SYSTEMS ANALYSIS OF CLINICAL INCIDENTS: THE LONDON PROTOCOL 2024

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PREFACE

Reflecting on the journey of a patient through the healthcare system can be illuminating in many ways. The experiences and illnesses of patients have, from time immemorial, been used to educate medical students on patterns of symptoms, the process of diagnosis and the underlying pathologies. Patient journeys can also be used to illustrate the process of clinical decision making, the weighing of treatment options and the critical role of the patient and family themselves in managing and living with the illness. Incident analysis, for the purposes of improving the safety of healthcare, may encompass all of these perspectives but critically also includes reflection on the broader healthcare system, its strengths and vulnerabilities and opportunities for change.

Over 25 years ago, a group of researchers, clinicians and risk managers collaborated to develop a method of incident analysis, the ALARM/CRU protocol, which was published in the British Medical Journal. The group used the organisational accident model of James Reason as the underlying model, but the method was developed by constant iteration and testing in multiple clinical settings. An expanded version, the London Protocol, was published in 2004. The purpose, then as now, was to develop a structured approach which did not constrain those reviewing an incident, but which fostered incisive analysis and thoughtful reflection.

The London Protocol has been widely used around the world and we now have considerable knowledge of its use for education and training, research and for analyses to support patient safety programmes in low, middle and high incomes countries. However, healthcare has changed in many ways since 2004 and our approach to incident analysis and prevention needs to be refined to reflect these changes in terms of patient engagement and care outside the hospital, as well as the recognition of patient safety as a global priority. We have drawn on developments in safety science, human factors and ergonomics, the findings of incident analyses and our own experience to produce a new, expanded version of the London Protocol. The authors and reviewers of this document come from many different countries and backgrounds, each with its own particular culture and healthcare system. We use examples from many different systems, but we have deliberately not aligned the new London Protocol with any particular organisation or country.

We believe the London Protocol can be used in any healthcare system, though we appreciate that some adaptations may be needed in different contexts. We believe that it is important to adhere to the core ideas and principles. However, we encourage people to adapt the London Protocol for their own needs and situation under the terms of the Creative Commons licence. We know from experience that the approach can be used both for long and complex investigations and for quick team-based discussions and reflections that only require a little shared time together.

We hope you find the new London Protocol useful in our shared quest for safer healthcare.

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1. INTRODUCTION

The investigation of incidents and accidents, together with subsequent reflection and action, is the foundation of safety management in every safety critical industry. Incident investigation is of course only one component of safety management but nevertheless an essential one. When conducted thoughtfully, incident analysis facilitates learning, safety improvement and supports the development of a proactive safety culture. Reflections and analysis of positive outcomes can also be valuable, particularly when safety was threatened and then recovered.

The London Protocol is a method of analysing incidents in healthcare which provides a window on the healthcare system illuminating its strengths, vulnerabilities and capacity for change [1]. The essential idea is that much can be learned about the wider healthcare system from the close examination of a single patient journey. Since the publication of the London Protocol in 2004 [2], healthcare has evolved and changed which means that the investigation of safety incidents must be adapted in a number of ways that are discussed below.

The most important change is that patient and families are increasingly engaged in their own care and that their contribution is critical to many, if not most, safety investigations. We have emphasised that the priority in any investigation or analysis is to look after the patient, family, and staff who are affected. We need to support them and address their needs before engaging them directly in the review and analysis. This new version of the London Protocol is not designed to address this critical issue in detail, but we provide some directions and guidance to support this process.

1.1. The scope and purpose of the London Protocol

The London Protocol 2024 provides, as the earlier version did, a structured means of analysis and reflection on an incident or patient journey. This latest version builds on the experience, practice and research of many people involved in incident investigation. Using this approach requires thinking, reflection and active exploration. It is not a routine process or a tick-box exercise, nor is it a search for 'root causes'. The London Protocol leads one away from a narrow focus on who did what towards a comprehensive examination of what the incident reveals about the wider system and what the implications are for improving safety.

This protocol covers the process of investigation, analysis and recommendations for action. In practice, this process will be set, and perhaps constrained, by the local context and conditions of use. A structured and systematic approach means that the ground to be covered in any investigation is, to a significant extent, already mapped out. The protocol helps to ensure a comprehensive review and facilitates the production of reports. We have

not been prescriptive about how incidents should be identified, or which should be investigated, as this will differ depending on local circumstances and national priorities [3].

This document describes a full investigation, but we wish to emphasise that much quicker and simpler investigations can also be conducted using the same basic approach. Experience has shown that it is possible to adapt the basic approach of the protocol to many different settings and approaches. For example, it can be used in a team discussion for quick 5 or 10-minute analyses, just identifying the main problems and contributory factors. The protocol can also be used for teaching, both as an aid to understanding the method itself and as a vehicle for understanding the many factors which may either enhance or degrade safety.

We stress that this approach needs to be separated from any disciplinary or other procedures used for dealing with persistent poor performance by individuals. While blame and disciplinary action may be appropriate in some circumstances, it should never be the starting point. If an investigation reveals behaviour that might be considered culpable then this should be addressed separately within the appropriate process. Most safety problems stem from wider systemic issues and it is generally not only unfair but completely pointless to blame individuals. The emphasis in any investigation should be on looking after those affected by the incident and its consequences, restoring trust and contributing to a wider culture of fairness, learning and safety enhancement [4].

2. A BRIEF HISTORY OF THE LONDON PROTOCOL

Our first approach to incident analysis was developed at the Clinical Risk Unit, University College London (CRU), with the Association of Litigation and Risk Management (ALARM). We had previously extended Reason's organisational accident model and adapted it for use in healthcare, classifying the error producing conditions and organisational factors in a single broad framework of factors affecting clinical practice [5-6]. This provided the foundation for the ALARM/CRU protocol which was published in the British Medical Journal in 2000 [1]. An expanded and refined version, the London Protocol, was published in the journal Clinical Risk [2].

2.1. The London Protocol

The original London Protocol drew on ideas from safety science, described below, but was grounded from the beginning in the realities of clinical practice and the narratives of patients and clinicians. The approach has been successively refined and developed in the light of experience and research into incident investigation both within and outside healthcare.

The London Protocol has been widely employed in analyses of incidents and safety events in hospital care, community and primary care and mental health. These analyses have been conducted in many clinical settings and have revealed the range of vulnerabilities in health

systems and the many factors that may contribute to error and harm. The ideas underlying the London Protocol, notably the framework of contributory factors, have been used more widely in a variety of studies and improvement initiatives. For instance, in a study of medication errors, Dean and colleagues identified a range of contributory factors which in turn suggested methods of intervention and error reduction [7].

The original London Protocol has been translated into many languages. These include Arabic, Danish, Finnish, French, German, Italian, Japanese, Norwegian and Spanish. The protocol has been recommended for use in many different countries and contexts. For instance, the Swiss Patient Safety Foundation has taught and recommended the London Protocol for two decades. In Tuscany, Italy the protocol has been extensively taught in both academic and professional contexts and has become one of the fundamental pillars of safety management. The protocol was first used in hospitals in Tuscany and then extended to mental health [8], long term care facilities and nursing homes [9], prison healthcare, and mortality and morbidity reviews [10]. The Clinical Excellence Commission in Australia recently released a London Protocol toolkit to guide investigation in New South Wales [11].

2.2. The need for reassessment

The systematic analysis of incidents has expanded our understanding of both the causes and prevention of harm. These approaches have been widely employed in healthcare over the last twenty years but are now subject to critique and reassessment [12-13]. We believe that the essential concepts and practices underlying the London Protocol remain robust although the approach needs to be adapted to current challenges.

The primary need for a renewed vision of incident analysis is that healthcare itself is changing dramatically [14-15]. People are living longer, often with multiple co-morbidities which are managed over long timescales [16]. Care is being delivered in the home and in community settings; patients and families are playing an ever-greater role in their own care, often with the support of digital health services and implantable/wearable devices [17]. The patient and family may be providing quite complex care in the home and their perspective in any review, especially of home or community-based care, is absolutely critical. We therefore need to pay much more attention to safety issues that arise outside the hospital, at home, in the community and in primary care settings. Our vision of safety analysis needs to expand concomitantly to embrace much longer timescales. Rather than thinking only in terms of the prevention of specific incidents, we need to consider the balance of benefit, harm and risks over long time periods [18].

Reviews conducted by healthcare organisations suggest that the quality of incident analysis can be highly variable and is often poor. Many of the analyses that are conducted do not lead to effective actions or improvements [19]. Organisations are often under pressure to deliver a large number of mandated investigation reports, which means that the analyses can degenerate into a bureaucratic process producing repetitive reports identifying 'root causes' and making formulaic and unachievable recommendations [20]. We need fewer,

deeper, and more thoughtful investigations and analyses rather than multiple routine and repetitive reports. The new London Protocol gives much more attention both to the art of report writing and the development of appropriate recommendations.

In summary, in the new London Protocol:

- We have given much greater emphasis to the importance and potential of engaging of patients and families as partners in the review.
- We have stressed the need to consider both the physical and psychological impact on the people involved in an incident.
- We have allowed for the examination of much longer time periods and the assessment of contributory factors at different points in the patient journey.
- We have considered the aftermath of an incident in more detail and indicated that reviewers should assess the consequences and support after an incident as well as the causes and contributory factors.
- We have sought to understand success and recovery as well as failure.
- We have cautioned against making recommendations on the basis of a single incident.
- We have outlined a much more structured approach to recommendations, which includes critique of existing standards, policies, and procedures.
- We have provided explicit guidance on how to write reports.

2.3. The purpose of incident analysis: a window on the system

Before turning our attention to the science of safety and the process of investigation we need to reflect on a fundamental issue, namely the purpose of the investigation. Surely the purpose is obvious? To find out what happened and what caused it? We believe that this is important but not the most illuminating perspective or the most useful for developing interventions and recommendations. Certainly, it is necessary to find out what happened and why in order to explain to the patient and family and others involved. However, if the purpose is to achieve a safer healthcare system, then finding out what happened and why is only the first stage in the overall analysis.

The real purpose is to use the incident to reflect on what it reveals about the gaps and inadequacies in the healthcare system. Because of this orientation we have called our approach a 'systems analysis' [21], by which we simply mean a broad examination of all aspects of the healthcare system in question and the interplays between human, technical and organisational factors. We emphasise that this includes the people involved throughout the system and how they communicate, interact, and create the safety culture of the organisation.

Most healthcare organisations prioritise incidents in which patients are seriously harmed as requiring the most intensive investigation. Patients and families rightly insist that organisations should learn from such events and the investigation, if done in a supportive manner, can

help all those affected in their recovery. However, analysing 'near misses', in which harm was narrowly averted, can also provide valuable insights into the wider system [22].

Our vision of a window on the wider system, and the many features and contributory factors revealed, means that we do not use the term 'root cause analysis'. In practice the term 'root cause analysis' is often used as a generic term to cover any kind of incident investigation, but we regard it as misleading in several respects. To begin with, it implies that there is a single root cause, or at least a small number. Typically, however, the picture that emerges is much more fluid and the notion of a root cause seems a gross oversimplification. Usually there is a chain of events and a wide variety of contributory factors, often combining in unexpected ways, leading up to the eventual incident. In addition, looking for a root cause implies that the primary purpose is to look back. For us, once those involved have had the explanations they need and deserve, the primary purpose is to look to the future and enhance and sustain the safety of the healthcare system [21].

3. SAFETY SCIENCE

The theory underlying the ALARM and London Protocols and their application is based on research originally conducted in settings outside healthcare. Studies of accidents in industry, transport and military spheres led to a much broader understanding of accident causation, with less focus on the individual who makes the error and more on pre-existing organisational factors. Analyses both within healthcare and other settings showed that major incidents and accidents were preceded by a complex chain or set of events and highlighted the importance of wider organisational and system factors in the genesis of harmful events.

The pioneering work of Jens Rasmussen and others in the 1980s and 1990s laid the foundations for a more sophisticated, yet practical, approach to understanding error and accidents. Rasmussen showed the importance of examining factors across multiple levels of any system, of understanding the different perspectives of those involved and emphasised the variability and adaptation in all work processes [23-24]. Much of the early work was distilled and extended by James Reason into his organisational accident model, which provided the foundation for the ALARM and London Protocols [25-26].

3.1. Organisational Accident Model

The organisational accident model has been hugely influential in many industries, both as a means of understanding accidents and of developing safety improvements [26]. The model provides a general description of how accidents occur, from which we developed our review process. We provide a brief summary of the key points here.

Active failures are unsafe acts or omissions by those at the 'sharp end' of the system (pilots, air-traffic controllers, anaesthetists, surgeons, nurses, etc.) whose decisions or actions can have immediate adverse consequences. Active failures in health care come in various forms.

They may be slips, such as picking up the wrong syringe, lapses of attention or judgement, forgetting to carry out a procedure or deliberate departures from safe operating practices, procedures or standards. In our work we have employed the more general term 'care management problems' (CMP) in place of errors or unsafe acts to refer more broadly to any significant problems that arise in the care delivered to the patient. This is partly because we think it is helpful to use more neutral terminology. However, the term also covers problems which extend over some time, such as failing to monitor a patient for several hours, for which the term error does not seem appropriate [1].

Reason also described defences and barriers, which are designed to protect against hazards and to mitigate the consequences of equipment and human failure. These may take the form of physical protective barriers or equipment, procedural barriers (such as prescribing a distance from a radiation source), human actions (such as double-checking), automated programs to catch errors (such as computerised decision support) and administrative controls (such as restrictions on who can carry out a certain procedure).

Reasons' model then draws our attention to 'latent conditions' which are features of the organisations or system that influence those working on the frontline and which may increase the likelihood of 'active failures,' which are errors and other safety critical actions or omissions. These conditions include high workload and fatigue; inadequate knowledge, ability or experience; inadequate supervision or instruction; a stressful environment; rapid change within an organisation; inadequate systems of communication; poor planning and scheduling; inadequate maintenance of equipment and buildings. In healthcare we have used the more general term 'contributory factors', rather than latent conditions, to describe these wider system factors that influence the care patients receive [6]. These contributory factors include both those with a direct influence on care, such as equipment design or teamwork, and the higher-level organisational processes set out in Reason's model.

We have added an additional stage to the organisational accident model ('corrective measures, support and risk management') so that it now also encompasses the critical time after an incident occurs when actions need to be taken to protect and care for those involved, both patients, families and staff. In the analysis of an incident each element of the model is considered in turn, starting with the CMPs and failed defences, and working backwards to consider the role of contributory factors. Those reviewing incidents also need to assess the care provided in the aftermath as well as the events leading up to the incident that triggered the review.

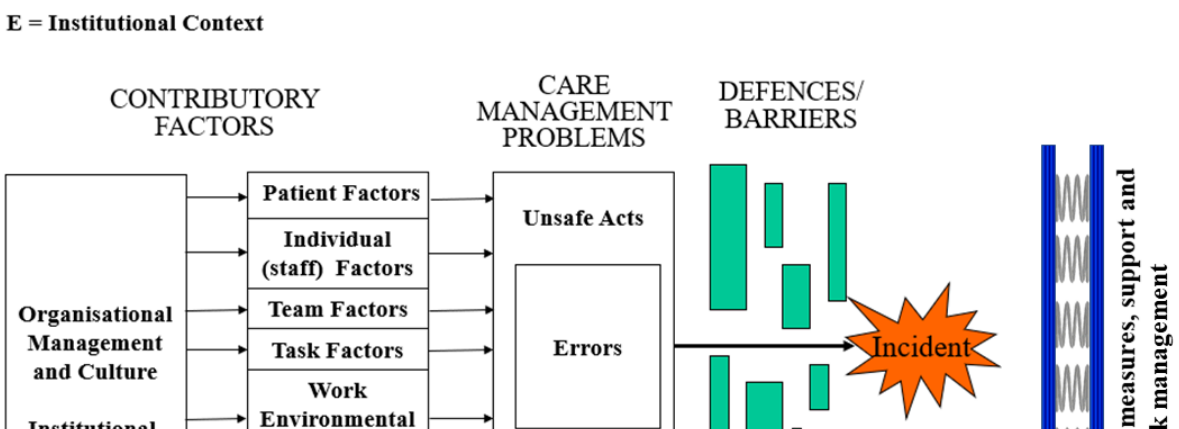

Figure 1. Extension of James Reason's Organisational Accident Causation Model, adapted from Reason [27].

3.2. Developments in safety science 2004-2024

In the last 20 years patient safety has achieved a prominence that would have been hard to imagine when the CRU/ALARM protocol was first developed in the 1990s. Many countries have enacted laws and regulations to guarantee and promote patient safety, including recommendations or requirements to perform incident investigation. Approaches to incident analysis have also been influenced by safety science, particularly developments in human factors engineering and ergonomics and by the ethos and conceptual frameworks of resilience engineering.

Human Factors/Ergonomics (HFE) approaches, in whatever form, emphasise the importance of understanding all elements and interactions of the work system, the people, the physical environment, the nature of the tasks and the working environment. For instance, the Systems Engineering Initiative for Patient Safety model (SEIPS) is a widely used model describing very similar categories to the contributory factors framework discussed below [28]. It was originally developed to address system safety concerns but then extended to address healthcare systems design and management [29-31].

HFE approaches are most commonly used to directly explore a system, such as a ward or an outpatient clinic. However, they can also be valuable in the investigation of an incident or patient journey. They can be helpful in initial data collection and analysis by suggesting a wider range of relevant phenomena, not only problems and contributory factors, but also the constraints, barriers and design features that may support or erode safety [32]. They also encourage reflection on what might most successfully enhance safety at frontline, management, organisational and regulatory levels [33]. HFE approaches are particularly relevant for such issues as improved usability of medical devices, the use of simulation to prepare teams for rare or unexpected events and the engagement of patients and families in the design of workflows and clinical pathways.

Resilience engineering is a broad field, with several contrasting and sometimes conflicting, visions of resilience. Resilience engineering, and the earlier traditions that underlie it, draw attention to the role of adaptation and flexibility in both everyday work and responses to pressures and crises [23, 34]. The delivery of healthcare relies extensively on the skill and flexibility of healthcare staff who make frequent use of adaptations, workarounds and shortcuts which may or may not be justified by the circumstances. The implications of this are that those investigating incidents need to understand that adaptations and deviations from procedures are commonplace and need to be understood in context [35-36].

Resilience engineering and HFE approaches stress the importance of understanding the realities of the workplace. This in turn points to the value of actually visiting the relevant environment, observing what happens and discussing day-to-day work with the staff. This will contextualise and enhance the understanding gained from statements, interviews and discussions with those involved in the event.

Both of these approaches also emphasise the need to understand and appreciate the positive aspects of human and system performance. They support the investigation of incidents and patient journeys but stress that there is as much to be learned from understanding successes and facilitating factors as there is from instances of problems and harm [37-38]. The learning potential of success stories may sometimes be richer because positive events are more easily discussed the shared. The methods of the London Protocol 2024 can be applied to any kind of incident or patient journey, whatever the eventual outcome for the patient. We do not yet know whether different safety lessons can be learned from using a variety of outcomes and patient journeys and this is an important topic for future research.

4. ESSENTIAL CONCEPTS

Our brief review of the underlying safety science has given us the concepts that we can use in practice to support and focus our investigation and analysis. While our own clinical and life experience provides considerable insight into any safety issue, our analyses will be sharper and more focussed if we work systematically to identify key events and system features. We first need to examine the care of the patient during their healthcare journey, building the story of their journey from records, on-site observations, and interviews with staff involved, patient, and family. Second, we need to assess the care provided, asking what went well, what problems occurred and if there were problems, how they were overcome. Next, we examine the role of defences and barriers, and how effective they were in protecting against harm. The fourth, most critical, stage in our analysis is to identify the contributory factors, the wider features of the system that influence care and which will lead us to recommendations and interventions.

4.1. The care provided: good practice and care management problems

Any safety analysis begins by developing an understanding of the care provided to the patient over the time period in question. This understanding will evolve over the course of the review as information is assembled from records, interviews and observations.

We first need to identify and explicitly acknowledge those aspects of care that went well or as well as could be expected in the circumstances. We then need to identify the care management problems (CMPs) which are significant problems that arise in the process of care. They may, or may not, have had an influence on the outcome for that particular patient. In analysing a patient journey, we may uncover a considerable number of CMPs,

and we will need to select those that were either most consequential for the patient, or which reveal important problems in the wider system of care.

Examples of CMPs are:

- Not listening to the concerns of patients and families.
- Inadequate monitoring or observation.
- Incorrect (with hindsight) decision or diagnosis.
- Incorrect or delayed prescribing.
- Failure to communicate critical information.
- Inadequate risk assessment.
- Not seeking help when necessary.
- Giving the wrong drug to a patient.
- Not prescribing an essential or time critical medication.

The assessment of CMPs relies on the judgement of the reviewer or team reviewing the incident and is more effective when clinical and safety science expertise is combined. They will recognise that, in a busy ward for instance, minor problems and delays are frequent, and that staff often need to adapt and adjust the pattern of care in the best interests of the patient. This means that the investigating team needs to understand the realities of practice, ignoring the minor variations that occur in all patient care, and focus on issues of significance to the patient in question and the care of future patients.

We also need to remember that decisions or actions which appear clearly wrong in retrospect may have seemed quite reasonable at the time. We need to understand the circumstances in which the problem occurred. We need to ask, in particular, if the action or omission in question was a necessary adaptation of usual practice. For instance, why did the nurse not double-check the medication in order to provide a pain medication or an antibiotic more quickly? Was there simply no one else available? Furthermore, it is sometimes necessary to also look more closely not only at the reasons for departures from standard procedures, but at the standards and procedures themselves. Are these standards and procedures appropriate for all patients and are they realistic in a busy clinical environment. If not, then the standards themselves may need to be revised and this must become a part of the analysis of the incident in question [13].

4.2. Defences and barriers

Defences and barriers are safeguards designed to protect against hazards and mitigate the consequences of equipment and human failure. They take various forms which share the common feature of controls or restraints to minimise risk. Barriers are usually intended to prevent exposure to hazards, while defences are designed to protect workers and patients to an exposure to a hazard that is an inherent feature of some clinical activity or task. For example, a physical barrier might be an automatic lock on a door to prevent exposure to

radiation during a CT scan, whereas a physical defence might be an anti-radiation vest. Some physical barriers set controls on technologies, such as setting a maximum flow rate of infusion pumps to prevent overdosing, while some others are warning signs, like alarms triggered by vital signs or alerts when medication are due. Individuals and teams can also use behavioural or procedural defences to reduce error, such as closed-loop communication to confirm understanding of information. At an organisational level, certain activities may be restricted to particular professions or levels of seniority (such as prescribing medicines).

Recommendations following analyses may include establishing or modifying barriers and defences. However, this should only be done after a review of relevant scientific literature and careful assessment of the potential impact of introducing or adjusting barriers. Barriers and defences are distinguished from contributory factors because they are specifically intended to improve safety, while contributory factors influence all aspects of the healthcare system.

4.3. Contributory factors: eight levels of safety

The term 'contributory factors' was designed to be broadly equivalent to the 'error producing conditions' or 'latent conditions' defined by James Reason. Again, we have adopted a neutral term to ask a broader question. We want to know what features of the working environment or wider organisation influenced the occurrence of problems in the process of care (the CMPs). We can, alternatively, examine successful aspects of the care process identifying, for instance, that a patient was only saved from harm by exceptional teamwork. Given the neutral framing of the term contributory factors, they can also be used to analyse success stories and interpreted as facilitating conditions.

Figure 2 shows the framework of contributory factors with examples of specific factors under each of the eight headings. Reviewers of incidents may need to add additional specific factors if they emerge as important during an investigation. The original framework developed in the 1990s included seven categories of contributory factors [6]. In the present version of the London Protocol, we have expanded the number of categories to eight, because of the increasing relevance of devices, digital applications and artificial intelligence in healthcare which have created a very different working environment from that of 25 years ago.

The contributory factors framework is a useful guide for the analysis of incidents because it invites clinicians and risk managers to take into consideration a wide range of factors that at different levels are determinants of the safety and quality of healthcare. If applied in a systematic way, it enables the investigation team to draw up a ranking of the factors which had a greater weight on the performance outcomes and prioritise interventions accordingly to enhance safety and prevent future system failures.

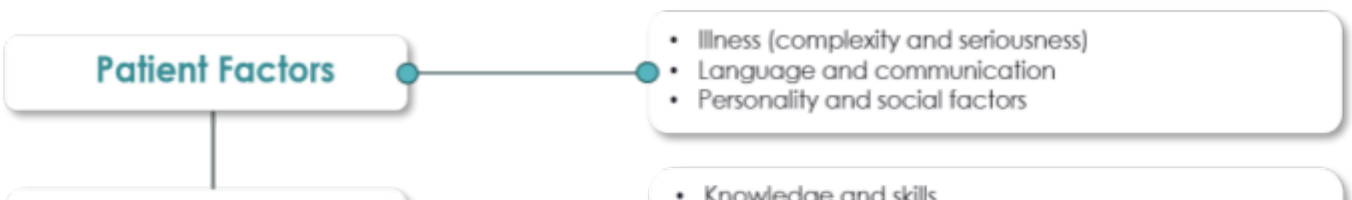

Figure 2. Framework of Contributory Factors. Adapted from Vincent et al. [6].

At the top of the framework are patient factors. In most clinical situations the patient's illness and co-morbidities will have the most direct influence on practice and outcome. Other patient factors such as personality, language and psychological factors may also be important as they can influence communication with staff. Individual staff factors include the knowledge, skills and experience of each member of staff, which will obviously affect their clinical practice. The design of the task, the availability and clarity of protocols and guidelines may influence the care process and affect the quality and safety of care. Each staff member is part of a team within the inpatient or community unit, and part of the wider organisation of the hospital, primary care or mental health service. Individual decisions and actions, and their impact on the patient, are constrained and influenced by other members of the team and the way they communicate, support and supervise each other.

The team is influenced by the working environment, which includes the physical layout and environment, the availability of drugs and equipment and the tools and support necessary to do the job. The team is equally influenced by the information systems and technologies they rely on, their design, interfaces, maintenance, integration into the workflow and other factors. Artificial intelligence is being rapidly introduced into healthcare in many countries and investigators will increasingly have to consider the role of clinical decision support and other automatic systems on the process of care. The working environment in turn is affected by management actions and by decisions made at a higher level in the organisation. These include policies for the use of locum or agency staff, support for continuing education, training and supervision and the availability of equipment and supplies. The wider culture of the organisation may also be relevant if, for example, staff find it difficult to speak up when patients are at risk or if the board of the organisation is not committed to ensuring patient safety. The organisation itself is affected by the institutional context, including financial constraints, external regulation and the broader economic and political climate.

The framework provides the conceptual basis for analysing adverse incidents. It includes both the clinical factors and the higher-level, organisational factors that may be influential. In doing so, it allows the full range of influences to be considered and can therefore be used to guide the investigation and analysis of an incident. Each level of analysis can be expanded to provide a more detailed specification of the components of the major factors. For example, team factors include items on verbal communication between junior and senior staff and between professions, the quality of written communication such as the completeness and legibility of notes, and the availability of supervision and support.

Many factors may contribute to a single CMP. For example:

- Patient factors might include the fact that the patient was very distressed, unable to understand instructions or unconscious and unable to give a history.
- Individual factors may include lack of knowledge or experience of staff.
- Task factors could be attributable to the lack of updated and clear protocols.
- Technology factors might include poor interface design.
- Team factors might include poor communication between staff.
- Work environment factors might include an unusually high workload, poorly designed clinic areas, or inadequate staffing.

As many factors may contribute to a single CMP, and many CMPs may be identified within a patient journey, this can result in a large number of contributory factors. In a major analysis it is however worthwhile to initially describe the full range of contributory factors before later focusing on those of particular significance to the patient or the system. This is where the multidisciplinary expertise of the investigating team is vital to maximise potential for improvement.

5. PREPARATION AND PLANNING

Reviewing and analysing incidents is one of the best ways of introducing and understanding patient safety. Discussing an incident with a group of medical or nursing students for instance, inevitably leads into a wider discussion of the nature or errors, problems in care and the many influences on clinical practice. For educational purposes, no special preparation is needed beyond a general understanding of the underlying ideas and the clinical context. However, if a review is to be conducted as part of an organisational safety programme, then some preparation is necessary both for the process of analysis and wider engagement with senior leaders in the organisation. Our suggestions in this section relate specifically to formal incident reviews conducted as part of an organisational safety or risk management programme.

5.1. The initial decision to investigate

In most healthcare organisations, an incident will either be investigated because of its seriousness for the patient and family, for the staff or the organisation, for its frequency or repetition, or because of its potential for learning about the functioning of the department or organisation. Serious incidents will generally be reportable on organisational incident forms or reporting systems. Some incidents require immediate initial investigation, whilst others can wait a few hours (e.g. until the morning) or a few days if there are no ongoing threats to clinical performance or service continuity.

The precise action to be taken is a decision for the most senior person on duty at the time or a dedicated patient safety officer or risk manager formally appointed by the organisation. They will be supported by the organisation's patient safety or risk management team, where available, especially for more severe or significant events. Consideration will need to be

given to what has actually happened, the patient's clinical status, immediate support for the patient and family, the wellbeing of staff involved and external pressures such as media interest. Each organisation needs to clearly specify the circumstances that initiate an incident investigation, mindful of the local, regional and national guidelines.

Organisations and risk managers have a responsibility to investigate incidents involving harm because of the need to explain and potentially make reparation to the patient and family and to support staff involved. There may be regulatory requirements, mandating the review of certain serious incidents as a condition of accreditation of the organisation. However, from the point of view of learning about the clinical system, it is not necessary or even desirable that there should be a bad outcome. Reviewing near misses is likely to be fruitful, together with some successful outcomes, particularly those where a team performed well against the odds, or a patient was rescued from a dangerous situation. Such incidents can also be less emotionally demanding to discuss as there and less risk of feelings of shame and guilt on the part of staff involved.

All healthcare organisations which conduct incident reviews need a policy which covers, at a minimum, the selection of incidents to review, the engagement of the patient and family, support for staff, the resources that should be devoted to the analysis and how recommendations should be integrated into safety and quality improvement programmes. Incident analysis, if poorly focussed and poorly conducted, can consume a great deal of resources for little return. In contrast, if a limited number of incidents are carefully and thoughtfully reviewed, with clear and well evidenced recommendations, then incident analysis can lead to major safety enhancements.

5.1.1. Thematic and aggregate analysis

Reviews of incidents in most safety-critical industries are deep, thoughtful and relatively few in number compared with the volume of activity. Healthcare, for a variety of reasons, has chosen to prioritise reviewing large numbers of incidents superficially. This has led to cursory investigations and numerous ill-considered recommendations. At worst, an organisation may have multiple reviews of the same kind of incident, all with similar findings, and a vast number of recommendations which are never adequately implemented. The exploration of themes which emerge from multiple similar safety incidents, rather than multiple investigations of single incidents is long overdue. This approach was used extensively by the Clinical Excellence Commission in Australia [39] and is now explicitly encouraged by the new Patient Safety Incident Response Framework (PSIRF) in the UK [40].

5.2. Training of reviewers

Hospital boards and community care organisations must decide what constitutes "appropriate training" for their reviewers and how to allocate investigatory responsibilities in different areas of clinical practice. For instance, in Italy, training on a systems approach to

incident investigation is required both for patient safety managers at board level and for clinicians with the role of facilitator/patient safety officer at the clinical unit level.

We suggest that the training of safety incident reviewers should take account of the following issues:

- Participants will have a clinical background or safety role in their job plan and ideally an existing knowledge of human factors and relevant safety science.
- Assurance of competence will depend on the type of investigation and depth of analysis needed (i.e. local incident review versus complex case involving the death of a patient).
- Expert faculty: the delivery of course content may require in-person teaching to ensure the necessary support is available to understand and apply safety principles and practice. Where this is not possible, online training offers an accessible and more cost-effective option.
- Training should also be available to support mentors in providing advice and support for investigators once they have been trained.
- It will be helpful for trainees to shadow or assist with a current investigation.

Reviewers also need to be prepared to sensitively manage challenging conversations and emotions in the aftermath of a safety incident. Support and training for investigators who will be routinely conducting interviews or managing a group discussion should include techniques for:

- Facilitating compassionate and constructive conversations.
- Being prepared and able to cope with the emotions of those affected, whether patients, family members or staff. These may include strong, sometimes overwhelming, experiences of anger, loss, and depression on the part of the patient and family.
- Staff may experience feelings of grief or guilt associated with self-blame, and anger at flaws in the system or a perceived lack of support after a safety incident.
- Ensuring all voices are heard in larger groups where some individuals may be worried about speaking up, including those from outside the ward or service.

Mentorship should form a part of the ongoing support for staff involved in the analysis of safety incidents and is crucial for reinforcing skills and providing pastoral care for investigators. When an investigation involves very distressing events then it may be useful to also consider support from professional psychologists or counsellors within or external to the organisation.

5.3. Leadership and organisational support

Executive leaders in hospitals or community healthcare settings are responsible for defining, organising and delivering the systems that support safe care for patients. In Japan, senior executives are required to take government approved courses on patient safety to foster engagement and leadership of safety programmes. This is a huge topic which we cannot address in detail here. However, it is necessary to point out that incident reviews will have limited impact unless they are part of a comprehensive and organisational safety programme or quality improvement system. The board's responsibilities include providing training and development opportunities for staff as described above, but also:

- Explaining, fostering and modelling a just culture.
- Engaging effectively with patients and their families and carers.
- Providing a functional, agile governance infrastructure.
- Providing a readily accessible incident reporting and learning system with capability for data analysis.

National or regulatory requirements will have an influence on leadership and organisational support. In the UK for example, the new PSIRF describes both the safety investigation process and the infrastructure required to support and embed them [40]. Other countries have similar requirements and guidelines, usually recognised within the accreditation systems. However, whether or not guidelines exist, organisational leadership and support for safety management is essential for useful and impactful incident review.

5.4. Leadership of the review

The leader of the investigation team should be someone who can objectively guide the process, ensure all relevant stakeholders are involved, maintain confidentiality, and communicate findings and recommendations effectively. It is crucial to establish a culture of safety and non-punitive reporting, allowing all team members to contribute their perspectives without fear of criticism or censure, thus fostering a learning environment focused on improvement.

The leader of the review team therefore needs to be impartial, experienced in incident investigation, and knowledgeable about the institution and the investigation protocol. For example, the leader could be a Patient Safety Officer, an experienced clinician or a leader in quality improvement or risk management. The protocol can also be used to investigate less serious incidents and near misses. In this situation, it might be that a departmental or ward manager with appropriate training would facilitate the incident investigation and analysis.

In some organisations, and in some countries, leadership of an investigation is automatically assigned to a senior manager, whether or not they have any experience or understanding of safety and methods of incident review. Senior managers are also unlikely to have the time to lead a serious investigation and quite possibly will not have the skills. Assigning people to lead investigations simply on the grounds of seniority can lead to rapid, trivial reviews of complex issues which do little to enhance safety. It is not necessary or desirable that the leader of the

review or investigation should be the most senior person in the group involved. Rather, they should be chosen based on having the necessary skills, expertise for the review and their sensitivity and understanding of the impact of serious incidents on those involved and on the wider organisation.

5.5. Building the team for a specific review

The investigation team should consist of a minimum two people: someone who understands the clinical environment but was not directly involved in the incident, and someone who understands and has experience of the methods and procedures of investigation. Either person may assume the responsibilities of the team leader. Members of the investigation team should not be the supervisors or managers of any of the staff being interviewed.

Depending on the nature of the incident being investigated, the team might be extended to incorporate specific skills and expertise. For instance, involving ergonomics and human factors experts who study how humans interact with systems, equipment and environments is likely to greatly improve the depth and understanding achieved in the review and the strength of ensuing actions and recommendations. They could consult on workflow analysis, ergonomic assessment and technology integration and evaluation. People with senior management and/or senior clinical expertise may also be beneficial to include, as well as public and patient involvement representatives or other patient advocates. In the state of Victoria, Australia have seen more than half of review teams now include a patient public involvement representative as part of a recent initiative [41].

6. SUPPORTING PATIENTS, FAMILY AND STAFF

While healthcare organisations are undoubtedly giving more attention to the engagement and involvement of patients, families and staff, the way they do this for patient safety incident investigations remains highly variable. Many patients and families still feel excluded from the process and sometimes the original trauma may be compounded by the insensitive and thoughtless manner in which the patient is cared for after the original harmful incident. Thankfully, it is now widely accepted that patients and families should be fully informed after a harmful event, although the extent of their trauma and need for longer term support may not be as readily recognised. We need to first understand and address the needs of the patients, families and carers affected by a safety incident before we consider how best to involve them in the investigation and to what extent they wish to be involved. In this section, we highlight some of the principal issues that must be considered, but there are useful sources for further guidance on this topic [42].

6.1. Disclosure and immediate support

The priority following any harm should be to address the immediate care of the patient and family, managing the patient's condition and addressing any wider concerns to mitigate or

prevent any further harm [42]. This may involve immediate medical or surgical intervention together with personal support and reassurance. Injured patients often report that staff withdraw and may even avoid them at the very time when they actually need more help. The key principle for both individual clinicians and managers and the organisation is everyone has a continuing duty of care to any injured patient and a responsibility to acknowledge and mitigate any harm. Depending on the nature of the event, the harm might extend to other patients and staff which also needs attention. There have, for example, been instances in which dental equipment was reused without adequate sterilisation, resulting in cross-patient contamination and required several hundred patients to be called back for HIV and hepatitis testing.

After attending to any immediate harm to the patient, a senior member of staff, who is ideally known to the patient, should inform them of what has happened. In most cases this will be a senior clinician with the expertise and authority to explain clearly what has happened. They should offer an apology, where appropriate, on behalf of the staff and the organisation, and explain what is being done to support them and their family and investigate the incident. This should be done immediately, even though the causes of the incident will not yet be fully understood. Further information should be communicated to the patient as it becomes available to mitigate any breakdowns in trust. The senior staff member should also ask the patient and family what questions they want answered and what help they need in the short and longer term. The information conveyed to the patient and family should be recorded in the patient's files so that all those in contact with the patient communicate consistent information.

The patient and family should be made aware if an investigation is taking place and clear lines of communication should be established. The state of New South Wales in Australia, for example, has mandated and defined a 'Dedicated Family Contact' whose role it is to consult with the family, identify their needs and keep them informed [43]. If the patient concerned is no longer under the care of the healthcare facility where the incident occurred, they should be contacted at the point of discovery to allow them to seek medical attention and support as needed.

Patients have a right to relevant information about all aspects of their care and healthcare providers have an ethical, and in some countries legal, obligation to tell patients openly and honestly when something has gone wrong. It is important that patients and families do not feel that information is being withheld as this causes increased anxiety and distress. Many patients and families will also want to know what will be done to minimise harm caused and what will be done to prevent similar events occurring in the future.

6.2. Longer term support for patients and families

Healthcare organisations need to have arrangements in place and dedicated staff to monitor and support patients harmed by healthcare and their families in the longer term. This needs to be done regardless of whether or not there is a formal complaint, compensation

process or legal action. The nature of the legal process and the extent of wider social support varies hugely from country to country. However, in every country the healthcare organisation continues to have a duty of care and the likelihood of complaint and litigation will only increase if the patient is abandoned by the organisation. Patients who have suffered serious harm, and their families, may need to have a series of discussions over time to provide the necessary apology, explanation and plans for ongoing support. This may include financial support for immediate needs, additional treatment, psychological support or childcare. Considering wider compensation and the legal processes that may be involved are beyond the scope of this document. We will only note that early, carefully targeted financial support for immediate needs will support recovery, build trust and protect an organisation's reputation.

6.3. Support for staff and carers

Staff involved in an incident in which a patient is harmed, perhaps seriously, may also be profoundly affected by the events. They may feel guilty, distraught and distressed in the short term and in the longer term may come to doubt their own skills, clinical judgement and even whether they should continue in their profession. In some cases, more serious psychological conditions may develop such as post-traumatic stress and depression. We usually think of staff as being paid professionals but care, even quite complex care, is increasingly being provided in the home which means that family members will be particularly distraught if care they provide has caused harm to a loved one.

Responses of course vary widely, depending on the circumstances and the extent of any harm, and the true impact may only become fully apparent over time. Support from colleagues, family and friends will be sufficient in the short term but if more severe emotional reactions, such as anxiety or depression, persist then more formal and regular support from colleagues or a psychologist or counsellor may be valuable. In many healthcare organisations formal support for staff is still extremely limited. However, in some countries there is guidance for organisations on supporting staff and mitigating the impact of adverse events on the healthcare professionals involved (for example, PSIRF in the UK [40]; Resilience in Stressful Events (RISE) and Communication and Optimal Resolution (CANDOR) in the US [44-45]; The European Researchers' Network Working on Second Victims (ERNST) in Europe [46]).

The investigation team needs to be aware of the potential for shock, distress and disorientation in the aftermath of a serious incident. While it may be important to gather some immediate facts, deeper and more reflective discussions of the incident may be best delayed. Staff who have been seriously affected need to be identified, contacted on a regular basis and offered more formal support where required. A period of temporary leave may be beneficial to them and the patients currently under their care. Appropriate support should be offered, which might include psychological support, legal support or advice from occupational health. These actions will reassure the staff member concerned of the support

of their team and the wider organisation. Open lines of communication should be kept with this staff member especially if they have taken any leave of absence.

7. CONDUCTING THE REVIEW

In this section we summarise the process of conducting a review of a particular incident or patient journey. In the initial stages, the main task is simply to gain an understanding of the circumstances and events leading up to the incident, though some early understanding of problems and contributory factors may emerge. The review team will prepare the chronology of an incident using a triangulation of data collected through the investigation, carry out a preliminary analysis of patient records and eventually an on-site visit to the relevant clinical areas combined with some initial interviews. The review team may also hold group meetings involving all actors who had a role in the case who can provide an adequate evaluation of CMPs and contributory factors. From this gathering of information, they will develop a narrative of events, an assessment of the strengths and problems in the care delivered, and an understanding of contributory factors which will guide the development of recommendations for improvement.

For clarity, we have set this out as a series of steps, which implies that a review will be an orderly sequence of stages. This can be achieved for simpler reviews but, in reality, the process will be much more fluid and dynamic as the reviewer comes to understand the strengths and problems in the care process and the contributory factors. Late in the process, the reviewer might return for further observations, to interview another member of staff or seek clarifications from the family to build a fuller understanding.

7.1. The boundaries of the review

The first task is to establish the initial boundaries for the review, though these can be revised as the review evolves. This encompasses the timescales that will be assessed, what documents and other evidence should be reviewed and who and how many people should be interviewed.

Taking a step back to look at a complete pathway may provide valuable insights into the whole system of care and lead to a more rigorous and illuminating investigation of the incident in question. Consider, for example, a patient who arrives in a Maternity Unit in early labour. Monitoring reveals fetal distress, and an emergency Caesarean section is carried out.

The baby is born in extremely poor condition and is immediately transferred to the neonatal intensive care unit, where questions are raised about timely recognition of fetal distress. In this case, it would be easy to assume that the primary focus of any review should be the final stages of care before birth, whereas the potentially more significant issue might be that closer monitoring was needed in the ante-natal period.

In the end, the decision of how far to go back and where to draw the boundaries of investigation will be a pragmatic one. There is never a simple 'stop rule' [23]. A balance must be struck between the time taken and the value of the wider understanding that might be achieved and, most importantly, the extent to which that might impact on any recommendations made.

7.2. Engaging patients and families in the review

As we have indicated above, the patient and family should be offered help and support before inviting them to engage in the review process. The patient and family may, or may not, wish to be involved and their wishes need to be respected. Sometimes the patient and family will share a lot of information in a first meeting, at other times they may wish to reflect and wait until trust has been established.

While the patient and family always need to be informed about an investigation, they do not necessarily need to play a major role. Some hospital safety issues, such as those in the operating theatre or concerning equipment maintenance, may not benefit from a patient perspective. Others will require only a brief interview with the patient. In contrast, understanding safety issues at home or during transitions between healthcare settings will require a much deeper collaboration and conversation with the patient and family. Clear explanations should be given of the purpose of the review and the need to understand all the factors contributing to the event. The patient and family need to understand that people will be held accountable if appropriate but that the main purpose of the review is to improve safety and prevent similar events happening to other patients.

Timing of engagement is critical and needs to be discussed with the patient and family. The patient may be receiving further medical treatment and prefer to wait until it is completed. They may need time to adapt and reflect but be willing to talk at a later point in the review. They also need to be reassured that the process will be open, transparent and collaborative and that they will have a chance to review and comment on the report before it is finalised. The parameters of their involvement and expectations about the outcome need to be set out early on so that there are no misunderstandings on either side.

Arrangements also need to be made for continued contact during the review. Maintaining contact and checking whether further help is needed, is important even if there are no significant updates from the review. Finally, the patient and family need to be asked if they want to see the final report and, if they do, when this should happen and whether they would like to give their views in writing or in an additional meeting.

While we believe that the voice of the patient and family are critical to an understanding of many safety issues, we are fully aware that many barriers remain to their involvement. Lawyers in some countries may advise organisations not to engage with families who may seek financial support or compensation for what has occurred. Wider social and cultural influences, such as an excessive distrust or fear of authority, can be a major barrier. Each organisation can however take some steps, however small, towards greater openness and engagement.

7.3. Documents gathering and review

All facts, knowledge and physical items related to the incident should be collected as soon as possible. These may include:

- Formal incident report, usually recorded in the organisation's or regional/national health service information system.
- All medical records (e.g. nursing, medical, community, social workers, general practitioner, etc.).
- Physical artefacts such as medication bottles or intravenous tubing.
- Documentation and forms related to the incident (e.g. protocols and procedures).
- Immediate observations noted from patient and family.
- Written statements from staff.
- Information about relevant working conditions (e.g. staff rota, availability of equipment, etc.).

The purpose of collecting documents at this stage is to firstly secure information to ensure it is available for use during the review of the incident and later if the case has any organisational consequence (such as a claim, complaint, media attention or external inspection); secondly, to allow an accurate description of the incident, including the sequence of events leading up to the incident; thirdly, to provide initial direction to the investigation team; fourthly, to identify relevant policies and procedures; and finally to collate statements from persons involved in the incident early, so that memorable information is not lost.

Written statements from staff can be a useful data source as they can supplement the information from the medical record. Statements should be primarily used to provide factual accounts, with interviews being used to explore the events in more depth, particularly in respect to sensitive or confidential issues or when staff members are distressed. The statement needs to contain the individual's account of the sequence and timing of events, a clear account of their involvement in the case and an account of any difficulties they faced and problems (such as faulty equipment) that may not be detailed in the medical records. Staff need to be reassured that the purpose of the review is to learn, reflect and improve safety and that they are not involved in a disciplinary or legal process. It is extremely important to maintain confidentiality of investigation data.

Information from statements will be integrated with other data sources such as audit reports, quality initiatives, maintenance logs, medical notes and prescription charts to gain an understanding of the evolution of events. Diagrams of various kinds can be used to visualise the patient journey and describe the activities of different clinical teams and different levels of the system [47]. The use of a numbering system or referencing system may also assist in organising and tracking the information gathered.

7.4. Observation of the clinical area

Structured observation is an underused technique in understanding healthcare systems [48]. It has value both in the aftermath of a safety incident and also as a tool to explore good practice and high performance. Evidence of the value of structured observations after safety incidents has emerged from investigations of errors in the emergency department, on medical and intensive care ward rounds and during administration of medication [48].

During an incident investigation it is almost always helpful to spend time in the work environment to gain an understanding of everyday working, teamwork and atmosphere. Observation can be conducted at different levels of detail, depending on the available time and resources. Environmental characteristics, for instance, can be easily appraised in a quick walkaround to observe light and noise, access controls, management of clean and dirty materials and the layout of the ward or other areas. A more focussed observation may include observing the use of medical devices and software interfaces as well as communications between staff members during rounds, briefings or handover, and interaction with patients and caregivers when taking a history, making clinical decisions or organising their discharge. It can be useful to ask involved staff to re-enact how they would perform a task under usual circumstances. However, a longer period of observation will be needed to properly understand how staff manage work in real time and what adaptations may be necessary to cope with physical infrastructure, equipment availability and varying staffing levels.

Structured observation is not intuitive. Observers collecting and evaluating data from clinical areas require training in how to observe (and not intrude), how to report their findings and how to make sense of their observations in the context of an incident. The most important attributes of an observer are the ability to develop a trusting relationship with the staff in the relevant clinical area, to merge unobtrusively into the environment, to focus on the agreed objectives and remain impartial [48]. Observation can be undertaken to different degrees, depending on the available time and resources as well as on the observer's existing knowledge of a clinical context.

Researchers in disciplines such as ergonomics and experimental psychology have developed many tools and techniques to ensure systematic data collection and standardisation of analysis. For example, the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) model [49] provides an accessible guide observation teamwork, while the Kalamazoo [50] or Calgary-Cambridge [51] models are well

established models of clinical communication. Healthcare organisations should be encouraged to train and support skilled observers from diverse backgrounds to provide the depth of understanding of work systems and safety culture currently lacking in most safety incident reports.

7.5. Interviews and focus groups

While a considerable amount of information can be gleaned from written records and other sources, one of the best means of obtaining information from staff and other people involved in the incident is through interviews. The investigation team will need to determine who needs to be interviewed and arrange for these interviews to take place as soon as possible.

Taking part in interviews about a serious incident can be an immensely stressful for the staff involved, and sometimes for the interviewers too. The interview needs to be conducted sensitively and the interviewer needs to explain that the purpose of the interview is to understand and not to apportion blame. Those involved are engaged in a collaborative process to understand the problems, contributory factors and how the safety of care can be enhanced. For more severe cases, the presence of a senior patient safety manager can help to guarantee a safe space for an open and fair discussion about what went wrong, guarding against any temptation to simplify or search for a scape goat. Specific rules should be in place to provide psychological safety for the involved parties, with a just culture and systems-oriented approach [52].

Individual interviews offer more confidentiality and freedom to express personal perspective, but they are time consuming. Focus groups can help to integrate different perspectives and build a shared interpretation of the story. However, focus groups need to be facilitated well, with clear explanation of the nature of system analysis and the value of participation. Facilitators need to be sensitive to the different responses of people to incidents, some reacting defensively while others may blame themselves unduly. Facilitators also need to ensure that groups explore all potential avenues and contributory factors and discourage the group from quickly unifying round a single viewpoint. In either interviews or focus groups, the 'story' and the facts are just the first stage. There are several distinct phases to the interview, and it is generally most effective to move through these phases in order (Figure 3). Staff are encouraged to identify both the CMPs and the contributory factors which enriches the interview and investigation.

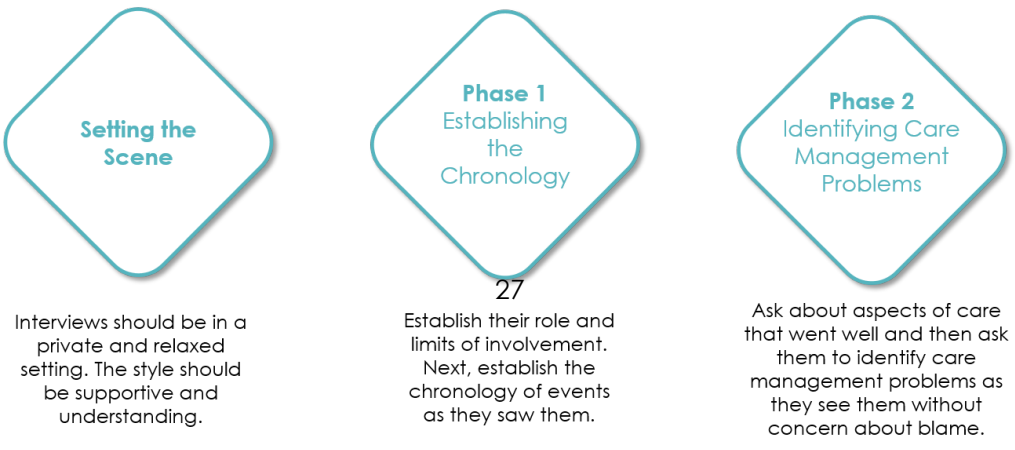

Figure 3. Process for conducting an interview

7.5.1. Setting the Scene

Interviews should be undertaken in private and, if possible, away from the immediate place of work and in a relaxed setting. It may be helpful to have two interviewers, so that one is always able to listen and record responses and subtle points that might otherwise be missed. Ask the member of staff if they would like a friend or colleague to be present. The style adopted should be supportive and understanding, not judgemental or confrontational. The interviewer needs to build and maintain trust with the interviewee throughout the review. Critical comments or attempts at cross-examination are most unhelpful as they lead to demoralisation and defensiveness.

7.5.2. Phase 1: Finding out what happened

First, establish the role of the member of staff in the events under discussion. Record the limits of their involvement. Next establish the chronology of events as the staff member saw them. Record these and compare this latest information with what is known of the overall sequence.

7.5.3. Phase 2: Identifying the CMPs

Ask the member of staff to summarise the aspects of care that went well, paying particular attention to times when staff were faced with challenging circumstances but managed to maintain a safe and good standard of care. Staff may also be able to recall actions that were taken which prevented more serious problems developing and protect the patient from more serious harm. Then, explain the concept of a CMP and provide an example. Ask the member of staff to identify the main CMPs as they see them, without concerning themselves about the reasons for the problems or whether anyone is to blame. The phrase "first facts then interpretation" captures the attitude and approach needed at this point.

Identify all important acts or omissions made by staff, or other breakdowns in the clinical process, which were (with hindsight) important points in the chain of events leading to any adverse outcome. Look for points in the sequence of events when care went outside acceptable limits, bearing in mind that there are always variations in how care is provided and that strict adherence to protocols and procedures is often simply not achievable. Where there are disagreements between accounts as to the course of events, these should be recorded.

7.5.4. Phase 3: Identifying the Contributory Factors

Go back and ask the interviewee specifically about each of the CMPs in turn, based on the framework (see Table 1). Suppose, for instance, the person identifies a failure in the routine observation of an acutely confused patient. The interview can prompt the staff member by asking about the relevance of patient factors, the clarity of the task, individual staff factors, and team factors and so on, and if necessary, pose specific questions, again following the general framework. For instance, was the ward particularly busy or short staffed?

7.5.5. Phase 4: Identifying the Strengths and Weaknesses of the Mitigation Process

Ask the clinicians taking care of the patient how care was adjusted to mitigate the consequences of the event, how the disclosure of the incident was managed and whether the family physician was informed. Ask also how the patient and family were supported and how the staff involved in the incident were supported. The goal here is to understand how the aftermath of the incident was managed, how the patient was cared for, how the family and staff were supported and to identify any further actions or support needed.

7.5.6. Closing the Interview

Ask the staff member if they have any other comments to make or questions to ask. They may have valuable suggestions about potential recommendations for safety improvements. A complete individual interview should take between 20-30 minutes depending on the degree of involvement but may take longer to allow the member of staff to explore their own role and express their feelings about what has happened as needed. A group interview usually takes between 1-2 hours, depending on the complexity of the incident and the depth of the investigation.

8. INTEGRATION AND ANALYSIS

Integrating documents, statements, interviews, observations and other material into a coherent narrative and analysis is always a challenging exercise. We present this process as a series of steps but, in reality, there may be several iterations and refinements of this process as understanding develops and a report is assembled. Developing an understanding of the events and writing the report will be a great deal easier if the essential features and structure of the London Protocol are kept in mind at every stage of data gathering and inquiry. The purpose is always to build the story, identify what went well and where there were problems and to move from there to identify the contributory factors.

8.1. Determining the Chronology

The first step in assembling the report is to establish a clear and reasonably detailed chronology of the events preceding the incident and the actions taken after it occurred. The chronology will be established from interviews, statements from people involved in the incident and a review of the medical records to identify what happened and when. The investigation team will need to ensure that this information is integrated and that any disagreements or discrepancies are clearly identified. There are several ways of doing this, including narrative description, timeline, time person grids and flow charts.

8.2. Identifying the CMPs and what went well

Having identified the sequence of events that led to the incident, the investigation team should now summarise the care that went well and identify the principal CMPs. Some will have emerged from interviews and records but may need to be discussed more widely. Once some of the key problems have been identified, it may also be useful to organise an additional meeting with people involved in the incident to reflect on the problems identified and identify anything missing from the preliminary assessment. The people involved in an incident are often able to identify what went well, and what went wrong and why, and can assist in the development of improvement strategies.

The review team need to clearly acknowledge aspects of care that went well while also being clear-sighted about the problems identified. The implicit comparison being made is between a reasonable standard of care and the care actually provided. The review team should not pedantically examine details of particular protocols but consider the care in a holistic manner and concentrate on significant problems in the care delivered. It is also important to understand that clinicians are often faced with decisions that must be made with highly imperfect information. Decisions that turn out to be wrong with hindsight may have seemed entirely reasonable at the time.

Ensure that all CMPs are specific problems, rather than more general observations on the quality of care. Noting 'poor communication' for instance is too vague to be useful and inappropriately judgemental, whereas 'surgeon not informed of patient's latex allergy' is a clear and neutral description of what occurred.

The analysis at this point should extend to actions taken after the incident to mitigate harm and care for people involved. For instance, the review needs to ascertain whether the incident has been disclosed to the patient and what has been done to support the patient and family. The review should also assess the support given to staff and whether, after a serious incident, the staff have been allowed a period to recover before they return to work.

8.3. Assessing defences and barriers

Defences and barriers were not emphasised in earlier versions of the London Protocol but are often relevant to a full understanding of an incident. We define defences and barriers as mechanisms to manage hazards, in contrast to contributory factors which have a broader influence on people and the work system. The reviewer should establish what defences and barriers were in place, the extent to which they prevented the incident or reduced its impact, and the reasons they either succeeded or failed to protect patients and staff. Defences and barriers can also have unintended adverse effects at times, such as preventing a corrective action.

When a defence fails or causes problems, then the defence itself can be questioned in terms of design and usability. For instance, the use of a protective glove during a dental procedure may negatively affect the process of care because the available gloves reduce touch sensitivity or increase the risk of infection transmission because they are not removed between patients. Improvement actions may then be targeted to more appropriate provision of gloves, re-training or supervision of their use. If a barrier has been effective in preventing a CMP resulting in an adverse event, such as a double-check before administering a transfusion, then this preventative strategy may be applied to other similar types of activity.

8.4. Identifying contributory factors

The next step is to use the contributory factors framework to discern the types of factors at play. The contributory factors framework guides the reviewer, or interviewer, through the many influences on patient care that may inform understanding of the events. For instance, patient factors, such as personality traits or language barriers, may significantly impact the communication between staff and the patient. The task's design, along with the availability and effectiveness of protocols and test results, can also shape the care process and affect the standard of care delivered. Equally as crucial are the individual staff factors, which refers to the knowledge, skills and experience of each staff member in the team. The team dynamics should then be considered (e.g. communication, support and engagement in supervision), as this will influence the way an individual member of staff behaves and

practises. While electronic information systems generally enhance safety, it is important to note that reliance on these systems can introduce novel risks (e.g. hardware or software failures, improper management of clinical content, breaches in data protection). It is imperative to consider the benefits and potential drawbacks of electronic systems in the pursuit of patient safety and quality of care.

The review team should make a practice of considering all categories of contributory factors in any significant investigation. It is easy to jump to the most obvious contributory factors and so limit the breadth and depth of the review. Working systematically through all the categories, which can be done quite quickly, will lead to a more thoughtful and comprehensive exploration of the safety issues revealed by the incident and can uncover unexpected issues.

8.5. Assessing the wider organisation and culture

The relationship between the incident and organisational, management and cultural factors is often harder to establish compared to patient factors, task-related variables, or team dynamics. Nonetheless, their significance should not be under-estimated and these wider issues should be discussed. Decisions and choices on strategy, recruitment and budget allocation may all have a bearing on the incident under review. It is also important to acknowledge that leaders and managers navigate a highly complex landscape, where top-level decisions invariably involve the delicate weighing of risks and benefits relating to multiple competing objectives.

Culture, in particular, is a strong determinant of safe or unsafe practice. A just culture refers to a system and philosophy that aims to create an environment where patient safety is a top priority while also promoting transparency, accountability, fairness and learning which is backed by a strong leadership commitment [53]. There has been extensive research and experience in healthcare and other industries stressing that safety can only be achieved in an environment where it is safe to speak up, both to prevent errors occurring and after mistakes have been made [54-55]. The review team may find it necessary to comment on the safety culture of the team or organisation.

8.6. Using the research literature

Major national or regional inquiries into safety issues make extensive use of the relevant research literature. Reports may be commissioned on specific clinical issues, such as surgical equipment or antimicrobial resistance, or on wider influences on the quality of care such as safety culture or the organisation of services. In contrast, local investigators seldom consult the wider literature, relying on their own experience and knowledge of the local context.

We suggest that consulting the research literature during an investigation should always be considered. A great deal of safety related research is now open access and easily accessible to anyone with an internet connection. Specialist sites, such as the Agency for

Healthcare Research and Quality (AHRQ) Patient Safety Network in the United States, provide an easy way of searching for authoritative reviews and reports on specific issues.

The research literature can save time and provide more focus to an investigation by addressing the following questions. First, how common are incidents of this kind? Are we dealing with a rare and unusual event, with unique contributory factors, or something commonplace with known causes? Second, what have other reviewers and researchers found to be the main causes of similar events? This may provide clues as to what to discuss in interviews and how to frame and interpret the findings. Third, and most importantly, the research literature will often provide guidance on what kind of interventions might be useful either for preventing future incidents or the more general enhancement of system safety. What has already been tried and found to be ineffective? What are the most promising approaches that should form the core of the recommendations for future improvements? If an intervention or good practice is identified and associated with a particular organisation, they may be contacted to share their knowledge and experience.

8.7. Drafting the report

Preparing a coherent and useful report after a safety incident can be challenging, especially if the events occurred across care or disciplinary boundaries, or if there was serious harm to the patient. The investigation of a serious safety incident can take a significant amount of staff time and the report writing process is a major part of the process. These documents form a lasting record of events which may be used for legal purposes (for example in coroner's hearings) and are almost always of immense importance to the patients and staff involved. A clearly written, well-argued report with effective recommendations can be a major safety contribution to an organisation, its patients and staff.

The London Protocol is designed to facilitate the writing of a report in that the steps of the investigation, and indeed the form of interviews and discussions, mirrors the essential features of the report. The team of risk managers who collaborated in the development of the first version of the London Protocol found that if they followed the approach systematically 'the report would write itself' in the sense that the material was already collated and organised in a conceptually grounded and consistent format. Investigators should collaborate in this endeavour with colleagues in the investigation team, subject matter experts and patients and their families (where they wish to be involved).

The language of the report needs to be clear, accessible and straightforward. Necessary technical terms should be explained or included in a glossary. The tone must be measured and respectful of everyone concerned. It is hard to specify a length for the report but a shorter report will have more impact and be more persuasive. As a rough guide, it should be possible to read and thoroughly understand the main report in 20-30 minutes, even for a very serious event.

The form of the report will vary depending on local requirements and the nature of the incident. However, we believe that there are certain key requirements of a strong and effective report (Box 1). Appendices can be added where it is necessary to provide supportive evidence and documentation. Necessary medical terms should be explained in footnotes or a glossary.

It can be helpful to use a template when writing such a report and we provide an example in Appendix 3. The template guides investigators in providing a clear and comprehensive account and supports quality assurance for governance teams overseeing investigations. Organisations are encouraged to adapt the document to local context and provide additional information for investigators as appropriate. Many healthcare organisations now collaborate with patient safety partners who can be helpful in ensuring reports are comprehensible, objective and sensitive to the experiences and emotions of those who have been affected by the events described.

Box 1. Key Requirements of a Strong and Effective Report

- A simple description of the incident or safety issue that has arisen and why the investigation is being carried out.
- The people involved in the review team, their professional backgrounds and roles in the review.
- The data sources that contributed to the report. Examples are patient record, protocols and policies, number of interviews, audits or other documents reviewed. Details should be given of the purpose, nature and extent of any observations made.
- A clear narrative of the evolution of the incident which provides a description of the incident and the role of various sources of information. This should include an account of the support given to patients, families and staff in the aftermath of the incident.
- Clear identification of high-quality aspects of care and the care management problems (CMPs) that also occurred in the patient journey.
- Contributory factors analysed using a systems-based approach. It may be helpful to include a table of contributory factors attributed to each of the categories described in the London Protocol along with an explanation of their relevance and importance in the incident.
- Where appropriate, a discussion of the role of wider organisational and cultural factors and any broader actions that might be taken to strengthen the overall approach to safety in future.
- The recommendations for improvement and how they link to the contributory factors. Explain how the team decided on these particular recommendations, how they were prioritised and where possible provide supporting evidence.

9. RECOMMENDATIONS AND IMPLEMENTATION

The development of proportionate and useful recommendations is the most difficult part of the review. We have already discussed the danger of multiple trivial investigations and argued that a smaller number of in-depth reviews will do much more to enhance safety. We believe similarly that it is also necessary to select and carefully prioritise recommendations and to consider the wider organisational context and the capacity of the organisation to implement them.

9.1. The nature and purpose of recommendations

A detailed review of a complex incident is likely to identify a number of problems in the process of care, each associated with a variety of contributory factors. The contributory factors are the primary targets for change, so there will be multiple possibilities for recommendations. Recommendations may encompass all eight levels, including patient focussed actions, staff focussed, task, team and so on. Further recommendations may address barriers and defences. Reports can also usefully note issues that have occurred repeatedly and been recognised in previous reports.

A single report can therefore generate many recommendations and a large healthcare organisation reviewing multiple incidents can be faced with implementing hundreds of recommendations in a single year. This scattergun approach will do little to enhance safety, and, in any case, it will be impossible to monitor the impact of all the proposed actions.

To achieve more focus, we need to consider the purpose of recommendations. The most obvious answer is that the recommendations and actions should prevent similar incidents. In some cases, changes to equipment or defences can achieve this objective. However, if an incident has multiple contributory factors, interacting in uncertain ways, it is naïve to think they can all be 'fixed' at the same time. Rather, we need to ask what the most important contributory factors were and, a slightly different question, what kind of changes to the wider system will most enhance safety?

9.2. Making and prioritising recommendations

As the investigation team begins the process of formulating recommendations, considering the robustness of interventions becomes pivotal, and substantiating this robustness with evidence adds considerable weight to the proposals made. For instance, measures like reminding teams to "be more careful," establishing rules and policies, and suggesting routine educational interventions tend to have less impact than more potent strategies such as forcing functions, fail-safes, automation, or standardisation. It may be helpful to follow a

structured approach to both prioritisation and assessment of evidence [see for example 56-57].

In risk management, a preventive action is stronger when it is employed to remove hazards or contributory factors within a working environment [58]. For instance, risk of falling may be reduced by adjusting the policy for blood pressure medications to reduce risk of falls caused by postural hypertension. Actions can also be taken to protect individuals or groups from a risk when the hazards cannot be removed. Protection from falls can be enhanced by providing accessible methods of patients calling for help when they need to move. Finally, there are actions taken to mitigate the adverse effects of an exposure to a given hazard. Mitigation of falls might come from lowering the height of beds to reduce harm should a fall occur.

While some recommendations will be locally focussed, making changes in a particular setting, others may address more substantial safety issues across an organisation. This will require a thematic analysis of many incidents together with a review of relevant literature and careful consultation with clinical teams and managers. Changes to fundamental clinical processes may carry major safety benefits, but need to be evaluated for feasibility, evidence of impact and unintended consequences. We should always be wary of making recommendations which add to staff workload or make processes more complex. Safety may also be enhanced by measures which simplify and standardise work, reducing staff workload and allowing more time for patient care.

The use of algorithms for decision making is very common, especially in fast paced clinical environments such as emergency medicine. The algorithm for resuscitation is an excellent example of how the ABC list of conditions (Airway, Breathing, Circulation) is an easy to remember guide that even a layperson can follow to assess a possible cardiovascular arrest and start the basic life support procedure. A standard operating procedure (SOP) can have practical and educational value for specific procedures. A checklist is another example of a form of decision support designed to guide teams on critical steps to prevent adverse outcomes and to comply with safety standards. When algorithms are integrated into information systems, the potential for decision support gets stronger and they are extremely helpful to simplify complex tasks. The rise of artificial intelligence and its application in healthcare today is very promising to further develop decision support systems and eventually replace human decisions in some activities [59]. At the same time, it presents potential new risks that should now be addressed in patient safety incident investigations.

The contributory factors framework, and frameworks such as SEIPS [31], also offer broad directions for making recommendations. Review teams can look back at their findings and consider the implications for staff skills and attitudes, quality of teamwork, the working conditions of staff and other factors and explore the potential for change at all levels of the contributory factors framework. Substantial organisational changes should not be made on

the basis of the findings of a single incident. Evidence that major change is required is more likely to come from aggregate analyses or a combination of incident analysis and analyses and monitoring of the relevant clinical environment.

The review team should explore any major recommendations with subject matter experts and those who will be affected if the recommendation is implemented (including patients, clinicians and managers). Conclusions drawn in this way, with the people who will be responsible for implementing the changes, are more likely to become embedded in practice and make a meaningful impact on safety. Gaining agreement and support from staff is particularly critical if major changes to work patterns are being proposed. Pragmatic factors must also be thoroughly assessed. To what extent can the recommendation be sustained over time? How seamlessly can it be integrated into existing workflows? How quantifiable is its impact? And how does its cost align with its anticipated benefits?

The primary objective is not to generate an overwhelming array of recommendations, but rather to pinpoint a select few with the highest potential to consistently enhance safety and diminish risks [60]. Once chosen, these recommendations need to be transformed into a well-structured action plan, which will then be communicated at the appropriate level, which could be local, institution-wide, or system level depending on the results of the analysis.

9.3. Developing and monitoring an action plan

The implementation and follow-up of an action plan are two of the most overlooked steps of an investigation. The ultimate aim of a systemic review of an incident is to implement and follow a preventative action plan, which relates to the contributory factors and includes the most relevant defences and safety barriers. Recommendations may be targeted at reducing or eliminating similar incidents or towards wider safety enhancements. Support for this is usually provided by the quality/safety department of the organisation. Consulting staff who will be involved in implementing action plans and seeking their views on what will be most effective is critical to both identifying actions that will enhance safety and implementing them successfully.

In order to give an action plan the best possible chance of success, it is vital to adequately describe each action and include the following:

- The most important contributory factors and actions to address them, as determined by the investigation team.
- An indication of how influential each action will be in enhancing safety by reducing the risk of particular hazards.
- A named person or team who are responsible for implementing the recommendations.
- The timeframe for implementation.
- Any resource requirements.

- A description of how the action will be monitored and how its impact will be evaluated.
- Evidence of completion, i.e. formal sign-off of actions as they are completed.
- An explicit date to evaluate the effectiveness of the entire action plan.

To improve the uptake and implementation of recommendations, they should be categorised as being under the control of an individual, a particular clinical team, a specified department of directorate so that the people from the correct management strata should be tasked with implementing recommendations relevant to their own area. This ensures ownership and appropriate implementation of recommendations, and also promotes a positive safety culture as people see positive actions coming from the accident investigation process.

When a risk management function is established at the board level, broader recommendations may be made about the design or improvement of elements of the healthcare system. These might include the purchasing of medical devices, recruitment and training of personnel, organisation of hospitals and primary care facilities, design and layout of facilities. Often these wider changes will be preceded by more focussed pilot interventions and evaluation. For instance, a clinical team might develop an enhanced checklist of process, which management would integrate into the electronic medical record and, if successful after evaluation, would be recommended to policy makers for wider dissemination.

10. BUILDING A SAFE SYSTEM: INCIDENT ANALYSIS IN CONTEXT

Incident analysis provides, as we have argued, an invaluable window on the system and a strong foundation for safety monitoring and improvement. However, incident analysis is only effective as part of a continual process of learning and reflection that characterises safe, high quality healthcare systems. Improvements in patient safety also need to be guided by the scientific literature and the promotion of evidence-based practice to ensure and maintain safety. Recommendations for improvement interventions drawn from incident analyses are therefore like seeds. They need to be planted in fertile ground, to be watered, and to be sustained and protected. The environment needed for improvement actions to be sustained and embedded include the following:

- Leadership commitment at both executive and board levels (actively and visibly engaged).
- A just culture which supports openness, safety and learning.
- A culture that values patient and family engagement and learning from the patient experience.
- Investment in safety programmes as a necessary core function.

- Safety committees and specialists integrated across the organisation and healthcare system to form a community of practice.
- Continuous monitoring and surveillance supported by accessible information technology.
- Continual assessment of outcomes and refining of processes to provide a feedback cycle for learning and improvement.
- Collaboration and learning networks to support education and training in safety and quality.

A learning health organisation is one that systematically integrates data from a safety incident with other evidence, such as from routine audits or patient experience surveys, and applies the lessons from all of the evidence to improve practice. Organisations need to monitor the major sources of harm and risk to patients on an ongoing basis. They should also monitor new evidence for patient safety solutions and remove obsolete solutions. A system needs to be in place to identify new recommendations on a rolling basis, analyse and assess their use for a given institution and action a plan to implement them if they have potential. A process for proactive risk assessment should be in place, particularly for new clinical activities, new equipment, or changes to moving wards or facilities.

The principles and practices outlined above are of course only some of the elements that underpin a safe, high quality healthcare organisation. We set them out simply to emphasise that incident reporting, analysis and actions are only one component of a safety management system. The purpose of incident analysis is to contribute to wider learning and safety enhancement. Incident analysis can be a powerful tool but will only achieve its full potential within a mature, developed approach to safety across the whole organisation.

10.1. A final reflection

Healthcare is always changing and evolving, bringing new benefits to patients and new risks. The review and analysis of incidents or single patient journeys is a source of constant learning about all parts of the healthcare system including the patient's home. Incident analysis is also a powerful means of teaching patient safety in a manner which is rooted in the realities of patient experience and clinical practice. The London Protocol has been used for over 20 years in many countries and many different settings. We hope that this new version will be a valuable guide and support for all those seeking to make healthcare safer in the future.

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APPENDIX 1

List of abbreviations and acronyms

CRU – Clinical Risk Unit

ALARM – Association of Litigation and Risk Management

CMP – Care Management Problem

HFE – Human Factors Ergonomics

SEIPS – Systems Engineering Initiative for Patient Safety

PSIRF – Patient Safety Incident Response Framework

RISE – Resilience in Stressful Events

CANDOR – Communication and Optimal Resolution

ERNST – The European Researchers' Network Working on Second Victims

TeamSTEPPS - Team Strategies and Tools to Enhance Performance and Patient Safety

AHRQ – Agency for Healthcare Research and Quality

SOP – Standard Operating Procedure

APPENDIX 2

Glossary

Term	Meaning
Access Controls	Access controls ensure that only authorised users can use resources within a system.
Active Failures	Unsafe acts, errors and other safety critical actions or omissions.
Adverse Event	Harm to a patient caused by healthcare rather than their illness.

Artificial Intelligence	Technology which can carry out tasks ordinarily done by people. In healthcare this may be administrative tasks, creation of reports, interpretation of images or clinical decision-making.
Audit	A systematic review of a practice, process or performance to establish how well it meets predetermined criteria. An audit cycle ideally includes identifying problems, developing solutions, making changes and then reviewing the whole operation or service again.
Automation	Making processes automatic with the use of machines or technology (i.e. without human input).
Barrier	Methods and devices intended to prevent exposure to hazards.
Care Management Problem	Significant problems that arise in the process of care.
Clinical Judgement	Healthcare professionals making decisions based on their assessment of patient's condition, evidence-based knowledge and critical thinking.
Clinical Pathway	The route that a patient follows from the first contact with a healthcare professional through referral to the completion of treatment.
Confidentiality	Protecting personal information shared by respecting it and keeping it private.
Contributory Factors	Factors that influence the performance of a healthcare system and the quality and safety of care provided to a patient.
Decision Support System	Provide knowledge and person-specific information, intelligently filtered or presented at appropriate times. Tools include computerised alerts and reminders.
Defence	Methods or devices designed to protect workers and patients to an exposure to hazard that is necessary to perform a clinical activity or task.
Electronic Medical Records	The systematised collection of electronically stored health information for a patient, which can be shared across different health care settings.
Forcing Functions/Fail-Safes	Mechanisms designed into the workflow to prevent a specific error or reduce its impact.
Focus Group	A small group of individuals have a group interview or discussion on a particular topic, guided by a facilitator.

Grey Literature	Literature that has not been formally published in sources such as books or journal articles.
Handover	Transfer of patient care responsibilities from one healthcare provider to another (e.g. at shift changes of patient transfers).
Human Factors and Ergonomics	The study of how humans interact with systems, equipment and environments to optimise safety and performance.
Information Technology	The application of information technology to the collection, storage, processing, retrieval, and communication of information relevant to patient care within a health care system.
Just Culture	A system and philosophy that aims to create an environment where patient safety has a high priority while also promoting transparency, accountability, fairness and learning.
Latent Conditions	Features of the organisation or system that influence those working on the frontline and which may increase the likelihood of active failures.
Medical Devices	All products, except medicines, used in healthcare to diagnose, prevent, monitor or treat illness or disability.
Just Culture	A culture which emphasises focusing on systemic issues rather than individual blame when understanding errors with the objective that people learn from these mistakes.
Patient and Public Involvement	Patients and citizens, and organisations representing their interests, are engaged in research, practice and improvement of healthcare.
Protocol	A plan or set of steps that defines how something will be done.
Quality Improvement	The use of methods and tools to continuously improve quality of care and outcomes for patients.
Resilience	The ability of a system exposed to hazards to resist, absorb, accommodate to and recover from the effects of a hazard in a timely and efficient manner, including through the preservation and restoration of its essential basic structures and functions.
Resilience engineering	Field of research which draws attention to the role of adaptation and flexibility in both everyday work and in the response to pressures, crises and emergencies.
Root Cause Analysis	Methods used to identify root causes from the investigation and analysis of incidents.

Safety Culture	The attitudes, values, perceptions and behaviours that provide the foundation of safe, high-quality care
Risk Management	The identification of hazards (things that could cause harm) and risks (the likelihood of a hazard causing harm) and the assessment and mitigation of risks.
Stakeholder	Any individual or group that has an interest or stake in the healthcare system, which include patients, healthcare providers, policy makers and regulators.
Standard	An established, accepted and evidence-based technical specification or basis for comparison.
Standard Operating Procedure	A document which describes and guides clinical procedures to ensure that they are carried out correctly and consistently.
Structured Observation	An individual or team of researchers ''live'' alongside a given workforce, monitoring healthcare domains to collect data on errors, adverse events, near misses, team performance, and organisational culture.
System-Orientated Approach	A way of thinking that focuses on understanding and analysing complex systems as a whole, rather than just their individual components.
Thematic Analysis	A method for identifying, analysing and reporting patterns (themes) within data.
Workarounds	Actions that staff take to deliver care and accomplish the work assigned to them, despite those actions' deviating from protocol and policy.

APPENDIX 3

Report Template

When writing the report, the following template can guide the process and act as an aide memoire to ensure all aspects of the care process are considered. The use of plain language in the report is vital in ensuring that key messages are easy to understand and share. The text under each of the section headings is designed to be deleted on completion of the report.

Title Page

Succinct description of the nature of the incident or safety issue, date of occurrence and details of investigation team.

Contents page

Full list of contents including appendices with page numbers

Summary of investigation and findings

This section should provide a summary of the key findings of the investigation and recommendations included in the main report. The summary should be no more than one page of text and include the following:

Brief Incident Description

Include the time, date and how the incident was detected.

Involvement and Support of the Patient and/or Relatives

Summarise the way in which patients and family were informed about the investigation and what involvement they had in the process.

Strengths of care provided and care management problems

Briefly summarise the key findings from the investigation and the care provided indicating both good practice and problems identified.

Contributory Factors

Describe key contributory factors using the London Protocol 2024 framework of eight categories.

Recommendations

Summarise the principal recommendations but leave the explanation for their design to the section below.

Purpose and Conduct of the Investigation

The aim of this section is to briefly summarise how the investigation or review was conducted, who was involved, and the nature of the information collected.

Overall aim

Briefly summarise the main aims of the investigation and any particular requests made by the patient and family, staff or wider organisation. It may also be helpful to outline any broad principles that guided the investigation, such as the use of a systems-based framework or a just culture approach.

Boundaries of the investigation

Specify the boundaries of the investigation, i.e. be clear what is included in the process and what is not. Describe the timescales, documents and other evidence required and the number of people to be interviewed.

Data Sources and Methods Used

Examples include:

- Gathering information – including discussion with patients and family members/ carers and staff involved either directly or because they have an important role in the clinical area e.g. a leadership role.
- The information gathered from the patient's notes and other relevant documentation e.g. emails with relevant staff members.
- Any methods used to provide additional insights, e.g. the drawing of a process map, use of tabletop simulation or structured observations in the workplace.
- Structured observations of clinical settings.

Investigation Team

Include names and roles here-check how patients and staff wish to be described as some may prefer anonymity. An acknowledgement and expression of thanks to those involved in the investigation should be included here.

Main Report

This is the largest section of the report and the most detailed. Provide a full account of what happened, the chronology of events, good practice and care management problems, contributory factors and recommendations. It is important to explain how the data collected supports the conclusions and why certain recommendations were prioritised.

Incident Description and Consequences

Provide an objective description of what happened in plain language. Include the date, the healthcare specialty/environments, the people involved, and the incident type. The type will vary e.g. a safety incident that directly impacted a patient, a near miss, an administrative problem or an environmental hazard (e.g. fire risk).

Detection of Incident

This may be through organisational reporting systems, through a governance meeting or at a handover meeting. Specify how quickly the incident was discovered (this may be immediate, e.g. in the case of a problem during a procedure, or after some time, e.g. in the case of missed diagnoses from a retrospective review of radiological investigations).

Background and Context

Describe the healthcare context in which the safety incident occurred. Provide an overview of the clinical activity in a department, how this has changed over time, any infrastructure problems or workforce planning issues and any external influencing factors such as changes in the healthcare system or government policy.

Chronology of Events

This can be displayed as a table (as below), a flow chart a time-person grid or simply in narrative form (see the London Protocol 2024 for further details).

Date & Time	Event

Involvement and Support of the Patient, Family and Carers

This will vary according to the incident type and must always be done in a sensitive and supportive way which respects the wishes of the patient and family. Describe the engagement and contribution of the patient, family and carers. Record how the patient and their family/carers were kept informed in accordance with their wishes.

Involvement and Support Provided for Staff Involved

This will also vary according to the incident and staff may be profoundly affected by what has happened. Describe who was involved in both the incident and the investigation, what support was available and how effective it was.

Investigation Findings: Good Practice and Care Management Problems

Summarise the care provided to the patient during their healthcare journey before the incident occurred. This may be across several healthcare settings, including the home. Identify and describe the periods of good practice and clearly identify the care management problems.

Investigation Findings: Contributory Factors

Using the eight categories described in the London Protocol 2024, describe the key contributory factors (they may not all have a role). It is likely that both barriers and facilitators to safe practice will be found, and it is important to highlight both. It may be helpful to set this out as a table.

Recommendations and Action Plan

The section should explain what recommendations were considered, how these linked to the contributory factors and which recommendations were prioritised for inclusion in the final report.

Recommendations

The recommendations will usually relate to the main contributory factors. However, wider recommendations may also be made to reflect additional problems identified in the course of examining the particular incident, such as staff being anxious about speaking up about safety problems.

Recommendations may be best displayed in a table and should include:

- How the recommendations link to contributory factors.
- How the team (including the patient and their family/carers where appropriate) decided on the recommendations and how they were prioritised.
- Any supporting evidence underpinning the recommendations.

Action Plan

Describe the arrangements for further action following the recommendations specifying who is responsible and the time taken for any action to be completed.

Arrangements for Wider Dissemination and Shared Learning

Describe how the investigation team intend to share learning. In many cases the findings will only need to be communicated locally. However, the findings of some investigations may need to be communicated to the wider organisation or beyond.

Arrangements for shared learning may include:

- Organisational communication systems including meetings, emails, safety bulletins.
- Use in teaching and staff induction processes (with appropriate permission) across the organisation, including podcasts, videos, design of simulation scenarios.
- Communication to national safety agencies.
- Publication in professional or academic journals.

Action, Monitoring and Follow-up

This section should describe what follow up actions are needed by individuals, committees or organisations to implement and monitor recommendations made or other actions. Recommendations and actions may result from a single incident, but it may sometimes be preferable to consider them within a wider assessment of a safety issue based on thematic analysis of incidents and other data.

The follow-up actions should be summarised:

- An outline of how recommendations will be implemented.
- The individual, committee or organisation responsible for each action.
- How the success of the recommendations will be monitored.
- The timing of follow-up.

It can be useful to include mitigations which might already have been put in place by the organisation/clinical team whilst the investigation is ongoing.

Distribution List

List everyone who will receive a copy of the report – there will usually be guidance in the organisation on who should be included.

References

Include any academic references, national or local guidelines or reports, websites etc.

Appendices

These might include photographs, diagrams, or documents relevant to the incident. They should be clearly labelled with an explanation of how they contribute to the investigation.