May 2003

INVESTIGATION OF DEATHS IN HEALTH CARE SETTINGS.

1. INTRODUCTION

1.1 The investigation of deaths in health care settings, be it at a hospital, dental Surgery, GP surgery or care home, pose unique and difficult issues for the Senior Investigating Officer (SIO). This chapter seeks to provide guidance to investigating Officers in managing investigations into questioned deaths occurring in 'Health care settings', that is in any place where a person is under the care of a health professional. It includes but is not restricted to; hospitals (NHS & Private), GP surgeries, Dental surgeries, residential care homes and hospices.

1.2 Medicine is an imprecise science. Quite distinct from any other professional discipline, it is possible and on occasions likely that even in the hands of the consummate professional, acting with utmost care, skill and diligence the outcome can result in the death of an individual.

1.3 The fact is that the vast majority of health care professionals are dedicated, caring, competent and professional. This makes the conduct of an investigation into their actions difficult for both them and for the SIO. The SIO must recognise that health care professionals will be affected by the death of a patient and are likely to be worried by the investigative process. There will be a need to reassure them as to the purpose, fairness and integrity of the investigation. There is a clear need for sensitivity in dealing with health care professionals whilst at the same time conducting a thorough, impartial and rigorous investigation.

1.4 The SIO must recognise that subject to the above there is evidence of a small number of people who abuse their position of trust within the health care community to commit deliberate acts of homicide.

1.5 Much work is being done nationally to improve survival rates of patients and a number of bodies have been set up by the Government to improve clinical standards and to minimise risk, examples are; The Commission for Health Improvement, The National Care Standards Commission, The National Patient Safety Agency and The National Clinical Assessment Authority. Regulatory bodies such as the General Medical Council, in respect of Doctors, the General Dental Council and the Nurses and Midwives Council, set and enforce professional standards and conduct in respect of the relevant professionals.

1.6 In addition to the examination of the individual culpability in such investigations, the SIO (Senior Investigating Officer) must consider the wider corporate liability of the governing or managerial body in deaths occurring in health care settings. This is particularly difficult against a rather confused legislative background. This will clearly have implications for the SIO in terms of his/her relationship with the management of the relevant Trust or service.

1.7 There has been a significant increase in the number of deaths in health care settings referred to the Police. Complaints as to questioned deaths arise either from Coroners, or from the families of the deceased. It may be speculated that in the latter case, the increase in complaints may be due to an increase in awareness on the part of the public that they have the opportunity to challenge public services, including health care bodies. Most complaints will be for genuine reasons, however the SIO must recognise that some complaints may be motivated by guilt on the part of the surviving relatives, who may feel that they should have done more for the deceased in life, or less commonly by a desire for financial compensation. The SIO must provide the appropriate support to the family, but at the same time manage their expectations, particularly if the investigation concludes that the death did not have an aspect of criminal culpability.

1.8 The health care structure in the United Kingdom is complex and will present difficulties to the SIO in terms of understanding the responsibilities and associations of individuals and of corporate bodies. At an early stage the SIO will need to obtain advice as to the structure of the particular part of the service or trust relevant to the matter that he/she is investigating.

1.9 In investigations involving health care institutions and professionals, there will be an understandable high level of public and media interest and concern, it is important that the SIO manages this aspect of the enquiry very carefully, in association with the relevant health care authority so as to minimise inappropriate and unnecessary alarm in the community, whilst ensuring that factual and appropriate information is provided to the media and to the public.

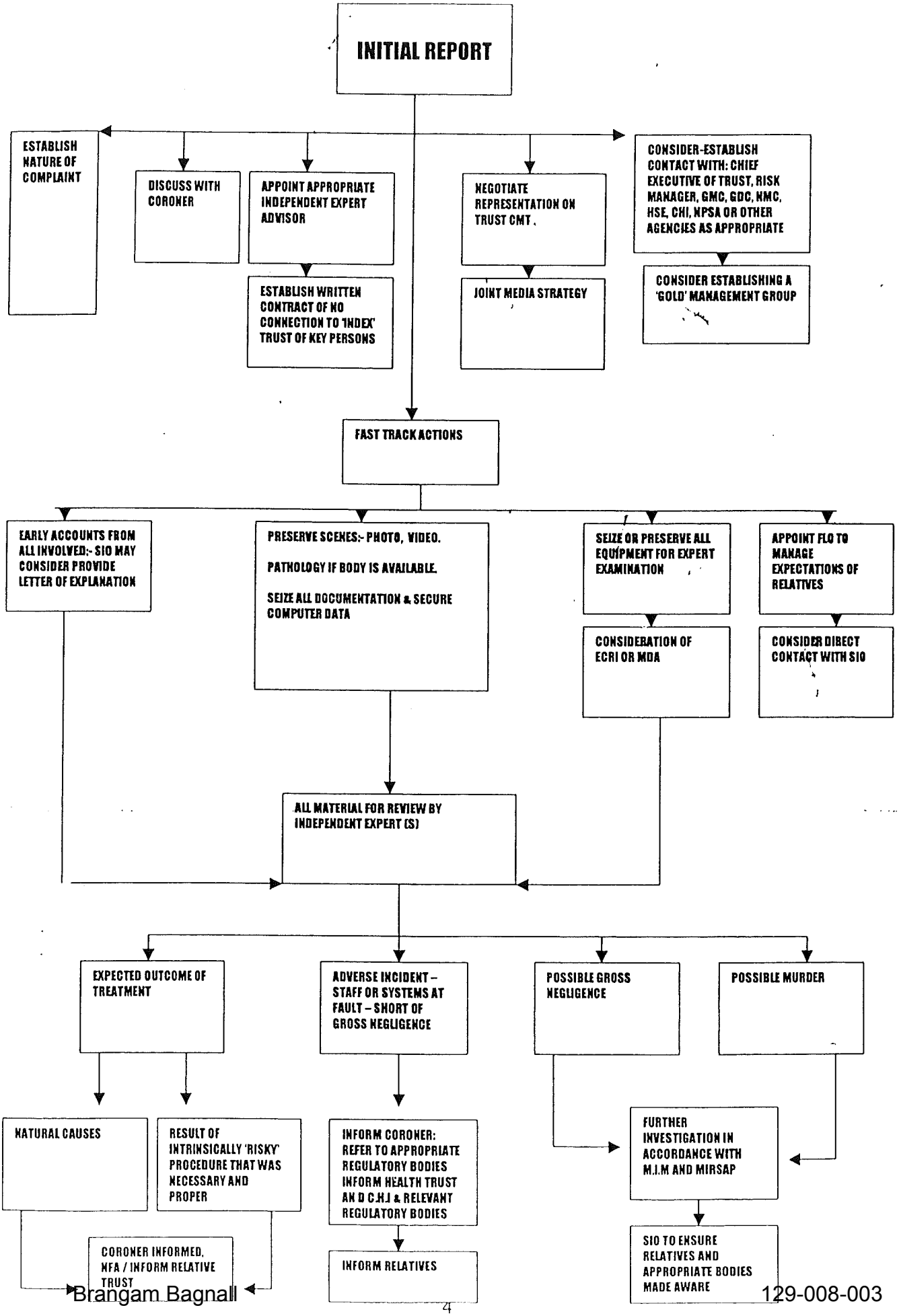
1.10 In addition to all of the above considerations, the SIO must recognise that the location of the death will be in most instances a 'workplace' and that there is a need to liase at an early stage with the Health and Safety Executive in accordance with the 'Work Related Deaths Protocol'

1.11 The challenge for the SIO is, therefore to conduct a thorough, professional and ethical investigation in order to discover the truth, on behalf of the Coroner, the family of the deceased, the health care professionals involved and the wider public.

1.12 Outlined in this chapter, is a model of best practice, which will assist the SIO in steering a course through the initial investigation and decision-making process. Subsequent sections expand on the model further describing in more detail the issues to consider at each stage.

2. THE MODEL

2.1 The model combines knowledge and experience of over 70 SIO's who attended a series of workshops in early 2002 to share their knowledge and experience of such enquiries in recent years. The model has also benefited from the input of the professional bodies representing every area of the health care community and professionals working within it.


INITIAL REPORT
ESTABLISH NATURE OF COMPLAINT
DISCUSS WITH CORONER
APPOINT APPROPRIATE INDEPENDENT EXPERT ADVISOR
ESTABLISH WRITTEN CONTRACT OF NO CONNECTION TO 'INDEX' TRUST OF KEY PERSONS
NEGOTIATE REPRESENTATION ON TRUST CMT.
JOINT MEDIA STRATEGY
CONSIDER-ESTABLISH CONTACT WITH: CHIEF EXECUTIVE OF TRUST, RISK MANAGER, GMC, GDC, NMC, HSE, CHI, NPSA OR OTHER AGENCIES AS APPROPRIATE
CONSIDER ESTABLISHING A 'GOLD' MANAGEMENT GROUP
FAST TRACK ACTIONS
EARLY ACCOUNTS FROM ALL INVOLVED:- SIO MAY CONSIDER PROVIDE LETTER OF EXPLANATION
PRESERVE SCENES:- PHOTO, VIDEO.
PATHOLOGY IF BODY IS AVAILABLE.
SEIZE ALL DOCUMENTATION & SECURE COMPUTER DATA
SEIZE OR PRESERVE ALL EQUIPMENT FOR EXPERT EXAMINATION
CONSIDERATION OF ECRI OR MDA
APPOINT FLO TO MANAGE EXPECTATIONS OF RELATIVES
CONSIDER DIRECT CONTACT WITH SIO
ALL MATERIAL FOR REVIEW BY INDEPENDENT EXPERT (S)
EXPECTED OUTCOME OF TREATMENT
ADVERSE INCIDENT – STAFF OR SYSTEMS AT FAULT – SHORT OF GROSS NEGLIGENCE
POSSIBLE GROSS NEGLIGENCE
POSSIBLE MURDER
NATURAL CAUSES
RESULT OF INTRINSICALLY 'RISKY' PROCEDURE THAT WAS NECESSARY AND PROPER
INFORM CORONER: REFER TO APPROPRIATE REGULATORY BODIES INFORM HEALTH TRUST AN D C.H.I & RELEVANT REGULATORY BODIES
FURTHER INVESTIGATION IN ACCORDANCE WITH M.I.M AND MIRSAP
CORONER INFORMED, NFA / INFORM RELATIVE TRUST
INFORM RELATIVES
SIO TO ENSURE RELATIVES AND APPROPRIATE BODIES MADE AWARE

3. INITIAL ACTION & CONSIDERATIONS

3.1 The investigation of questioned deaths in health care settings, fundamentally is no different to other deaths investigated by the Police, except for the particular contextual considerations that arise. The principles of the investigation remain the same, that of taking a logical problem solving approach that gathers and analyses all available information and intelligence, which allows the development and testing of hypotheses. This section deals with the initial action of the SIO in this particular sub set of investigations.

3.2 If the death is notified at a sufficiently early stage a conventional investigative approach in terms of crime scene management is possible. Typically however health care related deaths or more specifically the suspicions raised by them may not be reported for many days, months, and on occasion's years after the event. This removes the Forensic and Pathological opportunity provided by the body. In appropriate cases, however the SIO may consider exhumation if the issue turns upon drug toxicity. This consideration will require detailed discussions with the Coroner and Home Office Pathologist. Separate advice exists in respect of exhumation processes, available via the NCOF.

3.3 On receipt of the first report the SIO must consider all the usual fast track actions within the Murder Investigation Manual. Those of which apply more specifically in the health care setting are discussed in more detail below.

3.4 The SIO must at all stages of the investigation inform and discuss with the coroner issues which impact upon his/her areas of responsibility. In particular this is important should there be a need for autopsies and or exhumation.

3.5 The SIO should consider establishing early contact with the Chief Executive of the relevant trust, and the strategic health authority and the local 'Risk Manager' each will be readily identifiable on contacting the establishment concerned. If any difficulty is experienced the regional Department of Health representatives, whose details will be available via the Department of Health, should be consulted. Such people will be able to facilitate access to locations, documents, records and to people required during the investigation.

3.6 The commencement of a Police investigation is likely to be a difficult time for the trust who will have concerns regarding civil and criminal liability, the potential culpability of senior trust staff, civil litigation, and adverse media interest, for private hospitals the very existence of the business may be at stake. At the onset of a Police investigation the trust or appropriate body are likely to establish a crisis management team. The purpose of the CMT is to manage all of these concerns for the trust. Establishing early contact with the CMT and negotiating senior Police representation on the group will have long-term benefits for the enquiry.

3.7 Equally, consideration should be given to the formation of a Police 'gold' group or critical incident management team with appropriate representation from the trust or strategic health authority dependant on the nature and likely scale of the enquiry local concern and media interest should not be underestimated. A written constitution should be developed identifying the roles and responsibilities of the members of the group. All meetings must be minuted in

accordance with best practise and to service the requirements of the Criminal Procedure and Investigations Act 1996.

3.8 It is important that the SIO at all stages of the investigation into Health care related deaths consider the issue of corporate liability on the part of the health service providers. This will have implications for the composition of strategic groups formed to assist or oversee the investigation in addition to the nature and extent of information that the SIO will wish to share with individuals or corporate bodies.

3.9 An early media strategy must be negotiated in association with properly interested parties, it is important that a consistent message is given that both informs the public and minimises unnecessary concern. Members of the critical incident management team must all sign up to this approach.

3.10 The media strategy must also address the method by which additional complaints from or involving other Force areas should be dealt with. Where it is clear that other Forces may be approached it is important at an early stage that the SIO with relevant individuals in those other Forces, develop a strategy to deal with referrals.

3.11 The SIO should have regard to the ACPO Protocol on the notification and disclosure of information in respect of 'Managing Risks to Public Safety from Health Care & Teaching Professions' when deciding upon which agencies to notify of the investigation. The protocol is obtainable from the ACPO Intranet site..

3.12 In addition, the SIO should consider informing the following bodies and if appropriate invite them to join the investigation team or critical incident management team;

- Health and Safety Executive
- National Care Standards Commission
- The relevant Regulatory body, dependant upon the professionals involved (eg: The General Medical Council, The Nurses and Midwifes Association, The General Dental Council etc).
- National Patient Safety Agency (NPSA)
- Commission for Health Improvement (CHI)
- National Clinical Assessment Authority (NCAA)

The SIO will need to consider the extent of disclosure of information particularly if that material is sensitive in nature, to these organisations, since some are under an obligation to disclose the information further to other bodies or individuals including the person under suspicion and early understanding of the particular bodies responsibilities and practises in this regard will be important in developing an appropriate strategy.

3.13 The NCAA and CHI who conduct investigations into clinical practice and systems, and therefore have records of matters relating to individual clinical staff, have agreed to negotiate protocols allowing SIO's to examine their records in respect of individuals and establishments in appropriate circumstances.

3.14 If medical equipment is involved in the death, the SIO must inform the MDA (Medical Devices Agency), which has a responsibility to ensure the safety of medical equipment and issue warnings regarding problems that may impact across the health community. The MDA will also conduct examinations of medical equipment and give opinions as to operation and defects. In addition, an independent organisation exists, The Emergency Care Research Institute (ECRI), which will undertake examinations and will advise the SIO regarding equipment and systems issues.

3.15 As indicated earlier, this is a complex and difficult area to understand for most SIO's. It is important that the SIO gives consideration to engaging an 'operational expert advisor' to assist in focussing the enquiry. Investigations that have used such a person have found their advice crucial in directing the search for evidence and assisting in planning a strategy for interviewing health professionals. It is important that this expert is qualified and practicing in the relevant clinical area. In some cases more than one 'operational expert advisor' may be required. For example a senior nurse to advise on aspects of nursing care and a surgeon upon surgical procedures that may have been undertaken. Such assistance will incur financial costs, but in the long run it is likely to focus the investigation, leading to more rapid acquisition of relevant evidence

3.16 Operational expert advisors may be identified through the relevant professional colleges (i.e. Royal College of Surgeons, or Royal College of General Practitioners), however terms of reference and conditions will need to be negotiated with the individual concerned.

3.17 In the interests of the integrity and independence of the investigation, in each case it will be wise for the SIO to ensure that the 'operational expert advisor' has no association or contact, personal or professional with the health care professionals or the establishment concerned. This should be included in the written terms of reference, which the expert should be invited to sign.

3.18 In common with all Police investigations involving death, it is important that the family are professionally and sensitively dealt with. A family liaison Officer should be appointed. The family should be informed at all stages of the progress of the investigation, and be reassured that the investigation will be thorough, rigorous and independent. In addition it will be necessary to inform them at an early stage that the investigation may find that there is no criminal culpability, or that the death occurred in spite of all the proper care being provided. Unreal expectations should be minimised, and in this regard the SIO may consider it good practice to meet with the family to discuss the conduct of the investigation at the outset.

4. PHYSICAL & DOCUMENTARY EVIDENCE ACQUISITION

4.1 The SIO must endeavour to recover and preserve the scene for proper investigation at the earliest opportunity. However, common experience for many SIO's in health care related

investigations is the absence of a typical scene and often the absence of the body. This situation is a product of the nature of the death and the settings in which it takes place.

4.2 Deaths regularly occur in health care settings and in hospitals in particular. The usual medical routines of preparing a bed for the next patient, preparing treatment or operating rooms for the next case and removing the body from the 'scene' to the mortuary or preparing the deceased for viewing by relatives are all part of the normal hospital process.

4.3 The commencement of the Police enquiry will impose burdens and difficulties on the health care premises in question. Resources and facilities are in short supply and the loss of bed space, surgery, theatre or important equipment for any period of time could be resisted by individuals or the establishment. A good rapport with the governing body as described earlier should help facilitate access to all necessary areas and help manage any operational problems their loss will cause.

4.4 Ultimately it is the responsibility of the SIO to secure and preserve all relevant evidence as in the investigation into any death, although he/ she must consider the effect of allowing a location or equipment to continue in use if there is the potential of a risk to future patients. This decision will need to be discussed in particular with the MDA or ECRI.

4.5 The SIO should consider the use of both photographic or video services to capture evidence of the health environment. It has often enabled experts to later identify hazards or dangerous or inappropriate practices, based upon evidence of equipment, materials and drugs present in an area (or just as significantly missing from the area).

4.6 Advice from the operational expert advisor will assist the SIO to identify the documentation, medication, equipment and other materials necessary for seizure, recording or examination in situ. The advisor should also be able to assist in identifying 'normal' procedures and routines and thereby identify what to look for and where to look for it. The SIO should be aware that many different and separate official and unofficial records may exist in respect of patient care. The advisor will assist in this regard in identifying potential sources of remaining pathological samples, evidential documentation, or other records.

4.7 Bodies such as the MDA or ECRI will provide a service for the examination and testing of medical equipment. Many items of modern medical equipment store a vast amount of data which could prove vital to the enquiry. In much the same way a suspect would not be allowed to close down his computer during a search then consideration should be given as to whether medical staff present should be involved in securing the equipment involved.

4.8 It may be appropriate to involve the HSE at this early stage. Their area of Expertise will assist the SIO in identifying whether the working practices involved in the establishment are safe. They will be able to provide assistance in the safe examination of potentially dangerous equipment and

will benefit from early involvement should responsibility for the investigation eventually pass to them.

4.9 In short, in relation to the scene(s), the SIO should;

- Identify all relevant scenes and consider securing them based upon the time elapsed since the death, and the likely forensic yield against the impact upon the care of patients who need the facilities. An additional consideration will be whether it is safe for clinical procedures to continue until such time that the area and/or equipment are deemed safe.
- Photograph and preferably video the scene as found.
- If appropriate ensure a forensic examination of the scene with the caveats as above.
- If the body is available conduct a full forensic post mortem examination. If the body is buried, consider exhumation if appropriate and necessary.
- Locate and recover all pathological and toxilogical samples which remain including blood and urine for later analysis.
- Where medical equipment is involved, secure it and ensure that it is examined by MDA and if appropriate ECRI.
- Gather all documentary and computer records relating to the care of the patient(s). Remembering that there are a number of informal and local records that will depend on local practices. Ensure that appropriate advice is taken to maximise the acquisition of this important data. The SIO should be aware that many sources of clinical, care records and management minutes including review documents exist, he/she must ensure that all records are acquired, this will often require consultation with independent operational expert advisors.
- Gather all available witness evidence bearing in mind the vulnerability of some of the complainants who may be relatives.

5. ACCOUNTS OF HEALTH CARE PROFESSIONALS

5.1 Many investigations in respect of health care related deaths in the past have become overly protracted as a result of the perceived sensitivities around obtaining accounts from the professionals involved. This can also be combined with an understandable lack of knowledge of systems and procedures on the part of the Police along with suspicion and mistrust from health workers as to the motives of the Police involvement.

5.2 The SIO must be mindful of the fact that the health care workers may face disciplinary action for even minor breaches of rules including the failure to act or report concerns. Understanding this and the loyalties and the hierarchical structure of the nursing and medical profession in particular will aide the formulation of an appropriate strategy.

5.3 Without early accounts the SIO cannot hope to determine within a reasonable time frame whether continued Police involvement is necessary. The SIO must therefore as expeditiously as possible obtain from the health care professionals involved an account of their involvement and observations of the treatment of the patient(s) concerned.

5.4 In the absence of a clear indication of a crime it is appropriate to take first account statements from all those involved. This need not be under caution or at a Police station unless a clear suspicion of criminal liability exists.

5.5 Most health professionals will refer to their professional body or a medical defence organisation upon becoming aware of the Police investigation and before agreeing to speak. A letter of introduction and explanation from the SIO indicating the purpose of the enquiry and how it is proposed that it will be conducted may help evidence gathering teams establish a better early rapport, with the health care professionals, and facilitate a more open account. The defence unions state that they are better placed to advise their members if such early 'disclosure' is given, and in many cases will advise their clients to provide a full and open account. Clearly the SIO will have to balance the need to withhold information against the need and desire to obtain the fullest early accounts possible. An example of such a letter of explanation is attached at Appendix A.

5.6 The venue for conducting interviews and the taking of statements must also be considered. Use of Police premises may be intimidating and a bar to effective communication. Experience has also shown that use of health care premises can inhibit the process. This occurs when colleagues of witnesses become aware of the time an individual spends with the investigating Officers, drawing unjustified inferences. The SIO should also be mindful of the potential pressures exerted by the presence of senior medical staff and the close team and professional bonds, which form. It may therefore by helpful to arrange to conduct the interviews away from the workplace, either at home of the person concerned, or a neutral location.

5.7 The SIO will need to consider making a video record of the interview in accordance with Murder Investigation Manual advice regarding significant witness interviews.

5.8 If an operational expert advisor has been engaged, then they will be able to advise on the relevant areas to be covered in interviews and will be able to review the records of interviews/statements to ensure that all relevant issues have been covered.

5.9 Should interviews under caution or following arrest be appropriate, then use of an independent expert in formulating interview strategy and to assist in monitoring the interview will be helpful. This approach will provide the SIO with a real time assessment of the circumstances and evidence presenting, possibly removing the need to send transcripts off for an expert opinion. An added benefit is the ability to challenge or probe further at this stage considerably reducing the timescale of the evidence gathering stage.

6. ASSESSMENT / DECISION

6.1 Once an initial evidence gathering process is complete, in that all available Forensic, Physical and account evidence has been acquired an assessment of the further progress of the investigation is necessary.

6.2 The SIO cannot be expected to make decisions on the progress of the investigation without a full assessment of the evidence by an independent health care professional with the relevant expertise. Appropriate, independent expert opinion is very important. The SIO needs unambiguous guidance and interpretation of the circumstances uncovered. The family demand a thorough and impartial investigation of the cause of death of their loved one. Thereby removing any suggestion of institutional 'cover up'. Health care professionals and governing bodies and the public at large deserve and expect a fair assessment of the cause of death without unnecessarily undermining the provision of health services locally.

6.3 It is therefore advised that at this stage, the SIO seeks to deliver all relevant evidence to an appropriate independent and validated expert. The identification of such an expert is problematic, work is continuing on a national level to improve the validation of experts through the Council for the Registration for Forensic Practitioners and the Forensic Science Society and the NCOF. The expert that examines material gathered should be different to the operation expert advisor in order to ensure complete integrity and impartiality to the investigation and the assessment of evidence.

6.4 The choice of expert or agencies to use in assisting the Police investigation has been the cause of difficulty to enquiries in the past.

6.5 Selecting the 'wrong' expert can seriously mislead an investigation and expose the case to unnecessary criticism or weaknesses at a later stage.

6.6 Several agencies offer to provide experts. A degree of caution is required when using such agencies, to ensure that the 'expert' identified by the agency has the appropriate validated skills and experience to provide a proper assessment of the evidence in that particular field.

6.7 It is important for the SIO to consider and assess whether the expert has proper expertise in the relevant areas, what are their qualifications, how up to date are they. What is their experience in court and what is their professional standing ?

6.8 It is recommended that where a health care professional is required the best advice is that the SIO contact the NCOF to discuss with them his/her needs.

6.9 It is important that the SIO is involved in the evidential assessment process and he/she should seek to meet with the expert possibly in company with the operational expert if one has been utilised. The meeting, which must be minuted, should discuss the evidence acquired and the inferences that can be properly drawn.

6.10 Several outcomes may be apparent following the expert examination of the evidential material;

- The death may be rightly considered an expected outcome of the individual's illness or a reflection of the very real risk associated with some medical conditions and their treatment. Such a conclusion will point to an indication of death by natural causes. The evidence supporting this should be presented to the Coroner.

- The evidence may indicate that the death was a result of what is described as an 'adverse clinical event'. This could be as a result of an equipment failure, an inappropriate system of working or by genuine error by a health care professional, but which falls short of any test for gross negligence. Again the case papers would be passed to the Coroner and consideration given to liaison with agencies such as the HSE who may consider prosecution and the appropriate regulatory bodies such as the GMC, GDC or NMC who will consider disciplinary action and ultimately the continued professional registration of the individuals involved.

- The third outcome that the evidence may show is that an act or omission amounts to gross negligence sufficient to support a suspicion of involuntary manslaughter, or on rare occasions the evidence may suggest voluntary manslaughter or even murder. Clearly in these circumstances investigation will continue in accordance with MIRSAP and the Murder Investigation Manual.

6.11 The decision as to future course or conclusion of the investigation lies at all times with the SIO, based upon the advice his/her expert advisors have provided. In order to assist in that decision process early consultation with the Crown Prosecution Service may be appropriate and helpful.

6.12 Whichever outcome is identified, clear communication with all parties, the Coroner, the health care body and the family is paramount.

6.13 Again there may be a need to carefully manage the investigation through this stage and onwards dependant upon the outcome by way of a critical incident management team with a clear and consistent media strategy.

7. FURTHER INVESTIGATION

7.1 If it is determined that a potential case of murder or gross negligence is identified then the investigation takes a more familiar route. In accordance with the principles of MIRSAP and the best practise in the Murder Investigation Manual a full investigation must now be concluded.

7.2 The adoption of the best practise outlined earlier in the chapter should be continued and will facilitate an effective enquiry.

7.3 The co-operation of the health care body is still crucial even though at this stage relations with managers and health care staff may become difficult. Consideration will need to be given to a review of the membership of any critical incident management team dependant upon suspicions of personal or corporate liabilities.

7.4 Operational expert advice will continue to be important particularly as indicated earlier in the interview of medical staff with high levels of expert, procedural and technical knowledge in their own fields.

7.5 Media management will be a sensitive area determined by the scope and topicality of the matter under investigation.

7.6 Good communication with the family must be maintained. This is especially important given the complexities involved in gross negligence cases.

7.7 Most CPS branch offices do not have the expertise to deal with such cases. It is recommended therefore that early agreement be reached for the case papers to be handled by special caseworkers with experience of health care prosecutions

7.8 Finally, the reader will recognise the need for further work in this area. That work is ongoing, in particular, a memorandum of understanding is being developed between, the Police Service, Department of Health, and the HSE. This work is focused upon protocols to assist healthcare professionals to identify incidents that should be reported to the Police, how to secure evidence, and structures to facilitate effective working together of the various agencies to ensure an effective and expeditious investigation.