NHS Governance - Clinical Governance
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Background

Following the avoidable death of our son Lucas Morton on the 16th of November 2015 we (and other families) have campaigned tirelessly in order that the true circumstances surrounding Lucas’ death (and that of others) be revealed, and that the investigatory and learning processes were properly implemented. Following adverse national publicity on these issues by the BBC in November 2016 the Cabinet Secretary for Health was compelled to instruct Healthcare Improvement Scotland to review the management of adverse events within NHS Ayrshire and Arrans maternity unit. This was the 3rd report into the management of adverse events within NHS Ayrshire and Arran within a 4 year period.

NHS Ayrshire & Arran

On the 21st of February 2012, the Scottish Information Commissioner published a Decision Notice (036/2012) that was highly critical of NHS Ayrshire and Arrans response to a Freedom of Information (FOI) (Scotland) Act appeal to an employee, Mr Wilson. The object of Mr Wilsons FOI submission was to obtain Significant Adverse Event Reviews together with their action plans completed since January 2005. The Cabinet Secretary for Health, at that time Nicola Sturgeon, instructed Healthcare Improvement Scotland to carry out a review of the approach taken by NHS Ayrshire and Arran in managing significant adverse events.

The Chair of the 2012 review was Robbie Pearson, now CEO of Healthcare Improvement Scotland. The review team included Mark Aggleton, then Controls Assurance Manager for Healthcare Improvement Scotland. The 2012 reviews methodology did not allow for any contribution to the review by patients or patients families.

Strathclyde Police probed the circumstances surrounding deaths where the incident reports had been previously withheld by NHS Ayrshire and Arran.

The Management of Significant Adverse Events in NHS Ayrshire and Arran was published in June 2012. The report described a system that did not reliably or consistently apply adverse event policy or supporting guidance. The report produced 25 recommendations with recommendations 1 to 17 specific to NHS Ayrshire and Arran and recommendations 18 to 25 for the wider NHS Scotland.

Page 19, Point 42 of the 2012 Review states “the review group noted the apparently low proportion of ‘major’ and ‘extreme’ events that went to significant adverse event review.

NHS Ayrshire and Arrans Executive Director of Nursing, Fiona McQueen, whose responsibilities included patient safety was deemed to have no case to answer in her misconduct hearing at the Nursing and Midwifery Council in December 2012. This hearing was initiated as a consequence of the 2012 HIS review.
Robbie Pearson stated at the NMC hearing that “there was a failure of the execution of the policy as a whole across the organisation and board rather than one person.”

To date, I am unaware if anyone within the organisation or board has been held accountable for the failings in policy outlined by Robbie Pearson in his defence of Ms McQueen.

Subsequently, Fiona McQueen was appointed as the interim Chief Nursing Officer for Scotland in November 2014 and was appointed to the position permanently in March 2015.

NHS Ayrshire and Arran has publicly acknowledged significant issues related to their significant adverse event management system prior to 2009. Despite this fact it appears that they were given the freedom to produce policy in an area in which they had no real knowledge, experience or expertise?

Healthcare Improvement Scotland – Chronology of Inspection/Scrutiny

- October 2012 – HIS receive a copy of NHS Ayrshire and Arrans progress on implementing their Improvement Plan.
- In November 2012 – April 2103, NHS Ayrshire and Arran asked Healthcare Improvement Scotland to undertake a supplementary review of all documentation (from 2002-2012) to seek assurances as to the timely creation of the action plans of the 89 cases listed.
- Management of Adverse Events, Review Report, NHS Ayrshire and Arran was published in December 2013 following a return by Healthcare Improvement Scotland in October 2013.

The review highlighted progress that NHS Ayrshire and Arran had made in the management of adverse events since the initial 2012 report.

The Lead for the 2013 review report was Mark Aggleton, now Senior Programme Manager at Healthcare Improvement Scotland.

The review of NHS Ayrshire and Arrans governance arrangements and processes for managing adverse events involved:
- An analysis of evidence provided by the NHS board, and
- A visit to NHS Ayrshire and Arran on Wednesday 9th October 2013

- 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 and Arran in October 2014 and September 2015.
- In November 2014 and May 2016 Healthcare Improvement Scotland have published two summary reports which provide an overview of areas of good practise and challenges by NHS boards in implementing the national framework and sharing learning from adverse events.

Current Situation
Following adverse media publicity the Cabinet Secretary for Health, Shona Robison, instructed Healthcare Improvement Scotland to undertake an independent review focussing on the Ayrshire Maternity Unit at University Hospital, Crosshouse, NHS Ayrshire and Arran. The review was to consider aspects of the quality of care offered to mothers and babies within Ayrshire Maternity Unit and was to include discussions with families affected and invited members of the public to share their experiences of maternity services. The review was also set to examine the extent to which the NHS Board learns from adverse events and how they oversee the application of this learning to help improve the care they provide to women and their babies.

The terms of reference of the review states that “Healthcare Improvement Scotland reserves the right to extend the scope, including the period of time it covers, of this review should other matters come to our attention over the course of the review pertaining to safety and quality of care”.

The terms of reference for the 2017 review stated that in support of the improvement work undertaken by NHS Ayrshire and Arran that the review will focus on the time period between December 2013 and the present day. This assumption of any improvement is wholly unsubstantiated in our opinion.

The 2017 Review found “a system which requires investment and improvement”. “Protected staff training a major challenge”. “Low uptake of important training and development specifically for maternity unit staff”.

The review team also stated that the “maternity unit circumvented deficiencies in the NHS boards adverse event management policy”. And that NHS Ayrshire and Arran “carried out a very small number of SAERs using its established process”.

Since 2012 no SAERs were undertaken by the maternity service (and very little undertaken by any other service in comparison to pre 2012 figures). The maternity service, supported by senior management, adopted their own bespoke DAERs as a means to which routinely undertake reviews of significant adverse events. The 2017 Review shows this approach to be chaotic at best with the quality of investigations being wide and varied with confusion amongst staff on which process to follow. It would also indicate that the maternity unit’s staff were not consulted when the new policy was created in 2012 after intervention from Healthcare Improvement Scotland.

The statistical fallout of this approach was a ‘false positive’ of a far lower number of SAERs recorded across the entire board, which I believe was the managements aim from the outset. The 2017 Review states “It would have been appropriate, in the interests of transparency and governance, to expect the NHS Boards adverse event management policy to have been complied with”. The review goes on to state that “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 given the issues that gave rise to the original review in 2012”.

The review team go on to say that they found no evidence of any deliberate attempt to suppress SAERs by NHS Ayrshire and Arran, and nor would they given that this
objective was not within their narrow scope set by the Scottish Government, or field of expertise. However in response to the nationwide BBC report which sparked the 2017 review the board of NHS Ayrshire and Arran released a statement:

“Since 2008 up until March 2016, there has been four SAERs concerning stillbirth deaths at Ayrshire Maternity Unit. During this time 33,176 babies have been born at Ayrshire Maternity Unit”.

The review team correctly addressed this shameful and cynical statement by stating “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 of significant adverse events and those were investigated through the DAER process and therefore not identified as SAERs”.

It is for this committee to draw their own conclusions on the morality and integrity of the approach of the board and senior management of NHS Ayrshire and Arran with the release of this statement. We as a family believe that their approach in suppressing the number of SAERs and replacing their policy with a flawed, rogue and ad-hoc replacement, has effectively negated any opportunity to identify failings and patterns and trends of such failings, and therefore increased the risk to patients whilst also effectively muting any opportunity to implement remedial action and positive change. Allied to underfunding, understaffing and deficiencies in workforce planning and training, we firmly believe that this approach was a significant factor in the death of our son Lucas and undoubtedly others. This is not confined to the maternity unit.

**Healthcare Improvement Scotland – Clinical Governance**

The above section appears to show a chronology of failure on the part of Healthcare Improvement Scotland in ensuring that NHS Ayrshire and Arran had addressed their self-confessed weaknesses in the implementation of an effective adverse event policy. Despite this level of scrutiny they failed to identify that the number of recorded adverse events, which they deemed to be low in 2012, had effectively dwindled to all but zero. In fact in 2013, the first year in which their new policy was implemented, NHS Ayrshire and Arran recorded zero SAERs. Healthcare Improvement Scotland are on record as stating that they do not routinely receive or monitor SAER figures, which begs the question who does? They also appear to be unaware that departments within NHS Ayrshire and Arran had decided, with the support of senior management, to circumvent this newly created but seemingly deficient adverse event policy. Why were they allowed to develop it on their own in the first place?

During this period of scrutiny it also went undiscovered that NHS Ayrshire and Arran were not fully notifying the Crown Offices, Scottish Fatalities Investigation Unit of avoidable, unexpected and unexplained deaths as required by the national guideline. I’m sure that you will agree that this system is an effective safety net of our society in which any competent fiscal would be able to identify patterns and trends of deaths which may be of concern and deserving of further scrutiny.
It would be easy to criticise Healthcare Improvement Scotland but I believe that this is an organisation which has suffered from mission creep since its inception, and from our own experience of the 2017 review, effectively had its wings clipped due to the narrowness of the scope imposed on them in which they conduct their reviews. Healthcare Improvement Scotland is effectively hamstrung in its efforts due to the fact that it is not a regulator, has no powers, and is not entirely independent of the NHS. During the period from 2012 to the present, serious questions must also be asked of the board of NHS Ayrshire and Arran. Executive directors are required at intervals to provide assurances that things are going well and if this is not the case that there are effective plans in place to address this. The problem is that they know full well that underfunding, understaffing and other pressures make it almost impossible to provide an honest assurance to the board, but to say that they cannot guarantee patient safety is professional suicide. It is our position that in the case of the maternity unit that decisions taken purely on efficiency have undermined both the quality and safety of care.

Does this explain NHS Ayrshire and Arrans repeated failure in the management of adverse events? Doing something often is not a mistake but a pattern of behaviour and our behaviour is governed by the rules and regulations which are set for us. The problem with the NHS in Scotland is that we have no independent regulator and therefore no rules and regulations. Senior management of Healthcare Improvement Scotland are on record as expressing reluctance and caution of introducing a regulatory regime to healthcare in Scotland. But we cannot continue to expect Healthcare Improvement Scotland to continue with their flawed ideological hands off holistic approach to the clinical governance of healthcare in Scotland. Speaking softly and not being armed with a big stick is clearly not working.

We believe that the creation of an independent regulator for healthcare in Scotland is required.

We also believe that it is in the public interest to provide assurance, transparency and restore the trust of the people of Ayrshire and Arran in the safety and quality of the service of which they receive, that a public inquiry is called to fully investigate once and for all the issues surrounding the management of adverse events that have plagued the board of NHS Ayrshire and Arran.

Thank you for the opportunity to submit written evidence to the Health and Sport Committee on Clinical Governance.
REFERENCES

- The Management of Significant Adverse Events in Ayrshire & Arran report June 2012
  http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/nhs_ayrshire_arran_report.aspx
  (I would like to draw the committee’s attention to the statement by Robbie Pearson CEO of Healthcare Improvement Scotland when accessing this page.)

  http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/adverse_events_reviews/nhs_ayrshire_arran_dec_2013.aspx

- Review of Ayrshire Maternity Unit, University Hospital Crosshouse, NHS Ayrshire & Arran (Adverse Events) 2017.
  http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/programme_resources/ayrshire_maternity_unit_review.aspx
- Management of Adverse Event Review Report, NHS National Services Scotland
  December 2013

- Learning from adverse events through reporting and review.
  A national framework for Scotland: Second edition