Maternity and neonatal (perinatal) adverse event review process for Scotland

Operational guidance to supplement the HIS national framework

September 2021

Scottish Government
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Contents

Introduction

This perinatal adverse event review guidance has been produced in consultation with Healthcare Improvement Scotland (HIS) and acts as an addendum to the HIS 'Learning from adverse events through reporting and review'- A National Framework for Scotland. Stages 1 to 3 are consistent with the Framework and this document provides additional information that apply to stages 4 to 6 of the process.[1]

Background

In 2017 the Scottish Stillbirth Group conducted a survey of all health board processes. The review identified inconsistencies in terminology, definitions and methodology in perinatal service review processes across Scotland and this showed that the majority of stillbirths did not then undergo a Significant Adverse Event Review (SAER). It also highlighted different approaches to the involvement of families in reviews. Development of a consistent and standardised approach will support the ability to identify, to capture and to share learning and to provide a clear and robust explanation for women and families wherever they live in Scotland.

The survey also identified other areas of variable approaches across Health Boards, including:

- the range of multidisciplinary staff attending reviews;
- provision of training and protected staff time to participate in and to lead reviews;
- inclusion of external input into reviews;
- achieving local and national dissemination of learning and improvement from reviews.

In response to the recommendations from national audits, reports, and the Stillbirth Group review, the Scottish Government, alongside HIS and NES, has developed this standardised process for perinatal adverse event reviews and involving families and staff. This approach was tested in maternity services in two Health Boards and the process refined to incorporate the learning. Our thanks to NHS Lothian and NHS Ayrshire and Arran for leading the improvement work which contributed to this document.

1. Aims and scope

Aims

The aim of this document is to support Boards to apply a consistent approach to operationalise undertaking perinatal adverse event reviews incorporating the additional reporting required of maternity services, for example to the UK Perinatal Mortality Reporting Tool [PMRT][2] (see Appendix A for more detail). Through implementation this will contribute to national learning, drive high-quality care and involve and support affected families.

Scope

A number of UK and Scottish audits and reports into maternity services (e.g. MBRRACE[3], PMRT, Each Baby Counts[4]) have highlighted the importance within perinatal services of a standardised and structured approach to adverse event reviews to promote national learning and to endeavour to provide families, staff and organisations with the answers that they seek[5]. This maternity and neonatal adverse event guidance should be integrated into a wider strategy for risk management within an NHS board as per the National Framework for Scotland.

2. Principles and national reporting for perinatal adverse event reviews

The HIS National Framework includes a number of overarching principles. For a robust and consistent maternity and neonatal review process in Scotland the National Framework principles have been further enhanced where required to apply in maternity and neonatal settings, and were co-produced with maternity and neonatal professionals and service users.

1. **Openness and compassion:** Women and families understand and are fully involved in the review and are enabled to ask the questions that they would like answers to. Staff treat families with compassion and kindness, are open and transparent in their communication and are themselves treated with compassion and kindness by their employer.

2. **Teamwork:** Review panels should be multidisciplinary and reflect all professions involved in the care. Review panels should have at least one member external (as per HIS Framework) to the team to enhance transparency and objectivity.

3. **Review analysis:** The review should be conducted using a systems and human factors-based methodology.

4. **Training:** Roles and responsibilities in a review are clear and understood and staff involved have received appropriate training and guidance on the review process.

5. **Timescales:** Review processes should be carried out in accordance with the guidance timescales in the National Framework.

6. **Learning:** from maternity and neonatal reviews should be captured and shared locally and nationally across the Scottish Perinatal Network.

7. **Category 1 Event, Significant Adverse Event Reviews** (SAERs) commissioned are to be reported to HIS via the agreed national notification system process[6] (see Appendix B).

8. **Perinatal Mortality Review Tool** (PMRT) should be used for all perinatal death reviews.

9. NHS Boards should comply with statutory reporting of perinatal deaths to the Procurator Fiscal.

10. Reviews should incorporate and comply with the statutory Duty of Candour[7].

3. Overview of perinatal adverse event review pathway

The HIS National Framework identifies six stages of adverse event management.

1. Risk assessment and prevention
2. Identification and immediate actions following an adverse event, including consideration of duty of candour
3. Initial reporting and notification
4. Assessment and categorisation, including consideration of duty of candour
5. Review and analysis
6. Improvement planning and monitoring

When an adverse event occurs, the HIS Framework outlines the actions that should be taken (Fig 1):

Figure 1: Actions to be taken to effectively manage adverse events

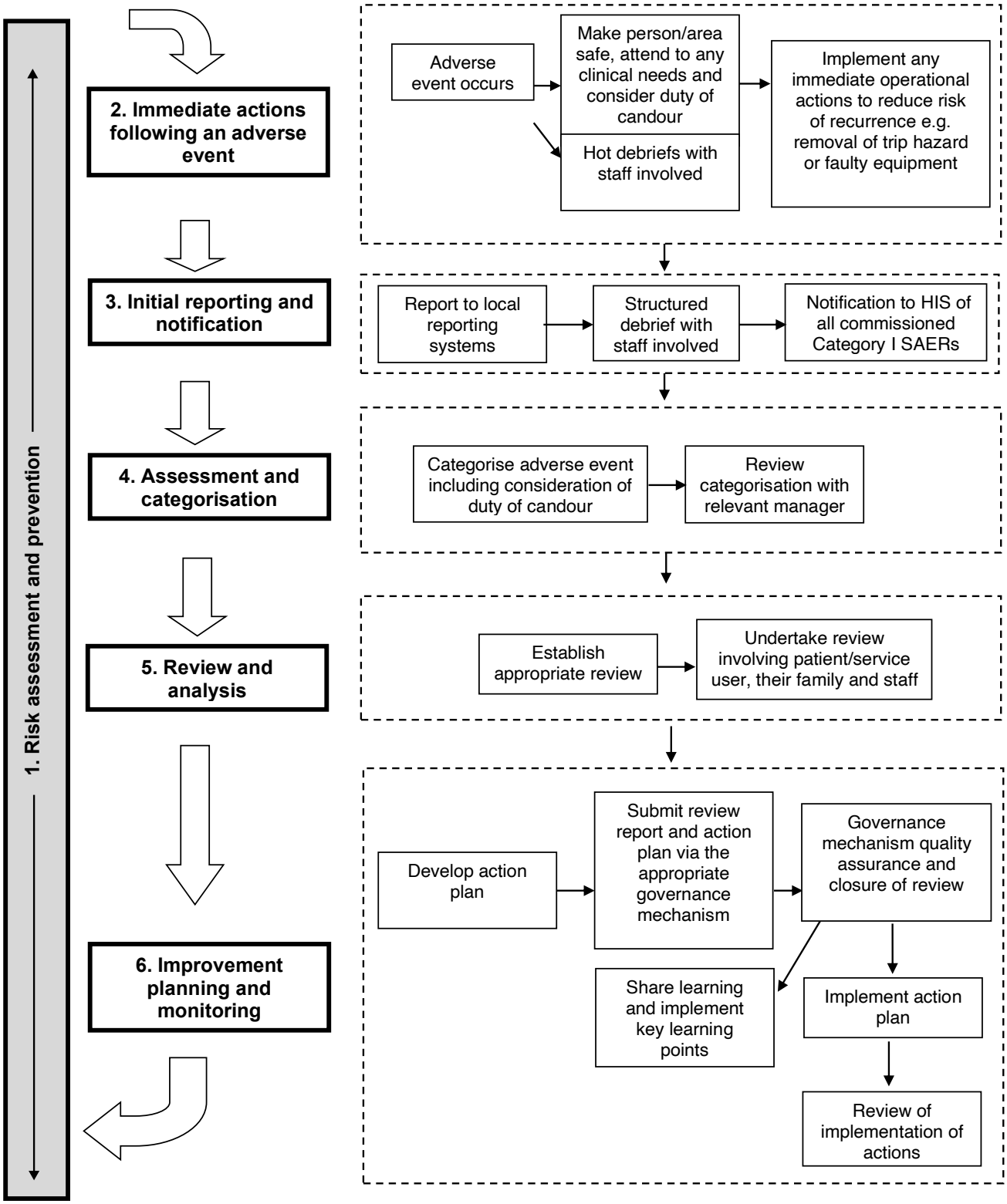


Figure 1: 6 stages of adverse event management

4. National Framework – additional guidance for perinatal services for stages 4-6

Stages 1-3 of the National Framework are standard across all healthcare settings. However for stages 4-6, as a supplement to the National Framework maternity and neonatal services should follow the process outlined below.

A) Stage 4: Assessment and categorisation

At Stage 4 the adverse event is categorised and duty of candour requirements considered.

This is how the National Framework categories of adverse event equate to the type of review required:

Category of Event	Type of Review	Review Team
Category 1	Significant Adverse Event Review (SAER)	Full review team
Category 2	Comprehensive Care Review (CCR) or local management team review	Service manager with multidisciplinary team input
Category 3	Local Review	Managers / staff locally

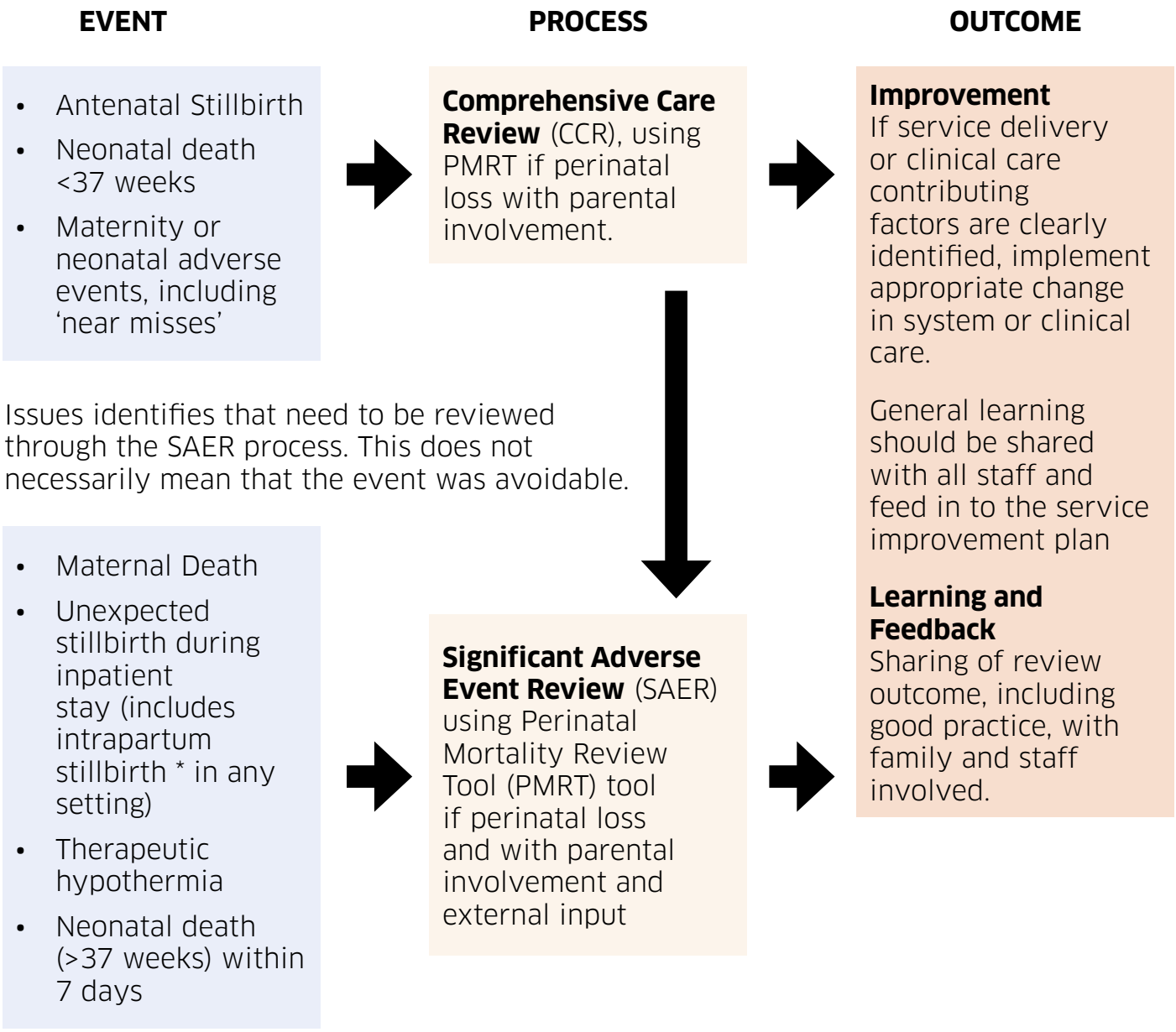
MBRRACE-UK has established a national standardised Perinatal Mortality Review Tool (PMRT) which was launched in early 2018. The PMRT should be used and completed for all stillbirths or neonatal deaths. The process outlined in this guidance is consistent with the PMRT process, and the clinical report and report for parents generated through the PMRT process should be included as part of the Level 1 or 2 review when there is a stillbirth or neonatal death.

Definition of Category 1 Perinatal Significant Adverse Events

A number of national UK reports have defined a core set of perinatal adverse events that should be reported as **Category 1** and have an SAER (e.g. MBRRACE, EBC).

1. Maternal death
2. Neonatal hypoxic-ischaemic encephalopathy (HIE) requiring therapeutic hypothermia
3. Unexpected stillbirth during inpatient stay (includes intrapartum stillbirth in any setting, using Each Baby Counts definition of intrapartum stillbirth – see Appendix C)
4. Unexpected neonatal death (>37 weeks) within 7 days of birth
5. Where triage process or a Comprehensive Care Review (CCR) (Local Management Review) identifies a need for further investigation

All other stillbirths and neonatal deaths are level 2 adverse events. Allocation of a level of review for stillbirths and neonatal deaths will be ascertained through the stage 4 assessment and categorisation process.



* Intrapartum Stillbirth: See Appendix 3

Figure 2: Categories of perinatal event, review process and outcome

Duty of Candour

The Duty of Candour Procedure (Scotland) Regulations 2018 came into force on 1 April 2018. The Regulations place a statutory duty on organisations that provide health, care and social care services to be open and honest when an unintended or unexpected incident occurs that results in death or harm, by following the Duty of Candour Procedure. Guidance has been produced for the organisations that provide health and social care services and other interested parties.

Organisations must now tell those affected, or acting on their behalf, when an unintended or unexpected incident resulting in death or harm has occurred during the provision of health or social care. Organisations must offer a written apology and carry out a review of what happened, fully involving the person who has been harmed, or their representative, at each stage of the process. In a SAER, the Lead Reviewer should consider whether the SAER process meets the requirements of the duty of candour procedure.

B) Stage 5: Review and analysis

At Stage 5, the review itself is established and undertaken, involving the patient/service user, their family and staff. The HIS National Framework provides guidance on methodology of review, reporting and communicating findings.

National Audit Reports (e.g. MBRRACE, PMRT) have made recommendations relating to reviews into maternity and neonatal adverse events. Taking account of these recommendations, maternity and neonatal adverse event reviews and comprehensive care reviews should incorporate the following additional features into their review process.

1. External panel input

1. **SAER: PMRT and MBRRACE**[8] recommend including an independent external member to support robust review. For SAERs in maternity and neonatal care in Scotland that external input should be provided by a clinician from another Health Board. This input could be provided in person or by videoconference.

2. **CCR (LMR)** Recognising the value external input brings to reviews but being cognisant of the manpower required to achieve this with the number of CCRs, it is proposed that one or two professionals external to the Board will review all CCR reports from each Board on a yearly or twice-yearly basis (based on size of Board and number of CCRs).

2. Governance, and operational management of the review process

Health Boards should have a governance process for perinatal adverse events reviews. This process should provide oversight for commissioning, recording of information, closure, completion of action plans, feedback to families and staff and sharing learning. Defined standardised operational processes (SOPs) are needed to support the delivery of the perinatal adverse event review process.

In line with the National Framework, staff roles and responsibilities for the operational process should be clearly defined. The roles should include coordination/administration of the process and a perinatal clinical leadership team.

The diagram below outlines an example of a process map for adverse event management in maternity and neonatal services. *fig3

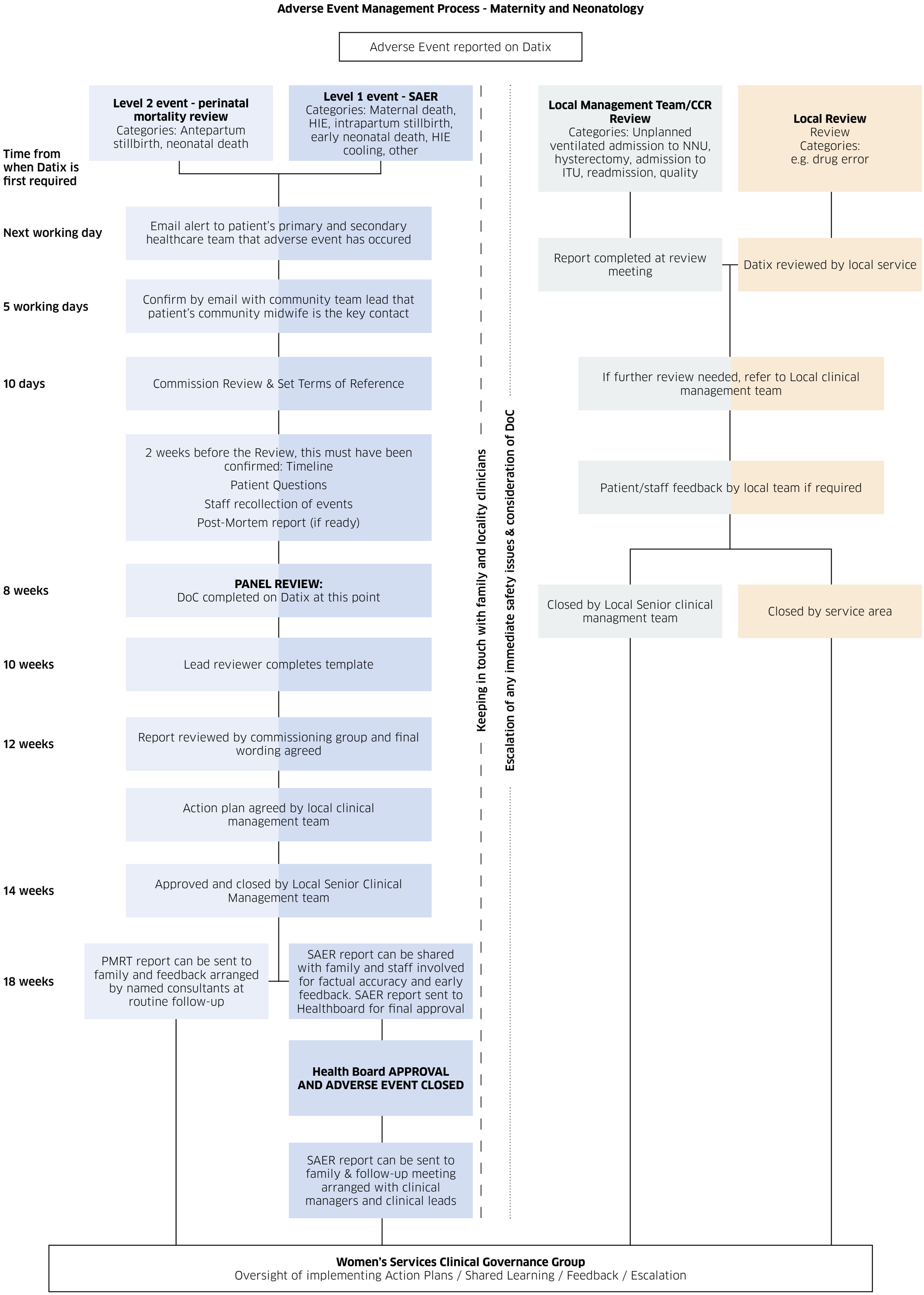


Figure 3 process map for perinatal event reviews

The table below summarises governance and panel composition for different types of review *fig4.

Core Review Team

Governance (including report sign off)	**SAER**	**Perinatal Mortality Review (PMRT)***	**Comprehensive Care Review (local management review)**	**Local Review**
	Category 1 Health Board governance structure	Category 1 or 2	Category 2 Perinatal services management/ clinical governance structures	Category 3 Perinatal services management/ clinical governance structures
Chair	1	1	1	1
Vice-Chair	1	1	X	X
Admin Support / Scribe	1	1	recommended	X
PMRT Champion	1	1	X	X
Obstetrician	2	2	*MDT panel where applicable	*MDT panel where applicable
Midwife	2	2		
Neonatologist / Neo Nurse (for all NND or where resuscitation commenced)	2	2		
Risk Manager / Governance Manager / Service Manager	1	1	1	X
Bereavement Team	1	1	X	X
External Panel Member	1	1	X	X

Service / Clinical Manager	x	x	1	X
Team / Ward Manager	x	x	1	1
Additional Named Members for invitation to PMRT and SAER reviews where applicable				
Pathologist				
Anaesthetist				
GP / Community Healthcare				
Radiographer / Sonographer				
Safeguarding Team Member				
Service Manager				
Any other relevant healthcare professional / team * consider transport team				

*** Review team members may fulfil multiple roles**

*** please note these are minimum expected standards**

Figure 4: review team composition

* PRMT guidance sets out who should be involved in PMRT reviews for stillbirths and neonatal deaths. In practice these reviews may be SAER's or they may be CCRs (local reviews). In either case teams should consider the recommendations of the PMRT guidance when considering membership of the review team.

3. Review analysis and PMRT

As outlined in the HIS National Framework, the panel should use a human factors and systems analysis to review the care and service delivery issues, understanding the dynamic system interactions that contributed to the event, exploring contributory factors, agreeing key issues and organisational duty of candour, capturing lessons learned and making recommendations. A report of the review findings should be sent to local clinical management and an organisational governance group.

In addition to the review process, for stillbirths and neonatal deaths, clinical teams should also complete the Perinatal Mortality Review Tool (the PMRT). This tool has been designed with user and parent involvement to support high-quality standardised perinatal mortality reviews on the principle of 'review once, review well'. The tool should be used as part of the review process for stillbirths and neonatal deaths.

4. Involving women and families in the SAER process

When families have been affected by an adverse event this can have lasting psychological consequences, and is often distressing for the professionals involved[9] [10]. Improving communication when discussing adverse events supports families' emotional adjustment, helps staff cope better with the after-effects of what has happened, and provides learning for improving performance and quality in the delivery of family-centred care[11].

The principles underpinning learning from adverse events and involving families in reviews are described within the National Framework. In addition to this, HIS have published Being Open In NHS Scotland - Guidance on implementing the Being Open principles[12] and the Scottish Government have published Organisational Duty of Candour Guidance, both of which underpin the National Framework for Scotland. In addition a number of national reports into maternity and neonatal services have made recommendations about involving families in adverse event reviews[13] [14].

Being Open provides a best practice framework for all healthcare organisations to create an environment where patients, their families, healthcare professionals and managers all feel supported when an adverse event occurs and have the confidence to act appropriately. Guidance on applying the Being Open principles and in communicating in a supportive and effective way with families and staff has been produced by HIS and can be accessed below the following link: 'Effective Communication about Adverse Events in Maternity Units - A guide to talking with parents, families and staff' [15].

MBRRACE-UK has developed parent engagement pathway materials through a multi-disciplinary group within the MBRRACE-UK/PMRT collaboration including bereaved parents and are based on the findings from the PARENTS study and the 'Being Open' process: Parent Engagement Materials[16].

These are the key learning points from testing a process to involve patients and families in the review (in line with the stages of adverse event management in HIS Framework) *fig 5

Steps	Goal	Process	Staff	When	Form
Allocate a key contact for the family	Helps the family manage and deal with distress from the event by reducing uncertainty, providing continuity, being open and honest and providing an apology	A single key contact person should be identified for the family throughout the review process (ideally this would be the woman's primary midwife)	Staff coordinating the review process	The key contact should be identified as soon as possible and no later than the 10-day timeline for commissioning	Email to community midwife team to confirm who will be the key contact
Discussing the review process with the family and how they can be involved		1. Explain how the review of their care will be carried out 2. invite them to be involved 3. provide them with written information about the review process and how they will be kept informed during the review, when and by whom 4. outline the role of the key contact and introduce them if they are present 5. note any early questions that the family have 6. apologise for any harm caused	Senior clinician and midwife or nurse	Ideally before discharge or within 7 days of adverse event	Face-to-face meeting
Ongoing involvement of patient with review		The key contact should offer to help a woman and families describe and document their thoughts, concerns and questions about the adverse event - these should be submitted in time for the review	Key contact, or any other healthcare professional the family shares questions with	Up until the panel review	Patient meeting, email, phone
Ongoing involvement of patient with review		The team responsible for the review should keep in touch with the family letting them about the progress of the review, when it has been completed and is ready to be shared with them	Risk team	Until review process is completed	Letter/ phone call
Sharing review findings		The clinical management team should offer to send the report, considering timescales relevant to individual circumstance	Clinical management team, clinical leads	When report is closed	Patient meeting

Figure 5: involving families in the review

5. Supporting staff training and wellbeing

Staff leading adverse event reviews should have training and be competent in investigative methodologies, techniques and analysis, including human factors and report writing, and protected time to take part. Individuals who feed back to families should be trained in effective communication in the management of adverse events.

In addition to bespoke staff training provided by NHS Boards, NHS Education for Scotland provide a suite of three workshops designed to provide NHS staff involved in investigation work, and those in leadership/management positions, with the skills required. These include training on learning from safety incidents in complex care environments, building a safety culture and other associated areas. Further details are available on the NES website[17]. NES can provide the package of these workshops in a combined bespoke half-day session[18].

NES also has an e-learning resource[19] for enhanced significant event analysis and entry-level Human Factors.

Staff involved in any adverse event process may need addition wellbeing support. It is therefore important that management ensure that appropriate measures are in place to support the wellbeing of the individuals throughout the adverse event review process.

6. Child Death Review Process

The Scottish Government are also developing a Child Death Review system, which ensure that a high quality consistent review is carried out into all child deaths (all live born children up to the age of 18 or 26 for care leavers or those in receipt of aftercare or continuing care at the time of their death). The Child Death Review system will include all neonatal deaths including those that require either a Significant Adverse Event Review or a Comprehensive Care Review. The Child Death Review process will complement the process described in this framework and there will be no requirement to undertake any additional investigation or review. The review process will include the information required to complete the Child Death Review core data set which will be collected for all deaths. Further information can be found here.

C) Stage 6: Improvement planning

Capturing and sharing learning from adverse events and CCRs

The HIS National SAER Framework aims to ensure any staff involved are supported in a consistent manner, events are reviewed in a consistent way, and learning is captured and shared locally and nationally to improve the quality of services. Events subject to Perinatal Mortality Review should also follow national PMRT guidance.

Current position

Currently, following an SAER in any service, colleagues can access a generic Learning Summary Template and Guidance at an Online Community of Practice on Knowledge Network. Following a review process, Boards are responsible for uploading their own Learning Summaries directly to the site, in order that other services or Boards may review findings and potentially share in any learning. Whether or when to share learning in this manner is at the discretion of each Board and relies on positive engagement.

There is no forum available for post-SAER learning activities relating specifically to maternity, neonatal or perinatal communities.

Improvement Planning

The templates and Online Community of Practice are currently under review and will cease in March 2022. They will be replaced with an improved approach developed through a Joint Commission for Openness and Learning between HIS & NHS Education Scotland (NES).

There is ongoing discussion with the clinical community exploring the best ways to share learning at a local level and with HIS and the Scottish Perinatal Network (SPN) about sharing at a national level.

Supporting this Perinatal Adverse Event Review Guidance

The SPN will support the perinatal community to implement this guidance, in collaboration with strategic partners such as NES and HIS – including its Adverse Events Network and (the) Maternity and Children Quality Improvement Collaborative (MCQIC), which is part of the Scottish Patient Safety Programme (SPSP). The SPN will:

- Develop a ‘safe space’ learning forum on MS Teams and a corresponding ‘collaboration space’
- Facilitate regular case review events at which Boards can present, discuss and share learning (quarterly or six-monthly)
- Facilitate tailored learning opportunities, as requested, following particular incidents or events.
- Develop a process to ‘buddy-up’ smaller with larger Boards for peer support and to add structure to request for external reviewers.
- Establish a perinatal SAERs working group through which to support implementation of the framework, provide support, and share learning and best practice.

Reporting deaths to the Procurator Fiscal

Boards must continue to comply with statutory reporting of perinatal deaths. Any category 1 stillbirth or neonatal death should be reported to the Procurator Fiscal's Scottish Fatalities Investigation Unit (SFIU) as soon as possible following a decision to carry out an SAER. It is accepted that events which go immediately to SAER will be reported sooner than events which undergo CCR first and are subsequently escalated to a level 1 review.

Where the Procurator Fiscal decides to investigate a death, if parents have not authorised a hospital post mortem, it is likely that SFIU will instruct one. Further details are available through the Crown Office and Procurator Fiscal Service (Reporting Deaths to the Procurator Fiscal, Information and Guidance for Medical Practitioners):

Reporting Deaths to the Procurator Fiscal[20]

Appendix A
Perinatal mortality review tool

The PMRT tool will support:

- systematic, multidisciplinary, high quality reviews of the circumstances and care leading up to and surrounding each stillbirth and neonatal death ensuring that the care of babies who die in the post-neonatal period in neonatal units can also be reviewed using the PMRT;
- active communication with parents to ensure they are told that a review of their care and that of their baby will be carried out and how they can contribute to the process;
- a structured process of review, learning, reporting and actions to improve future care;
- coming to a clear understanding of why each baby died if possible, accepting that this may not always be possible even when full clinical investigations have been undertaken; (this will involve a grading of the care provided);
- production of a report for parents of why their baby died and whether, with different actions, the death of their baby might have been prevented;
- other reports from the tool which will enable organisations providing and commissioning care to identify emerging themes across a number of deaths to support learning and changes in the delivery of care to improve future care and prevent the future deaths which are avoidable;
- production of national reports of the themes and trends associated with perinatal deaths to enable national lessons to be learned from the nationwide system of reviews.

PMRT Review Group

Core Group*

Roles within group:

- Chair and Vice-Chair
- Scribe/IT/Admin Support
- PMRT Champion

Minimum of 2 of each of the following:

- Obstetrician
- Midwife
- Neonatologist and Neonatal Nurse
  - All cases where resuscitation was commenced
  - All neonatal deaths
- Risk manager/governance team member (1 acceptable) e.g. service manager
- Bereavement team (1 acceptable)
- External panel member (1 acceptable)

* Group members can fulfil multiple roles

Additional Members

Named and invited to attend or contribute where applicable:

- Pathologist – when a PM was performed
- GP/Community Healthcare
- Anaesthetist
- Sonographer/Radiographer
- Safeguarding team
- Service manager
- Any other relevant healthcare team members pertinent to case

All opinions and views are equal, facilitate a breadth of discussion

Appendix B
National notification system for SAER

National Notification System for Category 1 Events

Two Stage Data Submission

Initial notification: date the decision is made to commission an SAER → **Learning and outcomes: outcome of the event after review completion**

Stage 1	
Initial notification system	
Data	**Definition/ explanation**
Month/year	Notification month and year i.e. Jan 2020
Unique identifier	Datix number or other identifier from local board incident reporting system
Date SAER commisioned	Date decision made to progress to SAER
Category of event	Free text summarising the type of event e.g. suicide and medicines
Subcategory of event	Further detail and context of event I.e. unexpected death: suicide or sepsis. If device involved please specify the device.
Speciality related to event	Area of speciality if relevant (free text)i.e. mental health, obstetrics, gyneaecology, surgery
*****Please ensure no patient identifiable data is sent to HIS*****	

Stage 2	
Learning and outcomes	
Data	**Definition/ explanation**
Date review completed	Date final sign off by appropriate governance group
Main learning points	TBD
Review outcome of event	Refer to Appendix 1, and grade outcome code accordingly
confirmed category of event	Confirmation/ correction of category following SAER
*****Please ensure no patient identifiable data is sent to HIS*****	

Appendix C
Each Baby Counts definition of intrapartum stillbirth

Definition:

Intrapartum stillbirth: when the baby was thought to be alive* at the start of labour but was born with no signs of life†. This includes when:

- labour was diagnosed by a healthcare professional. This includes the latent phase of labour, i.e. less than 4cm dilatation;
- the mother called the unit to report any concerns of being in labour, for example (but not limited to) abdominal pains, contractions or suspected ruptured membranes;
- the baby was thought to be alive at induction of labour;
- the baby was thought to be alive following suspected or confirmed premature rupture of membranes (PROM).

Notes:

* As assessed by any means, including but not limited to: pinard stethoscope, handheld Doppler, CTG, bedside ultrasound, assessment of fetal movements, or assumed to be alive without confirmation.

† Excludes babies that clearly died before labour (macerated stillbirth) if confirmed by post mortem.

Appendix D
Abbreviations

MBRRACE:	Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries
PMRT:	Perinatal Mortality Review Tool
SAER:	Serious Adverse Event Review
CCR:	Comprehensive Care Review
SOP:	Standard Operating Procedure
NES:	NHS Education for Scotland
SFIU:	Scottish Fatalities Investigation Unit

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This publication is available at **www.gov.scot**

Any enquiries regarding this publication should be sent to us at
The Scottish Government
St Andrew's House
Edinburgh
EH1 3DG

ISBN: 978-1-80201-305-4 (web only)

Published by The Scottish Government, September 2021

Produced for The Scottish Government by APS Group Scotland, 21 Tennant Street, Edinburgh EH6 5NA
PPDAS927286 (09/21)