

Document Control

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NWCHDN Clinical Governance Standard Operating Procedure

Date: 24th June 2021

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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 opportunity 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 and to review in more detail all incidents of category harm D and above
- 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 coroners inquest is required this must have concluded with an outcome prior to submitted to the Network.



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 occurred. 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 (harm category D and above).

Incident 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 will 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 accommodated.

The Incident 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 online via Microsoft Forms via this link:

<https://forms.office.com/Pages/ResponsePage.aspx?id=G888R1c5sE6Cur6KaqH2SmN9qHcxBZdEokjrHnPij-NUQTMxN1gyNIAwMTNTMk1STzVNOEVOQzVQNi4u>

The report includes:

Overall report of incidents in each Trust

- Total number of incidents over reporting period
 - > Number of never events
 - > Number of RCA's
 - > Number of category harm 'Level D' events
- Categories of incidents
 - > Medication errors
 - > Equipment
 - > Communication
 - > Clinical incidents
 - > Infection Control and Prevention
 - > Data quality issues
 - > Transition
 - > Transport
 - > Staffing
 - > Other



The report requires the categories of harm to be identified and in particular how many high level incidents (harm category D) and above have occurred. For each harm category D incident and above a more detailed summary is required. The following guide is provided to assist in filling in the form.

https://oregonpatientsafety.org/docs/psrp/Harm_Categories_and_Algorithm.pdf

Other information required:

The clinical effectiveness meeting will also explore:

- 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

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). All patient identifiable information is to be removed from the form prior to sending to the Network via email:

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 Category D harm events 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 Governance Leads will chair the clinical Governance meetings and will be supported by the Lead Nurse 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 of harm



category D 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:

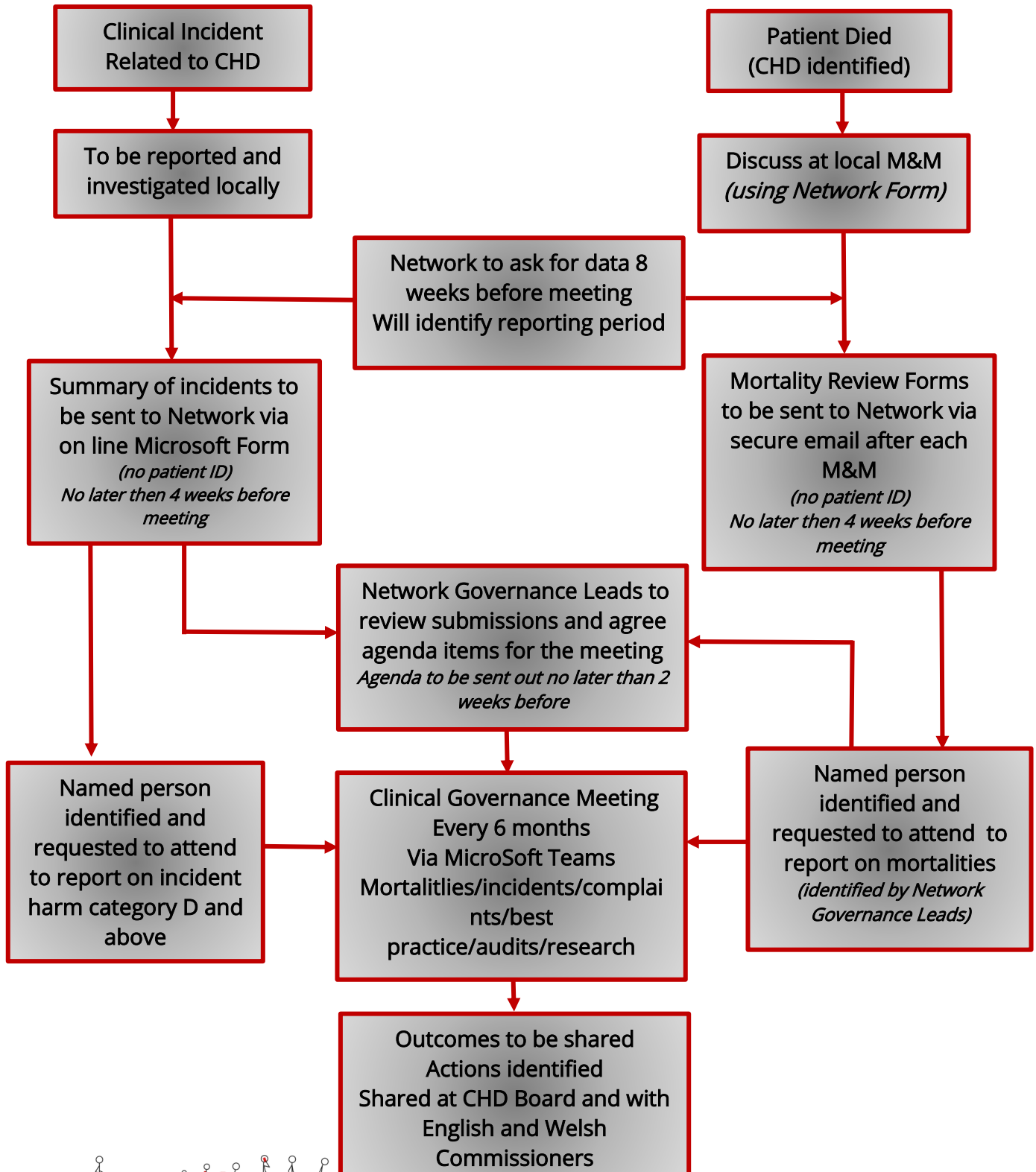
- Any actions that require operational input to ensure change occurs will be referred to the Network Operational Meeting
- A summary of the outcomes will be reported to the CHD Board
- Will be made available for commissioners in both England and Wales on request



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	
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(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.	Age at Death
1c.	Age Category	Neonate <input type="checkbox"/>	Paediatric <input type="checkbox"/>	Adult <input type="checkbox"/>
1d.	Place of Death	Hospital <input type="checkbox"/> Provide details Click or tap here to enter text.	Home <input type="checkbox"/>	Other <input type="checkbox"/> Please state Click or tap here to enter text.
1e.	Antenatal Diagnosis?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

2. Post-mortem/Inquest Information

2a.	Was the death discussed with the Coroner's Office?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Comments: Click or tap here to enter text.
2b.	Was a Post-Mortem Examination performed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
2c.	Was a Coroner's Inquest Required?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not required <input type="checkbox"/> Date performed: Click or tap to enter a date. Comments: Click or tap here to enter text.
2d.	Has a Cause of Death proforma been completed for this case	Yes <input type="checkbox"/>	No <input type="checkbox"/>	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 <input type="checkbox"/>	No <input type="checkbox"/>	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 Requested or Unrequested (<i>if No go to 4e</i>)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4b.	Was a palliative care referral made	Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Choose an item.	
4c.	Did the family/patient discuss preferred place of death	Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Comments: Click or tap here to enter text.	
4d.	Was the patient on appropriate end of life care?	Yes <input type="checkbox"/>	No <input type="checkbox"/>



4e.	Was the death explainable given the patient's condition(s)?	Yes <input type="checkbox"/> No <input type="checkbox"/> 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 (Yes/No)

5a.	<i>Please tick whichever description best matches the outcome</i>	The care provided was less than adequate and different management would reasonably be requested to have altered the outcome	<input type="checkbox"/>
5b.		The care provided was less than adequate and different management may have altered the outcome	<input type="checkbox"/>
5c.		The care provided was less than adequate and different management would not reasonably be requested to have altered the outcome	<input type="checkbox"/>
5d.		Adequate or above standard care was provided	<input type="checkbox"/>

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 <input type="checkbox"/> No <input type="checkbox"/> <i>(please note, all unrequested deaths must have a commentary of findings and agreed actions).</i> 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 Harm Categories Table

To access the entire document please hold Ctrl and click the below table

Category A	Circumstances that have the capacity to cause an adverse event	Unsafe condition or near miss
Category B	An event occurred that did not reach the patient (an "error of omission" does reach the patient)	
Category C	An event occurred that reached the patient but did not cause patient harm <i>Harm is defined as "any physical injury or damage to the health of a person requiring additional medical care, including both temporary and permanent injury"</i>	Adverse event, no harm
Category D	An event occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm <i>Monitoring is defined as "to observe or record physiological or psychological signs"</i> <i>Intervention is defined as including "change in therapy or active medical/surgical treatment"</i>	
Category E	An event occurred that may have contributed to or resulted in temporary harm to the patient but did not require a significant intervention <i>Significant intervention is defined as "an intervention intended to relieve symptoms that have the potential to be life-threatening if not addressed"</i>	
Category F	An event occurred that may have contributed to or resulted in temporary harm to the patient and required a significant intervention <i>Significant intervention is defined as "an intervention intended to relieve symptoms that have the potential to be life-threatening if not addressed"</i>	Adverse event, serious harm or death
Category G	An event occurred that may have contributed to or resulted in permanent patient harm <i>Permanent harm is defined as "harm lasting more than 6 months, or where end harm is not known ('watchful waiting')"</i>	
Category H	An event occurred that required intervention necessary to sustain life <i>Intervention necessary to sustain life is defined as including "cardiovascular and/or respiratory support (e.g., CPR, defibrillation, intubation)"</i>	
Category I	An event occurred that may have contributed to or resulted in patient's death	

Adapted from "NCC MERP Index for Categorizing Medication Errors." 2001 National Coordinating Council for Medication Error Reporting and Prevention.

APPENDIX C

APPENDIX C Incident Reporting Document – Microsoft Forms



NWCHDN - Incident Reporting Form MS

