HEE NE Revalidation Team Guidance to LEPs on Reporting Incidents Involving Trainees

Principles of Revalidation Incident Reporting:

The overarching principle that should be applied to all incidents involving trainees is to determine the incident severity and degree of involvement of the trainee and understand the implications for the individual’s revalidation and trainee’s fitness to practice. Only once this has occurred can the incident reporting process become an educational / learning process. The two processes can run concurrently but should not be confused.

Key issues covered:

1. How information goes into the Trust PG Education Team and what they do next to follow up locally regarding the trainees involvement (e.g. referral of incident to Supervisor, Supervisor then looks into the incident and meets with trainee to discuss and reviews reflective practice in portfolio, Supervisor then reports back to Education Team, Education Team then assesses if it should be reported to HEE NE, etc.)

2. Thresholds of reporting – which incidents should be reported and which shouldn’t.

3. How do trusts deal with those that aren’t serious enough to be reported to HEE NE? – incidents that don’t need to be reported on Form R or reported by ES on the annual ES report. The ARCP panel will look at incidents logged on the e-portfolio to see if they are satisfactorily reflected upon and will spot any repeated low level incidents.

4. Guidance for trusts on how to close incidents from a trainee’s perspective

How does information flow into the Education Team and then what they do next to investigate locally

Trusts have developed or altered existing incident reporting systems to allow Trust Medical Educational Team (TMET) access to incidents reported that involve trainees. Electronic systems (Datix or similar) can have a prompt box for details when a trainee is involved. TMET should then receive the incident form / notification.

Exemplars:

Newcastle – TMET receive a monthly summary of all trainee incidents. They also get an instant email alert and then can access the whole Datix form. Incidents rated amber and red in monthly reports are sent to TMET. Any red incidents go instantly to HEE NE. Trust has a regular Risk Team meeting – any further key issues identified are sent to the DME for consideration and action.

CHS – Trust has a weekly Rapid Review Group meeting which assesses incidents rated 3 and above (rating system based on a 5 point scale). MD, Heads of Risk, HR and Nursing attend. Trust has added a box on the incident reporting system to indicate the level of the trainee’s involvement and the trainee’s name. Trust is further developing the Safeguard system to allow the TMET to see on the system what stage each investigation is at. The Risk Team conduct lessons learnt seminars to trainees – best practice. Trust keeps a spread sheet of all incidents, including those lower level ones not reported to HE ENE and has used this to identify repeated lower level incidents for a trainee which is then sent to the ES to address.
Management of incidents and complaints involving a trainee

a) Managing incidents locally

Most incidents involving trainees will be managed locally with no need to inform HEE NE. Local processes for identifying trainees involved in such incidents will vary but you should be confident that the Risk Management department and Directorate / Business Unit managers are informing the TMET of any issues involving trainees.

b) Educational vs Clinical Supervisor

The process for dealing with incidents and complaints involving trainees should, in the main, be dealt with by the clinical supervisor and educational supervisor. The general approach should be that the supervisor with “local knowledge” of the situation surrounding the incident or complaint should investigate and report back to the trainee whilst the educational supervisor should be kept informed throughout the process. The Educational supervisor should provide support as well as identifying any remedial training or reflection needed. In every circumstance the ES should be asking for and reviewing a reflection on the event in question. The ES should ensure this is filed in the portfolio to evidence engagement in the process. The ES should also comment within their reports about such events and the degree of attainment in terms of reflection and participating in remedial training.

[A suggested management pathway is available as Appendix 1.]

Thresholds for Reporting to HEE NE Revalidation Team

The underlying principle for reporting issues is that the HEE NE revalidation team should be notified about anything which causes concern that the trainee may not be meeting the requirements of “Good Medical Practice”. The GMC define a significant event as

‘A significant event (also known as an untoward or critical incident) is any unintended or unexpected event, which could or did lead to harm of one or more patients. This includes incidents which did not cause harm but could have done, or where the event should have been prevented.’

The PG Dean (as Responsible Officer) and the HEE NE Revalidation Team are only interested in trainees for whom the ES, CS or DME / TMET has significant concerns about the doctor in question’s clinical performance or conduct. If there is a case in which it is deemed to be a significant incident (SI) in which the patient has come to significant harm and/or a Root Cause Analysis (RCA) is required, the HEE RT need to be notified. The ES, CS, FPT / TPD and/or TMET should evaluate whether the trainee’s clinical performance was below that expected of a trainee at their stage of training AND/OR was a major contribution to the harm which has occurred. If the answers to these questions are “No” then a referral is not necessary and the matter should be dealt with locally with reflection and remedial training as above. The level of involvement and contribution in a SI by the trainee is the key question rather than “any involvement in an SI”.

Example – A trainee who clerks a patient for a surgical procedure in which the patient later has an avoidable death should NOT be reported to HEE NE RT unless the ES/CS believe the quality of the clerking was significantly below the expected standard as to have had a major impact on the patient outcome and cause of death.
Conduct and probity

HEE NE RT must be informed of any issue of probity or conduct significant to have been reported to the GMC or being dealt with by a Trust’s formal HR processes. Any written warnings should be notified to HEE NE RT. Lower level conduct and probity issues should be dealt with locally by the TMET involving ES and CS as appropriate.

Complaints

Most complaints can be dealt with by local processes. If in the investigation of such complaints the trainee’s clinical performance was deemed to be significantly below that expected of a trainee at their stage of training AND/OR was a major contribution to the harm which has occurred, HEE NE RT should be informed. If the answer to this question is “No” then referral is not necessary and the matter should be dealt with locally with reflection and remedial training as deemed appropriate.

Repeated low level type incidents

A trainee involved in multiple low level incidents need not be reported to HEE NE RT. Such themes should be identified and dealt with by the TMET and the ES. The ES role in dealing with repeated low level incidents is key. ES should be working with the trainee to identify themes from such incidents which should lead to learning plans and reflection tailored to meet the trainee’s needs. These should form part of the ES report which informs ARCP. This is sufficient to identify and deal with repeated low level incidents.

[A suggested pathway for closing low level incidents is available as Appendix 2.]

Defining Thresholds for Incident Reporting

a) RAG rating / risk matrix for identifying levels of incidents

Newcastle and Sunderland Trusts have developed similar rating process which allow incidents to be allocated in 3 discrete levels of incidents; green, amber, red.

b) Areas where mandatory SIs arise

Areas of clinical practice have specific SI reporting practices e.g., O&G – unexpected still birth, or Psychiatry - psychiatric patient suicide. Often trainee involvement in these incidents can be negligible. They should however still be reported to HEE NE RT but Trusts should flag up these types of mandatory SIs when they report them. This is important as the trainee is likely to always report a mandatory SI on to the Form R.

[A suggested process for determining incident thresholds is available as Appendix 3.]

Categories on HEE NE Reporting Forms
The following reporting terms will be used on updated versions of HEE NE live flow and exit reporting forms which will be issued shortly:

1. Never event
2. Serious Incident (SI)
3. Significant Event

All three terms require a threshold level of concern to be reached that would require an LEP or host training organisation to undertake a formal review of the incident. Most would perform this within a root cause analysis (RCA) framework although external agencies may at times become involved e.g., the local coroner’s office.

Examples of Reported Incident Action Requirements

<table>
<thead>
<tr>
<th>Issue</th>
<th>Recommended action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ward Pharmacist notes prescribing error by Foundation trainee. No patient harm incurred</td>
<td>Review of error by clinical supervisor. Trainee reflects on this in e-portfolio and identifies how to avoid errors in the future. No need to notify HEE NE revalidation team.</td>
</tr>
<tr>
<td>Specialty trainee prescribes wrong formulation of insulin. Patient suffers severe hypoglycaemic episode</td>
<td>The trust will need to consider this as an issue of patient safety and investigate it as a SI. Consequently the HEE NE revalidation team should be informed, although ultimately with a suitable educational plan it may be resolved for the trainee.</td>
</tr>
<tr>
<td>Foundation trainee makes repeated prescribing errors, which do not result in patient harm, but seem to be recurrent</td>
<td>The Educational supervisor should be made aware of this and a management plan should be documented in the trainee’s portfolio. It is possible that this will lead to an adverse ARCP outcome, but is not an issue which needs to be reported to the HEE NE revalidation team at this point as it will be managed by educational processes as long as the individual is seen to be making progress and remains within the training programme. However, if it appears that the problem is failing to improve despite remediation this could imply that the trainee is not fit for practice and requires a more formal assessment of capability and so the HEE NE revalidation team should be notified.</td>
</tr>
<tr>
<td>Specialty trainee is named in a SI though was probably simply an uninvolved bystander</td>
<td>The trust will be conducting a formal investigation and so the HEE NE revalidation team should be informed. Once the investigation confirms that the trainee had no practical involvement then the record will be closed without further action.</td>
</tr>
<tr>
<td>A practice receives a complaint from a patient describing poor communication and brusque</td>
<td>The practice will need to conduct an investigation to respond to the patient.</td>
</tr>
</tbody>
</table>
Consequently the practice notifies the HEE NE revalidation team of the complaint/its outcome and confirms when issues have been resolved through the complaints process and the educational process.

The trainee should inform the LET as their employer. The revalidation team should be informed and will share information with the LET. Details of the caution will be recorded on the revalidation database but will not necessarily become a revalidation issue unless the behaviour is repeated.

The revalidation team should be informed as this raises concern about the trainee’s probity. They will inform the LET as this is a potential disciplinary issue.

The revalidation team should be informed as this raises concern about the trainee’s professional behaviour. They will inform the LET as this is a breach of social media policy and a disciplinary issue.

Supporting Information for Trusts

The following are definitions / guidance from a number of sources which may help inform Trust’s thresholds for referral:

1. GMC guidance – types of behaviour that may give rise to impairment:

   - The doctor’s performance has harmed patients or put patients at risk of harm
   - The doctor has shown a deliberate or reckless disregard of clinical responsibilities towards patients
   - The doctor’s health is compromising patient safety (e.g. through drug or alcohol abuse)
   - The doctor has abused a patient’s trust or violated a patient’s autonomy or other fundamental rights
   - The doctor has behaved dishonestly, fraudulently or in a way designed to mislead or harm others

2. GMC guidance on evaluating seriousness:

   - Is there a pattern of clinical concerns?
   - Dishonesty that puts patients or the public at risk?
   - Has the doctor taken advantage of a vulnerable person?
   - Doctor has refused to acknowledge a serious concern?
   - Doctor has refused to cooperate with a local investigation?
   - Doctor has recklessly or knowingly acted unsafely?
   - Is the concern so serious it cannot be managed safely locally
3. NPSA Definition of Serious Incidents needing Investigation and Never events


The framework takes account of the changes within the NHS landscape and acknowledges the increasing importance of taking a whole-system approach, where cooperation, partnership working, thorough investigation and analytical thinking is applied to ensure organisations identify and learn what went wrong, how it went wrong and what can be done to minimise the risk of the incident happening again.

They used the following definitions sets out circumstances in which a serious incident must be declared.

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
  - Unexpected or avoidable death of one or more people. This includes
    - suicide/self-inflicted death; and
    - homicide by a person in receipt of mental health care within the recent past
  - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
  - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
    - the death of the service user; or
    - serious harm;

- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
  - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
  - where abuse occurred during the provision of NHS-funded care.
An incident (or series of incidents) that prevents, or threatens to prevent, an organisation’s ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

- Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues
- Property damage;
- Security breach/concern;
- Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
- Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
- Systematic failure to provide an acceptable standard of safe care
- Activation of Major Incident Plan

Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death.

Surgical
1) Wrong site surgery
2) Wrong implant/prosthesis
3) Retained foreign object post-procedure

Medication
4) Mis – selection of a strong potassium containing solution
5) Wrong route administration of medication
6) Overdose of Insulin due to abbreviations or incorrect device
7) Overdose of methotrexate for non-cancer treatment
8) Mis – selection of high strength midazolam during conscious sedation

Mental Health
9) Failure to install functional collapsible shower or curtain rails

General
10) Falls from poorly restricted windows
11) Chest or neck entrapment in bedrails
12) Transfusion or transplantation of ABO-incompatible blood components or organs
13) Misplaced naso- or oro-gastric tubes
14) Scalding of patients


Definition of notifiable safety incident under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:

“Means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in –

a) The death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or

b) severe harm (a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user’s illness or underlying condition),

- Moderate harm (harm that requires a moderate increase in treatment (an unplanned return to surgery, an unplanned re-admission, a prolonged episode or care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care) and significant but not permanent harm; or

- Prolonged psychological harm (psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days)

to the service user.”

Acknowledgments

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HEE NE Revalidation Team
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Appendix 1:
Suggested pathway for Trusts dealing with complaints / incidents involving trainees

1. Incident or complaint involving a trainee identified
2. Risk Management Team or Clinical Manager informed
3. Trust Medical Education Team informed of trainee's involvement (via complaints team or incidents logged on incident reporting system)
4. Clinical Supervisor asked to investigate. Educational Supervisor asked to co-ordinate, record and assist the trainee through the process
5. CS and ES evaluate trainee's performance and any learning necessary
6. CS and ES record significant concern that the trainee's clinical performance was significantly below that expected of a trainee at their stage of training AND/OR was a major contributor to the harm which has occurred to the patient
   - Case discussed with DME or nominated clinician for final review/decision on whether to refer to HEE NE Revalidation Team
   - Incident or complaint dealt with locally via remedial training and reflection with comprehensive recording in the trainee's portfolio
7. CS and ES record NO significant concern that the trainee's clinical performance was significantly below that expected of a trainee at their stage of training or that trainee was NOT a major contributor to the harm which has occurred to the patient
   - Case referred to HEE NE and Trust share copy of report form with trainee. HEE NE notify relevant School to offer support to trainee and LET/NFS if appropriate. Revalidation Team liaise with Trust regarding investigation and close case once reports/outcome received
Appendix 2: Suggested pathway for Trusts to close an incident or complaint from a trainee’s perspective

- Supervisor to meet with the trainee to discuss the event

- Trainee reflects upon the event and uploads reflective practice entry into the e-portfolio – HEE NE need to see this to ensure that the incident is fully resolved, if the incident is referred to HEE NE Revalidation Team. The ARCP panel will look for the reflection and assess if it is satisfactory

- Supervisor to assess if there are any additional training requirements identified as a result in the trainee’s involvement in the incidents

- Supervisor to assess if there are any other actions arising that the trainee could undertake

- Supervisor to monitor compliance with any actions or additional training and to sign off in e-portfolio that they have been completed

- Supervisor to sign off incident as fully resolved with no on-going unresolved concerns regarding the trainee’s fitness to practice in the e-portfolio

- Trust to complete HEE NE’s ‘Incident Report Follow Up Form’ to advise of the above steps taken and to confirm to HEE NE that there are no unresolved concerns with regard to the trainee. A copy of this form should be shared with the trainee

- This will all feed into the trainee’s next ARCP

- It is imperative that trusts provide HEE NE with details of how involved the trainee was in the incident and what specific action they took in the incident

*Only required if incident is reported to HEE NE Revalidation Team
Appendix 3: Generic Trust Process for Determining Incident Thresholds

Trust reviews all serious incidents

Assess incident

1. Does trainee involvement in incident appear to be relevant?
2. Does incident require RCA?

If both 1 & 2 answered “Yes”:

DME and Trust Medical Education Team informed of need to notify HEE NE Revalidation Team

DME response to HEE NE 1
a. Info to “Collective Exit Report” template
b. Incident info form completed & forwarded to HEE NE Revalidation Team
c. Information to Ed Sup & trainee

Dept review of incident
a. RCA undertaken as per Trust policy
b. RCA shared with DME and Medical Education Team on completion

DME response to HEE NE 2
HEE NE “Exception Report” filled out
a. when RCA finally completed, or
b. at time of submission of annual collective exit reports update will be provided on progress of investigation

Department review of “Learning” incident
a. Review of incident by supervisor and trainee
b. Reflection included in trainee portfolio – learning points

Low – Mod risk incidents
Reported through incident reporting team and individual departments

If 1 is “Yes” and 2 is “No”:

DME and Trust Medical Education Team informed of need to notify Ed Sup - “learning” incident

DME response to HEE NE 1
a. Info to “Collective Exit Report” template
b. Incident info form completed & forwarded to HEE NE Revalidation Team
c. Information to Ed Sup & trainee

DME response to “Learning” incident
a. Local record maintained of lower order incidents
b. Information to Ed Sup & trainee

If both 1 & 2 answered “No”:

No notification of incident required either to DME or HEE NE Revalidation Team

Inquests *
Enquiries identifying potential concerns about trainee involvement in death of patient

Other sources
Incidents or situations leading to concern about conduct or capability of trainee

Info sharing with Medical director (+/- HR if Trust is employer)

Glossary
1. DME = Director of Medical Education
2. Ed sup = Educational supervisor
3. HR = Human resources
4. RCA = Root cause analysis

* denotes situation in which the team working within the trust in managing coroner’s inquests recognise issues or concerns that would be equivalent in seriousness to “incident” requiring RCA.