A PROTOCOL FOR THE INVESTIGATION AND ANALYSIS OF CLINICAL INCIDENTS

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1. INTRODUCTION

This document describes a formal, practical protocol for investigating and analysing clinical incidents. A process of investigation developed in a research context has been adapted and refined by clinicians and researchers to produce a tool to be used by risk managers and others trained in incident analysis. Only a minority of events will need to be analysed in this detail in clinical practice. However, in-depth analysis of a small number of incidents will bring greater dividends than a cursory examination of a large number. The protocol is still being developed and will be refined in the light of experience and formal evaluation.

Some may question why a protocol is needed at all. Is it not usually obvious to any experienced clinician why things have gone wrong? A number of points must be made:

- The protocol does not attempt to supplant clinical expertise. Rather the aim is to utilise clinical experience and expertise to the fullest extent.

- 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 very first step of the investigation.

- 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 can help to ensure a comprehensive investigation, and facilitate the production of formal reports.

- 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.

The protocol is restricted to the process of analysis and investigation. In practice this will be set, and perhaps constrained, by the local context and the management processes. In the case of a serious incident inquiry there will no doubt be many additional procedures to follow, explanations to many of the parties involved, together with legal and perhaps media involvement. These are clearly all-important matters, but beyond the scope of this protocol. However, we would suggest that subsequent decisions and actions would be more effective if grounded in a thorough and systematic investigation and analysis of the initial circumstance, irrespective of the nature of the incident and the complexity of the issues stemming from it.

The protocol has been designed to fit within a Trust Serious Clinical Event policy (recommended by the Clinical Negligence Scheme for Trusts). It complements the broad guidance given by such policies by providing a methodology, which is equally suited to operation at Trust or Directorate level. Local policy documents should simply refer to this protocol and be explicit about the circumstances, which trigger its use.

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. The assessment of accidents in large-scale systems has acquired a high profile in industry, after such disasters as the King's Cross London Underground Fire, Chernobyl and the Piper Alpha oil disaster. As a consequence 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 (Eagle et al, 1992; Reason, 1993, 1995). These and other analyses have illustrated the complexity of the chain of events that may lead to an adverse outcome (Cooper et al, 1984; Cook and Woods, 1994; Vincent and Bark, 1995; Stanhope et al, 1997; Taylor-Adams et al, 1999). The root causes of adverse clinical events may lie in factors such as the use of locum doctors and agency nurses, communication and supervision problems, excessive workload, educational and training deficiencies and so on.

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. All too often when something then goes wrong in healthcare those in charge will over emphasise the immediate problem. Attempts to pin blame may then follow, with a concomitant lack of appreciation of the much less obvious background factors, which, if allowed to persist can create the same circumstances again. 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. Blame and disciplinary sanctions lead inevitably to defensive reactions, withholding of information, and difficulty in ascertaining the facts. The following methods attempt to avoid these pitfalls and establish a different and more rational approach.

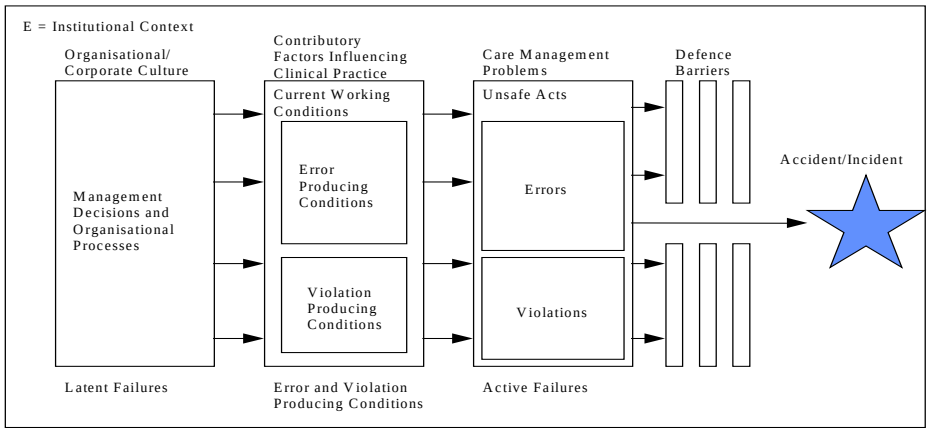
In a series of papers the Clinical Risk Unit has developed and refined the investigation of clinical incidents using a combination of record review, staff interviews and a human factors check-list highlighting psychological and organisational factors. We used Reason's (1995) model of organisational accidents to examine clinical incidents, reviewing both errors made and the background organisational factors that were also implicated as causes of the incident. This model will be described to introduce the ideas underpinning the protocol.

2.1 Reason's Organisational Accident Model

Reason's model was originally developed for use in complex industrial systems as a means of understanding the relationships between the various factors involved in the genesis of accidents and to identify methods of accident prevention. The method of investigation implied by the model is first to examine the chain of events that leads to an accident or adverse outcome and consider the actions of those involved. The investigator then, crucially, looks further back at the conditions in which staff were working and the organisational context in which the incident occurred.

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. These 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 term `care management problems' (CMPs) for active failures. Examples of CMPs and further explanation are given in section 3.2. Having identified the CMPs, however, the investigator then considers the conditions in which errors occur and the wider organisational context. 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; incompatible goals (e.g. conflict between finance and clinical need); 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. This model of the factors that lead to an adverse outcome is shown in the diagram below.

Figure 1: Reason's Adapted Organisational Accident Causation Model



2.2 A Framework for the Analysis of Risk in Medicine

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 (Vincent et al, 1998).

Table 1: Framework of Factors Influencing Clinical Practice

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

At the bottom of the framework are 'patient factors'. In any clinical situation the patient's condition will have the most direct influence on practice and outcome. Other patient factors, such as personality, language and any disability may also be important as they can influence communication with staff, and hence the probability of an incident.

Higher up in the framework are individual (staff) and team factors. 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. The team is influenced in turn by management actions and by decisions made at a higher level in

the organisation. These include policies regarding 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' includes 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 (see Appendix 1). 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.

Once the investigator has identified the various factors that contributed to the incident, a further distinction needs to be drawn between specific contributory factors and general conditions in the unit. That is the investigator should differentiate between those contributory factors that are only relevant on that particular occasion and those which are longstanding or permanent features of the unit or, in some cases, of a member of staff. For instance there may be a failure of communication between two midwives contributing to a care management problem. If this is unusual, and seldom occurs otherwise, then it is a specific contributory factor but one with no more general implications. If, on the other hand, this problem is quite frequent then the investigator would also want to note a general contributory factor of `poor communication' which would have clear implications for the safe and effective running of that unit.

3. DEFINITIONS AND ESSENTIAL CONCEPTS

Reason's model and our framework provide the conceptual foundations of the investigation process. Before describing the actual procedural steps of the investigation we will be define some basic terms used in the protocol. These are all explained in greater detail below and examples are given in the series of case analyses (Appendix 6).

3.1 The Incident

This is essentially something that happened to a patient, a clinical outcome probably with harmful or potentially harmful effects. The criteria for selection of an incident for investigation using the protocol are discussed in the following.

3.2 Care Management Problems (CMPs)

The CMPs are actions or omissions by staff in the process of care. They have two essential features, both of which are necessary for a CMP to be listed:

(a) Care deviated beyond safe limits of practice and

(b) The deviation had a direct or indirect effect on the eventual adverse outcome for the patient. (In cases where you cannot be sure of the impact on the patient it is sufficient that the CMP had a potentially adverse effect).

Examples of CMPs are:

- Failure to monitor, observe or act
- Incorrect (with hindsight) decision or action
- Not seeking help when necessary
- Failure to note faulty equipment
- Not following an agreed protocol (without clinical justification)
- Incorrect protocol applied
- Wrong treatment given

Note that each CMP is to be identified individually and each will be analysed separately to examine the reasons for its occurrence.

3.3 Clinical Context and Patient Factors

For each CMP identified the investigator records the salient clinical events or condition of the patient at that time (e.g. bleeding heavily, blood pressure falling) and other patient factors affecting the process of care (e.g. patient very distressed, patient unable to understand instructions).

3.4 Specific Contributory Factors

For each CMP the investigator uses the framework, both during interview and afterwards, to identify the factors that led to that particular CMP. For example:

- Individual factors may include lack of knowledge or experience of particular staff
- Task factors might include the non-availability of test results or protocols
- Team factors might include poor communication between staff.
- Work environment might include high workload or inadequate staffing.

All of these might contribute to the occurrence of a single CMP.

3.5 General Contributory Factors

The task here for the investigator, and also interviewees, is to consider how far the specific contributory factors identified reflect more general problems. These assessments may be tentative and, if so, should be indicated as such. For example:

- Does the lack of knowledge shown on this occasion imply that this member of staff requires additional training?
- Does this particular problem with the protocol mean that the whole protocol needs to be revised?
- Does this specific instance of poor communication reflect more general problems within the unit?
- Is the high workload due to a temporary and unusual patient set of circumstances, or is it a more general problem affecting patient safety.

4. STARTING THE INVESTIGATION

4.1 Which Incidents should be Investigated?

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 perhaps for the organisation, or because of its potential for learning about the functioning of the clinical department or organisation. Many incidents of course have both serious repercussions and great potential for learning. From the learning point of view incidents with either positive or negative outcomes might be investigated.

Serious incidents will always, by definition be reportable on the incident forms. What marks out a serious incident as requiring detailed investigation is the nature, scale and 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. Account will need to be taken of what has actually happened, the patient's clinical status, how the staff who were involved are feeling, and external pressures such as media exposure.

For serious clinical incidents the protocol facilitates rapid, yet comprehensive and effective investigation. It will of course always be necessary to investigate serious incidents but this may not always be the most productive clinical risk management activity from the point of view of `organisational learning'. There is much to be said for investigating a `near miss' or

a well-handled incident, as these are less emotive and are not generally open to external scrutiny. Such `lesser' incidents may be just as fruitful in terms of revealing the strengths and weaknesses of the unit and the care process.

4.2 Who should Investigate?

While every experienced clinician should be able to investigate clinical incidents from the perspective of clinical practice, following a systematic protocol is likely to bring additional benefits in terms of comprehensiveness and investigation expertise. Early experience with the protocol has suggested that some formal training and practice is needed before it can be used to its full effectiveness. Initially this protocol is likely to be used by the risk manager, with additional clinical input. However, we suggest that the next step is to designate and train investigators in each clinical area who can carry out an investigation to agreed guidelines. For instance in Obstetrics the investigators might be the Head of Midwifery and Specialty Director. The Specialty Director should keep in close contact with the patient's named consultant *who should not conduct his or her own interviews in parallel*. This will ensure a degree of objectivity and independence in the investigation. If the Specialty Director is simultaneously the named consultant he or she should decide whether (depending on the degree of direct personal involvement) to request a colleague to take over.

4.3 Preparing Staff for the Investigation

Although the protocol primarily concerns the investigation itself there are some essential pre-investigation matters that must always be considered, the most important of these obviously being the care of patients and staff. Any investigation is likely to be stressful for all concerned. (In this document we will assume that the patients and relatives concerned are already being treated, cared for and informed).

A number of simple measures will make the process of enquiry easier for the staff involved. First a definite time for the interview must be arranged, allowing staff to make arrangements for appropriate cover and to gather their thoughts in advance. They should also be given a written description of the policy of the Trust, which should emphasise that the investigation is not a disciplinary process. They should be encouraged to bring a colleague or friend if they wish, and allowed time to ask questions as well as answer them.

The investigators and the person in charge of the Unit must also decide early in their investigation, if events have been sufficiently traumatic, whether to send any member of staff off duty. This should not normally be considered as a suspension from duty, simply a compassionate measure to enable recovery. The member of staff may also not be able to work safely and effectively in the immediate aftermath of an incident. In sending any

member of staff off duty in these circumstances, it should be stressed that disciplinary procedures have not been commenced.

4.4 Disciplinary Matters

Both the protocol and the concepts underlying it shift attention from individual members of staff to more general organisational issues. Rather than seeking to assign blame the emphasis is that the occurrence of an incident or an error, however serious the outcome, is not in itself evidence of neglect, carelessness or dereliction of duty. Identifying errors, which are common in healthcare, is only one step in the investigation process. Only if evidence emerges of *repeated* poor performance which breaches professional standards of conduct, should action be considered in relation to any individual member of staff, be it retraining or disciplinary.

If for any reason, disciplinary action is considered to be appropriate, this must be made clear as soon as it emerges as a possibility. The conduct of the investigation should then take account of existing Human Resources/Personnel Policy and procedures and may have to be modified accordingly. Advice should be sought from the Human Resources or Personnel department before proceeding any further.

5. THE INVESTIGATION PROCESS

5.1 Reviewing the Case Records

Accounts of the incident may be taken from written reports of staff members, case notes or interviews with staff. The analysis may be limited if only written reports are considered, in that it may not be possible to explore the full range of conditions that allowed the event to occur. The protocol incorporates analyses from both interviews and records and assumes that much important material can only be gained from interviews. It is possible, if there is no other option, to carry out a less detailed and inevitably more superficial analysis from the case records alone, though the input of a expert clinician in the area will be essential if the clinicians involved in the incident are not available to be interviewed.

The first task, from the information immediately available is, to record the initial summary of the event and identify the most obvious Care Management Problems (CMPs) on form A (Appendix 3). In some instances there may only be one, but nearly always several problems conspire to create the event. Make an initial summary of the principal events (an outline chronology), as recorded in the notes, before starting the interviews. Next list the key staff involved and decide who should be interviewed, and in what order to see them.

5.2 Framing the Problem

The reported incident may not reveal the final outcome for the patient. For instance a patient may fall (and this may be reported), but the subsequent fracture may not be diagnosed for two days and the final outcome for the 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 longer and more complex story may unfold.

The next task is to decide which section of the process of care to examine. This is not always straightforward. It depends less on the condition of the patient at any particular time and more on when and where the problems first arose, which may only become apparent during the investigation. For instance, a haemorrhage may have been badly managed leading ultimately to the patient's death two weeks later. The chronology may summarise three weeks of care, most of which may be of high standard. However the analysis will concentrate on those aspects where problems were apparent, for example, in the preparation for surgery, conduct of the surgery and post-operative monitoring, in order that appropriate lessons may be learnt.

5.3 Undertaking the Interviews.

Interviews should be undertaken in private and, if at all possible, away from the immediate place of work in a relaxed setting. It is best if they are conducted by pairs of investigators. Before starting, agree who will lead and who will listen, record responses on form B (Appendix 4) and interject if necessary. That way more subtle points are less likely to be missed. If a member of staff wishes someone else to be present this should be permitted.

The purpose of the interview is simply to find out what happened and this should be explained at the outset. The style adopted should be supportive and understanding, and 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 will normally require additional support at this point and 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 will generally be more effective to move through these phases in order.

5.3.1 Establishing the Chronology

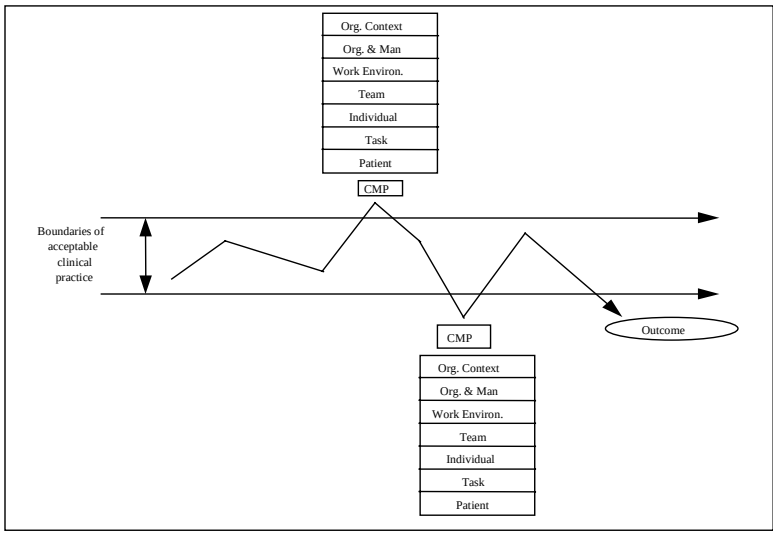
First, establish the role of the member of staff in the incident as a whole. Record the limits of their involvement. Next establish the chronology of events as the staff member saw them. Record these. Compare this new information with what is known of the overall sequence.

5.3.2 Identifying the Care Management Problems (CMPs)

In the second phase, first explain the concept of a Care Management Problem and possibly provide an example of a CMP. Then ask the member of staff to identify the main Care Management 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 CMPs. 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 and fluctuation. Where there are disagreements as to whether a particular action or omission is acceptable, 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. This idea of a process going beyond the boundaries of safe practice is illustrated in figure 2, which demonstrates the role of the contributory factors.

Figure 2: The Analysis of Incidents in a Medical Context:-integrating the framework and causal influences with the boundaries and fluidity of clinical practice



5.3.3 Identifying the Contributory Factors

In the third phase, go back and ask specifically about those CMPs that the staff member may have information about or experience of. Ask questions related to each CMP based on the framework, see table 1 (page 6).

Although the framework has higher level, organisational factors at the top it may be more natural in clinical terms to begin by enquiring about patients factors, then moving up the table through task factors, individual, team and so on.
In practice the discussion may range over many of these in any order, in which case it is simply a matter of checking through at the end to make sure all aspects have been covered. Where a factor is clearly very important, and has had a direct influence on the occurrence of the CMP it may be useful to look at the expanded framework to record more specific information (Appendix 1).

5.3.4 Distinguishing Specific and General Contributory Factors

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? If the factor is more general, record this on the form alongside the specific instance that related to this incident.

5.3.5 Closing the Interview

Each interview should take between twenty and thirty minutes depending on the degree of involvement. After discussion of a case present the interviewee with a checklist (Appendix 2) and:

- Ask them to indicate which, if any, of the items they felt were relevant to or had been influential in the case for example, communication or equipment difficulties.
- Give details and elaborate on any items they selected and say if, and how, their work had been affected by those factors

In previous analyses the contributory factors questionnaire has performed well as a tool to get clinicians to think about the non-clinical factors, that they felt affected their performance. It also acted as an effective prompt, jogging a person's memory about factors not mentioned in their account and as an encouragement to provide details about other issues they might otherwise have considered trivial and not worth mentioning. Finally ask the staff member if they have any other comments to make or questions to ask.

6. ANALYSIS OF THE CASE

The core of the process is to ask: What happened? How did it happen? Why did it happen? What can we learn from this and what changes should we make, if any?

6.1 Establishing a Chronology of Events

The first step in the analysis is simply to produce an agreed history of events, specifying any important areas of disagreement between accounts or between the case notes and the memories of the staff. The starting point for the chronology will generally be the point at which the patient entered hospital, though relevant events before their arrival (e.g. previous treatment, a misleading referral letter) may also need to be recorded. However it is then important to identify and focus on the most important part of the chronology (see `framing the problem' above).

6.2 Identifying the Principal Care Management Problems (CMPs)

The next stage is to identify the care management problems noted by staff involved in the case. These may be provided by the staff themselves or from the investigators' own clinical knowledge and expertise. List the main CMPs on Form A (Appendix 3). This is a core document in the final report and the basis of your subsequent analysis. Look back over the list and ensure that all the CMPs are specific actions or omissions on the part of staff, rather than more general observations on the quality of care, which should be recorded elsewhere. It is easy to note down `poor teamwork' as a CMP, which may be a correct description of the team but should be recorded elsewhere as a contributory factor.

6.3 Identifying the Contributory Factors

The next step is to attempt to specify the conditions associated with each of the clinical management problems, using the framework as a guide and as a way of reflecting on the many factors that may affect the clinical process. Interviews with staff will already have provided lists of both specific and general contributory factors. Where these conflict it may be necessary to make a judgement as to the most important causes of the events.

Each CMP may be associated with several factors at different levels of the framework that were implicated in its occurrence (e.g. poor motivation *Individual*, lack of supervision *Team*, inadequate training policy *Organisation and Management*). As in the interviews use the basic framework, turning to the expanded framework in appendix 1 if you want more detail on a particular aspect . Use form B (Appendix 4) to assist you in this task.

Carry out a separate analysis for each CMP, though the depth and detail of the contributory factors identified may vary for each CMP. Remember to clearly distinguish *Specific Contributory* Factors, which describe the reasons for the CMP on that particular occasion, from *General Contributory Factors* which in your judgement are more longstanding features of the individual, team or working conditions. Factors that are specific to that occasion and do not reflect more general problems probably have no long term implications for the quality and safety of practice and therefore probably do not require action or changes of any kind.

6.4 Complete Summary Forms for each CMP

From the individual interview forms and other written records prepare summary forms for each CMP, which provide an overview of the salient clinical events, specific and general contributory factors. Examine the final list of general contributory factors for each CMP and identify those that have implications for action. For each CMP record the implications and action points at the bottom of the summary form.

Complete one Form C (Summary Form - Appendix 5) for each CMP that you previously identified. At the bottom of each Form C there is a space for implications and action plans. This is for your own reflections on what changes in practice or other actions are indicated by this particular breakdown in the organisation of care. Essentially you examine the *General Contributory Factors* that you have already listed and consider what action, if any, can be effectively taken in respect of each one. Each CMP may have very different implications or perhaps no implications at all.

It is perfectly possible that a CMP may occur through a series of temporary and unusual circumstances, which are unlikely to recur, and so have no implications for future practice. Conversely a CMP may reveal general gaps and weaknesses in the system of delivery of care which have important implications.

6.5 Preparation of the Report

Once the interviews and analysis are completed make a composite of all of them detailing the whole incident from start to finish. Refer to staff by grade and initials only. In the process of undertaking the interviews new CMPs may have been identified. Add these to the list. If the interviews suggest a need to follow up anything with a particular member of staff go back and use the same structured process, but concentrating on the new CMPs. The original documents can be updated to take account of this.

If the protocol is followed systematically and the interview and analysis conducted thoroughly the report and implications of the incident should emerge from the analysis in a relatively straightforward fashion. When the composite is complete, there should be a clear

view of the problem, the circumstances which led up to it, and the flaws in the care process should be readily apparent. The final report will firstly provide a summary analysis of the incident in question. This should contain sections which:

- Summarise the chronology;
- Identify the care management problems and their contributory causes, giving most emphasis to general contributory factors;
- Emphasise positive features of the process of care;
- Recommended action and time-scales for each one of the general factors requiring attention.

The report will then consider what implications this incident has for the department or organisation. This section will summarise the general contributory factors and the implications for action. The lessons learnt can be drawn out and action plans to deal with the problems which occurred can be formulated. A summary outlining the main components of the investigation and analysis process can be found in table 2.

Table 2: The Investigation - a summary

All investigations contain a series of steps, which should be followed, as a matter of routine, when an incident is investigated. These are:-

1. Ascertain that a serious clinical incident has occurred and ensure it is reported formally. Alternatively identify an incident as being fruitful in terms of organisational learning.

2. Trigger the investigation procedure. Notify two of the senior members of staff who have been trained to carry out investigations.

3. Investigators will establish the circumstances as they initially appear and complete an initial summary. Decide which part of the process of care requires investigation and prepare an outline chronology of events. Identify any obvious Care Management Problems (CMPs) and record them on Form A.

4. Interview staff using the structured approach

    - Establish the chronology of events.
    - Revisit the sequence of events and ask questions about each of the clinical management problems identified at the initial stage
    - Use the framework to ask supplementary questions about the reasons for the occurrence of each clinical management problem. Record each CMP and its contributory factors on Form B.
    - Give staff the post interview checklist to complete and comment on.

5. If new CMPs have emerged during the interviews add them to the initial list. Re-interview if necessary.

6. Collate the interviews and assemble a composite analysis under each of the CMPs identified at the start. For each CMP identify both specific and, where appropriate, general contributory factors.

7. Compile the report of the events, listing the causes of the CMPs and make recommendations to prevent recurrence on form C.

8. Submit report to senior clinicians and management according to local arrangements.

9. Implement the action arising from the report and monitor progress.

7. REFERENCES

Cooper, J.B, Newbower, R.S. and Kitz, R.J. 1984. An analysis of major errors and equipment failures in anaesthesia management considerations for prevention and detection. Anaesthesiology, 60, 34-42.

Cook, R.I. and Woods, D.D. 1994. Operating at the sharp end: the complexity of human error. In: M.S. Bognor (Ed.), Human Error in Medicine. Lawrence Erlbaum Associates Publishers, Hillsdale, New Jersey.

Eagle, C.J., Davies, J.M. and Reason, J.T. 1992. Accident analysis of large scale technological disasters: applied to anaesthetic complications. Canadian Journal of Anaesthesia, 39, 118-22.

Reason, J.T. 1993. The human factor in medical accidents. In Vincent CA (ed). Medical Accidents. Oxford Medical Publications, Oxford.

Reason, J.T. 1995. Understanding adverse events: human factors. In Vincent CA (ed). Clinical Risk Management. London, BMJ Publications

Stanhope N, Vincent CA, Taylor-Adams S, O'Connor A, Beard R. 1997. Applying human factors methods to clinical risk management in obstetrics. British Journal Obstetrics Gynaecology; 104: 1225-32.

Taylor-Adams S.E, Vincent, C., and Stanhope, N. 1999. Applying Human Factors Methods to the Investigation and Analysis of Clinical Adverse Events. Safety Science. 31, 143-159.

Vincent C.A, Bark P. (1995). Accident analysis. In Vincent CA (ed). Clinical Risk Management. London, BMJ Publications.

Vincent C.A, Adams S, Stanhope N. 1998. A framework for the analysis of risk and safety in medicine. BMJ, 316 1154-7.