INDEPENDENT MATERNITY SERVICES OVERSIGHT PANEL

Cwm Taf Morgannwg University Health Board

Clinical Review Strategy
Summer 2021

 WG43296 Digital ISBN 978-1-80195-798-4

VERSION CONTROL

VERSION 1: PUBLISHED 8 OCTOBER 2019.

VERSION 2: PUBLISHED 27 APRIL 2020.

VERSION 3: PUBLISHED 19 AUGUST 2021.

KEY UPDATES SINCE LAST VERSION:
• The inclusion of the Neonatologist Clinical Lead (Alan Fenton) and the Neonatal Nursing Clinical Lead (Kelly Harvey) as members of IMSOP. • The inclusion of a peer review process and the corresponding responsibilities ascribed to the review teams and the IMSOP Clinical Leads. • The inclusion of an update regarding the scope and terms of reference for a 2010 to 2016 Look-Back. • The inclusion of updated responsibilities and membership of the QA Panel. • The inclusion of updated responsibilities of the Health Board within the process. • The inclusion of additional detail regarding the clinical review process. • The inclusion of additional detail regarding the process for escalating concerns. • The inclusion of additional detail regarding the feedback process for women and families. • The inclusion of additional detail regarding the reporting process.

TABLE OF CONTENTS

1 BACKGROUND

1.1 THE ROYAL COLLEGES' REVIEW

The Welsh Government commissioned the Royal College of Obstetricians and Gynaecologists (RCOG*)* and the Royal College of Midwives (RCM) to undertake a multidisciplinary review of aspects of the maternity service provided by the then Cwm Taf University Health Board following the discovery of under-reporting of Serious Incident (SI) cases. A look-back exercise to January 2016 had previously identified 43 cases for review. These 43 cases were subject to internal review which identified shortfalls in service delivery and were submitted to the Health Board during September 2018. By analysing the findings from a Datix search for stillbirths dating back to 2010, a Consultant Midwife also identified 67 stillbirths which had not been reported by the Health Board via Datix.

The Royal College assessors visited the Royal Glamorgan and Prince Charles Hospital sites within Cwm Taf University Health Board between 15 and 17 January 2019. The assessors found a service working under extreme pressure with sub-optimal clinical and managerial leadership. The Health Board's identification of SI under-reporting had resulted in increased internal and external scrutiny, highlighting that basic governance processes were not properly in place.

The service was also expected to imminently merge two separate consultant-led units onto one site with a freestanding midwifery-led unit on the other site, with no evidence that clinical teams were engaged with and supportive of this decision and process. This was further compounded by a shortfall in the midwifery establishment, sub-optimal senior clinical leadership, a significant use of locum medical staff at both junior and consultant levels alongside a lack of established standards of practice. The service was also seen to be operating under a high level of public and media scrutiny.

As part of the RCOG/RCM review, a patient and public engagement event was held in the form of a public meeting. In addition to this, an online survey was developed (hosted by RCOG) which remained open for six weeks and one-to-one telephone interviews were conducted. The overriding message from women and their families was a desire to prevent the reoccurrence of their experiences. A full report of the findings from the public engagement process was later published, entitled *Listening to women and families about maternity Care in Cwm Taf.*

1.2 WELSH GOVERNMENT RESPONSE

The immediate concerns regarding the safety of the maternity service were escalated by the assessors at 13:00 on 16 January 2019 to the Welsh Government and the Royal Colleges. Feedback was provided to the Welsh Government and key members of the Health Board's Executive Team on areas of concern requiring immediate action to ensure patient safety at 14:00 on 17 January 2019.

In response to the publication of the review, the maternity services of the former Cwm Taf were placed into 'special measures' by the Minister for Health and Social Services. Consequently, an Independent Maternity Services Oversight Panel (IMSOP) was commissioned by the Welsh Government to provide the oversight necessary to seek assurance that the Health Board is implementing the recommendations of the RCOG/RCM report in a timely, open and transparent manner.

It should also be noted that services within the Bridgend locality, including Princess of Wales Hospital, merged with Cwm Taf on 01 April 2019 to become Cwm Taf Morgannwg University Health Board (CTMUHB). Maternity services at Princess of Wales are not subject to the 'special measures' arrangements, albeit that the Health Board's Maternity and Neonatal Improvement Plan is designed to develop services across all three sites in a consistent way.

1.3 IMSOP Terms of Reference

1. Establish robust arrangements which provide assurance to stakeholders that the recommendations of the Royal Colleges' review and other associated recommendations are being implemented by the Health Board. Set and agree milestones and deliverables and track progress against them.

2. Establish and agree an independent multidisciplinary process to clinically review the 2016-2019 serious incidents identified by the Royal Colleges as requiring further investigation. Conduct a 'look back' exercise to 2010 and ensure that anyone who has justified concerns about their care is provided with the opportunity for it to be reviewed. Ensure that any learning which emerges from these reviews is acted upon by the Health Board and others.

3. Advise the Health Board on the actions it needs to take to establish effective engagement arrangements which actively involve patients and staff in the improvement of maternity and neonatal services and rebuild wider public trust and confidence in the Health Board.

4. Escalate any wider governance-related issues or concerns which emerge to the Health Board and the Welsh Government as appropriate.

5. Advise the Minister on any further action which the Panel considers necessary to ensure the provision of safe, sustainable, high quality, patient-centred maternity and neonatal services. This should include advice about the need for, and timing of, any follow-up independent reviews and the identification of any wider lessons for the NHS in Wales.

1.4 Overarching Aim of the Clinical Review Strategy

The Clinical Review Strategy seeks to ensure that:

- A robust clinical review process is in place;
- Identified findings/themes from the review process are reported back to CTMUHB in the form of a report to ensure learning and improvement;

- Mechanisms are in place to report cases to the Coroner or individuals to the NMC or GMC if required;
- Lessons are being learned by CTMUHB through the review of evidence to improve the safety, quality and responsiveness of the maternity and neonatal services;
- Women and their families are engaged in the process and given feedback as required;
- Staff engagement occurs during the review process and that feedback is given regarding the outcome;
- Quality assurance of Serious Incident investigations that have occurred post-October 2018 is completed in order to validate the current ways of working as fit for purpose going forward;
- Women and their families can have confidence in the maternity and neonatal services at CTMUHB.

In response, the Health Board have:

- Developed a comprehensive Maternity and Neonatal Improvement Plan which is work stream and pathway-led;
- Reviewed the maternity service governance structure with the establishment of the Quality and Safety Management Meeting for Maternity Services. The main purpose of the group is to receive and provide assurance of the quality and safety of maternity services, to monitor risks and, when appropriate, to escalate identified risks to the Maternity and Neonatal Improvement Board and the Health Board's Quality and Safety Committee.

2 SCOPE AND PURPOSE OF THE INDEPENDENT CLINICAL REVIEWS

The independent review of all identified cases will be carried out by multidisciplinary teams of independent external reviewers who have experience of undertaking clinical reviews.

The REVIEW TEAMS will submit their findings to the QUALITY ASSURANCE PANEL. Membership of this panel includes the IMSOP CLINICAL LEADS, namely:

- Alan Cameron, Obstetric Clinical Lead;
- Christine Bell, Midwifery Clinical Lead;
- Alan Fenton, Neonatologist Clinical Lead; and
- Kelly Harvey, Neonatal Nursing Clinical Lead.

In addition, the panel also comprises an Anaesthetic Lead, a representative from the NHS Wales Delivery Unit (DU), alongside a lay representative from Cwm Taf Morgannwg Community Health Council.

The QUALITY ASSURANCE PANEL will not be responsible for undertaking any of the reviews but will oversee and quality assure the process to ensure robustness and consistency.

There are four cohorts within the look-back review process:

1. The 01 January 2016 - 30 September 2018 cases identified in advance of the RCOG/RCM Review (previously referred to as the 43).
2. The 01 January 2016 - 30 September 2018 cases subsequently identified using the look-back inclusion criteria established by the IMSOP CLINICAL LEADS (see *Appendix 1*).
3. The 2010 to 2016 look-back. The criteria utilised for this group will be determined using the outcomes from the above two cohorts.
4. Those women and families who have self-referred will have a review of their care regardless of whether or not they fit the inclusion criteria, albeit that this may not necessitate a full independent clinical review. A separate process for considering self-referred cases has been agreed with the Health Board and will be managed separately but overseen by the IMSOP CLINICAL LEADS.

Priority will be given in the order the different cohorts appear above. However, some self-referred cases may fall within the other criteria and hence will be considered within the relevant cohort. The initial reviews will cover cohorts 1 and 2 above. This will be termed the 2016-2018 look-back. The pathway for these reviews can be found at *Appendix 2.*

The REVIEW TEAMS will consist at a minimum of an obstetrician and a midwife in cases of stillbirth. Teams reviewing neonatal mortality and morbidity cases will be comprised of an obstetrician, a midwife, a neonatologist and a neonatal nurse. In specific cases where there are potential anaesthetic issues or in all cases where the mother was admitted to the Intensive Care Unit, an anaesthetist will form part of the multidisciplinary review team.

Clinical reviewers will be sourced and recruited through the appropriate clinical networks by way of expressions of interest. Expressions of interest will be screened by the IMSOP CLINICAL LEADS to ensure the recruitment of clinicians with the relevant skills and experience.

Prior to commencement of the reviews the REVIEW TEAMS will undergo an induction programme to ensure they are fully aware of the background to the review, understand their role in supporting the review process and are familiar with the methodology which will be applied.

2.1 Independent Advocacy for women and Families

It is important that the clinical reviews are fully informed by families (where they wish to do so) in order for learning to be identified from their experiences. All women and their families will be offered the opportunity to tell their stories prior to their clinical review commencing, enabling them to present their record of events and put questions and concerns they may have in writing to the team reviewing their care, should they wish to do so. They will be provided with support by the Community Health Council's Advocacy Service if they wish to take up the opportunity.

The independent advocates will be able to provide the support necessary to ensure that the woman's journey as well as the overall experience of women and their families is brought into the heart of the review, alongside any safety and quality elements.

The Welsh Government will be responsible for procuring the clinical review teams and the independent advocacy service on behalf of and subject to the advice of IMSOP.

2.2 Post-October 2018 Reported Serious Incidents

All cases after 01 October 2018 are to be reviewed by the Health Board under normal 'business as usual' procedures. The Serious Incident investigation process will be quality assured by the IMSOP CLINICAL LEADS through a dip sample exercise to assess the quality and consistency of the investigations undertaken, as well as provide assurance to the Welsh Government on the robustness of the Health Board's governance processes. Additional professional expertise will be co-opted as necessary to inform this process.

2.3 Scope and Terms of Reference for the 2016-2018 Look-Back

The multidisciplinary REVIEW TEAMS will:

- Involve families in the process should they wish to be included by reviewing and considering any narrative or questions put forward;
- Review the case notes to determine if there were any modifiable factors present and, if applicable, provide a decision on the significance of these factors utilising an agreed review mechanism;
- For those cases where there was a local investigation (if applicable):

    a. Identify whether the investigation appropriately addressed the relevant concerns and issues pertaining to those incidents and provided sufficient externality and independence of opinion;
    b. Establish if recommendations were accepted and appropriate actions implemented within the timescales identified in the associated action plan;
    c. Consider how the parents and families were engaged with during these investigations and how the results of the investigation were communicated to them;
    d. Consider how staff members involved were engaged in the review process and how the outcomes/learning were shared either individually or throughout the wider maternity and neonatal services and embedded into practice;

- Undertake a peer review of cases clinically reviewed by another team to provide assurance regarding the modifiable factors and learning identified, alongside the accuracy of the clinical information contained in the review tools;
- Prepare their findings of the review of each case to the QUALITY ASSURANCE PANEL for challenge and quality assurance monitoring.

2.4 Scope and Terms of Reference for a 2010 to 2016 Look-Back

The RCOG/RCM report suggested that a further look back from 2016 to 2010 (or further) be considered. However, since the publication of their report, IMSOP, in developing the look back criteria, determined that the cases falling between 01 January 2016 and 30 September 2018 needed an independent clinical review given concerns regarding the quality of the look back exercise originally undertaken by the Health Board. In addition, the inclusion criteria agreed by IMSOP identified considerably more cases than the original 43 reviewed by the Health Board. Consequently, significantly more cases will now be reviewed within the period of 01 January 2016 to 30 September 2018 than would have been envisaged by the RCOG/RCM review.

Given that there are two main overarching aims of the Look-Back: to identify all possible learning to inform the improvements needed and importantly, to help answer any questions and concerns women and families may have about the care they received and potentially the impact on the outcome, these will be important considerations in determining any next steps for looking back further. IMSOP will therefore want to review the learning from the 2016-18 Look-Back, the self-referral

process, as well as the effectiveness of the current incident reporting arrangements within the Health Board in order to make recommendations to the Minister for Health and Social Services on any further review of historic cases.

2.5 Scope and Terms of Reference for Self-Referred Cases

The IMSOP CLINICAL LEADS will:-

- Review the self-referral recommendations made by the Health Board's Lead Midwife;
- Determine how a review of the care is best conducted, taking into account women's and families' views;
- Consider the findings and recommendations of those cases which are managed by the Health Board and ensure these are shared with women and their families.

In those cases which are assessed as requiring an independent clinical review by the IMSOP CLINICAL LEADS, the multidisciplinary REVIEW TEAMS will follow the procedure set out in 2.4.

A copy of the Self-Referral Process Map can be found at *Appendix 3*.

2.6 Role of the Independent Maternity Oversight Quality Assurance Panel

The QUALITY ASSURANCE PANEL's membership is as detailed in section 2.0. In addition, a Senior Midwife will support the panel by quality assuring clinical assessments prior to submission for grammatical and consistency purposes, as well as cross-reference clinical findings with the RCOG/RCM recommendations alongside relevant recommendations/guidelines from other health bodies and organisations.

The QUALITY ASSURANCE PANEL will:-

- Provide QA of the overall process to ensure consistency and to inform actions needed in response to identified outcomes of the clinical reviews. To include:

    a. QA the review of all cases within each of the three categories of the 2016-2018 look-back;
    b. Confirm that all relevant modifiable factors have been identified as well as the appropriateness of the significance attributed;
    c. Confirm that all learning has been identified and is appropriate;
    d. Confirm that the assessment of each area of care is appropriate;
    e. Identify and monitor themes both within and across each cohort of cases;
    f. Identify any immediate concerns which warrant escalation to the Health Board or other organisations.

- Provide individual advice relevant to their individual clinical speciality or area of expertise to inform recommendations to the Health Board as well as feedback to women and families;
- Adjudicate the peer review process where consensus cannot be reached between REVIEW TEAMS;
- Support the drafting and quality assurance of personalised feedback to women and families.

3 ROLE OF THE HEALTH BOARD IN THE REVIEW PROCESS

3.1 WOMEN AND FAMILIES DATABASE

The Health Board will maintain a database of information to support the clinical review process and will be responsible for ensuring that the database is:

- accurate and contains all of the information required by the Welsh Government and IMSOP to facilitate ongoing communication with women and families throughout the clinical review process;
- kept up to date and is compliant with GDPR principles;
- managed in a way which minimises the risk of reputational damage.

3.2 SUPPORTING THE CLINICAL REVIEW PROCESS

The Health Board will support the clinical review process by providing:

- Support during the review process to address queries/provide further information;
- Patient records including CTG's;
- Investigation paperwork/supervisory reports/staff statements;
- Patient stories;
- Guidelines in place at the time of the event;
- Action plans in relation to the incident;
- Complaint referral paperwork.

Specific checklists for each review cohort will be provided by IMSOP and completed by the Health Board to support the collation and uploading of case documentation.

Access to all documentation is to be compliant with the Health Board's Information Sharing Protocol. Documentation will be shared with REVIEW TEAMS remotely through a Secure File Sharing Portal (SFSP) hosted by the DU. All documentation will be anonymised and compliant with the Health Board's Redaction Policy.

The Health Board will be responsible for considering the findings from each clinical review and developing corresponding action plans to address issues identified. This includes any additional review, Root Cause Analysis or investigation work deemed necessary in instances where a local investigation has not previously been undertaken. This will also include determination of any additional redress requirements in line with the Putting Things Right (PTR) arrangements. The IMSOP CLINICAL LEADS will remain sighted on this process.

3.3 SUPPORTING FAMILIES

- The Health Board is responsible for ongoing communication with women and families during the review process, providing support as required.
- Women and families who have or are experiencing bereavement will be treated with compassion and empathy with communication and support in line with the Stillbirth Pathway (NBC Pathway). They will be supported by appropriately skilled Bereavement Midwives, Counsellors and have access to SANDS and other services, including CHC advocacy, in order to provide feedback on their experiences and identify their continuing needs.
- Additional psychological support services will also be provided by the Health Board through an external independent counselling agency.

4 THE REVIEW PROCESS

The IMSOP CLINICAL LEADS will provide the REVIEW TEAMS with direction in relation to the conduct of the reviews to ensure that there is a consistent approach to each case. To achieve this, the REVIEW TEAMS will use an agreed set of review tools. The maternal review tool will be based on the perinatal mortality review tool which was used in the Morecambe Bay inquiry (see *Appendix 4*). It has been agreed that this review tool is suitable for identifying modifiable factors in the care of both mothers and babies who sadly were stillborn.

The REVIEW TEAMS will also have access to a neonatal review tool which has been developed by the Neonatologist Clinical Lead (see *Appendix 5).* This will ensure additional modifiable factors specific to the care of a neonate are highlighted through the review process.

In addition to a clinical review, each case will also be subject to a peer review. This will be completed by a different REVIEW TEAM and seek to provide assurance that all relevant modifiable factors and areas of learning have been identified, as well as confirm the accuracy of all clinical information included within the review tools. A checklist has been developed to support this process, including escalation to the IMSOP CLINICAL LEADS for mediation should agreement not be reached between the REVIEW TEAMS.

The findings from both REVIEW TEAMS will be considered by the QUALITY ASSURANCE PANEL to monitor consistency between cases as well as ensure that all appropriate modifiable factors and learning have been identified. A QA Pro Forma will be completed which details the modifiable factors identified and significance attributed, an agreed assessment of the standard of care provided, alongside a summary of the relevant learning identified.

The QA Pro Formas will be shared with the Health Board to support the determination of any actions required in response to the findings. It is the responsibility of the IMSOP CLINICAL LEADS to oversee this process and ensure that appropriate and proportionate actions are identified and taken forward by the Health Board. The REVIEW TEAMS and the QUALITY ASSURANCE PANEL will give due consideration to the application of relevant policies and procedures that were in place both locally and nationally at the time of the incident, as well as during the subsequent investigation process. It is anticipated that the reviews conducted by the review teams will enable themes to be identified and these will be compared to the themes identified in other national inquiries such as Each Baby Counts and the Healthcare Safety Investigation Branch.

4.1 PROCESS FOR ESCALATING CONCERNS

An Escalation Policy has been agreed between the Health Board and the IMSOP CLINICAL LEADS which details the process that the Health Board is expected to follow should concerns be identified in relation to individual or team clinical practice within a case or across a number of cases. The Health Board is expected to analyse

practitioner involvement on an iterative basis as clinical reviews are completed and alert the IMSOP CLINICAL LEADS to any concerns regarding recurring practitioner involvement, as well as provide assurance regarding any consequential action deemed necessary.

Where individual or thematic concerns are identified as part of the review process, either by the REVIEW TEAMS or the QUALITY ASSURANCE PANEL, which require immediate assurance, referral or further investigation, these will be escalated to the Health Board's Director of Nursing and/or Medical Director as appropriate using an agreed Escalation Pro Forma. The IMSOP CLINICAL LEADS will be responsible for reviewing and signing off all information and documentation provided by the Health Board for assurance purposes as part of this escalation process. Should concerns be identified which warrant referral to a professional body, these will be managed through local Health Board mechanisms with the IMSOP CLINICAL LEADS updated and assured as appropriate.

The REVIEW TEAMS will be provided with a copy of the guidance 'Referral of deaths to HM Coroner, South Wales Central' (June 2019) as a guide. The IMSOP CLINICAL LEADS will provide the Health Board's Medical Director with any referrals on a case-by-case basis to ensure the capture of any themes for further investigation. The Health Board's Medical Director will then refer to the Coroner on a case-by-case basis via local mechanisms.

The IMSOP CLINICAL LEADS are working with the Safeguarding Board to ensure there is alignment between the clinical reviews and a number of safeguarding reviews being undertaken concurrently. Any safeguarding concerns identified during the review process will be escalated by the IMSOP CLINICAL LEADS to the Safeguarding Board.

It is also conceivable, albeit in extraordinary circumstances, that the clinical review process might identify information which would necessitate a referral being made to the Police to enable them to consider whether it would be appropriate to conduct a criminal investigation. A Memorandum of Understanding has been developed between IMSOP, South Wales Police and the Health Board which sets out the process to be followed if such a referral becomes necessary.

4.2 FEEDBACK TO WOMEN AND FAMILIES

Personalised feedback will be provided to women and families following completion of the clinical review of their care. Individual review findings will be shared in a phased approach to acknowledge that not all will wish to receive the full details of their review.

A letter will be sent to women and families to confirm that the review of their care is complete and that the findings are available upon request should they wish to receive them. Once a request has been received, a full report letter will be shared with the women and families which details information regarding the assessment of their care and provides a response to any questions submitted by families as part of the review process. Following this, the Health Board will be expected to contact

women and families to respond to the findings and detail what action it is taking to address any issues identified.

The personalised clinical review feedback will provide information about services and advocacy support available for women and families should they wish to access this. It will also offer a meeting with either the Health Board or the IMSOP CLINICAL LEADS to discuss their findings in more detail, should they wish to do so. Women and families will be provided with an opportunity to receive their personalised feedback prior to any public reporting on the findings of each of the review categories.

4.3 REPORTING

IMSOP will produce a thematic report following the completion of each of the three clinical review categories within the 2016-2018 Look-Back. These reports will summarise the identified findings and learning from each category and make any corresponding recommendations for the Health Board to take forward. These reports will also seek to contextualise the clinical review findings, making clear any alignment or lack thereof with the RCOG/RCM recommendations, as well as any progress already achieved by the Health Board through its Maternity and Neonatal Improvement Programme.

Once the clinical review of all three categories within the 2016-2018 Look-Back has been completed, including personalised feedback to women and families as well as public reporting, IMSOP will seek to produce an overarching thematic report which summarises all the findings and learning from the Clinical Review Programme.

It is conceivable that the thematic reports may also make all-Wales recommendations where IMSOP deem this to be appropriate to maximise shared learning and improvement within maternity and neonatal services.

5 KEY PRINCIPLES OF THE REVIEW

The review will be expected to:

- Engage widely, openly and transparently with all relevant individuals participating in the review process;
- Be respectful when dealing with individuals who have been impacted by the incidents being reviewed;
- Adopt an evidence-based approach;
- Acknowledge the importance of inter-professional cooperation in achieving positive outcomes for women and children; and
- Consider links to the time relevant national policy and best practice in relation to midwifery and investigation management.

The following questions will crucially inform each stage of the review process:

1. Did the Health Board have in place at the time of each incident mechanisms for the governance and oversight of maternity incidents? Does the Health Board now have these mechanisms in place?
2. Were incidents and investigations reported and conducted in line with the time relevant national and Health Board policies, including sufficient externality and independence?
3. Is there any evidence of learning from any of the identified incidents and the subsequent investigations?
4. Were staff members involved in the incidents engaged in the investigation process and were outcomes and learning shared?
5. Were families involved in the investigation in an appropriate and sympathetic way?

APPENDIX 1

INCLUSION CRITERIA FOR 2016-2018 CASES

Additional cases from 01 January 2016 – 30 September 2018 will be identified using the inclusion criteria set out below:

1. **MBRRACE reported cases >24 weeks**
2. **All Each Baby Count Cases**
3. **All maternal admissions to ICU**

To ensure wider learning, in addition to the above criteria, all cases of transfers out will be evaluated by the REVIEW PANEL to determine whether a clinical review is necessary. Therefore, the two additional criteria to be considered are:

4. **All cases where the mother was transferred out for delivery**
5. **All cases where the neonate was transferred out for further care**

Explanatory Notes

In order to achieve consistency it is crucial that the database of clinical cases has clear inclusion criteria. It is anticipated that the findings from this criteria will inform the criteria agreed for the 2010 look-back.

The most representative surrogate marker for quality care obstetric outcome is the criteria used in the Each Baby Counts (EBC) project at the Royal College of Obstetricians and Gynaecologists (RCOG). It is therefore recommended that the database includes all cases that have been reported to the EBC team.

The EBC criteria for eligibility are for babies born > 37 weeks gestation where the outcome was as follows:

1. **Intrapartum stillbirth**: when the baby was thought to be alive at the start of labour but was born with no signs of life.
2. **Early neonatal death**: when the baby died within the first week of life (i.e. days 0–6) of any cause.
3. **Severe brain injury** diagnosed in the first 7 days of life, when the baby:
    - was diagnosed with grade III hypoxic ischaemic encephalopathy (HIE); **OR**
    - was therapeutically cooled (active cooling only); **OR**
    - had decreased central tone **AND** was comatose **AND** had seizures of any kind.

The definition of labour for EBC includes:

- Any labour diagnosed by a health professional, including the latent phase of labour at less than 4 cm cervical dilatation;
- When the woman called the unit to report any concerns of being in labour, for example (but not limited to) abdominal pains, contractions or suspected ruptured membranes;
- Induction of labour;
- When the baby was thought to be alive following suspected or confirmed pre-labour rupture of membranes.

The EBC definition of labour will be used for this inclusion criteria. The rationale for this is to have an inclusive definition of labour to include as many babies as possible and to identify babies who are affected in the latent phase of labour.

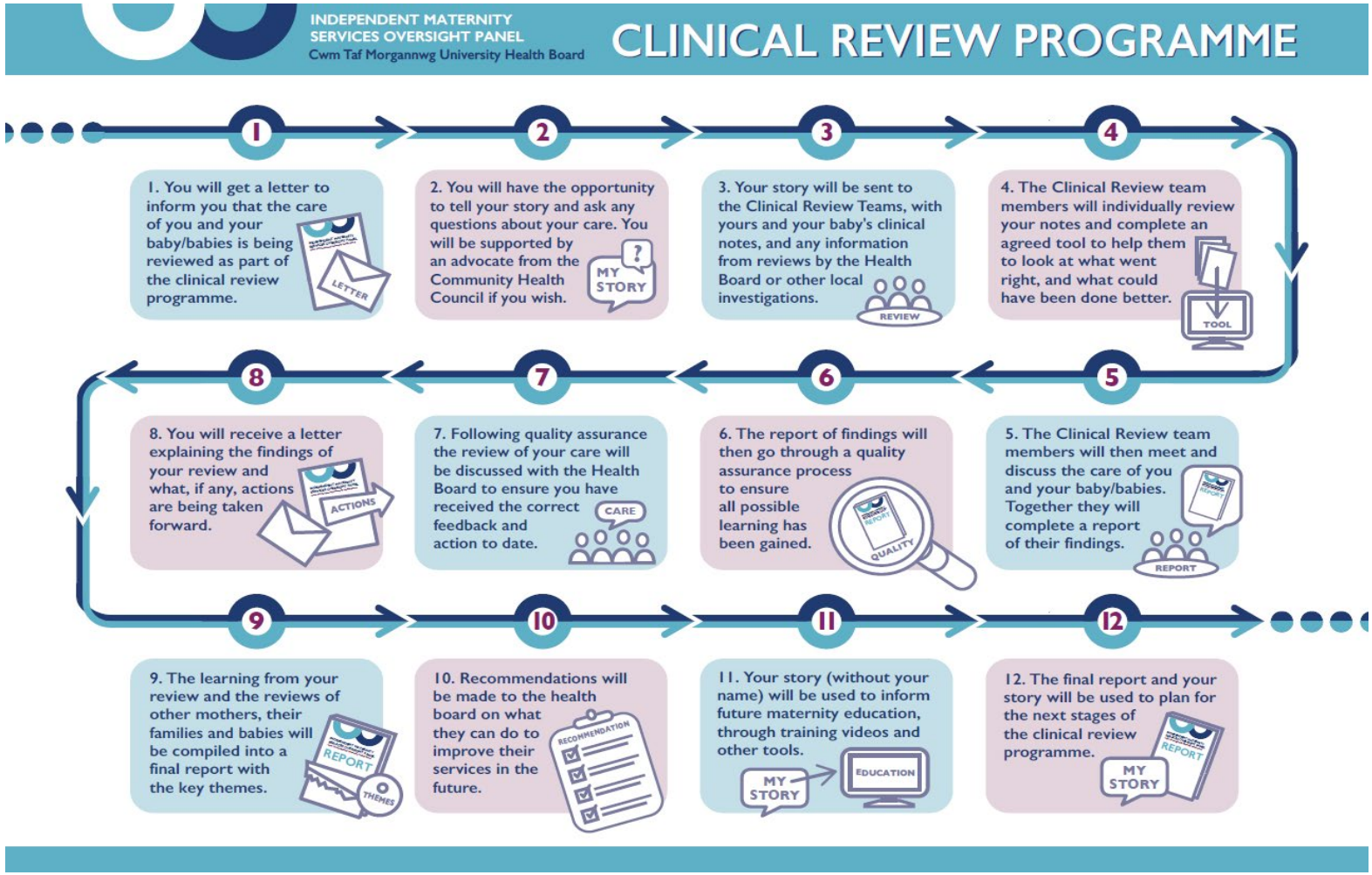
In addition to the EBC criteria, all cases of stillbirth at gestations > 24 weeks will be reviewed. These are the cases that are currently submitted to MBRRACE.

Cases where the mother was transferred out for delivery (e.g. prematurity) or cases where a baby was transferred out for further management will also be reviewed. This will ensure adverse outcomes on other sites following care in the former Cwm Taf UHB will be identified.

As a surrogate marker for maternal morbidity the panel will also review all cases where the mother is transferred to the Intensive Care Unit.

APPENDIX 2

CLINICAL REVIEW PATHWAY



APPENDIX 3

SELF- REFERRAL PROCESS MAP

Self-Referrals

How we're managing Self-Referrals

Working in partnership with women and families to answer questions, with a focus on learning and improvement.

1. If you have questions or concerns about your maternity care and that care was provided on or before 31 October 2018, you can ask for it to be considered under the Self-Referral Process. If you received care after that date, your concerns will be reviewed in accordance with the 'Putting Things Right' procedures managed by the Health Board.
2. If the Self-Referral Process applies to your care, we will look first to see if the criteria set by the Independent Maternity Services Oversight Panel for an independent clinical review are met. If so, we will refer your care to the Panel and they will contact you to directly to explain what will happen next.
3. If the criteria are not met, a Senior Midwife will contact you to talk through your questions or concerns, either by phone or in person. This may include going through previous records and reviews together to see if your questions or concerns can be answered.
4. You might decide at that stage that the questions and concerns which you had have been addressed to your satisfaction. If not, and you wish the matter to be reviewed further, the Lead Midwife will make a recommendation to the Independent Maternity Services Oversight Panel about how best that review might best be conducted.
5. The review could be conducted by the Health Board or it might be appropriate to arrange an independent review All reviews will be conducted in accordance with the 'Putting Things Right' principles The Lead Midwife will explain this process to you and will take your views into consideration when making a recommendation to the Panel.
6. The Independent Panel will consider the Lead Midwife's recommendation, together with the views which you have expressed and decide what is the most appropriate way for the review to be conducted. Their decision will be explained to you together with the reasons for it.
7. When the review has been completed, whether that be by the Health Board or independently, the findings and conclusions will be referred back to the Independent Panel for further consideration. The findings will also be shared with you and you will have the opportunity to ask any further questions.
8. Working with the Panel, we will ensure that any learning which emerges from the review of your care is carefully considered and results in improvements in the way we provide care in the future.

1

PUTTING THINGS RIGHT (PTR)

The process for managing complaints and concerns in the last 12 months or so.

2

INDEPENDENT CLINICAL REVIEW

The review of cases in the inclusion criteria for the first phase 2016-2018.

3

SELF-REFERRAL

To answer questions, concerns and/or to support reviews not managed under 1 or 2.

Self-Referral Team

New Lead Midwife in post. In the process of appointing more staff to respond.

Emotional Support

The Health Board has commissioned independent counselling services to support women and families.

How to contact

CTUHB_Concerns@wales.nhs.uk

or

01443 744915

APPENDIX 4

CLINICAL CASE REVIEW FORM – STILLBIRTH AND MATERNAL

Case reference:

Please add the name and profession of all reviewers:

Name of designated lead reviewer:

Please provide a brief overview of the case:

1. Were there modifiable factors present in this case?

- ☐ Yes
- ☐ No➔ *If no, please go to Section 15*

2. Please tick the category for each factor present in this case (*you may tick more than one*).

- ☐ Pre-pregnancy or preconception care➔ *Go to Section 3*
- ☐ Assessment or point of entry to care ➔ *Go to Section 4*
- ☐ Diagnosis or in the recognition of high-risk status ➔ *Go to Section 5*
- ☐ Referral to a specialist ➔ *Go to Section 6*
- ☐ Treatment ➔ *Go to Section 7*
- ☐ Clinical leadership ➔ *Go to Section 8*
- ☐ Education, Knowledge, Training ➔ *Go to Section 9*
- ☐ Documentation ➔ *Go to Section 10*
- ☐ Discharge or transfer from care ➔ *Go to Section 11*
- ☐ Communication ➔ *Go to Section 12*
- ☐ Policies and procedures ➔ *Go to Section 13*
- ☐ Woman and her family ➔ *Go to Section 14*

FACTORS RELATED TO HEALTHCARE PROFESSIONALS

Pre-pregnancy or preconception care

3. Was there an avoidable factor / event during pre-pregnancy or preconception care?

☐ Yes

☐ No

3a. If yes, then please tick each relevant factor or event.

☐ Professional failed to provide pre-pregnancy counselling

☐ Professional failed to get complete medical history

☐ Other pre-pregnancy or preconception issue *(please specify)*

3b. Description of relevant issue.

3c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

3d. If yes, were they followed?

☐ Yes ☐ No

3e. Please note the relevant guidelines or standards.

3f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

3g. Please note the main clinician or health care professional responsible for this factor or event.

- ☐ GP
- ☐ Hospital Midwife
- ☐ Community Midwife
- ☐ Obstetrician
- ☐ Anaesthetist
- ☐ A & E physician
- ☐ Psychiatrist
- ☐ Ambulance paramedic
- ☐ ICU physician
- ☐ Nurse
- ☐ Other *(please specify)*

3h. Please designate the status or grade of the main clinician or health care professional responsible for this factor or event.

Assessment or point of entry to care

4. Was there an avoidable factor / event during assessment or point of entry to care?

- ☐ Yes
- ☐ No

4a. If yes, then please tick each relevant factor or event.

- ☐ Mother was denied access to care or appointment
- ☐ Professional failed to offer preventative treatment
- ☐ Professional delayed assessment/evaluation of patient
- ☐ Professional failed to get complete medical history
- ☐ Other assessment or point of entry to care issue *(please specify)*

4b. Description of relevant issue.

4c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

4d. If yes, were they followed?

☐ Yes ☐ No

4e. Please note the relevant guidelines or standards.

4f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

4g. Please note the main clinician or healthcare professional responsible for this factor or event.

☐ GP

☐ Hospital Midwife

☐ Community Midwife

☐ Obstetrician

☐ Anaesthetist

☐ A & E physician

☐ Psychiatrist

☐ Ambulance paramedic

☐ ICU physician

☐ Nurse

☐ Other *(please specify)*

4h. Please designate the status or grade of the main clinician or healthcare professional responsible for this factor or event.

Diagnosis or in the recognition of high-risk status

5. Was there an avoidable factor / event during the patient's diagnosis or in the recognition of high-risk status at any stage?

☐ Yes

☐ No

5a. If yes, then please tick each relevant factor or event.

☐ Inappropriate diagnosis or categorisation of risk status

☐ Inadequate monitoring of fetal growth

☐ Inadequate fetal heart rate monitoring during labour

☐ Delay in diagnosis or recognition of high-risk status

☐ Delay in ordering or checking investigations

☐ Delay in recognition of abnormal vitals

☐ Delay in recognition of surgical complications

☐ Other delay *(please specify)*

☐ Failure in recognition of high-risk status (including failure to recognise intrauterine growth restriction)

☐ Failure in ordering or checking investigations (including failure to do or to repeat glucose tolerance test)

☐ Failure in recognition of abnormal vitals

☐ Failure in recognition of surgical complications

☐ Other failure *(please specify)*

5b. Description of relevant issue.

5c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

5d. If yes, were they followed?

☐ Yes ☐ No

5e. Please note the relevant guidelines or standards.

5f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

5g. Please note the main clinician or healthcare professional responsible for this factor or event.

☐ GP

☐ Hospital Midwife

☐ Community Midwife

☐ Obstetrician

☐ Anaesthetist

☐ A & E physician

☐ Psychiatrist

☐ Ambulance paramedic

☐ ICU physician

☐ Nurse

☐ Other *(please specify)*

5h. Please designate the status or grade of the main clinician or healthcare professional responsible for this factor or event.

Referral to a specialist

6. Was there an avoidable factor/event regarding the referral to a specialist?

☐ Yes

☐ No

6a. If yes, then please tick each relevant factor or event.

☐ Delay in referral

☐ Failure to refer

☐ Appropriate person was not available or did not respond

☐ Services not available

6b. Description of relevant issue.

6c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

6d. If yes, were they followed?

☐ Yes ☐ No

6e. Please note the relevant guidelines or standards.

6f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

6g. Please note the main clinician or health care professional responsible for this factor or event.

☐ GP

☐ Hospital Midwife

☐ Community Midwife

☐ Obstetrician

☐ Anaesthetist

☐ A & E physician

☐ Psychiatrist

☐ Ambulance paramedic

☐ ICU physician

☐ Nurse

☐ Other *(please specify)*

6h. Please designate the status or grade of the main clinician or healthcare professional responsible for this factor or event.

Treatment

7. Was there an avoidable factor/event regarding treatment?

☐ Yes

☐ No

7a. If yes, then please tick each relevant factor or event.

☐ No plan of care/management

☐ Delay in treatment (including delayed operation)

☐ Inappropriate treatment

☐ Poor diabetic management

☐ Failure to treat. *If yes, then was the failure one of the following:*

☐ Failure to act on high-risk situation/history

☐ Failure to act on intra-uterine growth restriction

☐ Failure to act on decreased fetal movements

☐ Failure to act on raised blood pressure and/or proteinuria

☐ Failure to act on suspicious antenatal cardiograph

☐ Failure to resuscitate a newborn

7b. Description of relevant issue.

7c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

7d. If yes, were they followed?

☐ Yes ☐ No

7e. Please note the relevant guidelines or standards.

7f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

7g. Please note the main clinician or healthcare professional responsible for this factor or event.

☐ GP

☐ Hospital Midwife

☐ Community Midwife

☐ Obstetrician

☐ Anaesthetist

☐ A & E physician

☐ Psychiatrist

☐ Ambulance paramedic

☐ ICU physician

☐ Nurse

☐ Other *(please specify)*

7h. Please designate the status or grade of the main clinician or healthcare professional responsible for this factor or event.

Clinical leadership

8. Was there an avoidable factor/event regarding clinical leadership?

☐ Yes

☐ No

8a. If yes, then please tick each relevant factor or event.

☐ Fail to check on junior's work (e.g., senior did not attend)

☐ Fail to consult superior

☐ Inappropriate grade of staff involved in care

8b. Description of relevant issue.

8c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

8d. If yes, were they followed?

☐ Yes ☐ No

8e. Please note the relevant guidelines or standards.

8f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

8g. Please note the main clinician or healthcare professional responsible for this factor or event.

☐ GP

☐ Hospital Midwife

☐ Community Midwife

☐ Obstetrician

☐ Anaesthetist

☐ A & E physician

☐ Psychiatrist

☐ Ambulance paramedic

☐ ICU physician

☐ Nurse

☐ Other *(please specify)*

8h. Please designate the status or grade of the main clinician or healthcare professional responsible for this factor or event.

Education, knowledge and training

9. Was there an avoidable factor / event regarding education of a health professional?

☐ Yes

☐ No

9a. If yes, then please tick the relevant factor or event.

☐ Lack of knowledge or training

9b. Description of relevant issue.

9c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

9d. If yes, were they followed?

☐ Yes ☐ No

9e. Please note the relevant guidelines or standards.

9f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

9g. Please note the main clinician or healthcare professional responsible for this factor or event.

- ☐ GP
- ☐ Hospital Midwife
- ☐ Community Midwife
- ☐ Obstetrician
- ☐ Anaesthetist
- ☐ A & E physician
- ☐ Psychiatrist
- ☐ Ambulance paramedic
- ☐ ICU physician
- ☐ Nurse
- ☐ Other *(please specify)*

9h. Please designate the status or grade of the main clinician or healthcare professional responsible for this factor or event.

Documentation

10. Was there an avoidable factor/event regarding documentation?

- ☐ Yes
- ☐ No

10a. If yes, then please tick each relevant factor or event.

- ☐ Poor documentation
- ☐ Failure to document/incomplete records

10b. Description of relevant issue.

10c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

10d. If yes, were they followed?

☐ Yes ☐ No

10e. Please note the relevant guidelines or standards.

10f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

10g. Please note the main clinician or healthcare professional responsible for this factor or event.

☐ GP

☐ Hospital Midwife

☐ Community Midwife

☐ Obstetrician

☐ Anaesthetist

☐ A & E physician

☐ Psychiatrist

☐ Ambulance paramedic

☐ ICU physician

☐ Nurse

☐ Other *(please specify)*

10h. Please designate the status or grade of the main clinician or healthcare professional responsible for this factor or event.

<u>Discharge or transfer from care</u>

11. Was there an avoidable factor/event regarding during <u>the post-delivery or discharge period</u>?

☐ Yes

☐ No

11a. If yes, then please tick each relevant factor or event.

☐ Inappropriate transfer home

☐ Inappropriate discharge from care

☐ Failure to counsel patient

☐ Failure to arrange appropriate ongoing treatment / care

☐ Failure to follow up after transfer home

☐ Inadequate screening following a stillbirth

☐ Problems with the post mortem examination including failure to send samples

☐ Insufficient bereavement support

11b. Description of relevant issue.

11c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

11d. If yes, were they followed?

☐ Yes ☐ No

11e. Please note the relevant guidelines or standards.

11f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

11g. Please note the main clinician or healthcare professional responsible for this factor or event.

☐ GP

☐ Hospital Midwife

☐ Community Midwife

☐ Obstetrician

☐ Anaesthetist

☐ A & E physician

☐ Psychiatrist

☐ Ambulance paramedic

☐ ICU physician

☐ Nurse

☐ Other *(please specify)*

11h. Please designate the status or grade of the main clinician or healthcare professional responsible for this factor or event.

FACTORS RELATED TO SERVICES

Communication

12. Was there an avoidable factor/event due to communication problems?

☐ Yes

☐ No

12a. If yes, then please tick each relevant factor or event.

☐ Between doctors

☐ Between midwives and doctors

☐ Between nursing and doctors

☐ Between departments / specialists

☐ Between hospitals

☐ Between health professional and woman (including importance of changes in fetal movement not explained to woman)

12b. Description of relevant issue.

12c. Were there national guidelines/standards related to the relevant factor or event?

☐ Yes ☐ No

12d. If yes, were they followed?

☐ Yes ☐ No

12e. Please note the relevant guidelines or standards.

12f. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

Policy or procedure problems

13. Was there an avoidable factor/event due to policy or procedure problems?

☐ Yes

☐ No

13a. If yes, then please tick each relevant factor or event.

☐ Regarding lab facilities or results

☐ Regarding oversight of others (e.g., no senior on call)

☐ Regarding scheduling and assessment

☐ Regarding emergency preparedness (e.g., ICU full or too distant, lack of theatre, lack of blood)

☐ Regarding patient education

☐ Regarding availability of records (e.g., at time of birth)

☐ Regarding staff workload

☐ Other *(please specify)*

13b. Description of relevant issue.

13c. Were there national guidelines/standards related to the relevant factor or event?

☐Yes ☐No

13d. Please note the relevant guidelines or standards.

13e. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

FACTORS RELATED TO THE WOMAN AND HER FAMILIY

14. Was there an avoidable factor/event due to the <u>woman and her family</u>?

☐ Yes

☐ No

14a. If yes, then please tick each relevant factor or event.

☐ Non-compliance with medical advice (e.g., refused treatment, refused blood)

☐ Failure to seek care (including failure to report decreased fetal movements until after delivery)

☐ Failure to attend scheduled care, including inadequate antenatal care

☐ Substance misuse

☐ Other *(please specify)*

14b. Description of relevant issue.

14c. Please note the significance of this factor or event.

☐ **Major**

Factor contributed significantly to the death. Different management would reasonably have been expected to alter the outcome.

☐ **Minor**

Factor was a relevant contributory factor. Different management might have made a difference, but survival was unlikely in any case.

☐ **Wider Learning**

Although lessons can be learned, it did not affect the eventual outcome.

ASSESSMENT OF CARE

15. Does the panel think overall care of the mother and baby was optimal, adequate or poor?

Antenatal Care	☐ Optimal	☐ Adequate	☐ Poor	☐ Insufficient information in notes
Intrapartum Care	☐ Optimal	☐ Adequate	☐ Poor	☐ Insufficient information in notes
Postpartum care	☐ Optimal	☐ Adequate	☐ Poor	☐ Insufficient information in notes

15a. Please highlight any particular instances of optimal care or care that went above and beyond expectations.

RECOMMENDATIONS AND LEARNING POINTS

16. Please summarise recommendations and learning points illustrated by this case.

INTERNAL REVIEWS

17. Was there a Serious Untoward Incident (SUI) triggered?

☐ Yes ☐ No

18. Was there a Health Board internal review?

☐ Yes ☐ No

18a. What was the conclusion of the internal review?

18b. Does the panel agree with the conclusion of the internal review?

☐ Yes ☐ No

18c. Please specify.

WOMAN AND FAMILIY'S QUESTIONS

Please provide a response to the woman and family's questions:

APPENDIX 5

CLINICAL CASE REVIEW FORM – NEONATES

SUPPORTING TRANSITION AND RESUSCITATION

Personnel

1.1 Were paediatric staff present at delivery?

1.2 If not present, reason:

1.3 Consultant present at delivery?

1.4 If not present, time of arrival (mins) *(if never present state 'never')*

1.5 Tier 1 trainee present at delivery? *(includes ANNPs working as Tier 1)*

1.6 If not present, time of arrival (mins) *(if never present state 'never')*

1.7 Tier 2 trainee present at delivery? *(includes ANNPs working as Tier 2)*

1.8 If not present, time of arrival (mins) *(if never present state 'never')*

1.9 Neonatal nurse present at delivery?

1.10 If not present, time of arrival (mins) *(if never present state 'never')*

1.11 Notes:

Events

1.12 Gestation at birth (weeks)

1.13 Time of birth (hh:mm)

1.14 Delayed cord clamping?

1.15 Heart rate at birth (beats/min)

1.16 Respiration at birth

1.17 Colour at birth

1.18 Notes:

Actions

1.19 Was intervention given?

1.20 If yes, what was done? *(tick all that apply)*

Hat	Ventilation breaths	Intravenous access
Plastic bag/wrap (preterm)	Adjunct airway	Blood transfusion
Facial O2	Intubation (unsuccessful)	Drugs
Airway opening	Intubation (successful)	Chest drain (needle)
Oropharyngeal suction	ETT suction	Chest drain (formal)
Inflation breaths	Cardiac compression	Passive cooling

1.21 First gasp (mins) *(if never state 'never')*

1.22 Time to regular respiration (mins) *(if never state 'never')*

1.23 Time to HR >100/min (mins) *(if never state 'never')*

1.24 Apgar score @ 1
Apgar score @ 5
Apgar score @ 10

1.25 Cord pH *(if unknown, state 'unknown')*

1.26 Notes:

<u>Communication</u>

1.27 Was there communication with the family?

1.28 When did this occur? *(tick all that apply)*

Never	During resuscitation
Prior to delivery	Following resuscitation

1.29 Who undertook this? *(list all that apply)*

Neonatal nurse	Tier 2 trainee
Tier 1 trainee	Paediatric Consultant

1.30 Notes:

<u>Equipment</u>

1.31 Were there equipment issues?

1.32 If yes, were these related to (tick all that apply)

Availability
Available but inoperative
Other

1.33 Notes:

Documentation

1.34 Were entries legible?

1.35 Were entries signed?

1.36 Were entries dated?

1.37 Were entries timed?

1.38 Did documentation describe events adequately?

1.39 Notes:

1.40 Grading - Supporting transition & resuscitation

No suboptimal care
Some suboptimal care which did not affect the outcome
Suboptimal care – different care might have made a difference to outcome (possible avoidable death)
Suboptimal care – would reasonably be expected to have made a difference to the outcome (probable avoidable death)

1.41 If sub-optimal care, select member(s) of team and select reason(s).

Paediatric Consultant	R: Failure to recognise problem
Tier 2 trainee	A: Failure to act appropriately
Tier 1 trainee	C: Communications failure
Neonatal nurse	S: Failure to supervise
	H: Any lack of human resource
	E: Any lack of failure of equipment
	O: Other (please specify)

1.42 Notes:

STABALISATION AND TRANSFER TO THE NEONATAL UNIT

2.1 Who was involved in transfer to NNU? *(tick all that apply)*

Neonatal nurse	Tier 2 trainee
Tier 1 trainee	Paediatric Consultant

Events

2.2 Was the baby stabilised prior to transfer to NNU? *(if 'No', enter reason in 2.3)*

2.3 Notes:

Actions

2.4 Was any new intervention given during transfer to NNU?

2.5 If yes, what was given? *(tick all that apply)*

Facial O2	Ventilation breaths	ETT suction
Airway opening	Adjunct airway	Cardiac compression
Oropharyngeal suction	Intubation (unsuccessful)	Intravenous access
Inflation breaths	Intubation (successful)	Blood transfusion

2.6 Notes:

Communication

2.7 Was there communication with the family?

2.8 When did this occur? *(tick all that apply)*

Prior to transfer
During transfer
After transfer

2.9 Who undertook this? *(list all that apply)*

Neonatal nurse	Tier 2 trainee
Tier 1 trainee	Paediatric Consultant

2.10 Notes:

Equipment

2.11 Were there equipment issues?

2.12 If yes, were these related to *(list all that apply)*

Availability
Available but inoperative
Other

2.13 Notes:

Documentation

2.14 Were entries legible?

2.15 Were entries signed?

2.16 Were entries dated?

2.17 Were entries timed?

2.18 Did documentation describe events adequately?

2.19 Notes:

2.20 Grading - Stabilisation & transfer to NNU

No suboptimal care
Some suboptimal care which did not affect the outcome
Suboptimal care – different care might have made a difference to outcome (possible avoidable death)
Suboptimal care – would reasonably be expected to have made a difference to the outcome (probable avoidable death)

2.21 If sub-optimal care, select member(s) of team and select reason(s)

Paediatric Consultant	R: Failure to recognise problem
Tier 2 trainee	A: Failure to act appropriately
Tier 1 trainee	C: Communications failure
Neonatal nurse	S: Failure to supervise
	H: Any lack of human resource
	E: Any lack of failure of equipment
	O: Other (please specify)

2.22 Notes:

ADMISSION AND FIRST HOURS

Personnel

3.1 Who was involved in admission and 1st hour?

Neonatal nurse	Tier 2 trainee
Tier 1 trainee	Paediatric Consultant

Events

3.2 Temperature on admission (degrees C)

3.3 Heart rate on admission (beats/min)

3.4 Systolic blood pressure on admission (mm Hg) *(if unknown enter 'unknown')*

3.5 Mean blood pressure on admission (mm Hg) *(if unknown enter 'unknown')*

3.6 pH on admission

3.7 PaCO2 on admission

3.8 Base deficit on admission

3.9 Lactate on admission

3.10 Did the baby require on-going stabilisation?

3.11 Notes:

Actions

3.12 What actions were undertaken following admission? *(tick all that apply)*

CPAP	Umbilical venous catheter	Passive cooling
Intubation (unsuccessful)	Umbilical arterial line	Active cooling
Intubation (successful)	Intravenous fluids	Cranial ultrasound scan
Chest drain (needle)	Blood transfusion	Chest x-ray
Chest drain (formal)	Antibiotics	Abdominal x-ray
Intravenous access	Inotropic support	Vitamin K

3.13 Notes:

Communication

3.14 Was there communication with the family?

3.15 When did this occur? *(tick all that apply)*

Never	Within 12 hours
Within 6 hours	Within 24 hours

3.16 Who undertook this? *(tick all that apply)*

Neonatal nurse	Paediatric ST 3-4
Paediatric ST1-2	Paediatric Consultant

3.17 Notes:

Equipment

3.18 Were there equipment issues?

3.19 If yes, were these related to *(tick all that apply)*

Availability
Available but inoperative
Other

3.20 Notes:

Documentation

3.21 Were entries legible?

3.22 Were entries signed?

3.23 Were entries dated?

3.24 Were entries timed?

3.25 Did documentation describe events adequately?

3.26 Notes:

3.27 Grading - admission & first hours

No suboptimal care
Some suboptimal care which did not affect the outcome
Suboptimal care – different care might have made a difference to outcome (possible avoidable death)
Suboptimal care – would reasonably be expected to have made a difference to the outcome (probable avoidable death)

3.28 If sub-optimal care, select member(s) of team and select reason(s)

Paediatric Consultant	R: Failure to recognise problem
Tier 2 trainee	A: Failure to act appropriately
Tier 1 trainee	C: Communications failure
Neonatal nurse	S: Failure to supervise
	H: Any lack of human resource
	E: Any lack of failure of equipment
	O: Other (please specify)

3.29 Notes:

ON-GOING TREATMENT

Personnel

4.1 Who was involved in on-going treatment? *(tick all that apply)*

Neonatal nurse	Tier 2 trainee
Tier 1 trainee	Paediatric Consultant

Events

4.2 Was the baby reviewed by a consultant within 12 hours?

4.3 Was the baby reviewed at least 12-hourly during admission?

4.4 If yes, by whom? *(tick all that apply)*

Neonatal nurse	Tier 2 trainee
Tier 1 trainee	Paediatric Consultant

4.5 Did the baby receive on-going respiratory support?

4.6 If yes, tick all that apply

Ambient oxygen
CPAP
IPPV

4.7 Did the baby receive on-going cardiovascular support?

4.8 If yes, tick any that apply

Fluid bolus(es)
Inotrope(s)

4.9 Did the baby receive fluid restriction?

4.10 Did the baby receive cooling?

4.11 Did the baby receive anticonvulsants?

4.12 Notes:

<u>Actions</u>

4.13 Were changes in blood gases acted upon promptly?

4.14 Were changes in blood gases acted upon appropriately?

4.15 Were changes in blood pressure acted upon promptly?

4.16 Were changes in blood pressure acted upon appropriately?

4.17 Were changes in renal output acted upon promptly?

4.18 Were changes in renal output acted upon appropriately?

4.19 Were seizures acted upon promptly?

4.20 Were seizures acted upon appropriately?

4.21 Were other acute events acted on promptly?

4.22 Were other acute events acted on appropriately?

4.23 Notes:

<u>Communication</u>

4.24 Was there on-going communication with the family?

4.25 When did this occur? *(tick all that apply)*

12 hourly	48 hourly	None
24 hourly	>48 hourly	

4.26 Who undertook this? *(tick all that apply)*

Neonatal nurse	Paediatric ST 3-4
Paediatric ST1-2	Paediatric Consultant

4.27 Notes:

Equipment

4.28 Were there equipment issues?

4.29 If yes, were these related to *(tick all that apply)*

Availability
Available but inoperative
Other

4.30 Notes:

Documentation

4.31 Were entries legible?

4.32 Were entries signed?

4.33 Were entries dated?

4.34 Were entries timed?

4.35 Did documentation describe events adequately?

4.36 Notes:

4.37 Grading - on-going treatment

No suboptimal care
Some suboptimal care which did not affect the outcome
Suboptimal care – different care might have made a difference to outcome (possible avoidable death)
Suboptimal care – would reasonably be expected to have made a difference to the outcome (probable avoidable death)

4.38 If sub-optimal care, select member(s) of team and select reason(s)

Paediatric Consultant	R: Failure to recognise problem
Tier 2 trainee	A: Failure to act appropriately
Tier 1 trainee	C: Communications failure
Neonatal nurse	S: Failure to supervise
	H: Any lack of human resource
	E: Any lack of failure of equipment
	O: Other (please specify)

4.39 Notes:

REFERRAL

Personnel

5.1 Who was involved in referral? (tick all that apply)

Neonatal nurse	Tier 2 trainee
Tier 1 trainee	Paediatric Consultant

Events

5.2 How old was the baby at the time of referral? (hours)

5.2 Reason for referral (tick all that apply)

Advice only	Transfer – on-going IC/HD care
Transfer – no capacity	Transfer - other specialist care

5.4 If transferred, was this within Network pathway?

5.5 Notes:

Actions

5.6 Was the referral made at an appropriate time after admission?

5.7 Was the baby stable at the time of referral?

5.8 FiO2 at time of referral (%)

5.9 Systolic blood pressure on admission (mm Hg) *(if unknown enter 'unknown')*
Mean blood pressure on admission (mm Hg) *(if unknown enter 'unknown')*

5.10 pH at time of referral

5.11 PaCO2 at time of referral

5.12 Base deficit at time of referral

5.13 Lactate at time of referral

5.14 Notes:

Communication

5.15 If transfer occurred were the family aware of the transfer?

5.16 How long after referral were they informed? (hours) *(if never, state 'never')*

5.17 Who informed them? *(tick all that apply, if not informed leave blank)*

Neonatal nurse	Tier 2 trainee
Tier 1 trainee	Paediatric Consultant

5.18 Were there problems making the referral?

5.19 If yes, list the problems *(tick all that apply)*

Unable to contact referral centre	Transfer team unavailable
Unable to contact transfer team	No cots in region

5.20 Notes:

<u>Documentation</u>

5.21 Were entries legible?

5.22 Were entries signed?

5.23 Were entries dated?

5.24 Were entries timed?

5.25 Did documentation describe events adequately?

5.26 Notes:

5.27 Grading – referral

No suboptimal care
Some suboptimal care which did not affect the outcome
Suboptimal care – different care might have made a difference to outcome (possible avoidable death)
Suboptimal care – would reasonably be expected to have made a difference to the outcome (probable avoidable death)

5.28 If sub-optimal care, select member(s) of team and select reason(s)

Paediatric Consultant	R: Failure to recognise problem
Tier 2 trainee	A: Failure to act appropriately
Tier 1 trainee	C: Communications failure
Neonatal nurse	S: Failure to supervise
	H: Any lack of human resource
	E: Any lack of failure of equipment
	O: Other (please specify)

5.29 Notes: