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Systems analysis of clinical incidents: development of a new edition of the London Protocol

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ABSTRACT

The investigation of incidents and accidents, together with subsequent reflection and action, is an essential component of safety management in every safety-critical industry, including healthcare. A number of formal methods of incident analysis were developed in the early days of risk management and patient safety, including the London Protocol which was published in 2004. In this paper, we describe the development of a new edition of the London Protocol. We explain the need for a revised and expanded version of the London Protocol, addressing both the changes in healthcare in the last two decades and what has been learnt from the experience of incident analysis across the world. We describe a systematic process of development of the new edition drawing on the findings of a narrative review of incident analysis methods. The principal changes in the new edition are as follows: increased emphasis and guidance on the engagement of patients and families as partners in the investigation; giving more attention to the support of patients, families and staff in the aftermath of an incident; emphasising the value of a small number of in-depth analyses combined with thematic reviews of wider problems; including proposals and guidance for the examination of much longer time periods; emphasising the need to highlight good care as well as problems; adding guidance on direct observation of the work environment; providing a more structured and wide-ranging approach to recommendations and including more guidance on how to write safety incident reports. Finally, we offer some proposals to place research on incident analysis on a firmer foundation and make suggestions for the practice and implementation of incident investigation within safety management systems.

INTRODUCTION

The investigation of incidents and accidents, together with subsequent reflection and action, is an essential component of safety management in every safety-critical industry including healthcare. The WHO guidance on incident reporting and learning systems recognises the importance of a systematic approach and methodology for the analysis of incidents, referring to systems analysis but not defining a particular approach.[1] The essential idea is that much can be learnt about the wider healthcare system from the close examination of a single incident or patient journey. A structured approach to analysis is required to gain comprehensive insights into the features of the system that either enhance or degrade safety.[2 3]

A number of formal methods of incident analysis were developed in the early days of risk management and patient safety. For example, in the USA, the Joint Commission developed a method of root cause analysis,[4] for which the US Veterans Health Agency National Center for Patient Safety has a series of tools and advisory documents.[5] In the UK, the Clinical Risk Unit, University College London (CRU), with the Association of Litigation and Risk Management developed a protocol, which later evolved into the original London Protocol.[6 7] The original London Protocol was described as a 'systems analysis' because the process of analysis aims to provide a 'window on the system' in the sense of using reflection on an incident or patient journey to examine the strengths and vulnerabilities of the wider healthcare system.[8] In common with other systems models, the London Protocol endeavours to assess contributory factors and potential improvements across all levels of the system from front-line to regulatory and policy.

The London Protocol has been widely employed in the analysis of incidents and safety events in hospital care, community and primary care and mental health.[9–13] The original London Protocol has been

Box 1 Examples of international use of the London Protocol

Australia. The Clinical Excellence Commission in Australia recently released a London Protocol toolkit to guide investigation in New South Wales.[55]
France. The Haute Autorité de Santé regulatory and improvement authority has recommended the Association for Litigation and Risk Management (ALARM) protocol for use since 2010.[56]
Italy. In Tuscany, the protocol has been extensively taught in the Centre for Clinical Risk Management and Patient Safety in both academic and professional contexts and has been one of the fundamental pillars of safety management and incident analysis over the last 20 years.[57]
Spain. The Ministry of Health recommends the use of the London Protocol to conduct in-depth analyses of adverse events, especially those that cause serious harm.[58]
Switzerland. The Swiss Patient Safety Foundation has taught and recommended the London Protocol for two decades.[59]
WHO. The London Protocol has been included in the WHO's Patient Safety Curriculum.[60]

translated into many languages. These include Arabic, Danish, Finnish, French, German, Italian, Japanese, Norwegian and Spanish. The protocol has been recommended for use in incident analyses in many different countries and across a range of healthcare services (Box 1).

The aim of this paper is to introduce and share the new edition of the London Protocol (online supplemental file 1). We explain the need for a new edition, describe the development process and outline the new elements of the revised protocol. We also suggest some directions for future research and consider implications for policy and practice.

THE NEED FOR A NEW EDITION OF THE LONDON PROTOCOL

The original London Protocol drew on ideas from safety science[14 15] but was grounded from the beginning in the realities of clinical practice and the narratives of patients and clinicians. Studies of accidents in healthcare and other industries had 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.[15–18] The London Protocol provided a structured, yet flexible, approach to investigation and analysis of clinical incidents. We recognise that many organisations prefer the term 'incident review' rather than investigation; the London Protocol can be used for either review or investigation.

The primary reason for developing a new edition of the London Protocol is that healthcare itself has changed.[19] People are living longer, often with multiple comorbidities that are managed over long time scales across multiple healthcare settings. The first edition was principally focused on hospital care, gave comparatively little attention to longer patient journeys or the engagement of patients and families in the investigation. Analyses of incidents now need to pay much more attention to safety issues that arise outside the hospital, at home, in the community and in primary care settings. Rather than thinking only in terms of the prevention of specific incidents, it is necessary to consider the balance of benefit, harm and risks of healthcare interventions and interactions over long time periods.[20] This in turn highlights the need to think more carefully about the nature of clinical work in different contexts, which varies from highly standardised to dynamic, flexible and complex according to patient need, the clinical processes, working environment and availability of resources.[20 21]

Engaging patients and families in understanding incidents and the patient journey has become ever more important, and their involvement is valuable for two main reasons. First, patients and families are critical contributors to many incident analyses as they are the only people who understand the patient journey across multiple settings including the home.[22 23] They therefore have knowledge, and indeed expertise, not available elsewhere. Second, the opportunity to contribute to the investigation may, if done well, support recovery and healing and maintain trust in healthcare staff and organisations.[24]

A NARRATIVE REVIEW OF STUDIES USING INCIDENT ANALYSIS METHODS

To support the development of the new edition, we conducted a narrative review to identify studies of the methods of incident analysis between the years 1990 and 2024. A full account of the review is provided in online supplemental file 2. We followed the approach described by Arksey and O'Malley and Levac *et al*.[25 26] We addressed the following questions: (1) What are people's experiences of using the London Protocol or similar incident investigation methods? (2) What learning has been reported from the use of the London Protocol or similar incident investigation methods? (3) What have we learnt about the validity of the London Protocol or similar incident investigation methods through their use?

Our inclusion criteria specified that research papers should be empirical studies set in any healthcare or community health setting. The core focus must be clearly relevant to the process of incident analysis and contribute to one or more of the research questions. The study design must use an incident analysis method to investigate an incident or group of similar incidents shortly after they occur (rather than identify system problems years after the event). Incidents are investigated individually even if findings are aggregated later.

The search, limited to English language publications, identified 20 studies that met our inclusion criteria. Studies were carried out in the UK (n=6), the USA (n=5), Brazil (n=2) and single studies from Australia, India, Iran, Malta, Saudi Arabia, Switzerland and Uganda. The most commonly used method for incident review was 'root cause analysis' (n=12), followed by the London Protocol (n=5), then equal use of the Critical Incident Technique, AcciMap and Human Factors Analysis and Classification System (HFACS; n=2 each). One study included Work Domain Analysis and another incorporated Systems Theoretic Accident Modelling and Processes (STAMP) analysis.

The majority of studies (n=15) described the findings of an incident, providing little or no critique of the method employed. Only two of these studies interviewed patients as part of the investigation process, and only three studies mentioned disclosure or apology to the patient and family concerning the incident. There were many recommendations for change but almost no prioritisation or weighting of importance for these recommendations.

We identified only five studies of the process of analysis itself, which variously examined the usability, strengths and limitations of one or more methods. No studies used an experimental format or made direct comparisons between methods. Comparisons were drawn between approaches from the experience of participants in the process and the reflections of the authors of the studies. Root cause approaches were considered to be simple and accessible but lacking an appreciation of wider system influences. STAMP, AcciMap, HFACS and the London Protocol gave much more weight to system influences and the interactions between factors but required significant expertise and understanding of human factors for effective application.[27–30]

From the limited data available, the more comprehensive and theory-driven frameworks, such as HFACS, developed by the US Navy, appear to have higher validity and a greater capacity to develop recommendations.[27] Users of the London Protocol reported that it is easily adaptable and flexible while providing a structure to enable thorough and time-efficient investigations.[9 31–34] However, all of these methods require some degree of training and expertise in human factors and patient safety.[35] In contrast, the various approaches described in the research literature as 'root cause analysis' tend to be quicker and simpler but correspondingly more limited in their conclusions.

The findings of our narrative review, and the experience of many of the authors, suggest that the generation of recommendations is a critical and neglected issue. Recommendations need to have some justification in the findings of the analysis, ideally to have an evidence base and some reasonable prospect of being put into practice. We also need to consider whether it is sensible to make recommendations on the basis of a single incident, or whether we first need to aggregate findings and integrate with other data to produce a more carefully prioritised longer term implementation plan. Finally, unless reports are clearly written and well structured, the chance of effective safety improvements is remote.[36]

Many commentaries also suggest that many of the analyses that are conducted are of poor quality and that they do not lead to effective actions or improvements.[2 37 38] Organisations are often under pressure to rapidly produce a large number of mandated investigation reports, which means that the analyses can degenerate into a bureaucratic process leading to formulaic recommendations that are not clearly related to the contributory factors identified.[3 39] Where recommendations are made, they are often weak, fail to address substantial underlying problems, are not supported by evidence and are unlikely to result in sustained improvements in safety.[1 40 41]

THE DEVELOPMENT OF THE NEW EDITION OF THE LONDON PROTOCOL

The new edition of the London Protocol was developed over a period of almost 2 years by the two previous authors and four further authors, each of whom had considerable practical experience of conducting incident analyses in the context of wider organisational safety and quality programmes. The development process followed the following stages:

- *Stage 1:* A core working group was formed by CV to drive the project, supported by the involvement of a wider international advisory expert group. A series of meetings were set up among the core group members to discuss the project, their experience with the previous version and what changes or updates would be beneficial to the new release.
- *Stage 2:* A project plan was made setting out additional material to be written by members of the core group. We formed a wider international advisory group of patient representatives, clinicians, healthcare leaders and patient safety researchers who agreed to critically review the new edition of the London Protocol and to contribute to the present paper.
- *Stage 3:* A narrative review, described above, was conducted to learn from studies which had examined methods of incident analysis (online supplemental file 2). Alongside this review of the academic literature, we conducted a wider search of national service guidance documents and other grey literature to help inform this paper and the protocol itself. We shared the findings of the search and review with the international advisory group who provided comments which were incorporated in the final review.
- *Stage 4:* The core author group prepared additional material for specific sections of the new edition of the London Protocol. The lead author integrated these to produce a full working draft. The core authors then

Box 2 Principal changes in the new edition of the London protocol

More attention is given to both the physical and psychological impact on the patients, families and staff involved in an incident before engaging them in the investigation process.
There is increased emphasis and guidance on the engagement of patients and families as partners early in the investigation, mindful that the degree and nature of the engagement will vary according to the wishes of the patient.
We have suggested that healthcare organisations be more proportionate and strategic in choosing which incidents and safety issues to investigate and should also conduct thematic analyses across multiple incidents.
The new edition provides more explicit suggestions for the examination of much longer time periods and emphasises the need to highlight good care as well as problems.
We have added guidance on the importance of direct observation of the work environment to understand the everyday experience of processes and procedures, the adaptations required, communication and culture.
We have also outlined a much more structured and wide-ranging approach to recommendations and emphasised the need for careful prioritisation and integration into wider organisational learning and improvement programmes.
We have provided more guidance on how to write safety incident reports as a means to planning and mobilising safety improvements.

successively reviewed, critiqued and further developed the core document in an iterative process.

- *Stage 5:* A draft of the updated London Protocol was then circulated to the international advisory group for review and comment, and a final version prepared.
- *Stage 6:* Preparations were made for the wider dissemination of the updated London Protocol with international organisations and conferences, and the translation of the document into other languages to increase its accessibility.

We provide a brief summary of the specific changes between the original and new editions of the London Protocol in Box 2.

FUTURE RESEARCH ON INCIDENT ANALYSIS

Incident analysis is a critical part of safety management, but this activity needs to be studied systematically in healthcare to understand how it can contribute most meaningfully to safety improvement.[42] This question needs to be addressed in both high- and low-resource settings, particularly as focused analysis is a potentially fruitful and cost-effective means of understanding system safety in low-resource settings.[43 44] We suggest some directions for research to support more focused and constructive approaches to incident analysis.

Terminology and assumptions

There is a need for much greater clarity on terminology and on the assumptions and theoretical models underlying methods of investigation.[41] For instance, the term 'root cause analysis' is used to cover a wider range of approaches with different underlying assumptions. We cannot meaningfully compare different approaches to investigation and analysis without clearly defining and describing the underlying models, conceptual framework, information collected and process of analysis.

Involvement of patients and families in investigations

Studies should examine the best approaches to involving patients and families, how their perspectives and contributions enrich the understanding of events, and the nature of the recommendations made.[45] It is particularly important to understand in what circumstances involvement in an investigation is healing and restorative for families and when it might add to their distress.[46]

Assessment of investigation quality and outcomes

We need to develop formal methods of evaluating the quality of both investigations and recommendations and how this affects later actions and improvements. Studies could also examine the extent to which investigators agree or disagree on the interpretation of events and the recommendations made. Developing measures of the quality of investigations would provide a basis for assessing the competencies of investigators and evaluating training programmes.

The development of recommendations and prioritisation of interventions

An urgent task for research is to develop and evaluate methods of deriving recommendations from contributory factors and other findings. This should include the use of evidence from safety sciences, ergonomics and human factors to provide an explicit strategy for prioritising recommendations and a realistic approach to implementation. More research is also needed on the relative strength, impact and unforeseen consequences of recommendations resulting from incident analyses in practice.[40] Many organisations struggle to complete thematic or aggregate investigations and yet these are most likely to result in focused, strategic recommendations and long-term safety improvements.[47–49]

Finally, in order to support research and evaluation more generally, we need to encourage the publication of both individual and thematic analyses of incidents where the findings have implications beyond the local setting. Even where sharing is actively encouraged, many healthcare organisations fail to participate through fears of legal action or other reasons.[50] There are some organisations in different countries

Box 3 Examples of open publications of incident reviews across countries

In the UK, the Health Services Safety Investigations Body supports the open publication of the findings from all national investigations.[61]
In France, the Haute Autorité de Santé releases a series of short publications on prominent safety topics that are informed by a review of adverse events declared to the regional health agency by healthcare organisations.[62]
In Switzerland, the Swiss Patient Safety Foundation releases 'Quick Alerts', which are informed by reviews of incidents reported on its central database and available scientific evidence.[63]
In Norway, the Norwegian Health Investigation Board (Ukom) conducts independent multilevel and multidisciplinary investigations of serious adverse events and concerns involving Norwegian healthcare services, set up to promote system-wide learning and patient safety.[64]
In the USA, the federally listed Patient Safety Organizations are required to submit incident reports to the national database which are then shared widely. The Pennsylvania Patient Safety Authority publishes 'safety alerts' based on learning from incident reports on their website.[65]
In Japan, a national reporting and learning system funded by the government and run by the Japan Council for Quality Health Care regularly publishes reports which are generated through a collection and analysis of incidents reported from medical institutions across the country.[66]
In Italy, a maternal mortality surveillance system, including incident reporting and confidential enquiries along with a retrospective analysis of administrative data sources, emerged as the best option for case ascertainment and for promoting avoidable maternal deaths.[67]

that publish incident analysis findings in order to share learning, but this needs to be supported more widely (Box 3).

IMPLICATIONS FOR POLICY AND PRACTICE

When conducted thoughtfully, incident analysis facilitates learning, supports recovery for all involved, enhances safety and supports the development of a proactive safety culture.[9 12 28 29] The review of incidents makes important contributions to learning in clinical settings.[51 52] The WHO has emphasised the value of incident reporting and analysis as part of a wider learning healthcare system with ongoing reflection, learning, feedback and actions to improve safety.[1] This approach needs to be fostered at policy level, promoting incident analysis as an approach to learning rather than a regulatory instrument.

National policy documents may provide a valuable framework and guidance to healthcare organisations.

Box 4 Actions for healthcare organisations

Establish the process of involving, or at least consulting, patients and families as a routine part of safety investigations. This should include guidance on the sharing of findings with patients and families.[23]
Conduct fewer, deeper and more thoughtful investigations and multidisciplinary analyses rather than many routine and repetitive reports. The findings and recommendations should be integrated within local, regional/national and international programmes for patient safety.[1 22]
Provide training and mentorship in reviews of incidents and the patient journey, based on safety science and combined with relevant clinical expertise.[2 3]
Give much more attention to the art of report writing and the development of appropriate recommendations.
Emphasise that developing recommendations from the analysis of a single incident should be undertaken cautiously.[36 40]
Conduct aggregated and thematic reviews of recurring similar adverse events to identify overarching areas of concern and learning.[53]
Support the publication and sharing of individual or thematic incident reviews if they have implications for wider learning and system safety.

For example, the new Patient Safety Incident Response Framework (PSIRF) is an overarching framework for the National Health Service (NHS) organisations in England which provides guidance on system-based approaches to safety incident analysis.[53] PSIRF provides standards and templates for investigations, but was not intended to provide detailed guidance on how to undertake safety investigations. The London Protocol complements PSIRF and similar frameworks by providing step-by-step guidance on how to undertake an investigation at each stage, giving detailed advice on how to use a system-based approach to analyse contributory factors and describing how to write a coherent report, as well as how to co-design and deliver a meaningful plan for improvement. The recognition of one or more approaches to systems analysis of patient safety incidents should be encouraged at the national and international level to develop expertise and a coordinated national approach.

Healthcare organisations too can take a number of steps to increase the value, efficiency and impact of incident investigation and analysis. We provide a number of suggestions in Box 4, drawn from national and international experience and from frameworks such as PSIRF.[53] The most important development required, however, at both organisational and policy levels, is the training of those conducting incident analyses so that tools and methods are used effectively in a thorough and professional manner.[54] Simply designating someone to be a 'patient safety officer' is burdensome

for that individual and will do little to enhance safety. In the experience of many of the authors, those undertaking this role often have little training in human factors and patient safety. Without a solid grounding in the use of these tools and procedures, the resulting analyses lack depth, produce weak recommendations and miss key opportunities for improvement.

FINAL REFLECTIONS

Incident analysis is a potentially valuable and efficient means of understanding and enhancing safety. We should, however, avoid the naïve view that reporting and analysis of incidents should be the dominant activity in a safety management system. A full system safety engineering approach embraces other methods of hazard analysis and a variety of approaches to designing safe systems and assuring safe operations.[45] Incident analysis can only achieve its full potential alongside these other activities within a mature, developed approach to safety across the whole organisation.

We have highlighted the need for more research on incident analysis. In spite of vast investment in reporting systems, little has been done over the past 20 years to assess the validity, effectiveness and sustainability of different methods of investigation and analysis. Much could be done to assess the value of different approaches, how effective recommendations can be generated, and the role incident analysis should play in an integrated safety and quality management system.

Healthcare is always changing and evolving, bringing new benefits to patients and new risks. The analysis of incidents or single patient journeys is a source of constant learning about the healthcare system. The London Protocol has been used for over 20 years in many countries and many different settings. We hope that this latest version will be a valuable guide and resource for all those seeking to make healthcare safer in the future.

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