

NHS England and NHS Improvement Board meetings held in common

Paper Title: Patient Safety and the role of the Healthcare Safety Investigation Branch

Agenda item: 9.2 (Public session)

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Paper type: For discussion

Organisation Objective:

NHS Mandate from Government	<input type="checkbox"/>	Statutory item	<input type="checkbox"/>
NHS Long Term Plan	<input type="checkbox"/>	Governance	<input checked="" type="checkbox"/>
NHS People Plan	<input type="checkbox"/>		

Summary/recommendation:

This paper describes NHS England and NHS Improvement's work to improve the identification and response to safety concerns across the NHS as part of the NHS Patient Safety Strategy. It also describes the role of the Healthcare Safety Investigation Branch in responding to safety concerns across the system, including in maternity services. This paper should be read alongside the accompanying Board paper on the response to Shrewsbury and Telford Hospital NHS Trust.

Action required:

The Boards are asked to note and discuss the content of this report.

Risk:

This paper links to the care quality events risk.

Background

1. The Ockenden review of maternity services at Shrewsbury and Telford Hospital (SaTH) NHS Trust published a report on 10 December 2020 (see <https://www.ockendenmaternityreview.org.uk/first-report/>) making system-wide recommendations to improve maternity care. All trusts were subsequently **required** by NHS England and NHS Improvement to confirm they had implemented the immediate and essential actions by 21 December.
2. Recognition and response to patient safety concerns is a key theme in the report, as it is in the NHS Patient Safety Strategy published in 2019 which sets out an ambitious plan of work to improve how the NHS learns when things go wrong.
3. This paper describes these activities in more detail and also discusses the role of the Healthcare Safety Investigation Branch (HSIB).



Considerations

Quality management

4. The situation at SaTH demonstrates failures in the organisation but also opportunities missed in the wider system to support the three key quality functions described in the Juran Trilogy, i.e. quality planning; quality assurance; and quality improvement. SaTH as a Trust is primarily responsible for ensuring it plans its operations, assures the quality of what it is doing and seeks to continuously improve services. However, it is also useful to consider the roles of the wider system in these three functions:
 - quality planning should be supported by the wider commissioning and operations systems and includes NICE, Royal College Guidance and research evidence;
 - assurance is primarily the responsibility of relevant regulators, such as CQC, professional regulators and MHRA. CQC in particular have invested significant resource in creating metrics to identify where organisations may be experiencing quality failures; and
 - supporting continuous improvement is the role of the improvement functions in NHS England and NHS Improvement, including the Maternity Transformation Programme (MTP), the NHS National Patient Safety Team including via patient safety collaboratives, and the Improvement Directorate.
5. The discussion below will link to these distinct functions and roles, including where HSIB sit and current work to improve maternity safety and wider concerns.

Responding to the Ockenden Report and the MTP

6. In response to the Ockenden Report, NHS England and NHS Improvement sought immediate action from all relevant trusts. Most reported either fully or partially meeting the requirements, with responses indicating that further work is being undertaken to meet them in full. In addition, work is already ongoing to improve the system's approach to quality management of maternity services. This work is described in the accompanying board paper.

HSIB's role

7. HSIB was launched in April 2017 to conduct independent investigations into patient safety concerns in NHS-funded care across England. HSIB works on the principle, established in other safety-critical industries, that most harm results from problems within the systems and processes that determine how services are delivered. HSIB's national investigations identify contributory factors that have led to harm to patients and make recommendations to national bodies to reduce risks. HSIB has commenced 58 national investigations since 2017.

8. Concerns about the quality of some maternity services led the previous Secretary of State to ask HSIB to undertake investigations into all incidents in the NHS that meet RCOG's Each Baby Counts programme criteria – maternal and neonatal deaths, stillbirths and neonatal brain injuries. This started on 1 April 2018 (well after the Ockenden Review had begun). HSIB has now conducted over 1400 maternity investigations.
9. HSIB's maternity investigation currently replaces the local investigation that would have previously occurred in all relevant trusts. The local trust does still complete the '72-hour report' and logs the incident on the national StEIS database.
10. HSIB is not a regulator and has no enforcement capability. However, it does seek assurance that organisations are acting in response to its recommendations and escalates any serious ongoing concerns to regulators. HSIB identified concerns at East Kent University NHS FT resulting in the ongoing review there.
11. HSIB could in future undertake some investigations and reviews currently commissioned from independent investigators or members of the judiciary, such as that at SaTH, East Kent or Southern Health. This function was among the reasons why HSIB was proposed to be established in 2015 –rather than continuing to commission one-off, expensive and lengthy enquiries.
12. HSIB is also working to establish a healthcare safety investigator training and education programme aimed at improving the quality of local NHS investigations. This will be trialled with the trusts participating in the Patient Safety Incident Response Framework pilot and is being aligned with the Patient Safety Syllabus work both of which form part of the NHS Patient Safety Strategy described below.

The NHS Patient Safety Strategy

13. The NHS Patient Safety Strategy was approved by the NHS England and NHS Improvement Board and published in July 2019. An update to the Strategy was published on 11 February. The Strategy is concerned with safety improvement, but it does describe a range of work to support the NHS to identify and learn from patient safety incidents, which also supports quality planning and assurance.

Culture

14. The NHS's ability to identify problems and effectively and sustainably reduce risks is dependent on organisations promoting openness, learning, continuous improvement and ensuring a just culture, where people are not inappropriately blamed for things going wrong. A common theme with major tragedies in healthcare organisations is the prevalence of blame, denial and fear leading to failure to respond meaningfully in a way that supports improvement. Safety

culture also links strongly to equality and diversity issues and there is evidence of patient safety inequalities among different groups.

15. Work under the NHS Patient Safety Strategy is examining the key features of safe organisations, including how leaders engender a just culture as well as examining better ways of assessing patient safety culture. There is an intention to build an evidence base for interventions that support culture improvement, as well as identifying and addressing inequalities in safety.
16. The NHS Staff Survey asks a range of questions that relate to safety culture. Responses can be benchmarked against peers and used to track change over time. SaTH was in the mid-range compared to peers, with the exception of a marked dip in 2017 on a single question 'I would feel secure raising concerns about unsafe clinical practice'.¹

Incident reporting

17. The NHS is a world-leader in incident reporting with well over 2 million incident reports made every year. Incident reporting rates cannot be used to tell us which organisations are safer than others (i.e. for assurance) and reporting rates can only identify problematic organisations with very low reporting. However, incident reporting does allow providers to examine and respond to risks; a first step in undertaking improvement. The NHS's unique, and longstanding National Reporting and Learning System (NRLS) allows the identification of emerging themes and trends nationally, supporting creation of national patient safety alerts and other responses that reduce risks to all patients, as has been possible during Covid.
18. Work is ongoing to improve incident reporting and response by replacing the NRLS. The new system will record information about incidents in ways that better reflect how incidents are identified, allow real-time updates as new information emerges, and will be available to more providers as well as remotely. The new system will also support the use of machine learning and other digital techniques to improve how we learn. Public launch is planned in Spring 2021.

Incident response

19. There are up to 20,000 SII's conducted across the NHS annually, but we know from multiple reports and reviews that the quality of these is variable. Patients, families and staff are not always well informed, involved and supported. Staff may need more training in addition to their day jobs.
20. A new Patient Safety Incident Response Framework is being piloted, which supports organisations to take a less reactive approach to incident response. This means planning the allocation of resources to investigation and identifying local priorities for learning, while placing the provider board as the accountable body to receive and sign off investigation reports, not the commissioner. It is

¹ [NHS Staff Survey 2018 Benchmark Reports \(nhsstaffsurveyresults.com\)](https://www.nhs.uk/press-releases/2019/07/24/nhs-staff-survey-2018-benchmark-reports) p35-36

worth noting this is consistent with the first recommendation from the Ockenden Report that “All maternity SI reports (and a summary of the key issues) must be sent to the Trust Board...for scrutiny, oversight and transparency”. Other proposed changes include:

- describing incident management as part of a system-based, cross-setting approach to safety rather than narrowly defining ‘serious incidents’;
- focussing on safety and learning rather than performance management, ‘avoidability’ or liability and emphasising a fair response to incidents;
- removing the hard 60-day deadline for investigation reports to be completed;
- promoting increased transparency and the need for support for those affected by patient safety incidents (patient, family and staff); and
- introducing new Patient Safety Investigation Standards.

21. 25 early adopter organisations are testing this approach throughout 2021. If successful, the PSIRF will be rolled out more widely from April 2022.

Medical examiners

22. A new medical examiner system is being rolled out through acute trusts in England to provide independent scrutiny of deaths, including the deaths of children and neonates. Work on analysing the responses to the consultation on Coronial investigations of stillbirths has been delayed during the Covid-19 pandemic, but DHSC and MoJ hope to publish the response to the consultation as soon as possible.

23. A core element of the ME system is to provide bereaved families with an opportunity to ask questions about the cause of death, and to raise concerns about the care provided before death. When medical examiners detect concerns, they refer these for further review and action, e.g. through case record review or other clinical governance processes.

24. The system has been rolled out across acute trusts and a majority of deaths in this setting are now being scrutinised.

Increasing knowledge, expertise and involvement

25. Work is ongoing with HEE and the Academy of Medical Royal Colleges (AoMRC) to create the NHS’s first Patient Safety Syllabus. This will set out the knowledge and skills relevant to different levels of patient safety expertise and will support inclusion of patient safety in all healthcare education. Work is also underway to develop an ‘essentials’ training course for all current and future NHS staff, including content on incident reporting, investigation and just culture.

26. A network of over 600 Patient Safety Specialists has been created. These are existing staff who are being directly supported to lead safety in their organisations. They will:

- act as their organisations' senior lead for patient safety providing expertise and oversee their organisations' safety activities
 - supporting implementation of national safety priorities, such as national patient safety alerts and the roll out of PSIMS
 - provide feedback and highlight priorities for action regionally and nationally
 - form a mutually supportive community
 - engage in ICS safety oversight and governance
27. At first, we are exploring their existing knowledge to understand their training needs. We will then work with the AoMRC and HEE to develop that training.
28. A third area of involvement is the creation of a Framework for Involving Patients in Patient Safety. Due for publication by April, this will set out how patients and their families can support their own safety as well as how we expect patients and lay leaders to be involved in organisational safety. Organisations will be required to have a minimum of two patient/lay members on key safety committees. This will support openness and put patients at the centre of safety decision-making.
29. Consideration is being given to how these 'Patient Safety Partners' can be aligned with the work of Healthwatch, the newly proposed Patient Safety Commissioner and other patient safety advocates.

Improvement

30. There are 5 national patient safety improvement programmes within the Strategy;
- The Maternity and Neonatal Safety Improvement Programme works with the Maternity Transformation Programme to make care safer through a range of initiatives including a focus on maternal and neonatal deterioration and improving pre-term optimisation.
 - The Mental Health Safety Improvement Programme is focussing on improving sexual safety for inpatients, reducing restrictive practice, and reducing suicide and deliberate self-harm.
 - The Adoption and Spread workstream continues to focus on supporting adoption of proven interventions such as the safe tracheostomy care bundle.
 - The Medication Safety Improvement Programme is designing interventions to improve the safety of primary care prescribing, developing anticoagulation safety improvement plans, reducing high dose prescribing of opioids, reducing harm from methotrexate and reducing problematic polypharmacy.
 - The Managing Deterioration Programme is leading on the implementation of virtual wards and remote monitoring. This includes supporting work to implement pulse-oximetry in community settings like care homes.

Summary and key points

31. Issues with maternity services highlighted in recent years have led to an ongoing focus on improving our system. There is significant work across organisations including engagement of the Royal College of Obstetrics and Gynaecology and Royal College of Midwives, led by our National Clinical Director for Maternity and the NHS's first ever Chief Midwifery Officer. Action in relation to East Kent, triggered in part by HSIB, was more rapid than was seen in with SaTH and indeed Morecambe Bay. Further action is needed although it is promising that national data are showing improvement.
32. More broadly, work under the NHS Patient Safety Strategy is designed to address challenges across the NHS to improve the recognition and response to patient safety issues. This work builds on the understanding from other industries that most harm results from problems with systems and processes, not individuals, and that the right approach is to encourage open and transparent cultures, that support staff and patients when things go wrong, embrace diversity and where no-one fears inappropriate blame.