

Name of Guidance	Serious Incidents; reporting of trainee involvement, and investigation - the role of Health Education England in Yorkshire and the Humber	
Category	Quality Management Patient Safety Revalidation	
Authorised by	Postgraduate Dean's Senior Management Team	
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Version	ersion Date Author	Notes	
			Reason for Change, what has changed, etc
1.0	April 2011	David Eadington	New guidance
2.0	April 2014	David Eadington	Revised and updated
3.0	March 2016	Jill Hanson, Business Manager	Amended in line with new HEE branding guidelines
4.0	August 2018	David Eadington	Updated, impact of reflective practice expanded

Related Document (hyperlink)

• National Framework for Reporting and Learning from Serious Incidents requiring investigation

Section 1: Introduction

Proper investigation of clinical incidents is an essential part of maintaining patient safety. A previous survey of all Yorkshire and Humber trainees showed that:

- many have been involved in a serious clinical incident during their training
- most have incomplete understanding of the investigation processes following clinical incidents
- very few understood the role of the Deanery (as was) in this area
- attitudes and support behaviours exhibited by colleagues after serious incidents vary
- · overall the experience is often negative

This guidance is written to fill some of these gaps and to explain the role of Health Education England working across Yorkshire and the Humber (HEE YH) in supporting trainees who are involved in serious clinical incidents. More detailed background material is given in the National Framework for Reporting and Learning from Serious Incidents requiring investigation.

Every Trust has a public policy on how it will manage clinical incidents; these documents are available via Trust's local internet pages.

Section 2: Who does this guidance apply to

- Doctors and dentists in training posts working across Yorkshire and the Humber
- Educational and clinical supervisors employed across Yorkshire and the Humber
- All HEE YH Staff

Section 3: Definitions and abbreviations used throughout the document

- ARCP Annual Review of Competency Progression
- GMC General Medial Council
- HCAI Healthcare Associated Infections
- HEE YH Health Education England working across Yorkshire and the Humber
- LEP Local Education Provider
- MRSA Methicillin-resistant Staphylococcus Aureus
- SI Serious Incident

Section 4: Roles and responsibilities of the users

Doctors and dentists in training may be involved in serious incidents (SI's) at any time in their careers. They have a responsibility to inform their supervisors at the time of the event.

Educational and Clinical Supervisors are required to escalate information on trainee involvement in SI's (including the less severe level 2 Root Cause Analysis events that are not reported outside the Trust) to their Trust based Director of Medical Education for completion of revalidation Exception Reports for HEE YH Responsible Officer records. HEE YH is responsible for retaining SI information on file.

Section 5: Monitoring and compliance

This guideline will be reviewed every 3 years by the Postgraduate Dean's Senior Management Team. Trainees are required to include information on any SI's that they have been involved in when submitting Form R for Revalidation purposes prior to their ARCP. LEPs are expected to submit an Exception Report for each SI with trainee involvement in order to enable HEE YH to triangulate the data received.

Section 6: Appeals Process

n/a

Section 7: What is a Serious Incident?

There is a large body of evidence on the risk of clinical incidents associated with healthcare activity. Serious incidents are uncommon but cause major distress to the patient(s) and families affected, and often also to the staff involved. All clinical incidents require a prompt and effective response to address immediate patient safety issues, and to identify causal factors that can be modified as part of individual or organisational learning to avoid recurrence.

'Serious Incident' (SI) defines the most serious clinical incidents (including Never Events) which are reported externally to NHS England by the Trust. Among various definitions, one simple view is to say that a SI has occurred "whenever a patient(s), member of staff, visitor, or other member of the public has suffered unexpected death or serious harm, or where avoiding a catastrophic outcome requires major corrective intervention". The practical definition is inclusive and often includes 'near miss' events which point towards system failures that could recur and require organisational change.

In governance terms the management of a clinical incident investigation is usually classified at one of three levels;

- Level 1 little or no harm, no organisational learning, handle within Department or Directorate.
- Level 2 moderate or potentially moderate harm, organisational learning opportunity, handle by Root Cause Analysis investigation by Trust governance team
- Level 3 (Serious Incident) serious or potentially serious harm, organisational learning needed, Root Cause Analysis and external reporting, dissemination of learning needs to be demonstrated.

The sort of events that would usually be notified as a SI include:

- diagnostic or management failures leading to serious harm or death
- · serious medication incidents
- medical equipment failure (even if a near miss)
- surgery/procedure performed on wrong side of body (one of the defined Never Events)
- outbreaks of disease in hospital (including MRSA), and death related to HCAI (especially clusters)
- major system failures (such as a diagnostic service not reporting a critical result in a timely way)
- major environmental incident in the hospital, or service disruption
- major confidentiality breaches (i.e. a lost laptop with patient data on)

- serious injury from deliberate self-harm while in NHS care
- patients detained under the Mental Health Act who abscond, or who harm staff, visitors or other patients

Medical Directors and Chief Executives have some discretion over whether a particular incident is declared to NHS England as a SI, but in many organisations clinical incidents which do not actually involve an extreme outcome are reported, in a spirit of openness. Once classified as a SI, local reporting mechanisms to the Clinical Commissioning Group must be followed, both for immediate actions to be taken, and for epidemiological purposes.

There are wide variations in reporting rates by different Trusts, which are regularly reviewed by HEE-YH as part of quality assurance processes. Absolute reporting rates give no insight on their own - high reporting rates may indicate an important underlying safety problem OR an organisation with an open culture and good governance—whilst a low reporting rate may indicate an excellent and effective safety culture OR may just disguise poor recognition systems and poor governance.

Section 8: What is the involvement of HEE YH?

In considering the impact of changing working hours on the quality of training the Temple Report concluded that "training is the most important investment in patient safety for the next 30 years"; training and service delivery are inextricably linked. Revalidation of doctors by the General Medical Council began in 2013 and has had an impact on the approach taken when clinical incidents occur.

Every healthcare organisation, classed as a Designated Body for revalidation, has a Responsible Officer. This is usually the Medical Director, who has the responsibility for monitoring and collating the evidence required to make recommendations to the GMC about the revalidation of senior doctors. For doctors in training the responsibility for providing revalidation recommendations lies with the Postgraduate Dean, who is the Responsible Officer for all doctors in training. Most of the evidence required is provided by assessment of evidence in the trainee portfolio as part of the ARCP process. Employers are required to provide HEE YH with relevant information about adverse trainee experience in the workplace, including any involvement in serious clinical incidents, complaints, or conduct concerns.

The national Revalidation Support Team/HEE has created an Exception Reporting system to ensure early notification to HEE YH of trainee involvement in a serious incident by the Director of Medical Education within a Trust. There are three purposes for this notification:

- the first is to ensure that trainees are getting suitable support at what can be a difficult time; most doctors feel personally responsible when things go wrong, even when their involvement in the case is only peripheral, and this can have a significant impact on wellbeing and work.
- the second purpose is to identify any learning needs and when necessary provide suitable remedial training.
- third is the role of HEE YH as a central reporting point, so that evidence required for the portfolio and for the GMC revalidation process is collated reliably.

Section 9: What happens a SI has occurred?

Junior doctors are at the frontline of healthcare processes and will often be involved in the events surrounding a clinical incident. That involvement may be conscious or unconscious, depending on the nature of the event and timescales – and it may also be central to the event or peripheral. When a serious incident is reported, a preliminary investigation within the Trust seeks to establish who may have had a relevant role in the event; those people will contribute to the more detailed investigation that will follow.

The first priority of the investigation is to establish the facts and the cause(s); it is not an exercise to apportion blame (if any is actually attributable). Being involved in a SI investigation makes no presumption about responsibility or fault, and trainees must not feel any prejudgement is being made in advance of the investigation. The degree of trainee involvement in an SI bears no direct relationship to the severity of the outcome.

SI investigations often take months rather than weeks and are conducted confidentially. Some cases have potential for legal action, and a very small number have police interest. The involvement of junior doctors in a coroner's inquest is an overlapping but separate issue which is dealt with in a separate document;

https://www.yorksandhumberdeanery.nhs.uk/learner_support/policies/coroners_inquests

The investigation report (Root Cause Analysis or RCA) is written to indicate what happened, and to analyse what/how relevant causal factors contributed. Most investigations reveal system failures in organisational structures and/or processes alongside some degree of individual error(s). It is common that a sequence of actions/inactions, each of which was not in itself an outright error, combine to produce the serious event; the 'Swiss cheese' model. Patient pathways need to be redesigned in ways which prevent a series of small mishaps or errors being able to escalate cumulatively into a severe event.

Section 10: Impact on Training Progression

Many trainees experience problems during their training, this is discussed in the HEE YH 'Trainees Experiencing Difficulties' guidance. HEE YH keeps a central register of trainees with significant problems to ensure that consistent support is given - being involved in a SI investigation does not make a trainee a Doctor in Difficulty, instead during the investigation process we adopt the term "Doctor at Risk" to acknowledge that the investigation is a stressor which may lead to the need for more support.

Where an investigation reveals an important individual error by a trainee, that will first be viewed as identifying a learning need(s); this requires reflection by the trainee and planning of remedial targets with the Educational Supervisor/Training Programme Director. This process would take account of any other concerns that had been recognised during training. Lack of progress in meeting remedial targets at the next ARCP could influence progression in training, but a decision to delay progression would never follow directly from the occurrence of the SI itself.

Section 11: Serious Incidents and Reflection

High profile events have put the process of reflection in the spotlight, and there is understandable anxiety that written reflections create personal risks.

However, there is wide agreement that reflection is an essential learning tool for all doctors, providing a valuable opportunity to review practice, and consider developmental needs. Doctors in training are required to demonstrate evidence of reflection in their portfolios to satisfactorily complete their training program.

In the light of concerns national guidance now exists on how to structure and record reflective entries; any trainee who feels the need should also seek personal guidance from faculty at any level.

www.aomrc.org.uk/wp-content/uploads/2018/08/MCJ15414-Academy-ReflectivePractice-Main-v3.pdf

www.copmed.org.uk/images/docs/reflective practice/Academy and COPMeD Reflective Practice Toolkit.pdf

Rarely, an employer may decide that a disciplinary process needs to be followed after a SI. This is handled entirely separately to educational processes involving HEE YH, but again suitable pastoral support should be provided to the trainee. HEE YH may be asked to give evidence about training progress at a disciplinary hearing, but HEE YH faculty must not sit as members of the panel.

Very rarely concerns can be so serious that a question arises about the Fitness to Practice of the trainee, and the General Medical Council would become involved. There are additional support processes within HEE YH for doctors in this position.

Trainees should take reassurance from the fact that five years after revalidation was introduced no adverse revalidation decision for a doctor in training in Yorkshire and Humber has been based solely on the investigation findings following a SI Exception Report.

Section 12: Summary – best practice process

- You should be informed as early as possible if you have been involved in a SI (you may not already be aware of it). Your Educational Supervisor/Director of Medical Education should also be informed, so that suitable pastoral support for you can be organised. Everyone recognises the stresses involved, whatever the findings of the investigation. Support can come from any combination of your clinical department, the Trust education department, and the Specialty School.
- In some situations, you may find it useful to consult the Trust Occupational Health service or seek advice from the counselling services. HEE YH offers Take Time or Workplace Wellbeing and many Trusts also have local resources.
- You should meet with your Clinical or Educational Supervisor as soon as possible to discuss the
 case and begin the process of reflection. If they were also involved in the incident one or both of you
 might decide that support would be better coming from an alternative source.
- You will be interviewed as part of the Trust investigation. Give as open and full an account as you
 can. Writing down your recollections of events and actions as early as possible will help you
 contribute accurately to the investigation. You should have access to the case notes to assist you in
 giving your account of your involvement. If the notes are not available, you should indicate that the
 statement is composed entirely from memory without access to the clinical records.
- Once the investigation is complete, if individual learning needs are identified you will be expected to engage in forming a plan to meet these, within a defined timescale (using SMART objectives).

• Whether or not there are any specific learning needs identified for you, you must mention the event when you complete a new Form R before your next ARCP panel and make a reflective practice portfolio entry about your reactions to the SI.

Section 13: Equality & Diversity

This guidance applies to all, irrespective of age, race, colour, religion, disability, nationality, ethnic origin, gender, sexual orientation or marital status, domestic circumstances, social and employment status, HIV status, gender, reassignment, political affiliation or trade union membership. In overseeing Equality and Diversity, Health Education England, working across Yorkshire and the Humber, will treat those concerned in a fair and equitable manner and reasonable adjustments will be made where appropriate.

A full Equality Impact Assessment of this guidance is available upon request.