



*Protecting the breathing
circuit in anaesthesia*

**Report to the Chief Medical Officer
of an Expert Group on blocked anaesthetic tubing**

May 2004

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Foreword

In 2002 I set up an Expert Group on blocked anaesthetic tubing following the conclusion of Operation Orcadian, a linked police investigation into similar cases where tubing had become blocked. In two of the cases patients tragically died. I was keen to ensure that there was a full scrutiny of the cases from a health service perspective. The remit of the Expert Group was to examine these incidents further and to establish whether there were any lessons for the NHS to learn. The outcome of this work and the recommendations are set out in this report.

The Expert Group has carefully considered technical issues relating to equipment and other items which are the causes of the blockages; behavioural factors; investigating and learning from adverse incidents; and security. It has made some very practical and achievable recommendations that I believe will significantly help to improve patient safety.

In particular, I am pleased that by working closely with the Association of Anaesthetists and Royal College of Anaesthetists the Expert Group was able to contribute to the revision and strengthening of the Association of Anaesthetists' guidelines. I was happy to endorse this publication when it was launched in January 2004.

I am also pleased that the Expert Group has recognised the importance of safety alerts. The Department of Health, the National Patient Safety Agency, NHS Estates and the Medicines and Healthcare products Regulatory Agency have been working together to develop the means of sending important safety and device alerts to the NHS in a more consistent and streamlined way by email. Our Safety Alert Broadcast System, introduced this year, aims to do this. With a simple web-based feedback form to confirm that action has been taken in response to each alert, the system will provide an easily accessible source of data for NHS organisations to help assure themselves that they are managing important safety issues effectively.

I should very much like to thank Professor Kent Woods and members of the Expert Group for their work. I welcome this report and accept those recommendations aimed at the Department of Health, on its behalf. I strongly commend the other recommendations to the National Patient Safety Agency, the Medicines and Healthcare products Regulatory Agency, the Royal College of Anaesthetists and NHS Trusts.



SIR LIAM DONALDSON
CHIEF MEDICAL OFFICER

Acknowledgements

I would like to thank all members of the Expert Group for their support and helpful comments in preparing this report and the Association of Anaesthetists of Great Britain and Ireland for allowing the Expert Group to contribute to the revision of its guidance, *Checking Anaesthetic Equipment*. My thanks are also due to the secretariat for their help in the completion of the report.

The Expert Group was greatly assisted by the thoroughness of the police work in Operation Orcadian and the clarity with which it was documented.

Finally I would also like to record my gratitude to John Broughton, Assistant Chief Constable, Essex Police and Gina Radford, Regional Director of Public Health, East of England for taking the time to ensure the report was factually accurate with regard to the events leading up to, and during, Operation Orcadian.

PROFESSOR KENT WOODS

Chapter 1: Introduction

1.1 Operation Orcadian was set up as a linked police investigation in August 2001 following a number of incidents in different hospitals in which an anaesthetic breathing circuit became blocked by impaction of a small plastic object within it. The effect in each case was to obstruct the flow of oxygen to the patient. One patient died in the operating theatre and several other potential fatal tragedies were narrowly averted. Operation Orcadian was one of the largest linked police enquiries undertaken, bringing together nine police forces investigating thirteen reported incidents.

1.2 After extensive investigation, it was concluded that none of these incidents could be conclusively attributed to a deliberate act. However, much was learned of the contributing factors which had allowed them to happen. For the safety of future patients, it is essential that this knowledge is fully applied. When Operation Orcadian ended, the Chief Medical Officer, Sir Liam Donaldson, set up an Expert Group to take forward that process.

1.3 The Expert Group was given the following terms of reference:

- to examine the “Operation Orcadian” incidents which occurred in the NHS, to determine the causality in each case and whether there are any residual concerns;
- to examine what lessons can be learned for the NHS as a whole; and
- to make recommendations to the Chief Medical Officer on improvements which should be made within the NHS.

The membership is listed in Appendix 1. The Expert Group met on five occasions between January and October 2003.

1.4 This report presents the conclusions and recommendations of the Expert Group. In considering the large amount of evidence available to us from Operation Orcadian, we have considered four broad areas:

- issues relating to the design of anaesthetic equipment, considering specifically the components which contributed to the incidents under review;
- behavioural issues, encompassing the definition and dissemination of safe practice in anaesthesia and its reinforcement by training;
- efficient working relationships between agencies (NHS and other) in investigating and acting on adverse incidents affecting patients; and
- security; although deliberate tampering was not conclusively shown to have occurred in any of the Orcadian incidents, it was initially suspected and the NHS should seek to learn lessons pre-emptively from other industries where it has occurred.

1.5 Improving patient safety has been a high priority for the NHS in recent years. There has been increasing recognition internationally of the scale of potentially avoidable mortality and morbidity arising from adverse events in healthcare. *An Organisation with a Memory* (1) reviewed the topic from an NHS perspective and set out a strategy to improve the reporting of incidents, their systematic analysis and the correction of contributing factors. Health services can learn a great deal from the experience gained in other industries where complex tasks must be carried out repeatedly and the consequences of error are

severe. It is now recognised that most adverse outcomes occur because of multiple “system failures” which individually may be inconsequential but which collectively allow the adverse event to happen. It follows that prevention rests on a full understanding of the components of system failure and corrective action aimed at multiple points. We have adopted this approach in our analysis of the Orcadian incidents.

- 1.6 Solutions based on improved equipment design can be more effective than those aimed at changing human behaviour, though in practice the two are interdependent. Design changes can themselves give rise to unanticipated hazards if not carefully thought through. In Chapter 3 we consider the technical issues relating to patient breathing circuits (PBCs) and to the range of medical equipment which was the source of the small objects causing blockage. We recommend modifications to the design and packaging of critical components which would greatly reduce the risk of blockages occurring and allow rapid detection should it occur.
- 1.7 Human factors are considered in Chapter 4. Much valuable work has been done in recent years by the Association of Anaesthetists of Great Britain and Ireland (AAGBI) to develop a checklist for equipment used by anaesthetists, and by the Royal College of Anaesthetists to incorporate safe practice into training and assessment. The Expert Group has worked with both bodies to ensure that lessons learned from the Orcadian incidents are disseminated effectively as revised guidance. In considering professional roles and responsibilities in anaesthesia, we have also benefited from the participation of the Association of Operating Department Practitioners.
- 1.8 Operation Orcadian was a police enquiry, having its origin in a referral from the Coroner. However, several other agencies also had a role in the investigation of the incidents: the Health and Safety Executive (HSE), the (former) Department of Health Eastern Regional Office (ERO), the Medical Devices Agency (MDA) (now part of the Medicines and Healthcare products Regulatory Agency (MHRA)), the Commission for Health Improvement (CHI). There have been substantial recent changes in the management structure of the NHS (*Shifting the Balance of Power*) (2) and through the establishment of new NHS bodies (National Patient Safety Agency (NPSA), National Institute for Clinical Excellence (NICE), and from April 2004, the Healthcare Commission with a remit to improve quality of care). The role of the Coroner is under active review and wide-ranging proposals for reform are being developed. The Expert Group therefore considered how these agencies could most effectively share their responsibilities in investigating adverse events in the NHS. It is beyond our remit to make recommendations, since many of the complexities are being addressed elsewhere. However, we draw attention (as our remit requires) to the lessons to be learned from Operation Orcadian in this regard. We also refer to the other fora in which relevant discussions are now taking place.
- 1.9 The Orcadian enquiry illustrates why the initiatives set out in *An Organisation with a Memory* are so timely and necessary. With hindsight there had been a number of incidents similar to the one which ultimately caused the tragic and untimely death of a 9 year old boy, Tony Clowes. Because they did not all have a fatal outcome, the signals they gave of the existence of this particular hazard were not analysed and acted on effectively to prevent recurrence elsewhere. It is essential that the NHS implements the means to learn from near misses. Progress towards this goal has been achieved, as described in *Building a Safer NHS for Patients* (3), but it has an urgency and importance far beyond anaesthesia – which as a specialty has been at the forefront in developing safe systems of practice (4).

Chapter 2: Background

Operation Orcadian

- 2.1 Operation Orcadian was the linked police investigation of thirteen incidents involving blocked anaesthetic tubing in hospitals in England and the Isle of Man. Eleven of these incidents occurred in NHS hospitals.
- 2.2 Nine police forces took part, making this one of the largest linked investigations undertaken in the UK. Evidence and intelligence gathered by each police investigation was shared and examined in order to identify possible connections between the incidents. Each investigation continued to be conducted by the force in the area in which the incident(s) took place and the respective Chief Constable was fully accountable for this work. The Assistant Chief Constable of Essex Police was nominated to the role of Lead Chief Officer and was responsible for linking the investigations.

Events investigated as part of Operation Orcadian

- 2.3 The incident which led to the setting up of Operation Orcadian was the death of a patient at Broomfield Hospital, Chelmsford, in July 2001. Tony Clowes was due to undergo surgery for an injury to one of his fingers. Induction of general anaesthesia was followed by an inability to ventilate the child. The problem was eventually discovered to be a disposable protective cap from an intravenous (IV) giving set blocking the angle connector in the PBC (Fig 1). However this was discovered too late and the patient died. The death was reported to the Coroner.

Figure 1



- 2.4 Staff in the ERO had earlier set up a Serious Untoward Incident database and informed the police of a similarity between the Broomfield incident and an event which had occurred at Watford Hospital in April 2001. On that occasion, a cap from the non-writing end of a ball point pen was found to be blocking a catheter mount in the PBC (Fig 2). The patient suffered no harm.

Figure 2



- 2.5 The MDA, which had investigated the Watford incident, informed Essex Police that the problem was unlikely to be related to a manufacturing problem as the cap and PBC were from different manufacturers and there was no commonality in the manufacturing process that could give rise to this occurrence. MDA also had a report on a further incident at the Royal Bournemouth Hospital where a cap from an IV extension set was found blocking an angle connector (Fig 3). Again, the patient suffered no harm.

Figure 3



- 2.6 In August 2001, similar incidents occurred at Basildon Hospital. Problems were experienced in ventilating two patients when they were connected to the PBC. In the first case, the patient was moved into theatre and no further problems were encountered. In the second case, the PBC components were changed and the patient was then successfully anaesthetised. Examination of the PBC in this case led to the discovery of a disposable protective cap from an IV wide bore extension line in the tubing connector (a “straight T adapter”)(Figs 4a, 4b). These incidents came to the attention of Essex police who decided to investigate the Basildon and Broomfield incidents together.

Figure 4a

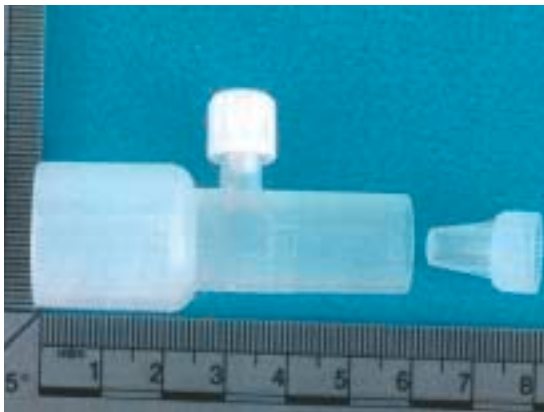


Figure 4b



- 2.7 A press conference was held by the Assistant Chief Constable of Essex Police and the ERO Regional Director of Public Health following the death of Tony Clowes. This attracted wide media interest and drew attention to the similarities of the events described here. A meeting with senior police officers in the relevant forces was arranged in August 2001 and it was agreed that a linked investigation should be established.
- 2.8 Following a police seminar in October 2001, and a trawl of the other Regional Directors of Public Health and the Chief Medical Officers of the other UK Countries by the ERO Regional Director of Public Health, seven further incidents which had occurred between 1985 and 1994 were identified and added to the linked investigation. One of these had resulted in anoxic brain damage; the patient died some years later without having regained consciousness. In other cases the problem had been identified without the patient suffering any apparent harm, though in one incident a partial occlusion of the PBC had persisted for several hours until it was detected following a hospital transfer.
- 2.9 Further details of the incidents in NHS hospitals which were included in Operation Orcadian are provided at Appendix 2.

Police investigation

- 2.10 The consensus of opinion among the police forces initially involved was that the incidents had occurred as a result of criminal acts. The concern was that deliberate acts of sabotage or malicious tampering were being carried out by the same person/people in different hospitals.
- 2.11 As part of the linked investigation a Central Research and Co-ordination Group was set up, in August 2001, to co-ordinate the locally managed investigations. A joint statement of intent was drawn up between the various parties involved: police; HSE; NHS; MDA; ERO; Forensic Science Service; and ECRI (previously the Emergency Care Research Institute). The National Crime Faculty provided current and historic information about hospital related incidents. They also assisted with their specialist

knowledge of serious and serial offenders, including all aspects of offender and psychological profiling. Independent specialist advice was provided by ECRI.

- 2.12 Investigations continued in order to establish a likely cause and to exclude the possibility that the incidents were caused by poor practice or systems failure.
- 2.13 The investigators noted that whilst the PBC and its components were recommended by manufacturers for single use, in some hospitals it was the practice for certain components of the PBC to be re-used after cleaning. The filter was the only component of the PBC that was consistently replaced for each patient procedure. However, it was concluded at an early stage of the investigation that re-use of items was not a significant contributory factor. Guidance on the re-use of equipment has been issued by the MDA (5) and by AAGBI (6).
- 2.14 A further point noted by the police was the ad hoc storage of component parts in various locations throughout the operating theatre environment and the presence of other items that were discarded during operating procedures, for example, discarded disposable protective caps of IV sets “flicked” onto work surfaces, trays or storage areas. Instances of bad practice were identified (such as carrying PBC components in a pocket prior to use) which created risk of blockage by small objects.

Simulation of tubing blockages

- 2.15 In November 2001, at a device manufacturer’s site in Hatfield, simulation tests were carried out with an anaesthetic machine and ventilator, using various assemblies of PBCs. The main reason for this was to familiarise police investigators with the functions of the ventilator, both in normal use and also with blocked PBCs.
- 2.16 During the course of these tests the police decided to try to reproduce the blockages that had occurred. Storage methods were replicated and various experiments undertaken. IV caps were placed with angle connectors in a tray which was then shaken. As the numbers of angle connectors and caps in the tray were increased, a cap was observed to have blocked an angle connector.
- 2.17 This result was unexpected and was a significant turning point for the investigation. The police concluded that despite the storage conditions having been exaggerated for the simulation experiment, accidental blockage could no longer be excluded from the investigation.
- 2.18 A suitable scientific system to replicate anaesthetic room storage was sought. At the Forensic Science Service laboratory at Huntingdon in January 2002, various storage arrangements were set up with an increasing number of caps and angle pieces. These were shaken, replicating the movement of drawers and trays. The blockages occurred again with caps entering and settling securely in angle connectors.
- 2.19 In the light of the simulation tests, and the information gathered by investigators, the balance of the investigation swung from the likelihood of criminal acts to systems failure in either the manufacture, storage or use of components. However, investigations continued to ensure that all lines of enquiry were completed and every effort was made by the police to prove or disprove deliberate acts or individual or corporate negligence.

Conclusions of the Orcadian enquiry

- 2.20 In July 2002 the police concluded that there was no evidence of a criminal offence having been committed by a single offender or several offenders. The linked police investigation was therefore closed.
- 2.21 The outcome of Operation Orcadian was provided to the constituent forces who determined what further action, if any, to take in resolving their local investigations. All police investigations in NHS hospitals are now closed as either “no crime” or “not detected”.
- 2.22 The HSE and NHS were formally advised of the police decision to close Operation Orcadian. The Chief Medical Officer set up the Expert Group to examine the incidents to establish what lessons the NHS might learn. The HSE have carried out an investigation into breaches of Health and Safety legislation and the papers are being considered by their legal advisers.

Additional UK cases reported as a result of Operation Orcadian

- 2.23 Two hundred and twenty seven further anaesthetic related incidents were reported to the police as a result of the publicity generated by Operation Orcadian and at the request of the Chief Medical Officer. They represented a diverse mix of incidents and many were investigated locally. The NPSA was asked to review these incidents to see whether there were any further lessons to be learnt.
- 2.24 The NPSA endeavoured to:
- categorise incidents of a similar nature; and
 - develop themes for further consideration, offering likely reasons for the occlusions where possible.
- 2.25 The first had occurred in 1956 and the last in 2002. The information available was often very limited and it was only possible to categorise 85 (37%) of the incidents. For the remaining cases the details given were either inadequate or not related to blocked anaesthetic tubing. Themes were developed using the 85 analysable incidents.
- 2.26 From the reported incidents, narrative categories were created. Within each category common themes were identified and developed and, where possible, a brief explanation was also offered as to the likely cause of the occlusion.
- 2.27 The incidents fell into one of three categories:
- “soft” anaesthetic related – concerned with occlusions within the anaesthetic circuit (catheter mount, valve, mask, connector and endotracheal (ET) tube);
 - “hard” anaesthetic related – concerned with problems in the anaesthetic machine and other supporting equipment (used as part of the anaesthetic process); and
 - other – concerned with malicious or reckless conduct and rule violation.

“Soft” incidents

- 2.28 This group contained 52 (61%) of the 85 incidents reviewed and was the largest category.
- 2.29 In 41 of the 52 incidents, foreign bodies in anaesthetic breathing circuits were the cause of blockage which most commonly occurred at the catheter mount. Instances of obstruction in connectors, masks, valves, ET tubes and elsewhere in the breathing circuit were also reported. The identified foreign bodies included disposable protective caps from IV giving sets, bungs from arterial blood gas sampling syringes, breathing filter caps, small pieces of rubber or sticky tape. In addition, there were four reports of obstruction due to manufacturing faults in which the internal section of hollow components had not been removed.

“Hard” incidents

- 2.30 The “hard” incidents category, five (6%) from a total of 85 incidents reviewed, was the smallest category of reported incidents. None was due to a foreign body. Lapses with set-up checks of system controls and deviations from policies and procedures were recurrent themes.

Other incidents

- 2.31 A third of the incidents (n=28) were in the “other” category, in which the majority were alleged instances of rule violation, tampering or other deliberate acts including malicious conduct. Because of the lack of detail available, and the often long lapse of time since the incidents took place, it was not possible to draw useful inferences from these data.
- 2.32 The NPSA from its data and from liaison with other relevant organisations identified in particular the following themes for the Expert Group to consider:
- storage and wrapping / packaging of single-use devices;
 - raising the issue of present specifications for IV administration sets with the British Standards Institute (BSI); and
 - implementing design changes so that disposable protective caps are tethered to the device and cannot become detached.

International experience of blocked anaesthetic tubes

- 2.33 The NPSA agreed to establish links with international agencies to establish whether they had records of adverse events involving blocked anaesthetic tubes and, if so, whether these had been analysed and preventive measures identified.
- 2.34 In the United States, the Joint Commission on Accreditation of Healthcare Organisations had issued a Sentinel Event Alert in February 2002 which reviewed 23 reports of deaths relating to long-term ventilation. However, none of these related to blocked tubes; the causal factors included malfunction or misuse of alarms, tube disconnections and dislodged airways.
- 2.35 The Australian Patient Safety Foundation searched a database of 8,088 anaesthetic incidents recorded in Australia and New Zealand since 1984. Of 39 incidents retrieved using the search terms (tub* and

block*), the predominant concern of those making the reports were with extrinsic compression of soft tubing during anaesthesia. No information on blockage by extraneous foreign bodies was retrieved.

- 2.36 The American Society of Anesthesiology Closed Claims Project examined all closed claims files of 35 US professional liability insurance companies relating to adverse anaesthetic outcomes associated with the use of gas delivery devices (anaesthetic machine, breathing circuit, supplemental oxygen delivery tubing, gas supply tank or line, vaporizer, or mechanical ventilator) (7). These comprised 72 of 3,791 anaesthetic claims (excluding claims for dental damage) dating from 1961 to 1994. The PBC was the most common source of injury (39%) and equipment misuse was three times more common than equipment failure. “Misuse” was defined as human fault or error associated with the preparation, maintenance or deployment of a medical device. However, no instances of obstruction by a foreign body were reported.

Conclusions

- 2.37 In considering the case series generated by Operation Orcadian and by subsequent publicity and requests for reports, the Expert Group drew the following conclusions on the frequency of blocked anaesthetic tubes:
- The apparent clustering of cases in time and place, although initially suggestive of linked malicious acts, was plausibly attributed to chance and to reporting bias in the identification of similar incidents in the absence of any evidence of tampering.
 - The number of similar incidents over several decades, retrospectively identified, suggests that many such events went unrecorded. This is particularly likely for quickly recognised or near miss events where no clinical harm ensued, but it cannot be excluded that some adverse outcomes were not ascertained (either because the cause was not correctly identified at the time or because reports were subsequently lost).
 - It is impossible to estimate the true frequency of anaesthetic tube blockage by extraneous small objects. Though it is certainly very low in relation to the several million anaesthetics administered every year, the clinical consequences can be disastrous. However, the incidents examined in the Orcadian investigation and subsequently have shown certain common features which open the way to preventive strategies. These are discussed in later chapters of this report.
 - It is unlikely that the absence of information from other healthcare systems throughout the world is due to the absence of incidents. The structure of the NHS can facilitate the sharing of information on adverse incidents, though mechanisms for recording, analysing and acting on reports have been inadequate. A strategy to remedy the deficiencies was set out in *An Organisation with a Memory* and is now being implemented.

Chapter 3: Analysis of causal factors

- 3.1 The critical incidents described in Chapter 2 had as their final common path the obstruction of a narrow section of the PBC by a foreign body having the same external diameter as the internal diameter of the PBC component. The blocked component, and the blocking object, were not the same in all cases. Nor was the clinical outcome the same in each case, depending on the time taken to recognise the problem and success of recovery action then instituted.
- 3.2 This chapter reviews the causal sequence to identify the latent conditions and the active failures which together resulted in the death of one patient and irreversible brain injury in another. Such an analysis is an essential step towards recommending modifications to equipment and practice which will insert multiple layers of safety into the causal pathway. No single intervention can of itself ensure that there will be no repetition of these tragedies. What is required is a multi-layered defence which is robust under all conditions and circumstances of anaesthetic practice.
- 3.3 The key factors are:
- the occluding object coming into contact with a part of the PBC;
 - a component of the PBC which by reason of its internal diameter is liable to become obstructed;
 - failure of detection of the blocked component when the PBC is assembled or later when the PBC is used;
 - failure to identify the blockage as the cause of inability to ventilate the patient, either:
 - because a block of the PBC is not suspected, or
 - if suspected, is not correctly identified;
 - failure to supply oxygen to the patient by completely independent alternative means, e.g. self-inflating bag and mask directly applied to the airways, while the underlying cause of the problem is being sought.

These are considered separately below.

The occluding object

- 3.4 Of necessity, the item causing the blockage will be of a critical size – close to the internal diameter of the item being blocked. In the great majority of the cases examined, the foreign body causing blockage was found to be a plastic disposable protective cap from one of many different types of clinical equipment such as an IV giving set, extension line or syringe. The external shape and diameter are not important for their function, but by chance are often close to the internal shape and diameter of the narrower PBC components such as angle pieces and catheter mounts. Every time a patient has an IV cannula inserted, or an IV infusion put up, one or more plastic caps is likely to be discarded. Although it is usual practice to dispose of them into a waste bin or bag, this is only possible when the bin or bag is within arm's length of the operator. The caps therefore often are discarded on work surfaces, on the floor, into drawers or coat pockets where they can remain for some time.

- 3.5 The quantity of discarded plastic caps will number millions per year and they are therefore almost ubiquitous environmental contaminants in clinical areas such as wards and anaesthetic rooms.
- 3.6 Some capped disposables (e.g. certain makes of IV cannula) have the cap attached to them by a short plastic tether which allows the cap to be removed without detaching it from the device. Such a design is not always feasible without increasing the complexity and cost of manufacturing what is often a cheap, high-volume disposable item. To require caps on all medical devices to be tethered would entail the re-design of a large number of individual items and re-tooling of production facilities. We also have to recognise the world-wide nature of the medical devices industry and that it may both be difficult and take some considerable time for this to be carried forward since, at best, this can only be a general recommendation.
- 3.7 The Expert Group considered whether the outer diameter or shape of plastic caps could be modified to prevent blocking. For example, oval or lobed caps would not form an airtight internal seal if they entered the PBC. However, they would still be likely to impact at some point to create a partial blockage. This might actually be harder to identify than a complete blockage, since the persistence of some gas flow at increased resistance would simulate a clinical problem such as bronchospasm while still carrying the risk of hypoxia and inappropriate potentially harmful treatment.
- 3.8 Any design modification to disposable caps would have to be implemented throughout the (multi-national) industry to give security. This approach would not prevent risks posed by other small objects such as the pen top (Watford incident), bungs from arterial blood gas sampling syringes, breathing filter caps or pieces of rubber or tape (NPSA reports).
- 3.9 Trusts should consider design safety in their purchasing decisions. Guidance is provided in the Medical Devices Controls Assurance Standard (www.casu.org.uk/standards/docs/medicaldevices). In this context, preference should be given to disposable devices (e.g. IV cannulae) which will not generate environmental contamination by detachable small components in routine use.
- 3.10 Additionally, attention should be given to routine cleaning of the clinical environment to remove waste such as plastic caps. Mesh storage baskets rather than bins would help to prevent small discarded items accumulating. However, it is recognised that such steps could only reduce and not of themselves eliminate the risk posed by small waste items.

The vulnerable PBC component

- 3.11 In all the Orcadian incidents, the blocked component was some form of angle connector or catheter mount. These are the narrowest part of the PBC. In the additional cases classified by the NPSA, there were some reports of other components being blocked (e.g. ET tube, face mask or laryngeal mask) but details are scant and it is likely that these blockages were quickly identified.
- 3.12 The Expert Group considered whether any design modification of the PBC could reduce the risk of blockage. Although possible solutions could be devised (e.g. internal dividers), they were not thought feasible in the high-volume production of disposable plastic items. Their greater complexity could give scope for manufacturing faults and failures in use.
- 3.13 Consideration was given to whether the internal diameter of these vulnerable components could be increased. Members pointed out that any small object entering the PBC would nevertheless be likely to become impacted at the narrowest part of the system, e.g. the ET tube or in the patient's bronchial tree, with potentially serious consequences.

- 3.14 Given the diversity of the objects which have caused blockage, a more effective preventive measure would be to protect narrow-bore PBC components such as angle pieces and catheter mounts by keeping them wrapped until use. This is a separate issue from that of single-use or re-usable components, which concerns the level of cleanliness/sterility required and the physical deterioration which might occur on repeated use. In principle, items could be cleaned for re-use and wrapped before distribution. The key point is that vulnerable PBC items should not be exposed unwrapped in a pocket, kidney dish or storage box. In only one Orcadian incident (Watford) had the blocked component been taken from a sealed pack. Here the blockage was caused by a pen top. It remains unclear when the top entered the catheter mount, which was thought to have been left unwrapped for a brief period of time. Although, as indicated in paragraph 2.5 a manufacturing problem was ruled out, contamination at the manufacturing plant could not be excluded, since that make of pen was marketed in the country where the catheter mount was manufactured as well as in the UK.
- 3.15 Many clinical disposable items are supplied in sealed packs to ensure sterility. There are no substantial manufacturing obstacles to supplying PBC components individually wrapped, and at least one manufacturer now does so. This would prevent both accidental blockage (as reproduced in the simulation experiments) and deliberate tampering. Good clinical practice could be reinforced by a package label stating that the component should be kept wrapped until use. This should be taken into consideration when purchasing decisions are taken by Trusts.
- 3.16 Safety considerations in equipment purchasing and the Medical Devices Controls Assurance Standard have been referred to above (3.9). Breathing system components should be preferentially sourced from suppliers able to offer individual sealed packs with appropriate labelling.

Detection of a blocked component prior to use

- 3.17 Two factors could have prevented a clinical complication arising from the obstruction of a PBC component. Firstly, visual inspection during assembly of the PBC and immediately before use might have revealed the presence of the foreign body. Secondly, functional testing of the circuit before use would have shown it to be blocked. Why did these active failures occur?
- 3.18 Visual inspection was made more difficult in many instances by the fact that the obstructing object was colourless, and/or the blocked plastic component was not fully transparent (Fig. 3). Both of these are remediable by design. Plastic caps on IV disposables can, ideally, be highly coloured in manufacture. Where possible all breathing circuit components should be made of fully transparent plastic – as indeed many already are.
- 3.19 Transparency alone does not ensure that an obstruction will be detected before the component is used (Fig. 2). It was also noted that rare instances have been recorded of manufacturing faults leaving a residual “membrane” inside a hollow component, causing complete obstruction which is unlikely to be visible (8). A simple functional test of patency provides an added safeguard. Recommendations on routine checking procedures are made in Chapter 4.

Effective recovery strategies

- 3.20 Correct diagnosis of a blocked breathing circuit as the cause of failure to ventilate the patient is critical to successful recovery of a life-threatening situation (9). Many of the incidents identified as a result of the Orcadian enquiry were near misses because the block was detected quickly and rectified. The key determinants are:

- clinicians' awareness that blockage of the PBC was a possible cause of inability to ventilate the patient;
- ease of visual checking for obstructions within the breathing circuit (see above); and
- systematic replacement of all parts of the breathing circuit to exclude a blocked component. A common feature of the Orcadian incidents which resulted in death or injury to the patient was that some parts of the breathing circuit were replaced in an attempt to establish ventilation but the unrecognised blocked component was left in place.

3.21 An effective recovery strategy is promoted by training and by reinforcing awareness that a blocked anaesthetic tube (although a very rare event) is possible. Clear labelling of packs containing PBC components could provide reinforcement with a simple message such as:

“Keep wrapped until use. Risk of obstruction by small objects”

3.22 A safe and effective default in the emergency situation is to establish ventilation independently of the breathing circuit, for example by self-inflating bag and mask directly applied to the airways. This will:

- ensure that the patient is ventilated if the problem lies within the PBC;
- immediately confirm that the problem lies in the breathing circuit (or upstream of it) rather than in the patient; and
- allow time for a systematic examination of equipment.

Recommendations on training are made in Chapter 4.

Recommendation 1

The MHRA should recommend to manufacturers and the relevant Standards Committees that all components of the PBC be made of transparent plastic and that detachable caps (e.g. on intravenous cannulae and giving sets) be manufactured in brightly coloured material, preferably red, to aid visibility. Where feasible, caps should be tethered rather than fully detachable.

Recommendation 2

The MHRA should recommend to manufacturers and relevant Standards Committees that narrow-bore components vulnerable to blockage by extraneous objects (e.g. angle pieces, catheter mounts) be supplied wrapped and carry a clear warning notice stating that they should remain wrapped until use, referring to the risk of blockage by small objects.

Recommendation 3

Trusts should give careful consideration to design safety in their purchasing policies. Guidance is provided in the Medical Devices Controls Assurance Standard. Breathing system components, intravenous giving sets and cannulae should be preferentially sourced from suppliers able to offer the design features described in Recommendations 1 and 2 above.

Recommendation 4

Trusts must ensure that narrow-bore PBC components remain wrapped when delivered to anaesthetic areas. Where components are cleaned, decontaminated, sterilised and presented for re-use, Trusts should ensure that they are wrapped after they have been cleaned. Trusts should ensure that all components (whether single-use or re-packed) carry a warning notice as described above.

Recommendation 5

Anaesthetic staff should ensure that components are unwrapped only when needed, and if a PBC is assembled in advance its end should be kept covered to prevent entry of foreign bodies.

Recommendation 6

Trusts and their clinical staff should regard discarded plastic caps as a potentially dangerous contaminant of the clinical environment and should ensure that they are kept from work surfaces, trolley drawers and storage bins where PBC components are placed. This will require good design of working areas. Regular cleaning of anaesthetic areas should be an agreed and scheduled responsibility of an operating department practitioner (ODP) or qualified anaesthetic nurse. Storage bins (preferably of mesh rather than solid design) should be emptied fully when restocked in order to remove any extraneous objects.

Recommendation 7

Trusts and anaesthetic teams should ensure that alternative means of ventilating and oxygenating the patient (e.g. self-inflating bag and mask) are immediately available at all times for use if a problem with ventilation arises and malfunction of the PBC is suspected or possible.

Chapter 4: Safe practice

- 4.1 Analysis of the incidents described in Chapter 2 has identified both device-related and human factors which contributed to patient harm. Interventions directed towards the design and protection of equipment have been set out in Chapter 3. This chapter considers the human factors, and the ways in which they might be modified by procedural changes and training to reduce patient risk.
- 4.2 Once a breathing system component is occluded, by whatever mechanism, a series of omissions has to occur before an adverse outcome results:
- the component must be incorporated into the breathing system without checking the integrity of either component or total system;
 - the breathing system must be deployed on an anaesthetised patient again without checking the integrity or function of the system; and
 - there must follow a failure to identify the cause of the difficulty with ventilation and to remedy the situation within the very short time available to prevent morbidity or mortality.
- 4.3 The Expert Group gave attention to the following areas:
- routine checking procedures;
 - roles and responsibilities for checking equipment;
 - response to identification of problems; and
 - training.

Checking anaesthetic equipment

- 4.4 AAGBI, through its safety committee, has for many years published a guidance document, *Checking Anaesthetic Equipment* (referred to here as “the checklist”). This has been widely accepted in the profession and has been a key source document in the training and ongoing education of anaesthetists. From the outset it was recognised that revision would be required from time to time as anaesthetic equipment changed. The second edition was published in 1997. A third edition was in preparation at the time the Expert Group was established and it was therefore able to contribute to the revision, which incorporates lessons learned from the Orcadian incidents (10). The final text of the third edition is attached as Annex 3.
- 4.5 The checklist covers the following types of routine checking:
- servicing of the anaesthetic machine at regular intervals according to the manufacturer’s instructions and with a service record kept;
 - routine checking of the anaesthetic machine by trained staff at the start of each operating session, with a record attached to the machine to log the date of the check and the identity of the checker;

- routine checking of the entire anaesthetic circuit / breathing system at the start of each operating session;
- specific checks to be carried out for each new patient, covering any alterations or additions to the entire breathing system. All components of the breathing circuit between the filter and the patient should be changed for each patient; catheter mounts and angle pieces require particular attention – this was not included in the previous checklist because the use of filters and single-use equipment was not prevalent in 1997 when version 2 was published; and
- routine checking that the necessary standard of monitoring is in place and functional prior to every induction of anaesthesia.

4.6 As with previous editions, a summary of the checking procedure will be made available in abbreviated form as a laminated sheet to be attached to anaesthetic equipment and used to assist in the checking process.

4.7 Of particular relevance to the Orcadian incidents are the following elements in the revised checklist:

- Section E. Breathing System. "... should be visually and manually inspected for correct configuration and assembly....Breathing systems should be protected at the patient end when not in use to prevent the intrusion of foreign bodies...A new, single-use bacterial/viral filter and angle piece/catheter mount must be used for each patient. It is important that these are checked for patency and flow, both visually and by ensuring gas flow through the whole assembly when connected to the breathing system."
- Section J. Machine Failure. ... "It is essential that an alternative oxygen supply and means of ventilation (e.g. self-inflating bag, circuit and oxygen cylinder, which must be checked as functioning correctly with an adequate supply of oxygen) are always readily available".
- Section K. Recording and Audit. "...A clear note should be made in the patient's anaesthetic record, that the anaesthetic machine check has been performed, that appropriate monitoring is in place and functional, and that the integrity, patency and safety of the whole breathing system has been assured."

4.8 It is essential that these checking procedures in conjunction with manufacturer guidance are fully implemented in all cases.

Recording and audit

4.9 The contemporaneous note in the patient's record that the specified checks have been carried out serves a dual function. Firstly, it provides an audit trail. Secondly, it gives regular reinforcement of good practice. These arrangements should be set in the context of controls assurance standards.

4.10 As with all records, there is a balance to be struck between brevity which omits key items and comprehensiveness which is over-burdensome and liable to be poorly observed. The three elements specified in section K of the checklist (see above) strike that balance well. The Expert Group took the view that all patient anaesthetic records should have these three items pre-printed on them, in dual columns for both anaesthetic room and operating theatre, with space for initials to confirm that the checks have been done.

4.11 The Group favoured the implementation of a standard NHS patient anaesthetic record form, to include these audit items and to ensure that staff moving from one hospital to another are presented with familiar documentation. However, it was recognised that a standard NHS record raises wider issues which are currently being considered elsewhere. The Expert Group would like its views on this matter to be conveyed to those developing the standard record.

Professional roles and responsibilities

- 4.12 Medical care is increasingly delivered by a team of health professionals, and anaesthesia is no exception (11). Anaesthetists (both trained and in training), ODPs and anaesthetically trained nurses will normally have their individual roles, and each may have occasion to “hand over” that role to another person during the anaesthetic care of a single patient. Delegation of tasks improves efficiency but it is essential to safe practice that individual roles and responsibilities are mutually understood at all times. This is particularly important in relation to routine checks, since without clarity of responsibility they may be assumed to have been done and to the specified standard, when they have not. However, although some of the duties of checking equipment may be delegated to other members of the team, the anaesthetist still retains overall responsibility for the patient and equipment used.
- 4.13 Teams of individuals develop their own patterns of interaction which can become unspoken habit. Problems arise when a team member is absent or is replaced by someone else who is not familiar with the unspoken assumptions. Continuity of care is vulnerable to shift systems, staff rotations for training and use of agency staff. It is therefore important that the checking procedures set out in the AAGBI checklist, if delegated, remain ultimately the responsibility of the anaesthetist in charge of the patient’s care. He/she must explicitly ensure that any delegated tasks are carried out as intended, and in completing the anaesthetic record is accepting responsibility for the adequacy of checks. When the anaesthetist in charge passes responsibility to a colleague before the procedure has been completed, an account of the checks carried out should be part of the hand-over.

Training

- 4.14 “The use of checklists and associated procedures is an integral part of training in Anaesthesia, and as such is part of the Royal College of Anaesthetists’ Competency Based Training.” (AAGBI’s *Checking Anaesthetic Equipment*, Introduction). The wide acceptance and use of the AAGBI document helps to ensure that the potential hazard of blocked tubes is thoroughly covered in all training programmes and that the appropriate preventative procedures are learned.

Recommendation 8

The Department of Health should strongly endorse AAGBI’s *Checking Anaesthetic Equipment*, third edition, as part of its response to the Orcadian enquiry.

Recommendation 9

Trusts should ensure that AAGBI’s *Checking Anaesthetic Equipment*, current edition, is available in all anaesthetic departments and that the laminated abbreviated version is attached to each anaesthetic machine.

Recommendation 10

Anaesthetists, ODPs and anaesthetic nurses should ensure that AAGBI’s guidance on checking anaesthetic equipment is followed consistently and that appropriate, initialled records are made to confirm that this has been done.

Recommendation 11

Anaesthetists should ensure that whenever responsibility for parts of the checking procedure is delegated to other appropriate members of the clinical team, this is done explicitly and the anaesthetist retains responsibility for ensuring that all checks have been satisfactorily completed.

Recommendation 12

Trusts should ensure that the anaesthetic patient record is designed to hold information to show that the anaesthetic machine check has been performed, that the recommended standard of monitoring is both functional and applied to the patient, and that the integrity, patency and safety of the whole breathing system has been assured. This should be initialled by the anaesthetist in charge of the patient's care.

Recommendation 13

The Royal College of Anaesthetists should require that anaesthetists in training demonstrate their competence in routine checking procedures as set out in the current edition of AAGBI's *Checking Anaesthetic Equipment*, including the recording and audit specified therein.

Recommendation 14

The Royal College of Anaesthetists should ensure in the competency based training programme, that anaesthetists in training are familiar with the potential hazards of breathing circuits, and are taught to:

- recognise the different manifestations of "difficulty with ventilation";
- identify the origins of the problem; and
- implement an expeditious and effective recovery plan.

Chapter 5: Investigating and learning from adverse incidents

- 5.1 A number of agencies played a role in investigating the incidents which have been described here, some of them within the NHS and Department of Health (e.g. ERO, MDA) and some external (Coroner, police, HSE). New bodies have recently been set up with responsibilities for different aspects of quality of care – NPSA, Healthcare Commission (which took over responsibility from CHI on 1 April 2004), National Clinical Assessment Authority (NCAA) and MHRA. Professional organisations also contribute to patient safety in diverse ways, e.g. General Medical Council (GMC), Royal Colleges and specialist societies. Collectively, these create a complex environment in which roles need to be clearly defined and communicated.
- 5.2 *Shifting the Balance of Power* has changed the management structure of the NHS substantially since the Orcaidian incidents occurred. In this formative environment the Expert Group considered what lessons might be learned from Orcaidian concerning the most efficient and effective approach to the investigation of adverse incidents in future. It noted that relevant work is currently in progress elsewhere, such as the review of the Coroner system, and that the new NHS agencies are in the process of developing their working methods and inter-relationships.
- 5.3 The Coroner and police had leading roles in this investigation because of the death of a patient under circumstances which initially suggested the possibility of a criminal act. The linked police enquiry found no evidence of crime but instead drew attention to system failures of two broad kinds. One of these was the series of events in Broomfield Hospital, Chelmsford which resulted in the tragic death of Tony Clowes while being anaesthetised for routine surgery in July 2001. The other, now clear in hindsight, was the failure of the NHS over many years to act effectively in response to a large number of similar incidents which had occurred elsewhere. That latter failure encompassed the detection, systematic recording and analysis of incidents of blocked anaesthetic tubes and steps to prevent recurrence. Incidents were not notified to a well-established national reporting system for device-related adverse events operated by the MDA (12).
- 5.4 The deficiencies of the NHS in learning from adverse events had been clearly set out in the report *An Organisation with a Memory* (June 2000) written by an expert group chaired by the Chief Medical Officer. Its recommendations proposed radical changes, including the setting up of a national system for reporting and analysing adverse events and near misses and for disseminating lessons learned from them. The NPSA was established as a Special Health Authority in July 2001 – the month of Tony Clowes' death. The NPSA has since developed a National Reporting and Learning System (NRLS) which is now being implemented throughout the NHS. This initiative should reinforce and complement the work of the MHRA on device safety. The preferred route for reporting problems involving medical devices will still be via the MHRA, who will continue to issue device related guidance as necessary. This message is reinforced on the NPSA's e-form version of the NRLS.
- 5.5 In anaesthesia, a professionally-led reporting system for adverse events has been in existence for some time. Members of the Expert Group were concerned that the level of detail required for understanding anaesthetic incidents should not be lost in a generic national reporting system, and favoured the inclusion of specialty-specific data fields within the national system. It is also important that central reporting of incidents should not by-pass local Trust management.

Creating a safety culture

- 5.6 Public confidence in the NHS has been shaken over the past decade by a number of widely publicised lapses in standards of care. The resulting intense media scrutiny has tended to focus on personal culpability rather than to make a distinction between individual failures, system failures and genuine untoward outcomes which were not the result of failure on any one person's part.
- 5.7 *An Organisation with a Memory* recommended that “the NHS should encourage a reporting culture amongst its staff which is generally free of blame for the individual reporting error or mistakes, and encourage staff to look critically at their own actions and those of their teams”. The rationale for this new approach of “open and fair” inquiry is that most adverse events have multiple contributory causes and are seldom attributable to the action of one individual. Emphasis on personal culpability therefore will miss the weaknesses latent in the system which will allow recurrences to happen. It will inhibit, rather than encourage, the reporting of critical incidents and the informed analysis which allows effective preventive steps to be taken.
- 5.8 The “blame culture” is reinforced by the multiple threats to the career and reputation of the individual clinician when something goes wrong: NHS disciplinary procedures, professional disciplinary procedures (e.g. by the GMC), the criminal courts, the civil courts, the Coroner's court and the media. There are large disincentives to full reporting and free communication of adverse events and near misses so that lessons can be learned. There will be a small minority of cases in which individuals should be held to account for wilful or recklessly negligent acts, but far more commonly there will be system failures to be analysed and acted upon. Thus there will continue to be a very real tension between “blame” and “open and fair” modes of investigation.
- 5.9 These two approaches – one concerned with individual culpability, the other with organisational learning – cannot easily run in parallel since each might jeopardise the other. While the Orcadian police investigation was in progress, the police limited the release of information which might have undermined a successful prosecution or (on a presumption of tampering) encouraged copycat incidents. This constrained the information which could be circulated in two key areas: firstly in MDA Hazard Notices, creating difficulties for clinicians who were having to act on incomplete data; and secondly in preventing the Royal College of Anaesthetists from fulfilling its duty of care to clinicians and their patients in the rapid transmission of information, which might prevent similar incidents occurring. Three Hazard Notices were published in August, September and November 2001 (13-15) (the MDA having previously circulated a Safety Notice in March 2001 (16)) as it became possible to give out more specific details. In addition, individuals may not feel able to contribute fully to an “open and fair” mode of investigation while police or disciplinary actions are in hand.
- 5.10 Appendix 4 shows the range of agencies which might have a role in the handling of an adverse incident. The initial response within an NHS organisation will be critically important in setting the direction and mode of investigation. The NPSA has developed an Incident Decision Tree (in consultation with the NHS Confederation, NCAA, Royal Colleges, trades unions and patients' representatives) as a support tool to help decision makers respond appropriately to adverse incidents and near misses. It draws on philosophy and policies developed in the aviation industry. The intended purpose of this tool is to:
- encourage the reporting of adverse events and near misses;
 - encourage fairness and consistency of approach by all organisations and for different professional groups;
 - encourage fairness in responding to incidents prior to full investigation when an immediate review may be needed;

- be a decision support tool for chief executives, medical and human resources directors and other senior staff;
- help decision makers to think about systematic and organisational issues in error management; and
- protect managers and staff alike and encourage a consistent and fair approach to determining the outcome of an “error”.

The Incident Decision Tree is now being piloted prior to general release throughout the NHS.

5.11 In the light of what has already been said of the inherent tension between alternative modes of investigation, it is important that there should be agreement between the Department of Health and NHS on the one hand and the police and HSE on the other on the most effective approach to be adopted when more than one agency is conducting an investigation. As one result of the experience gained in Operation Orcadian, a Memorandum of Understanding is being drawn up by a working group of the Department of Health, NHS, Association of Chief Police Officers and HSE with the overriding objective of enhancing public safety. Its terms of reference are to:

- agree on the role and responsibility of each agency when dealing with incidents involving NHS patients in England;
- provide guidance to the NHS about identifying incidents which require, or may require, referral to the police, HSE or other agencies, and the procedure to be followed;
- determine and agree the process for the initial referral and response (the first 24 hours) by the relevant agency (or agencies); and
- provide guidance for the NHS, the police and others about working together effectively, including points of contact.

The Working Group is undertaking consultations and convened a workshop in June 2003. Following on from this, meetings are being held with key organisations with a view to publishing the Memorandum in late 2004.

5.12 Death certification and the Coronial system have recently been examined in depth both by the Shipman Inquiry and by an Independent Review set up by the Home Secretary under the chairmanship of Tom Luce. The Home Office has recently published a position paper setting out the Government’s proposals on the way forward (17). The Expert Group noted that in the future there may be significant changes in the way in which deaths during NHS care are investigated.

5.13 An effective “systems” approach to safety within the NHS will require the trust of staff and the confidence of managers in handling initial assessment of incidents and reporting these to the appropriate organisation(s). The MDA/MHRA has had some successes as seen by the growth of detailed reports on device-related problems to their national reporting system. The NPSA initiative will widen data collection to all areas of healthcare. It is also relevant to note that the demise of Regional Offices with *Shifting the Balance of Power* has removed a source of authority and expertise in the handling of adverse incidents, which must be re-created in Strategic Health Authorities. Clinical governance and risk management arrangements are in a formative stage of development in Trusts. Among the many demands placed upon them, Trusts should give a high priority to:

- implementation of the NPSA’s NRLS, which should enhance and improve existing reporting and learning systems;
- dissemination of the Incident Decision Tree; and
- dissemination of the Memorandum of Understanding, when finalised.

New guidance to Trusts and clinicians on death certification and referrals to the Coroner is likely to be required in due course.

- 5.14 Attention to central reporting of adverse events should not be a substitute for local analysis and learning. The NPSA is developing a number of training programmes to equip NHS staff to undertake root cause analysis which are being rolled out across the NHS during 2004. A root cause analysis training toolkit is now available on the NPSA's website at <http://www.npsa.nhs.uk/rca/default.asp>.

Communication of safety alerts

- 5.15 Effective and prompt dissemination of information on identified hazards is an essential element if the NHS is to be a learning organisation. Mention has been made of the Safety Alert and the three Hazard Alerts put out by the MDA during 2001 on the subject of blocked anaesthetic tubes. The Operation Orcadian report questioned whether the format and distribution of such Alerts were effective in getting safety information to its target audience within the NHS.
- 5.16 In January 2003 and following wide consultation within the Health Service, the MDA introduced a single format for its safety warnings with the aim of improving the clarity of the message and the required response. A recent questionnaire found that the Medical Device Alert format has been well received by the Health Service and it has formed the basis for the electronic alerts referred to in Paragraph 5.18.
- 5.17 Any paper-based system has certain limitations:
- within a large organisation it must be cascaded through several intermediates before reaching the individuals who need to know its contents;
 - if it reaches those individuals, it will have to compete for attention with much other information; and
 - it must be remembered or kept to hand (along with much other information) until such time as its contents might be needed.
- 5.18 Attention to design, format and routes of distribution can only partly overcome these generic problems of paper-based systems. With increasing using of IT within the NHS, electronic alerts become a feasible alternative. A Safety Alert Broadcast System has been piloted in a range of NHS organisations from July 2003 as a joint initiative of the Department of Health, MHRA, NHS Estates and NPSA and is being rolled out in 2004. This will offer the following advantages:
- speed of communication;
 - simpler targeting and cascading;
 - simpler updating;
 - searchability; and
 - confirmation of both receipt and of action taken by recipients.

Conclusions

- 5.19 Operation Orcadian revealed that similar incidents had occurred but had not been reported to the MDA. Since Operation Orcadian, much has been done to increase the capacity of the NHS to identify, learn from and prevent adverse incidents. Initiatives taken over the past 2-3 years should now begin to

make a real contribution to patient safety. It is essential that NHS reorganisation should not impede the development of a “safety culture” and that all staff should actively contribute to it. NHS managers have a key role to play in the initial assessment and reporting of adverse incidents, and in setting up local systems to respond promptly to safety alerts. While not neglecting the importance of individual responsibility for safe practice, the Expert Group welcomed the new emphasis on a “systems” approach to safety.

Recommendation 15

Trusts should actively foster an open learning culture amongst their staff, where the reporting of adverse incidents or near misses is valued. Trusts should give a high priority to implementing the NPSA National Reporting and Learning System (NRLS). Local management with responsibility for clinical governance, risk managers and Medical Device Liaison Officers should be kept fully informed of adverse incidents.

Recommendation 16

The NPSA and MHRA should continue to work with pre-existing reporting systems within specialties such as anaesthesia to ensure that an adequately detailed NRLS data set for full analysis is used for reporting at a national level. They should also continue to work with risk management software system providers to ensure that the NRLS data set can be held locally.

Recommendation 17

Trusts should ensure that senior managers are trained and supported in the initial assessment of adverse events, including the use of the Incident Decision Tree, so that institutional learning is emphasised and any referrals to other agencies are appropriate.

Recommendation 18

The Department of Health, NPSA, MHRA, NHS Estates, Strategic Health Authorities and Trusts should work together to ensure that the Safety Alert Broadcast System is established as an effective and rapid route for the communication of safety alerts throughout the NHS and for monitoring implementation of the required actions.

Chapter 6: Security

- 6.1 The pattern of incidents which led to the setting up of Operation Orcadian was initially thought to be strongly suggestive of deliberate tampering with anaesthetic equipment. As has been described, the balance of evidence later moved towards accidental obstruction of PBC components by small objects. Nevertheless, in considering patient safety for the future, the possibility of deliberate tampering cannot be dismissed. The NHS employs over one million staff, and many millions of people enter NHS premises every year. There have been tragic instances of criminal behaviour causing death and injury to patients (18, 19).
- 6.2 Having established that blockage of anaesthetic tubes can occur accidentally, the Expert Group considered as part of its remit the prevention of such incidents which might conceivably occur as a result of a malicious act.

Literature review

- 6.3 All organisations are vulnerable to sabotage, but the potential consequences are particularly severe in certain industries such as health care, transport, food and nuclear power. To help inform the Expert Group of what might be learned from this wider perspective, the NPSA commissioned for the Chief Medical Officer a literature review of sabotage and/or tampering, by the Centre for Reviews and Dissemination, University of York. The objective of the work was to scope the literature relating to:
- sabotage or tampering, with intent to injure, of equipment or medical products by staff, patients, carers or anyone else with access to healthcare equipment; and
 - solutions that help minimise the risk of sabotage or tampering; this may be from fields other than healthcare.
- 6.4 Standard electronic search techniques were used. A total of 6,846 records were identified in the world literature. Of these, 173 were included in the review. The studies covered: the nuclear industry, focusing on vulnerability, safety or risk assessment of facilities (n=48); detection, relating to adulteration, usually of food, drugs or samples for laboratory tests (n=44); interventions to prevent or identify sabotage or tampering (n=39); identifying the extent of the sabotage or tampering problem (n=26); emergency planning (n=6); and factors which may cause or foster the development of sabotage or tampering (n=8).
- 6.5 The Expert Group considered the review. Most of the published reports were from the United States. Overall, the research literature relevant to sabotage and tampering in a health service context is very limited. Reports concerning tampering with equipment for patient controlled analgesia, with alarm systems and with tamper-evident packaging were of potential interest to the NHS and will be considered further by the NPSA and MHRA. The only publication relevant to anaesthetic equipment concerned failure of home ventilators. None of the incidents examined was attributable to malicious damage or tampering, most being due to incorrect use by caregivers. Remedial action was through improved training.

- 6.6 In the absence of relevant literature, the Expert Group considered three aspects of the prevention of sabotage:
- vetting of staff;
 - security of access to anaesthetic areas; and
 - protection of vulnerable items of anaesthetic equipment from tampering.

Vetting of staff

- 6.7 Standard procedures for the employment of permanent staff will include background checks including the taking up of references. Junior doctors in training will normally be participating in supervised rotations, with established mechanisms to detect and follow up any concerns about health or performance which might arise in any Trust in which they work. Employment of short-term staff (e.g. locum medical staff or ODPs) of unknown background is, however, a source of vulnerability for Trusts. A pattern of adverse events or near misses associated with a particular individual over time might not be recognised if they were to occur in different hospitals.
- 6.8 Trusts have in place routine checking procedures for the employment of temporary staff. In addition, medical and nursing staff are statutorily registered with their professional bodies (GMC, Nursing and Midwifery Council). These have mechanisms to investigate allegations of professional misconduct and the power to suspend or erase individuals from the relevant register.
- 6.9 ODPs, formerly called Operating Department Assistants, have not hitherto been subject to statutory registration. In March 2000 guidance was issued to the NHS that employment of ODPs should be limited to those whose names appear on the voluntary register held by the Association of Operating Department Practitioners. Draft legislation is now in preparation to create a statutory register for ODPs in 2004.

Security of access to anaesthetic areas

- 6.10 Control of access to anaesthetic areas is one aspect of the wider issue of security of NHS premises, and falls within the scope of the NHS Security Management Manual. A revision of the Manual, which was originally published in 1992, is currently in preparation by the Counter Fraud and Security Management Service, with a planned publication date of summer 2004.

Protection of anaesthetic equipment from tampering

- 6.11 The principle of establishing anaesthetic rooms as secure areas, with access limited to authorised staff who have been subjected to appropriate checks at the time of employment, will be undermined if anaesthetic equipment is left in corridors or otherwise stored in an insecure environment. It is essential that staff maintain “security awareness”, however small the risk of tampering may be.
- 6.12 Although primarily intended to prevent accidental blockage, the recommendations that have been made for the supply of wrapped PBC components and labelling to warn of the possibility of blockage by small objects will also provide protection against tampering.

Conclusions

- 6.13 It is a challenging task for clinical governance to sustain vigilance within busy organisations without impeding the smooth flow of normal clinical activity – and thereby creating new risks to patients. Furthermore, the idea of deliberate sabotage is alien to the ethos of health care and perhaps for that reason is seldom considered as a risk to be countered. The triple barriers set out here – proper screening of staff, control of access and the safe packaging and storage of equipment – will protect patients from the small risk of sabotage without imposing disproportionate (and therefore unsustainable) extra burdens on busy NHS organisations.

Recommendation 19

Trusts should ensure that pre-employment checks on staff are consistently applied.

Recommendation 20

Trusts should observe the guidance set out in the NHS Security Management Manual. In particular, Trusts should ensure that access to anaesthetic areas is controlled to prevent entry of unauthorised individuals. Anaesthetic equipment should be stored only in secure areas.

Chapter 7: Conclusions and summary of recommendations

- 7.1 In accord with its terms of reference (1.3), the Expert Group has carefully considered the evidence gathered by the Orcadian investigation and examined related experience from within the NHS and elsewhere over several decades. The picture which has emerged is of a very rare but potentially catastrophic hazard created by a widespread contaminant of the anaesthetic environment. The resulting adverse events and near misses have differed in detail but the pattern is highly characteristic. It is therefore possible to devise a multi-layered preventative strategy. The essential elements are:
- to keep small disposable plastic waste out of the anaesthetic environment;
 - to protect vulnerable PBC components by keeping them individually wrapped until use;
 - to create and maintain awareness of the hazard by professional guidance, by training and by labelling of wrapped PBC components; and
 - to reinforce effective routine checking procedures by professional guidance and training, supported by prompts within the anaesthetic record form.
- 7.2 Although the emphasis has been on anaesthetic rooms attached to operating theatres, our recommendations should be taken to apply to all areas in which anaesthetic equipment is used. This will include, for example, accident & emergency, intensive care and high dependency units.
- 7.3 The resources needed to implement such a strategy are small and it will impose very little on the time of busy staff. Implementing it is a shared responsibility of anaesthetic staff and clinical governance leads in Trusts. Steps have already been taken to support the strategy, for example by the revision and dissemination of the AAGBI guidance on checking procedures. The recommendations listed below set out the key tasks and where the responsibilities for action lie.
- 7.4 The Orcadian investigation examined in depth the possibility of deliberate tampering. Although this was not shown to have occurred, a vulnerability to malicious acts was revealed and therefore the Expert Group considered the relevant security issues for Trusts.
- 7.5 The Expert Group considered what could be learned from the failure of the NHS to identify and act on similar incidents which had occurred in the past. This area has already been given detailed consideration in work which was under way within the Department of Health at the time of the Tony Clowes' tragedy. A major programme to increase patient safety has now been initiated within the NHS following publication of *An Organisation With A Memory*. The Orcadian incidents have shown how vital that programme is. The Expert Group has drawn attention in its recommendations to a number of current initiatives which must be given high priority for implementation at Trust level.
- 7.6 The Expert Group also considered the rapidly changing organisational framework of the NHS, both in its management structure and in the national bodies contributing to quality of care in diverse ways. Creating a "safety culture" is a task of fundamental importance for the NHS which will require leadership as well as management. Trust managers must quickly acquire the knowledge and skills to handle adverse incidents effectively so that preventive action is promptly taken locally and throughout the service if necessary.

Summary of recommendations

Recommendation 1

The MHRA should recommend to manufacturers and the relevant Standards Committees that all components of the PBC be made of transparent plastic and that detachable caps (e.g. on intravenous cannulae and giving sets) be manufactured in brightly coloured material, preferably red, to aid visibility. Where feasible, caps should be tethered rather than fully detachable.

Recommendation 2

The MHRA should recommend to manufacturers and relevant Standards Committees that narrow-bore components vulnerable to blockage by extraneous objects (e.g. angle pieces, catheter mounts) be supplied wrapped and carry a clear warning notice stating that they should remain wrapped until use, referring to the risk of blockage by small objects.

Recommendation 3

Trusts should give careful consideration to design safety in their purchasing policies. Guidance is provided in the Medical Devices Controls Assurance Standard. Breathing system components, intravenous giving sets and cannulae should be preferentially sourced from suppliers able to offer the design features described in Recommendations 1 and 2 above.

Recommendation 4

Trusts must ensure that narrow-bore PBC components remain wrapped when delivered to anaesthetic areas. Where components are cleaned, decontaminated, sterilised and presented for re-use, Trusts should ensure that they are wrapped after they have been cleaned. Trusts should ensure that all components (whether single-use or re-packed) carry a warning notice, for example:

“Keep wrapped until use. Risk of obstruction by small objects”

Recommendation 5

Anaesthetic staff should ensure that components are unwrapped only when needed, and if a PBC is assembled in advance its end should be kept covered to prevent entry of foreign bodies.

Recommendation 6

Trusts and their clinical staff should regard discarded plastic caps as a potentially dangerous contaminant of the clinical environment and should ensure that they are kept from work surfaces, trolley drawers and storage bins where PBC components are placed. This will require good design of working areas. Regular cleaning of anaesthetic areas should be an agreed and scheduled responsibility of an ODP or qualified anaesthetic nurse. Storage bins (preferably of mesh rather than solid design) should be emptied fully when restocked in order to remove any extraneous objects.

Recommendation 7

Trusts and anaesthetic teams should ensure that alternative means of ventilating and oxygenating the patient (e.g. self-inflating bag and mask) are immediately available at all times for use if a problem with ventilation arises and malfunction of the PBC is suspected or possible.

Recommendation 8

The Department of Health should strongly endorse AAGBI's *Checking Anaesthetic Equipment*, third edition, as part of its response to the Orcadian investigation.

Recommendation 9

Trusts should ensure that AAGBI's *Checking Anaesthetic Equipment*, current edition, is available in all anaesthetic departments and that the laminated abbreviated version is attached to each anaesthetic machine.

Recommendation 10

Anaesthetists, ODPs and anaesthetic nurses should ensure that AAGBI's guidance on checking anaesthetic equipment is followed consistently and that appropriate, initialled records are made to confirm that this has been done.

Recommendation 11

Anaesthetists should ensure that whenever responsibility for parts of the checking procedure is delegated to other appropriate members of the clinical team, this is done explicitly and the anaesthetist retains responsibility for ensuring that all checks have been satisfactorily completed.

Recommendation 12

Trusts should ensure that the anaesthetic patient record is designed to hold information to show that the anaesthetic machine check has been performed, that the recommended standard of monitoring is both functional and applied to the patient, and that the integrity, patency and safety of the whole breathing system has been assured. This should be initialled by the anaesthetist in charge of the patient's care.

Recommendation 13

The Royal College of Anaesthetists should require that anaesthetists in training demonstrate their competence in routine checking procedures as set out in the current edition of AAGBI's *Checking Anaesthetic Equipment*, including the recording and audit specified therein.

Recommendation 14

The Royal College of Anaesthetists should ensure in the competency based training programme, that anaesthetists in training are familiar with the potential hazards of breathing circuits, and are taught to:

- recognise the different manifestations of 'difficulty with ventilation';
- identify the origins of the problem; and
- implement an expeditious and effective recovery plan.

Recommendation 15

Trusts should actively foster an open learning culture amongst their staff, where the reporting of adverse incidents or near misses is valued. Trusts should give a high priority to implementing the NPSA National Reporting and Learning System (NRLS). Local management with responsibility for clinical governance, risk managers and Medical Device Liaison Officers should be kept fully informed of adverse incidents.

Recommendation 16

The NPSA and MHRA should continue to work with pre-existing reporting systems within specialties such as anaesthesia to ensure that an adequately detailed NRLS data set for full analysis is used for reporting at a national level. They should also continue to work with risk management software system providers to ensure that the NRLS data set can be held locally.

Recommendation 17

Trusts should ensure that senior managers are trained and supported in the initial assessment of adverse events, including the use of the Incident Decision Tree, so that institutional learning is emphasised and any referrals to other agencies are appropriate.

Recommendation 18

The Department of Health, NPSA, MHRA, NHS Estates, Strategic Health Authorities and Trusts should work together to ensure that the Safety Alert Broadcast System is established as an effective and rapid route for the communication of safety alerts throughout the NHS and for monitoring the implementation of the required actions.

Recommendation 19

Trusts should ensure that pre-employment checks on staff are consistently applied.

Recommendation 20

Trusts should observe the guidance set out in the NHS Security Management Manual. In particular, Trusts should ensure that access to anaesthetic areas is controlled to prevent entry of unauthorised individuals. Anaesthetic equipment should be stored only in secure areas.

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Abbreviations

AAGBI	Association of Anaesthetists of Great Britain and Ireland
BSI	British Standards Institute
CHI	Commission for Health Improvement
ECRI	Emergency Care Research Institute
ERO	Eastern Region Office of Department of Health
ET tube	Endotracheal tube
GMC	General Medical Council
HPA	Health Protection Agency
HSE	Health and Safety Executive
IIU	Investigations and Inquiries Unit
IV	Intravenous
LMA	Laryngeal mask airway
MDA	Medical Devices Agency
MHRA	Medicines and Healthcare products Regulatory Agency
NCAA	National Clinical Assessment Authority
NHSFT	National Health Service Foundation Trust
NHSLA	National Health Service Litigation Authority
NMC	Nursing and Midwifery Council
NPSA	National Patient Safety Agency
NRLS	National reporting and learning system
PBC	Patient breathing circuit
PCT	Primary Care Trust
RDPH	Regional Director of Public Health
SHA	Strategic Health Authority
SHOT	Serious Hazards of Transfusion Group

Appendix 1: Expert Group on Blocked Anaesthetic Tubing

Chair

Professor Kent Woods, NHS Health Technology Assessment Programme (until 31 December 2003, now Medicines and Healthcare products Regulatory Agency)

Members

Dr Michael Dominic Bell, Leeds General Infirmary

Mr Clive Bray, Medicines and Healthcare products Regulatory Agency (Devices)

Dr John Carter, Association of Anaesthetists of Great Britain and Ireland

Dr Helen Glenister, National Patient Safety Agency

Mr Peter Gosling, patient representative (Royal College of Anaesthetists)

Professor Archie Malcolm, Association of Clinical Pathologists

Mr Daniel McCormack, Association of Operating Department Practitioners

Mr John Mead, NHS Litigation Authority

Dr Linda Patterson, Commission for Health Improvement

Professor Alastair Scotland, National Clinical Assessment Authority

Dr Peter Simpson, Royal College of Anaesthetists

Mrs Madeleine Wang, patient representative (Royal College of Anaesthetists)

Secretariat

Ms Elaine Edgar, Department of Health

Miss Samantha Savage, Department of Health

Appendix 2: Operation Orcadian NHS Incidents

Outcome for patient	Timing of discovery of blockage	Component of breathing system blocked	Item causing blockage	Details of incident
Patient died	During use and after some time	Angle connector	Cap from IV giving set	<p>The patient was anaesthetised and ventilation was started using a Laryngeal Mask Airway (LMA) when it became apparent that he was not responding correctly.</p> <p>As the emergency situation progressed all items of the patient breathing circuit (PBC) were changed except the angle connector. Attention was directed towards possible medical conditions. This continued for some time.</p> <p>A specialist registrar who was asked to assist eventually checked the PBC, taking it apart and reconnecting it. He then discovered the blockage. Unfortunately the patient could not be revived.</p>
No adverse effect	During use	Straight T adapter	End cap from IV wide bore extension line	<p>Two patients were involved. Problems were experienced in the anaesthetic room with the first patient on the afternoon list, so she was moved straight to the operating theatre. No further problems occurred in theatre.</p> <p>The next patient was taken to the anaesthetic room, anaesthetised and then connected to the PBC. Once connected to the PBC the patient began to show signs of oxygen starvation.</p> <p>Staff identified a system failure and changed all components, including the PBC. The patient was then successfully ventilated.</p> <p>Examination of the PBC led to discovery of the blockage.</p>

Outcome for patient	Timing of discovery of blockage	Component of breathing system blocked	Item causing blockage	Details of incident
Patient made full recovery, apparently without after-effect	During use	Catheter mount	Pen end cap	<p>Normal procedures were being carried out when on application of the LMA, the patient began to show signs of oxygen starvation. The LMA was removed and the patient began to breathe normally via the application of a face mask. This prompted another attempt to induce her, which failed.</p> <p>The team assumed the patient was reacting to the anaesthetic procedure and so decided to intubate. Following intubation the problem persisted and the patient's condition deteriorated. During the emergency procedures which followed, the blockage in the PBC was discovered. Appropriate action was taken and the patient was transferred to intensive care.</p> <p>The catheter mount had been removed from a sealed pack.</p>
No adverse effect	During use	Angle connector	Cap from extension set	<p>The patient was successfully intubated in the anaesthetic room and moved to theatre. In theatre the anaesthetist requested an additional angle connector. This connector was obtained from a storage box within the theatre.</p> <p>On connection it immediately became apparent that there was a problem with the PBC. The anaesthetic staff suspected that there was a failure in the PBC and began to examine the system. A blockage was found in the additional connector which was then replaced. The operation continued without event.</p>
Patient made a rapid recovery once blockage discovered	During use	Angle connector	End cap from IV extension set	<p>The patient underwent the preoperative anaesthetic procedure in the anaesthetic room. On application of the facemask, following routine procedures, the anaesthetic team was unable to ventilate the patient. A guedal airway was inserted and the facemask reapplied. However they were still unable to ventilate and assistance was summoned. Intubation was then attempted. When this failed a medical condition was suspected. Administration of drugs also failed and so they checked the PBC. No blockage was detected and the reason for the failure to ventilate was thought to be a medical condition.</p> <p>The patient's condition deteriorated, became life threatening and she required cardiac massage. A further examination of the PBC led to the discovery of the blockage. Following discovery and removal of the blockage, the operation continued without event.</p>

Outcome for patient	Timing of discovery of blockage	Component of breathing system blocked	Item causing blockage	Details of incident
Brain damage – patient died without regaining consciousness	During use	Anaesthetic tubing	'Biro' type of cap	Attempted induction for emergency surgery. The ventilator bag and several other items of equipment were changed in response to inability to ventilate. Assumed that the patient was suffering from an adverse reaction, and/or broncho-spasm. Subsequently tubing found to be blocked by foreign body. There is anecdotal evidence of a similar blockage found in another tubing set, stored and awaiting use at the same hospital.
No adverse effect	Prior to use	Anaesthetic tubing		
No adverse effect despite the connector being partially blocked for several hours	During use	Angle connector	Cap (sterile guard connector)	The patient underwent preliminary anaesthetic procedures without incident. Problems were experienced when he was connected to the PBC. Various changes were made to the PBC but the connector was not changed and difficulties continued in ventilating the patient. It was therefore decided that the patient was suffering from an undetected medical condition. Following various treatments and drug treatment, the patient was transferred to another hospital where the blockage was discovered.
Patient died the next day but Coroner determined that lack of oxygen had not contributed to her death.	During use	Swivel (angle) connector	Cap from IV giving set	A patient was undergoing general anaesthesia, when following application of an endotracheal (ET) tube, the patient began to show signs of oxygen starvation. The patient responded to bagged ventilation but not continued application of the ET tube. The patient was then transferred to the operating theatre where the procedure was abandoned, ventilation commencing with a facemask and oxygen. Another registrar was called for assistance and he immediately checked the swivel connector which was found to be blocked. The registrar completed a successful intubation of the patient and the operation was performed without any further complications.
No adverse effect	During use	Swivel (angle) connector	Cap from IV giving set	A registrar introduced a LMA to the patient and connected it to the PBC. It became apparent that the patient's chest was not inflating, prompting removal of the LMA. A new LMA was sought and in the meantime the registrar checked the PBC and discovered the blockage.

Outcome for patient	Timing of discovery of blockage	Component of breathing system blocked	Item causing blockage	Details of incident
No adverse effect	During use	Angle connector (elbow joint) – catheter mount	Cap from IV giving set	The patient was intubated ready for surgery in the pre-operative room. When the airway was connected to the catheter mount, he began to show signs of oxygen starvation. Testing of the PBC components identified the blockage in the catheter mount.

Note: Details of the two incidents that occurred in private hospitals have not been included.

Appendix 3: Checking Anaesthetic Equipment, Third edition

Association of Anaesthetists of Great Britain and Ireland



CHECKING ANAESTHETIC EQUIPMENT

3

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The Association of Anaesthetists of Great Britain and Ireland,
21 Portland Place, London W1B 1PY
Telephone: 020 7631 1650, Fax: 020 7631 4352
E-mail: info@aagbi.org Website: www.aagbi.org

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In addition, advice and input is acknowledged from members of the Safety Committee and the Standards Group of the Association, Anaesthetic Equipment Officers, members of the British Anaesthetic and Respiratory Equipment Manufacturers Association, and members of the Department of Health Expert Group on Blocked Anaesthetic Tubing.

This document has been endorsed by Sir Liam Donaldson, the Chief Medical Officer, and the Royal College of Anaesthetists.

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Bibliography

Section 1

INTRODUCTION

To check the correct functioning of anaesthetic equipment before use is a mandatory procedure. In 1997 the Association of Anaesthetists of Great Britain and Ireland published the second edition of its 'Checklist for Anaesthetic Machines' which gained widespread acceptance in the profession. This document recognised that changes in anaesthetic equipment and the introduction of microprocessor-controlled technology would necessitate continued revision of the document in the future. This new edition further updates the procedures recommended in 1997.

The principles set out in previous booklets have governed amendments to this new edition. It must be emphasised that a major contributory cause of anaesthetic misadventures, resulting at worst in hypoxic brain damage or death, has been the use of anaesthetic machines and/or breathing systems which had not been adequately checked beforehand by an anaesthetist. It is the responsibility of all Trusts and other Hospitals to ensure that all personnel are trained in the use and checking of relevant equipment. This is usually devolved to the Department of Anaesthesia, but where such a department does not exist other arrangements must be made. The use of checklists and associated procedures is an integral part of training in Anaesthesia, and as such is part of the Royal College of Anaesthetists' Competency Based Training.

This checking procedure is applicable to all anaesthetic machines, should take only a few minutes to perform, and represents an important aspect of patient safety. It is not intended to replace any pre-anaesthetic checking procedures issued by manufacturers, and should be used in conjunction with them. For example, some modern anaesthetic "workstations" will enter an integral self-testing cycle when the machine is switched on, in which case those functions tested by the machine need not be re-tested by the user. The intention is to strike the

right level of checking so that it is not so superficial that its value is doubtful, nor so detailed that the procedure is impracticable.

The checking procedure covers all aspects of the anaesthetic delivery system from the gas supply pipelines, the machine and breathing systems, including filters, connectors and airway devices. It includes an outline check for ventilators, suction, monitoring and ancillary equipment.

There must be a system of implementing the routine checking of anaesthetic machines by trained staff according to the checklist, together with the manufacturer's instructions in every environment where an anaesthetic is given. **A record should be kept, with the anaesthetic machine, that this has been done.**

In addition, Trusts, Independent Hospitals, Service Hospitals and other organisations must ensure that all machines are fully serviced at the regular intervals designated by the manufacturer and that a service record is maintained. Since it is possible for errors to occur in the reassembly of machines, it is essential to confirm that it is correctly configured for use after servicing. **The 'first user' check after servicing is therefore especially important and must be recorded.**

Faults may develop during anaesthesia which were either not present or not apparent on the preoperative equipment check. This may include pipeline failure, electrical failure, circuit disconnections etc. In the event of any mishap it should not be presumed that the equipment is in the same state as when checked before the start of the case.

The checking procedure described in this publication is reproduced in an abbreviated form as a laminated sheet entitled "Checklist for Anaesthetic Equipment 2004". This laminated sheet should be attached to each anaesthetic machine and used to assist in the routine checking of anaesthetic equipment.

Section 2

PROCEDURES

The following checks should be carried out at the beginning of each operating theatre session. In addition, specific checks should be carried out for each new patient during a session on any alteration or addition to the breathing system, monitoring or ancillary equipment. **Implementation of these checks is the responsibility of the anaesthetist, who must be satisfied that they have been carried out correctly.** In the event of a change of anaesthetist during an operating session the checked status of the anaesthetic equipment must be agreed.

Before using any anaesthetic equipment, ventilator, breathing system or monitor, it is essential to be fully familiar with it. Many of the new anaesthetic 'workstations' are complex pieces of machinery. It is essential that anaesthetists have a full and formal induction on any machines they may use. A short 'run-through' prior to an operating session is not acceptable.

The anaesthetic machine should be connected directly to the mains electrical supply (where appropriate), and only correctly rated equipment connected to its electrical outlets. Multi-socket extension leads must not be plugged into the anaesthetic machine outlets or used to connect the anaesthetic machine to the mains supply.

To check the correct function of the oxygen failure alarm involves disconnecting the oxygen pipeline on some machines, whilst on machines with a gas supply master switch, the alarm may be operated by turning the master switch off. Because repeated disconnection of gas hoses may lead to premature failure of the Schraeder socket and probe, the following guidelines recommend that the regular pre-session check of equipment includes a "tug" test to confirm correct insertion of each pipeline into the appropriate socket.

It is therefore recommended that, in addition to these checks, the oxygen failure alarm must be checked on a weekly basis and a written record kept, by disconnecting the oxygen hose whilst the oxygen flowmeter is turned on. In addition to sounding an alarm which must sound for at least 7 seconds, oxygen failure warning devices are also linked to a gas shut off device. Anaesthetists must be aware both of the tone of the alarm and also what gases will continue to flow with the make of anaesthetic machine in use.

A. ANAESTHETIC MACHINE

Check that the anaesthetic machine and relevant ancillary equipment are connected to the mains electrical supply (where appropriate) and switched on. Switch on the gas supply master switch (if one is fitted). Check that the system clock (if fitted) is set correctly. Careful note should be taken of any information or labelling on the anaesthetic machine which might refer to its current status.

B. MONITORING EQUIPMENT

Check that all monitoring devices, especially those referred to in the AAGBI Monitoring Standards document, are functioning and that appropriate parameters have been set before using the anaesthetic machine. This includes the cycling times, or frequency of recordings, of automatic non-invasive blood pressure monitors. Check that gas sampling lines are properly attached and free from obstruction or kinks. In particular check that the oxygen analyzer, pulse oximeter and capnograph are functioning correctly and that appropriate alarm limits for all monitors are set.

C. MEDICAL GAS SUPPLIES

1. Identify and take note of the gases which are being supplied by pipeline, confirming with a 'tug test' that each pipeline is correctly inserted into the appropriate gas supply terminal.
2. Check that the anaesthetic apparatus is connected to a supply of oxygen and that an adequate reserve supply of oxygen is available from a spare cylinder.
3. Check that adequate supplies of any other gases intended for use are available and connected as appropriate. All cylinders should be securely seated and turned **off** after checking their contents.
4. Carbon dioxide cylinders should not normally be present on the anaesthetic machine. A blanking plug should be fitted to any empty cylinder yoke.
5. Check that all pressure gauges for pipelines connected to the anaesthetic machine indicate 400 - 500kPa.
6. Check the operation of flowmeters, where these are present, ensuring that each control valve operates smoothly and that the bobbin moves freely throughout its range without sticking. If nitrous oxide is to be used the anti-hypoxia device should be tested by first turning on the nitrous oxide flow and ensuring that at least 25% oxygen also flows. Then turn the oxygen flow off and check that the nitrous oxide flow also stops. Turn on the oxygen flow and check that the oxygen analyser display approaches 100%. **Turn off all flow control valves.** (Machines fitted with a gas supply master switch will continue to deliver a basal flow of oxygen.)

7. Operate the emergency oxygen bypass control and ensure that flow occurs without significant decrease in the pipeline supply pressure. Ensure that the emergency oxygen bypass control ceases to operate when released.

D. VAPORIZERS

1. Check that the vaporizer(s) for the required volatile agent(s) are fitted correctly to the anaesthetic machine, that any back bar locking mechanism is fully engaged and that the control knobs rotate fully through the full range(s). Ensure that the vaporizer is not tilted. **Turn off the vaporizers.**
2. Check that the vaporizer(s) are adequately, but not over, filled and that the filling port is tightly closed.
3.
 - (i) Set a flow of oxygen of 5 litres/min and, with the vaporizer turned off, temporarily occlude the common gas outlet. There should be no leak from any of the vaporizer fitments and the flowmeter bobbin (if present) should dip.
 - (ii) Turn each vaporizer on in turn and repeat this test. There should be no leak of liquid from the filling port. **After this test, ensure that the vaporizers and flowmeters are turned off.**
 - (iii) Should it be necessary to change a vaporizer at any stage, it is essential to repeat the leak test. Failure to do so is a common cause of critical incidents.
 - (iv) Removal of a vaporizer from a machine in order to refill it is not considered necessary.
 - (v) Vaporizers must always be kept upright since tilting can result in the subsequent delivery of dangerously high concentrations of vapour.

E. BREATHING SYSTEM

1. Check all breathing systems which are to be employed. They should be visually and manually inspected for correct configuration and assembly. Check that all connections within the system and to the anaesthetic machine are secured by 'push and twist'. Ensure that there are no leaks or obstructions in the reservoir bags or breathing system and that they are not obstructed by foreign material. Perform a pressure leak test on the breathing system by occluding the patient-end and compressing the reservoir bag. Breathing systems should be protected at the patient-end when not in use to prevent the intrusion of foreign bodies.
2. Bain-type and circle co-axial systems - Perform an occlusion test on the inner tube and check that the adjustable exhaust valve, where fitted, can be fully opened and closed.
3. Check the correct operation of the unidirectional valves in a circle system.
4. If it is intended to use very low fresh gas flows in a circle breathing system, there must be a means to analyse the oxygen and vapour concentration in the inspiratory limb. (Under other circumstances these may be monitored at the anaesthetic machine fresh gas outlet.)
5. A new, single-use bacterial/viral filter and angle piece/catheter mount must be used for each patient. It is important that these are checked for patency and flow, both visually and by ensuring gas flow through the whole assembly when connected to the breathing system.

F. VENTILATOR

1. Check that the ventilator is configured correctly for its intended use. Ensure that the ventilator tubing is securely attached. Set the controls for use and ensure that adequate pressure is generated during the inspiratory phase.
2. Check that disconnect alarms are present and function correctly.
3. Check that the pressure relief valve functions correctly at the set pressure.

G. SCAVENGING

Check that the anaesthetic gas scavenging system is switched on and functioning. Ensure that the tubing is attached to the appropriate exhaust port of the breathing system, ventilator or anaesthetic workstation.

H. ANCILLARY EQUIPMENT

1. Check that all ancillary equipment (such as laryngoscopes, intubation aids eg intubation forceps, bougies, etc.) which may be needed is present and in working order. Ensure that all appropriate sizes of face masks, laryngeal masks, airways, tracheal tubes and connectors are available, and checked for patency at the point of use.
2. Check that the appropriate laryngoscopes function reliably.

3. Check that the suction apparatus is functioning and all connections are secure; test for the rapid development of an adequate negative pressure.
4. Check that the patient trolley, bed or operating table can be rapidly tilted head-down.

I. SINGLE USE DEVICES

Any part of the breathing system, ancillary equipment or other apparatus that is designated “single-use” must be used for one patient only, and not re-used. Packaging should not be removed until the point of use for infection control, identification and safety. (For details of decontamination of re-usable equipment, see the AAGBI Infection Control document.)

J. MACHINE FAILURE

In the event of failure some modern anaesthetic workstations may default to little or no flow. It is essential that an alternative oxygen supply and means of ventilation (e.g. self-inflating bag, circuit and oxygen cylinder, which must be checked as functioning correctly with an adequate supply of oxygen) are always readily available. Consideration should be given to alternative methods of maintaining anaesthesia in this situation.

K. RECORDING AND AUDIT

A clear note should be made in the patient's anaesthetic record, that the anaesthetic machine check has been performed, that appropriate monitoring is in place and functional, and that the integrity, patency and safety of the whole breathing system has been assured. There must also be a logbook kept with each anaesthetic machine to record the daily pre-session check and weekly check of the oxygen failure alarm. Documentation of the routine checking and regular servicing of anaesthetic machines and patient breathing systems should be sufficient to permit audit on a regular basis.

The Association of Anaesthetists of Great Britain and Ireland cannot be held responsible for failure of any anaesthetic equipment as a result of a defect not revealed by these procedures.

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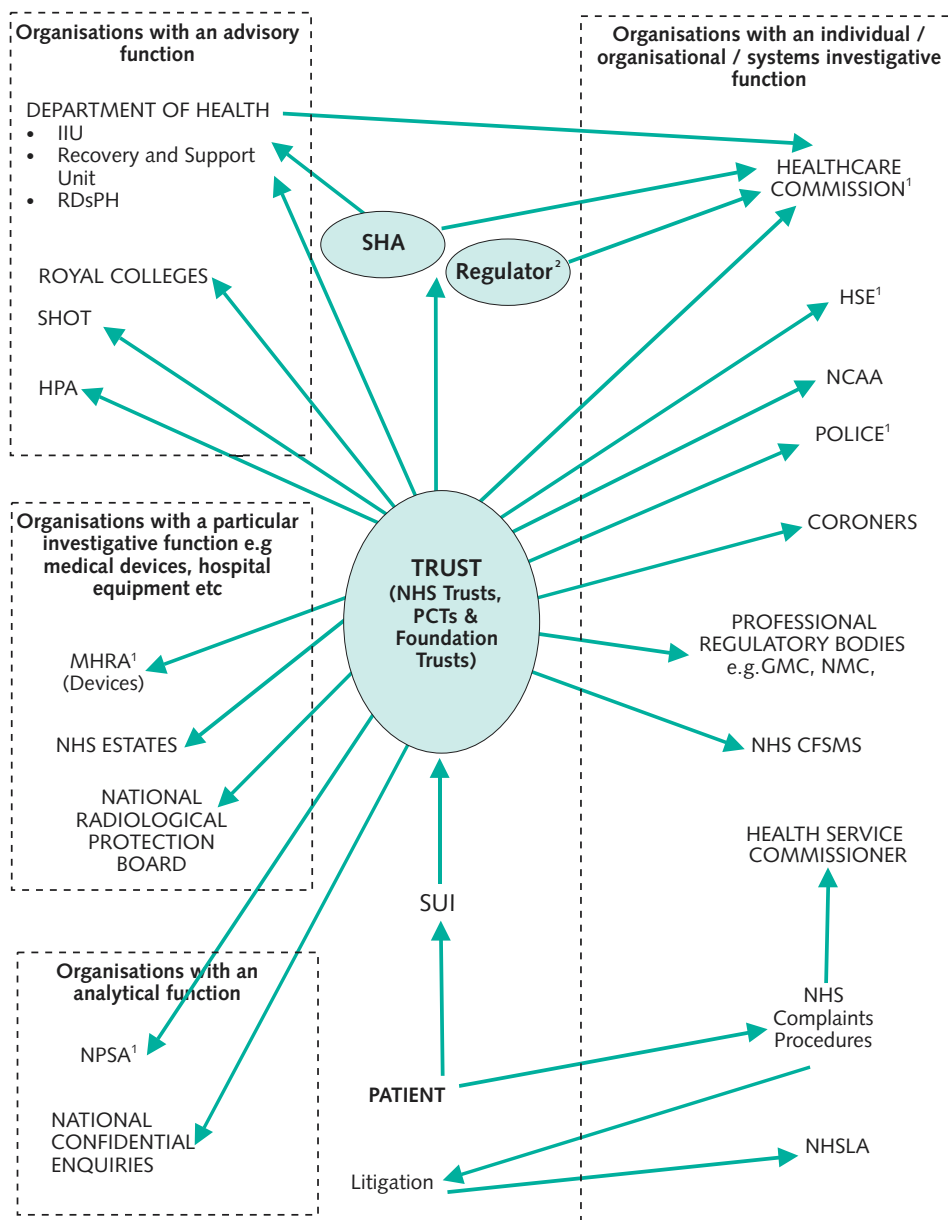
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Appendix 4: Agencies which may be involved following a serious untoward incident



Key

1. Organisations that patients/public can also report to direct.

2. NHS Foundation Trusts (NHSFTs) are not subject to Direction by the Secretary of State for Health and are not performance managed by Strategic Health Authorities (SHAs). NHSFTs are accountable to the Independent Regulator of NHSFTs for abiding by their terms of authorisation ('licence' to operate). NHSFTs should ensure that SUIs are reported to the Independent Regulator in order that it may consider what action, if any, should be taken in respect of the NHSFT and its licence. In addition, NHSFTs should agree with their PCTs local arrangements for reporting SUIs to ensure that valuable learning is disseminated throughout the wider health and social care community.

3 The Independent Regulator of NHSFTs has no investigative responsibilities in respect of SUIs.

SUI – SERIOUS UNTOWARD INCIDENT

A serious untoward incident might usefully be defined as:

“An accident or incident when a patient, member of staff (including those working in the community), or member of the public suffers serious injury, major permanent harm or unexpected death in hospital, other health service premises or other premises where NHS care is provided and where actions of health service staff are likely to cause significant public concern.”

This is likely to include:

- Serious incidents involving patients e.g. operation on wrong limb, serious drug error;
- Serious injury or unexpected death involving a member of staff, visitor, contractor or another person to whom the organisation owes a duty of care;
- Major health risk, e.g. outbreak of infection such as salmonella, legionella or radiation incidents;
- Suspension of a health professional because of concerns about professional practice or criminal activity; or
- Major breach of security.



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