Document Control

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V2.0	15/12/22	Draft	Confidential email changed to Network email address
V2.1	13/04/23	Draft	Categories of harm updated, online Incident reporting form simplified and separate incident reporting form added and Appendices updated
V2.3	05/07/23	FINAL	Mortality reporting form updated. More in depth description of secure emails added. clarified when an incident reporting form is to be used
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NWCHDN Clinical Governance Standard Operating Procedure

Date: 5th July 2023

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Background

This document sets out the process by which all incidents and mortalities are to be reviewed within the North West, North Wales and the Isle of Man Congenital Heart Disease Operational Delivery Network. It describes how learning from investigations is shared across the all age network. It should be read in conjunction with the Network Risk Procedure Document (NWCHDN_13) and other Network governance documents. It also provides an oppurtunity to learn from complaints and to celebrate and share best practice where this has occurred.

Network Responsibility

These requirements do not replace an individual provider's responsibility to report and act upon incidents and mortality reviews within their own institution. The reporting to the Network should be seen as additional to and not instead of local reporting and actions.

In line with the Congenital Heart Disease Standards & Specifications, NHS England, May 2016 (Standard F3) the Network will operate within a governance framework that will include:

- Clinical Governance meetings to be held every 6 months
- To have oversight of all incidents relating to congenital heart disease that have occurred throughout the Network footprint
- To review individual incidents that had the potential to or have actually caused harm where there is a Network wide implication or lessons to be learnt
- To review all mortalities where a diagnosis of congenital heart disease has been a cause of death
- To provide a summary of all lessons learnt and ensure these are shared
- To action any resultant action plans that result from learning at an operational level within the Network
- For any changes in pathways to be agreed at the CHD Network Board
- To inform clinicians and providers of any changes in practice that have been identified as being necessary

Providers responsibility

Each hospital is required to follow its own internal incident reporting process and mortality reviews locally. All incidents need to have been investigated and any lessons learnt identified prior to reporting to the Network. If a serious incident has occurred requiring a Root Cause Analysis (RCA) to be conducted, this must also have been completed prior to submitting to the Network. All deaths similarly need to have been discussed locally and if a cororners inquest is required this must have concluded with an outcome prior to being submitted to the Network. Where it is deemed clinically appropriate to discuss cases more urgently and prior to any local investigations being

concluded – this will need to be discussed and agreed with the Network Clinical Governance Leads.

Each provider is requested to nominate a named individual to be responsible for submitting clinical incidents to the Network every 6 months. It will be their responsibility to submit the online report based on the incidents that have occured. They will also be asked to provide the name and contact number of the person identified to attend the clinical governance meeting to provide a summary of the high level incidents.

Reporting Process

The Network will inform all providers of the reporting dates every six months. These will be provided at least 8 weeks prior to each clinical governance meeting. Providers will be given a period of a month to gather the information with a request that submissions be provided to the Network within one month of the clinical governance meeting. Dates for the Network clinical governance meetings will be shared at least six months in advance to allow clinical activity to be accomodated.

The Clinical Governance Reporting Form

Providers are requested to complete one form every 6 months. No patient identifiable information is to be submitted to the Network. The report will be submitted securely on line via Microsoft Forms via this link:

https://forms.office.com/e/Gsu3i1ktMk

The Clinical Governance Report includes:

- An overall number of incidents in each Trust
- Categories of harm to be identified as per NHS England patient safety recomendations below
- Lesson learnt locally and any actions plans agreed
- Report any change of practice that may be useful to share across the Network
- All complaints reported via PALS
- Share best practice
- Celebrate excellence
- Update regarding relevant audits or research

Categories of Harm

A summary of all complaints received **Level of Harm**	**Degree of harm (Severity/Actual Impact on patient)**
No code	No harm has two sub categories **No harm (Impact prevented)** – Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. This may be locally termed a 'near miss'. **No harm (impact not prevented)** - Any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care.
B	Low (Minimal harm - patient(s) required extra observation or minor treatment)
C	Moderate (Short term harm - patient(s) required further treatment, or procedure)
D	Severe (Permanent or long term harm)
E	Death (Caused by the Patient Safety Incident)

Reference: Severity Mapping and Examples (england.nhs.uk)

Incident Reporting Process

Incidents that require discussion at the clinical governance meeting should be reported to the Network by completing an Incident Reporting Form (See Appendix B). This should include all Category harm C-D incidents. This may on occasion include low level harm incidents if it is felt that benefit would be derived from lessons learnt and shared across the Network footprint.

Mortality Reporting Process

All deaths where congenital heart disease has been identified as a cause of death are reportable to the Network using the standardised Mortality Reporting Form (see Appendix A).

Confidential emails

All patient identifiable information is to be removed from incident and mortality reporting forms prior to sending to the Network via email. It is the responsibility of the person sending the email to ensure that data protection and information governance considerations are complied with. Information sent between email addresses that are both registered as being compliant with DCB1596 standards do not need to be encyrpted. This can be checked here: https://digital.nhs.uk/services/nhsmail/the-secure-email-standard#list-of-accredited-organisations . Otherwise all emails are to be encrypted.

The Network secure email address: northwestchdnetwork@alderhey.nhs.uk
This is compliant with DCB1596 standards

Prior to the Clinical Governance Meeting

A summary of all reports will be collated by the Network. All reportable Incidents will be allocated a reference number and will be reviewed by the Network Clinical Governance Leads for Paediatrics and ACHD prior to the meeting. Similarly all deaths will be reviewed and where shared learning has been identified at a Trust level they will be allocated a reference number for submission to the meeting. Additional information may be required and requested prior to the meeting. An agenda will be circulated 2 weeks prior to the clinical governance meeting.

During the Clinical Governance Meeting

The Network Lead Nurse will chair the clinical governance meetings and will be supported by the Governance Leads for the Network. Meetings will be held remotely via Microsoft Teams. A summary report of all incidents and deaths will be shared and reviewed followed by a more detailed discussion of high level incidents and any mortalities identified by Clinical Governance Laeds as needing discussion across the Network. In addition the following items will be discussed:

- All actions will be identified and tracked
- Person/Trust/Network responsible and time frames to review/complete
- Summary of lessons learnt
- Key themes from each meeting
- Any good catches
- Examples of good practice
- Summary of audits/research

Following the Clinical Governance Meeting

A summary of the meeting will be circulated to everyone within the Network. This will be in the form of a dashboard with outcome data identifying key themes and actions from the meeting. This will be available via the Network website for future reference.
In addition:

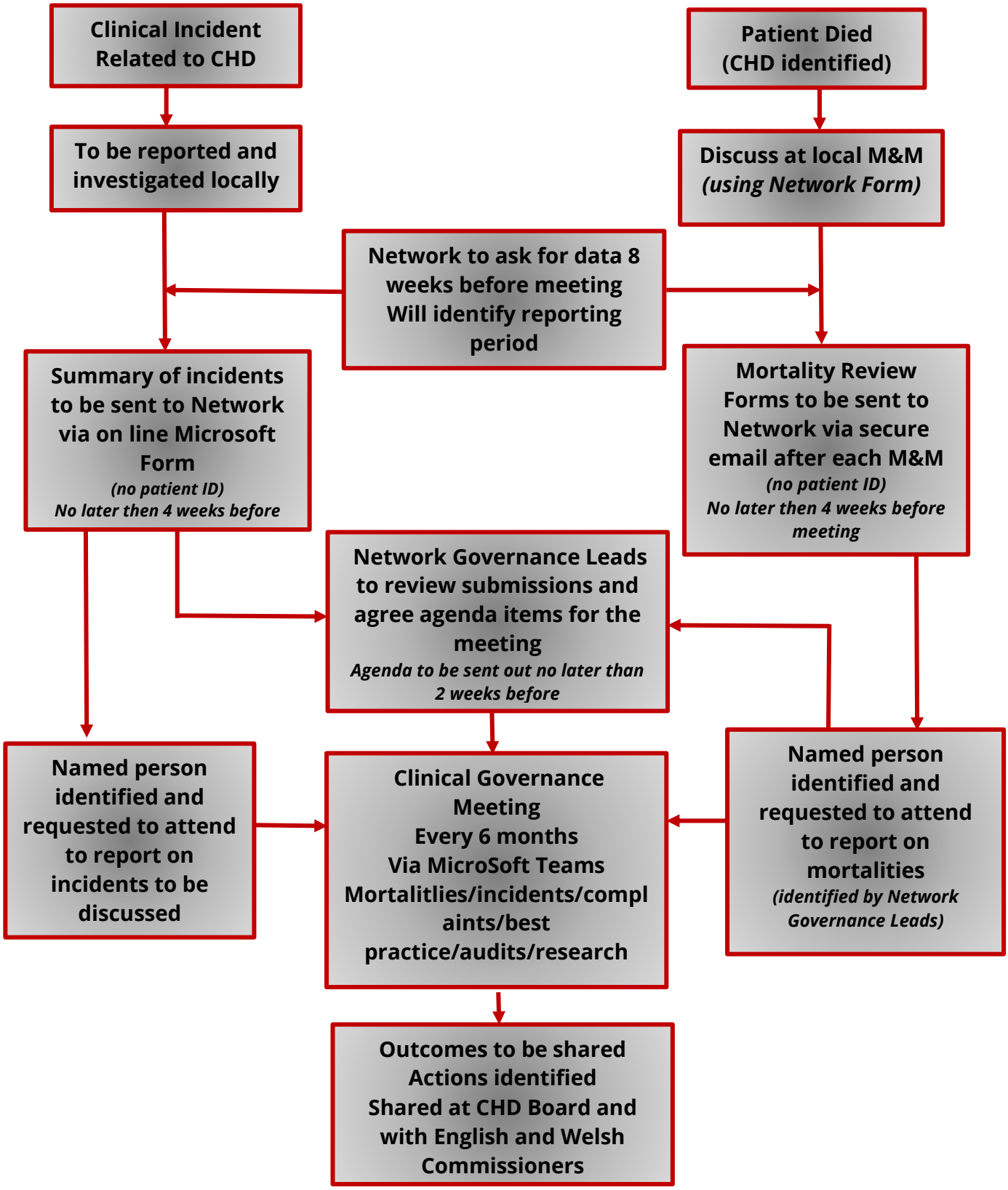
- Any actions that require operational input to ensure change occurs will be referred to appropriate services/providers and the Network will continue to provide support

- A summary of the outcomes will be reported to the Network CHD Board
- Will be made available for commissioners in both England and Wales on request

Diagram 1

Clinical Governance Meetings

Every 6 months (dates to be supplied a year in advance)



Appendix A

North West Congenital Heart Disease Mortality Reporting Form

Network Use Only				
NWCHDN Reference Number				
(Please note all patient identifiable information to be removed prior to sending copy to Network)				
1. Demographic Information				
1a.	Trust Responsible for Patient	Click or tap here to enter text.	Consultant	Click or tap here to enter text.
1b.	Name Click or tap here to enter text.	DOB: Click or tap to enter a date.	Gender: Choose an item.	Date of Death
1c.	Age Category	Neonate ☐	Paediatric ☐	Adult ☐
1d.	Place of Death	Hospital ☐ Provide details Click or tap here to enter text.	Home ☐	Other ☐ Please state Click or tap here to enter text.
1e.	Antenatal Diagnosis?	Yes ☐	No ☐	
2. Post-mortem/Inquest Information				
2a.	Was the death discussed with the Coroner's Office?	Yes ☐	No ☐ Comments: Click or tap here to enter text.	
2b.	Was a Post-Mortem Examination performed?	Yes ☐	No ☐	
2c.	Was a Coroner's Inquest Required?	Yes ☐	No ☐	Not required ☐ Date performed: Click or tap to enter a date. Comments: Click or tap here to enter text.
2d.	Has a death certificate been completed?	Yes ☐	No ☐ If no, please provide further details and actions taken: Click or tap here to enter text.	
2e.	Has the case been discussed at local M&M?	Yes ☐	No ☐ Where Click or tap here to enter text. Date: Click or tap to enter a date.	
2f.	Cause of death (as recorded on Medical Certificate)	a.		1a.
		b.		1b.
		c.		1c.
		d.		
		e.		
3. Medical History and Details of Death				
3a.	Other Named Consultants/Surgeons Involved	1.		
		2.		
		3.		
		4.		
		5.		
3b.	Measurements	Height: Click or tap here to enter text.		
		Weight: Click or tap here to enter text.		
3c.	Medical Diagnosis	1.		6.
		2.		7.
		3.		8.
		4.		9.
		5.		10.

3d.	Surgical Interventional History	1.	6.
		2.	7.
		3.	8.
		4.	9.
		5.	10.
3e.	Medication	1.	6.
		2.	7.
		3.	8.
		4.	9.
		5.	10.
3f.	Background History		
3g.	Provide brief history of events leading to death		
3h.	Were there any other important findings?		
4. Family Support			
4a.	Was the death expected? *(if No go to 4e)*	Yes ☐	No ☐
4b.	Was a palliative care referral made	Yes ☐ No ☐ Choose an item.	
4c.	Did the family/patient discuss preferred place of death	Yes ☐ No ☐ Comments: Click or tap here to enter text.	
4d.	Was the patient on appropriate end of life care pathway?	Yes ☐	No ☐
4e.	Was the death explainable given the patient's condition(s)?	Yes ☐ No ☐ Please give further detail: Click or tap here to enter text.	
4f.	Additional Important Clinical/Social Factors		

4g.	Were there any communication issues?		
5. Conclusion			
5a.	*Please tick whichever description best matches the outcome*	The care provided was less than adequate and different management would reasonably be requested to have altered the outcome	☐
5b.		The care provided was less than adequate and different management may have altered the outcome	☐
5c.		The care provided was less than adequate and different management would not reasonably be requested to have altered the outcome	☐
5d.		Adequate or above standard care was provided	☐
6. Recommendations			
6a.	Example of good practice	Provide details: Click or tap here to enter text.	
6b.	Adequate or standard practice	Provide details: Click or tap here to enter text.	
6c.	Aspects of clinical care could have been better	Provide details: Click or tap here to enter text.	
6d.	Aspects of organisational care could have been better	Provide details: Click or tap here to enter text.	
6e.	Provide a summary of lessons learnt	Provide details: Click or tap here to enter text.	
6f.	Any actions agreed against this case	Yes ☐ No ☐ *(please note, all unexpected deaths must have a commentary of findings and agreed actions).* Click or tap here to enter text.	
6g.	Action Plan	Plan:	
		Time frame of Action Plan:	
		Lead for Action Plan:	
7. Details of person completing proforma			
Name			
GMC Number			
Grade			
Trust			
Contact Number			
Signature			
Date			

Appendix B

North West Congenital Heart Disease Network Incident Reporting Form

Network Use Only			
Network Reference Number			
(Please do not send any patient identifiable data to the Network)			
Reporting Information			
Trust where incident occurred		Date of incident	Click or tap to enter a date.
Name of person completing the form		Designation of person completing the form	
Consultant *(Where applicable)*		Where did it happen *(If applicable)*	
Who was involved?			
Staff member ☐	Patient ☐	Relative/carer ☐	Member of the public ☐
Age Category	Neonate ☐	Paediatric ☐	Adult ☐
Briefly described what happened			
PLEASE Identify the Level of Harm			
No Harm	**No harm (Impact prevented)** Any patient safety incident that had the potential to cause harm but was prevented. This may be locally termed a 'near miss'. ☐	**No harm (Impact not prevented)** Any patient safety incident that occurred but no harm resulted ☐	
Low Level Harm	This is described as "**Minimal harm** - patient(s) required extra observation or minor treatment ☐		
Severe Harm	**Severe** (Permanent or long-term harm) includes any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons. ☐		
Death	Any unexpected or unintended incident that directly resulted in the **death** of one or more persons ☐		
Local Reporting			
Please confirm that the incident has been reported locally		YES ☐ NO ☐	
Please ensure that the incident has been reported locally before submitting to the Network			
If the incident needs discussing urgently at the Network prior to the outcome of any local			

investigations – please indicate reason for urgent discussion	
Outcome of local Investigation	
Describe outcome of local investigation	
Please describe any lessons learnt	
Please tell us what actions resulted	
Network Discussion ***To be completed after discussion at Network Clinical Governance Meeting***	
Date discussed	Click or tap to enter a date.
Main points of discussion	
Network Lessons Learnt	
Network Actions identified	
Who is responsible	
Network Use Only	
Outcome fed back to reporter	Date Click or tap to enter a date.
Outcome fed back to Provider Hospital	Date Click or tap to enter a date.
Lessons shared	Date Click or tap to enter a date.