SYSTEMS ANALYSIS OF CLINICAL INCIDENTS

THE LONDON PROTOCOL

Sally Taylor-Adams & Charles Vincent

Clinical Safety Research Unit
Imperial College London
Department of Surgical Oncology and Technology
10th Floor QEQM Building
St Mary's Hospital
Praed Street
London
W2 1NY
Email: c.vincent@imperial.ac.uk

Contributors

Principal Authors

Sally Taylor-Adams, PhD – is Assistant Director of Patient Safety (Midland and East Region) at the National Patient Safety Agency, UK (NPSA)

Charles Vincent, PhD – is Director of the Clinical Safety Research Unit and the Smith and Nephew Foundation Professor of Clinical Safety Research at Imperial College, London.

Other Contributors

Stephen Rogers, FRCGP, University College London
Maria Woloshynowych, PhD, Imperial College London

ALARM Research Group
David Hewett
Jane Chapman
Sue Prior
Pam Strange
Ann Tizzard

Mental Health Research Group
Alison Prizeman
Yvonne Connolly
Mohamed Sheikh
Ann Rozier
Valli Agbolegbe

Primary Care Research Group
Kathy Caley
Louise Worswick,
Janet Cree
Greg Cairns
Andrew Harris
Juliet Swanwick
Kim Allen
Sarah Raymond
Amee Fairburns
Pauline Grace

CONTENTS

Figures and Tables

1 INTRODUCTION

The London Protocol is the revised and updated version of our original 'Protocol for the Investigation and Analysis of Clinical Incidents'[1]. The protocol outlined a process of incident investigation and analysis developed in a research context, which was adapted for practical use by risk managers and others trained in incident investigation. This approach has now been refined and developed in the light of experience and research into incident investigation both within and outside healthcare.

The purpose of the protocol is to ensure a comprehensive and thoughtful investigation and analysis of an incident, going beyond the more usual identification of fault and blame. A structured process of reflection is generally more successful than either casual brainstorming or the suspiciously quick assessments of 'experts'. The approach described does not supplant clinical expertise or deny the importance of the reflections of individual clinicians on an incident. Rather the aim is to utilise clinical experience and expertise to the fullest extent. The approach we describe assists the reflective investigation process because:

- While it is sometimes straightforward to identify a particular action or omission as the immediate cause of an incident, closer analysis usually reveals a series of events leading up to adverse outcome. The identification of an obvious departure from good practice is usually only the first step of an investigation.
- A structured and systematic approach means that the ground to be covered in any investigation is, to a significant extent, already mapped out. This guide can help to ensure a comprehensive investigation and facilitate the production of formal reports when needed.
- If a consistent approach to investigation is used, members of staff who are interviewed will find the process less threatening than traditional unstructured approaches.
- The methods used are designed to promote a greater climate of openness and to move away from finger pointing and the routine assignation of blame.

1.1 Changes to the Second Edition

The first edition of the protocol was primarily aimed at the acute medical sector. The present edition can be applied to all areas of healthcare including the acute sector, mental health, ambulances and primary care. We have found the basic method and concepts to be remarkably robust when tested in these different contexts.

Those familiar with the first edition will find that the basic process is unchanged, though there is more emphasis on following through with recommendations and action. We have endeavoured to simplify both the structure and the language of the protocol where possible. We have abandoned the absolute distinction between 'specific' and 'general' contributory factors as unworkable, although the importance of identifying contributory factors that are of wider significance remains. Finally, we have removed the forms used for recording data in this edition, to allow teams and individuals more flexibility when producing case summaries. However, we have

attempted to summarise cases in a standard manner, using a template which we have found straightforward and helpful.

1.2 Is this approach a Root Cause Analysis?

The term 'root cause analysis' originates from industry, where a group of tools are used to identify root causes from the investigation and analysis of incidents. To us the term root cause analysis, while widespread, is misleading in a number of 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 leading up to the eventual incident. The investigation team needs to identify which of these contributory factors have the greatest impact on the incident and, more importantly still, which factors have the greatest potential for causing future incidents[2].

A more important and fundamental objection to the term root cause analysis relates to the very purpose of the investigation. Surely the purpose is obvious? To find out what happened and what caused it? We believe that this is not the most penetrating perspective. 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 a way station in the analysis. The real purpose is to use the incident to reflect on what it reveals about the gaps and inadequacies in the healthcare system. This proactive, forward-looking approach is more strongly emphasised in this second edition. Because of this orientation we have called our approach a `systems analysis', by which we simply mean a broad examination of all aspects of the healthcare system in question. We emphasise that this includes the people involved throughout the system (from management to those working at the sharp-end), and how they communicate, interact, work as a team, and work together to create a safe organisation.

1.3 Different ways of using the protocol

The original protocol was designed at a time when investigations were generally carried out by individual risk managers. It was therefore 'investigator led', in that the description and format assumed that one or two individuals would assemble and collate the information, carry out interviews and then report back to the board or the clinical team to consider what action should be taken. However, many organisations now prefer to assemble a team of individuals with different skills and backgrounds. Serious incidents are certainly likely to require a team of people using both interviews and other documents as their sources of information. This version of the protocol can be used by either individuals or teams.

This document describes a full investigation, but we wish to emphasise that much quicker and simpler investigations can also be carried out 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 instance it can be used 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 introducing systems thinking. While reading about systems thinking is helpful, taking an incident apart in a structured manner brings the approach alive for a clinical team.

1.4 Context of the guide's use

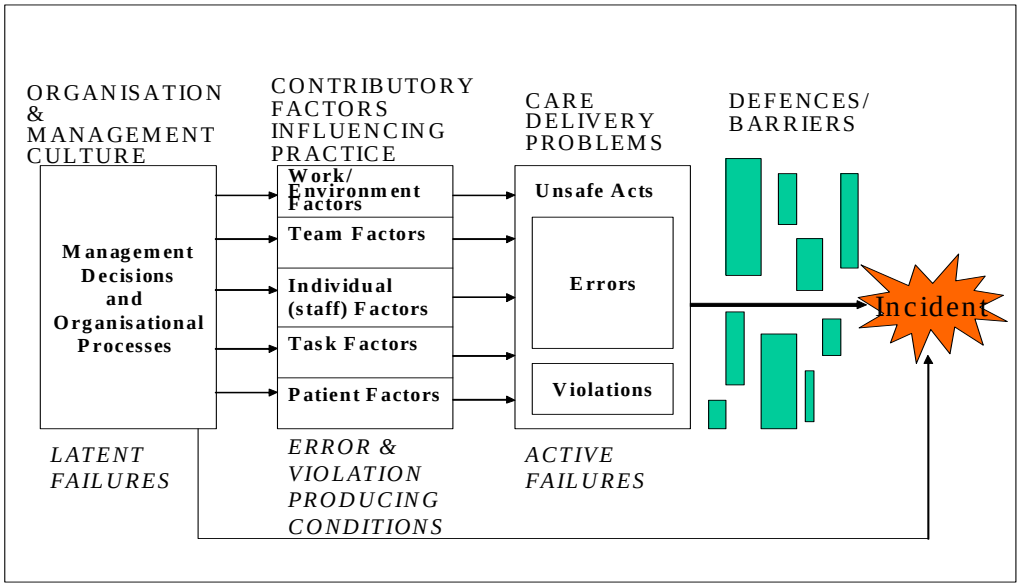
This protocol covers the whole process of investigation, analysis and recommendations for action. In practice, this process will be set, and perhaps constrained, by the local context and conditions of use. We have deliberately not discussed the broader context of clinical governance or other arrangements for assuring the quality of care. We intend that this document should be a stand alone module set within other procedures for the reporting of incidents, reporting to the team or board and so on. We have not been prescriptive about how incidents should be identified or which should be investigated, as this will vary depending on local circumstances and national priorities, which will vary from country to country. Whatever the local circumstances however, we believe that decisions and actions following inquiries would be more effective if grounded in a thorough and systematic investigation and analysis, irrespective of the nature of the incident and the complexity of the issues stemming from it.

We emphasise that this approach needs, as far as possible, to be separated from any disciplinary or other procedures used for dealing with persistent poor performance by individuals. All too often when something goes wrong in healthcare those in charge will over emphasise the contribution of one or two individuals and pin the blame for the incident on them. While blame may be appropriate in some circumstances, it should not be the starting point. Immediate blame will put paid to any chance of a serious and thoughtful investigation. Effective risk reduction means taking account of all the factors and changing the environment as well as dealing with personal errors and omissions. This cannot take place in a culture where disciplinary considerations are always put first. Accident investigation can only be fully effective within an open and fair culture.

2 RESEARCH FOUNDATIONS

The theory underlying the protocol and its application is based on research in settings outside healthcare. In the aviation, oil and nuclear industries for instance, the formal investigation of incidents is a well established procedure. Researchers and safety specialists have developed a variety of methods of analysis, some of which have been adapted for use in medical contexts though few have been explored in depth[3-5]. These and other analyses have illustrated the complexity of the chain of events that may lead to an adverse outcome[6-10].

Figure 1: Adapted Organisational Accident Causation Model



2.1 Organisational Accident Causation Model

Studies of accidents in industry, transport and military spheres have 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. Our approach is based on James Reason's model of organisational accidents (Figure 1). In this model fallible decisions at the higher echelons of the management structure are transmitted down departmental pathways to the workplace, creating the task and environmental conditions can promote unsafe acts of various kinds. Defences and barriers are designed to protect against hazards and to mitigate the consequences of equipment and human failure. These may take the form of physical barriers (e.g. fence), natural barriers (e.g. distance), human actions (e.g. checking) and administrative controls (e.g. training). In the analysis of an incident each of these elements is considered in detail, starting with the unsafe acts and failed defences and working back to the organisational processes. The first step in any analysis is to identify active failures - unsafe acts or omissions committed by those at the `sharp end' of the system (pilots, air-traffic controllers, anaesthetists, surgeons, nurses, etc) whose actions can have immediate adverse consequences. The investigator then considers the conditions in which errors

occur and the wider organisational context, which are known as contributory factors. These conditions include such factors as 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. These are the factors which influence staff performance, and which may precipitate errors and affect patient outcomes.

We have extended Reason's model and adapted it for use in a healthcare setting, classifying the error producing conditions and organisational factors in a single broad framework of factors affecting clinical practice[11], see Table 1.

Table 1: Framework of Contributory Factors Influencing Clinical Practice

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

2.2 Framework of Contributory Factors

At the top of the framework are patient factors. In any clinical situation the patient's clinical condition will have the most direct influence on practice and outcome. Other patient factors such as personality, language and psychological problems may also be important as they can influence communication with staff. The design of the task, the availability and utility of protocols and test results may influence the care process and affect the quality of care. Individual factors include the knowledge, skills and experience of each member of staff, which will obviously affect their clinical practice. Each staff member is part of a team within the inpatient or community unit, and part of

the wider organisation of the hospital or mental health service. The way an individual practises, and their impact on the patient, is constrained and influenced by other members of the team and the way they communicate, support and supervise each other. All members of the team are influenced by the working environment, both the physical environment, (light, space, noise) and factors which affect staff morale and ability to work effectively. The team is influenced in turn 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, continuing education, training and supervision and the availability of equipment and supplies. The organisation itself is affected by the institutional context, including financial constraints, external regulatory bodies and the broader economic and political climate.

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 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. 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 whole range of possible influences to be considered and can therefore be used to guide the investigation and analysis of an incident.

2.3 How the concepts translate into practice

Active failures in health care come in various forms. They may be slips, such as picking up the wrong syringe, lapses of judgement, forgetting to carry out a procedure or, rarely, deliberate departures from safe operating practices, procedures or standards. In our work we have substituted the more general term `care delivery problems' (CDP) for unsafe acts. This is because we have found, in healthcare that this more neutral terminology is helpful and because a problem often extends over some time and is not easily described as a specific unsafe act. For instance a failure of monitoring of a patient may extend over hours or days.

Having identified the CDP, the investigator then considers the conditions in which errors occur and the wider organisational context, which are known as contributory factors. These are the factors which influence staff performance, and which may precipitate errors and affect patient outcomes.

3 ESSENTIAL CONCEPTS

Reason's model and our framework provide the conceptual foundations of the investigation and analysis process. However, before incident investigation can be undertaken, key essential concepts need to be defined.

3.1 Care Delivery Problems (CDPs)

CDPs are problems that arise in the process of care, usually actions or omissions by members of staff. Several CDPs may be involved in one incident. They have two essential features:

- Care deviated beyond safe limits of practice
- The deviation had at least a potential direct or indirect effect on the eventual adverse outcome for the patient, member of staff or general public.

Examples of CDPs are:

- Failure to monitor, observe or act
- Incorrect (with hindsight) decision
- Not seeking help when necessary

3.2 Clinical Context

Salient clinical events and the clinical condition of the patient at the time of the CDP (e.g. bleeding heavily, blood pressure falling). The essential information required to understand the clinical context of the CDP.

3.3 Contributory Factors

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

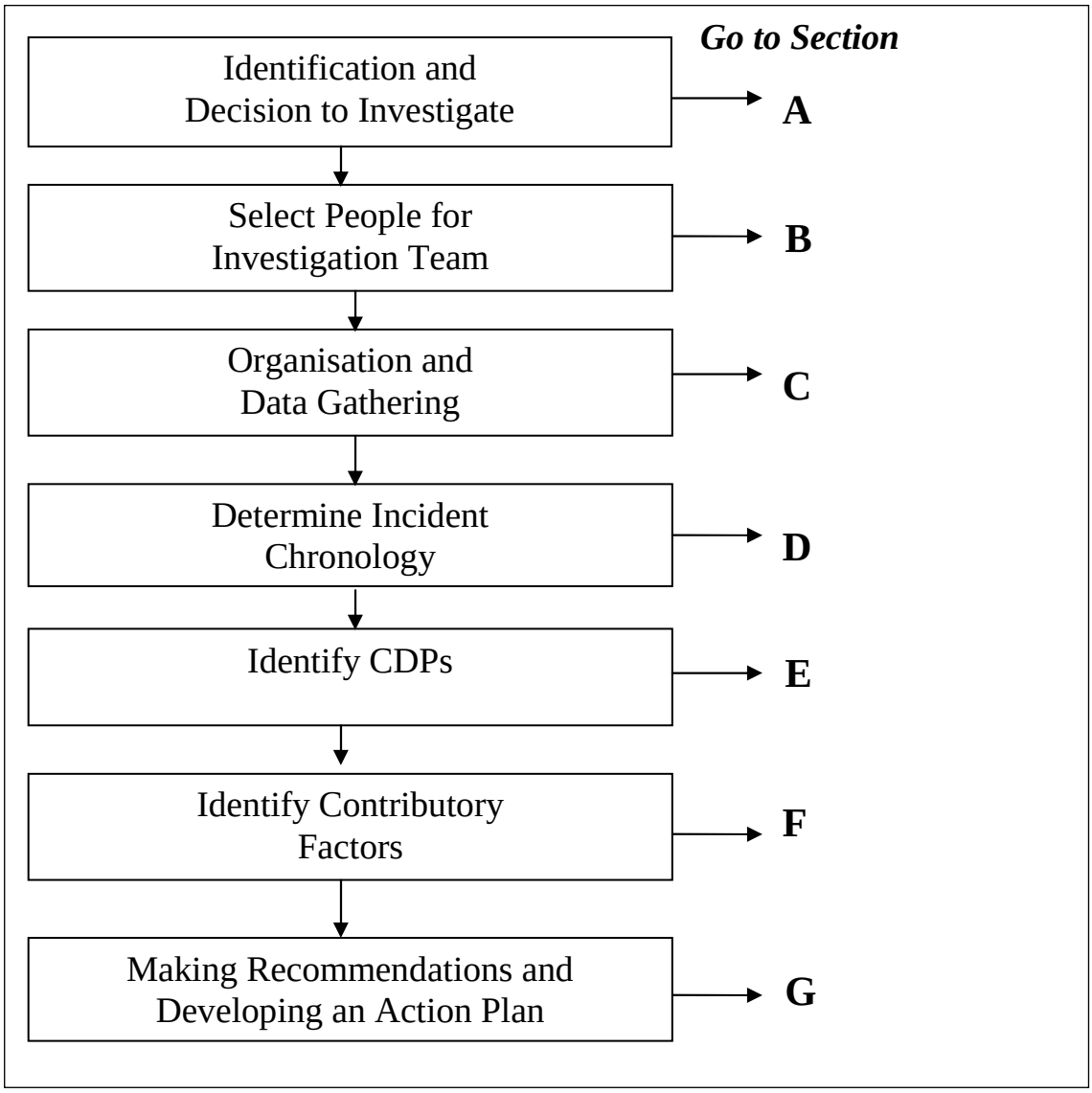
- Patient factors might include that fact that the patient was very distressed or unable to understand instructions.
- Task and technology factors might include poor equipment design or the absence of protocols
- Individual factors may include lack of knowledge or experience of particular staff
- Team factors might include poor communication between staff
- Work environment factors might include an unusually high workload or inadequate staffing.

4 ACCIDENT INVESTIGATION & ANALYSIS PROCESS FLOWCHART

The accident investigation and analysis process flowchart (see figure 2) provides a overview of all the stages of the incident investigation and analysis process. The flowchart shows the objectives of each stage and how each objective is achieved.

The basic process of incident investigation and analysis is relatively standardised, and will be followed whether investigating a minor incident or a very serious adverse outcome; the process is essentially the same where an individual or a large team are responsible for the investigation. However, the team can choose whether to quickly run through the main issues in a short meeting or to carry out a full, detailed investigation over several weeks, making full use of all associated techniques to comprehensively examine the chronology, CDPs and contributory factors. The decision on the time taken will depend on the seriousness of the incident, potential for learning and the resources available.

Figure 2 – Accident Investigation and Analysis Process Flowchart



SECTION A: Identification and Decision to Investigate

There are a number of reasons for considering that an incident warrants detailed investigation. Broadly speaking the incident will either be investigated because of its seriousness for the patient and family, for the staff or the organisation, or because of its potential for learning about the functioning of the department or organisation. Many incidents will not have serious repercussions, but nevertheless have great potential for learning.

Serious incidents will always, by definition be reportable on incident forms. What marks out a serious incident as requiring detailed investigation is the nature and scale of the consequences. Some incidents require immediate initial investigation, whilst others can wait a few hours (for example until the following morning). The precise action to be taken is a decision for the most senior person on duty at the time. In deciding whether and when to investigate an incident account will need to be taken of what has actually happened, the patient's clinical status and emotional state, how the staff who were involved are feeling, and external pressures such as media interest. Each organisation needs to clearly specify the circumstances that initiate an incident investigation.

The reported incident may not reveal the final outcome for the patient. For instance a patient may assault another patient (and this maybe reported), but the subsequent fracture may not be diagnosed for three days and the final outcome for the injured patient may not be known for some months. The investigator needs to take a pragmatic look at the problem and decide what timescale is to be the focus of immediate attention, while allowing that a more elaborate and complex story may unfold. Analysis should initially focus on the time period where problems were most apparent.

SECTION B. Select the People for the Investigation Team

Appropriate experts are essential for investigation of serious incidents. Ideally, an investigation team should consist of 3 or 4 people facilitated by the investigation leader. It is important to identify team members with multiple skills and the time to commit to the process. For very serious incidents, the investigation team may need to be given leave from 'their usual duties' to focus on incident investigation and analysis.

An ideal team to investigate a serious incident might include:

- Incident investigation and analysis experts.
- External expert(s) view (this can be a non-executive board member with no specific medical knowledge).
- Senior management expertise (e.g. medical director, director of nursing, chief executive).
- Senior clinical expertise (medical director or senior consultant).
- It is also valuable to have someone with knows the relevant unit or department well, though they should not have been directly involved in the incident.

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. They would lead the process, but would call on relevant clinical and other expertise as necessary.

SECTION C. Organisation and Data Gathering

Documenting the Incident

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

- All medical records (e.g. nursing, medical, community, social workers, general practitioner, etc).
- Documentation and forms related to the incident (e.g. protocols and procedures).
- Immediate statements and observations.
- Conduct interviews with those involved in the incident.
- Physical evidence (e.g. ward layout schematics, etc).
- Secure equipment involved in incident (e.g. shower rail used to commit suicide).
- Information about relevant conditions affecting the event (e.g. staff rota, availability of trained staff, etc).

Statements can be a useful data source, but only if guidance is provided on the type of information needed, otherwise they tend to be just summaries of the medical records. 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 notes. Some issues, such as not being properly supported or supervised, may be best discussed in interviews. Information from statements will be integrated with other data sources such as audit reports, quality initiatives, maintenance logs, medical notes, prescription charts, etc to get a complete picture of the factors likely to have impacted the incident

Information is best collected as soon after the incident has occurred. The use of a numbering system or referencing system may assist in referring to and tracking information easily. The following is an example of a referencing system and tracking form, but it can be adapted to suit organisational need:

Ref Nos	Information/Data Source	Date requested	Date received	Stored?
Case 25/02	*Copy of incident form*	*24/10/01*	*24/10/01*	*Cabinet A RM Office*
Case 25/02	*Nursing notes*	*24/10/01*	*25/10/01*	*Cabinet A RM Office*
Case 25/02	*Medical notes*	*24/10/01*	*26/10/01*	*Cabinet A RM Office*
Case 25/02	*Shower curtain*	*24/10/01*	*26/10/01*	*Cupboard G Legal Office*

The purpose for collecting information at this stage is to:

- Secure information to ensure it is available for use during the investigation and later if the case was to go to court.
- Allows an accurate description of the incident, including the sequence of events leading up to the incident.
- Organisation of the information.
- Provides initial direction to the investigation team.
- Identifies relevant policies and procedures.

Conducting Interviews

One of the best means of obtaining information from staff and other persons involved regarding 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 early as possible. Interviews lie at the heart of effective investigation.

While a considerable amount of information can be gleaned from written records and other sources interviews with those involved are the most important route to identifying the range of background contributory factors to an incident. Interviews are especially powerful when they systematically explore these factors and allow the member of staff to effectively collaborate in the process of investigation and analysis. In the interview sequence that follows the story and `the facts' are just the first stage. The staff member is then encouraged to identify both the CDPs and the contributory factors which greatly enriches both the interview and investigation. It would also be possible, and usually desirable, to interview the patient and the family, though it is vital to consider whether the interview may distress them unduly and cause additional trauma. They should of course be informed of the results of the inquiry, but again care should be taken that the timing is right and that they have the necessary support.

Setting the scene

Interviews should be undertaken in private and, if at all possible, away from the immediate place of work 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 may 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 judgmental or confrontational. Where it becomes clear that a professional shortcoming has occurred, this should be allowed to emerge naturally from the conversation, and should not be extracted by cross examination. Errors and mistakes in clinical care are rarely wilful and most staff are genuinely disturbed when it becomes clear that something they have done has contributed to an incident. The staff member should be allowed, through supportive discussion, to start to come to terms with what has happened. Adverse comment and judgement at this stage is most unhelpful as it leads to demoralisation and defensiveness.

There are several distinct phases to the interview and it is generally most effective to move through these phases in order.

Establishing the Chronology
First, establish the role of the member of staff in the incident as a whole. Record the limits of their involvement. Next establish the chronology of events as the staff member saw them. Record these. Compare this new information with what is known of the overall sequence.

Identifying the Care Delivery Problems
In the second phase, first explain the concept of a Care Delivery Problem and possibly provide an example of a CDP. Then ask the member of staff to identify the main Care Delivery Problems as they see them, without concerning themselves about whether or not anyone is or is not to blame for any of them. Identify all important acts or omissions made by staff, or other breakdowns in the clinical process, that were (with hindsight) important points in the chain of events leading to the adverse outcome. These are the CDPs. Clinicians, whether those involved or those advising, will have an implicit knowledge of the clinical process as it should ideally occur, allowing for acceptable levels of variation in clinical practice. Where there are disagreements between accounts as to the course of events these should be recorded.

If clinical practice is specified by guidelines, protocols or pathways, it may be possible to specify major departures with some precision. Generally however there will be a degree of acceptable variation in practice. Look for points in the sequence of events when care went outside acceptable limits.

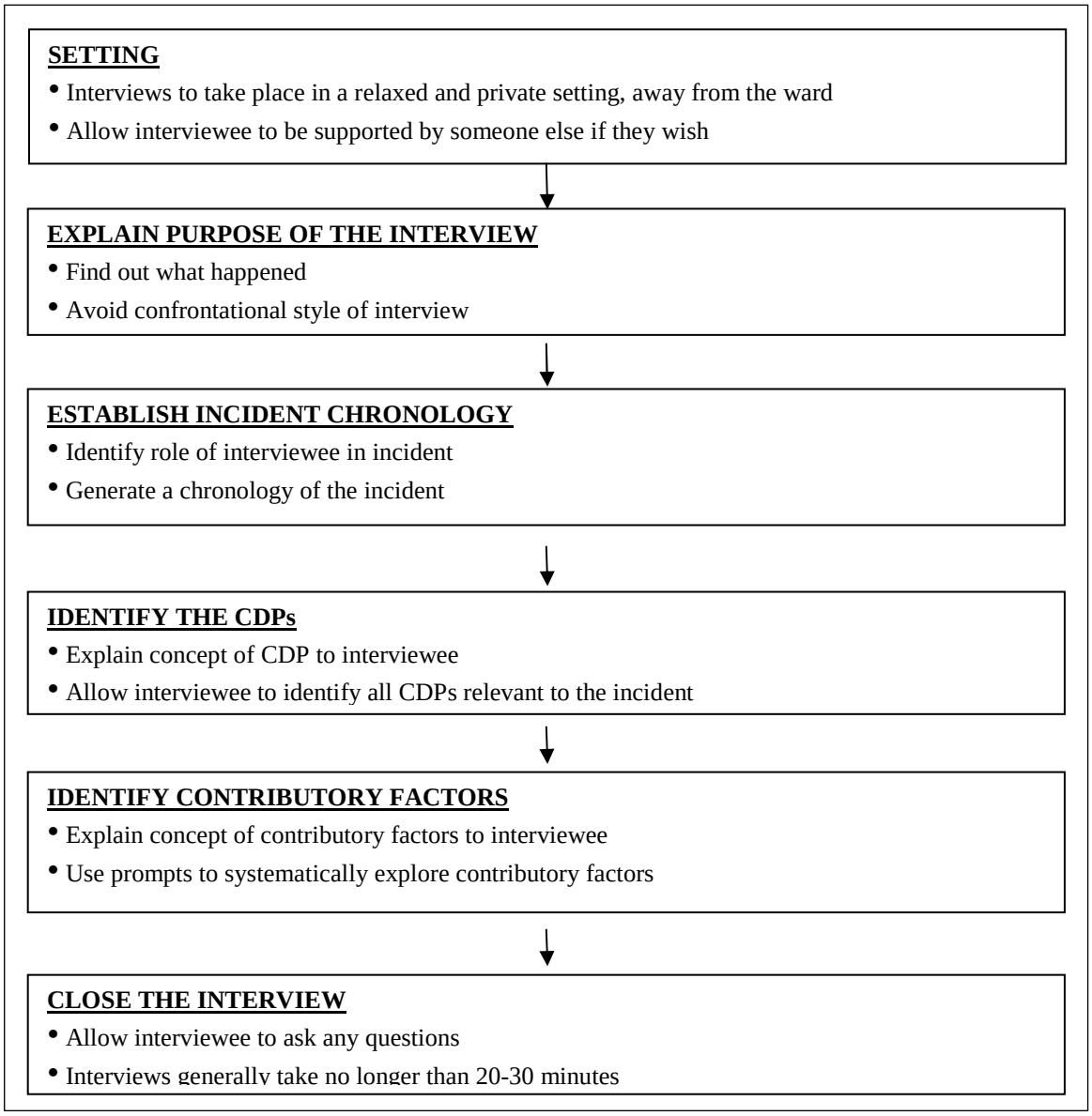
Identifying the Contributory Factors
In the third phase, go back and ask specifically about each of the CDPs separately. Ask questions related to each CDP based on the framework, see table 1. Suppose, for instance, the person identifies a failure in the routine observation of a disturbed patient. The interview can prompt the staff member by asking in turn about the relevance of patient factors, the clarity of the task, individual staff factors, team factors and so on. If necessary pose specific questions, again following the general framework. Was the ward particularly busy or short staffed? Were the staff involved sufficiently trained and experienced?

Where a member of staff identifies a clearly important contributory factor be sure to ask a follow-up question. For example, was this factor specific to this occasion or would you regard this as a more general problem on the unit?

Closing the Interview
A complete interview should take between twenty and thirty minutes depending on the degree of involvement. However they may be much longer if the member of staff is distressed and needs to talk to explore their own role, assess their own responsibility and express their feelings about what has happened. Finally ask the staff member if they have any other comments to make or questions to ask.

Figure 3 provides a summary of the interview process and the information to be obtained during the interview.

Figure 3: Summary of the Protocol's Interview Process



Conducting interviews is resource intensive and it may be that this approach to data gathering can either only be applied to very serious incidents or where only the key persons involved in an incident can be interviewed. If interviews cannot be used fully the protocol investigation process can still be followed, by relying more on other data sources.

SECTION D. Determine the Chronology of the Incident

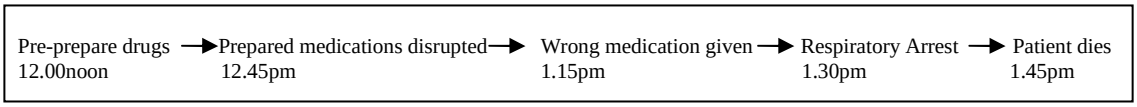
The next step in the investigation is to establish a clear and reasonably detailed chronology of the incident. Interviews, statements from persons involved in the incident, and a review of the medical records identify what happened and when. The investigation team will need to ensure that this information is integrated and that any disagreements or discrepancies are clearly identified. When a group is working together it is useful to map the chronology on a wall chart, to which CDPs and

contributory factors can be added once the chronology is complete. There are various ways of doing this.

- **Narrative of chronology** – both interviews and medical records will generate a narrative of events, which allows one to show how events unfolded and the roles and difficulties faced by those involved. A narrative chronology is always necessary in any final report of an incident

> **Monday 17th March 2001, 9.15am**
> Patient A absconded from secure unit. Police informed that Patient A was missing
> **Monday 17th March 2001, 10.25am**
> Patient A had been found by the Police. He was located at home, covered in blood as he had killed his common-law wife.

- **Timeline** – tracks the incident and allows the investigators to discover any parts of the process where problems may have occurred. This approach is particularly useful when a team works together to generate the chronology.



- **Time Person Grids** – allows you to track the movements of people before during and after an incident.

	9.02am	9.04am	9.06am	9.08am
SHO	With patient	At Drs station	At Drs station	With patient
Ward Manager	In office	In office	With patient	With patient
Nurse	With patient	With patient	With patient	With patient

- **Flow Charts** – draw a picture of the movement of people, materials, documents or, information within a process. In determining the sequence of events it may be useful to develop separate flow charts that illustrate (a) the sequence of events as documented in the policies and procedures; (b) the sequence of events that occurred during the incident.

SECTION E. Identify CDPs

Having identified the sequence of events that led to the incident, the investigation team should now identify the CDPs. Some will have emerged from interviews and records but may need to be discussed more widely. It is often useful to organise a meeting with all the people (consultant to porter) involved in the incident to let them tease out the CDPs. The people involved in an incident are often able to identify what went wrong and why, and can assist in the development of improvement strategies. The views and opinions of all participants need to be elicited in a supportive setting. The skill of the facilitator in choosing and using the methodologies appropriately is vital to the successful management of these meetings.

Ensure that all CDPs are specific actions or omissions on the part of the staff, rather than more general observations on the quality of care. It is easy for example to put down 'poor teamwork' as a CDP which maybe a correct description of the team, but should be recorded as a contributory factor as it was likely that poor teamwork influenced the CDP. Although in practice CPDs and contributory factors may engage together, it is best not to explore the contributory factors until the team is sure they have a complete list. A variety of techniques are available to both an individual investigator or team to tease out the CDPs, such as brainstorming, brain writing and failure modes and effects analysis.

SECTION F. Identify the Contributory Factors

The next step is to specify the conditions associated with each of the CDPs, using Figure 1 as a guide and as away of reflecting on the many factors that may affect the clinical process. With a large number of CPDs, it is best to select a small number of these regarded as most important. Note that each CPDs are analysed one at a time as each will have their own set of contributory factors.

Each CDP maybe associated with several factors at different levels of the framework (e.g. poor motivation *Individual*, lack of supervision *Team,* inadequate training policy *Organisation and Management).* A variety of methods can be used to record the contributory factors associated with a specific CDP, though two main approaches seem to be favoured. Figure 4 (best placed on A3 paper in landscape format) provides a means of recording the basic incident chronology along with the CDPs and associated contributory factors as a sequence. Figure 5 shows a fishbone diagram associated with one CDP, which represents the same contributory factor information, in an alternative format.

Figure 4: Chronological Mapping of CDPs and Associated Contributory Factors

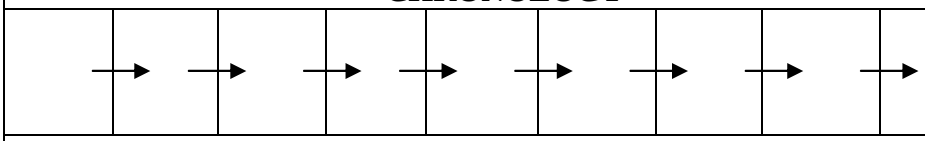
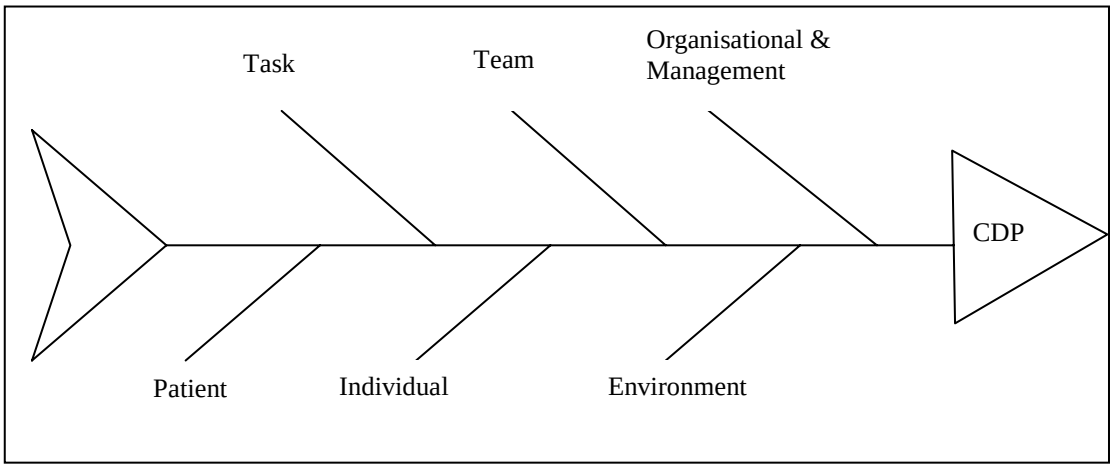
	CHRONOLOGY
	
	TIME
CDPs	
Contri-Butory Factors	
Recom-menda-tions	

Figure 5: Fishbone Diagram CDP



SECTION G. Making Recommendations and Developing an Action Plan

Once the CDPs and their associated contributory factors have been identified the analysis of the incident is complete. The next step is to generate a set of recommendations/improvement strategies to tackle the system weaknesses that have been revealed.

The action plan should include the following information:

- Prioritise the contributory factors in terms of their importance for the safety of future healthcare delivery.
- List the actions to address these contributory factors as determined by the investigation team.
- Identify who is responsible for implementing the actions
- Identify the timeframe for implementation
- Identify any resource requirements
- Evidence of completion. Formal sign-off of actions as they are completed
- Identify the date to evaluate the effectiveness of the Action Plan

Many incident investigators focus on very complex, resource intensive solutions or recommendations that are outside their own remit or control. To improve the uptake and implementation of recommendations, they should be categorised as being under the control of the individual/group, local (team), department/directorate or organisation and 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.

Table 2 provides a recommendation/improvement strategy recording and tracking system, which maybe useful to ensure implementation has taken place. The organisation can immediately identify where the main emphasis of change management needs to occur. As previously mentioned it is normal to identify more factors that contributed to an incident and the investigation team will need to prioritise the solutions proposed.

Table 2: Proposed Action Plan Summary Document

Contributory Factors	Actions to Address Factors	Level of Recommendation (Individual, Team, Directorate, Organisation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off

5 REFERENCES

1. Vincent, C., Taylor-Adams, S., Chapman, E.J., Hewett, D., Prior, S., Strange, P. et al. How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management Protocol, Br Med J. 2000;320:777-81
2. Vincent, C.A. Understanding and responding to adverse events, N Engl J Med. 2003; 348: 1051-56
3. Eagle, C.J., Davies, J.M. and Reason, J.T. Accident analysis of large scale technological disasters: applied to anaesthetic complications. Can J Anaesth. 1992; 39: 118-22
4. Reason, J.T. The human factor in medical accidents. In Vincent C.A. editor. Medical Accidents. Oxford: Oxford Medical Publications; 1993
5. Reason, J.T. Understanding adverse events: human factors. In Vincent C.A. editor. Clinical Risk Management. London: BMJ Publications; 1995
6. Cooper, J.B., Newbower, R.S. and Kitz, R.J. An analysis of major errors and equipment failures in anaesthesia management considerations for prevention and detection. Anesthesiology, 1984; 60: 34-42.
7. Cook, R.I. and Woods, D.D. Operating at the sharp end: the complexity of human error. In: Bognor M.S. editor. Human Error in Medicine. Hillsdale, New Jersey; Lawrence Erlbaum Associates Publishers: 1994
8. Vincent, C.A., Bark, P. Accident analysis. In Vincent CA editor. Clinical Risk Management. London; BMJ Publications: 1995.
9. Stanhope, N, Vincent, C.A., Taylor-Adams, S., O'Connor, A., Beard, R. Applying human factors methods to clinical risk management in obstetrics. BJOG. 1997; 104: 1225-32.
10. Taylor-Adams, S.E., Vincent, C., and Stanhope, N. Applying Human Factors Methods to the Investigation and Analysis of Clinical Adverse Events. Safety Science. 1999; 31: 143-159.
11. Vincent, C.A., Adams, S. and Stanhope, N. A framework for the analysis of risk and safety in medicine. Br Med J. 1998; 316: 1154-7

Acknowledgements

Over the years the research that led to this protocol has been supported by a number of organisations and charities. In particular, we thank BUPA Foundation, UK Department of Health Patient Safety Programme and the Nuffield Trust and the Smith and Nephew Foundation.