Serious Adverse Event Review

Systems Analysis of Clinical Incidents - London Protocol workbook for teams

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

Background

The Systems analysis of clinical incidents – London Protocol[1] (LP) workbook has been developed to support LP teams to complete all of the necessary steps of the review process. It contains instructions and templates for the team to work through during each of their meetings.

The LP process focuses on answering these three questions:

- What happened?
- Why did it happen?
- What action can we take to prevent it happening again?

In general, LP teams can address these questions over three meetings. This workbook provides guidance on the tasks for completion at each of the three meeting.

This document acts as compendium to the *Serious adverse event review: Systems analysis of clinical incidents – London Protocol toolkit.* Teams are encouraged to consult the toolkit for additional guidance.

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London Protocol flow

The following flow is recommended flow for conducting a LP review. The flow and process may vary depending on the complexity of the case.

Before the first meeting

The team leader gathers information from all available sources and constructs a timeline for review by the LP team at the first meeting

Meeting 1

1. The LP team review the incident chronology and at each identify if there were any CDPs that arise in the process of care.
2. CDPs are documented on the "Chronological Mapping of CDPs and Associated Contributory Factors" table
3. If CDPs are identified, staff interviews are required. Questions are developed and interviews allocated to team members.

After the first meeting

Relevant information is gathered through meetings with patients, carers and families, staff interviews and the collation and review of documents.

Meeting 2

1. Team member provide feedback on outcomes of interviews
2. The team review and update the initial flow diagram with consideration given to information gathered.
3. The team review each CDP separately and identify / brainstorm contributory factors outlined in the table above. Information from staff interviews is used to inform this process
4. The identified contributory factors are documented in the Chronological Mapping of CDPs and Associated Contributory Factors table
5. Causation statements / factors linked to outcome are developed

After the second meeting

The Findings Report is written and is shared with the family following CE approval. Additional experts are appointed to the team to assist with developing recommendations if indicated

Meeting 3

1. Any new team members are briefed
2. Causation statements / factors linked to outcome are reviewed
3. Actions, recommendations and key outcome measures are written

After the third meeting

The Recommendations Report is finalised and submitted to the CE for approval. The approved report is submitted to the Ministry of Health and shared with the family.

Planning Calendar / Gantt Chart / Checklist

Instructions for using template

1 Review task list and modify to suit local processes
2 Enter dates into Week ending column
3 Determine the date the Recommendations report is due to CE +/- date for CE Sign off / endorsement. Ensure you allow enough time for CE to review and consult with stakeholders. Highlight these dates using shading tool (NB Findings and Recommendations Reports need to be completed within 60 days of incident notification. This is a little over 8 weeks)
4 Work backwards to ensure that all tasks are sign posted for completion prior to due date. Use shading tool in Home ribbon to highlight dates
5 As tasks are completed tick them off in the 'tick box' column

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending										
	Appoint a team										
	Team leader sends medical record, incident report, PRA report & other documentation to team for review prior to first meeting										
	Team leader develops flow diagram of sequence of events										
	Team leader completes Falls Factor Analysis tool if incident was an inpatient fall										

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending										
	First team meeting scheduled										
	Additional meeting dates scheduled including date for CE sign off meeting (as appropriate).										
	Rooms booked for meetings										
	Team review Falls Factor Analysis (if indicated)										
	Team review sequence of events										
	Identification of care delivery problems										
	Information / questions to be gathered identified										
	Information gathered including: - Patient, carer and family interviews - Staff interviews										
	Incident chronology confirmed										
	Identification of contributory factors										
	Chronological mapping of CDPs and associated contributory factors completed										
	Factors that caused or contributed to the incident identified										

Tick box	Tasks	1	2	3	4	5	6	7	8	9	10
	Week ending										
	Circulate draft findings report to team for approval										
	Submit findings report to CE for approval										
	CE appoints additional team members to team, if required, to prepare recommendations										
	Brief new team members on findings of RCA										
	Develop recommendations										
	Specify an outcome measure, timeframe, person responsible and oversight committee for each recommendation										
	Team leader finalises draft recommendations report										
	Circulate draft recommendations report to team for approval										
	Submit recommendations report to CE										
	CE endorsement meeting / sign off										

Section one: What happened?

Usually, the LP team learn 'what happened' is over two meetings.

Meeting one tasks

- ☐ Introductions
- ☐ Team leader provides overview of LP process (references made toolkit and workbook)
- ☐ Meeting rules established
- ☐ Brief overview of incident by team leader who ensures incident report, medical record and PRA report are available
- ☐ Team review Falls Factor Analysis (if indicated)
- ☐ Team review sequence of events
- ☐ Team identify care delivery problems
- ☐ Team brainstorm additional information they would like to know
- ☐ The team identify who they need to talk to and which team member will meet with them
- ☐ Action plan developed with responsibilities and timelines for gathering information
- ☐ Future meeting dates agreed

Step 1: Organise and gather data

Instructions

I. The team leader gathers and reviews all facts, knowledge and physical items related to the incident including medical records, incident reports, relevant policies, physical evidence and information about conditions affecting the event (e.g. rosters)

II. The team leader develops a simple flow diagram of key events prior to the first meeting.

III. If the incident was an inpatient fall, the team leader completes the Falls Factor Analysis

IV. At the first meeting, the LP team review and agree on simple flow diagram the and Falls Factor Analysis (if indicated)

V. The team leader documents a draft sequence of events based on the LP team discussion at the first meeting.

Falls Factor Analysis

Post fall management	Yes	No	NA	Comment
Did the incident cause an injury? Head Injury If yes, was it open? ☐ or closed? ☐				
Did the patient have a fracture as a result of the fall?				
What was the fracture? Please note: #NoF, #Pelvis, Other#:				
Other injury e.g. soft tissue? Please note:				
Were investigations- (*e.g. X-ray, CT scan)* attended What did investigations reveal?				
Post fall vital signs observations (as per CEC Adult or Paediatric post-fall chart) documented?				
Following the fall was that patient showing signs of altered mental status /confusion? *(eg wandering/restless/aggressive* *Poor attention/memory/anxious/* *behaviour change)* Was a medical review conducted? What diagnosis was made? What was investigated? What plan was implemented?				
Medical Officer reviewed the patient Time taken within 60 mins Time taken > 60 mins				
Was family/carer contacted and informed of the fall? *When was the family contacted*				
When was the admitting doctor notified?				

Risk identification	Yes	No	N/A	Comment
Prior to the fall had risk factors been identified and was a plan of care in place? *(history of falls, poor vision, unsteady when walking/mobilising, continence/incontinence issues)*				
Was the patient identified as being malnourished/dehydrated? *(was as a plan in place ie needing assistance with meals & fluids?***)**				
Was anyone surprised that this patient fell?				
History of previous falls?				
Mental status				
Prior to the fall was that patient showing signs of altered mental status /confusion? *(eg wandering/restless/aggressive Poor attention/memory/anxious/ behaviour change)*				
Recorded Diagnosis of Dementia?				
Cognition screen completed?				
Recorded Diagnosis of Delirium?				
Delirium screen completed?				
If delirium was identified were underlying causes addressed? *e.g. infection, pain, constipation, dehydration, inadequate nutrition, physical restraint)*				
Was a clinical review completed?				
Was the patient impulsive and not able to reliably follow instructions, were the following in place?				
Located to allow adequate surveillance by staff (*e.g. located close to Nurses station or cohort in 2 -4 bed room)*				
Intentional rounding in place				
Regular toileting provided				
Strategy for close supervision in the bathroom: *(e.g. never being left on their own for planned toileting and self-care).*				
Use of hi-lo/lo-lo/floor bed?				
Audible alerts (*e.g. bed/chair alarms, sensor mats, other)*				

Risk identification	Yes	No	N/A	Comment
Increased supervision (*e.g. IPS, family/carer or volunteer companion observer/sitter.*				
Were **bed rails** involved with the fall? (eg. bed rails up and patient tried to climb over or around them)				
Mobility				
Did the patient mobilise without assistance if required?				
Did the bed height contribute to the fall? *(e.g. too high too low)*				
Patient attachments – e.g. IV pole, O2 etc				
Toileting needs				
Did the patient attempt toileting without assistance if required?				
Was a toileting plan in place? *(continence/frequency/urgency/nocturia)*				
Medications				
Was the patient on fall –related medications? (antipsychotics, antidepressants, Sedatives/hypnotics or opioids) *(e.g was night sedation administered?)*				
Was the patient on medications (*anticoagulants, antiplatelets or coagulopathy)* identified at the time or medical review? (*may increase severity/ consequences of injury)*				
Was a medication review completed?				

Ward Factors – environmental and cultural				
Team Safety Fundamentals				
Safety risks identified at: • Clinical bedside handover • Safety Huddles				
Intentional/Proactive Rounding in place				
Ward and staffing factors				
Environment *(e.g. layout of ward, access to bathroom, isolation, adequate lighting, able to be seen by staff, patient able to contact staff, hazards such as wet floor/clutter*)				
Ward Equipment *(e.g. availability and maintenance of mobility aids, height adjustable beds)*				
Staffing (e.g. staff shortages, staff member aware of falls prevention plan, skill mix, rostering, meal breaks, regular team, PS)				

Unusual activity in the ward at the time of the fall *(e.g. outbreak of illness: COVID – 19, Flu/Gastro, acuity of other patients, fire alarm etc)*				

Sequence of events

Step 2: Identify the care delivery problems

Instructions

I. The LP team review the incident chronology and at each step ask if there were any CDPs that arose in the process of care.

II. CDPs are documented on the "Chronological Mapping of CDPs and Associated Contributory Factors" table

III. The team determine who needs to be interviewed, questions are developed, and interviews allocated to team members.

Question / information to be sourced	Who can help with response?	LP team member /s allocated

Step 3: Staff and family interviews

Interviewing staff, patients, carers and families

Instructions

I. The staff member is asked to describe their observation and understanding of the events leading to the incident

II. The LP team member /s explain what CDPs are and ask the interviewee their opinion on the CDPs involved in the incident.

III. The LP team member /s explain what contributory factors are and ask the interviewee their opinion on the contributory factors involved in the incident.

IV. Interview is closed, ensuring interviewee has had an opportunity to ask any questions about the SAER process

Meeting two tasks

- ☐ Recap of process to date
- ☐ Overview of tasks to be achieved this meeting
- ☐ Team leader invites each member to share information gathered
- ☐ Incident chronology reviewed and amended if needed
- ☐ Contributory factors identified
- ☐ Chronological mapping of CDPs and associated contributory factors completed
- ☐ Causation statements developed
- ☐ Discussion about whether to add any team members to assist with development of recommendations
- ☐ Agreement on next steps including process for writing and approval of Findings Report

Step 4: Confirm incident chronology

Instructions

I. Team provide feedback on outcomes of interviews
II. The team review the initial flow diagram with consideration given to information gathered.
III. Amendments are made if required and incident chronology is finalised

Section two: Why did it happen?

Step 5: Identify any factors that caused or contributed to the incident

Instructions

I. The team review each central CDP separately and identify / brainstorm contributory factors outlined in the table above. Information from staff interviews is used to inform this process

II. The identified contributory factors are documented in the Chronological Mapping of CDPs and Associated Contributory Factors table

Some teams may choose to use a fishbone diagram to explore the contributory factors. One fishbone diagram is needed for each CPD. This step is not mandatory however LP teams have reported that this is a useful tool. Instructions are listed separately

Factor types	Contributory factor
Patient factors	Condition (complexity and seriousness) Language and communication Personality and social factors
Task and technology factors	Task design and clarify of structure Availability and use of protocols Availability and accuracy of test results Decision-making aids
Individual (staff) factors	Knowledge and skills Competence Physical and mental health
Team Factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership, etc)
Work Environmental Factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support Environment Physical
Organisational & Management Factors	Financial resources & constraints Organisational structure Policy, standards and goals Safety culture and priorities
Institutional Context Factors	Economic and regulatory context National health service executive Links with external organisations

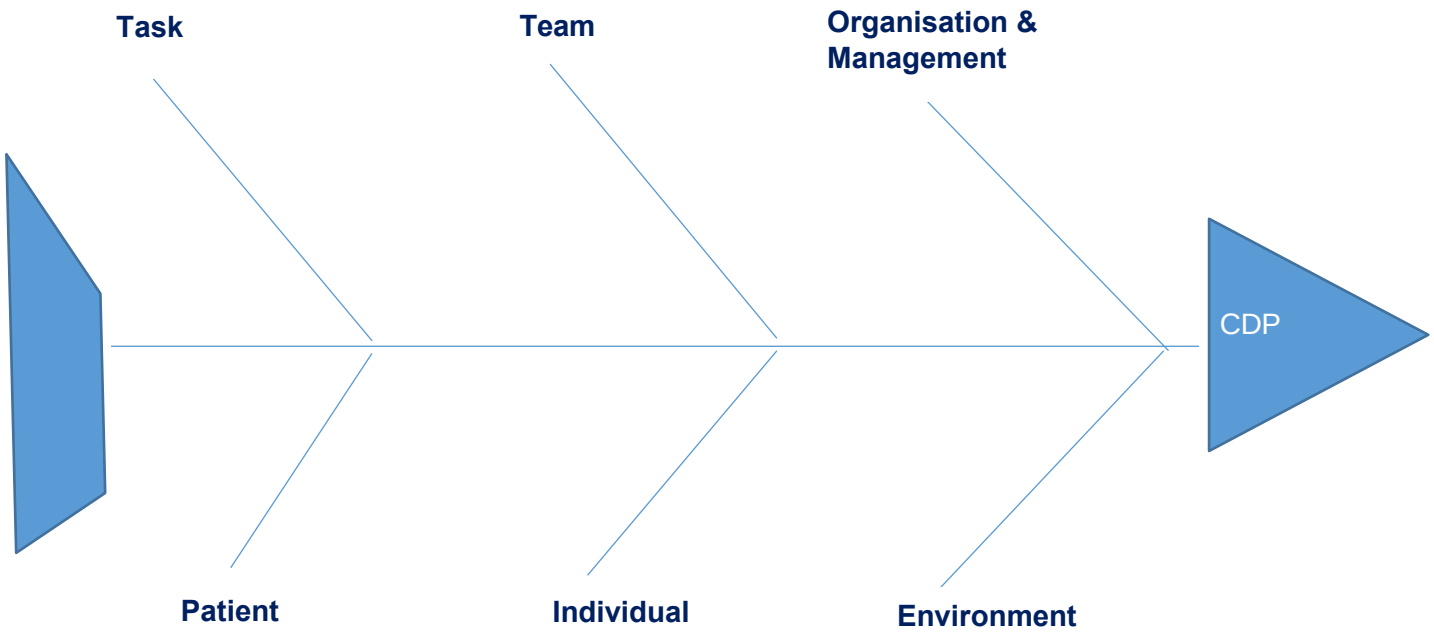
Chronological Mapping of CDPs and Associated Contributory Factors

Chronology						
	→	→	→	→	→	→
Care delivery problems						
Contributory Factors						
Recommendations						

Using fishbone diagrams to explore contributor factors – optional step

Instructions

I. As individuals, the team brainstorm all of the factors they believe contributed to the CPD in silence. One idea per post it note.
II. On completion of brainstorming the team group the post it notes under the headings of the contributing factor types. The ideas listed on the post it notes become the sub-categories
III. The team repeat the process described to review each CPD separately



Step 6: Write up factors linking them to outcome

Instructions

I. Identify contributory factors

II. Prioritise the order of potential impact i.e. begin with the factor with the greatest potential to prevent this event from occurring in the future.

III. Write up factors linking them to outcome. Some teams may wish to do this by developing causation statements for each contributing factor

IV. Check each factor / causation statement against the five rules of causation[2]

#	Linking factors to outcome OR causation statement
1	
2	
3	
4	

Causation statement worksheet

A causation statement has three parts:
The cause: “This happened… **{contributory factor}”**
The effect: “…which led to something else happening…” **{care delivery problem}**
The event: “…which caused this undesirable outcome.”

Causation statements should be checked against the 5 rules of causation

#	Causation statement	5 rules of causation
1		☐ Clearly shows cause and effect relationship ☐ Uses specific & accurate descriptors for what occurred ☐ Human errors have a preceding cause ☐ Violations of procedure are not major contributing factors / root causes ☐ Failure to act is only causal if there is a pre-existing duty to act
2		☐ Clearly shows cause and effect relationship ☐ Uses specific & accurate descriptors for what occurred ☐ Human errors have a preceding cause ☐ Violations of procedure are not major contributing factors / root causes ☐ Failure to act is only causal if there is a pre-existing duty to act
3		☐ Clearly shows cause and effect relationship ☐ Uses specific & accurate descriptors for what occurred ☐ Human errors have a preceding cause ☐ Violations of procedure are not major contributing factors / root causes ☐ Failure to act is only causal if there is a pre-existing duty to act
4		☐ Clearly shows cause and effect relationship ☐ Uses specific & accurate descriptors for what occurred ☐ Human errors have a preceding cause ☐ Violations of procedure are not major contributing factors / root causes ☐ Failure to act is only causal if there is a pre-existing duty to act

Step 7: Identify any practices, process or systems that could be reviewed

Instructions

I. The team review the causation statements and discuss the practices, processes or systems that could be reviewed.

II. The agreed areas are documented in preparation for the writing of the Findings Report

#	Area for review
1	
2	
3	
4	

Step 8: Write Findings Report

Instructions

The team:

I. Agree on the findings at a meeting or via email confirmation to the team leader
II. Submit the findings to the CE or nominated officer for approval

#	Causation statement	Could the team benefit from additional expertise to develop recommend actions?	Suggested expertise	Name and details of possible experts
1		Yes / No		
2		Yes / No		
3		Yes / No		
4		Yes / No		

Findings report checklist		
Element of the final report	**Needs to include;**	**Avoid;**
Description of Reportable incident	☐ less than one page in length Includes: ☐ Patient's age, sex, ☐ diagnosis, reason for admission, co-morbidities, ☐ relevant dates, planned or actual procedure, ☐ key points related to the patient's course of care.	☐ Dot points ☐ Non-factual information – not assumptions ☐ Identifying information such as hospital name, service, initials or locations titles to be referred to by function e.g. JMO ☐ Irrelevant information
Report Summary	☐ Demonstrate the team's comprehensive analysis ☐ Clear statements in regard to the appropriateness of deficiencies of policy or guidelines ☐ System vulnerabilities and the associated risks identified	☐ Repeating statements or opinions obtained from staff interviewed under privilege such as the nurse stated "…" to ensure that the requirements of the privilege applied to the process are not breached ☐ - Repeating the narrative – rather comment on the inter-relationship of interventions in the course of care
Element of the final report	**Needs to include / consider;**	**Example;**
Causation Statements / Factors Linked to Outcome	☐ Clearly convey the contributing system vulnerabilities identified by the team and clearly demonstrate how each of these factors contributed to the incident. ☐ Must demonstrate the cause and effect relationship ☐ Must meet the five rules of causation ☐ Have you got to the contributing factors?	"The lack of an effective process in the allocation of casual staff that takes into consideration the skill level of a staff member resulted in a staff member functioning beyond their level of experience. This resulted in the administration of a rectal medication being administered orally". Are you able to ask a why question against your causal statement / factor linked to outcome and get an answer? - If so, it is likely that the root cause / contributing factor has not been determined.

Section three: What action can we take to prevent it happening again?

Meeting three tasks

- ☐ Recap of achievement to date
- ☐ Feedback from findings report e.g. CE or delegate, family
- ☐ Overview of tasks to be achieved this meeting
- ☐ Review causation statement
- ☐ Recommendations developed
- ☐ Action plans developed
- ☐ Action plan developed with responsibilities and timelines for gathering information
- ☐ Summary of next steps including process for writing, approval and submission of Recommendations Report

Step 9: Recommend actions

Instructions

The team:

I. Review and clarify causation statements for all identified contributing factors.

II. Brainstorm actions that could prevent the incident recurring or reduce the severity should it recur.

III. Consider any suggested recommendations from the family.

IV. Assess the strength of each action against the Action Hierarchy ensuring at least one strong or intermediate action have been identified for each causation statement. These actions require the least reliance on people to remember to perform the task correctly and are more likely to eliminate or greatly reduce the likelihood of an event. Weaker actions are useful to establish expectations but are less likely to achieve sustained improvement because they rely too heavily on human memory or performance.

V. Follow the process above for any other recommendations not related to the contributing factors

VI. The team consult with another service if actions are recommended for a service not represented on the SAER team. An interview letter is provided to ensure privilege is maintained.

Action Hierarchy

	Action Category	Recommended action/s
Stronger actions (these tasks require less reliance on humans to remember to perform the task correctly)	• Architectural / physical plant changes • New devices with usability testing • Engineering control (forcing function) • Simplify the process • Standardise on equipment or process or care maps • Tangible involvement and action by leadership	
Intermediate Actions	• Redundancy • Increase in staffing/decrease • in workload • Software enhancements, • Modifications • Eliminate/reduce • Distractions • Education using simulation based • training, with periodic • refresher sessions and • observations • Checklist/cognitive aids • Eliminate look- and • sound-alikes • Standardised communication • tools • Enhanced documentation, • communication	

	Action Category	Recommended action/s
Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	• Double checks • Warnings • New procedure/ • memorandum/policy • Training	

Action hierarchy levels and examples adapted from National Patient Safety Foundation[4].

Step 9: Develop action plan

Instructions

The team:

I. Examine the findings report, particularly factors that caused or contributed to an incident and the areas for review findings.

II. Brainstorm actions that could prevent the incident or mitigate the harm should a similar incident occur.

III. Consider any suggested recommendations from the family.

IV. Assess the strength of each action against the Action Hierarchy.

V. For each proposed action, the team ask if this recommendation was implemented would it have prevented the incident or mitigated the harm?

VI. Consult if required –The team consult with another service if actions are recommended for a service not represented on the SAER team. An interview letter is issued beforehand.

VII. Consult with another organisation if actions are recommended for an organisation not represented on the SAER team (issue interview letter beforehand) and ensure CE from other organisation approves the recommendation/s

Action Hierarchy

	Action Category	Recommended action/s
Stronger actions (these tasks require less reliance on humans to remember to perform the task correctly)	• Architectural / physical plant changes • New devices with usability testing • Engineering control (forcing function) • Simplify the process • Standardise on equipment or process or care maps • Tangible involvement and action by leadership	
Intermediate Actions	• Redundancy • Increase in staffing/decrease • in workload • Software enhancements, • Modifications • Eliminate/reduce • Distractions • Education using simulation based • training, with periodic • refresher sessions and • observations • Checklist/cognitive aids • Eliminate look- and • sound-alikes • Standardised communication • tools • Enhanced documentation, • communication	

	Action Category	Recommended action/s
Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	• Double checks • Warnings • New procedure/ • memorandum/policy • Training	

Action hierarchy levels and examples adapted from National Patient Safety Foundation[4].

Step 10: Develop action plan

Instructions

I. For each recommendation, the team define a measurement plan that details what is being measured and includes a numerator and denominator. Measurement plans need to be specific and measure the effectiveness of actions not just whether they have been completed.

II. A length of time to implement the recommendation is documented.

III. Responsibility for each recommendation is assigned to one person. This should be someone with the right level of authority to effect change and the resources to implement the action.

IV. An oversight committee is named. Regular updates and evidence of implementation will be sent to this group by the person responsible.

V. The team follow the same process for any recommendations for system issues identified during the review but unrelated to the contributing factors

#	Recommendations	Link to underlying factors statement /s (A,B,C etc.)	Outcome measure	Timeframe	Oversight Committee	Position responsible for implementation
1						
2						
3						
4						

Step 11: Write Recommendations Report

Instructions

The team:

I. Agree on the recommendations at a meeting or via email confirmation to the team leader

II. Follow local processes for submission of the Recommendations Report to the CE. This often includes a sign off meeting with the team leader, senior clinicians +/- Director Clinical Governance.

Recommendations report checklist	
Recommendations	☐ Appropriate numbering to correspond to causation statements ☐ Is this the strongest possible recommendation which can be made to address the issue identified? ☐ Does the wording of the recommendations clearly convey to those who will be responsible for implementing them what it is the RCA team wants to happen? ☐ Recommendation focuses on the intent of the change, rather than become overly specific about the detailed process. ☐ Does the recommendation directly address the issue identified in the causation statement to which it relates (or is it part of another agenda) and is it realistic? ☐ Do the recommendations specify who is responsible for their implementation by title and role? ☐ Do the recommendations include an oversight committee? ☐ Do the recommendations describe how the effectiveness of actions will be monitored over time? Are the proposed outcome measures realistic? Measurable? ☐ Has a realistic time frame been allocated? ☐ If all recommendations were implemented, would patient safety be improved or are there more effective recommendations that could be made?

References

1. Taylor-Adams S & Vincent C 2004. *Systems analysis of clinical incidents: The London Protocol.* https://www.imperial.ac.uk/patient-safety-translational-research-centre/education/training-materials-for-use-in-research-and-clinical-practice/the-london-protocol/

2. US Department of Veterans Affairs (VA) National Center for Patient Safety (2015). *Root cause analysis tools.* https://www.patientsafety.va.gov/professionals/onthejob/rca.asp