Review of Ayrshire Maternity Unit, University Hospital Crosshouse, NHS Ayrshire & Arran (Adverse Events)

June 2017
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Foreword

This is the third report produced by Healthcare Improvement Scotland at the request of the Scottish Government relating to the management of adverse events within NHS Ayrshire & Arran. This report specifically focuses on the management of adverse events in the Ayrshire Maternity Unit at University Hospital Crosshouse following public concerns raised initially by a number of local families.

It was essential to listen to the families who approached Healthcare Improvement Scotland to try and fully understand what these ongoing concerns are, to make sure that those concerns within the remit of the review were explored (thus enabling learning and changes in practice to avoid similar events happening again), and to provide reassurance to the public about NHS Ayrshire & Arran’s management of adverse events. It was very sad to hear from families devastated by the death of their baby around the time of birth, and I thank them for having the strength to come and talk to us. Their narratives gave us insights we otherwise would not have had and strengthened the review by enabling us to explore specific areas with the staff at University Hospital Crosshouse.

I would also like to thank the staff of NHS Ayrshire & Arran for participating actively in the review, for responding to our numerous requests for further information and clarity, and for talking openly and honestly with us. It was clear how difficult the constant scrutiny with repeated reviews, as well as the ongoing adverse publicity, is for the staff within the maternity unit. We found them to be a cohesive and highly motivated team with strong leadership, committed to providing high quality care to those they look after, and their resilience is to be commended. We saw some excellent examples of learning and improvement, but also saw that their achievements are not openly shared with the public. We felt that the staff members within the maternity unit were doing their best within a system that requires improvement and investment, some of which is already under way.

There are lessons to be learned from this review, not just for NHS Ayrshire & Arran but for Scotland as a whole, and these lessons should be embraced as ways to learn and improve care, with the aim of reducing avoidable harm and death. It must be remembered, however, that even when care is of the highest standard, unfortunately death or harm can still occur, and it is vital that families are given a full explanation of the circumstances surrounding the events which led to their baby’s serious illness or death. In moving forwards, thought must be given to developing a system that will allow direct involvement of parents in the investigatory process. Only with full engagement with the families will come full understanding, allowing them to feel all their questions have been answered and enabling them to come to terms with what happened to them.

Dr Tracey Johnston
Consultant Obstetrician
Birmingham Women’s and Children’s NHS Foundation Trust
Executive summary

In 2016, Healthcare Improvement Scotland was asked by the Scottish Government to undertake an independent review focusing on the Ayrshire Maternity Unit at University Hospital Crosshouse, NHS Ayrshire & Arran. This review was prompted by concerns raised by some families who believed that failures had occurred relating to the care they received at the Ayrshire Maternity Unit and in the management of the subsequent review of their care within the Ayrshire Maternity Unit.

The review considered aspects of the quality of care offered to mothers and babies in the Ayrshire Maternity Unit. It specifically focused on the way in which adverse events are managed and how the organisation learns lessons with a view to improving care for women and their babies. An important aspect of this review included an invitation to meet with families who had raised concerns about the quality of care they received.

Healthcare Improvement Scotland has previously carried out two reviews of adverse event management at NHS Ayrshire & Arran: in June 2012, which was then followed up in December 2013. The remit of this current review has therefore looked specifically at the time period from December 2013 onwards and seeks to understand what progress and changes have been made since earlier reports were produced. Similarly, it seeks to highlight where there is a need for further action.

An essential aspect of this review process was to hear from people who wanted to share their experiences of the Ayrshire Maternity Unit. We invited any member of the public who wanted to share their experiences of the unit to contact us regardless of when these experiences took place. We understand how difficult it was for people to share their experiences and we would like to thank them as the stories they shared were invaluable in helping to inform this review.

Membership of the multidisciplinary review team is detailed in Appendix 1.

The review team also met with staff at all levels of the organisation and conducted a visit over two days to University Hospital Crosshouse on Wednesday 1 March and Friday 3 March 2017. In total, 35 members of staff spoke directly with the review team.

At the same time, a clinical case review into specific cases has been conducted by a multidisciplinary panel of clinical experts from the University of Leicester using the methodology developed for Mother and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK). The results from the panel have been presented and summarised in a report for the NHS board. This clinical case review was commissioned by NHS Ayrshire & Arran and the results of this were considered by the Healthcare Improvement Scotland review team.
Healthcare Improvement Scotland key findings

- The NHS Ayrshire & Arran Significant Adverse Event Review (SAER) process was not used for significant adverse events in the maternity unit. The maternity unit circumvented deficiencies in the NHS board’s adverse event management policy in order to maximise local clinical engagement in reviews. The review team believes that this is indicative of the need to strengthen the wider organisational adverse event process.

- The adverse event documentation, within the initial assessment process, is not consistently completed and fails to provide clear rationale for deciding the level of adverse event review required.

- Once the event has been initially reported, there was uncertainty amongst maternity unit staff regarding the appropriate local and board level process to follow in response to an adverse event.

- NHS Ayrshire & Arran has carried out a very small number of SAERs using its established and published process.

- There was not a standardised or consistent approach to undertaking Directorate Adverse Event Reviews (DAERs) within the maternity unit.

- Adverse event action plan documentation was incomplete and with insufficient evidence relating to recommendations and follow-up.

- The learning and actions from SAERs undertaken through the DAER process did not, routinely, come to the attention of the NHS board’s Healthcare Governance Committee.

- A major challenge to supporting improvement initiatives (within the maternity unit) is the availability of protected staff time.

- The publication of redacted SAER reports on the NHS Ayrshire & Arran website does not encourage shared learning.

- The review team was presented with several examples of high quality audit and quality improvement initiatives completed within the maternity unit from 2013 onwards.

- The family experiences highlighted the importance of NHS boards engaging with families in line with the Learning from Adverse Events through Reporting and Review: A National Framework for Scotland' (referred to as the National Framework).

- The importance of continual training and education and that the local training programme for staff should also be used as a mechanism to share and embed learning from adverse event reviews, allowing real-time implementation of improvements in practice.

- There is low uptake of important training and development specifically for maternity unit staff.
Recommendations

While this review focused on the adverse event management processes within the Ayrshire Maternity Unit, the findings, conclusions and recommendations should be, where appropriate, applied across the organisation and more widely across other NHS boards in Scotland.

Recommendations for NHS Ayrshire & Arran

Recommendation 1: Strengthen the process

The NHS board must strengthen its current adverse event management policy to make sure it adheres to the National Framework and provides useful and practical processes that can be quickly and simply followed. This should include reference to/ further guidance on:

- clinical engagement in reviews, completion of documentation, the level of review and analysis required based on adverse event category, and the improvement planning and monitoring arrangements for reviews,
- taking advice from other NHSScotland boards to find practical ways of implementation, and
- involving clinicians from across the organisation, including maternity services, in its development.

The revised adverse event management policy must provide information for families about stillbirth, neonatal death and adverse events that communicates accurate, clear and consistent messages about the type of review that is being undertaken. This should aim to avoid any additional distress by raising uncertainty about the type of review that is being conducted.

Recommendation 2: Improve family engagement

NHS Ayrshire & Arran must make sure that families are provided with appropriate information, support and opportunities to enable them to be involved in any significant adverse event process, in line with the National Framework. This should include:

- reference to, and implementation of, the guidance from the Being Open NHSScotland 2015 document – this document provides support for NHS boards when developing policy and procedures around communication and engagement
- opportunities for staff to have communication training to support Being Open, and
- further opportunities for those families that have come forward through this review process to discuss their experiences with NHS Ayrshire & Arran and to make sure that any remaining questions are answered*.
*This part of the recommendation was discussed with the NHS board ahead of the report being published for those families who expressed a desire to meet again with the NHS board. At the time of publication, some of these families had already met with representatives of NHS Ayrshire & Arran.

**Recommendation 3: Support for staff**

NHS Ayrshire & Arran staff must be adequately supported to be involved in the management of adverse events across the maternity unit. This support must include:

- dedicated and protected time for staff to be involved in all aspects of adverse event reviews,
- appropriate support to undertake the review process, including co-ordination and administrative support, and
- training in adverse event reviews for those taking part in this process.

**Recommendation 4: Promote shared learning**

NHS Ayrshire & Arran should promote, internally and externally, the changes and learning resulting from their improvement work, including the publication of learning summaries of adverse event reviews. The learning summaries should:

- be shared with staff, patients, families and carers and published on the Adverse Events Community of Practice website\(^1\)
- include a summary of what happened, the learning gained, improvement work taken forward and resultant service improvements, and
- be considered as a mechanism for sharing examples of positive outcomes from improvement work taken forward following adverse event reviews to benefit services across NHSScotland.

**Recommendation 5: Stop publishing redacted SAER reports**

NHS Ayrshire & Arran should stop publishing redacted SAER reports on its website as these reports do not encourage shared learning and risk breaching patient and family confidentiality. Instead, NHS Ayrshire & Arran should publish learning summaries, as per recommendation 4.

**Recommendation 6: Improve staff training and education**

NHS Ayrshire & Arran must make sure that the training and development needs of staff are identified and met in a timely manner. This should include:
• producing a training needs analysis
• ensuring access to training programmes, and
• monitoring attendance at training.

Recommendations for NHSScotland and Healthcare Improvement Scotland

Recommendation 7: Identify training needs across NHSScotland

NHSScotland should develop and agree a list of mandatory skills and competencies for maternity services to support ongoing training programmes in NHS boards. This process should include how NHS boards can be supported to implement and monitor their training programmes.

Recommendation 8: Take forward national learning

Healthcare Improvement Scotland should review the findings, conclusions and recommendations in this report to support further development and implementation of the National Framework as well as external quality assurance under the Quality of Care approach3.
Section 1: Background to this review

About this review

1. Healthcare Improvement Scotland was asked, in 2016, by the Scottish Government to undertake an independent review focusing on the Ayrshire Maternity Unit at University Hospital Crosshouse, NHS Ayrshire & Arran. This review was prompted by concerns raised by some families who believed that failures had occurred relating to the care they received at the Ayrshire Maternity Unit and in the management of the subsequent review of their care.

2. The review considered aspects of the quality of care offered to mothers and babies in the Ayrshire Maternity Unit. It specifically focused on the way in which adverse events are managed and how the organisation learns lessons with a view to improving care for women and their babies. An important aspect of this review included an invitation to meet with families who had raised concerns about the quality of care they received.

3. The review looked specifically at the time period between December 2013 and present day. This timescale took account of the previous review of adverse event management that Healthcare Improvement Scotland carried out at NHS Ayrshire & Arran in June 2012 and then followed up and reported in December 2013. The review did not include any further assessment of the adverse event process prior to December 2013 as this had already been reviewed and recommendations made in these previous reports. The remit of the current review was to understand what progress and changes have been made since these earlier reports.

4. This review was carried out by a multidisciplinary team (Appendix 1) of individuals with a wide breadth and depth of knowledge and experience. The review team, appointed by Healthcare Improvement Scotland, included representatives from NHSScotland as well as colleagues working in the NHS in England. The review team gathered evidence for the review by:
   - listening to bereaved families who shared their experiences at the Ayrshire Maternity Unit, University Hospital Crosshouse
   - reviewing documentation, including policies and procedures, pertaining to the maternity unit
   - assessing maternity specific governance mechanisms
   - analysing data and statistics relating to the maternity unit in NHS Ayrshire & Arran, as well as NHSScotland
   - interviewing key staff in NHS Ayrshire & Arran
   - holding drop-in sessions open to all NHS Ayrshire & Arran staff, and
   - providing access to a confidential email address for staff to contact the team.

5. The review team conducted a series of regular teleconferences to discuss and analyse the information that had been gathered. These meetings allowed the team to agree key areas of focus and key lines of enquiry for the review team to follow. A visit to NHS Ayrshire & Arran was conducted over two days: Wednesday 1 March (with a selection of the review team members present) and Friday 3 March, where the whole review
team attended at University Hospital Crosshouse. The review team met with a range of staff over both days.

6. The review visit was structured so that the team could meet with staff at all levels of the organisation at different times, and independent of each other. The review team also held drop-in sessions and carried out walk-rounds to clinical areas in order to speak with as many frontline staff as possible. In total, 35 members of staff spoke directly with members of the review team, including midwives, obstetricians, neonatologists, neonatal nurses and senior management. A confidential email address was created so staff could email privately with any issues they wished to raise or experiences they wished to share. The review team would like to thank the NHS board and its staff for supporting and assisting the team during this review.

7. In response to the concerns that had been raised, NHS Ayrshire & Arran independently commissioned a clinical case review into specific cases, conducted by a multidisciplinary panel of clinical experts using the methodology developed by MBRRACE-UK. The aim of this review was to help inform the local quality processes and to support the development of a comprehensive picture. An extract of the clinical case review report is provided in Appendix 2.

**Context and data**

8. An adverse event is defined as an event that could have caused (a near miss), or did result in, harm to people or groups of people. Harm is defined as an outcome with a negative effect. Harm to a person or groups of people may result from unexpected worsening of a medical condition, the inherent risk of an investigation or treatment, violence and aggression, system failure, provider performance issues, service disruption, financial loss or adverse publicity.

9. Not all harm is avoidable, for example the worsening of a medical condition or the inherent risk of treatment. However, it is often not possible to determine if the harm caused was avoidable until a review is carried out and often areas for improvement are identified even when harm is not avoidable.

10. The term ‘expected death’ is used to indicate if a stillbirth or neonatal death was likely to occur. There are many babies who are stillborn or die in the neonatal period because of known underlying conditions or complications of pregnancy. In some cases of stillbirth, the cause of death is unknown, even after a thorough pathological examination of the baby and the placenta. In the majority of cases of neonatal deaths, the cause of the death is due to premature delivery or a congenital abnormality which is life-limiting. The presumption that a stillbirth or neonatal death will be due to a failure of care is not accurate.

11. The term ‘avoidable death’ is used if the stillbirth or death of a baby could have been prevented if the care had been different. The term ‘avoidable’ should be restricted to the specific context of an adverse event review; otherwise families may suffer unnecessary distress thinking that the death of their baby was avoidable.

12. In June 2015, MBRRACE published a national report of perinatal mortality statistics from January to December 2013. To enable comparisons, the rates are stabilised (to
allow for effects of chance variation due to small numbers) and adjusted for maternal age, socio-economic deprivation based on mother’s residence, baby’s ethnicity and sex, multiple births and in the case of neonatal deaths for gestation age. Under all these headings, NHS Ayrshire & Arran was more than 10% higher than the UK average. A supplementary report published in December 2015, which enabled comparison against similar types of unit, again demonstrated that NHS Ayrshire & Arran had rates more than 10% higher than the average for the comparator group, across the UK (a red rating).

13. For the purposes of context, other factors that are not routinely collected (and therefore not adjusted for in the MBRRACE reports to enable fairer comparison) can also influence perinatal mortality. For example, NHS Ayrshire & Arran records the highest rate of women smoking during pregnancy, which is known to be associated with an increased risk of perinatal mortality, of any NHS board in Scotland during the period 2012–2013 to 2014–2015.

14. However, the relatively small numbers of stillbirths and neonatal deaths in one year in an individual NHS board suggest that variations from year to year are heavily influenced by the effect of chance and are therefore not generally statistically significant. The effect is mitigated to some extent by aggregating years. When the stillbirth and neonatal death rates for NHS Ayrshire & Arran are aggregated for the years 2011 to 2015 they are both below 2 standard deviations and are therefore not statistically significant.

15. The subsequent MBRRACE report published in May 2016⁴, covering the period January to December 2014, showed an improvement for NHS Ayrshire & Arran, with their figures now being up to 10% higher (an amber rating). The most recent MBRRACE report, published in June 2017, covering the period January to December 2015, shows continued improvement in NHS Ayrshire & Arran, with their figures now being up to 10% better than the UK average (a yellow rating). This demonstrates externally validated year on year improvement since 2013⁵.

16. When assessing socio-demographic data for Scotland, 36% of women who gave birth in NHS Ayrshire & Arran between 2011 and 2015 were in the most deprived quintile of the Scottish Index of Multiple Deprivation (SIMD). This compares with 26% of all women who gave birth in Scotland between 2011 and 2015. Table 1 below shows the numbers and rates of stillbirth and neonatal deaths in NHS Ayrshire & Arran 2011-15 taken from the National Records Scotland.
Table 1: Numbers and rates of stillbirth and neonatal deaths in NHS Ayrshire & Arran 2011-15 (National Record Scotland)

<table>
<thead>
<tr>
<th>Year</th>
<th>All births</th>
<th>Stillbirths</th>
<th>Stillbirths per 1,000 births</th>
<th>Live births</th>
<th>Neonatal deaths</th>
<th>Neonatal deaths per 1,000 live births</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>3,816</td>
<td>15</td>
<td>3.9</td>
<td>3801</td>
<td>7</td>
<td>1.8</td>
</tr>
<tr>
<td>2012</td>
<td>3,619</td>
<td>19</td>
<td>5.3</td>
<td>3600</td>
<td>10</td>
<td>2.8</td>
</tr>
<tr>
<td>2013</td>
<td>3,592</td>
<td>26</td>
<td>7.2</td>
<td>3566</td>
<td>11</td>
<td>3.1</td>
</tr>
<tr>
<td>2014</td>
<td>3,526</td>
<td>21</td>
<td>6.0</td>
<td>3505</td>
<td>5</td>
<td>1.4</td>
</tr>
<tr>
<td>2015</td>
<td>3,521</td>
<td>15</td>
<td>4.3</td>
<td>3506</td>
<td>6</td>
<td>1.7</td>
</tr>
</tbody>
</table>

Source: National Records Scotland

17. Table 2 below shows the rates of stillbirths and neonatal deaths (per 1000 births) for University Hospital Crosshouse compared with the Scottish average.

Table 2: Rates of stillbirth and neonatal deaths 2011-15 –University Hospital Crosshouse and Scottish average (National Records Scotland)

<table>
<thead>
<tr>
<th>Year</th>
<th>Stillbirths</th>
<th>Neonatal deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>University Hospital Crosshouse</td>
<td>3.9</td>
</tr>
<tr>
<td></td>
<td>Scottish Average</td>
<td>5.1</td>
</tr>
<tr>
<td>2012</td>
<td>University Hospital Crosshouse</td>
<td>5.3</td>
</tr>
<tr>
<td></td>
<td>Scottish Average</td>
<td>4.7</td>
</tr>
<tr>
<td>2013</td>
<td>University Hospital Crosshouse</td>
<td>7.2</td>
</tr>
<tr>
<td></td>
<td>Scottish Average</td>
<td>4.2</td>
</tr>
<tr>
<td>2014</td>
<td>University Hospital Crosshouse</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>Scottish Average</td>
<td>4.0</td>
</tr>
<tr>
<td>2015</td>
<td>University Hospital Crosshouse</td>
<td>4.3</td>
</tr>
<tr>
<td></td>
<td>Scottish Average</td>
<td>3.8</td>
</tr>
</tbody>
</table>

Source: National Records Scotland

18. Following publication of the MBRRACE-UK (2016) perinatal surveillance report, NHS Ayrshire & Arran commissioned a local review on perinatal mortality rates for the local authority areas of North Ayrshire, South Ayrshire and East Ayrshire.

19. The local review was conducted by two external consultants: a Local Supervising Authority Midwife, and a Consultant Obstetrician and Gynecologist, who were approached by NHS Ayrshire & Arran in response to the MBRRACE-UK (2016) report. The reviewers visited Ayrshire Maternity Unit, University Hospital Crosshouse and Community Midwifery Team bases throughout June, July and August 2016. The main element of the review process involved conducting confidential and anonymous interviews with a range of healthcare professionals and support staff within or associated with the maternity services. A review report was delivered to the Board in October 2016 concluding that: “The overall quality of care delivered to pregnant women and their babies in NHS Ayrshire & Arran was considered to be of a high standard.” However, the report highlighted that insufficient staffing levels and inadequate resources were challenges which the NHS board faces.

20. The local review report made nine recommendations, including points relating to service provision, midwifery staffing and a dedicated maternity clinical risk resource (in
the form of a clinical risk midwife). The NHS board developed an action plan following publication of the report to identify the work required to take these recommendations forward. The NHS board provided a progress update against these actions, dated April 2017. This highlighted that progress had been made against each of the nine recommendations. Examples of this progress include the following.

- The NHS board’s request for funding to expand its radiology imaging services and secure two full-time sonographer posts for maternity services had been approved and released to NHS Ayrshire & Arran in July 2016.
- Funding was agreed for 6.6 whole time equivalent (wte) midwife posts in April 2016, which were subsequently recruited. In March 2017, this was progressed to securing further funding for 10.7wte midwife posts, recruitment for which is ongoing.
- Recruitment for a dedicated maternity clinical risk midwife began in May 2017.
Section 2: The National Framework for the management of adverse events in NHSScotland

Background

21. The review of NHS Ayrshire & Arran in 2012 led to the publication in September 2013 of the National Framework. The publication was accompanied by Scottish Government guidance setting out expectations for NHS boards (CEL 2013 203).


23. The framework provides definitions, tools and supporting documentation based on a framework of six steps to manage an adverse event (Appendix 3). The framework sets out six steps:

   - Risk assessment and prevention
   - Identification and immediate actions following an adverse event
   - Initial reporting and notification
   - Assessment and categorisation
   - Review and analysis
   - Improvement planning and monitoring

24. The framework states that organisations need to build their own local procedures to support the implementation of this nationally defined process.

Essential elements of the national adverse event review framework

25. The National Framework states that no matter where an adverse event occurs in Scotland:

   - the affected person receives the same high quality response
   - any staff involved are treated in a consistent manner
   - the event is reviewed in a similar way, and
   - learning is shared and implemented across the organisation and more widely to improve the quality of services.

26. A key concern arising from the review of NHS Ayrshire & Arran in 2012 was the lack of transparency in relation to the sharing of learning from adverse events.

27. The National Framework makes it clear that: “The process must be transparent and include all those involved in the adverse event: patients, service users, families and carers, and staff. To support this, SAER reports should be shared with everyone.
involved in the event, and a one-page learning summary completed and published in order to share key learning points more widely”. This is a core aspect of this review.

**Principles from the National Framework**

**Emphasis on learning and promoting best practice across Scotland** – the system is focused on learning, locally and nationally, and makes extensive use of improvement methodology to test and implement the necessary changes. Near misses are reviewed regularly to promote learning and system improvements.

**System approach** – adverse events act as a ‘window’ on the care system allowing a systems analysis. This is important to allow a reflection on the weaknesses of the system, or in the case of near misses, the strengths, and prevent future events.

**Openness about failures** – errors are identified, reported and managed in a timely manner, and patients, service users and their families are told what went wrong and why. Reviews of events happen frequently and quickly following their occurrence. We expect adverse event reporting to increase as we move to a more open culture.

**Just culture** – individuals are treated fairly. Organisational culture is based upon the values of trust, openness, equality and diversity which encourages and supports staff to recognise, report and learn from adverse events.

**Positive safety culture** – avoidance, prevention and mitigation of risks is part of the organisation’s approach and attitude to all its activities and is recognised at all levels of the organisation. Decisions relating to the management of adverse events are risk based, informed and transparent to allow an appropriate level of scrutiny.

**Personal, professional and organisational accountability** – everyone is responsible for taking action to prevent adverse events, including speaking up when they see practice that endangers safety, in line with the organisation’s whistle-blowing policy. Roles and responsibilities will be explicit and clearly accepted with individuals understanding when they may be held accountable for their actions. The principal accountability of all care providers is to patients, service users, their families and carers.

**Teamwork** – everyone who works for Scotland’s care system is an essential and equal member of the team and needs to be valued, treated well and empowered to work to the best of their ability. Teamwork is recognised as the best defence of system failures and is explicitly encouraged and fostered within a culture of trust, mutual respect and open communication.

**Significant adverse events in the context of the National Framework**

28. The National Framework defines significant adverse events as **Category I: events that may have contributed to or resulted in permanent harm**, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m) or ongoing national adverse publicity. Events such as these are likely to be graded as major or extreme impact on the NHSScotland risk assessment matrix, or Category G, H or I on
National Coordinating Council for Medical Error Reporting and Prevention (NCC MERP) index.

29. The National Framework states that broadly Category I events should be subject to a SAER (see Appendix 5). Table 3 below defines the expectations.

**Table 3: National Framework - Guide to levels of review (Category I)**

<table>
<thead>
<tr>
<th>Adverse event category</th>
<th>Suggested minimum level of review</th>
<th>Review team</th>
<th>Reporting of findings and learning</th>
<th>Guidance timescale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category I</strong></td>
<td><strong>Level 1:</strong> significant adverse event analysis and review. Use of validated analysis tools or evidence of screening and clear rationale for any not progressing to analysis.</td>
<td>Full review team: commissioning manager to agree review lead and Terms of Reference (the review team should be sufficiently removed from the event, and have no conflict of interest, to be able to provide an objective view).</td>
<td>Via division/service governance structures with evidence of improvement plans as required. The development of the improvement plan should sit within the team/department where the adverse event took place.</td>
<td>Commence review within 2 weeks and complete within 3 months.</td>
</tr>
</tbody>
</table>

30. The National Framework emphasises that for Level I significant reviews: “A review team should be identified with a lead reviewer appointed and roles within the team clearly defined (the review team should be sufficiently removed from the event, and have no conflict of interest, to be able to provide an objective view).” It is also important that there is appropriate expertise in the review process.

**Implementation of the National Framework**

31. Healthcare Improvement Scotland carried out a follow-up review of progress across all NHS boards. The report⁴, published in May 2016, highlights ongoing challenges across NHSScotland in respect of capacity, governance and consistency/standardisation of adverse event management.

32. The Cabinet Secretary for Health and Sport has stated that she expects all NHS boards to make sure they have a consistent approach to recording, management and learning from adverse events.
33. The NHS boards were written to in March 2017, in a joint letter from the National Clinical Director, the Chief Medical Officer and Chief Nursing Officer. This letter clarified expectations around the NHS boards’ assurance processes to make sure that they can demonstrate that they follow the National Framework.

34. This letter outlined the following key areas.

- Leaders should make a clear, public commitment to staff that the organisation fully supports an open and fair culture: when things do go wrong, staff need to feel able to be open, that they will be treated fairly and they are supported to identify the failures in the system and improve delivery.

- The basic process of adverse event review and analysis should essentially be the same irrespective of the level of review applied. There should be a clearly recorded accountability and decision-making process when commissioning the level of the review and determining who should be involved. There needs to be a clear mechanism for reporting adverse events to external organisations as required (a list is provided on page 15 of the National Framework).

- The process must be open and transparent and should aim to include all those involved in the adverse event as appropriate: patients, service users, families and carers, and staff. Reasons for key people not being involved in the review must be clearly documented.

- NHS boards need to demonstrate there are effective processes for sharing review findings and recommendations for improvement with all those involved in the adverse event. This is essential in building staff and public confidence in the learning system. Adverse event review reports should be shared with everyone involved in the event. To support learning across teams, services and organisations, key learning points should be shared in a one page learning summary and published to share learning for improvement more widely.

- Engaging with patients and families and carers is not a one-off event. Review teams must demonstrate mechanisms used to communicate with, and value the contribution of, patients, families and carers throughout the process according to the level of review. Documentation of engagement with patients, families and carers is a suggested measure for supporting implementation and monitoring of the National Framework (set out in Appendix 4). Other measures include surveys of patient, family and carer involvement and engagement with adverse event review processes. This can provide a further means of seeking feedback on understanding, involvement and satisfaction of patients, service users and families on the level and approach to review that has been applied.

**Recommendation: Take forward national learning**

Healthcare Improvement Scotland should review the findings, conclusions and recommendations in this report to support further development and implementation of the National Framework as well as external quality assurance under the Quality of Care approach.
Section 3: The management and learning from adverse events in the maternity unit, NHS Ayrshire & Arran

Background

35. In 2012, a Freedom of Information request was made to NHS Ayrshire & Arran for copies of all Critical Incident Reviews (CIRs) and SAERs. NHS Ayrshire & Arran refused to disclose the CIRs and SAERs, on the basis that they were exempt from disclosure. This request was referred to the Scottish Information Commissioner for a decision.

36. Following an investigation, the Commissioner concluded that the FOI request was not unreasonable. The Commissioner ordered NHS Ayrshire & Arran to provide anonymised versions of the CIRs and SAERs to the individual who requested them. Following discussion with the Information Commissioner’s Office, this led to NHS Ayrshire & Arran committing to publish their redacted SAER reports on its website.

37. This investigation by the Information Commissioner prompted the Cabinet Secretary for Health, Wellbeing and Cities Strategy to instruct Healthcare Improvement Scotland to carry out a review in March 2012 of the clinical governance systems and processes in NHS Ayrshire & Arran, in particular those that relate to their management of critical incidents, adverse events, action planning and local learning.

38. Following the visit to NHS Ayrshire & Arran in 2012, a series of follow-up interviews were held by teleconference in April and May 2012. The findings were published in a detailed report in June 2012. The report outlined a number of recommendations for NHS Ayrshire & Arran as well as issues to be addressed and learning points for other NHS boards in Scotland and for NHSScotland as a whole.

39. NHS Ayrshire & Arran gave a commitment upon the publication of the report produced following this review to significantly improve their systems and processes in response to the recommendations made by Healthcare Improvement Scotland.

40. In 2012, NHS Ayrshire & Arran published an improvement plan which set out the actions they would have in place “to establish an improved process for responding to and reviewing significant adverse events. This process would enable:
   - greater involvement of staff, patients and families;
   - learning and improvement; and
   - robust governance and reporting;
   - all supported by a business control system which would track every stage of a review.”

41. Following the announcement of a national rolling programme of reviews from autumn 2012 – autumn 2013, it was agreed that NHS Ayrshire & Arran would be towards the end of the visit schedule to allow time to implement recommendations from the original review and demonstrate improvements. In October 2012, we received an update on NHS Ayrshire & Arran’s progress in implementing the improvement plan. There were
30 files embedded within this improvement plan to demonstrate progress against the recommendations.

42. In November 2012-April 2013, NHS Ayrshire & Arran asked Healthcare Improvement Scotland to undertake a supplementary review of all documentation (from 2002-2012) to seek assurance as to the timely creation of the action plans of the 89 cases listed in Appendix 3 of our 2012 review report. This report was published in April 2013. Healthcare Improvement Scotland received an update on progress in implementing the board’s original improvement plan as part of NHS Ayrshire & Arran’s updated baseline submission, ahead of their scheduled review visit in October 2013.

43. In October 2013 Healthcare Improvement Scotland returned to NHS Ayrshire & Arran to review its adverse event management processes. The report of this review is available on the Healthcare Improvement Scotland website. In December 2013, the review report was published, and Healthcare Improvement Scotland received NHS Ayrshire & Arran’s action plan in response to the review report in January 2014. The action plan was sent to the review team for comment and further follow up was undertaken through progress meetings.

44. During 2014 and 2015 progress meetings were held with all NHS boards to discuss and learn from their experiences of implementing the national framework for learning from adverse events. The progress meetings were held with NHS Ayrshire & Arran in October 2014 and September 2015. At the September 2015 meeting, NHS Ayrshire & Arran provided examples of learning notes that had been disseminated following adverse event reviews.

45. Healthcare Improvement Scotland have published two summary reports (November 2014 and May 2016) which provide an overview of areas of good practice and challenges identified by NHS boards in implementing the national framework and sharing learning from adverse events. NHS Ayrshire & Arran featured in both reports and an overview of their progress is reflected in the national report published in May 20166.

46. Since 2012, NHS Ayrshire & Arran has continued to update its adverse event management policy. The most recent adverse event management policy was published in February 20177. For the purpose of this review, the review team used the policy as at September 2014 to provide its reference point.

Key lines of enquiry for the review

47. The review’s terms of reference outlines the following lines of enquiry:

- the extent to which NHS Ayrshire & Arran complied with the National Framework and its own policies in respect of the management of adverse events
- the limited number of SAERs being carried out as referenced by the small number of reports published on NHS Ayrshire & Arran’s website
- the balance between DAERs and NHS board level SAERs
- the extent to which learning was cascaded in a meaningful, practical and timely way to make sure that improvements could be made, and
Review of Ayrshire Maternity Unit, University Hospital Crosshouse
June 2017

- the involvement and support afforded to individual families, as within the review’s terms of reference, but also more broadly in relation to all families that engaged with the review.

48. The review team acknowledged the complexity of managing a system of learning and improvement from adverse events and assessed progress made since 2012.

49. In order to assess the adverse event management process followed by the maternity unit, the review team identified some of the key elements of the National Framework that it would have expected the NHS board policy to include and sought evidence on how the policy had been applied.

50. This assessment has been undertaken in a number of ways and includes a detailed review of the documentation provided, including the application of the adverse event management policy against four significant adverse events that occurred since December 2013. The review team also asked all levels of staff to describe their understanding of the process and what they do when an adverse event occurs.

**Significant adverse event reviews published since 2012**

51. In response to the Information Commissioner review in 2012, NHS Ayrshire & Arran published 88 SAER reports on its website. These redacted reports covered a range of specialties, including maternity services (see Table 4 below).

<table>
<thead>
<tr>
<th>Service area</th>
<th>Significant adverse events occurring between 2001-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternity</td>
<td>9</td>
</tr>
<tr>
<td>Medical</td>
<td>33</td>
</tr>
<tr>
<td>Mental Health</td>
<td>21</td>
</tr>
<tr>
<td>Surgical</td>
<td>19</td>
</tr>
<tr>
<td>Others</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>88</strong></td>
</tr>
</tbody>
</table>

52. According to NHS Ayrshire & Arran’s adverse event management policy, all SAERs are to be escalated through the NHS board’s Healthcare Governance Committee and published on NHS Ayrshire & Arran’s website. Between 2012 and present day NHS Ayrshire & Arran reported that 23 SAERs have been undertaken. Of these, 8 have been published on the website following approval by the Healthcare Governance Committee.

53. This issue has been an area of media and public concern with the implication that review reports are being suppressed, or reviews not being undertaken in line with the National Framework or the NHS board’s local policy.
The adverse event review system

54. The investigation of an adverse event forms part of a wider strategy for risk management within an NHS board. NHS Ayrshire & Arran’s management of adverse events policy outlines the steps which should be taken in managing adverse events.

55. This policy outlines the NHS board’s commitment to taking all reasonably practical steps to minimise and manage risk. The stated overall objective is to protect patients, staff, visitors and members of the public through the consistent monitoring and review of adverse events that result, or had the potential to result, in injury, damage or loss. The policy acknowledges the importance of learning from adverse events and through the introduction of standardised reporting and management arrangements.

56. The flow chart (Figure 1), developed by NHS Ayrshire & Arran and included in its management of adverse events policy, encourages the user to follow the six stages in the National Framework. In addition to this policy, NHS Ayrshire & Arran has devised a supplementary Supporting Guidance and Resources (August 2014) document, the contents of which are summarised in Appendix 4.

Figure 1: NHS Ayrshire & Arran’s management of adverse events policy flow chart

![Flow Chart](image-url)
57. NHS Ayrshire & Arran reported that it was committed to a ‘Just Culture’: “Individuals are treated fairly. Organisational culture is based upon the values of trust, openness, equality and diversity which encourages and supports staff to recognise, report and learn from adverse events.”

58. In discussion with staff, the review team heard of a working environment where there was a clear commitment to an open and transparent culture, where adverse events are routinely reported.

59. The risk management committee reviews and ratifies the NHS board’s strategy on risk and is responsible for monitoring the organisation’s risk profile. This committee reports to the governance committees of the NHS board, including the Healthcare Governance Committee where SAER reports are presented.

60. Within the maternity unit, significant adverse events are reported and discussed at the relevant local group before being progressed successively through four governance groups (Figure 2). Only SAER reports are considered at the Healthcare Governance Committee.

Figure 2: NHS Ayrshire and Arran - Ayrshire Maternity Unit Governance Structure

61. The NHS board’s adverse event management policy sets out a number of responsibilities for senior management in relation to the management of adverse events such as:

- promoting a culture of safety which encourages adverse event reporting, management of such events and the subsequent learning and improvement, and
• making sure that NHS Ayrshire & Arran’s policies and procedures are implemented to enable effective reporting, recording, management, investigation and monitoring of all adverse events.

62. NHS Ayrshire & Arran employees are made aware of the importance of adverse event reporting through the staff induction process and ongoing training provided by the central risk management team and the occupational health and safety team. The adverse event management policy highlights that all staff members are responsible for reporting and recording adverse events, including details of what immediate action was taken to manage the adverse event.

Immediate actions following an adverse event

63. The NHS Ayrshire & Arran adverse event management policy describes the actions that should happen when an adverse event occurs in order to ensure the immediate safety and welfare of all those involved or affected. The process is described in more detail in the NHS board’s Supporting Guidance and Resource document. These supporting tools provide staff with a list of actions to be completed, with timescales, following an adverse event and include a checklist to support the completion of appropriate actions.

64. The main route for reporting any adverse events within NHS Ayrshire & Arran is through DATIX (a web-based incident reporting and risk management software for healthcare and social care organisations). A trigger list categorises adverse events in line with the National Framework. The risk assessment undertaken initially by staff supports decision making, initial notification and escalation.

65. A risk matrix is used to determine the incident’s grade based on the impact and likelihood of recurrence. These grades are: Insignificant, Minor, Moderate Major and Extreme. Based on the risk matrix grading, the Associate Nurse or Associate Medical Director determines the level of review that is required. This is detailed in the NHS board’s policy and is in line with national guidance. Appendix 4 of NHS Ayrshire & Arran’s adverse event management policy provides information consistent with the National Framework which details the level of review required for each of the categories (see Appendix 5).

66. NHS Ayrshire & Arran’s policy stipulates that adverse events must be reported immediately to a manager or senior member of staff on shift when the event takes place. The NHS board policy further states that the adverse event SBAR (a briefing template widely used in the NHS, which sets out Situation, Background, Assessment and Recommendations) must be completed as soon as possible and definitely within 24 hours of the adverse event occurring.

67. Fast-track reporting may be required where an adverse event is thought to have had a consequence impact score of 4 (major) or 5 (extreme). NHS Ayrshire & Arran’s policy states that these events should be immediately escalated, and done so in accordance with its supporting guidance and resources for the management of significant adverse events. The response to each adverse event should be proportionate to its scale, scope, complexity and opportunity for learning.
68. NHS Ayrshire & Arran’s Executive Team reported that further support and guidance on the role of the Procurator Fiscal in SAERs would be welcomed. The review team noted that there was also uncertainty from families about this process. Appendix 6 outlines the advice currently available from the Procurator Fiscal.

**Assessment and categorisation of adverse event reviews**

69. NHS Ayrshire & Arran has three principal routes for undertaking adverse event reviews, as set out in its policy:

- Significant Adverse Event Review (SAER)
- Directorate Adverse Event Review (DAER), and
- Departmental/Manager Adverse Event Review.

70. The position in relation to the types of reviews is set out below in Table 5.

**Table 5: NHS Ayrshire & Arran adverse event management policy - review descriptors**

<table>
<thead>
<tr>
<th>NHS Ayrshire &amp; Arran review type</th>
<th>Local description</th>
<th>National Framework equivalent category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant Adverse Event Review</td>
<td>A Significant Adverse Event can be described as an <strong>unexpected or avoidable event</strong> that could have resulted, or did result in, <strong>unnecessary</strong> serious harm or death of a patient, staff, visitor or member of the public (Healthcare Improvement Scotland (Healthcare Improvement Scotland), 2012) or an increase in organisational liabilities.</td>
<td>Level 1</td>
</tr>
<tr>
<td>Directorate Adverse Event Review</td>
<td>An event which does not meet the requirements of an SAER, however, its consequence requires a more thorough review than that undertaken by a manager.</td>
<td>Level 2</td>
</tr>
<tr>
<td>Departmental/Manager Adverse Event Review</td>
<td>An event which meets the criteria for a manager led investigation (DATIX investigation)</td>
<td>Level 3</td>
</tr>
</tbody>
</table>

71. The local descriptions in Table 5 are drawn from the NHS Ayrshire & Arran adverse event management policy (2014).
72. The distinction between the SAER and DAER approaches becomes important in relation to the handling and public perception of the transparency of findings.

73. NHS Ayrshire & Arran’s policy states that after the initial review of an adverse event, the Associate Medical Director and Associate Nurse Director will inform the relevant Clinical Director of their findings and also refer the event to the Medical Director and Nurse Director for a decision as to whether to progress to a SAER.

74. The Associate Medical Director and Associate Nurse Director may recommend a DAER if they feel this is more appropriate. The policy states that the initial assessment led by the Associate Medical Director and Associate Nurse Director is not an in-depth systems analysis.

75. The Healthcare Improvement Scotland follow-up review of adverse events in NHS Ayrshire & Arran (published in December 2013) highlighted the following:

- During the review period of October 2012 to June 2013, NHS Ayrshire & Arran staff reported 339 adverse events which were graded as ‘major’ or ‘extreme’. These were then reviewed by the risk management team and the final number of adverse events classed as a significant event was reduced to 205 from across all departments of the organisation.
- Of these, six were progressed to a full SAER. Those adverse events that are classed as significant, but are not subject to a SAER following the initial SBAR, are then investigated by way of a directorate-level review. A significant proportion of these were undertaken by NHS Ayrshire & Arran’s mental health services. During discussion with the NHS board’s Chief Executive, he reported to the review team that he is assured of the decision-making process undertaken by the risk management team, medical director and nurse director when deciding which adverse events to progress to a full SAER.
- Directorate-level reviews vary across directorates, although they were reported to be based on the SAER process. Senior management reported to the review team that they felt that a systematic structure for these reviews would be beneficial. The NHS board is currently assessing the consistency of these reviews.

76. The NHS board’s policy describes that the rationale for which type of review is carried out is determined by the potential to cause significant harm or death. However, through discussions with some staff, it was clear to the review team that often reviews are conducted on the basis of actual harm sustained, as opposed to the potential for learning (including from ‘near misses’).

77. The National Framework makes it clear that: “Organisations are ultimately responsible for determining, through their own governance and decision-making arrangements, the action that should be taken following an event occurring. Within this it is acknowledged that there may be circumstances where a decision is made to apply a different level of review to that suggested below. For example, a Level 1 (significant) review process may be applied to a Category II or III event or a Level 2 review to a Category I event. Organisations should clearly document the decisions for the level of review
undertaken.” The last point about documenting decisions is particularly important in the interests of transparency.

78. NHS Ayrshire & Arran’s policy outlines that adverse events of a more serious nature and deemed as ‘significant’ would be “managed in accordance with the SAER procedure.” Significant adverse events are grouped into specific categories: events that should never happen, unexpected events related to care and treatment, and environmental events.

79. The NHS board’s policy states that an initial consequence score should be determined quickly. However, this initial score may be re-graded during or following investigation. The scoring should consider the adverse event outcome in terms of people, resources, environment and organisation reputation and the level of investigation should be appropriate to the consequence impact.

80. One of the appendices to NHS Ayrshire & Arran’s adverse event management policy outlines the steps which should be taken to assess the consequence impact of an adverse event. This aligns itself closely to the Healthcare Improvement Scotland categorisation of events provided as a guide in the National Framework.

81. Figure 3 below was provided by NHS Ayrshire & Arran to illustrate the process that is followed by the maternity unit when an adverse event occurs.

**Figure 3: Maternity services adverse events policy**
82. The local approach for the maternity unit, as set out in Figure 2, does not specifically describe SAERs or DAERs, or the approach for choosing the appropriate avenue for a review.

83. The staff who the review team spoke with highlighted uncertainty as to whether the NHS board SAER policy or the maternity services policy (figure 2) should be followed when an adverse event occurs, after they have initially reported it.

**Key finding**
Once the event has been initially reported, there was uncertainty amongst maternity unit staff regarding the appropriate local and board level process to follow in response to an adverse event.

84. Healthcare Improvement Scotland received a list of 58 DATIX entries from the maternity unit (logged December 2013–present), 18 of which were initially categorised as ‘major’ or ‘extreme’ events. Of these, nine were de-escalated due to not meeting the criteria of an adverse event and the remaining nine were escalated for further review.

85. Four of these were considered ‘significant’ and prompted a full review by NHS Ayrshire & Arran. These are the cases the review team has assessed against the NHS board’s policy. None of these cases were reviewed by the maternity unit using the NHS board’s SAER policy.

86. Instead the four that were considered ‘significant’ were reviewed by the maternity unit using a hybrid approach consisting of a combination of the SAER and DAER processes.

87. Of the four cases reviewed by the review team, two had evidence of the escalation SBAR being completed and submitted, although there were missing data, including the rationale for the decision taken as to what level of review should be conducted. In two cases there was no evidence of an SBAR having been completed but a rationale to undertake a review was described in email communications for one of these cases. Of the two cases that had SBARs completed, one was completed within 3 days of the event and one was completed within 12 days of the event; the latter was over the festive period and completion was likely to have been impacted by staff leave. The absence of consistently completed documentation of the decision, which sets out the rationale for the level of review to be conducted, is a significant weakness.

**Key finding**
The adverse event documentation, within the initial assessment process, is not consistently completed and fails to provide clear rationale for deciding the level of adverse event review required.

**Review and analysis**

88. The NHS board’s DAER process is similar to the SAER process, in that they both use root cause analysis methodology to find out what caused the event.
89. NHS Ayrshire & Arran staff described that the key difference between the two processes is the involvement of certain staff: effectively, SAERs are conducted by senior colleagues outside the department that the adverse event occurred within, with only one specialist from that department involved in the review, thus losing the benefit of expert discussion and challenge. Whereas in the DAER process, a team of clinicians with appropriate expertise review the care, rendering the review, in the view of the maternity unit staff, more meaningful and robust.

90. However, the review team noted significant differences between the two processes – especially in relation to transparency – set out later in this report.

91. The follow-up review of NHS Ayrshire & Arran, in 2013, by Healthcare Improvement Scotland identified that within directorate-level reviews, each directorate follows different processes. The NHS board provided the following information in relation to these processes.

- Mental health service: an adverse event review group reviews all adverse events and associated reports and action plans. This group may also commission a review of the adverse event, if the decision not to progress to a SAER is taken by the executive nurse director or medical director. This review will take the form of a clinical record review or adverse event review.
- Maternity services: the department manager will manage all adverse events not progressed to a SAER. This manager will make sure that all documentation in relation to communication, actions taken and improvements are attached to the Datix record.
- The NHS board reported that “cases where it appears care has been substandard are forwarded to Maternity Clinical Governance Risk Management Group (CGRM)” who will review the adverse event. This review produces a report and action plan, which is attached to DATIX, with assigned individuals to take the work forward. The rationale for referral to the CGRM group is not consistent with the wider SAER process.
- Directorate-level reviews vary across directorates, although they were reported to be based on the SAER process. On discussion with senior management, they reported that they felt that a systematic structure for these reviews would be beneficial. The NHS board is currently assessing the consistency of these reviews.

92. The DAER is conducted with specialists from the department who were not involved in the incident, with one external specialist to make sure unbiased conclusions are reached. In both approaches, the staff directly involved in the event would only be interviewed as part of the review, and not directly involved in the review itself. NHS Ayrshire & Arran argues that the DAER process is more appropriate to make sure the right expertise is available from more than one individual to make sure issues are fully explored and important factors are not missed. The review team agrees that the right expertise is an important factor when undertaking adverse event reviews to make sure objective informed discussion and appropriate robust challenge take place.
93. Since 2012, no SAERs have been undertaken by the maternity service. The maternity service, supported by senior management, has adopted DAERs as a means by which to routinely undertake reviews of significant adverse events.

94. For the four cases submitted to Healthcare Improvement Scotland to review, all four were conducted as DAERs. The rationale provided for this was not because the staff felt that an SAER was not warranted, but rather that the correct methodology would enable rigorous and informed investigation, and so the maternity service opted to follow the DAER process. Of the four cases reviewed: one was concluded in 10 weeks, one in 8 weeks, one in 29 weeks and the timescale of the fourth is unknown as the root cause analysis is currently a live investigation.

95. On the basis of the evidence, the review team would have reasonably expected NHS Ayrshire & Arran to have carried out SAERs on the four cases in question, in line with its own policy and the National Framework, for example National Framework Level 1 reviews.

96. NHS Ayrshire & Arran’s policy did not set out the basis for standardisation or consistency in relation to the conduct of DAERs. Wider board level support, from sources such as the risk management team and the templates, tools and guidance described within NHS Ayrshire & Arran’s process for SAERs, are not always applied to the DAERs.

**Key finding**

There was not a standardised or consistent approach to undertaking DAERs within the maternity unit.

97. The decision to proceed with DAERs has raised questions about the transparency of the process in not placing the learning from such DAERs on NHS Ayrshire & Arran’s website, and has implications for the wider dissemination of learning across NHS Ayrshire & Arran.

98. The NHS Ayrshire & Arran maternity team highlighted the difficulties in undertaking SAERs, without the sufficient involvement of relevant expertise. It was clear from the evidence that it was not that the four cases were not significant adverse events, rather the perception that the SAER process impeded, in the view of those in the maternity service, the appropriate investigation of the incidents.

99. The National Framework states that for Level 1 significant reviews: “A review team should be identified with a lead reviewer appointed and roles within the team clearly defined (the review team should be sufficiently removed from the event, and have no conflict of interest, to be able to provide an objective view).”

100. It would have been appropriate, in the interests of transparency and governance, to expect the NHS board’s adverse event management policy to have been complied with, pending the outcome of an open discussion and debate about the perceived challenges in implementing the policy in its current state.

101. In circumventing the SAER policy to achieve greater and relevant clinical engagement in the investigation of adverse events, there are significant implications for public
confidence in the robustness and transparency in the management and learning from adverse events. The implications of this should have been all the more important for NHS Ayrshire & Arran given the issues that gave rise to the original review in 2012.

102. NHS Ayrshire & Arran stated in November 2016:

“Since 2008 up until 31 March 2016, there have been four SAERs concerning stillbirth deaths at Ayrshire Maternity Unit. During this time, 33,716 babies have been born at Ayrshire Maternity Unit.”

103. This statement gives the impression that there were only four significant adverse events concerning stillbirths between 2008 and 2016 which merited an SAER. However, it is clear that there were a greater number of significant adverse events and these were investigated through the DAER process and therefore not identified as SAERs.

104. The review team does not question the motivation of the clinical staff in seeking to pursue the investigation of significant adverse events at directorate level. The staff described concerns that the effectiveness of SAERs was undermined by the absence of appropriate specialists that understood the ‘nuances’ in relation to the particular specialty.

105. The Review Team did not find any evidence of a deliberate and systematic attempt to suppress SAERs by NHS Ayrshire & Arran. However, the progression of DAERs, without a consistent and agreed framework for their operation, and a clear and connected reporting line to NHS Ayrshire & Arran’s Board, runs the risk of undermining confidence in the overall approach to the management of adverse events in NHS Ayrshire & Arran.

**Key finding**
The NHS Ayrshire & Arran significant adverse event review process was not used for significant adverse events in the maternity unit. The maternity unit circumvented deficiencies in the NHS board’s adverse event management policy in order to maximise local clinical engagement in reviews. The review team believes that this is indicative of the need to strengthen the wider organisational adverse event process.

106. There are important differences between the SAER and DAER processes. This is particularly in relation to the profile and support they have at Board level.

107. The SAER process is set out in detail within the board’s policy and has the previously described tools and guidance to support the process, including reporting to NHS Ayrshire & Arran’s Healthcare Governance Committee. The Board reported that SAERs are also supported by staff from the NHS board’s risk management department. In contrast, the DAERs do not trigger the same level of support which has a resultant impact on the ability of frontline staff to complete them in a timely manner.

108. The profile afforded SAERs also allows for awareness across the organisation of any key issues which come out of the review. This is of particular significance if a theme emerges amongst the reviews that could have an impact across the organisation and
support is required from the Board to make sure appropriate steps are taken to prevent further adverse events.

109. The SAER process states that reports arising from such reviews will be published on the NHS board’s website. The apparent lack of public reporting of such reviews has resulted in some of the families believing that reviews have not been undertaken or that the NHS board is seeking to evade their publication.

110. The classification of investigations into significant adverse events as DAERs has a substantial bearing on the number of reviews that have been published and learning disseminated. Moreover, it has implications for the process followed in each.

111. The review team noted for the reasons set out, NHS Ayrshire & Arran has channeled the majority of SAERs through the DAER process. The number of SAERs undertaken has therefore been relatively small.

Key finding
NHS Ayrshire & Arran has carried out a very small number of SAERs using its established and published process.

112. The clinical case review from the University of Leicester concluded similar findings regarding the apparent lack of robustness of the NHS Board’s adverse event review process. When comparing the findings of the cases there were general themes consistent with those found by the review team including: a lack of a consistent approach to the review of deaths occurring in the service and the need to ensure sufficient time for senior staff to be actively involved in each review.

Recommendation: Strengthen the process

The NHS board must strengthen its current adverse event management policy to make sure it adheres to the National Framework and provides useful and practical processes that can be quickly and simply followed. This should include reference to further guidance on:

- clinical engagement in reviews, completion of documentation, the level of review and analysis required based on adverse event category, and the improvement planning and monitoring arrangements for reviews,
- advice from other NHSScotland boards to find practical ways of implementation, and
- involve clinicians from across the organisation, including maternity services in its development.

The revised adverse event management policy must provide information for families about stillbirth, neonatal death and adverse events that communicates accurate, clear and consistent messages about the type of review that is being undertaken. This should aim to avoid any additional distress by raising uncertainty about the type of review that may be conducted.
Resource implications of reviews

113. The review team heard that DAERs took a significant amount of time. Staff told us that these reviews may require 3 half day meetings, which can take up to 6 months to conclude. This length of time has an impact on staff as well as the families. It also creates possible delays to the implementation of any remedial action.

114. The review team noted the enthusiasm and commitment demonstrated by the clinicians within the maternity directorate to make sure robust reviews of cases take place. Some staff undertake this work outside of their contracted hours, recognising the importance of the review process. The maternity unit currently does not have a Clinical Risk Midwife in post. The review team believes that this type of post would provide much needed help to the team and allow co-ordination, changes and improvements to the service. Currently a senior member of staff within the unit undertakes a similar role but does this in addition to her contracted working hours, without additional time or resource.

115. Staff members acknowledged that the support of a Clinical Risk Midwife would have a significant impact on the ability of the unit to manage their adverse events. The NHS board confirmed that funding has been secured for this post and the maternity unit is in the process of drawing up a job description so that they can begin to recruit to this post.

Recommendation: Support for staff

NHS Ayrshire & Arran staff must be adequately supported to be involved in the management of adverse events across the maternity unit. This support must include:

- dedicated and protected time for staff to be involved in all aspects of adverse event reviews,
- appropriate support to undertake the review process, including co-ordination and administrative support, and
- training in adverse event reviews for those taking part in this process.

Action plans in response to adverse events

116. An action plan template is provided within the Supporting Guidance and Resources document which has been designed to document the status of an action plan and detail specific evidence of progress towards implementation.

117. The clinical risk management group, consisting of senior charge midwives, consultant obstetricians, neonatal consultants and paediatric consultants, meet weekly to discuss all levels of DATIX entries, which have been escalated to them for review. Approximately one or two DATIX cases are reviewed and closed each week.

118. The member of the group who is responsible for each DATIX entry is appointed to create an action plan and timeline for that case, covering pre-booking to delivery care, although this is not accounted for in this person’s job plan. Staff reported that attendance at this weekly meeting is often challenging due to clinical commitments. The Clinical Risk Midwife previously undertook the task of collating information in
preparation for these meetings. This task is difficult for other group members to undertake due to clinical commitments and time constraints.

119. Action plans from this group are progressed locally and reported on at the fortnightly adverse events review group, following which they are discussed at the relevant governance committees. Staff noted that time constraints and other clinical priorities impact on their ability to complete actions arising from adverse event reviews. Of the four cases that were reviewed, three had action plans provided and one case is ongoing. Actions were noted as completed in most cases. The incomplete actions had notes recorded against them and indicated that work was being carried out. Two of the action plans showed that actions were completed within 4 months. The remaining action plan did not have any dates recorded against the actions to indicate if they had been completed or not. Although noted within the action plans, evidence was not provided to the review team of these completed actions.

120. There was, however, evidence to show that actions that could be implemented with immediacy were picked up at daily staff safety briefs and, where necessary, were recorded on safety brief templates and added to the agenda as a standing item at these meetings.

121. In one case, a recommendation was made that the ‘Labour and Birth Record Initial Assessment Page’ should be completed on admission to the labour ward. The safety brief was used to highlight the importance of completing this documentation for risk identification and staff handovers. An audit of completion of the assessment page was carried out and indicated that further work is required.

**Key finding**
Adverse event action plan documentation was incomplete and with insufficient evidence relating to recommendations and follow-up.

**Governance and reporting**

122. Robust governance of adverse events is necessary in order for lessons which are identified to be appropriately shared amongst staff. Appropriate governance arrangements also make sure systems and processes are adapted and developed following adverse events to ensure the same incident does not happen again. A good system would also provide staff members who have been involved in an adverse event with support, and guarantee that any training and education needs identified are met.

123. Of the four cases reviewed by the review team, all were presented and discussed at various levels of governance groups within NHS Ayrshire & Arran, including:

- one case was discussed by the adverse events review group, with a view to discussing at a future maternity clinical governance group meeting
- three cases were discussed by the maternity clinical governance group
- two cases were discussed by the acute clinical governance committee, and
- one case was escalated and discussed by the Healthcare Governance Committee.
124. It was noted that DAER action plans are not discussed at board level governance groups. Had the cases proceeded through the SAER process, they would have been discussed by the NHS board’s Healthcare Governance Committee.

125. NHS Ayrshire & Arran did not appear to question the small number of SAER reports appearing through its governance channels and ultimately being published on the website. Given the fact that the DAER process does not require bringing these events to the attention of the Healthcare Governance Committee, the board was not effectively informed about the nature and learning from significant adverse events which were not reviewed by the SAER process.

126. The most recent NHS Ayrshire & Arran adverse event management policy (dated February 2017) states that DAER action plans will now be submitted to the Healthcare Governance Committee. Only redacted SAER reports will be placed on NHS Ayrshire & Arran’s website.

**Key finding**
The learning and actions from significant adverse event reviews undertaken through the DAER process did not, routinely, come to the attention of the NHS board’s Healthcare Governance Committee.

**Improvement and learning from adverse events**

127. The NHS board’s adverse event management policy describes the importance of learning from experience, including the investigation of individual adverse events and analysis of trends and patterns from a series of events. The NHS board reported that these thematic reviews take place through discussion at maternity governance meetings and are taken forward using quality improvement methodology.

128. As well as working with local maternity colleagues on specific local improvement work, the review team also heard of the work undertaken through the national Scottish Patient Safety Programme – Maternity and Children Quality Improvement Collaborative (MCQIC).

129. The NHS Ayrshire & Arran maternity champion, who has 15 hours per week dedicated time to MCQIC activity, is engaged with all aspects of MCQIC. They participate in national core focus groups to develop new measures, regularly present local improvement work on WebExes and at maternity networking events, and liaise regularly with the national team on a variety of issues and topics. There is a positive working relationship between the NHS board and the national team in order to support the work to continually improve the safety culture across maternity services.

130. The review team noted that the Maternity Directorate in NHS Ayrshire & Arran has made significant improvements with some of the MCQIC measures. For example, the stillbirth rates have almost halved in the past 4 years. This has been achieved by focusing on improvement activity such as smoking cessation, introduction of carbon monoxide monitoring for all pregnant women at booking and increased education around awareness of fetal movements. This tailored package of care for smokers was
presented by the board to the MCQIC learning session for shared learning in February 2015.

131. In addition, Sepsis 6, an improvement programme that aims to improve the outcomes of patients diagnosed with sepsis, has now been implemented across all inpatient wards in NHS Ayrshire & Arran. This was an area that started at 13% compliance and now has 100% sustained improvement reported each month.

**Key finding**
The review team was presented with several examples of high quality audit and quality improvement initiatives completed within the maternity unit from 2013 onwards.

132. The NHS board provided the review team with further examples of themed improvements, which have been implemented as a result of learning from adverse events and complaints since December 2013. These examples include the following:

- **Bereavement care** – a number of initiatives have been developed to provide the support needed for patients and staff when adverse events occur. This includes the creation of a bereavement team, where some of the midwives within the unit are designated bereavement champions. These midwives support families by providing support and acting as a link for parent input into reviews. These bereavement midwives have some protected time to undertake this role. This includes attending appropriate study sessions and days out to develop the service.

- **Birth after caesarean section** – a number of improvement activities arose from a specific adverse event as well as themes identified through DATIX analysis. These improvement activities have included reviewing admissions, and birth/care plan documentation.

- **Care for women with diabetes in pregnancy** – focus on this area following recognition that there is an increased prevalence of diabetes in pregnant women in the NHS board area and that there is a need to be more proactive to support these women. There is a dedicated midwife for diabetes in pregnancy.

- **Induction of labour** – an induction of labour short life working group was established, focusing on improvements to the safe and effective planning and booking process. As a direct result of an adverse event review, a number of initiatives have been introduced, including improved information and communication with patients and staff. The implementation of a syntocinon protocol (medication for the use of induction/augmentation of labour) has also made sure there is a safer and standardised approach to administration of the drug in labour. This work has been presented at the International Forum on Quality and Safety in Gothenburg (April 2016) and won a Healthcare Improvement Scotland quality improvement award.

- **Diagnosing the fetus at risk of stillbirth** – a detailed review of factors that can impact on stillbirth was undertaken, including understanding the associated risk factors, implementation of Royal College of Obstetricians and Gynaecologists (RCOG) guidance on fetal movements, smoking cessation and protocol for the
management of SGA (small for gestational age). There has been a significant reduction in the stillbirth rate since 2013.

- **Postpartum haemorrhage** – since national reporting ceased in 2012 (the Scottish Confidential Audit of Severe Maternal Morbidity - SCASMM), local governance processes have reviewed any cases of major obstetric haemorrhage. These local processes have allowed specific guidance and processes to be implemented and ongoing continuous assessment has identified a number of improvements in the management of postpartum haemorrhage.

- **Care of the vulnerable woman in pregnancy (including addictions)** – there has been increased focus to support women with drug addiction in pregnancy through COMPASS (Combined Pregnancy Addiction Support Service). In NHS Ayrshire & Arran, an improvement methodology was employed to develop the format of a clinic to improve the impact of addictions on women and their babies. There is now a dedicated monthly clinic for these vulnerable women.

- **Behaviours and communication** – staff within the maternity unit have demonstrated, through a number of ongoing initiatives, their willingness to continuously reflect and review their working culture and teamwork. This includes measuring patient safety culture across a number of domains, for example job satisfaction and working conditions.

133. The review team noted that NHS Ayrshire & Arran has processes in place that allow the identification of issues, and has the desire, through the maternity governance structure, to support change and improvement. This is evident in the examples of improvement work listed above. The review team considers that every effort should be made by NHS Ayrshire & Arran to share the outcomes of their improvement work both internally and externally.

134. Staff reported that it has become increasingly difficult to participate in this improvement work which can be time consuming for staff, due to day to day pressures placed on clinical staff.

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<tr>
<th>Key finding</th>
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<td>A major challenge to supporting improvement initiatives (within the maternity unit) is the availability of protected staff time.</td>
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**Publication of Significant Adverse Event Review reports**

135. As previously mentioned, in 2012, NHS Ayrshire & Arran took the decision to publish its SAER reports on its website, to ensure transparency and to promote the sharing of learning. It is noted that no other NHS board does this.

136. The review team considers that the future publication of these review reports is not appropriate given the rarity of the cases and the potential for inadvertent identification of patients and staff, thus increasing the possibility of breaching confidentiality. The redaction of the reports also makes it difficult to meaningfully learn from these reports.
137. NHS Ayrshire & Arran should promote, internally and externally, the changes and learning resulting from their improvement work, including the publication of learning summaries of adverse event reviews. Learning summaries should be shared with staff, patients, families and carers and published on the Adverse Events Community of Practice website. Learning summaries include a summary of what happened, the learning gained, improvement work taken forward and resultant service improvements. The NHS board should consider learning summaries as a mechanism for publishing examples of positive outcomes from improvement work taken forward following adverse event reviews to benefit services across NHSScotland. This approach is supported by the Information Commissioner and is consistent with the National Framework.

138. The National Framework states: “The organisation should make sure arrangements are in place to share learning and improvements from adverse event reviews across services, the wider organisation and nationally as appropriate. Although it is our aim for adverse event review reports to be written in a way that can be shared and others can learn from the event, a brief learning summary is likely to be a better way to share key learning points.”

**Key finding**
The publication of redacted SAER reports on the NHS Ayrshire & Arran website does not encourage shared learning.

**Recommendation: Promote shared learning**

NHS Ayrshire & Arran should promote, internally and externally, the changes and learning resulting from their improvement work, including the publication of learning summaries of adverse event reviews. The learning summaries should:

- Be shared with staff, patients, families and carers and published on the Adverse Events Community of Practice website
- Include a summary of what happened, the learning gained, improvement work taken forward and resultant service improvements, and
- Be considered as a mechanism for sharing examples of positives outcomes from improvement work taken forward following adverse event reviews, to benefit services across NHSScotland.

**Recommendation: Stop publishing redacted SAER reports**

The NHS board should stop publishing redacted SAER reports on its website as these reports do not encourage shared learning and risk breaching patient and family confidentiality. Instead NHS Ayrshire & Arran should publish learning summaries, as per recommendation 4.
Wider learning and lessons

139. This review highlights important wider learning and lessons beyond NHS Ayrshire & Arran. These also apply to Healthcare Improvement Scotland and will be taken forward through the implementation of recommendation 8.
Section 4: The experience of families

Introduction

140. This section of the report sets out:

- the expectations within the National Framework about engagement with families following a significant adverse event, and
- what Healthcare Improvement Scotland’s review team heard from families who got in touch during the review about their experiences of the maternity unit in NHS Ayrshire and Arran.

The National Framework

141. The National Framework sets out clear expectations about engagement with families, and include the following.

- The family or carers must be cared for and involved where a person has been harmed.
- Compassion and understanding should be shown at all times even if simply making regular contact to keep people involved and informed.
- Communicating effectively with people is a vital part of dealing with errors or problems in the delivery of care. Saying sorry, providing an explanation and keeping them informed will help people cope when things have gone wrong.
- The organisation should give early consideration to the provision of information and support to families and carers involved in the adverse event, including details on available support systems.
- The needs of families and carers should be met and supported.
- Reports should be shared with families and carers.

142. A leaflet designed for patients, families and carers has been produced alongside the National Framework, and can be adapted for NHS boards to use. It explains what a SAER is, what happens during a review, how people can be involved and what will happen after the review.

143. Healthcare Improvement Scotland considers that engagement with families and carers is an essential part of a review process, particularly in cases involving maternity services. Families and carers can often provide key information and perspectives which might otherwise be missed in a review. They are entitled to be treated with dignity and respect, and should have the opportunity to be involved, informed and supported throughout the entire significant adverse review process. This participation can include providing their perspective of events in advance of the review and submitting questions to be addressed as part of the process.
Cases within the review period

144. The review team focused specifically on the experience of the families in the adverse event review process. This included conversations with families whose experiences occurred between 2009 and 2015.

145. Given the sensitivity of the subject, the review team asked families to voluntarily come forward to participate in the review. Whilst only a small number of families participated in this review out of the approximately 3,500 deliveries a year in NHS Ayrshire & Arran, the review team valued the important input the families had to this process. This report does not reflect the locally collated complaints, comments or compliments received about the maternity unit.

146. A total of 16 families contacted Healthcare Improvement Scotland, either directly or through the Scottish Government. Nine of these families took up the invitation to meet with the review team. Their experiences occurred between 2009 and 2015. The year of each event is outlined below:

- 2009 – one family
- 2011 – two families
- 2012 – two families
- 2013 – one family
- 2014 – one family
- 2015 – two families

147. Of these nine families, the experiences of three families fell within the timescale of the review’s terms of reference. The review team considered documentation from four significant adverse events that occurred after December 2013, of those, two of the families came forward to speak with the review team and is reflected in this section of the report as Family A and Family B.

What the review team heard from families – key themes

148. The review team felt it was essential to hear from families in order to get their views and perspectives to inform this review.

149. There are a number of ways in which the review team engaged with families, including:

- regularly highlighting the way that families could contact us following any media coverage of the review
- providing updates and information on Healthcare Improvement Scotland’s website and through social media
- directly meeting with family members to listen to their experiences, and
- inviting the families who met with the review team to hear key messages from this report prior to its publication.

150. Each family was offered the opportunity for a representative from the Stillbirth and Neonatal Death (SANDS) charity to be present at meetings with the review team. The
SANDS charity exists to support anyone affected by the death of a baby, to improve the bereavement care received by parents and families, and to influence policy makers and promote research to reduce the number of babies dying. The review team was in contact with the Scottish Network Co-ordinator for SANDS throughout the family engagement process, and wishes to thank SANDS for the advice and support it provided.

151. Healthcare Improvement Scotland is very grateful to the families that contacted us, and to those who felt able to share their experiences with the review team. We know that talking about what happened to them must have been very difficult, and we appreciate the courage and openness that they showed.

152. The themes which emerged from discussion with the families are reflected below. These are reported in general terms in order to protect the privacy of those who spoke to us. These themes have been collated from all of the meetings and reflect experiences dating back to 2009.

153. The following themes emerged from meetings with all nine of the families met with:

- All families perceived that there had been failings in the care provided by the maternity unit, often exacerbated by poor communication and lack of clear explanation about what had happened.
- Several families expressed concerns about staffing levels and staff training within the maternity unit.
- Poor communication with families following the adverse event was a common theme – families were often unclear about whether any investigation had been carried out by NHS Ayrshire & Arran, and had found it difficult to find out what, if anything, was happening. One family reported having a more positive experience, following making a complaint, and being kept informed by a named link person throughout the process, as well as receiving contact details for SANDS.
- Several families noted that they had not been provided with an acknowledgement or apology about what had happened, and that this would have helped them.
- Many families felt that they were still left with unanswered questions about what happened to them, and that they would like these questions to be answered.
- Some families either did not know, or did not feel confident, that any lessons had been learned from their experience.
- Several families reported that they had subsequent experience of the maternity unit, which had been positive.
- A number of families also spoke of their positive experiences of the unit and commended the staff there.

154. Examples of the positive feedback received include:

- one family noted that they decided to use the service again following reassurances by the staff at the maternity unit and reported being incredibly well looked after,
- one family spoke very positively about the care they received during the recent birth of their child and was very complimentary of the staff that looked after them, and
• one family shared that they were provided with excellent care during the birth of their newest baby and that management within the unit had communicated well with the family and gave prompt responses to any queries that they had.

155. The Being Open Framework states that: “Openness about what happened and discussing adverse events promptly, fully and compassionately can help people cope better with the after-effects of adverse events”. This highlights the impact that good communication can have on the family’s experience.

**Key finding**
The family experiences highlighted the importance of NHS boards engaging with families in line with the *Learning from Adverse Events through Reporting and Review: A National Framework for Scotland* (referred to as the National Framework).

**Family A**

156. Members of the review team met with Family A in early 2017 to discuss their experiences of the care they had received when their baby died at University Hospital Crosshouse.

157. At the meeting, Family A highlighted their concerns with NHS Ayrshire & Arran’s implementation of the original Healthcare Improvement Scotland recommendations from the investigation of adverse events in 2012. They also expressed wider concerns about the absence of a regulatory regime for health care that is similar to the Care Quality Commission (CQC) in England.

158. Family A also specifically raised concerns about:

• the low number of SAERs published on NHS Ayrshire & Arran’s website
• the apparent low number of deaths reported to the Scottish Fatalities Investigation Unit by NHS Ayrshire & Arran
• the previous examples of significant adverse events on the NHS Ayrshire & Arran website related to similar situations in which their baby had died
• the quality of the subsequent investigation of the adverse event, especially the root cause analysis, and
• the apparent low staffing levels in the unit.

159. Family A made it clear to the review team that they want lessons to be learnt, changes made to the system in NHS Ayrshire & Arran, and what happened to their family and other families not to happen again.

160. In a letter sent to NHS Ayrshire & Arran, Family A stated that they wished to see:

• a full transparent and comprehensive investigation into the management, delivery and outcomes of care provided to Mother and Baby A by the Ayrshire Maternity Unit at University Hospital Crosshouse and associated units during the course of the pregnancy.
• an answer to the 15 questions submitted in their letter
• an assurance that the sequence of failures of care that resulted in Baby A’s death have been identified, lessons learnt and acted upon and measures taken to prevent their recurrence, and
• a full and unreserved apology for the death of Baby A.

161. In a letter to the family, the Board described the decision to proceed with a DAER due to the perceived deficiencies with the composition of SAER teams.

162. The documentation in this case has no evidence that the SBAR recommending this approach was drafted, approved or signed off by senior management. This decision making process was instead communicated through an email.

163. The NHS board’s significant adverse event management policy states that:

“The family contact person will provide regular contact with the family to share information and updates on the progress of the review. The contact person will have the required skills to respectfully disclose sensitive information. This person may be the Lead Reviewer and this decision will be made by the LOG [Leadership Oversight Group]."

164. The policy further states that: “At the family meeting, the family will be asked what their wishes are in relation to ongoing contact. The family contact person will be responsible for documenting this information in the system and for updating the system with:

• the date and time of contact
• information discussed at those contacts
• actions agreed at those contacts
• recording when actions are delivered and what the action was."

165. The family had multiple contacts with NHS Ayrshire & Arran following Baby A’s death. Family A, in considering the SAER policy, expected that there would have been a systematic and consistent approach to their involvement throughout the review.

166. Shortly after their baby’s death, Family A was asked to submit questions for the ‘Adverse Event Review’.

167. The results of the review were shared with the family by post in advance of a meeting with clinical staff at the Board. This was in the form of a root cause analysis report. There was no SAER report produced. The report provides a graphic and, at times, upsetting account of events leading up to Baby A’s death. The family’s experience of their care is absent from the report.

168. The family has demonstrated considerable resilience in an extremely upsetting experience for them, with a strong focus and relentless determination in establishing the truth.

169. The NHS board did have meetings with the family to hear their complaints but it is clear that Family A were left with many unanswered questions. In the context of the terms of
reference of this review, it is clear that the family did not experience a considered and systematic approach to their involvement in the investigation of this adverse event.

Family B

170. Members of the review team met with Family B to discuss their experiences of the care they had received when their baby died at University Hospital Crosshouse.

171. The Board provided a senior manager contact details at discharge from hospital. Family B was made aware that there would be a review of their case and they would be able to ask the question that they were keen to have answered, including would their baby still be alive if there had been different actions. The Board also met with and offered further opportunities to meet about the review.

172. Family B reported that the NHS board had not sufficiently explained the detail of the review or discussed the final report. The report was received 6 months after the loss of their baby. Family B stated that NHS Ayrshire & Arran had not apologised to them for their loss. Family B was aware that a post-mortem examination was carried out but no one had met with them to explain the findings and implications.

173. Family B received the report from NHS Ayrshire & Arran by email. It was received at a very difficult time for the family and they felt unable to read through such a long report.

174. The extract from the SBAR form seeking permission not to proceed with a SAER is set out below:

“A full review of the management of this case is warranted to identify any factors that could have been done differently that may have resulted in a different outcome. This may be better provided by an expert review as the nuances of care in this situation are very specialty specific. A directorate level review perhaps with input from an external clinician may be more productive, in conjunction with results of post mortem.”

175. The review proceeded as a DAER.

176. The review team was supplied with a copy of the written response to the questions posed by Family B and an action plan. However, there was no evidence supplied in relation to a root cause analysis being undertaken.

Importance of family involvement

177. As stated in the report, An Organisation with a Memory (Department of Health 2000)3, adverse events involve a huge personal cost to the people involved, both patients and staff. Many patients suffer increased pain, disability and psychological trauma. On occasions, when the incident is insensitively handled, patients and their families may be further traumatised when their experience is ignored, or where explanations or apologies are not forthcoming. The psychological impact of the event may be further compounded by a protracted, adversarial legal process. Staff may experience shame, guilt and depression after a serious adverse event, which may again be exacerbated by follow-up action.
178. Since the publication of the Department of Health’s report, there has been an even greater focus in building a different relationship between healthcare professionals and patients, carers and their families.

179. The National Framework acknowledges that:

“Compassion and understanding should be shown at all times even if simply making regular contact to keep people involved and informed. The Institute for Healthcare Improvement (IHI) publication Respectful Management of Serious Clinical Adverse Events (Second Edition) suggests that an adverse event does not necessarily break down the trust between people involved. However the way in which the organisation responds after such events often does”.

NHS Ayrshire & Arran’s commitment to families

180. NHS Ayrshire & Arran’s adverse event management policy states that: “The organisational response to such an event will be:

- compassionate;
- transparent;
- honest;
- timely;
- consistent; and
- with a focus on the needs of the patient and/or carers/family.”

181. The policy also states that: “Patients and/or their carers/families can expect the following:

- We will keep you informed of our actions from the time that the adverse event happens through to the point when we have identified the learning and improvements to be made.
- We will communicate with you respectfully and honestly, in a way that compassionately acknowledges and recognises the emotional impact of the adverse event on you and your family.
- We will support you by providing a consistent and named contact person.
- We will work with you to involve you in the review process, taking account of your preferences and providing you with the opportunity to share details of your experiences with staff to support their learning, and
- We will provide you will a sincere and honest apology for identified failings.”

182. The National Framework states that:

“The process must be transparent and include all those involved in the adverse event: patients, service users, families and carers, and staff. To support this, SAER reports should be shared with everyone involved in the event, and a one-page learning summary completed and published in order to share key learning points more widely.”
**Recommendation: Improve family engagement**

NHS Ayrshire & Arran must make sure that families are provided with appropriate information, support and opportunities to enable them to be involved in any significant adverse event process, in line with the National Framework. This should include:

- reference to, and implementation of, the guidance from the Being Open NHSScotland 2015 document – this document provides support for NHS boards when developing policy and procedures around communication and engagement
- opportunities for staff to have communication training to support Being Open, and
- further opportunities for those families that have come forward through this review process to discuss their experiences with NHS Ayrshire & Arran and to make sure that any remaining questions are answered*.

*This part of the recommendation was discussed with the NHS board ahead of the report being published for those families who expressed a desire to meet again with the NHS board. At the time of publication, some of these families have already met with representatives of NHS Ayrshire & Arran.
Section 5: Staffing levels and skills

183. Some of the families identified a concern that the number of medical and midwifery staff working on the maternity unit when their incident occurred could have been a contributory factor to their poor outcome. The benchmarking information provided to the review team by NHS Ayrshire & Arran, comparing other NHS boards’ midwifery establishments, suggests that NHS Ayrshire & Arran staffing levels are comparable to those of similar sized maternity units in NHSScotland.

184. Activity levels within any service are variable and this may be managed through the use of supplementary staffing. This escalation policy may recommend the use of supplementary staffing on a short term basis.

185. In the Review of Maternity Service of NHS Ayrshire & Arran, this locally commissioned report identified that midwifery staffing was not adequate for the workload and that there was a deficiency of 15.65 whole time equivalent midwives. Paragraphs 187 and 188 show the current staff absence levels (at the time of this review).

186. For the year ending December 2016, for registered staff in maternity and neonatal services, the absence rates were as follows:

- sickness absence rate was 6.9% which is 2.9% above the 4% uplift included within all staffing budgets
- maternity leave rate of 2.7%
- other leave 2.3%, and
- study Leave of 0.8% is below the 2% uplift included within the staffing budget and may have offset other pressures.

187. The rates for the first 2 months of 2017 are detailed below and demonstrate no significant change.

- sickness absence rate of 6.0%
- maternity leave rate of 3.1%
- other leave 3.1% and
- study leave 0.7%.

188. A senior manager NHS Ayrshire & Arran acknowledged in an update paper in March 2017: “...the impact all of sickness / absence and maternity leave is contributing to our ability to deal effectively with day to day workload and provide effective and safe care for women, children and neonates.” This paper goes on to describe:

- “These rates are also impacting on our ability to release staff for education and training. We are not achieving the desired 2% and the potential cumulative risk of this is that staff will not be trained to the standard to provide assurance of the quality of care being delivered.
- “While it is recognised that pooling of maternity leave funds should support us in managing the higher levels of this type of leave; the challenge is trying to recruit
nursing/ midwifery staff on a fixed term basis, filling through bank use, or offering additional hours.”

189. In March 2017, NHS Ayrshire & Arran provided information about recent further investment in Ayrshire Maternity Unit. The majority of this investment was as a direct result of the completion of the national workload tool for midwifery and includes:

- 6.6 whole time equivalent, Band 6 midwife posts recruited and in post by end of January 2016 (circa £377,000)
- Midwife/Supervisor of Midwives released 2 days per week to support the Clinical Risk and Governance agenda
- commitment of circa £625,000 investment for additional midwifery and nursing staff of 9+ whole time equivalents
- Clinical Risk Midwife and Quality Improvement Advisor in recruitment process, and
- a consultant job plan review is currently under way to understand if further consultant staff members are required.

190. The review team acknowledges the difficulties in recruitment in maternity services. NHSScotland is experiencing difficulty in recruiting to midwifery posts in a number of areas. After many years of having an oversupply of midwives, we are now experiencing shortages. This has been discussed with the Royal College of Midwives and the Scottish Government who are working to address these issues. NHS boards are addressing recruitment issues by advertising all vacancies as permanent posts, flexible working and national recruitment drives.

Training and education

191. The NHS board has acknowledged the importance of learning from adverse events in its policy. An important aspect of this learning is the ability to identify and undertake training and education. The NHS board provided the review team with information relating to their training and education to support the adverse event process to allow staff to appropriately report and investigate adverse events.

192. The NHS board reported that all staff had been appropriately trained in the investigation/review of adverse events in the maternity service. This training has included DATIX Reviewer and Final Approver training, Risk Assessment and also root cause analysis training. The review team noted that much of the adverse event review associated training, for example root cause analysis training, had been undertaken as ‘a one-off’, and in some cases this was a few years ago. Some staff noted that they would benefit from refresher training in how to undertake root cause analysis. There does not appear to be a clear mechanism for ensuring staff training is up to date.

193. All staff members have access to the DATIX drop-in sessions, which the NHS board runs on an ad-hoc basis, based on demand. Different levels of training have been provided to staff, however all staff reported that they knew how to report incidents onto the DATIX system.

194. Some staff told the review team that new starters to the unit have to seek out risk training relevant to their role. The board identified that 16 staff have been trained to
undertake risk assessments. Staff members are accountable for identifying their own needs for undertaking risk training, and refreshing this training, as required. The board stated that this should be picked up as part of annual personal development plans by line managers.

195. As part of the learning process, following adverse event reviews, the NHS board highlighted that it provides training sessions to address issues raised by the reviews. The NHS board acknowledged, however, that risk training has not yet been identified as a mandatory learning need.

196. NHS Ayrshire & Arran provides a number of maternity-specific training programmes, notably PROMPT (Practical Obstetric Multi-Professional Training - an evidence-based multi-professional training package for obstetric emergencies), and online cardiotocography (CTG) training using the K2 package (a well-recognised and widely used e-learning tool). Table 6 below shows the attendance rates for PROMPT between 2014 and 2016 across the maternity service by area in NHS Ayrshire & Arran.

Table 6: PROMPT training attendance rates in NHS Ayrshire & Arran (2014–2016)

<table>
<thead>
<tr>
<th>Department</th>
<th>Attended 2016</th>
<th>2015</th>
<th>2014</th>
<th>No record of attendance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community</td>
<td>20 (51%)</td>
<td>20</td>
<td>2</td>
<td>9 (18%)</td>
</tr>
<tr>
<td>Maternity outpatients</td>
<td>13 (42%)</td>
<td>7</td>
<td>2</td>
<td>9 (29%)</td>
</tr>
<tr>
<td>Inpatients ward</td>
<td>7 (13%)</td>
<td>14</td>
<td>2</td>
<td>32 (58%)</td>
</tr>
<tr>
<td>Maternity suite</td>
<td>1 (4%)</td>
<td>12</td>
<td>3</td>
<td>11 (41%)</td>
</tr>
<tr>
<td>Labour ward</td>
<td>27 (36%)</td>
<td>16</td>
<td>10</td>
<td>22 (28%)</td>
</tr>
<tr>
<td>Theatre*(trained staff)*</td>
<td>3</td>
<td>5</td>
<td>0</td>
<td>2 (20%)</td>
</tr>
</tbody>
</table>

197. The NHS board has acknowledged that PROMPT training undertaken by all staff on an annual basis would be considered the ‘gold standard’. During staff feedback sessions, it was noted that service pressures have meant that some training sessions have been cancelled and that whilst there has been a year on year increase since 2014, there is still a very low uptake of this training ranging from 4–51% of staff across the various maternity departments. Last year (2016), four out of six of the PROMPT sessions were cancelled. This training is associated with direct improvements in perinatal outcomes and has been proven to improve knowledge, clinical skills and team working.

198. K2 training is an online computer based training package for clinical staff who use cardiotocography (CTG) to assess fetal wellbeing, in particular during labour. All doctors and midwives who interpret CTG should complete the CTG K2 package on an annual basis. The Board reported that between April 2016 and March 2017 88% of midwifery staff from maternity outpatients, labour suite and maternity inpatient wards had completed this training. This data includes five members of staff who did not
complete their training due to maternity leave and long term sick leave. There were no data available as to the percentage of medical staff who had completed their CTG training.

<table>
<thead>
<tr>
<th>Key finding</th>
</tr>
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<tbody>
<tr>
<td>There is low uptake of important training and development specifically for maternity unit staff.</td>
</tr>
</tbody>
</table>

Further work should be undertaken by NHS Ayrshire & Arran to identify, address and monitor the ongoing training and development needs of its maternity unit staff. In addition, the review team noted that there is not an agreed list of mandatory skills and competencies for maternity services across NHSScotland. Local NHS boards are required to make sure that the training and development needs of their staff are identified and met. Further support should be offered to NHS boards to allow them to achieve this.

<table>
<thead>
<tr>
<th>Key finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>The importance of continual training and education and that the local training programme for staff should also be used as a mechanism to share and embed learning from adverse event reviews, allowing real-time implementation of improvements in practice.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommendation: Improve staff training and education</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Ayrshire &amp; Arran must make sure that the training and development needs of staff are identified and met in a timely manner. This should include:</td>
</tr>
<tr>
<td>• producing a training needs analysis</td>
</tr>
<tr>
<td>• ensuring access to training programmes, and</td>
</tr>
<tr>
<td>• monitoring attendance at training.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommendation: Identify training needs across NHSScotland</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHSScotland should develop and agree a list of mandatory skills and competencies for maternity services to support ongoing training programmes in NHS boards. This process should include how NHS boards can be supported to implement and monitor their training programmes.</td>
</tr>
</tbody>
</table>
Section 6: National initiatives

200. A number of national initiatives are in development that will support NHS boards in Scotland to apply a consistent approach to engaging with families as part of the adverse event review process. Three of these are noted below.

Perinatal Mortality Review Tool

201. It is a sad fact that some pregnancies do not result in the birth of a healthy child. In the UK, the stillbirth rate in 2015 was 3.87/1000 births with a neonatal death rate of 1.74/1000 live births. It has been acknowledged for some time that the perinatal mortality rate in the UK is higher than some other similar countries, and different initiatives have been implemented to try and understand why this is, learn lessons and reduce avoidable deaths. An essential part of understanding why a baby dies, whether before or after birth, is to look at the circumstances and care provided during pregnancy, birth and after birth. It is now recognised that input by the parents into this process is essential to enable full understanding. To this end, the MBRRACE-UK collaborative\(^3\) is leading a UK-wide initiative to develop and establish a national standardised Perinatal Mortality Review Tool (PMRT).

202. This tool, which is currently being developed, will be piloted over summer 2017 with the roll-out planned by the end of the year. The PMRT is being designed with user and parent involvement to support high quality standardised perinatal reviews on the principle of ‘review once, review well’.\(^3\)

203. The aim of the PMRT programme is to iteratively develop, pilot and facilitate the introduction of standardised perinatal mortality reviews across NHS maternity and neonatal units in England, Scotland and Wales. The tool will support:

- systematic, multidisciplinary, high quality reviews of the circumstances and care leading up to and surrounding each stillbirth and neonatal death
- active communication with parents to make sure 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, 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 which includes a meaningful, plain English explanation of why their baby died and whether, with different actions, the death of their baby might have been prevented
- organisations providing and commissioning care to identify emerging themes across a number of deaths, to support learning and changes in the delivery and commissioning of care to improve future care and prevent the future deaths which are avoidable and
• production of national reports of the themes and trends associated with perinatal deaths to enable national lessons to be learned from the nation-wide system of reviews.

204. Parents whose baby has died have the greatest interest of all in the review of their baby's death. Alongside the national annual reports, a lay summary of the main technical report will be written specifically for families and the wider public. This will help local NHS services and baby loss charities to help parents engage with the local review process and improvements in care.

**Being Open principles**

205. Open and effective communication with people should begin at the start of a patient’s care and continue throughout all the care they receive. This should be no different when an adverse event happens. Being open when things go wrong is key to the partnership between patients and those who care for them. The Being Open framework states that healthcare professionals have a professional duty to acknowledge when something has gone wrong and provide an honest explanation. Openness about what happened and discussing adverse events promptly, fully and compassionately can help people cope better with the after-effects of adverse events. Being open involves:

- acknowledging, apologising and explaining when things go wrong
- if appropriate, conducting a thorough review into the adverse event which involves patients, families, carers and staff, and aims to identify lessons that will support improvements and help prevent the adverse event being repeated, and
- providing support for those involved to address any physical and/or psychological consequences of what happened.

206. The *Being Open in NHSScotland: Guidance on implementing the Being Open principles* includes:

- Acknowledgement
- Truthfulness, timeliness and clarity of communication
- Apology
- Recognising expectations
- Culture and professional support
- Risk management and systems improvement
- Multidisciplinary responsibility
- Clinical governance
- Confidentiality
- Continuity of care

207. This framework supports NHS boards to develop their own approach to communicating and engaging with people who have suffered moderate or severe harm following an adverse event (predominately category 1 or 2 in the National Framework). The
information can be used to guide and inform local policy and procedures and applies across all care settings within NHSScotland.

208. The principles within the framework also align with the Scottish Government’s proposal to introduce a Statutory Duty of Candour for Health and Social Care Services, as described below.

**Duty of Candour**

209. A new legislation has been ratified in Scotland called the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill. This Bill contains provisions for the ‘duty of candour’. This is a new policy in Scotland to strengthen the consistency and rigour of approach taken to releasing information in the event of unexpected death or harm in a care setting. The Bill states³:

“The purpose of the new duty of candour provisions is to support the implementation of a consistent response from health and social care providers when there has been an unexpected event or incident that has resulted in death or harm (that is not related to the course of the condition for which the person is receiving care).

“The principles of candour already inform the approach that is taken in many organisations. It also applies to many health and social care professionals across Scotland, as this is a part of the requirements of their practice by their professional regulators.

“Regulations will be developed using powers created by Section 22 of the new Act. These will set out the detail of the Duty of Candour Procedure to be followed by each organisation. These Regulations will be legally binding and require the approval of the Scottish Parliament.”

210. Guidance will be issued to support implementation of the Duty of Candour part of the Act and outline supportive information on how the Act is applied in practice. It will address how the duty can be integrated with existing processes for responses to complaints, adverse event and incident reporting — emphasising the requirements for support, training and identification of learning and improvement actions.

211. Key principles:

- Providing health and social care services is associated with risk and there are unintended or unexpected events resulting in death or harm from time to time.
- When this happens, people want to be told honestly what happened, what will be done in response, and to know how actions will be taken to stop this happening again to someone else in the future.
- There is a need to improve the focus on support, training and transparent disclosure of learning to influence improvement and support the development of a learning culture across services.
Candour is one of a series of actions that should form part of organisational focus and commitment to learning and improvement.

Transparency, especially following unexpected harm incidents is increasingly considered necessary to improving the quality of health and social care.

Being candid promotes accountability for safer systems, better engages staff in improvement efforts, and engenders greater trust in patients and service users.
Next steps

212. Healthcare Improvement Scotland will expect a detailed action plan to be developed by NHS Ayrshire & Arran to support the implementation of recommendations 1–6 of this report. Evidence of progress will be followed up at regular intervals (every 3 months in the first instance) with regular updates published on Healthcare Improvement Scotland’s website.

213. Recommendations 7 and 8 will be taken forward in discussion with wider NHSScotland colleagues and progress provided on Healthcare Improvement Scotland’s website.

214. Whilst the focus of this review has been on NHS Ayrshire & Arran’s maternity unit, the findings and recommendations in this report should be considered across NHSScotland.

215. The review team would like to thank the families who contacted us to share their experiences, as well as all of the staff at NHS Ayrshire & Arran throughout this review process.
## Appendix 1 – Review team membership

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tracey Johnston</td>
<td>Consultant in Maternal Fetal Medicine</td>
<td>Birmingham Women’s and Children’s NHS Foundation Trust</td>
</tr>
<tr>
<td>(Chair)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nicky Berry</td>
<td>Associate Nurse Director / Head of Midwifery.</td>
<td>NHS Borders</td>
</tr>
<tr>
<td>Karon Cormack</td>
<td>Head of Clinical Risk</td>
<td>NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>Kim Hinshaw</td>
<td>Consultant Obstetrician &amp; Gynecologist</td>
<td>City Hospitals Sunderland NHS Foundation Trust.</td>
</tr>
<tr>
<td>Penny Leggat</td>
<td>Public Partner</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Edile Murdoch</td>
<td>Consultant Neonatologist</td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Coralie Rogers</td>
<td>Independent Midwifery Advisor</td>
<td>–</td>
</tr>
</tbody>
</table>
Appendix 2 – Clinical case review extract

N.B. The clinical case review, completed in April 2017 has been conducted by a multidisciplinary panel of clinical experts from the University of Leicester using the methodology developed for Mother and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK). The results from the panel have been presented and summarised in a report for the NHS board. This review was commissioned by NHS Ayrshire & Arran and the results of this were considered by the Healthcare Improvement Scotland review team.

Due to the small number of clinical cases, the Healthcare Improvement Scotland team has redacted some words in the extract to this report below. Where there is a potential that individual people or families could be identified a word or phrase has been replaced with a black rectangle.

NHS Ayrshire & Arran has committed to discussing through the details and findings of the independent clinical case review with the families.

**University of Leicester Review – April 2017 – EXTRACT**

Aspects of good and poor care were classified using a standardised system of documentation developed by The Infant Mortality and Morbidity Studies (TIMMS), with discussions and conclusions based on the clinical notes and other records provided by the Board. These findings have been summarised both in narrative format and also using point by point descriptions of the individual issues agreed by the panel in relation to the care provided to each mother and baby.

Issues to be reviewed within panels:

- Overview of the quality of the care provision for each stillbirth and neonatal along all points of the care pathway – including use of the transport team – with final assessment of the overall quality of care for each case
- Clinical decision making processes for every case identified for review.
- Medical, nursing and midwifery staffing profiles (adequacy of staffing was judged based on comments in the clinical notes) for every case identified for review.
- Availability and access to clinical support services for every case identified for review.

Once the records were received copies were taken and sent to each member of the review team. Each team member was asked to make a narrative description of the cases and to grade all notable aspects of the care received using the standard template employed by TIMMS.

**General themes**

These cases were reviewed without any background detailed knowledge of events / issues at the hospital during the time that the births took place (e.g. staffing structure, levels of activity, use of agency staff, vacancy rates etc.). However during the review of records certain issues arose which appeared relevant. These included:
### Activity levels / staffing levels

In [ ] of these cases events ran across a weekend and the [ ] others occurred [ ].

In [ ] of the cases there is specific reference to the service being busy and/or staff being tied up elsewhere and unable to attend when requested. Certainly the impression from the records was of a service under pressure.

### Sub-optimal care

In [ ] of the cases the panel took the view that different management would probably have led to a different outcome. However there was no obvious pattern detected in terms of the nature of the problems identified.

### Case review

Evidence of a review being carried out after the death was provided for [ ] of the cases. These varied in approach both in relation to the methodology adopted and in terms of whether there was external involvement. In general the focus of these reviews was primarily on the obstetric care and the view of the panel was that they did not contain specific or measurable actions.

The picture that emerged from the detailed notes review of the [ ] cases (and of course this was the only information available to the panel) and review panel consensus was of a service under great pressure and that at times this compromised the care that could be delivered. The nature of this compromise emerged in different ways depending on the circumstance. It would therefore seem to be important to review current staffing structures (particularly midwifery and obstetric) against workload.

There does seem to be scope for a more consistent approach to the review of deaths occurring in the service. This would involve looking carefully at the methodology to be employed and also ensuring that there is sufficient time for senior staff to be actively involved in the each review.
Appendix 3 – Actions to be taken to effectively manage adverse events

1. Risk assessment and prevention

2. Immediate actions following an adverse event
   - Adverse event occurs
   - Mako person/area safe and attend to any clinical needs
   - Hot debriefs with staff involved
   - Implement any immediate operational actions to reduce risk of recurrence e.g. removal of trip hazard or faulty equipment

3. Initial reporting and notification
   - Report to local reporting systems
   - Structured debrief with staff involved

4. Assessment and categorisation
   - Categorise adverse event
   - Review categorisation with relevant manager
   - Establish appropriate review
   - Undertake review involving patient/service user, their family and staff

5. Review and analysis
   - Develop action plan
   - Submit review report and action plan via the appropriate governance mechanism
   - Governance mechanism quality assurance and closure of review
   - Share learning and implement key learning points
   - Implement action plan
   - Review of implementation of actions

6. Improvement planning and monitoring
Appendix 4 – Supporting guidance and resources

- Adverse event/near miss reporting and escalation process: immediate action guidance
- Checklist for immediate management actions following a Significant Adverse Event
- Checklist for decision making in commissioning a SAER
- Checklist for process of managing SAER
- Checklist for implementing system analysis
- Yorkshire Contributory Factors Framework (YCFF)
- Guidance on disclosure of confidential information from SAERs
- Evaluation of the SAER process
- SAER staff evaluation questionnaire
- SAER team evaluation questionnaire
- Action Plan Guidance Document
- SBAR recommended reading and resources
Appendix 5 – Immediate action guidance

<table>
<thead>
<tr>
<th>ADVERSE EVENT OR NEAR MISS OCCURS</th>
<th>IMMEDIATE ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep yourself safe.</td>
<td></td>
</tr>
<tr>
<td>Raise the alarm for help from others (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Make patient(s) area safe</td>
<td></td>
</tr>
<tr>
<td>Label and remove equipment involved</td>
<td></td>
</tr>
<tr>
<td>Report</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial assessment of consequence impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you have answered yes to the question about death or significant harm then the consequence score must be either MAJOR or EXTREME.</td>
</tr>
<tr>
<td>For all other adverse events the consequence score should be INsignificant, MINor or MODerate.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. INsignificant or 2. MINor</th>
<th>3. MODerate</th>
<th>4. MAJOR</th>
<th>5. EXTREME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injury requiring no or some first aid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical outcome or reduced quality of patient experience not related / directly related to care delivery - readily resolvable</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Short term low staff levels results in minor impact to service / patient care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short term disruption in service with minor impact to patient care / project / objective</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organisational financial loss &lt; £10 k</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local media short term adverse publicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injury requiring clinical treatment / intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical outcome resulting in short term adverse effects - expect recovery &lt; 1wk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing low staff levels affecting service / safety delivery of patient care</td>
<td></td>
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<td></td>
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<tr>
<td>Disruption in service with significant impact to delivery of patient care / project / objective</td>
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<tr>
<td>Organisational financial loss &gt; £10k</td>
<td></td>
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<tr>
<td>Local media long term adverse publicity</td>
<td></td>
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<tr>
<td>Significant harm requiring intervention to save life</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Major injury or injury likely to result in long term incapacity / disability</td>
<td></td>
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<tr>
<td>Adverse clinical outcome resulting in long term effects - expect recovery &gt; 1 week</td>
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<tr>
<td>Sustained loss of service which has serious impact on delivery of patient care / project / objective</td>
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<tr>
<td>Organisational financial loss &gt; £100k</td>
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</tr>
<tr>
<td>National media adverse publicity &gt; 3 days</td>
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<tr>
<td>Adverse event leading to actual death</td>
<td></td>
<td></td>
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<tr>
<td>Adverse event leading to major or permanent incapacity / disability</td>
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</tr>
<tr>
<td>Adverse clinical outcome resulting in continued ongoing long term effects</td>
<td></td>
<td></td>
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<tr>
<td>Permanent loss of core service / facility</td>
<td></td>
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<tr>
<td>Organisational financial loss &gt; £1m</td>
<td></td>
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<tr>
<td>National media adverse publicity &gt; 3 days</td>
<td></td>
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<table>
<thead>
<tr>
<th>ACTION &amp; ESCALATION</th>
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</thead>
<tbody>
<tr>
<td>Reporter Action:</td>
</tr>
<tr>
<td>Complete on line Datix Form</td>
</tr>
<tr>
<td>Inform your line manager or supervisor next available opportunity</td>
</tr>
</tbody>
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<table>
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<tr>
<th>ACTION &amp; ESCALATION</th>
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<tbody>
<tr>
<td>Reporter Action:</td>
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<tr>
<td>Immediately inform your chit / line manager or supervisor</td>
</tr>
<tr>
<td>Complete on line Datix Form</td>
</tr>
<tr>
<td>Shift / line manager or supervisor must:</td>
</tr>
<tr>
<td>Consider escalating further</td>
</tr>
<tr>
<td>Consider taking staff statements</td>
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<tr>
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</thead>
<tbody>
<tr>
<td>Reporter Action:</td>
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<tr>
<td>Immediately inform your chit / line manager or supervisor</td>
</tr>
<tr>
<td>Ensure the scene is left undisturbed until informed otherwise</td>
</tr>
<tr>
<td>Complete on line Datix Form</td>
</tr>
<tr>
<td>Shift / line manager or supervisor must:</td>
</tr>
<tr>
<td>Notify Manager - Who will refer to Immediate Management Action Checklist</td>
</tr>
<tr>
<td>Escalate to relevant Director; inform / seek advice from Head Communications / Occupational Health and Safety</td>
</tr>
<tr>
<td>Ensure the scene is left undisturbed until informed otherwise</td>
</tr>
<tr>
<td>Contact police if required</td>
</tr>
<tr>
<td>Request staff statements to be collected</td>
</tr>
<tr>
<td>Check on line Datix Form completed</td>
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</tbody>
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Appendix 6 – Scottish Fatalities Investigation Unit (SFIU) advice on all sudden, suspicious, accidental and unexplained deaths

Within the Crown Office and Procurator Fiscal Service (COPFS), the Scottish Fatalities Investigation Unit (SFIU) is a specialist unit responsible for investigating all sudden, suspicious, accidental and unexplained deaths. The death of a child must be reported if:

- it is a sudden, unexpected and unexplained perinatal death
- where the body of a newborn is found
- where the death may be categorised as a Sudden Unexpected Death in Infancy (SUDI), and
- if the death arises following a concealed pregnancy.

A key issue the SFIU will consider is where there has been a systematic systemic failure in care which contributed to the death. All sudden, suspicious, accidental and unexplained deaths of adults and children that occur under medical care must be reported if:

- the nearest relatives are concerned about the medical treatment given to the deceased with a suggestion that the medical treatment may have contributed to the death
- the circumstances of which might indicate fault or neglect on the part of medical staff or where medical staff have concerns regarding the circumstances of death
- the circumstances of which indicate that the failure of a piece of equipment may have caused or contributed to the death
- a complaint is received which suggests that an act or omission by medical staff caused or contributed to the death
- if it was caused by the withdrawal of life sustaining treatment or other medical treatment to a patient in a permanent vegetative state
- the circumstances are likely to be subject to an Adverse Event Review (as defined by Healthcare Improvement Scotland), and
- it occurs in circumstances raising issues of public safety.

There are three SFIU regional teams (North, East and West) which consider reported deaths in their respective geographical area. The teams will ordinarily request and consider the relevant NHS board’s adverse events review reports into a significant adverse event. In addition, when investigating cases SFIU may consider instructing an independent expert to consider the circumstances of the death, which may include consideration of the review report and its learning outcomes. At the conclusion of its investigation, the SFIU will consider whether there should be a Fatal Accident Inquiry (FAI).
There are particular categories of deaths that will require an FAI to be held. In addition, COPFS may decide to hold an FAI where it is considered that it is in the public interest to do so – the aim being to identify learning and prevent future deaths occurring in similar circumstances. This is known as holding a discretionary FAI. When considering whether an FAI is appropriate, COPFS will assess if identified learning has already been shared nationally to prevent a similar event occurring in the future. One way of achieving this is through an agreement between COPFS and Healthcare Improvement Scotland to develop and disseminate adverse event learning summaries.

The aim of this process is to make sure that learning from death investigations is shared in the most efficient and effective way possible on a national basis, making sure that this is done in collaboration with the NHS board in which the review took place. Prior to a decision being taken to hold a discretionary FAI, the SFIU will share the terms of the investigation with the nearest relatives of the deceased and consider their views on whether there should be an FAI. If a decision is taken not to hold an FAI, SFIU will explain the reasons for this decision to the nearest relatives, including information about the dissemination of any learning.
References


## Glossary

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<tr>
<th>Term</th>
<th>Meaning</th>
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<tr>
<td>DATIX</td>
<td>A web-based incident reporting and risk management software for healthcare and social care organisations.</td>
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<td>Directorate Adverse Event Review (DAER)</td>
<td>A mid-level review undertaken following an adverse event.</td>
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<td>intrapartum</td>
<td>The period from the onset of labour to the end of the third stage of labour.</td>
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<td>Maternity and Children Quality Improvement Collaborative (MCQIC)</td>
<td>A Scotland-wide collaboration of maternity services staff, supported by the Scottish Patient Safety Programme within Healthcare Improvement Scotland.</td>
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<tr>
<td>Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries (MBRRACE)</td>
<td>A national collaborative programme of work involving the surveillance and investigation of maternal deaths, stillbirths and infant mortality.</td>
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<tr>
<td>multidisciplinary</td>
<td>Combining or involving several professional specialisations in an approach to a topic or problem.</td>
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<tr>
<td>neonatal</td>
<td>Refers to newborn babies.</td>
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<tr>
<td>perinatal</td>
<td>The time, normally from 24 weeks gestation, until 7 days postnatal.</td>
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<tr>
<td>postpartum</td>
<td>Time immediately following childbirth.</td>
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<tr>
<td>Practical Obstetric Multi-Professional Training (PROMPT)</td>
<td>A package of practical training sessions to prepare for maternity services specific emergencies.</td>
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<td>sepsis</td>
<td>The presence in tissues of harmful bacteria and their toxins, typically through infection of a wound.</td>
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<td>Significant Adverse Event Review (SAER)</td>
<td>A high-level review undertaken following serious adverse events, including serious harm and death.</td>
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<td>webEx</td>
<td>Online meeting, web conferencing and videoconferencing platform.</td>
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<td>whole time equivalent (WTE)</td>
<td>A unit that indicates the workload of a member of staff.</td>
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