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Swansea Bay University
Health Board

External Independent Review of Maternity & Neonatal Services
Swansea Bay University Health Board

Terms of Reference

DRAFT V3

1. Introduction

This document sets out the scope and Terms of Reference for an independent review into the Maternity and Neonatal Services of the Health Board (the Review). The Review has been commissioned by the Health Board following concerns raised by families about service safety as well as MBRRACE-UK outcome data, and a number of prior external and internal reviews. The Health Board would like to take the opportunity to ensure that a broader range of information is analysed and triangulated in order to identify all available learning and implement improvements which can be sustained.

2. Background

The Health Board's Maternity and Neonatal services have been the subject of scrutiny since at least 2019 and in the last five years there have been a number of internal and external reviews including:

June 2019	Health Inspector Wales (HIW) Inspection: a) Labour Ward; b) Ward 18 & Ward 19 (including Antenatal Assessment Unit); and c) Midwifery-Led Unit, Singleton Hospital.
October 2019	HIW Inspection: Freestanding North Port Talbot Hospital Birth Centre.
May 2022	Maternity and Neonatal Network assurance framework incorporating the three key report recommendations from: a) Shrewsbury and Telford Hospital Trust; b) Cwm Taf University Health Board; and c) HIW (2020) National Review: Maternity Services
August 2022	Maternity & Neonatal Network: Maternity Services Governance Process Review.
January 2023	Welsh Government Maternity and Neonatal Improvement Programme site visit.
July 2023	Improving Together for Wales: Maternity Neonatal Safety Support Programme Cymru - Discovery Phase Report (July 2023).
September 2023	HIW Inspection: a) Maternity Unit, Singleton of Ward 20; b) Ward 19; c) Antenatal Assessment Unit (AAU); d) Labour ward (including bereavement room); e) Bay Birthing Unit; and f) Low Dependency Unit.

The findings of those reviews included common themes around patient experience, governance, departmental culture and clinical care. The Health Board has previously accepted the findings of these reviews and developed resultant improvement plans to support services to learn and improve outcomes for women, babies, and their families. In view of the on-going concerns raised by families and in light of MBRRACE-UK data, the current Review has been commissioned to determine whether recommendations arising from previous reviews identified all learning and resulted in appropriate improvements in the service. The Review will also examine the safety and effectiveness of the current service.

3. The aims of the Review are to:

- a) Ensure that family and staff experience of the Maternity and Neonatal Services is central to this review, its findings and impact so that learning from experience can be identified.
- b) Ensure that any harm identified in individual cases is communicated to service users in line with the Health Boards obligations under the Duty of Candour.
- c) Undertake a rapid review of **departmental risk** to establish if there are any significant unaccounted risks within the current service. This will inform the need for any safety actions required at an early stage whilst the broader review is ongoing.
- d) Consider the **clinical care** within the scope of these Terms of Reference to determine its role in outcomes for mothers, babies and families.
- e) Understand key **contextual data** such as demographics; health inequality data; and departmental activity to identify contributory issues.
- f) Consider the wider **impact of the pandemic** on activity and governance.
- g) Consider, on a ward to board basis, the current leadership, quality, culture and **governance** arrangements within and (relationships) between services and understand why previous reviews have not led to sustained improvements;
- h) Consider themes across all review strands and provide **overarching analysis and reporting** of both historic and contemporaneous issues within maternity and neonatal services.
- i) Provide recommendations to improve the Health Board's Maternity and Neonatal Services and outcomes for babies and their families.
- j) Identify actions the Health Board needs to take to establish effective engagement arrangements which actively involve patients, families and staff in the improvement of Maternity and Neonatal services and rebuild wider public trust.
- k) The Oversight Panel will seek evidence and assurance that high priority actions have been implemented on an urgent basis and that all other recommendations arising from this Review have also been implemented and embedded within a reasonable timeframe.

4. Terms of Reference

The Review, as above, will comprise of 7 strands and final review output coordination:

- a) A review of any current departmental risks

- b) clinical care provided (the Clinical Review);
- c) family and staff experience (the Engagement Review);
- d) data and contextual analysis;
- e) pandemic impacts;
- f) leadership; quality; culture, learning, and governance (the Governance Review); and
- g) Output coordination.

This will be a coordinated review comprised of independent expert reviewers who will undertake the Review. Teams will work collaboratively with one consultancy team pulling together an overarching final report with recommendations.

5. The Role of the Oversight Panel

- [REDACTED], will be Chair of the oversight panel and will report Review progress as well as to escalate any project risks and relevant matters arising directly to the Health Board's Board.
- Any immediate risks to patient safety (not identified in the current controls report) will be escalated immediately to the relevant clinical team and notified to the Oversight Panel.
- To undertake an ongoing assurance process in respect of the scope of the Terms of Reference with a view to considering any feedback from the Review teams regarding a need to expand the scope of cases being considered. For the avoidance of doubt the Oversight Panel has the ability to agree a widened scope.
- The role of the Oversight Panel is to provide independent scrutiny to ensure the Review is completed in line with the Terms of Reference. However, the Oversight Panel is aware that it does not have the right to amend, alter or influence the primary findings of the independent review.
- Following completion of the Review, it will continue to oversee the implementation by the Health Board of any recommendations made against agreed milestones.
- As this is a report in the public interest, the Oversight Panel will be responsible for any legal review prior to publication. The legal review will predominantly confirm whether the final report has met the Terms of Reference and whether the report is suitable for publication. The legal review will not have the power to override any of the independent findings.

6. Scope and Methodology

6.1 Review of current departmental risks

This is an important initial stage in a multi-factorial review process (which may take extended time to complete) and offers up-front assurances on current departmental safety as well as any urgent remedial actions which are required (and may not already currently be being addressed). This will include and assessment of:

- current live operational and safety risks;
- any risks which have not yet been captured or scored appropriately;
- any risks which may be compounded (and therefore more urgent);
- the risk mitigation and decision making on the risk; and

- any urgent remedial actions required (if at all).

6.2 Clinical Review

To determine the safety of the current service, the Clinical Review will assess maternal and neonatal care provided in the calendar year 2022 using a standardised assessment tool as follows:

- All MBRRACE-UK reported stillbirths and neonatal deaths;
- All neonatal deaths <24 weeks gestation (not currently reported by MBRRACE-UK);
- All babies who died on the neonatal unit >28days;
- All babies who received therapeutic hypothermia for presumed hypoxic ischaemic encephalopathy;
- All babies transferred out for intensive or high dependency care; and
- All term babies who received intensive care.

These cases encompass the sickest babies admitted to the neonatal service.

Secondly, all deaths reported by MBRRACE-UK for the calendar years 2020 and 2021 will be reviewed to specifically identify whether themes arising from clinical care contributed to the health board being flagged 'red'.

Thirdly, individual cases which are self-referred by service users within the Review timescale (January 2019 to date) will be considered. These may include cases which have already been investigated or which are subject to a complaint or legal case (details of how service users can self-refer, the process that will be followed to identify cases, and the timeframe for self-referral will be published separately).

The Clinical Review team will ensure full compliance with all of the Health Board's Information Governance protocols and the approach will consist of:

- engaging with the perinatal team prior to the Review commencing, to describe the Review. Meetings will also be held with the Executive Team and Service Group;
- review all health records in the groups described above, including clinical incident records and any investigation reports (including rapid reviews, full investigations, PMRT reports) covering the antenatal, intrapartum, postnatal care of the women and neonatal care;
- working with the governance and data review team to support the identification of trends and themes, producing relevant source materials (including data, graphs, trends, diagrams) which can be transferred into the overarching report;
- highlight any case in which the Clinical Review team judge that any modifiable factors might have impacted the outcome of care for mother and/or baby;
- consider whether the national and local standards for reporting deaths were met;
- ensure that the experiences, views and questions of families are included in the review of their care;
- produce a document of key findings with recommendations to feed into the overarching report which help facilitate the Health Board in developing an action plan with the Oversight Panel;
- to provide detailed clinical information to the Health Board to support their onward communications with families under Duty of Candour; and

- To provide a feedback session to the clinical teams.

6.3 Engagement Review

Families' perspectives and recognition of the impact on families are key components of any perinatal service review, and their lived experiences are essential in identifying areas both for service improvement and where service delivery is exemplary. *"Parents,, are the only individuals who were present for the whole of the pregnancy and therefore have a unique perspective on everything that happened to them and their baby" (NPEU, Parent Engagement Materials)".*

Consequently, the independent external engagement lead will work closely with families, service users and others who have an interest in improving maternity and neonatal care to make sure that their voices are heard throughout the engagement process and that methods used meet their needs.

The feedback from service user experience will be captured from January 2019 to date (although it is important to note that other cases will be considered for inclusion).

The core activities of the Engagement Review Team are:

- Establish an *Engagement and Communication Group* to ensure that all perspectives, especially those of families, are heard and shape the co-production of the engagement process, communication and information;
- Identifying families who wish to be involved in the review (they may include existing complainants, families who have had positive experiences, families who have suffered loss and damage and anyone who has used maternity and neonatal care during the five year period);
- Devise multi-platform communication approaches and provide information relating to the conduct and progress of the review and its independence, ensuring there are opportunities for families to shape how they might want to be involved and receive feedback on findings and the impact on change and improvement;
- Liaise with independent, community and third-sector organisations and groups, including the Maternity and Neonatal Voices Partnership (MNVP) and Llais for support in accessing different groups and communities to ensure that everyone impacted has the opportunity for their voice to be heard;
- Work with families to understand how they want to be supported to share their experience, especially in telling their stories in contributing to the clinical review process, and explore what further support mechanisms they may want to access;
- Undertake a mixture of interviews, focus groups, drop-in sessions, visits, surveys, listening exercises and other approaches suggested by families and service users to understand their views;
- Review experiential feedback from existing mechanisms such as Friends and Family questionnaires, surveys, complaints, concerns and other methods for gaining feedback on satisfaction with care; and
- Understanding the views of other stakeholders such as GPs, community groups, voluntary, self-help and support organisations with an interest in maternity and neonatal care.

Themes, findings and case-studies will be developed into a thematic document of key findings with recommendations to feed into the overarching report which identifies the messages, concerns and recommendations for improving care. This will be a key component of the overarching review report.

6.4 Staff Engagement

- Undertake an exercise with staff where engagement 'key lines of enquiry' can be developed to understand the experiences of staff at all levels and within all disciplines, working within these services over three years;
- Working closely with the governance review team to devise a specific staff survey which covers aspects of experience, governance and culture;
- Reviewing existing information on any issues with culture or staffing through 'speak-ups' existing staff surveys and any culture reviews previously undertaken; and
- To identify and approach staff who may have left the service.

6.5 Data and contextual analysis

Build a bank of contextual data in order to support and cross-reference with other findings to add a depth of understanding to the final report, including:

- Departmental capacity and patient flow (including outcomes such as ambulance divers);
- Birth rates on a rolling month by month basis – comparable to yearly averages (over 3-5 years);
- Core demographic information (ethnicity, age, wealth indicators, health indicators, health inequalities);
- Epidemiological analysis (population risk factors, GP liaison, genetic risk factors)
- Staffing and safety (staffing levels (adjusted), staffing skill mix (inc. locum), shift fill rates, departmental activity by incident); and
- Reports from regulators, royal colleges, etc.

6.6 Pandemic impacts

Using both data and governance review information we will examine the main impacts of the pandemic, which impacts upon the timeline under review, this will include:

- changes to process and governance which may have impacted upon access to services / outcomes;
- epidemiological information (latest maternal/covid research);
- impacts upon incident rates;
- definitive before and after picture along a timeline, with contextual data; and
- links to demographic impact/maternal outcomes of COVID.

6.7 Governance Review

The governance review team will:

- review historical governance arrangements between 2021, 2022 and 2023 including changes to governance during the pandemic and the potential impact of this on outcomes;
- review current governance arrangements and identify whether residual gaps exist;

- understand whether actions arising from previous reviews have been delivered and are sustained;
- understand whether processes for risk management are sufficient to effectively mitigate risks to the quality of care;
- understand current culture, safety culture / system, culture changes and strategic plans to improve culture;
- understand the overall incident profile of the units across the three years;
- understand the complaint and claims profile across the units across the three-year timescale;
- understand how intelligence is being routinely extracted to understand the quality of services;
- review meaningful learning and understand how it is shared and acted upon;
- review Board information, timeliness and understand the sufficiency to provide proper assurance on the quality of services and patient experience;
- review systems of control and establish if there is clear accountability around those systems. Are escalation routes robust and is action taken where issues are identified?
- understand inter-relationships between partners, service-users, regulators and staff;
- review processes for service changes and policy updates throughout maternity and neonatal services; and
- establish if roles are clearly defined and are structures designed to support collaborative working.

6.8 Output coordination.

Includes the governance review team undertaking a core secretariat role in pulling the review together into a singular report plus appendices. Ensuring responsibility for seeking assurance from both the clinical team and the engagement team on findings in order to ensure that findings are cross referenced and that there is a final, cohesive report, particularly to:

- Support the clinical review team and experience review team to optimise the scope to ensure that appropriate quantitative and qualitative data can be extracted to support 'the findings'. This will ensure that correct approaches are used from the outset;
- Coordinate regular check-ins so that emerging findings can be fed between each of the work streams. This is helpful to expand key lines of enquiry as they arise;
- To provide formal project updates to the Oversight Panel on a bi-weekly basis and to coordinate feedback to the standing Oversight Panel across all work streams;
- Ensure that duplication of effort is minimised between teams;
- To seek clarification on any information which is used to form the basis of 'the findings', to request further information if necessary and to ensure information is provided in a reliable format;
- To produce a draft, evidence-based report and recommendations and to oversee all quality control and validation checks on the final report;
- To oversee the factual inaccuracy checking process and any right of to produce a final, validated report; and
- To produce an abridged learning bulletin for further distribution if required.

7. Required Output of the Review

The outcome of the Review will be a detailed 'overarching report' incorporating the findings from the seven core aspects of the Review (and any matters arising during the review which are deemed significant within the context of the scope). The overarching report will make recommendations to the Health Board to take forward any learning. The Report will ensure all staff and service user data and audit information is anonymised through appendices which are FOIA exempt.

The Oversight Panel will provide a monthly update on progress to the Health Board.

8. Access to Documents

The Health Board will cooperate with the Review Teams to provide documentation / access to information / staff as required. The Health Board understands that any delays in the provision of staff or valid information for review may impact the timescales, reliability, and cost of the Review work streams. See resources.

9. Timescale

The aim is for the Review to conclude within 12 months, once all of the baseline information for review has been received by the review teams. The Review timeframe could be extended depending on the level of self-referral cases to be considered. Any immediate departmental risks will be reviewed at the outset of the Review to provide assurance to Service Users.

10. Resources

Resources for the Review will be arranged by the Health Board, noting that such resources will be, as far as possible, commissioned from an independent source. However, the Health Board recognises that there will be a significant resource requirement for internal teams in order to supply the information required to deliver a review of this nature. This must be assessed fully for the impacts on operational performance during the timescale of the review. The clinical review team particularly, will require care records and case associated documents in a format which is orderly and accessible.