

The fifth report from the Patient Safety Observatory

Safer care for the acutely ill patient: learning from serious incidents

PSO/5

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Endorsement

The nature of health and healthcare is changing. In hospitals we deal with an increasing number of older people who have complex and acute problems with multiple co-morbidities, but we do so with increasingly effective treatments and highly skilled staff.

Improving the care of acutely ill patients is an area where staff throughout the service have active contributions to make. This includes nurses, doctors and other healthcare professionals caring for them on general hospital wards, staff on critical care units, the senior management and medical/nursing leadership in trusts, through to commissioners of services and those nationally responsible for policy and guidance.

We fully endorse this National Patient Safety Agency report as a key component of a coordinated approach to improving the quality and safety of the care of acutely ill patients in hospital. With local leadership on safety, together with the many resources and developing work highlighted here, we can all truly make a difference. We invite you to take up this challenge and help to put patient safety at the top of the national and local agenda.

Signed by:

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| Prof Kent Woods, CEO | Medicines and Healthcare products Regulatory Agency |  |

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The National Patient Safety Agency (NPSA) would like to thank all the organisations and individuals who have made this report possible. These include:

- NHS staff who have reported incidents, both to their local risk management systems and to the NPSA directly;
- risk managers who have submitted incident reports to the Agency's National Reporting and Learning System;
- members of the coordinating group working to improve the safety of acutely ill patients (see Appendix 1);
- NHS organisations and practitioners who gave permission to include their local practice examples in this report;
- organisations who shared their data with the Patient Safety Observatory.

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| | The fifth report from the Patient Safety Observatory |
| | <h1>Foreword</h1> |

Patient safety reporting is a relatively new development internationally. Ideally, these systems, such as the National Reporting and Learning System in England and Wales, help us identify hazards and evaluate why patients are being harmed, rather than helped, by their healthcare. However, international experiences suggest that often we pay too little attention to analysing the data collected by patient safety reporting systems and using what we learn to improve patient safety. This is why a publication such as this is so important. We need to ensure that we both identify and mitigate hazards.

This publication reports on the analysis of data within the National Reporting and Learning System in which patients are reported to have died following shortcomings in the safety of their care. We know that such events are not random occurrences. Indeed, three common and important themes emerge from this analysis.

First, it often takes busy healthcare staff too long to recognise patients who are clinically or physiologically deteriorating. Second, we do not always do what is needed to address this deterioration once it is identified. Third, the right people to do the right things are not always available when and where patients have cardiac arrests.

These problems are not unique to the NHS; indeed, they are global. I know that in my own health system within the USA, the same shortcomings exist. Patients suffer preventable harm from our inability to prevent, detect and treat acute physiologic decompensation. Often such events are preceded by hours or days of physiologic changes that go unrecognised.

Of course, it is not enough to simply surface risks and hazards and not seek to address them. The National Patient Safety Agency wants, indeed needs, hospitals to use this report to review local systems for identifying and responding to patients who are acutely ill, and to ensure that they are as robust as possible in efforts to prevent, detect and treat decompensating patients.

There are already many healthcare facilities from which we can learn. A strength of this report is not only that it describes some of the problems, but it also highlights examples of good practice underway throughout the NHS. Learning from each other is an under-used resource in healthcare. Repeatedly, our own work in patient safety in the USA has demonstrated the value of working together to address safety problems. We have learned that the world is small, we are more alike than different, and we cannot do it alone.

The need to improve patient safety is great. Our resources are limited and we need to focus our efforts where they can be most effective. This report highlights some important issues in how we might better respond to the needs of some of our sickest patients. This is a timely and important contribution to the continuing quest to make healthcare as safe as possible as soon as possible. I hope you use this report to help reduce these risks in your trust.

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Summary

Every year, 13 million people, on average, are admitted to acute hospitals in England and Wales. Inevitably, some of these people will die as a result of their illness. However, this publication from the National Patient Safety Agency (NPSA) focuses on 107 patients whose deaths in acute hospitals in one year were reported to the National Reporting and Learning System (NRLS) because of concerns about the safety of their care.

These incident reports have been analysed, drawing on clinical and risk management expertise. This analysis has identified safety problems related to patient deterioration not recognised and not acted upon, and problems with resuscitation. This publication reports on that analysis and suggests that hospital staff and their organisations can make a real difference through identifying problems and acting early.

The nature of healthcare is changing and as a result hospitals are dealing with an increasing number of older people who have complex and acute problems and multiple co-morbidities. At the same time there are increasingly effective treatments available and highly skilled and trained staff in acute settings.

Patient safety is the first priority for healthcare. However, serious incidents can and do happen. By identifying the two key themes of deterioration and resuscitation and giving frontline staff guidelines and actions for improvement, this publication aims to contribute to a reduction in the harm caused and even the number of deaths.

The National Reporting and Learning System

The Agency has responsibility for the NRLS, through which patient safety incidents are reported and analysed nationally. In any given year, several hundred thousand incidents that occur in local hospitals are reported. This wealth of data enables the Agency to analyse and interpret the information to identify risks and ways in which patient safety can be improved.

There are some notes of caution in interpreting the NRLS data. As with any other voluntary reporting system, the data are subject to bias. It may be incomplete and may be

reported immediately following an incident before the patient outcome is fully known. However, each reported incident is important and provides background facts and description. Taken with other data sources, it can provide a picture of what has happened in a certain situation and can give health professionals and hospital managers a focus for identifying systematic safety problems and required changes to improve the safety of their patients.

Interpreting the data

In deciding to focus on two specific elements relating to patient deaths in 2005, the NPSA first completed a detailed analysis of the 1,804 serious incidents that were reported to have resulted in death. These incidents were expertly reviewed and analysed, reducing the number to 576 deaths that could be interpreted as potentially avoidable and related to patient safety issues.

Of these reported deaths, 425 occurred in acute/general hospitals. Of these:

- 71 were reported to relate to a diffuse range of diagnostic errors;
- 64 related to patient deterioration not recognised or not acted upon, and;
- 43 involved a problem with resuscitation after cardiac arrest.

The other deaths relate to a wide variety of patient issues including medication error, suicide and still births.

The NPSA determined that more detailed analysis is needed to be undertaken in the areas of diagnostic errors. This will be the subject of separate consideration. Safety problems associated with patient deterioration and resuscitation form the basis of this report. It is the first time that the Agency has focused specifically on avoidable deaths in hospitals as a means of assisting in the identification of issues that can lead to significant harm to patients. The report also outlines ways in which these incidents can be mitigated and reduced.

Deterioration: issues and actions

The study found that by identifying patients who are deteriorating and by acting early, staff and their organisations can make a real difference. They can also enhance patient safety by improving systems to resuscitate patients when they have a cardiac arrest.

Of the 64 cases of patient deterioration identified in 2005 in acute hospital settings, it was reported that in 14 cases, no observations were made for a prolonged period prior to death and changes in vital signs were not detected. In 30 cases, despite the recording of vital signs, it was reported that there was no recognition of clinical deterioration and/or no action taken. In 17 cases, deterioration was recognised and assistance sought, but, it was reported, there was a delay in the patient receiving medical attention. In the remaining three cases the information provided was not detailed enough to apply the sub-themes.

Key actions recommended are:

- Better recognition of patients at risk of, or who have deteriorated
- Appropriate monitoring of vital signs
- Accurate interpretation of clinical findings
- Calling for help early and ensuring it arrives
- Training and skills development
- Ensuring appropriate drugs and equipment are available

Resuscitation: issues and actions

Of all the incidents reported via the NRLS associated with death in acute hospital settings in 2005, 43 were associated with resuscitation. In many of the reports, the description of the incident suggested that medical and nursing staff did not have the depth of knowledge and skills required. In most cases the delay in starting the resuscitation was reported to be because staff did not recognise the acute situation, failed to call the resuscitation team or did not make an attempt themselves to resuscitate the patient.

Key actions recommended are:

- Improving communication
- Better situation analysis
- Regularly risk assessing resuscitation processes locally
- Training and skills development
- Ensuring appropriate equipment is available

Conclusion

In addition to the Agency's recommendations and resources, a concerted national programme is already underway to provide support and guidance in the coming months. The guidelines being published by the National Institute for Health and Clinical Excellence (NICE)¹ alongside this report make a significant contribution to the information that has already been analysed and presented. Previous work and examples of good practice will complement the NICE guidelines and will be supported by a partnership approach with relevant organisations in England and Wales.

NICE Guidelines

Guidelines published by the National Institute for Health and Clinical Excellence (NICE) alongside this report¹ (see page 27) provide further definitive advice.

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Introduction

Each year, over 13 million patients are admitted to hospital in England and Wales. Inpatient services provide care to the most critically ill patients treated by the NHS, and over a half of all deaths in England and Wales occur in hospital. Although most care is provided safely and effectively, sometimes errors are made which in some cases affect the outcome for patients.

The NRLS gathers information about patient safety incidents which occur in NHS organisations in England and Wales. It is a voluntary system and will be subject to bias and incompleteness of information. Reported incidents alone cannot tell the whole story about risks to patients. For this reason, the NPSA also analysed the data from litigation organisations, as well as recent research, in order to understand more about what goes wrong and why.

These two areas are:

- *clinical or physiological deterioration not recognised or not acted upon;*
- *resuscitation after cardiopulmonary arrest.*

A comprehensive analysis of the reports of serious incidents has highlighted two key associated areas that, if changes in practice are implemented, will result in an improvement in the outcome of acutely ill patients.

These are not new concerns and, in spite of much high quality work over many years, still more energy and commitment towards improvement is needed.

This report outlines and identifies some of the key areas of risk and actions that NHS organisations can take immediately to ensure that acutely ill patients are monitored and managed effectively. In addition, improvements in systems and training for resuscitation could enhance safety after patients have arrested through better management and replenishment of resuscitation equipment.

Our analysis of events and incidents gives impetus to further review of these issues and has generated a collaborative approach across national organisations that has the potential to make a real difference.

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The problem

The Agency's NRLS received 484,441 reports of patient safety incidents which occurred in 2005, including 1,804 (0.4 per cent) that reported the death of the patient.

Drawing upon clinical and risk management expertise, review of these incidents identified 576 events in which the death of the patient was, or might have been, directly related to a patient safety incident (see Appendix 2).

The patterns and themes uncovered from analysis of these incidents are important; they can highlight areas where action can be taken to improve patient safety. The 576 reports of death were analysed in detail to reveal the reasons for incidents, and to uncover any common themes.

Of these reported incidents, 425 occurred in acute/general hospitals. Seventy-one of these related to a diffuse range of diagnostic errors widely distributed across the service and across specialties and care settings. Sixty-four related to patient deterioration not recognised or not acted upon, and 43 involved a problem with resuscitation.

There are real opportunities to learn from these incidents and reduce the risk and harm through concerted local and national action.

These findings from reported incidents have been analysed alongside other data sources, published literature, previous reports, national audits and expert clinical opinion to confirm both the importance of these themes and the potential to make practice safer for the acutely ill patient.

Key theme 1: clinical or physiological deterioration not recognised or not acted upon

Early identification of clinical deterioration is important to prevent subsequent cardiopulmonary arrest and to reduce mortality. Patients whose deterioration is not picked up early, but who do not proceed to cardiac arrest, will also have increased avoidable morbidity, increased length of stay and associated avoidable healthcare costs.

Incident reports

Sixty-six of the incidents associated with death in the NRLS over one complete year described patient deterioration not recognised or not acted on. The vast majority (64) occurred in acute/general hospitals and most of those reported came from general medical and surgical specialties:

| Specialty | Number |
|------------------------|-----------|
| Surgical | 23 |
| Medical | 22 |
| Accident and Emergency | 12 |
| Diagnostic services | 2 |
| Other or unknown | 5 |
| Total | 64 |

Source: Incidents reported to the NRLS that described clinical deterioration not recognised or not acted upon and were associated with death in acute general hospitals during 2005.

Sixty-one of the 64 incidents that occurred in acute/general hospitals could be categorised within three sub-themes:

1. failure to measure basic observations of vital signs;
2. lack of recognition of the importance of worsening vital signs;
3. delay in responding to deteriorating vital signs.

In 14 of these incident reports, it was reported that **no observations** had been made for a prolonged period before the patient died; hence changes in a patient's vital signs (for example, blood pressure, pulse, respirations) were not detected.

Excerpts from incident reports*

"Outreach nurse attended cardiac arrest ... On review of MEWS chart no observations performed for two days and therefore no early warning score available."

"BP 80 / 50, pulse 120, sats 74% ... no further sats done, no action taken until noticed on transfer to ward X. Drs contacted to review. Transferred to ITU, died later same day."

In 30 incident reports, despite recording vital signs, sometimes regularly and frequently, the importance of the clinical deterioration **had not been recognised** and/or no action had been taken, other than the recording of the observations.

Excerpts from incident reports

"Patient found by accident on ward by Acute Pain Team on round, one day post op elective aortic aneurysm repair with Epidural running on 10mls an hour. First blood pressure recording 80 systolic - no action documented. Two further readings both hypotensive. No urine output recorded since 7am the day before, no EWS recorded. Present staff still unaware of potential problem – blood pressure recorded by nurse prior to us seeing patient and systolic 95 – no action taken. Patient tried to stand up and walk"

"Patient transferred, handover given. Routine observations showed low oxygen saturations 80% – no oxygen prescribed. No urine output and no information given at handover re oxygen or urine output."

In 17 incident reports, it was reported that while deterioration was recognised and medical assistance sought, there was **delay in the patient receiving medical attention**. These incidents often involved nurses who recognised the clinical deterioration but could not get medical help quickly enough.

Excerpt from incident report

"Doctor called by fast bleep as patient was unresponsive, the doctor said the patient's potassium was low... Staff member suggested that the doctor spoke to the registrar about treatment ... and to ask the registrar (to) come to see the patient urgently. The doctor was very indecisive and the patient's condition was deteriorating, staff member suggested the doctor speak to the ITU outreach team and they went to phone them. The patient's condition was still deteriorating and crashed. Staff member asked the doctor to put out a crash call but the doctor said that the patient wasn't that bad. The call was put out..."

*The examples used throughout this report are taken from incidents reported to the NRLS by NHS staff in England and Wales.

For the majority of the 64 reports (42 cases) the timing of the incidents was documented as occurring in the evening or over night; only 15 incidents occurred during the day and for seven incidents the time is unknown.

In half of these 64 incidents when clinical deterioration was the key theme, it was detected during the transfer of the patient between wards or departments.

A search of NRLS data for similar incidents with less severe outcomes was undertaken for the same time period (see Appendix 2). Fifty-eight further incidents were identified and classified into the same themes as above. Of the 58, for 24 no observations were taken, for 26 there was failure to recognise the significance of deteriorating observations, and for eight there was a delay in the patient receiving medical attention.

These reports may represent only a very small proportion of incidents that actually occurred. The literature strongly suggests that such incidents are likely to be much more common in practice, but are often not reported² or even recognised^{3,4}.

Other sources of data

The NHS Litigation Authority (NHSLA) is responsible for handling negligence claims made against NHS bodies in England. It has shared de-identified data it holds on clinical negligence claims with the NPSA to enable comparative analysis of the diverse datasets and enhance learning from patient safety incidents. An analysis of 605 claims related to patient deaths notified to the NHSLA in 2005 was undertaken; these made up 13.9 per cent of all claims notified in that year. The majority of notified claims involved acute trusts (529; 87.4 per cent), with 32 (5.3 per cent) involving mental health trusts, 18 (three per cent) primary care trusts, and 17 (2.8 per cent) ambulance trusts.

The claims were classified by applying the same themes as identified for the incidents associated with death reported to the NRLS. In contrast to NRLS reports, only seven claims notified to the NHSLA in 2005 associated with patient death described deterioration. The reasons for this difference are difficult to explain but might reflect the different purposes for which the datasets are used. Six of the seven notified cases alleged lack of observation.

Literature and research

Cardiopulmonary arrest can occur in many acutely ill patients. Improvements in resuscitation have led to increased survival, with up to 17 per cent of people suffering in-hospital cardiac arrest leaving hospital alive.^{5,6} Audit data^{5,7} suggest that between 1992 and 2000 there may have been an improved outcome for ventricular fibrillation and ventricular tachycardia

arrest, but not necessarily for other cardiac arrest rhythms (for example, asystole). This is important since these other cardiac arrest rhythms, with high mortality once they have occurred, commonly follow identifiable patient deterioration, emphasising the value of early detection of deterioration and early intervention to prevent further deterioration and cardiac arrest.

Indeed, between 30 per cent and 84 per cent of patients who suffer cardiopulmonary arrest show signs of deterioration in the 24 hours before the arrest.^{8,9} Furthermore, there is a documented association between sub-optimal care and deterioration. In a retrospective chart review, Franklin and Mathew (1994)¹⁰ found that in 25 out of 99 cardiopulmonary arrests with a documented clinical deterioration of the patient, the nurse had not notified a physician. In 42 cases, a junior doctor did not contact an intensive care unit triage physician and, in 30 cases, an arterial blood gas sample was not taken. In cases where a blood gas sample was taken, the result was not always acted upon despite being abnormal.

McQuillan and colleagues (1998)¹¹ carried out a confidential enquiry into the quality of care of 100 patients before admission to a critical care unit. In 54 per cent of cases, patients received sub-optimal care before admission to an intensive care unit. Smith (2006)¹² quotes two studies where approximately 50 per cent of patients admitted to intensive care units as emergencies had no documented physiological abnormalities.

It has been estimated that approximately 23,000 in-hospital cardiac arrests (in the UK) and at least 20,000 unanticipated intensive care unit admissions (in England, Wales and Northern Ireland) could be avoidable with better care.¹²

In 1999, an Audit Commission report, *Critical to Success*,¹³ included a strong recommendation that acute hospitals develop an outreach service with appropriate critical care knowledge and skills to support ward staff in managing patients at risk. In 2000, a Department of Health national expert group¹⁴ recommended outreach as an integral part of each trust's critical care services. In 2003, a report by the NHS Modernisation Agency, in conjunction with the National Outreach Forum,¹⁵ concluded that outreach was delivered variably across the country and that it should be a fundamental goal that all staff providing acute care should be able to: "recognise basic signs of deterioration and appreciate the necessity of obtaining timely and appropriate help".

There is a range of available screening tools (track and trigger warning systems) to detect the deteriorating patient; most of which rely on a combination of straightforward observation of vital signs, usually conducted by nurses. These generally

include recording of pulse rate, blood pressure, temperature and respiratory rate. Some instruments include additional, more complex measures and most produce a score with a threshold for referral. Whilst there is no clear evidence to identify the ideal track and trigger warning system, the National Outreach Report¹⁵ concluded: “the principles of physiological track and trigger warning are as important as is focusing on the detail when selecting a model for implementation”.

Guidelines published by the National Institute for Health and Clinical Excellence (NICE) alongside this report¹ (see page 27) address these issues and provide definitive advice.

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) study, *An acute problem?*¹⁶, reported on an audit of adult patients admitted to critical care units. It concluded that:

- patients often had prolonged periods of physiological instability prior to admission to a critical care unit;
- there were considerable time delays between physiological instability and subsequent critical care unit referral;
- vital signs observations were rarely done in sick patients, even in the immediate period prior to critical care unit admission;
- pulse rate, blood pressure and temperature were the most frequently recorded vital signs, but respiratory rate was the least recorded variable, despite the fact that this is an early and sensitive indicator of deterioration;
- it was very uncommon for there to be clear instructions to the nursing staff about when to call for assistance;
- one in four hospitals did not use a physiological track and trigger warning system;
- only 56 per cent of hospitals had an outreach service, and only 23 per cent of patients referred for critical care were reviewed by an outreach service.

Key theme 2: resuscitation after cardiopulmonary arrest

Improvements in the use of resuscitation techniques over recent decades have led to enhanced survival for patients. Ideally, in the hospital setting, unexpected cardiac arrest should largely be a thing of the past, as a result of early recognition of patient deterioration, early intervention and appropriate use of 'Do Not Attempt Resuscitation' decisions. However, when it does occur, recovery from cardiopulmonary arrest requires early recognition, early call for help, early cardiopulmonary resuscitation with defibrillation, and early advanced life support. Having appropriate equipment and drugs readily available, and staff with adequate skills, are critical components of delivering effective cardiopulmonary resuscitation.

Incident reports

Fifty-nine of the incidents associated with death which were reported to the NRLS from 2005 described issues associated with resuscitation. Forty-three of these incidents were reported from acute/general hospitals. Of these, 19 were reported from medical specialties, eight occurred in an accident and emergency department and six within surgical specialties.

The following table provides details of the sub-themes that emerged from review of the reports describing resuscitation incidents in acute hospitals:

| Sub-theme | Number |
|---|-----------|
| Limited resuscitation skills | 16 |
| Missing or poorly functioning equipment/drugs | 14 |
| Communication problems | 5 |
| Lack of resources/medical assistance | 4 |
| Other | 4 |
| Total | 43 |

Source: Incidents that occurred in 2005 and reported to the NRLS that were associated with the patient's death and that related to resuscitation in acute hospitals.

Limited resuscitation skills

In 16 incident reports it was suggested from the description of the incident that medical and nursing staff did not possess the required knowledge and skills when dealing with the acute problem.

In nine cases it was reported that there was a delay in starting the resuscitation because staff did not recognise the acute situation, failed to call the resuscitation team or did not make an attempt to resuscitate. Underlying causes of some of these problems were identified by reporters as staff shortage and communication problems.

Excerpts from incident reports

"Patient newly admitted with pneumonia and had cardiac arrest on ... an acute care of elderly ward which is staffed by only one trained nurse overnight therefore when patient arrested, nursing staff unable to give immediate CPR. Patient died."

"Staff failed to recognise cardiac arrest, failed to initiate crash call, despite the fact that patient was for active resus. Patient subsequently died."

In seven incident reports it was noted that resuscitation had started but nursing staff were unable to assist the first rescuer or did not follow resuscitation protocols.

Excerpts from incident reports

"Attempted resuscitation but staff on ward not helpful, nurse remained in handover despite patient being close to death. Long waits for essential equipment. I asked for a central line trolley and was eventually given a crico-thyroid[otomy] airway kit. The only member of staff who was helpful was a student nurse who was limited by their experience."

"Elderly patient collapsed in corridor. Dr ... reassessed patient, no longer breathing and no pulse. CPR initiated. Dr asked for monitoring to be put on patient. It was not. The ED nurse and another member of staff decided that patient should be transferred to ED. The Dr asked again that they should see whether patient was in shockable rhythm, he was told 'I have only the AED'. The paramedics and nurses attending patient did not put on any monitoring and appeared more focused on getting patient to ED... Patient taken to ED, was intubated, was in ventricular fibrillation and did not survive. Dr felt that valuable time had been lost, and also there was lack of recognition of importance of identifying shockable rhythm and ALS protocol not followed."

"Upon arrival in the A&E department the patient was handed over following a cardiac arrest and was undergoing external pacing. Despite advising the hospital not to remove the pacing leads, they did remove them resulting in the loss of capture of any electrical activity within the heart. Consequently this resulted in the death of the patient."

Missing or not functioning equipment/drugs

Fourteen reported incidents related to equipment. In eight incidents the necessary equipment (including electrodes, defibrillator leads and paddle, suction devices and drugs) was reported as not available when needed.

Excerpt from incident report

"During a cardiac arrest defibrillator found not to have the correct leads and paddle to fit the defibrillator. This caused a delay of approx 5 minutes during the arrest."

There were six incident reports where the equipment was reported as being available but was not functioning. These incidents include reports of empty oxygen cylinders and faulty defibrillators and suction equipment.

Excerpts from incident reports

"Patient arrested in x-ray. O2 cylinder on crash trolley empty."

"Cardiac arrest. Patient had mouth full of stomach contents... Both portable suctions not working. Aspiration."

Communication problems

In five reported incidents, it was stated that inadequate communication had caused problems with resuscitation, for example, the resuscitation team being directed to the wrong ward or calling a neurology rather than a resuscitation team. In two incidents, the patient's notes were not available at the time of the cardiopulmonary arrest and the patient's resuscitation status was unknown.

Lack of resources or assistance

In four incident reports, it was stated that there were nursing staff present at the scene, but there was a delay or lack of staff with skills in airway intervention, intravenous cannulation or with the ability to undertake advanced resuscitation skills.

Excerpts from incident reports

"No anaesthetist attended arrest call, prolonged resusc, cardiology registrar intubated patient."

"Patient became unresponsive and had cardiac arrest, call made and patient recovered, however, quickly deteriorated, no anaesthetist attended from 1st call. Bleeped via switch, 1st on - call responded but was busy in theatres, said they would send 3rd on call. 3rd did not respond or attend, 2nd did not respond, patient died."

Other sources of data

The aim of the Medicines and Healthcare products Regulatory Agency (MHRA) is to safeguard public health by making sure that medicines and medical devices work properly and are acceptably safe. The Agency relies on manufacturers, healthcare professionals and the public to report defects, side effects and misleading information; it operates the following reporting systems:

- potential side effects of prescription and over-the-counter medicines and herbal remedies (Yellow Card Scheme);
- design or manufacturing faults/failures/poor instructions or maintenance/incorrect use of devices (Adverse Incident Reporting Scheme);
- defective medicines;
- serious side effects involving blood and blood components (SABRE).

The MHRA shared information on adverse incident reports from their database which relate to defibrillators and suction equipment. The information includes a brief description of the incident and this was reviewed in order to gain better understanding of the context and contributing factors to the incident. The data support the view that equipment can be an issue in resuscitation care.

During 2006, the MHRA received 141 reports of adverse incident involving defibrillators, many of which related to electrode or battery issues. In the first six months of 2007, it received a further 86 reports and it continues to receive on average 14 incident reports each month on these devices (some of these will be duplicate reports from manufacturers).

For suction equipment, 36 adverse incidents were received during 2006, with a further 16 received in the first six months of 2007. Several of these incidents occurred in resuscitation situations, when user error may have contributed to the incident, for example, incorrect connection of suctioning tubes.

Summary

A detailed analysis of incidents reported to the NRLS, using clinical and risk management expertise, and drawing upon the valuable text within the reports describing the incidents, has revealed two key themes related to deaths and serious harm to patients in acute hospitals: clinical deterioration not recognised or not acted upon, and problems with resuscitation. Whilst these safety issues have been recognised previously, this is the first analysis of these types of incidents by the NPSA and more remains to be done to enhance patient safety in these areas.

For the first of these themes, guidelines published alongside this report by NICE are a significant additional contribution to improving patient safety.¹ Previous work and examples of good practice and other forthcoming initiatives will complement the NICE guidance and will be supported by a coordinated multi-organisational and multi-professional approach.

The following section describes actions that can be taken now. Pages 26 to 35 describe available resources and next steps.

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What can be done to make care safer

NHS staff and organisations can make a real impact on the safety of patients by identifying the clinically deteriorating patient and acting early, as well as improving systems for resuscitating patients when they do have a cardiopulmonary arrest.

The key areas for action are:

- improving the recognition of patients who are at risk, or who have clinically deteriorated;
- appropriate monitoring of vital signs;
- accurate interpretation of clinical findings;
- calling for help early enough and ensuring that help is forthcoming;
- training and skills development; and
- ensuring that appropriate equipment and drugs are available.

There are specific actions that can be taken to tackle these issues. In the case of care of the acutely ill patient, definitive guidance is available within the NICE guidelines published alongside this report.¹ These guidelines will be followed up by further implementation advice later this year from NICE and the Department of Health.

Actions points: healthcare organisations

Understanding your own context

- Review past investigations (for example root cause analyses) and undertake local root cause analysis of incidents that involved patients whose condition deteriorated, and problems relating to resuscitation, in order to determine local contributory and causal factors, and safety problems that may require solutions.
- Discuss this report and the NICE guidelines with critical care and ward-based clinicians (doctors, nurses and other healthcare professionals) and resuscitation officers to better understand any local concerns and ascertain suggestions for improvement that could address problems that can address safety of patient care.
- Regularly review reports of death, severe harm or high risk incidents to identify opportunities for safer practice. Deaths and severe harm associated with a patient safety incident should have a full root cause analysis undertaken.
- Report all adverse incidents involving resuscitation equipment to the MHRA (guidance on reporting is available at www.mhra.gov.uk)

Standards and training

- Ensure that those responsible for providing resuscitation services are able to effectively implement standards and safely treat any patient who has a cardiopulmonary arrest.
- Regularly risk assess resuscitation; this should include regular audit of emergency equipment and action plans to rectify areas of deficiency.

Equipment and infrastructure

- Routinely assess infrastructure, response, and skills retention and application throughout the organisation with the provision of mock emergency exercises to test the readiness of establishments to respond to regular patient emergencies.
- Standardise resuscitation equipment throughout the organisation and establish robust systems of replenishment; this should include good record keeping in relation to checking and accounting for the readiness of emergency equipment. See also MHRA publication *Managing Medical Devices* (Device Bulletin 2006 (05)).¹⁷

Actions points: healthcare commissioners

- In light of the release of the NICE guidelines¹ and associated guidance due later in 2007, review systems with your local providers.
- Consider whether your local providers have safe and effective systems in place to review policy for patients whose condition deteriorates and for cardiopulmonary arrest, including systems for training, audit and review.
- Consider how you will be sure that local organisations have effective systems for incident reporting and investigation, particularly for severe harm, death and high risk incidents. Are safety-related deaths and severe harm incidents investigated using a structured approach such as root cause analysis? Are the lessons from such investigations disseminated, implemented and monitored? Are they shared between organisations?

Actions points: healthcare staff

- Make sure you have appropriate training to respond to cardiopulmonary arrest, and that you understand local procedures.
- Report failure to recognise or act upon patient deterioration and problems with resuscitation to your local risk management system.

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Resources and good practice examples

For both clinical deterioration not recognised or not acted upon, and resuscitation following cardiopulmonary arrest, there is a vast array of resources, tools and initiatives available that could enhance the quality of care of the acutely ill patient.

However, data from the NRLS suggest that, despite much guidance and recognition of the issue, problems remain. Comparisons with the literature suggest that reports to the NRLS represent only a small proportion of incidents that occur. If so, the potential for impact on survival if safety is improved is considerable.

This section offers NHS organisations and staff a comprehensive set of resources that they can use to take action in the key areas highlighted by the analysis of serious incidents. Coordination of these resources offers the NHS the opportunity to enhance their impact and thereby reduce the risk of serious harm to patients.

NICE guidelines: *Acutely ill patients in hospital: Recognition of and response to acute illness in adults in hospital*

The NICE guidelines,¹ also released in July 2007, are a major new contribution. In 2006, NICE were asked by the Department of Health to 'prepare guidance on the care of acutely ill adults in hospital' for use in the NHS in England and Wales. This is the first short clinical guideline issued by NICE. It has a tightly focused scope, covering a small number of clinical questions.

The guidelines cover the care of all acutely ill adult patients in hospital, including patients in emergency departments. It addresses three key areas:

1. **Identification of patients** who are either at risk of clinical deterioration or whose clinical condition is deteriorating. This includes assessment of: scoring tools that record physiological parameters and neurological state; the level of monitoring needed; and the recording and interpretation of the data obtained.
2. **Response strategies**, including the timing of response and patient management, and the communication of monitoring results to relevant healthcare professionals, including the interface between critical care and acute specialties.
3. **Discharge of patients from critical care areas** back to ward-based care. This includes monitoring requirements on the ward and the timing of transfer.

NICE implementation package

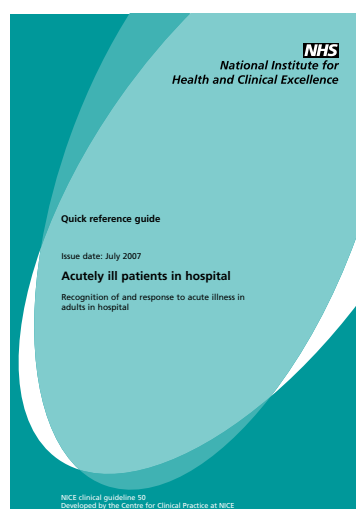
Release of the NICE guidelines will be followed by an implementation package in autumn 2007 that will include:

- examples of track and trigger systems with sensitivities and specificities;
- a framework for clinical ward team competencies, drawing upon Department of Health work (see below);
- an audit tool for trusts to assess their own performance.

Objectives and competencies

Comparative audit between different models of critical care outreach services has been hampered by the frequent lack of clear service objectives for each model. The Department of Health Critical Care Team has, with assistance from professional bodies, identified appropriate, measurable and auditable objectives which critical care outreach services can adopt to describe and develop their services.³⁵

In addition, the Department of Health is also working with organisations and clinicians to identify and describe a framework of core competencies that need to be held by clinical ward teams caring for acutely ill patients. This will assist the development of appropriate training and educational programmes (where these do not already exist) necessary to equip clinical staff with the skills to implement the NICE guidelines.



Resources and good practice examples for key theme 1: clinical or physiological deterioration not recognised or not acted upon

Track and trigger warning systems and critical care outreach services

It has been suggested that early detection of the deterioration of a patient can be enhanced through the use of screening by physiological track and trigger warning systems (incorporating selected basic vital signs). These aim to identify patients who are deteriorating and then prompt the seeking of appropriate assistance (often linked to Critical Care Outreach Services^{15,18}).

However, it is also recognised that outreach services can be delivered in a variety of forms and the provision of care for the acutely ill will need to take account of local provider context. Furthermore, a key component of many such services lies in providing education and enhancing the relevant skills of ward-based staff.

The Intensive Care National Audit and Research Centre (ICNARC),¹⁹ in collaboration with the University of Sheffield, has been funded to undertake several associated research projects into track and trigger warning systems and critical care outreach services. These include:

- a systematic review of the literature on outreach services in critical care and a narrative review of other specialist support services in acute wards;
- a systematic review of the literature on physiological track and trigger warning systems;
- an analysis of the available data on physiological track and trigger warning systems;
- a survey of the implementation, introduction and development of outreach services within acute NHS trusts in England;
- a qualitative study to characterise the impact of outreach services;
- an interrupted time series analysis of the impact of outreach services at the critical care unit level;
- a prospective evaluation of the impact of outreach services at the patient level, comparing admissions receiving outreach with those that do not.

The survey of hospitals²⁰ showed that 73 per cent of acute hospitals have some form of critical care outreach services, but with wide variation in the wards covered, the size and composition of the team, the availability (24 hours or restricted times) and the balance between direct care and advice. The survey also showed that many different (often locally adapted) track and trigger warning systems were in place. Many of these were derived from the original Early Warning Score which has also been used in the Institute for Healthcare Improvement/The Health Foundation project and the Modernisation Agency's 'Move your mortality dot' project.²¹

A systematic review and evaluation of track and trigger warning systems²² showed that published evidence on reliability, validity and utility is limited. Published papers were identified describing 25 different tools. Generally, such tools have poor sensitivity and positive predictive value. The conclusion is that such tools should not be discontinued, but chosen carefully in light of existing evidence on performance, and would benefit from further evaluation.

Larger prospective studies would be valuable to develop a high quality tool for timely recognition of acutely ill patients in a variety of clinical settings. In addition, further work is needed to validate the tools currently in use.

A systematic review of the effectiveness of critical care outreach services²³ found evidence of improvements in patient outcomes, including reduction in mortality, cardiac arrest rates and length of stay, but the strength of evidence was not robust. In part this reflects the design of studies undertaken, as well as the wide variety of different models of critical care outreach services, making comparison difficult. The authors conclude that there is no reason to discontinue or halt such developments, but that more evaluation is needed.

The results of these studies (with updated analysis) have informed the NICE guidelines¹ that are published alongside this report (see page 27).

Safer practice example: Hand held personal digital assistants (PDA)

Organisation: Portsmouth Hospitals NHS Trust and The Learning Clinic

Objective(s): To effectively collect data at the bedside on vital signs to support better monitoring, recognition of deterioration and appropriate action.

A system has been designed in which nurses collect routine vital signs at the bedside using handheld computers. These PDAs integrate these data with a locally agreed track and trigger algorithm to calculate and display an early warning score (EWS). Based on the value of the EWS, and its trend, the PDA provides decision support regarding future monitoring or the need to involve more senior staff (e.g., outreach service or intensive care team). Each data set is accurately dated, timed and auditable to the level of patient location and the person inputting the data. Automatic calculation of EWS removes the need for staff to know the correct weightings for individual physiological parameters, reduces calculation errors and saves staff time.

The PDAs link via a wireless local area network (W-LAN) to the hospital's intranet system, where raw and derived data are integrated with other patient information, e.g. name, hospital number, laboratory results. This permits instantaneous access to physiology data, EWS and vital signs charts by any member of the hospital healthcare team working within the W-LAN or, more widely, via the hospital intranet. The system has been designed to facilitate early and direct contact with members of the patient's primary clinical team or hospital's outreach service through an automated alerting system, triggered by the EWS data.

The system ensures the collation of complete vital signs datasets and alerts staff to overdue observations. Whilst patients are within the W-LAN, paper copies of vital signs charts are not required, as charts are displayed electronically. For the purposes of ward rounds, case conferences and the input of simple clinical details (e.g., diagnosis), vital signs and other data are viewed on PC Tablets. When patients are moved to areas outside the W-LAN, high quality, legible, paper charts can be printed.

Currently, approximately 13,500 vital signs datasets are captured each month from the 90 beds in the medical and surgical assessment units, and work using these data is currently underway to develop a validated EWS.

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Other initiatives

The first phase of The Health Foundation's *Safer Patients Initiative*²⁴ set out a specific aim to reduce adverse events by 50 per cent over a two year period and then sustain the improvement beyond this initial period.

In 2004, The Health Foundation commissioned the Institute for Healthcare Improvement to design and run an organisation-wide programme where every hospital works on implementing the same package of evidence-based improvements that cover infection control, medicines management, intensive care, surgical care and care on general wards. Senior leadership is required to prioritise patient safety and give its full support to the clinical teams to help them achieve their goals, and is actively involved through executive team walkrounds.

The programme includes the use of early warning systems and outreach teams. Four demonstration sites from across the UK are working on the initiative, which is being evaluated by a team from the Universities of Birmingham, Leicester and London. The Health Foundation has recently recruited a further 20 hospitals from across the UK to participate in the second phase of the initiative.

Safer practice example: A hospital-wide approach to recognising and responding to early signs of deterioration.

Organisation: Luton and Dunstable Hospital NHS Foundation Trust

Objective: To introduce a system to aid staff in reducing the number of avoidable deaths in hospital

In 2003, Luton and Dunstable had a higher than average hospital standardised mortality rate and had already begun taking steps to reduce it prior to applying for the *Safer Patients Initiative*. It has now seen its rate drop from 111 in 2003 to around 90 at the beginning of 2007. Luton and Dunstable is realising significant improvements in patient safety through using an early warning scoring system on general wards coupled with a critical care outreach team and backed up by improved communication between clinical staff.

Luton and Dunstable introduced a colour banded early warning observation chart to help nursing staff identify patients who are at risk of deteriorating through critical illness. An observation in red needs a response; two yellow observations together or consecutively also trigger follow up. When alerts are raised by the nursing staff from their observations, an outreach team from the ICU gives bedside diagnoses and management, along with staff support, if doctors on the ward are unable to respond timely.

Staff use a communication tool to help prompt them to give and receive relevant information. The Situation-Background-Assessment-Recommendation (SBAR) technique provides a framework for communication between members of the healthcare team about a patient's condition. It helps to frame any conversation, especially critical ones, requiring a clinician's immediate attention and action. Ward staff receive training in how to use the EWS charts and SBAR technique, and the team leading these changes is looking at ways of ensuring that staff retain their confidence in using this approach.

Use of these systems is measured through frequent run charts on surgical, medical and care of the elderly wards, compiled by individual wards. The ICU outreach team collects patient data each week, showing their end-of-process actions are saving lives. A run chart of weekly cardiac arrests (2222 calls) has had a step drop per week from the time the outreach team started, amounting to about two arrest calls prevented per week since 2004. This has taken courage by clinicians and managers to talk openly about methods to achieve this, and has required the sustained input of staff.

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The NHS Institute for Innovation and Improvement has recently published an evaluation of the *Mortality Community of Practice*.²¹ Initially, this was a community of three hospitals that formed part of the Modernisation Agency's 'Pursuing Perfection' programme. In a second phase, the learning from these three sites was used to support a further nine hospitals, all working to address avoidable mortality. They employed broadly the same Institute of Healthcare Improvement methodology as The Health Foundation's *Safer Patients Initiative*.

The *Mortality Community of Practice*, the four *Safer Patients Initiative* sites and Walsall Hospital recently joined forces for a one-day meeting run jointly by the NHS Institute for Innovation and Improvement and the Health Foundation to discuss avoidable death and share practical experiences of how to address the problems. The Institute has published guidance directed at chief executives²⁵ and medical directors²⁶ drawing on the discussion at this meeting and further guides are in preparation.

Safer practice example: A hospital mortality reduction programme

Organisation: Bradford Teaching Hospitals NHS Trust

Objective(s): To eliminate all unnecessary hospital deaths

A detailed case note audit was undertaken of consecutive hospital deaths to identify where improvement efforts should be targeted. Teams consisting of an intensivist, lead clinician, pharmacist and nurse were established for the four specialties with the majority of hospital deaths: care of the elderly, medicine, surgery, and trauma and orthopaedics. Each team was asked to audit a sample of case notes of 30 consecutive patient deaths using a detailed structured audit form. Analysis revealed a high prevalence of suboptimal clinical observations, hospital acquired infections and medication errors. In addition, an audit of 411 consecutive hospital deaths was carried out by the palliative care team. This identified a high proportion of patients coming in to hospital for terminal care, or being in hospital for a long time prior to death.

The results of the audit were used to direct the change strategies based on the identified priority areas of clinical observations, medication errors, end-of-life care and infection control. The modified early warning score (MEWS) was introduced through a series of training sessions for nursing staff and junior medical staff to improve clinical observations. The score was integrated into a standardised clinical observation record to ensure it was used routinely, and training sessions on acute life threatening emergency recognition and treatment (ALERT) were introduced. The hospital infection control policy was reviewed and strengthened and a programme of medication safety was established focusing on reducing errors with high risk medicines, and during admission/discharge transitions. End of life care guidelines were developed and implemented in hospital and in primary care. Statistical process control charts and death summaries were used to enhance feedback of timely data in accessible formats.

Standardised hospital mortality (HSMR) was taken as the main measure for monitoring change, and fell significantly in the three years following the start of the programme (94.6 to 77.5).

This is an example of where a detailed audit of patients dying in hospital enabled the identification of processes of clinical care that could be improved. The hospital identified the key factors in creating change as senior leadership, contextual analysis in the form of a rigorous audit, strong professional support, robust measurement, partnership across a health community (for end of life care and medication safety), and good communication. Through its involvement in the *Safer Patients Initiative*, Bradford is continuing to embed its work on MEWS and safety improvement.

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Resources and good practice examples for key theme 2: resuscitation after cardiopulmonary arrest

Work by the NPSA

To reduce risks associated with resuscitation, the NPSA issued a patient safety alert in 2004 advising all acute trusts to standardise the cardiac arrest telephone number to 2222.²⁷ It was known that many different numbers were being used within the NHS and clinicians who moved between hospitals could put patient safety at risk by using an incorrect number leading to delay in the team being called. By February 2006, all acute hospitals should have implemented this number.

The Agency highlighted the risk of missing or faulty equipment to cardiopulmonary arrest patients in its *Patient Safety Bulletin*,²⁸ published in July 2005. It recommended risk assessment alongside improvements in staff training. Guidance was also issued by the NPSA in March 2005 on improving emergency care for patients who breathe through their neck.²⁹

The Agency has also collaborated with other organisations to undertake design work on resuscitation trolleys. This redesign of the hospital resuscitation trolley won an award at the Medical Futures Innovation Awards 2007, beating 1,200 entries and 30 finalists to win the overall award in the category of Anaesthesia and Critical Care. Trials of the latest prototype will begin at St Mary's Hospital, London, in October 2007.

National guidelines and standards

In October 2004, the Resuscitation Council (UK), in collaboration with the Royal College of Anaesthetists, the Intensive Care Society and the Royal College of Physicians, published *Cardiopulmonary Resuscitation – Standards for Clinical Practice and Training*.³⁰ This joint statement provides advice on all aspects of a resuscitation service. Key recommendations include: early recognition of patients at risk of cardiopulmonary arrest; standardisation of equipment within each healthcare institution; and a system for assuring that the appropriate equipment is available, checked and functioning correctly. These have become the standard of care for cardiopulmonary resuscitation clinical practice and teaching in the UK.

Other publications issued by the Resuscitation Council (UK) include:

- *Resuscitation Guidelines 2005*³¹, which provide full details on basic and advanced, adult and paediatric resuscitation. These also cover peri-arrest arrhythmias, prevention of in-hospital cardiac arrest and decisions about cardiopulmonary resuscitation.

Safer practice example: Smart Resuscitation Trolley

Organisation: Helen Hamlyn Centre at the Royal College of Art; Department of Surgical Oncology and Technology, Imperial College, London; St. Mary's Hospital, Paddington; and the NPSA

Objective(s): To demonstrate how the effectiveness and safety of a resuscitation trolley could be greatly improved through design by taking full account of user and process needs, and through introducing 'intelligence' to the trolley through technologies such as Radio Frequency Identification (RFID).

The work included observational studies of resuscitation procedures and a full risk assessment of the process using a Failure Modes and Effects Analysis (FMEA). A working prototype was built and user-tested in numerous virtual resuscitation scenarios at St. Mary's and Chelsea and Westminster hospitals.

Following interest from manufacturers, the coming year will be spent improving the concept and turning the prototype into a manufacturable design and the NPSA's project partners are continuing the project's development.

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- *Advanced Life Support (5th edition) 2006*,³² which provides healthcare professionals with the essential knowledge to treat any adult in cardiac arrest. Illustrations accompanied by step-by-step instructions guide the reader through the key interventions involved in cardiopulmonary resuscitation. All healthcare professionals who attend cardiopulmonary arrests as part of a resuscitation team should be familiar with its content.

The Resuscitation Council (UK) Advanced Life Support Course, attended by thousands of healthcare professionals each year, now places great emphasis on earlier recognition of the deteriorating patient and cardiopulmonary arrest prevention.

Safer practice example: Revising cardiac arrest team 'call out' criteria**Organisation:** Gloucestershire Hospitals NHS Foundation Trust**Objective(s):** Improve cardiac arrest outcome and prevent cardiac arrest. Allow 'Do Not Attempt Resuscitation' order to be implemented before CPR commenced.

For the last six to seven years at Gloucester Royal Hospital, and more recently at Cheltenham General Hospital, the cardiac arrest call out criteria have been altered such that patients who are very ill and close to having a cardiac or respiratory arrest can have the full cardiac arrest team arrive (summoned by the cardiac team number i.e. 2222) before they actually arrest.

The concept is not new and many institutions have worked from a 'top down' approach for some time now i.e. scoring systems to pick up patients who are becoming ill and deteriorating, for example EWS/Outreach. The policy worked from the worse case scenario upwards. There was concern that until a patient actually had a cardiac arrest the nursing staff felt they could only fast bleep a doctor for help until the patient actually arrested, and then a whole series of multiply qualified individuals arrived. By changing the cardiac arrest call out criteria, the nurses feel much more empowered to call the cardiac arrest team prior to an arrest actually occurring. This also has the added benefit of allowing an appropriate 'Do Not Attempt Resuscitation' order to be made in certain circumstances prior to cardiac arrest and therefore avoids unnecessary CPR being undertaken.

The revised call out criteria are very severe in terms of abnormal patient physiology, but they have been chosen to reflect a patient who is about to have a cardiac or respiratory arrest. A less severely ill patient is picked up by the EWS or outreach team much earlier and dealt with appropriately. The revised criteria are as follows:

Call the Cardiac Arrest Team on 2222 for:

- All cardiac arrests
- All respiratory arrests
- For any UNRESPONSIVE patient (P or U on the AVPU score) with
 - heart rate >150
 - heart rate <40
 - respiratory rate >40
 - respiratory rate <8
 - systolic blood pressure <80mmHg
 - oxygen saturation < 90%

Patients have to be severely ill to fulfil the criteria, but nursing staff find it helpful to know that they can call the cardiac arrest team for these patients without the fear of being criticised because the patient had not arrested. This stemmed from anecdotal reports of staff waiting for the patient to arrest before calling the team; a practice that has stopped since the introduction of the revised criteria. About 15-20 per cent of our cardiac arrest calls are now as a result of patients fulfilling these parameters of abnormal physiology.

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Other initiatives

The NHS Litigation Authority has included resuscitation in its Risk Management Standards for acute trusts³³ (Standard 4: Clinical Care, criterion 8: Resuscitation). As a minimum, the approved documentation which describes the process for managing the risks associated with resuscitation must include a description of:

- a. duties;
- b. early warning systems in place for the recognition of patients at risk of cardio-respiratory arrest;
- c. post-resuscitation care;
- d. 'Do Not Attempt Resuscitation' orders;
- e. the process for ensuring the continual availability of resuscitation equipment;
- f. training requirements for all staff, as identified in the training needs analysis;
- g. process for monitoring the effectiveness of all of the above.

The Welsh Risk Pool has included resuscitation in several Welsh Risk Management Standards; standard 6 requires trusts to have a policy in place covering resuscitation; three further standards for specialists areas cover resuscitation requirements in more detail (standard: 15: Maternity, standard 16: Operating Department Services, standard 17: Accident and Emergency).

Safer practice example: A review of checking resuscitation equipment

Organisation: Basildon & Thurrock University Hospitals NHS Foundation Trust

Objective(s): To ensure compliance with resuscitation policy regarding checking and stocking equipment

A review of resuscitation trolley checking identified that there was not consistency across a particular directorate. A number of incident forms had been completed when the resuscitation officer had attended arrests and resuscitation trolleys were not adequately stocked. In order to ensure compliance with the policy, which stated that the trolley should be checked on a daily basis, an audit tool was designed by the risk co-ordinator for the directorate.

Each ward manager would nominate a staff member to check the trolley; this was identified on the duty rota. It meant that staff on all shifts checked the trolley and became familiar with the trolley in the event of an arrest. It also meant that if the trolley was not checked, the ward manager could discuss with the identified individual why the trolley was not checked and what actions they had taken to ensure that it was.

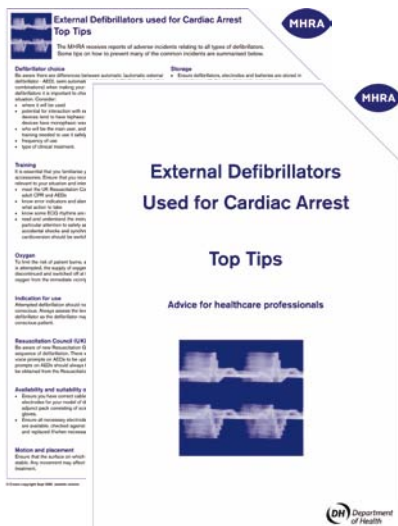
At the end of each month the risk co-ordinator would go to each area and review the checklist. A report was then produced and the results given out at the department meeting. Non-compliance issues and associated action plans could be developed. Within six months the areas audited were reporting 100 per cent compliance with the policy.

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The MHRA has issued several Medical Device Alerts and other publications about resuscitation equipment, including defibrillators and suction units.

Medical Device Alert 2005/035 reflected concern over the mis-assembly of suction systems during emergency use.³⁴ It reiterated how important training, maintenance and original purchase decisions are for these devices.

In addition, the MHRA has recently issued information in the form of a *Top Tips* leaflet and poster on the use of external defibrillators, which highlights many of the areas where their investigations have found problems.



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Conclusion

The themes of clinical or physiological deterioration not recognised or not acted upon, and of resuscitation following cardiopulmonary arrest, highlighted by analysis of serious incidents reported to the NRLS, are well recognised challenges to safety improvement. Despite many initiatives, the problems remain, as evidenced by analysis of NRLS data along with other data sources and the literature.

To improve safety for acutely ill patients, national coordination of a range of linked initiatives and the concerted effort of a collection of national bodies and expertise is needed to raise and maintain the profile of the problem. More importantly, these issues must be embedded at hospital and ward level as key areas for improvement and safer practice.

To that end, this report, alongside the publication of the NICE guidelines, aims to raise the profile of these critical themes once again, as part of a coordinated programme of national initiatives.

The leaders of acute trusts, and the staff who treat and monitor patients on hospital wards, are called upon to work together, drawing upon the resources contained within this report, the examples of good practice, and the NICE guidelines¹² and their forthcoming implementation package, supported by the national Patient Safety Campaign later this year, to make a real difference to the care of these patients.

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Appendices

Appendix 1: multi-agency group membership

**Professor Richard Thomson (Chair),
Director of Epidemiology and
Research, NPSA**

**Kate Beaumont, Deterioration Project
Lead, NPSA**

Dr Mary Armitage, Royal College of
Physicians and Chair National Institute
for Health and Clinical Excellence rapid
guidelines on the critically ill patient

Dr Maureen Baker, Connecting
for Health

Dr Anna Batchelor, Intensive
Care Society

Jennifer Benjamin, Patient Safety Team,
Department of Health

Maura Buchanan, President, Royal
College of Nursing

Dr John Curran, Vice-President and
Chairman of the Professional Standards
Committee, Royal College
of Anaesthetists

Dr Jane Eddleston, Clinical Care
Director Critical Care, Clinical Head
of Division Clinical & Scientific
Services, Manchester Royal Infirmary;
Department of Health Clinical Advisor
for Critical Care

Dr George Findlay, Clinical Lead,
Cardiac Arrest Study, National
Confidential Enquiry into Patient
Outcome and Death

Dr David Gabbott, Executive Committee
Member, Resuscitation Council

Dr Kevin Gunning, Intensive
Care Society

Dr Gill Hastings, Assistant Director,
The Health Foundation

Dr Ann McDonnell, Senior Lecturer,
Sheffield Hallam University

Mr Charlie McLaughlin, Director of
Professional Standards, Royal College
of Anaesthetists

Ros Moore, Chief Nursing Officer's
Office, Department of Health

Mandy O'Dell, National Secretary,
British Association of Critical Care
Nurses

Dr Hugh Rogers, Associate, Service
Transformation, NHS Institute for
Innovation and Improvement

Dr Kathy Rowan, Director, Intensive Care
National Audit and Research Centre

Dr Paul Rylance, Royal College
of Physicians

Professor Gary Smith, Consultant
in Critical Care Medicine, Queen
Alexandra Hospital, Portsmouth

Dr Tim Stokes, NICE Lead, rapid
guidelines on the critically
ill patient

Linda Watterson, Royal College
of Nursing

Keith Young, Emergency Care Team,
Department of Health

NPSA Membership

Vivienne Allan, Acting Director
of Communications

Donna Forsyth, Patient Safety Manager

Dagmar Luettel, Research Associate

Joan Russell, Safer Practice Lead

Dr John Scarpello, Deputy
Medical Director

Appendix 2: methods

The National Reporting and Learning System

The NRLS is the primary mechanism for the NPSA to collect information on patient safety incidents from across England and Wales. The NRLS data set is designed to collect a notification report of a single patient safety incident soon after it occurs. It focuses on what happened, when and where it happened, the characteristics of the patient(s) involved (such as age, gender and ethnicity) and the outcome for the patient(s). The data set includes contributory factors, and factors that might have prevented harm. Reports contain free text that explains what happened in varying degrees of detail. Additional detail is provided in reports involving medication and medical devices.

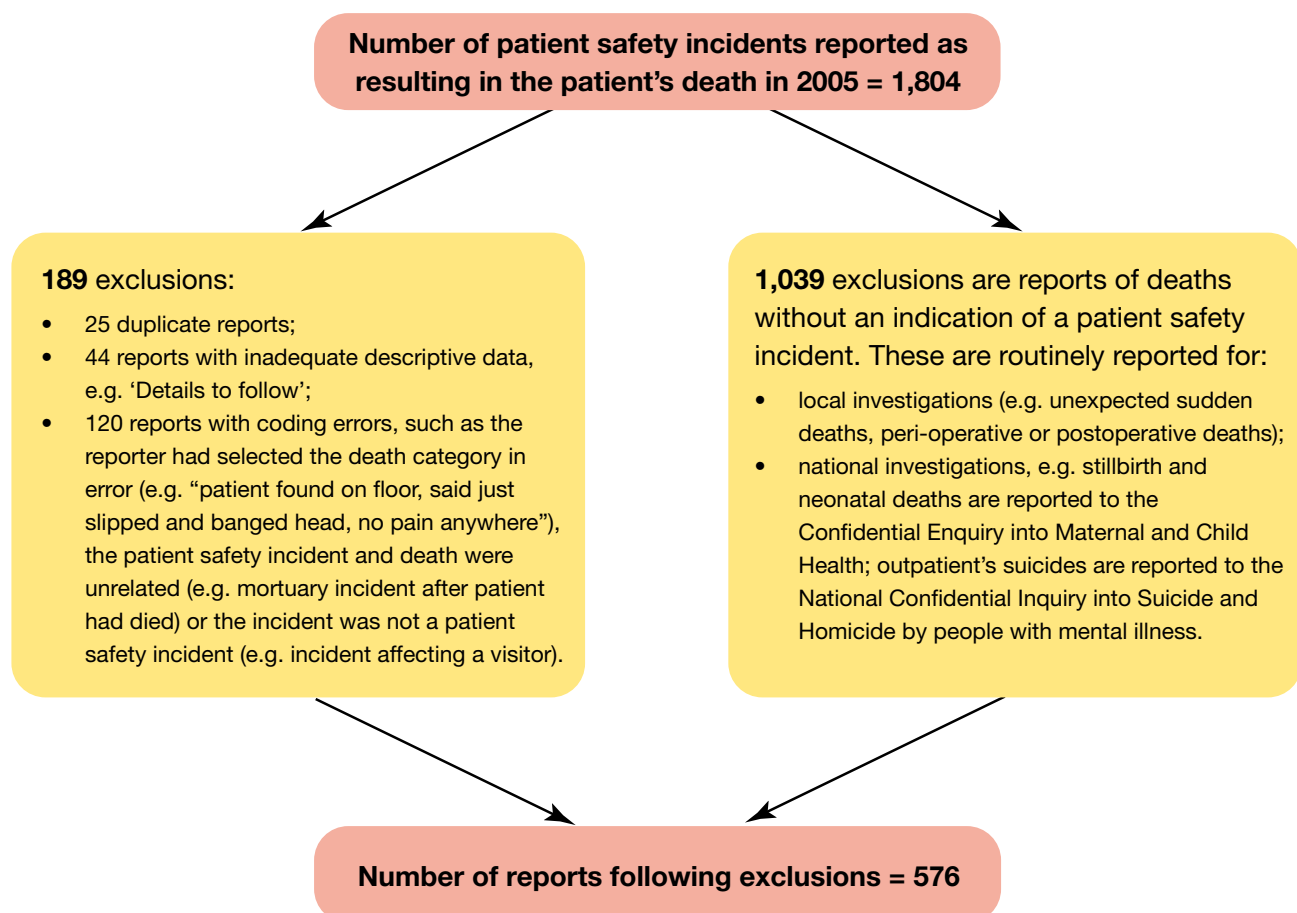
The NRLS is the first national reporting system of its kind in the world. It collects data from across all healthcare settings and provides a springboard for developing national solutions to patient safety problems and for identifying priorities for the NPSA and the wider health service.

Identifying patient safety incidents associated with death

All incidents with the outcome categorised as death, which occurred in 2005 and were reported to the NRLS up to the end of May 2006, were reviewed independently by two reviewers with clinical and risk management expertise. In order to identify the number of reported patient safety incidents associated with death, incidents were excluded if they were duplicates or contained inadequate descriptive data, a clear coding error, or no indication that a patient safety incident occurred.

The initial level of agreement between the two reviewers was 92 per cent. Agreement was reached on a further seven per cent following discussion, and the one per cent of reports where the two reviewers could not agree was arbitrated by a third medical reviewer.

Exclusions of reports where the death was not directly related to a patient safety incident



Thematic analysis of patient safety incidents associated with death

Analysis of the free text describing the incidents suggested themes not identified by categorisation into the standard high level incident types within the NRLS dataset. Hence, the descriptive text of all incidents was reviewed to group similar incidents and identify key themes that might better inform safety improvement.

Two reviewers with clinical and risk management expertise undertook this analysis. There are a number of ways by which incidents could be classified; the purpose of this secondary analysis and categorisation was to identify themes that might be helpful in setting priorities for further action and it is complementary to the classification by incident type within the NRLS dataset.

Search for further incidents

A search of the NRLS for incidents with less severe outcomes describing clinical deterioration not recognised or not acted upon was undertaken for the same time period using text searching software. This was a text search of the incident descriptions developed from key words and phrases identified within the incidents associated with death.

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We recognise that healthcare will always involve risks, but these risks can be reduced by analysing and tackling the root causes of patient safety incidents. We are working with NHS staff and organisations to promote an open and fair culture, and to encourage staff to inform their local organisations and the NPSA when things have gone wrong. In this way, we can build a better picture of the patient safety issues that need to be addressed.

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