1. Introduction

This paper sets out suggested good practice guidance to the NHS on how to conduct local investigations into service problems. Discussions have been held internally and with colleagues in the NHS with experience of local investigations.

The guidance will not address the decision making process around whether or not to convene an investigation or the grounds for doing so and assumes that the decision has already been made. The audience for the guidance is NHS/NHS Executive and NAW staff responsible for establishing investigations and investigation panel members. This paper describes the ways in which such guidance can be drawn together and suggests a way forward for CHI.

Whilst attempting to capture good practice in the conduct of investigations for the NHS, CHI would not wish to undermine the considerable expert knowledge of local managers. This guidance is intended as a framework, to be adapted and augmented by NHS managers to suit individual circumstances.

Initially, the guidance is very much a work in progress and will depend on feedback from the NHS in order to maximise its effectiveness. The document will be reviewed in April 2002 to take account of feedback.

Background

In the absence of clear guidance there is an inconsistent approach (agreed), both in terms of conduct and outcome of internal investigations undertaken by the NHS. CHI has been charged with the early production of good practice guidance to improve the quality of such investigations. Can Regional and Trust investigations be treated the same? I don't think so eg. Eastbourne Review compared to a single SUI in a Trust. Trusts do not have sufficient resources to do full scale investigations with panel members and secretary's for the number of SUI's that fall into the present categories so we need to look at what does need a full investigation. One of the differences may be in multiple or single events?

Review of recent NHS investigative reports demonstrate a considerable difference in approach, content and style. There is also concern regarding how recommendations are followed up and the lessons learnt as a result disseminated throughout the NHS. The benefit of CHI guidance will be an improvement in the quality of investigations and greater public accountability. Greater standardisation will facilitate the dissemination of learning throughout the NHS.
There is no national guidance on how to conduct investigations in the NHS, though The Health Advisory Service (HAS 2000) has produced a draft series of proposals for responding to serious untoward incidents in mental health. There is also evidence of some Regional Office guidance, though this is largely around the reporting and press handling arrangements for various levels of untoward incident, rather than on how to conduct investigations.

The urgent need for national guidance has been stressed by a number of local NHS reviews and inquiries. The 1997 review of cervical screening services at Kent and Canterbury NHS Trust identified weaknesses in the initial inquiry undertaken by the Trust and recommended that: "The NHS Executive should follow up guidance on the conduct and reporting of inquiries in the NHS." This recommendation was strongly supported by the panel which reported on serious untoward incidents at Chesterfield and North Derbyshire Royal Hospital NHS Trust in 1999.

In addition, the CMO confirmed in "An Organisation with a Memory" (2000) that CHI should develop, as an early priority, a national role in advising on the process and conduct of

internal investigations, with the aim of ensuring greater standardisation. CHI is pleased to contribute to this important work.

2. Definition of Different Kinds of Investigation

It is important to differentiate between the number of different ways in which an investigation can be established in the NHS.

1 Statutory Inquiry
An inquiry convened by the Secretary of State under Section 84 of the 1977 NHS Act which can compel witnesses to attend. Such inquiries have tended to be for extremely serious issues, such as that at Bristol Royal Infirmary.(multiple) The Inquiry into the activities of Harold Shipman has been convened under the Tribunal of Inquiry (Evidence) Act 1921. (multiple) Statutory inquiry rules also apply to CHI investigations under the 1999 Health Act.

2 Non-Statutory Inquiry
An external inquiry without statutory powers ordered by the NHS or the Secretary of State. A recent example is the inquiry into the retention of children's organs at Alder Hey Hospital date published in 2001. (multiple)

Mental Health Inquiry
Established under HSG (94) 27 "Guidance on the discharge of mentally disordered people and their continuing care in the community". These inquiries deal with serious incidents, particularly homicides, involving people in contact with mental health services. HAS 2000's draft guidance mentioned previously relates to these inquiries.(need to get a copy - does this relate to the inquiry or to a local investigation?)

3 Local NHS Investigations
Established by either the trust, primary care trust, health authority or regional office/NAW. This internal investigation process is used following the majority of serious untoward incidents in the NHS. Existing local policies such as those covering the Risk Management Strategy, Emergency Response Plan and whistlebowing will link into an investigation. **This paper deals with such investigations**. What follows may be unrealistic in terms of resources available to Trusts??

A recent strategy meeting of the NHS Executive Board (January 2001) agreed to the establishment of a dedicated unit within the Department of Health to determine which form of investigation is most appropriate and ensure timely completion. This is Marcia's team I guess.

3. Possible CHI Approach

Depending on the commitment CHI would wish to make and when, CHI could produce guidance for the NHS on two levels. In line with CHIs organisational learning approach, any guidance would be reviewed annually to ensure that best practice is shared throughout the NHS.

Option 1 - Short Term

This level of CHI good practice guidance could be pulled together by March 2001 and would run in parallel to the evaluation of completed CHI investigations in late February 2001. The key question would be whether this level of guidance would meet immediate external expectations. The process for the production of the guidance is being worked up with COMMS and would be available on the CHI web site initially. The possibility of piloting the

guidance in an NHS organisation about to begin an internal investigation would assist the evaluation of the guidance. Discuss the CHI remit now, what work COMMS have done, ?nothing on web, link with Marcia and where next?

The relevance of the guidance would need to be reviewed annually to take account of feed back from the NHS, CHIs developing expertise in investigation work and to take account of any national policy developments.

4 Outline of CHI's suggested approach to internal investigations and general principles. Appendix 1
5 Action flowchart. Appendix 2
6 Process for convening an investigation. Appendix 3
7 Suggested format of completed report. Appendix 4
8 Suggested further reading, eg "An Organisation with a Memory", "A Protocol for the Investigation and Analysis of Clinical Incidents" by University College London/Alarm 1999 and the Eastern Regional Office Serious Untoward Incident Procedure (contains a useful appendix on conducting inquiries).

Option 2 - Longer Term

A complex piece of guidance on this scale would require a dedicated resource, which could be steered by the Research & Development Programme Board. Is this within CHI? There is a considerable amount of literature available around the analysis of risk in healthcare and methods of investigation to review (where and what?). It would also be sensible for the evaluation (is this something available I can see? Has it been analysed yet?) of the completed CHI investigations to be fed into this process.

A large area of work, though not necessarily for CHI, would be the development of the competencies (this would need to be done across a range of positions in the process eg. A Chair of a Regional investigation to a staff nurse involved in producing a report for a SUI review) within the service for undertaking investigative work. CHI would be able to feed into this work as CHIs own experience in this field evolves.

Such a piece of work would take some time to complete and has been provisionally scheduled for 2004 in the Corporate Plan. The appropriateness of the following suggested components need to be worked through.

1 A fully worked up piece of guidance on CD Rom including:
2 thorough analysis of methods of investigation
3 work with the CMOs on mapping exercise to determine which events should trigger different levels of investigation

2 Telephone helpline on the practical implementation of the good practice guidance to NHS organisations and panel members.
3 Database of national contacts, such as chairs and secretaries to past investigations.
4 Database of completed investigations.
5 Mechanism for feeding recommendations into the whole NHS.

4. Key Issues

1 The support CHI would wish to give in both the short and longer term?

There is a potential conflict of interest between any advice CHI would provide to an internal investigation which then led to a CHI investigation or fed into a fast track clinical governance review. There is an issue over to what extent CHI would wish to become involved in internal

investigations. (This is an important issue and may well be a reason for CHI's advice and support but ownership from DH with H&SC directorate support - does the old regional role devolve to StHA's? Has that been decided yet?)

Early discussions with Regional Offices suggest that this is an area which they see as resting with them, especially given the Regional Office role in the handling of serious untoward incidents (But was this before StBoP?). Discussions will continue with Regional Offices and NAW to determine what they see as their role in this. CHI would wish to work with the Regional Offices and NAW to develop joint capability.

2 CHI's role in disseminating lessons learnt from internal investigations throughout the NHS?

CHI's involvement here could depend on the extent to which local investigation reports are in the public domain. If CHI (Might this be more appropriate with NPSA????) had a database of all internal inquiries, it would be relatively straightforward, though time consuming, to distil key themes and patterns in an annual summary and a more immediate information bulletin on the CHI web site. Such key themes and the implementation of recommendations should also be fed into the clinical governance review process (as should other external visits eg. CNST, NHSLA, MHA comm etc., etc).

3 Role of lay people?

Does CHI agree with a recommended role for lay people similar to that in CHI investigations and reviews? Should user groups be invited? Who should attend if no established groups? Is there a role for the CHC/PALS here. (Unless the definition changes CHC/PALs probably wouldn't have the resources let alone Trusts to do this)

1 Legal Issues

The legal issues involved in an investigation are complex, particularly around confidentiality. CHIs own work steered by the Confidentiality Working Group will cover a number of key legal issues and will be used to inform the guidance.

General Principles Appendix 1

Given the fact that an investigation has been established, the background will most likely be stressful to all concerned. As the organisation leading the investigation process, it is important to take time at the outset to ensure that good practice principles underpin every aspect of the process.

1 **Patients/relatives/carers must be at the centre of the process**.

The needs of this group of people should be paramount. Contact should be made as soon as possible; to inform them of the incident, make assurances that it is being taken very seriously and to listen to their concerns. Appropriate support and counselling should be made available immediately. (internal or external or both??)

Patients and relatives will want to know what happened, why it happened and what will be done to prevent a reoccurrence. Steps should be taken to keep this group informed throughout the process and to ensure that the outcome is communicated. A mechanism may need to be established with an appropriate spokesperson if a large group of patients/relatives are involved.

2 **Opportunity to learn.**

There should be clear understanding throughout the organisation of the purpose of investigating events or potential events in order to prevent reoccurrence and improve risk management.

The thorough investigation of an incident and its service context should be seen as an opportunity to identify systems failures and improve the service. (Root cause analysis demonstrated!)

Learning should be fed back into plans for improving patient care and audited to ensure continuous improvement. Any resulting training needs should be addressed.

3 **Process must be fair and follow the rules of natural justice.**

All parties involved requesting an input must be allowed to do so, though this will be at the discretion of the investigation panel. Staff under investigation must have the right to attend their interview accompanied by someone of their choice. It should be stressed that any suspension of staff is a neutral act and does not indicate blame.

4 **Process to establish facts, not to allocate blame.**

The aim here should be to establish the circumstances and the events leading up to the incident being investigated and to produce an authoritative and impartial account of the facts. All conclusions drawn should be clearly supported by evidence and explained as such in the final report.

This work will inevitably necessitate close examination of the work of staff. It is important to maintain the view that individuals are working within a complex, often multi agency system. These structures must be examined before determining whether an individual is at fault. Any disciplinary decisions must be kept separate from the investigation process. (This is a critical aspect of the work I am doing - to fully get to grips with why's etc) Though the investigation may contribute towards a judgement about whether or not a disciplinary hearing is appropriate.

5 Confidentiality

Rigorous attempts should be made to ensure the confidentiality of everyone at all times. This will be subject to professional obligations to refer on poor performance and suspected criminal activity. Public whistleblowing and leaks should be planned for. As mentioned previously, CHIs specific work will inform this general principle.

Care should be taken to seek appropriate permission for the release of medical notes, (this is crucial however there must be recognition that it could also create delays sometimes minimal but often longer) making it clear to patients that staff not directly involved in their care could be reviewing notes. Proper care to access the medical notes of deceased patients should be taken. All patients must be anonymised completely in the final report.

All record, background information must be stored appropriately and careful minutes of panel deliberations taken.

6 Openness

In order to ensure public accountability, the presumption from the outset should be that some element of the final report must be in the public domain. This could mean that the entire report is published or the key findings discussed in an open board meeting. This is a matter for local discretion. Whatever method of public communication is decided upon, clear and demonstrable reasons must back up the decision. (This does raise issues about staff's openness and their own responsibility and making things public and trying to learn lessons rather than pointing the finger if the report is made public particularly if at an inquest.)

Process for Convening a Local NHS Investigation
Appendix 3

Terms of Reference

These will outline precisely what the panel (or an individual) are being asked to investigate. Though not part of the term of reference, the timescale for producing the report must be discussed and confirmed at this point as well.

1 Important to spend time getting right, especially in turbulent period following a crisis or serious untoward incident.
2 Important to draft (so who should do this? The CE, MD?) before panel membership finalised, as the drafting process may suggest the need for expertise not already considered.
3 Must be clear and concise, break down into short paragraphs if necessary.
4 Include period of time investigation refers to.
5 State clearly who reporting to?
6 Seriously consider getting a legal opinion.
7 Allow some scope for investigation to cover any unforeseen issues which may emerge.

Selection of Chair (This is usually the service manager for most SUI's but in more serious cases may be different)

1 When possible, select chair before terms of reference are drafted to ensure their input.
2 Chair must be a strong team player with credibility and independence.
3 Responsibility of chair to deliver the report must be explicit.
4 Consider the selection of a lay chair.
5 Ensure chair is thoroughly briefed.

Membership of Panel (This seems more appropriate for independent inquiries and those identified by RO e.g. Eastbourne Review)

6 All members of team must have sufficient time and be able to see the investigation process through.
7 All members of team must be impartial and free of potential implication. Establish a process for identifying potential conflicts of interest.
8 Consider seeking references and CVs.
9 Consider whether panel members should be publically identified or not.
10 The involvement of lay panel members is recommended.
11 Avoid duplication in membership of investigation panel and any potential disciplinary/Independent Review Panels.
12 Work towards ensuring that the collective membership reflects different multi-professional and lay perspectives.
13 Panels should comprise of an odd number of members (including the Chair). With careful thought, three members should be sufficient to investigate the majority of untoward incidents.

Investigation Support Officer (Secretariat) (In my experience this has never happened there has been a PA but insufficient resources for this role. Only experience of this is with an Independent inquiry.)

1 Important role, needs careful thought and will demand a significant time commitment.
2 Knowledgeable enough to source and sift supporting information.
3 Sufficiently skilled in report writing/minute taking/project management.
4 Takes practical steps to maintain confidentiality.
5 Confident and experienced enough to deal with complex detail and senior staff.
6 Organises expenses/room bookings/secretarial assistance/travel arrangements etc.
7 A budget may need to be explicitly agreed.
8 Coordinates any support to panel members such as counselling.

Legal Issues

1 Request legal advice from appropriate source if in any doubt. Eg be clear if requesting a technical, employment law or defamation opinion.
2 Whistleblower Policy - how does remit of investigation fit with policy?
3 Proof and status of evidence must be clear, avoid making unsubstantiated statements.
4 Confidentiality - patients/staff.
5 Beware of implications of Human Rights Act**.** Eg it is good practice that ~~that~~ when an individual is required to provide information or explanation, they should not be required to incriminate themselves.
6 Data Protection Act - is the involvement of Caldicott Guardian necessary?
7 Fairness to witnesses, apply the Salmon Principles. These are not rules of law but are worth considering; the following are the most pertinent.
8 Principle 1: before any person becomes involved in an inquiry, the inquiry team should be satisfied that there are circumstances that affect them which the inquiry proposes to investigate.
9 Principle 2: Before any person who becomes involved in an inquiry is called as a witness they should be informed of any allegations which are made against them and the substance of the evidence in support of them.
10 Rules of natural justice.

Methods of Investigation

1 Determine, source and review background information.
2 Sub-divide tasks to individual/smaller groups within the panel. For example, clinicians on the team review case notes.
3 Draw up a chronology of events.
4 Interview structure and style must encourage full exchange of information and notes should be taken to assist understanding.
5 Determine when to refer to other bodies.
6 Ensure that interviewees can be supported - MDU/UNISON/friend
7 Visit the area the incident occurred.
8 Need to be aware of balance between speed and thoroughness.
9 Avoid straying away from terms of reference by regularly referring back to them.
10 Build sufficient time into the report drafting process for proof reading and obtaining a legal opinion.

Decisions to Make

11 Who is responsible for action planning and will this be incorporated into the report?
12 Consider circulating report to those interviewed for factual accuracy check only.
13 What information do staff being interviewed receive on the events being investigated prior to their interview?
14 Consider the need to hold a public meeting, possibly a Board meeting, in addition to private deliberation and public report? Generally incorporated into CG report and tabled at Trust Board but depends on severity. Certainly any SUI's serious enough to inform

RO would be reported to Board members prior to or at Board meetings (closed or informal to alert them in case of media interest)

15 Draw up clear, defensible reasons for any decision not to make any part of the report available to the public.
16 Is statistical support needed in order to analyse data and qualitative information?
17 Determine structure of report and who is responsible for drafting it.
18 Consider meeting with concerned parties before report publication.

Communications

1 Ensure formal notification to appropriate staff/colleagues consistent with untoward incident reporting protocols.
2 Draw up a communications plan as soon as investigations is announced, covering all relevant interests and audiences. Determine who the audiences will be and build communications plan around this. Ensure staff and board/authority are included in plan.
3 Establish links with other communication channels, such as trust, health authority and Regional Office/NAW.
4 Be aware that press will have a legitimate interest & issue early press statement explaining that an investigation is taking place and outlining any interim arrangements. Consider joint statements with other NHS organisations.
5 Determine how to communicate with implicated/suspended staff and staff-side representatives.
6 Any arrangements for writing to patients will require careful coordination. Ensure GPs (to whom patients may turn) are fully aware of circumstances.

Support to Patients

1 Be aware of implications of an investigation on recent/potential patients.
2 Helpline/counselling support. The provision of a helpline, its publication, availability and the experience of those staffing it should be carefully thought through. The effect on staff handling these calls should not be underestimated. Ensure the rapid provision of additional telephone lines is possible, inline with the Emergency Response Plan.
3 Write to patients to advise of investigation and offer support.
4 Inform potential patients of alternative centres if necessary and arrange care quickly.
5 Brief patients/relatives before publication of report and review helpline arrangements.

Support to Staff

6 Ensure firm message that any suspension is a neutral act.
7 Consider moving staff to alternative places of work if viable in order to prevent suspension
8 Brief staff before publication
9 Consider offering counselling support
10 Apply all relevant existing internal employment procedures and policies.

Recommendations

1 Must refer to Terms of Reference.
2 Be specific.
3 Disciplinary recommendations must be avoided this is a matter for the employing body and is subject to the disciplinary processes of the employer.
4 Determine how to deal with any recommendations which have financial/staff/other implications?

Action Planning

1 Determine who is responsible for delivery of recommendations and their monitoring.
2 Timeframe for completion/milestones.
3 Acknowledge any positive change made to date.

Publication of Report

4 If date delivering the report is different to publication, consider how to make it leakproof.
5 Ensure involvement of all press officers and that appropriate health authority, Regional Office/NAW etc. are aware of publication date in good time.
6 Be prepared and plan for media interest, eg Q & A's.
7 Consider media training for all staff involved and panel members.
8 Consider how to ensure that lessons for the wider NHS are communicated appropriately.

Evaluation

1 Undertake and evaluation by the investigation panel (and key stakeholders) of the process followed.
2 Audit impact of investigation at appropriate intervals and report to the Board.
3 Review local arrangements in the light of experience.

Suggested Format of the Report Appendix 4

The following are suggested chapter headings and should be adapted where appropriate. The skills of the secretary to the investigation are fundamental to the success of the report and must not be underestimated.

Terms of Reference

Glossary

- ensure as many terms as possible are explained in the body of the text.
- consider a simple diagram to explain medical procedures if appropriate.

Executive Summary

- brief outline of events, possibly including a brief chronology.
- who reporting to?
- key outcomes.
- key recommendations.
- what will happen next?

Context

- national context
- background to organisation
- background to service being investigated
- reasons for investigation

Findings (for each recommendation)

- evidence
- discussion
- recommendation

Conclusions and recommendations linked to Reference to Terms of Reference

Action Plan

- provided by Trust/organisation being investigated.

Appendices

- membership/panel
- chronology of events
- organisational structure
- bibliography
- list of documents reviewed
- interview schedule
- acknowledgements