
to enable a more beneficial review * 🤍			

Attachments Attachments are limited to a maximum of 10mb in size each. A maximum of 5 attachments may be added	Choose File no file selected			
Donor ID status	<ul> <li>ID not allocated</li> <li>Not related to an individual dor</li> <li>Donor ID</li> </ul>	nor	Recipient ID status	<ul> <li>ID not allocated / not known</li> <li>Not related to an individual recipient</li> <li>Recipient ID</li> </ul>
NHSBT donor ID number(s) and type(s	) involved in this incident	•	ID number(s) of the recipient involv	ed in this incident?
Details Of Those Involved Releva	ant To The Report		T	
Organ Donation Services Team (ODST)	<b>y</b>		Transplant Centre	*
Retrieval Team		•	Coroner / Procurator Fiscal jurisdiction	• 🕜
Please Select		\$	Enter Coroner / Procurator Fiscal juris	sdiction name
Donating hospital – search by town / city	0		Microbiology / Virology lab 👩	
Please type town and select from list, if n	ot listed enter name and town		Please type town and select from list,	if not listed enter name and town
NHSBT site where incident occurred 📀			Haematology / Biochemistry lab 💽	
Please Select		\$	Please type town and select from list,	if not listed enter name and town
H & I lab 🕜			Histo-pathology lab 🕜	
Please Select		\$	Please type town and select from list,	if not listed enter name and town
Additional Information				
The incident has also been reported to the Select organisation(s)	ese organisations 💿 F o C re	Reference n organisation One per line. I eference nun	umbers for reports to other s  Please list organisation hber	
Please Select	\$			
• To print a copy of this form and the incid	lent details please use the browser's	print functio	n BEFORE submitting the form	Cuba

· Form data can be saved in pdf format AFTER the incident has been submitted

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CA/PA		ODT-INC-7	ODT occ	Corneal retrieval- protocol not followed	Cl 19/11/2012 0	<u> </u>			
		ODT-INC-8	ODT occ	Damage to liver-Loss of organ	Cl 19/11/2012 1				
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	Any	ODT-INC-12	ODT occ	Inadequate Donor characterisation	Cl 19/11/2012 1				
L (	Status	ODT-INC-13	ODT occ	Pancreas damage at retrieval - but pancreas transplanted.	Cl 19/11/2012 1				
•	Any	ODT-INC-14	ODT occ	Duty Office failure to communicate clinical information	Cl 20/11/2012 0	<u></u>			
l Occurrences	Severity	ODT-INC-15	ODT occ	Poor perfusion at retrieval	Cl 20/11/2012 1				
	Any	ODT-INC-16	ODT occ	SNOD Transcription Error	Cl 21/11/2012 1				
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Recently Viewed	Any	ODT-INC-18	ODT occ	Duty Office Organ Outcome form- Incorrect information	Cl 21/11/2012 1	<u>^</u>			
E Folders	Event Date	ODT-INC-19	ODT occ	Duty Office Organ Outcome form- delayed information to SNOD team	Cl 21/11/2012 1	<u> </u>			
	Any	ODT-INC-20	ODT occ	Loss of cornea for transplant- administration error	Cl 21/11/2012 1	<u> </u>			
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Incidents	Any	ODT-INC-22	ODT occ	SNOD misinterpretation of MPD 886- storage of organs awaiting allocation	Cl 21/11/2012 1				
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		ODT-INC-25	ODT occ	Failure of voice recording system	Cl 20/11/2012 1	<u> </u>			
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	Search	ODT-INC-27	ODT occ	Incorrect packaging-lymph/spleen/paperwork missing from kidney	Cl 22/11/2012 1				
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		ODT-INC-31	ODT occ	Delay recieving EBV Donor Virology results	Cl 27/11/2012 1				
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### **Serious Adverse Event (SAE)**

any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or lifethreatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity

### **Serious Adverse Reaction (SAR)**

an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, lifethreatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity'



### **GOVERNANCE INCIDENTS**



**2019 2020** 



Number of deceased donors and transplants in the UK, 1 April 2010 - 31 March 2020, and patients on the active transplant list at 31 March

<sup>1</sup> Waiting list as at 29 February 2020

Source: Transplant activity in the UK, 2019-2020, NHS Blood and Transplant

# Organ Damage



- Retrieval delay team related, transport, theatres, equipment, technical difficulty
- Abdominal vs cardiothoracic
- Communications
- Innate properties versus damage
- Perfusion and new technologies
- Prolonged ischaemia time
- HTA form A vs HTA form B



# Managing Organ damage

- Masterclass
- Formalised NORS training
- On line training
- NORS Lead
- Increase reporting
- Correct use of technology
- Photography and video recording
- Communication with recipient centres

# Case Study – QUOD biopsies



# CUSUM and Organ Specific Reports





# Donor Derived Disease

- Autoimmune ITP, anti-cardiolipin, GvHD, Haemolytic anaemic
- Metabolic Fabry's, porphyria, Urea cycle disorders
- Infection Hepatitis, encephalitis, herpes viruses
- Neoplasia Donor origin
  - Donor transmitted
  - Donor derived

#### The NEW ENGLAND JOURNAL of MEDICINE ESTABLISHED IN 1812 MARCH 6, 2008 VOL. 358 NO. 10

#### A New Arenavirus in a Cluster of Fatal Transplant-Associated Diseases

Gustavo Palacios, Ph.D., Julian Druce, Ph.D., Lei Du, Ph.D., Thomas Tran, Ph.D., Chris Birch, Ph.D., Thomas Briese, Ph.D., Sean Conlan, Ph.D., Phenix-Lan Quan, Ph.D., Jeffrey Hui, B.Sc., John Marshall, Ph.D., Jan Fredrik Simons, Ph.D., Michael Egholm, Ph.D., Christopher D. Paddock, M.D., M.P.H.T.M., Wun-Ju Shieh, M.D., Ph.D., M.P.H., Cynthia S. Goldsmith, M.G.S., Sherif R. Zaki, M.D., Ph.D., Mike Catton, M.D., and W. Ian Lipkin, M.D.

ABSTRACT

#### BACKGROUND

Three patients who received visceral-organ transplants from a single donor on the From the Center for Infection and Immusame day died of a febrile illness 4 to 6 weeks after transplantation. Culture, polymerase-chain-reaction (PCR) and serologic assays, and oligonucleotide microarray analysis for a wide range of infectious agents were not informative.

#### METHODS

We evaluated RNA obtained from the liver and kidney transplant recipients. Unbiased high-throughput sequencing was used to identify microbial sequences not found by means of other methods. The specificity of sequences for a new candidate pathogen was confirmed by means of culture and by means of PCR, immunohistochemical, and serologic analyses.

#### RESULTS

High-throughput sequencing yielded 103,632 sequences, of which 14 represented an Old World arenavirus. Additional sequence analysis showed that this new arenavirus was related to lymphocytic choriomeningitis viruses. Specific PCR assays Drs. Palacios and Druce contributed equally based on a unique sequence confirmed the presence of the virus in the kidneys, liver, blood, and cerebrospinal fluid of the recipients. Immunohistochemical analysis revealed arenavirus antigen in the liver and kidney transplants in the recipients. IgM and IgG antiviral antibodies were detected in the serum of the donor. Seroconversion was evident in serum specimens obtained from one recipient at two time points.

#### CONCLUSIONS

Unbiased high-throughput sequencing is a powerful tool for the discovery of pathogens. The use of this method during an outbreak of disease facilitated the identification of a new arenavirus transmitted through solid-organ transplantation.

nity, Mailman School of Public Health, Columbia University, New York /G.P. T.B. S.C., P.-L.Q., J.H., W.I.L.]; Victorian Infectious Diseases Reference Laboratory, Victoria, Australia (J.D., T.T., C.B., J.M., M.C.); 454 Life Sciences, Branford, CT (L.D., J.F.S., M.E.); and the Centers for Disease Control and Prevention, Atlanta (C.D.P., W.-J.S., C.S.G., S.R.Z.). Address reprint requests to Dr. Lipkin at the Center for Infection and Immunity, Mailman School of Public Health, Columbia University, 722 W. 168th St., New York, NY 10032, or at wil2001@columbia.edu, or to Dr. Catton at the Victorian Infectious Diseases Reference Laboratory, Locked Bag 815, Carlton South, Victoria 3053, Australia, or at mike.catton@mh.org.au.

to this article.

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N Engl | Med 2008;358:991-8. Copyright (2) 2008 Manuchusetts Medical Society.

Recipient No.	Age	Diagnosis	Organ Transplanted	Clinical Course	Interval between Transplantation and Death
	γr.				days
1	63	End-stage renal failure due to polycystic kidney disease	Kidney	Fever, sepsis, encephalopathy, acute tubular necrosis, graft re- jection, radiographic evidence of chest infiltrates	36
2	64	Decompensated cirrhosis and hepatocellular cancer due to hepatitis C infection	Liver	Fever, confusion, encephalopathy with myoclonus, chest infil- trates	30
3	44	End-stage renal failure due to polycystic kidney disease	Kidney	Fever, graft rejection, intraabdom- inal hematomas and effusion, transplant nephrectomy, en- cephalopathic illness	29

N ENGL J MED 358:10 WWW.NEJM.ORG MARCH 6, 2008

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## Patients given kidneys rejected 'unfit' by other hospitals

() 18 November 2014





Halicephalobus

HSV2 HHV6 HHV8 Strongyloides

Final version 1 Published 21.02.11

# SaBT0

Advisory Committee on the Safety of Blood, Tissues and Organs

## GUIDANCE ON THE MICROBIOLOGICAL SAFETY OF HUMAN ORGANS, TISSUES AND CELLS USED IN TRANSPLANTATION

### **Cautionary Tales**

in Organ Donation and Transplantation Clinical Governance Team, ODT

Issue 26, Sept 2020

NHS

Blood and Transplant

The last edition of Cautionary Tales was back in February. When May's edition was due we made a conscious decision to delay as clearly people's focus was elsewhere. There has been a lot going on since then, but as we all start to enter the world of 'new normal' we continue to ensure that we are learning from everything we do to support practice and improve patient safety and staff wellbeing.

The last few months have shown how we can adapt and learn from things more rapidly than we ever thought we could. Whilst that pace of change and adjustment maybe unsustainable long term, it shows how much we can achieve when we all work together with a common aim.

In February we were pleased to share that the learning from excellence system was live. This provides a route for all those working within organ donation, organ retrieval and transplantation, both internal to OTDT and external, to highlight excellence within the pathway. This edition of Cautionary Tales focuses on some of the learning that has been highlighted through this route and the impact of positive feedback.

Please share the link below with your colleagues and encourage to submit: <u>https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-guality/learning-from-excellence/</u>

Cautionary Tales has historically been a way of sharing learning from incidents, but the title could easily be felt to be negative. The aim in the future, as learning from excellence reports are received more, is to ensure that we share the lessons learnt from excellence as well as incidents. For that reason we are looking at 're-branding'. We are asking for ideas for a new, short, snappy title for Cautionary Tales that would encompass both learning from excellence and incidents. If you have any suggestions please email <u>Jeanette.folev@nhsbt.nhs.uk</u>



#### Positive actions from the Pandemic

Dr Rommel Ravanan is Chair of the Kidney Advisory Group and part of the extended clinical team formed in response to COVID-19. This team was formed to enable rapid decisions to be made with regards to the entire organ donation and transplantation pathway. Here he reflects on the positive work that can be taken from that time:

"Despite the COVID-19 pandemic causing significant service disruption to organ donation and transplant programs in the UK, clinical teams have identified and fast tracked innovations that will have long term benefits for patients and clinicians. These include:

(1) Regional collaborations of transplant centres for mutual aid such as COX-net and the Northern and London transplant collaborative. These enable the establishment of (and strengthening of pre-existing) clinically led regional alliances which will provide the foundation for long term partnership working and mutual benefit. These strong partnerships will be hugely beneficial during a potential second surge.

- (2) Regular virtual meetings of clinical and operational leaders enabling responsive and timely decision making, such as changes to donor criteria during and post height of pandemic. These meetings also allowed for sharing of resources such as transplantation specific guidance documents, patient information material and key procedures/processes.
- (3) Active centres shared clinical experiences 'what works and what does not'. They were also able to evidence successful and safe outcomes for patients helping other centres with the support and reassurance for safely recovering suspended transplant programs.
- (4) Being able to access expertise from Public Health (PHE)/Public Health Scotland (PHS) to enable embedding of a SARS-CoV-2 rapid testing kits. This was alongside developing clear processes and procedures for timely and accurate testing of organ donors and potential recipients to minimise risks of COVID-19 transmission.
- (5) Self reporting and novel data linkages with PHE/PHS and NHS digital permitting near realtime reporting on incidence of SARS-CoV-2 infections and survival in transplant recipients. This enabled clinical teams to access to up to date, real world information on specific various patient cohorts, facilitating informed consent on risks vs benefits of transplantation during the pandemic.
- (6) Successful conduct of virtual meetings with participation from across the UK, greatly minimising travel times and environmental impact.

Whilst the past few months have clearly been challenging, it is important to reflect on how well everyone worked together to ensure the best outcomes for patients, whilst minimising impact on already stretched hospital services. The above key points highlight just some of the ways rapid changes were made; the aim is to ensure we maintain that ability to be responsive and make changes in a more timely way."



As mentioned above, we can learn and strengthen practice from when things go well, or when

someone does something different. Healthcare often highlights situations where there isn't a 'right' answer and a recent learning from excellence report has shown this.

The report was submitted to highlight the good practice of a heart being referred for heart valves after being taken off the Organ Care System (OCS). It is not common for a heart not to be transplanted after arriving at a transplant centre on the OCS, but for various reasons this was the case in this report.



The national DCD programme is due to 'go live' imminently which will lead to more hearts being placed onto the OCS. Obviously the aim is for these hearts to be transplanted, however it is accepted there may be occasions where the heart is subsequently deemed unsuitable. Whilst this may not be the first time a heart previously placed on the OCS has been accepted for heart valves, by reporting this positive practice it has highlighted the need to ensure this consideration is incorporated into standard practice in the future.

#### Page 2 of 4

#### Page 1 of 4

# Conclusions

- Please Report!
- Importance of Teamwork
- Right to feel at ease
- Cautionary Tales
- Resources HTA, SABTO, BTS, NHSBT

# NHSBT OTDT Governance Team Blood and Transplant



John Forsythe **Derek Manas** Olive McGowan Jeanette Foley **Claire Mitchell Michelle Hunter Catherine Slater** Sarah Jones Jane Rowlands Kay Sybenga Victoria Gauden Ruth Clarke Ines Uchiro-Lumb

# Thank you