Clinical Lead Survival Guide – Serious Incidents

The ROYAL COLLEGE of OPHTHALMOLOGISTS

As a clinical lead, you will be involved in managing patient safety issues, and may need to be involved in investigating incidents, root cause analysis, producing reports, and formulating action plans. This document is a simple guide for how to approach this.

Remember – your need to read and follow your hospital's policies on incidents and risk management.

Some definitions

***Incident*:** An unintended event that could have resulted, or did result, in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff or visitor.

Serious incident (SI): Events where the potential for learning is so great, or the consequences to patients, families/carers, staff or organisations are so significant, that they warrant using additional resources and a comprehensive response. SIs can include not only incidents which affect patients directly but also those which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare. Note – no one calls this a SUI or serious untoward incident any more.

Never event (NE): A type of SI that is supposed to be wholly preventable, if national safety recommendations are implemented by all healthcare providers. Only certain kinds of incident can be a never event. For ophthalmology, the key ones are: retained foreign object post procedure; wrong site surgery; and wrong implant/prosthesis.

How are SIs identified?

Usually via staff entering them on the incident reporting system or notifying a senior colleague, but they may be identified through these other routes - you should get these reported as incidents if they warrant it:

- Patient Complaints
- Medicolegal claims
- Allegations or concerns expressed by staff
- Audits
- Whistleblowing.

Management of incidents

Early actions

- Staff should report the event as soon as possible, usually using an electronic reporting system (e.g. Datix or Safeguard).
- For anything with actual or potential moderate or serious harm, then more than just reporting needs to be done early by staff:
  - Tell the person in charge of the area and/or the consultant immediately.
  - If an incident is possibly or clearly an SI or NE, the consultant/clinical lead and the patient safety team should be phoned immediately, as soon as any urgent patient treatment / immediate risk mitigation requirements are dealt with.

18 Stephenson Way, London, NW1 2HD T. 020 7935 0702 contact@rcophth.ac.uk rcophth.ac.uk @RCOphth
2018/PROF/391

- The most senior person, ideally the consultant, must discuss with the patient and family then and there what has happened, the implications, give an apology no matter whether it's poor practice or just bad luck, and write all this down accurately in the notes - duty of candour is a legal requirement.
- Think about any additional support for patients and staff – staff might need to be supported as it can be more upsetting than you might think, whether they are at fault or not.

Later actions

- An investigation is undertaken, usually by a manager. For low harm incidents, this is informal. For bigger concerns (such as an SI) this is formal, and you may need to input or even lead this.
- Feedback by the investigating manager to the person who reported it and other key people, for instance the local team.
- Disseminate / publicise / undertake post incident learning and actions ensuring coverage of all relevant areas and disciplines.

Risk rating

All incidents should undergo a risk rating, and this is often used to make the decision as to whether it is an SI or not (e.g. rating of ≥12). This involves a judgement of the level of actual or potential harm and multiplies that by the likelihood of it happening again. The likelihood is a judgement call based on what you know about the preventative mechanisms, whether it has happened before, which can be subjective. Trusts use a table along the following lines to do the multiplication.

Table 3 Risk rating = consequence x likelihood (C x L)

Consequence scores (C)	Likelihood scores (L)				
	1	2	3	4	5
	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

For grading risk, the scores obtained from the risk matrix are assigned grades as follows

1 - 3	LOW risk
4 - 6	MODERATE risk
8 - 12	HIGH risk
15 - 25	EXTREME risk

From Moorfields Risk Management Policy (with permission)

Declaring an incident

The trust will be required to report a serious incident on the Strategic Executive Information System (StEIS) within 48 hours to their commissioners and potentially the CQC. An SI will also be reported to the National Reporting and Learning System (NRLS) via the trust's incident reporting system and risk team.

Investigating

Getting started

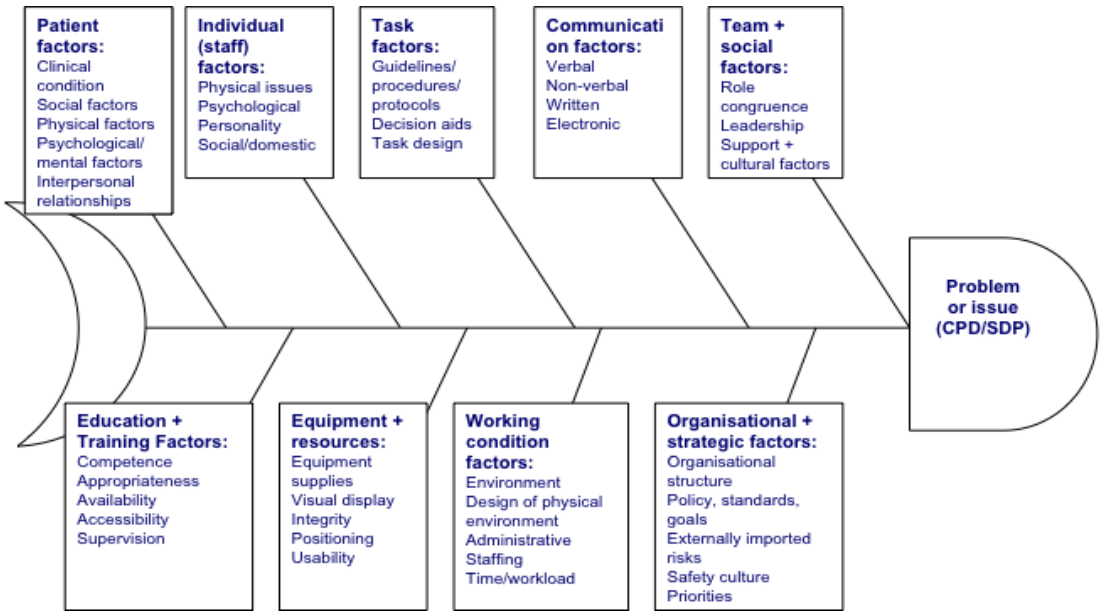
Keep in mind what you are trying to achieve. You want to find out **what** happened, you want to find out **why**, and you want to recommend **actions** to stop it happening again. You might need a small multidisciplinary team to help you and someone from the patient safety department.

Why use root cause analysis (RCA)?

Because the obvious immediate cause is only one factor, such as *'the staff gave the wrong medication to the wrong eye'*. Underlying that, are all the contributory "system" factors which may include *'the staff were busy, the drug chart has just been changed, the ward was extra busy that day, staff are all locum'* and so on. The investigation looks beyond the obvious into all the other factors and determines the real cause, i.e. the ROOT cause.

If you do not understand the real cause, you will make superficial conclusions and you will not develop actions that prevent further incidents.

People often use a "fishbone" diagram to think of all the possible contributory causes.:



From Moorfields Risk Management training materials with permission

Scoping of the RCA Investigation

- How far back in the episode of care do you need to consider within your investigation?
- Do you need to involve another healthcare provider within the RCA?

- What information are you going to collect to support the investigation?
  - People –those directly involved (staff, patient, family) and witnesses
  - Equipment – phaco machine, syringe drivers, curtain rail, etc.
  - Documentation / Evidence – interviews, statements, reflections, records, guidelines, policies, audits, training, rotas etc.
  - Site – photographs, position of equipment, people, etc.
  - You may need local experts e.g. other clinicians, theatre staff to comment on the evidence or records
  - You might need external people to comment e.g. clinicians from another trust if either potential conflicts of interest or no expertise in house

You then need to go and collect the evidence and start thinking about what it is telling you.

Writing the report

The trust will usually have a template which guides you as to what evidence to collect and how to write it. Headings are usually along the lines of:

- Title/author/index
- Exec summary
- Incident description and consequences
- Chronology (a detailed timeline is usual in the appendix)
- Detection of incident
- Notable practice (any good practice identified)
- Care and service delivery problems
- Background and context (e.g. explanations about ophthalmology, cataract surgery etc. for those who do not know about this)
- Terms of reference
- Investigation team
- Scope and Level of Investigation
- Info and evidence gathered
- Involvement and support for patient and relatives
- Involvement and support for staff
- Contributory factors
- Root causes
- Lessons learned
- Recommendations and action plan

This looks like a lot, but many of those sections are very brief. For inspiration, look at a previous report and how that was written if unsure.

Timeline example

Date	Event	Comment
18 January 2016	Left cataract surgery	Uneventful
7 March 2016	Review of the patient's notes by the surgeon	Lens selection documented in the notes but not on the IOL selection sheet, pending a conversation with the patient the next day
8 March 2016	Right cataract surgery	Insertion of the wrong IOL
9 March 2016	Patient telephoned by the operating surgeon	Patient confirmed the eye is settling well and happy with the vision
11 March 2016	Post op review by Glaucoma Consultant	Eye settling well with vision of 6/24 6/12PH
14 March 2016	Post op review by Glaucoma Consultant after visiting his optician	The eye continued to heal well and the optician found the right eye refraction was +1.75/-0.50 x 20 giving 6/6 vision and in the left eye +0.50/-0.50 x 120 also giving him vision of 6/6. The patient was happy not to have the lens exchanged and continue as he is with the new prescription.

Action plan

This must address service delivery / care delivery problems including the root causes. However, most plans fail because they have far too many actions and are impractical. So:

- Prioritise the most important actions and do not have too many
- Make them realistic, doable, time defined and measurable, and show who it is responsible for what action(s) – this is best done in a table
- Aggregate with other actions arising from similar incidents so you have a consistent approach and you do not reinvent the wheel
- Include how you disseminate the incident and the learning to targeted relevant groups: in the service, all disciplines, trust wide, specific staff groups

For example:

Action	Lead	Completion by	Status
Send an e-mail to all ophthalmic team advising that the SI has occurred and warning them to perform the checks scrupulously AND check the biometry print out format	Medical Director	June 2016	Complete
Review the 'guideline for the selection of intraocular lens' for any improvements and amend/update and re-circulate	Cataract Lead & Head of Risk	July 2016	Not yet started
Audit compliance with the 'guideline for the selection of intraocular lens '	Head of Clinical Audit & Clinical Lead	May 2016	Ongoing
Review the 'cataract specific WHO checklist' and revise to be clear who leads each check including check for IOL model as well as power.	Cataract Lead and Lead Ophthalmic Theatre Nurse	Oct 2016	Not yet started
Audit compliance with the 'WHO cataract checklist'	Head of Clinical Governance	Nov 2016	Ongoing
Present case at next CG meeting and discuss learning with whole team	Ophthalmology Clinical Governance Lead	18th July 2016	Complete

Learning from incidents

The whole point of reporting and investigating incidents is to learn and take preventative action. Ways to discuss the learning and actions, and to disseminate them widely in trusts may include:

- Local:
  - direct feedback to reporter
  - formal debrief to whole team if serious
  - team meetings
  - Schwartz rounds
- Directorate or specialty:
  - clinical governance meetings
  - Morbidity and mortality meetings
  - Clinical improvement groups
- Trust:
  - SI panels
  - Incident or quality safety formal reports
  - Risk / clinical governance / quality / safety committees or groups

- Staff safety newsletters or communications
- Emails to key groups from medical or nursing directors

Fair culture

Effective learning can only take place in a non-threatening environment and any fear of disciplinary action may deter staff from reporting an incident. All incidents should be the subject of a fair and objective review. Reported incidents will NOT normally lead to disciplinary action, apart from in very unusual circumstances such as those below:

- where staff actions go way beyond acceptable professional practice
- consistent failure to report an incident by a member of staff involved or a witness
- where actions are criminal or malicious in nature

It is not appropriate to shut out involved staff from the investigation and it is not appropriate to suspend people in most circumstances. As well as inhibiting staff from reporting when things go wrong, it can lead to a lack of clinical expertise informing the investigation. If you think the approach is excluding important people or not fair you need to speak to senior management at the trust, and where necessary, your Freedom to Speak Up Guardian.

Duty of candour

- Requires providers to notify anyone who has been subject (or someone lawfully acting on their behalf, such as families and carers) to a 'notifiable incident' ie an incident involving moderate or severe harm or death within 10 working days.
- The definitions of harm are as follows, and the threshold for moderate harm is lower than many clinicians realise:
    - Moderate harm - any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, readmission or transfer to another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.
    - Severe harm –Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons
- This notification must include an appropriate apology and information relating to the incident.
- Apology is not an admission of liability and always needs to be given.
- Have the discussion face to face or on the phone, write it all down in the notes, and follow up with a letter.
- Do it properly. This is an incredibly important step for the patient and their family / carers.
- Failure to do so may lead to regulatory action.
- NHS Resolution (formerly known as NHSLA) provides guidance on saying sorry: http://www.nhsla.com/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf
- Share the report with the patient and family if they wish it, once completed, and keep them up to date with any learning or changes arising.

Remember - reporting an incident helps the wider system through national analysis via *NRLS which helps to general national Patient Safety Alerts*

Authors

- Kaajal Chothai, Deputy Director of Quality, Governance and Assurance
  London Ambulance Service & member of RCOphth Quality and Safety Group
- Melanie Hingorani, RCOphth Chair of Professional Standards

Reading

- *SI Framework - NHS England, March 2015*
  https://improvement.nhs.uk/uploads/documents/serious-incidnt-framwrk.pdf
- SI FAQs https://improvement.nhs.uk/uploads/documents/serious-incdnt-framwrk-faqs-mar16.pdf
- Never Event List – NHS England https://www.england.nhs.uk/wp-content/uploads/2015/03/never-evnts-list-15-16.pdf
- Never Events Policy and Framework
  https://improvement.nhs.uk/uploads/documents/never-evnts-pol-framwrk.pdf