Update on Investigations in the NHS

National policy and guidance
In March 2015 two documents were published which have influenced significant change in relation to investigation in the NHS. These are:
• NHS England – Serious Incident Framework: Supporting learning to prevent recurrence;
• Public Administration Select Committee: Investigating clinical incidents in the NHS.

The latter sets out important recommendations for the way in which patient safety is improved and lessons are learned from untoward clinical incidents that help prevent reoccurrence. The Select Committee report concluded by recommending the establishment of a single independent investigative body: the Independent Patient Safety Investigation Service (IPSIS). Its role will be to provide national leadership and support local capability while acting as a catalyst to promote a just and open culture across the whole health system. IPSIS is currently being developed by an Expert Advisory Group and is expected to launch in April 2016.

Further information on the establishment of IPSIS was made available in July 2015 when the government published its response to the Freedom to Speak Up consultation, the Public Administration Select Committee report: ‘Investigating Clinical Incidents in the NHS’ and the Morecambe Bay Investigation.

Board Responsibilities
Following the publication of a number of national inquiries and high profile investigations, it has become evident that the quality and robustness of serious incident investigations in the NHS requires improvement. This has led to increased scrutiny from patients, regulators, the media and politicians. With changes afoot in relation to the way serious incidents are investigated, NHS boards must be assured that systems and processes for investigating serious incidents are robust and can stand up to external scrutiny. They must be assured that their organisations have the capacity and capability to undertake high quality, comprehensive investigations which are timely and involve the patient, family or carers of those affected by the incident. In addition and of equal importance, health provider and commissioner boards have a role to play in creating a positive culture and environment in which patient safety incidents are openly investigated, the facts are identified and the organisation faces up to the truth and promotes learning for improvement and better outcomes for patients.

Briefing Purpose
• Provide an update on national policy and change following briefing note 3: Investigations in the NHS;
• Reflect on the potential impact of national change and consider your organisation’s state of readiness;
• Pose some questions for Boards to consider.

There is a duty on NHS boards to report openly on the findings of any external investigations into clinical services, governance or other aspects of the operation of the organisation; this includes prompt notification of relevant information to external bodies such as commissioners and regulators and the open exchange of information with external scrutiny and investigations.
NHS England Serious Incident Framework: Supporting learning to prevent recurrence

The new framework emphasises the key principles of serious incident management; to explicitly define the roles and responsibilities of those involved in the management of serious incidents; to promote the principles of investigation best practice across the system and focus attention on identification and implementation of improvements that prevent recurrence rather than completion of a series of tasks. It highlights the importance of working in an open, honest and transparent way where patients, their families and carers are put at the centre of the process.

Two key operational changes have been made in the new framework, these are:

• Removal of grading – all incidents meeting the threshold of a serious incident must be investigated and reviewed according to principles set out in the framework;

• Timescale – single timeframe of 60 working days has been agreed for completion of investigation reports (local level).

The removal of grading means that organisations need to have clear processes for assessing whether an incident is considered a serious incident or not – some will be self-evident but where there may be ambiguity the framework requires the provider and commissioner to work together to agree whether it is a serious incident or not.

The framework sets out seven key principles: open and transparent; preventative; objective; timely and responsive; systems based; proportionate and collaborative. Each of the principles is set out with a clear objective outlined in the framework. One of the main requirements is that those involved in the investigation process must not be involved in the direct care of those patients affected, nor should they work directly with those involved in the delivery of that care.

The framework still advocates the use of the Root Cause Analysis system but stresses that involvement of patients, victims and families/carers is critical. The framework confirms that the publication of serious incident investigation reports and action plans is considered best practice. It requires local commissioners to work with their providers to encourage and support publication of reports and action plans. This includes a need to protect the anonymity of persons involved and compliance with relevant Data Protection Act requirements.

Public Administration Select Committee: Investigating Clinical Incidents in the NHS

The report sets out important recommendations for the way in which patient safety is improved and lessons are learned from untoward clinical incidents that help prevent recurrence. The role of the committee was to scrutinise the work and adjudications of the Parliamentary and Health Service Ombudsman (PHSO). The report references the public inquiry into Mid Staffordshire NHS Foundation Trust and the Morecambe Bay inquiry into maternity services.

The committee highlighted the Department of Health report published in February 2015 ‘Culture change in the NHS’. This stated that ‘it made sense to concentrate and consolidate national expertise and capability on safety within a single organisation that can provide strategic leadership across the whole healthcare system’. The report refers to the impact that untoward clinical incidents have on patients and their families, as well as on medical professionals. There is a recognition that the current complaints system often heightens harm and distress to families following an incident. The report emphasises the importance of good local investigation and recognises the need for independent investigation so that causal factors or patterns of failure can be analysed across a region, system or entire country. It refers to Root Cause Analysis (RCA) investigation and the fact that many local investigations over-rely on RCA rather than simpler and potentially more effective methods such as The Human Analysis Classification.
System. The report highlights the importance of learning and sharing lessons and the fact that a failure to learn from incidents and disseminate lessons has been a long-standing weakness of the NHS.

It is important to note paragraphs 107 and 108 of the report. This stresses that the Government should avoid doing anything that might weaken the responsibility of local NHS providers to carry out effective investigations. Dr Mike Durkin of NHS England is quoted: ‘We should not undermine the process of local accountability through the boards of the hospitals of the NHS, which are absolutely responsible for the quality of care.’

The NHS will need the right people and resources to carry out its investigations supported by training.

The major recommendation of the Select Committee report is the establishment of a single, independent, investigative body. Its role would be to provide national leadership and support of local capability and act as a catalyst to promote a just and open culture across the whole health system. Key points for the new body are:

- Permanent and independent to ensure a dispassionate and system-wide view of safety;
- Ensure a safe space for disclosure, witnesses should be given legal immunity for what they say and evidence exempted from Freedom of information Act;
- Must enable and promote good investigatory practice with its own substantial investigative capacity;
- Clear mandate and criteria to be established regarding when it should undertake an investigation, conducted by trained and expert investigators including or drawing on expertise in clinical disciplines, human factors and the safety sciences;
- To establish a single set of incontestable evidence for use in investigation.

The committee recommended that the Secretary of State brings forward proposals and legislation to establish a national independent patient safety investigation body. It must be a centre of expertise and promotor of good investigatory practice and expertise, with its own substantial investigative capacity to lead by example, oversee local investigations and conduct its own investigations when necessary.

Independent Patient Safety Investigation Service (IPSIS)

IPSIS will be led by Dr Mike Durkin, National Director of Patient Safety, NHS England and it will be hosted by NHS Improvement. IPSIS will conduct investigations in the NHS as well as offering support and guidance to NHS organisations. The aim would be to promote a culture of learning and a more supportive relationship with patients, families and staff.

The new service will select incidents to investigate and ensure that lessons from serious incidents are learned and acted on across the NHS. The transfer of the National Reporting and Learning System (NRLS) to NHS Improvement will require new legislation to amend the Health and Social care Act 2012. The Department of Health (DH) intends to launch a consultation regarding ‘forcing’ NHS providers to notify regulators when they commission external investigations.

Role of IPSIS

The service provided by IPSIS will have the capacity to examine only a small proportion of patient safety incidents. A key role will be for it to champion high quality local investigations and lead on approaches which will enhance the capabilities of providers to conduct their own investigations.

The role of the new service includes:

- Conduct independent, expert-led investigations into patient safety incidents;
- Be selective about the incidents it selects to ensure optimum effectiveness;
- Focus on incident types which signal systemic or apparently intractable risks within the local healthcare system;
- Examples are: incidents which lead to high cost litigation, claims, certain never events, and incident types such as medication errors;
- Examine cross-cutting themes from these investigations.

The terms of reference for the Expert Advisory Group and contact details can be seen at www.gov.uk/government. IPSIS is currently inviting views on the new service and how it will work.
Key questions

Strategy and vision

- Can the Board evidence investment in specialist posts, training and safety improvements as a result of serious incident investigations?
- Does the Board have a systematic approach to anticipating future risks to patient safety?
- Does the organisation consider and implement the learning from national and local patient safety investigations and can this be evidenced?

Assurance

- Does the Board review the processes and outcomes of investigations? If so what was the key learning for the organisation?
- Is the Board confident that its systems and processes following serious incident investigations enable lessons to be identified, shared and embedded across the organisation and system?
- Is there a comprehensive action plan to address areas of weakness in relation to the investigation of serious incidents and does the Board receive progress reports?
- How does the Board gain assurance that actions following serious incident investigations are sustained and have been embedded in everyday practice?
- Does the Board have a mechanism for tracking and monitoring the outcomes from serious incident investigations? Think of an example of a specific investigation and describe what you have learnt as a director and as an organisation.

Commissioner responsibilities

- As a commissioner how do you use the analysis of incidents to indicate possible wider issues with patient safety within the wider system?
- As a commissioner are you confident that systems and processes for investigating serious incidents are robust and can withstand external scrutiny?
- As a commissioner are you confident that relevant information about serious incidents is shared openly and in a timely manner?
- As a commissioner how do you gain assurance on the completion and implementation of action plans?
- As a commissioner do you have arrangements in place for comprehensive reporting on action plans and outcomes from SI investigations and lessons learned across all levels?
- As a commissioner what arrangements do you have in place for gaining assurance on the robustness and quality of serious incident investigations?

Training and development

- Does the organisation provide training and development for staff who are either leading or participating in investigations?
- How does the Trust support staff who are called as witnesses to an investigation?
- Are those affected by serious incidents offered the opportunity to access the findings and comment on recommendations?

Accountability, openness and transparency

- Does the organisation have a clear process for the publication of investigation reports and the process for notifying those affected?
- Is there a comprehensive serious incident tracking system and process for reporting to Board?
- Does the provider have clear and effective procedures for notifying commissioners and regulatory bodies when serious incidents occur?
- As a provider are you confident that systems and processes for reporting to commissioners and regulators are robust and that communication is open and transparent?

Contact Us

Please contact us if you would like to discuss how we may be able to support you and your organisation with any aspects covered within this briefing note.

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