

Investigation

# Investigation into Staffordshire Ambulance Service NHS Trust

April 2008



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# The Healthcare Commission

The Healthcare Commission's full name is the Commission for Healthcare Audit and Inspection. We exist to promote improvements in the quality of healthcare and public health in England. We are committed to making a real difference to the provision of healthcare and to promoting continuous improvement for the benefit of patients and the public.

The Healthcare Commission was created under the Health and Social Care (Community Health and Standards) Act 2003. The organisation has a range of new functions and took over some responsibilities from other commissions. We:

- have replaced the Commission for Health Improvement, which ceased to exist on 31 March 2004
- have taken over responsibility for the independent healthcare sector from the National Care Standards Commission, which also ceased to exist on 31 March 2004
- carry out the elements of the Audit Commission's work relating to the efficiency, effectiveness and economy of healthcare.

We have a statutory duty to assess the performance of healthcare organisations, award annual ratings of performance for the NHS and coordinate reviews of healthcare with others.

We have created an entirely new approach to assessing and reporting on the performance of healthcare organisations. Our annual health check examines a much broader range of issues than in the past, enabling us to report on what really matters to those who receive and provide healthcare.

## Investigating serious failings in healthcare

The Healthcare Commission is empowered by section 52(1) of the Health and Social Care (Community Health and Standards) Act 2003 to conduct investigations into the provision of healthcare by or for an English NHS body.

We will usually investigate when allegations of serious failings are raised, particularly when there are concerns about the safety of patients. Our criteria for deciding whether to conduct an investigation are set out in appendix A.

In investigating allegations of serious failings in healthcare, we aim to help organisations to improve the quality of care they provide, to build or restore public confidence in healthcare services, and to seek to ensure that the care provided to patients is safe throughout the NHS.

# Summary

The Healthcare Commission carried out this investigation at Staffordshire Ambulance Service NHS Trust as a result of serious concerns first raised by West Midlands Strategic Health Authority and further serious concerns identified by the Healthcare Commission.

The aim of the investigation was to establish whether the ways of working at the trust were adequate in ensuring the safety of users of the service and staff, and in providing a good quality of service.

We looked at the trust's arrangements for clinical governance and its management of medicines. We also examined its management of its community first responder schemes. (Community first responders are volunteers who respond to certain medical emergencies on behalf of an ambulance trust and give immediate assistance and treatment until the arrival of an ambulance paramedic or technician.) In addition, we explored how well the trust worked with other local NHS organisations. Finally, we looked at the management and leadership of the trust, together with strategic arrangements for ensuring the safety of users of the service and staff.

We carried out the investigation between January 2007 and August 2007. Staff from the Healthcare Commission worked with a team of expert advisers. We met with patients, their relatives and members of the public who had used the emergency and GP out-of-hours services, and we carried out visits to the trust – both scheduled and unannounced. We used the information from these alongside evidence from interviews and analysis of documents, including policies, reports, minutes of meetings and observations.

## Background

Staffordshire Ambulance Service NHS Trust was created in 1992 and covered most of the county of Staffordshire. Until late 2004, there was little change in the executive and non-executive team. From then on, a number of changes took place: a new chairman and a non-executive director were appointed to the trust's board and, in March 2006, the chief executive, who had been in post since the trust was created, left the trust. The medical director, who was also the deputy chief executive and who had been working in the trust since 1999, left at the end of March 2006.

Following the departure of the previous chief executive, an acting chief executive was appointed, along with an acting medical adviser who left the trust at the end of July 2006. The previous medical director returned to the trust on 25 July 2006 and on 1 August 2006 he was appointed acting medical adviser.

A joint director of clinical performance (with West Midlands Ambulance Service NHS Trust) was appointed in November 2006. In March 2007, a chief operating officer was appointed and replaced the acting chief executive.

On 1 October 2007, the trust merged with West Midlands Ambulance Service NHS Trust.

In the five years preceding the merger, Staffordshire Ambulance Service NHS Trust consistently achieved and exceeded the Department of Health's standards for national response times. It had always tried to be innovative, both in the type of services it delivered and the way it delivered them.

## Summary of events

The concerns, first raised in August 2006, related to the trust's management of

medicines, including the use of controlled drugs and the range of medicines and drugs that it allowed its community first responders (CFRs) to administer, as well as its systems for introducing new equipment. The fitness to practise of the acting medical adviser was also called into question, resulting in him being referred to the General Medical Council. To date, the concerns raised have been considered by two GMC panels, both of which decided to take no action on his registration.

West Midlands Strategic Health Authority carried out a review of the trust's management of medicines. This was completed in November 2006 and found that the trust allowed its paramedics to possess and administer drugs, for example midazolam by the buccal (cheek) route, that they were not authorised to hold. Authorisation can only be granted if a body such as the Joint Royal Colleges Ambulance Liaison Committee (a national forum that provides advice and guidance on all clinical aspects relating to care provided by ambulance staff) makes an application to the Home Office for a group authorisation for paramedics to administer midazolam.

The review also found that protocols were not always dated, few had review dates and there was no evidence that they had been reviewed. The protocols did not specify to whom they were applicable, that is whether they applied specifically to paramedics, ambulance technicians, CFRs or all of them.

At the same time, the Independent Police Complaints Commission (IPCC) was investigating an incident involving the trust and Staffordshire Police Service, where a man had died. The IPCC published a report of its investigation in December 2007. The investigation found that staff from both organisations "made poor decisions or failed to comply with organisational policies and procedures ...". It also identified systemic failure by staff in the control rooms of both Staffordshire Police and the trust to "work effectively together".

We also became aware that the trust's CFRs were driving using blue lights and sirens. They had been told by the trust that they could exceed the speed limit by a maximum of 20 miles per hour and drive through red lights. They were allowed to do this without having completed a course of advanced driving instruction.

Our findings are set out in the full body of this report and are summarised below.

## Management of medicines

The management of medicines is a complex area and expertise is required to ensure that medicines legislation and regulations are interpreted and applied correctly.

The nature of the work of ambulance trusts means that they are often faced with unique problems. However, they are still required to ensure they comply with medicines legislation. The trust did not have robust arrangements in place for the management of medicines and controlled drugs, and did not have the necessary resources or expertise available to ensure their practices complied with the relevant legislation and regulations.

It took the practice of paramedics administering morphine seriously, but it did not consider all the potential implications and risks. There was too much focus on the potential risk of abuse of morphine by staff, rather than looking at all the risks of paramedics administering morphine.

The trust's patient group directions (PGDs) – written instructions for the administration of named medicines to groups of patients who may not be individually identified – were not always signed and there were too many versions in circulation, with little or no version control. Only specific groups of health professionals can supply or administer medicines under a PGD. A PGD must be signed by a senior doctor (or if appropriate a dentist) and a senior pharmacist, both of whom should have been involved in developing the PGD, as well as a senior representative of the trust. Some of the PGDs contained only

the electronic signature of the previous medical director. Others included the name, but not the signature, of a pharmacist from South Western Staffordshire PCT. The pharmacist told the Commission that she had not been involved in the development of the PGDs.

It was also unclear which PGDs had been distributed to staff, and there were different versions of PGDs on the trust's internet and intranet. The trust did not provide sufficient training for staff about PGDs.

The trust supplied its CFRs with drugs that contravened legislation for controlled drugs, and allowed them to administer medicines that were outside their remit. This was a potential risk to the safety of patients and to the CFRs, who were operating outside the law.

When these concerns were first raised, the trust was unable to provide an assurance that it was compliant with medicines legislation or that the CFRs had received sufficient training. This issue caused considerable anxiety to individual CFRs, and such was the level of concern about the withdrawal of the drugs and medicines from use by CFRs that it was discussed in the House of Commons. The CFRs sought advice, independently of the trust, from the Medicines and Healthcare products Regulatory Agency and there was a suggestion that some CFRs might withdraw their services.

It was not unusual for medicines to be missing or unaccounted for. Some staff did not seem to be aware of the seriousness of this. There was a general lack of knowledge about the importance of complying with medicines legislation.

Although the trust sought advice about its arrangements for the management of medicines from pharmacists, the advice provided was not comprehensive or robust. There were misunderstandings about roles and expectations. One pharmacist had stopped giving advice in October 2005, yet both the previous chief executive and previous medical director were unaware that they were no longer receiving pharmaceutical advice.

## Introduction of new equipment

There is no doubt that the trust wanted to provide the best possible care for patients and recognised the role of new technology in helping it achieve this. However, it did not always carry out comprehensive risk assessments before introducing new equipment, or provide adequate training for staff. This resulted in some equipment being used inappropriately and on groups of patients for whom it was not intended. For example, the automated gas-driven chest compression device should not be used on elderly frail people or women who are pregnant. Although the device was introduced in 2004, this information was not circulated to staff until 2007. Once the trust became aware of problems with equipment, however, it took appropriate action and either removed it or modified how it was used.

When introducing pioneering equipment, the trust did not always take the time to gather the necessary evidence that would prove the benefits to the care and treatment provided to patients. This has resulted in the trust missing opportunities to lead or participate in research to establish the effectiveness of the equipment, and potential damage to its reputation for providing a safe service.

It is a significant omission that the standard operating procedure for introducing new equipment made no reference to the role of medical staff, or indeed the clinical services manager in this area. The clinical services manager and the previous medical director clearly had some responsibility for introducing new equipment.

Although we have not found any evidence of harm to patients, and while some equipment – such as the automated gas-driven chest compression device – may reduce risks for ambulance staff when trying to resuscitate patients in a moving vehicle, the benefits for patients have yet to be established.

## Management of community first responders

It is clear that improving the care provided to patients was the key reason the trust introduced community first responders (CFRs). Although in many ways the CFR schemes were a success, there were flaws in the trust's management of them.

Some of the problems may have arisen because the trust perpetuated the belief that the role of a CFR was broadly equivalent to that of an ambulance technician. Although the trust, when compared with other ambulance trusts, provided more training for CFRs, this was not comparable to the training given to ambulance technicians. This blurring of roles caused tension between staff groups and the CFRs.

Unlike other ambulance trusts, the trust allowed CFRs to use blue lights and sirens when driving and to exceed the speed limit, without providing the necessary driver training. This potentially jeopardised the safety of CFRs and other drivers.

When we first voiced our concerns about this practice, the trust was initially reluctant to put any constraints on CFRs using blue lights and sirens.

At some point the trust lost sight of the fact that, as volunteers and without a formal agreement setting out the working arrangements between the trust and the CFR schemes, the CFRs were not bound by the same terms and conditions as staff employed by the trust. The CFRs had the power to withdraw their services, which would have affected significantly the care provided to patients.

What had started as a volunteer service, providing care and treatment to discrete groups of patients, almost mushroomed into a parallel ambulance service with the power to potentially disrupt the service provided by the trust.

## Management of staff, and training and education

Over the period covered by this investigation, there had been pressure on resources and a gradual decrease in support and resources to help staff to carry out their jobs. In addition, in May 2004, the trust took on some aspects of the GP out-of-hours service, which created an increase in the demand for the service. Community paramedic officers played a key role in the GP out-of-hours service, resulting in the expansion of their role and requiring them to learn new skills. Staff and managers were often working long hours.

Delays in handing patients over in accident and emergency (A&E) departments were not unusual. The increased demand on the service made it even more imperative that there was no delay to staff in handing patients over in A&E; any delays led to increased pressure on ambulance staff and managers. The way the managers handled this was at times inappropriate. One of the problems was that staff were sometimes paged by a number of managers in the trust: their area manager, the manager in the emergency operating centre and senior managers. It was not unknown for ambulance staff who had been delayed in A&E to then be called to the trust headquarters to account for themselves. This served only to increase the pressure on staff, without necessarily resolving the problem.

Managers were not always allowed to manage. Where it was felt there was a problem in the skills and knowledge of staff in a particular area, responsibility was taken away from them rather than addressing the shortfall. This approach was seen in relation to formal disciplinary hearings, where in many cases the decision about whether a hearing was necessary was made by the previous chief executive. He believed that "managers were not good at managing disciplinary procedures, and HR, whose responsibility was to advise managers prior to disciplinary action being taken, were often reluctant to do so".

Some of the managers found this frustrating, as there were occasions when they felt it was



necessary to discipline a member of staff and were unable to do so. Similarly, if a department was not functioning well, the responsibility was transferred elsewhere. In the short term, this may have been a reasonable decision if the intention was to address the underlying problem. However, the trust did not always go on to tackle the problem.

There was a gradual reduction in the education and training opportunities provided by the trust. This was due to an increase in demand for the service, and resources were redirected to ensure the trust was able to meet the additional demand. The trust provided little or no support for staff to attend training provided by external organisations, or training that would have helped them with the management aspects of their role.

## Clinical governance and the management of risk

The arrangements for clinical governance and the management of risk had remained relatively unchanged for a number of years.

The main forum for clinical governance, the risk and clinical governance committee, met only four times a year. This had a huge remit, as the trust did not have a separate committee responsible for the management of risk. It was unrealistic to believe that all the items on each meeting agenda could be given the attention they required, and the committee should have considered meeting more frequently.

The trust tried to introduce other committees to look at governance for specific areas, for example the GP out-of-hours service, but it was unsuccessful, partly because of key staff leaving the trust.

The system for the management of clinical risk was fragmented. A number of staff formally or informally were involved in investigating incidents, yet very few of them had received any training from the trust in how to carry out this role. Staff were reporting incidents using anonymised forms, and their comments suggest a perception that a blame

culture existed. If more managers had been given training on how to carry out investigations, this may have helped dispel some of the concerns of staff.

One area where the trust was particularly effective was engaging with members of the public, and there is no doubt that the trust was held in high esteem by patients, their relatives and the public.

The structure for governance was changed in early 2007 with the introduction of the integrated governance and performance committee. This was done as part of a full review of the trust committee structure. The committee was chaired by a non-executive director and met monthly.

## Leadership and management

The leadership style of the trust was very 'hands on'. In some ways it is to be commended that senior managers, executive directors and the previous chief executive would make themselves available to respond to emergency calls and "go to where the problems were". On some occasions this may have been helpful. On others, it seems to have exacerbated what was already a difficult situation. It reinforced the perception of a lack of confidence in the ability of managers and of managers not being allowed to manage. It is difficult to see how they had time to fulfil their obligations as executive directors, and perhaps accounts for why many of them often worked beyond their contracted hours.

There was relatively little turnover in members of the executive and non-executive teams. Although the previous medical director was also the deputy chief executive and not a member of the trust's board, he was involved in much of the decision making about new clinical equipment and the management of medicines. He was also the only director who had a clinical background.

When a new chairman was appointed in 2005, the dynamics of the board began to change. For example, the chair successfully challenged the view of the previous chief executive that the clinical negligence scheme

for trusts assessment was no more than a “tick box assessment”.

Although there had been earlier requests, it was not until February 2007 that the trust changed the format for information for board meetings. While it can be difficult getting the balance right, between giving too much or insufficient information to non-executive directors, the trust should have responded earlier to the request by the non-executives for clearer and less detailed information. If the information had been presented in a more meaningful way, it may have enabled the non-executives to be more questioning and challenging about some of the decisions that the executive directors were making. Equally, the non-executive directors should have persisted with this issue.

The trust was very open about its intentions and what it was trying to achieve. The trust’s board, the previous SHA and the PCTs did not ask searching questions about how the trust was balancing the requirements to meet the Department of Health’s response time targets, be at the forefront of new technology and introduce new services, all against a background of a reduction in resources and an increase in demand for the service. There was complacency at a strategic level, brought about by the trust’s continued ability to exceed the Department of Health’s response time targets. If there had been more rigorous questioning and challenge, it may have been recognised earlier that the achievements, and the pace the trust was operating at, were not sustainable.

### **Joint working arrangements with local community health partners**

There was clearly some tension between the trust and local acute trusts, much of it generated because of delays in handing patients over in A&E. The trust is perhaps not alone in this. However, the way in which senior staff sometimes responded to this problem – for example by threatening to put up tents in the car park of a local acute trust to receive patients – only served to exacerbate the situation. Despite this issue being identified in

2003, the trust seemed to have taken little action to address the problem.

The language used in some correspondence with PCTs could also be described as antagonistic. In terms of the GP out-of-hours service, there was a significant problem between the trust and the PCTs about the role and qualification of the doctors employed by the trust to provide the service.

### **Conclusions**

The trust was keen to be innovative, and to be at the forefront of embracing new practices and technology, in order to improve the care provided to patients. While this is to be commended, and the Commission would not wish to stifle innovation in the NHS, the pace of innovation was too quick. Being innovative requires expertise and resources, and this was not always available to the trust.

Innovation also brings risks and the trust did not always anticipate the risks or manage them as well as it might have done. When concerns were raised, the trust was unable to provide the necessary assurance that its practices were safe. Particularly, given that this was a trust that wanted to be innovative and at the forefront of introducing new equipment, the arrangements for clinical governance should have been more robust.

The fact that the majority of ambulance staff deal with emergencies, work in pairs or as single responders, and are regularly travelling rather than located in specific premises, presents ambulance trusts with unique challenges. It can make it difficult to standardise procedures and ensure good practice is embedded across a trust. However, all trusts are still required to ensure they comply with the relevant legislation and have good governance arrangements in place for the management of medicines.

This lack of management training and support may have contributed to the ineffective way managers addressed some issues, such as how they carried out disciplinary procedures and managed delays in A&E departments.

In allowing the role of CFRs to develop in the way it did, and without a formal agreement outlining the working arrangements between the trust and the CFR schemes, the trust found itself in a situation that was very difficult to manage and unwittingly put the good working relationship between the CFRs and the trust at risk.

During the course of the investigation, we became aware that there was a distinct absence of national guidance about the role of CFRs. However, unlike other ambulance trusts, the trust put relatively few boundaries around this role. Despite the lack of national guidance, the trust had a responsibility to ensure that CFRs did not attend calls or administer medicines and drugs that were outside their remit and experience.

In order to be clear about the role of CFRs nationally, we undertook a national survey of CFR schemes in NHS ambulance services in England. We published the findings from the survey in December 2007 (available on our website [www.healthcarecommission.org.uk](http://www.healthcarecommission.org.uk)).

There were occasions when the trust should have paused and taken time to consolidate what it had already achieved, rather than rushing to embrace the latest equipment. However, despite these serious problems, the trust and staff were committed to improving the care and treatment they provided to patients.

## Recommendations

The Healthcare Commission considers the findings of this investigation to be extremely serious, and to constitute a significant failing on the part of Staffordshire Ambulance Service NHS Trust, which, although committed to improving the quality and expanding the range of services provided, failed to protect the interests of patients and staff.

We are mindful of the fact that, in October 2007, Staffordshire Ambulance Service NHS Trust ceased to exist and its services became the responsibility of West Midlands Ambulance Service NHS Trust. Our recommendations,

therefore, relate to West Midlands Ambulance Service NHS Trust (WMAS).

We expect WMAS to consider all aspects of this report. Here we highlight areas where action is particularly important.

## Clinical governance and the management of risk

Risk management is a key component of improving patient care and is a central part of an organisation's strategic management. The WMAS board must satisfy itself that there is an effective framework in place to monitor the quality of care and the safety of the services provided by WMAS, and that it receives information that enables it to assess whether WMAS is compliant with national standards and other regulatory requirements.

Before introducing any significant new services, practices or equipment, WMAS must carry out robust assessments of potential risk to the safety of patients and ensure there is clear evidence demonstrating the benefits to the care of patients. It must also take into account the need for any additional training and education that may be required.

WMAS must review its arrangements for reporting, investigating and learning from incidents, to ensure that they are effective and clearly understood by all staff.

## Management of medicines

WMAS must ensure that it has robust arrangements in place for the management of medicines, including sufficient and appropriate expertise from specialist advisers.

It must continue to align its policies and practices for the management of medicines, and ensure that good practice is consistently applied across the organisation and that all staff are aware of their responsibilities.

## Community first responders

WMAS must carry out a review of the training, education, support and governance

arrangements for its community first responders (CFRs) to ensure that they are able to carry out their role safely and effectively. This must include the use of blue lights and sirens by CFRs. Findings and actions from this review must be clearly communicated to the CFRs.

## **Training and education**

WMAS must take the necessary steps to ensure that staff attend mandatory training and education. This must include specific training on the management of risk.

WMAS should, where appropriate, provide access to mentoring and coaching for managers, to help develop skills in leadership and to encourage staff to adopt new ways of working.

## **Communication**

WMAS must ensure that it has effective methods of communicating with staff, to ensure they are up-to-date with new working practices and developments within the trust.

## **Joint working arrangements with local acute trusts**

In partnership with local acute trusts, WMAS must develop procedures to assist the timely handover of patients in accordance with their needs, and to ensure that ambulances are available to respond to other emergency calls.

## **National recommendations**

All NHS ambulance trusts must read this report, review their services in light of the findings and, where appropriate, take the necessary action. In particular, they must ensure their boards receive information that enables them to assess if users are receiving a high quality, safe service that complies with national standards and other regulatory requirements and identifies potential areas of risk.

Any NHS ambulance trust that expands the range of services it provides, to include for example GP out-of-hours services, must carry out comprehensive risk assessments to identify any potential risks to the safety of patients. It must ensure there is clarity about the scope of the service it will provide and adhere to national and professional guidelines related to the service.

When introducing any significant new services or practices, NHS ambulance trusts must take into account the need for additional training and education that staff may require, and ensure this is provided.

NHS ambulance trusts must ensure that their arrangements for the management of medicines comply with legislation for medicines and controlled drugs, and that they have robust governance arrangements in place to assure and monitor compliance.

The Department of Health needs to liaise with the Home Office to clarify the circumstances in which NHS ambulance trusts require a licence to possess and supply controlled drugs to registered paramedics.

When introducing new equipment, NHS ambulance trusts must carry out robust assessments of potential risks to the safety of patients, and ensure there is clear evidence demonstrating the benefits to the care of patients.

All NHS ambulance trusts must ensure that CFR schemes are properly managed, supported and audited, and are in line with the national guidance recently agreed by the NHS ambulance service Chief Executive group.

Commissioners of NHS ambulance services should ensure that they, and ambulance trusts, have systems in place for monitoring and reporting on the quality and safety of services.

# Introduction

The Healthcare Commission carried out this investigation into Staffordshire Ambulance Service NHS Trust following a number of serious concerns first raised by West Midlands Strategic Health Authority, and further serious concerns identified by the Commission. The purpose of the investigation was to examine the systems that the trust had in place to ensure the safety of patients, understand why problems had occurred and make recommendations where necessary.

## The concerns

In November 2004, we were informed of a delay, involving the trust, in the transfer of a child from a ward to an intensive care unit. After considering the details of the concern and the action taken by the trust following the delay, we concluded that no further action needed to be taken.

However, shortly afterwards, we were informed of a concern about the GP out-of-hours service provided by the trust. The trust had taken over responsibility for providing this service for south Staffordshire in 2004.\* There was a delay in responding to a call for a child who was having a severe asthma attack. The child subsequently died. This resulted in an external review of the out-of-hours service by independent clinicians. Shropshire and Staffordshire Strategic Health Authority, along with the Commission's regional staff, agreed to monitor implementation of the recommendations arising from the review.

In August 2006, we were notified of serious concerns about the trust from West Midlands Strategic Health Authority, which had replaced

Shropshire and Staffordshire Strategic Health Authority. These related to:

- the experience and qualifications of the doctors employed by the trust to provide the GP out-of-hours service
- the fitness to practise of the acting medical adviser (resulting in his separate referral to the General Medical Council)
- the trust's management of medicines, including the recording and storage of controlled drugs
- the range of drugs that the trust supplied to its volunteer community first responders, and allowed them to administer
- the trust's systems for introducing and evaluating new equipment.

Around the same time, we were notified that the Independent Police Complaints Commission was investigating an incident involving the trust and Staffordshire Police Service where a man had died, and also that the NHS Counter Fraud and Security Management Services had been informed of inappropriate storage and documentation of controlled drugs at the trust.

The SHA initiated a review of the trust's policies and procedures on the use and management of medicines. This resulted in a number of recommendations.

We obtained information from the trust and visited it to interview a range of staff including paramedics, technicians, community first responders, the acting chief executive, the chairman and one of the non-executive directors.

\* The General Medical Services contract came into force in April 2004. It allowed GPs to choose not to provide 24-hour care for patients. The out-of-hours period is from 6.30pm to 8.00am and all weekends and bank holidays. PCTs must make sure that all patients have access to out-of-hours care. Some GP practices may provide this service. Alternatively, PCTs may hire other organisations to provide the service.

From the information collected, we identified five problem areas:

- Community first responders (CFRs) – these are volunteers who respond to some medical emergencies on behalf of an ambulance trust, providing immediate assistance and treatment until the arrival of an ambulance paramedic or technician. The SHA review found that the trust was supplying CFRs with drugs that it was not legally allowed to supply to them.
- The trust’s policies and procedures for the management of medicines – the SHA review identified problems with how the trust was storing and managing controlled drugs and found that paramedics, ambulance technicians and CFRs were administering drugs for which they were not authorised.
- The trust’s working relationship with other NHS organisations – we were concerned that the trust had not developed effective working relationships with staff in local accident and emergency departments and that this may have compromised the care of patients.
- Clinical leadership and management at the trust – many of the issues identified were clinical in nature, and this raised questions about whether the trust was seeking, and receiving, appropriate medical and pharmaceutical advice.
- Clinical governance – the range and seriousness of these issues raised questions about the robustness of the trust’s arrangements for clinical governance.

Although the trust told us that it intended to carry out a review of the role of the CFRs, all of these issues raised serious doubts about the safety of the care and treatment the trust was providing to patients. In a letter dated 30 November 2006, we informed the trust of these five areas of concern and asked what action it intended to take in response.

In December 2006, the Commission and the SHA met with the chairman and the acting chief executive of the trust and the chief executive of West Midlands Ambulance Service NHS Trust (WMAS) to review what action the trust had already taken in response to the concerns and to agree what further action was necessary. The WMAS chief executive was acting as a formal adviser to the trust’s board under directions issued by the Secretary of State for Health in July 2006.

Among the key issues discussed was whether the trust had the resources to deliver the necessary changes within reasonable timescales to ensure the safety of patients. We also raised concerns about CFRs using blue lights and sirens when responding to calls, without having received the required driving instruction. The trust seemed reluctant to put any constraints around this practice and told us that the previous chief executive had discussed it with the Chief Constable of Staffordshire.

We were concerned about the willingness and ability of the trust to change its culture and encourage staff to understand and accept the necessary changes. It was agreed that the trust would provide us with a copy of a report being prepared for a meeting of the trust’s board in January 2007. The trust also promised to send us by 11 January 2007 a detailed action plan (including timescales) addressing the concerns.

The action plan, when received, did not address all of the issues raised.

Given the seriousness of the concerns, the failure of the action plan to address all the issues, and the fact that this was now the third time in less than two years that we had been made aware of problems about the quality of the services provided by the trust, we decided to launch an investigation.

## Terms of reference

The Commission's investigation committee agreed the terms of reference for the investigation in January 2007. The investigation would focus on the systems that the trust had in place to assure the safety of patients and the quality of the services provided by the trust, and would cover the period from 2004 to the beginning of 2007. This would include an examination of:

- the management and leadership of the trust
- the trust's arrangements for clinical governance, including the management of risk and the management and use of medicines
- management by the trust of its CFR schemes
- arrangements at strategic level to assure the safety of service users and the quality of services from the trust
- joint working arrangements between the trust and its local health community partners.

## Key elements of the investigation

Our investigation team worked with a team of expert advisers. The membership is listed in appendix B.

During the investigation, the investigation team:

- carried out seven site visits to the trust to interview staff in relation to the investigation
- conducted more than 190 face-to-face and telephone interviews with current and former staff from the trust, people from local organisations representing patients, people who had used services at the trust and their relatives, and members of the public (see appendix C for further details)

- analysed more than 3,000 documents provided by the trust and other organisations (see appendix D for a summary of sources of information and evidence).

## This report

In this report, we first summarise the national changes that have taken place in the NHS ambulance service in recent years, both in terms of reconfiguration and the evolution of the care and treatment provided to patients.

We describe the context of the trust and its arrangements for clinical governance, including the arrangements for the management of risk and medicines. We look at the management and leadership, including clinical leadership, of the trust and the action taken in response to the concerns raised.

We consider how the trust worked and engaged with other local NHS organisations and how the trust's board and other agencies were assured about the safety of patients.

# National context

## The role of the NHS ambulance service

In 1974, responsibility for ambulance services transferred from local government to the NHS. During the 1990s, ambulance services became NHS trusts.

Like the rest of the NHS, the ambulance service has undergone significant change and reorganisation to improve the quality and range of services for patients. Following the publication of *Taking healthcare to the patient: Transforming NHS ambulance services* (Department of Health, 2005) and after public consultation, the number of ambulance trusts was reduced from 31 to 12 in July 2006.

Traditionally, the role of the NHS ambulance service has been to provide a rapid response to all 999 emergency calls, stabilise the patients involved and take them to the nearest hospital for further treatment. Organisation of the service and training for staff has centred on the needs of patients in a life-threatening emergency such as a cardiac arrest (when the heart stops beating) or injury following a road traffic accident.

Some ambulance trusts also provide transport services for non-emergency patients, for example for pre-arranged hospital appointments and visits to day care centres. They may also carry patients between trusts or between different sites in the same trust.

Only 35% of incidents are consistently categorised as life threatening emergencies requiring urgent hospital care. Although many people require some form of urgent treatment or care, this is often given at the scene of the incident or in their own home. Some callers do not have a physical injury – instead they may have urgent mental health or social care needs.

The role of the NHS ambulance service has changed significantly over the last 10 years. There has been considerable development within the service to meet the changing needs of patients and the NHS. New roles have been introduced, such as emergency care practitioners. These are staff with additional training and education above that of a paramedic. Clinical practice is being improved by introducing new technology and better training so that ambulance staff can provide immediate care at the scene and administer a wider range of drugs.

Some ambulance trusts are also expanding their range of services, such as providing GP out-of-hours services. They may also offer advice over the telephone to 999 callers with needs that are not clinically urgent. Once the caller's needs have been assessed by trained experts, the ambulance service can link them in with the most appropriate service for them, such as their GP or the emergency nurse service.

## Response times

In 1994/1995, there were 2.61 million calls to the NHS ambulance service nationally. By 2005/2006, this had risen to six million (Health and Social Care Information Centre, 2005).

National standards for the maximum time an ambulance should take to attend to a call have been in place since 1974. They were revised in 1996 and again in 2004. Currently calls are prioritised using three categories:

- In **Category A calls**, patients are judged to have life threatening conditions and need the quickest response. The Government target is for trusts to respond to 75% of calls within eight minutes. If the initial



response is by a single responder such as a community paramedic officer, an ambulance must be on the scene within 19 minutes for 95% of calls.

- **Category B calls** relate to patients who have serious, but not life threatening, conditions. Trusts should respond within 19 minutes for 95% of calls.
- **Category C calls** are deemed to be neither life threatening nor serious. Response times for Category C calls are determined locally, not nationally, and are not included in the national targets.

Since April 2007, ambulance trusts are required to prioritise urgent calls from GPs in the same way that they prioritise other emergency calls. Before this, the response requirement for urgent calls from GPs was that patients had to arrive at the hospital within 15 minutes of the time stated by the GP.

Prioritisation of calls has reduced the number of emergency calls to which ambulance trusts have to send an ambulance. In 1994/1995, the number of emergency incidents attended by an ambulance was 2.61 million, the same as the number of calls made. In 2005/2006, the number of emergency incidents attended was 4.8 million compared with six million calls.

# Local context

## Staffordshire Ambulance Service NHS Trust

Staffordshire Ambulance Service NHS Trust was created in 1992 and covered most of the county of Staffordshire. The exception was the extreme south west of the county where ambulance services were provided by a neighbouring ambulance trust. The trust covered an area of around 1,000 square miles and served a population of about 1.05 million people.

On 1 October 2007, the trust merged with West Midlands Ambulance Service NHS Trust.

The trust served hospitals within University Hospital North Staffordshire NHS Trust, Queen's Hospital Burton NHS Trust, Mid Staffordshire General Hospitals NHS Trust, Walsall Manor Hospital NHS Trust and The Royal Wolverhampton Hospitals NHS Trust, as well as Good Hope Hospital (part of the Heart of England NHS Foundation Trust) and other hospitals around the border of the county.

The trust had 109 emergency and non-emergency ambulances and 38 paramedic response cars. In addition, it had seven support vehicles and 15 vehicles for the courier transport service (annual report 2005/2006). It also had access to the county air ambulance service (which is funded entirely through charitable donations).

In 2005/2006, the trust received 156,344 emergency calls that resulted in 89,922 emergency responses arriving on the scene.

## The strategic health authority

The trust was within Shropshire and Staffordshire Strategic Health Authority until the West Midlands Strategic Health Authority was formed in 2006. The role of the SHA includes establishing and managing annual

performance agreements with PCTs and NHS trusts.

In 2005, the Government accepted the recommendation in *Taking healthcare to the patient* that "there should be a reduction in the number of services broadly in line with SHA boundaries". In *Configuration of NHS ambulance trusts in England: A consultation* (Department of Health, 2006), it was proposed that the existing 31 ambulance trusts across England should be reconfigured to form 11 larger ambulance trusts.

However, following a public consultation, led by the predecessor Shropshire and Staffordshire SHA, the merger of the trust with other local ambulance trusts (to form the West Midlands Ambulance Service NHS Trust) was delayed. The public were concerned that the performance of the trust was better than parts of West Midlands Ambulance Service NHS Trust. The degree of concern from the public was such that it was agreed to postpone the merger.

In the interim, the Secretary of State issued directions to both trusts about a range of measures for working in partnership. These included establishing a partnership board, coordinating work in a number of areas, and appointing joint directors for finance, human resources, and information management and technology. Also, they were asked to consider the appointment of a joint director of clinical services. The role of these directors was to develop shared policies and procedures across both organisations, to promote best practice and safe governance.

Through the partnership board, it was agreed that there should be some criteria for when the two trusts should merge. One of these was that the performance should be comparable to the best of each of the services.

## Leadership

The trust's board, consisting of executive and non-executive directors, was responsible for the governance of the trust. In late 2004, a new non-executive director was appointed to the board, followed by a new chairman in 2005.

In March 2006, the chief executive, who had been in post since the trust was created, left the trust.

The previous medical director, who was also the deputy chief executive and who had been working in the trust since 1999, left at the end of the same month. During his time at the trust, he held a number of posts including medical adviser and field operations manager.

An acting chief executive was appointed, along with an acting medical adviser who was previously a doctor working in the GP out-of-hours service. The acting medical adviser reverted to the role of doctor on 31 July 2006 before leaving the trust on 30 September 2006.

The previous medical director returned to the trust on 25 July 2006 as a doctor for the GP out-of-hours service. On 1 August 2006, he was appointed acting medical adviser.

A joint director of clinical performance (with West Midlands Ambulance Service NHS Trust) was appointed in November 2006.

In March 2007, a chief operating officer was appointed in place of the acting chief executive.

## Structure

The trust operated from three bases in Stafford, Stoke and Lichfield as well as from a network of strategically placed standby locations. Its headquarters was at the base in Stafford.

The trust was organised into five directorates: human resources, finance, clinical services, distribution and production.

'Distribution' was responsible for forecasting the number of ambulances and ambulance crew required, and for deploying ambulances, emergency ambulance estate cars and community first responders to emergency calls and calls for the GP out-of-hours service.

This directorate was also responsible for managing the patient transport service.

'Production' was responsible for "matching supply to demand", that is ensuring there were enough staff and vehicles available to respond to calls. Within production, the scheduling department was responsible for ensuring there were enough staff on each shift to respond to calls. The scheduling department was also responsible for monitoring the levels of staff sickness, the number of hours that staff worked and managing requests from staff to change their shifts.

The services provided by the trust can be grouped into four areas:

- an accident and emergency ambulance service that responded to 999 emergency calls made by the public and to emergency and urgent requests from doctors, dentists and midwives
- the patient transport service (PTS), for those needing non-emergency transport. This included transporting patients to and from hospitals and clinics for appointments and treatments across the county. In August 2006, the majority of the contracts for the PTS were transferred to another provider, leaving the ambulance service to provide patient transport services in the east of the county only
- a GP out-of-hours service, including call handling and triage services for south Staffordshire
- other services including a courier transport service, a message answering and paging service for GPs and midwives, and medical support at public events.

In 1994, the trust introduced 'system status management'. This predicted where and when ambulances were going to be needed on an hourly basis. The system produced two sets of information: one on the chronological demand and one on the geographical demand of calls. This enabled the trust to predict where and when ambulances would be needed and site them accordingly, thereby improving response times and care for patients. Each site was

either an ambulance service base or a standby post. The standby posts had basic facilities, for example for staff to make a hot drink. They also had computers to give staff access to the trust's internet and intranet. It was the first ambulance trust in the country to adopt this model of delivery and in doing so, moved away from the traditional approach of having fixed ambulance stations.

## Staffing

The trust had a whole-time equivalent staffing establishment of 661. It employed 733 people, some of whom worked part-time. Of the total, 390 worked in the accident and emergency ambulance service and 132 worked in the patient transport service and the courier transport service.

The 390 staff who worked in the accident and emergency service consisted of ambulance paramedics, ambulance technicians and community paramedic officers (CPOs). CPOs were based in urban areas and rural towns and responded to emergency calls in their area in emergency ambulance estate cars. They also responded to calls for the GP out-of-hours service and often provided or arranged care within a patient's own home.

The accident and emergency service received support from volunteers in community first responder schemes. Community first responders (CFRs) were first introduced in 1999. A CFR is a volunteer who provides emergency medical assistance within their local community. The trust had 315 trained CFRs operating within 25 schemes across the county. The role of community first responders is discussed in more detail later in this report.

## Standards

In 2003, the Commission for Health Improvement (the predecessor of the Health Care Commission) carried out a clinical governance review of the trust. The report, published in May 2003, was generally positive about the arrangements the trust had in place for clinical governance. The key areas for

action included managing the risks in its CPO and CFR schemes, ensuring that new initiatives were supported by education, comparative audits and rigorous evaluation, and for the trust to work more closely with other NHS organisations to improve external perceptions of the trust.

In previous years, the trust consistently achieved and exceeded the Department of Health's standards for national response times.

In 2004/2005, the trust was awarded the maximum three stars in the annual performance (star) ratings. The trust was also awarded three stars for performance in 2002/2003 and 2003/2004.

More recently in the Healthcare Commission's annual health check for 2005/2006, the trust's overall rating was "weak" for quality of services and "fair" for use of resources. The trust was scored "weak" because the KA34 return it submitted to the Department of Health was declared inadmissible, due to it being completed incorrectly. (The KA34 is the annual national ambulance statistical return for activity and performance. The submission is based on activity – calls and responses in both of the categories, A and B.) It also declared that it had "almost met" the majority of the Department of Health's core standards required of all trusts. The trust declared itself compliant with the standards for clinical and corporate governance, recruitment and the safety of medicines.

In the 2006/2007 annual health check, it was rated as "fair" for quality of services and "fair" for use of resources.

# The management of medicines

## Sources of evidence

- Interviews with current and former staff
- Interviews with staff from other NHS organisations
- Minutes of internal and external meetings, including meetings of the risk and clinical governance committee and the local ambulance paramedic steering committee
- Patient group directions
- Correspondence between the trust and other NHS organisations
- Previous reports of the trust's arrangements for the management of medicines and clinical governance

The management of medicines encompasses all the processes for safe and secure handling of medicines: purchasing or ordering, safe and secure storage, prescribing, dispensing, preparation, administration to a patient and subsequent monitoring. The primary legislation relating to medicines is set out on page 20.

## Accountability and structure

The trust was unable to tell us which executive director had lead responsibility for the management of medicines before November 2006. When interviewed, the previous medical director told us that the director of production had responsibility for medicines and controlled drugs until May 2005, and then he himself took over responsibility for advising the previous chief executive on medicine management issues. The director of production retained executive responsibility for medicines and controlled drugs. He was also responsible for the "provisioning, storage and supply of medicines and drugs".

The director of production described his responsibilities as being around the provision of medicines for staff. He said that advice was taken from pharmacists and that a lot of the work sat in the clinical services directorate.

In November 2006, the joint director of clinical performance became the executive with lead responsibility for the management of medicines. He was also the named accountable officer for controlled drugs in line with The Controlled Drugs (Supervision of Management and Use) Regulations 2006 that came into force on 1 January 2007. (The accountable officer is responsible for ensuring the organisation has safe and effective systems in place for all aspects of the handling and management of controlled drugs.)

The clinical governance manager, who joined the trust in September 2006, had responsibility at senior management level for the management of medicines.

The trust did not have a dedicated committee where the management of medicines was discussed. Different aspects were discussed at a number of committees.

- The local ambulance paramedic steering committee approved new, and changes to existing, protocols for the emergency service. The previous medical director and previous clinical services manager attended this meeting on a regular basis. The GP who had lead responsibility for the out-of-hours service attended two meetings. The local ambulance paramedic steering committee was suspended in June 2005 and, although there was no pharmacy representation on this committee, it did leave a gap.
- Medicines were also discussed at the clinical steering committee, which had limited attendance and few meetings were

## Primary medicines legislation

### The Medicines Act 1968 and subsequent regulations

The Medicines Act 1968 was introduced following a review prompted by the thalidomide tragedy in the 1960s. It brought together most of the previous legislation on medicines and introduced a number of other legal provisions for the control of medicines.

The Act divides medicinal drugs into three categories:

- **Prescription only medicines** which, subject to certain exemptions, may be sold or supplied to the public only in accordance with a practitioner's prescription from a registered pharmacy by, or under the supervision of, a pharmacist.
- **Pharmacy medicines** which, subject to certain exceptions, may be sold or supplied only from registered premises by, or under the supervision of, a pharmacist.
- **General sales list medicines** which may be sold or supplied to the public in an unopened manufacturer's pack from any lockable premises.

### The Prescription Only Medicines (Human Use) Order 1997 (the POM Order)

The POM Order specifies the descriptions and classes of prescription only medicines which, subject to exemptions, may be sold or supplied only in accordance with an appropriate practitioner's prescription and may be administered only in accordance with the directions of such a practitioner.

Medicines for parenteral (that is, injectable) administration are all classed as prescription only. If not self-administered, parenteral medicines must be administered by a doctor or, in certain circumstances, an independent nurse or pharmacist prescriber, or a supplementary prescriber. They can also be administered by anyone acting in accordance with the patient-specific directions of a doctor or, again in certain circumstances, an independent nurse or pharmacist prescriber, or a supplementary prescriber.

Exemptions contained in the order allow ambulance paramedics to administer certain parenteral medicines on their own initiative. Further exemptions allow anyone to administer a list of parenteral medicines for the purpose of saving a life in an emergency.

### The Misuse of Drugs Act 1971

The Misuse of Drugs Act 1971 consolidated and simplified previous legislation relating to dangerous drugs. It sets which drugs are "controlled drugs" and divides them into Class A, B and C according to their perceived degree of harm.

The Act gives the Home Secretary the power to make regulations for the handling of controlled drugs by authorised persons. The current regulations are the Misuse of Drugs Regulations 2001 (as amended) and the Misuse of Drugs (Safe Custody) Regulations 1973 (as amended).

### The Misuse of Drugs Regulations 2001

The Misuse of Drugs Regulations 2001 divide controlled drugs into five schedules. They detail the restrictions on the manufacture, supply and possession of controlled drugs as well as prescription, record keeping and destruction requirements.

held, and the daily clinical meetings, where calls to the out-of-hours service were reviewed.

- The introduction and storage of morphine sulphate injection (a scheduled 2 controlled drug used to treat pain) was discussed at the production team meetings and the risk and clinical governance committee.
- The out-of-hours medicines management committee, which was an external committee, run in conjunction with a local PCT. The committee had terms of reference, but we have only been provided with the minutes of a few meetings.
- Other meetings where aspects of the management of medicines were discussed include the team leaders' meetings and the staff liaison committee meetings.

More recently, a joint medicines management group has been formed with the West Midlands Ambulance Service NHS Trust, to examine all aspects of medicines management and ensure that the trust is compliant with *Safer management of controlled drugs: The Government's response to the Fourth report of the Shipman Inquiry* (Department of Health and Home Office, 2004)

## Policies and procedures

The trust did not have an overarching policy and procedure for the management of medicines until November 2006, when the West Midlands Ambulance Service NHS Trust in partnership with the trust issued the medicines policy and procedure. Before this, information about the storage and management of medicines was documented in standard operating procedures and circulated to staff via the clinical routine instructions.

In June 2005, the trust introduced a policy for the management of controlled drugs. The previous medical director was responsible for the issue and amendment of the policy. The policy was discussed at meetings of the production team and approved by the executive committee.

The policy covered a number of areas including storage, access, record keeping and action to take if controlled drugs were lost or stolen. It also contained information about how to dispose of damaged or part used ampoules of morphine. The document states that "all used syringes containing unused CD must not be placed in sharp boxes. The CD should be disposed of in a drainage system such that it cannot be retrieved". This does not comply with the requirements of the Environment Protection Act 1990. Some staff were unclear about how to dispose of damaged or part used ampoules, although they were aware that it needed to be witnessed.

## Pharmaceutical advice

The trust received its medicines, including controlled drugs, from Mid Staffordshire General Hospitals NHS Trust. The trust did not have a contractual agreement with Mid Staffordshire General Hospitals NHS Trust regarding the supply of medicines and controlled drugs.

The senior pharmacist from Mid Staffordshire General Hospital NHS Trust told us that he advised the trust to seek advice about the system for managing medicines. He felt it was inappropriate for him to provide advice to the trust as they were also supplying medicines and controlled drugs to the trust. He thought there may have been a potential conflict of interest. In a letter he sent to the trust's director of production in July 2004, he stated that "changes in practice have required that the ambulance service handles drugs in a much more proactive way... My personal view is that perhaps your trust could consider purchasing some pharmaceutical advice. The storage, administration and supply of medicines is likely to become an increasingly important issue". The trust responded by saying that the concerns had been referred onto the medical adviser (who later became the medical director).

In March 2005, the senior pharmacist sent another letter to the trust about a change in a policy and also pointed out that he was aware

that "Staffordshire Ambulance does not have any formal pharmaceutical advice... I am sure you would appreciate the need for good clinical governance arrangements around the ordering, storage, issue and usage of drugs".

The previous chief executive responded by saying the trust would welcome formal pharmaceutical advice and asked if he could "advise on the amount we would need and the cost involved". The senior pharmacist responded saying that he did not think it was appropriate for his hospital to supply medicines and controlled drugs, and provide advice to the trust. He suggested that the trust contact the local PCTs to see if they could provide pharmaceutical advice. In April 2005, the previous chief executive sent another letter, in which he stated that the trust had "robust clinical governance controls in place relating to the distribution, use and recording of controlled drugs".

The medical director of the trust wrote to two local PCTs, East Staffordshire PCT and South Western Staffordshire PCT, to enquire if they would be able to assist the trust to review their systems for managing medicines.

South Western Staffordshire PCT was able to provide some assistance. Commencing in August 2005, one of its pharmacy advisers spent approximately half to one day a week in the trust carrying out this work. The trust sent a letter to the PCT asking the pharmacy adviser "to also review the trust's controlled drugs procedures within the context of palliative care standards of Securing Proper Access to Medicines Out of Hours". The PCT's pharmacy adviser described it as a scoping exercise to feedback to the trust on work that needed to be done. It involved looking at the trust's arrangements for the procurement, storage and ordering of medicines as well as their patient group directions (PGDs — see page 29).

Unfortunately, the pharmacy adviser was unable to carry on working in the trust after October 2005 due to competing priorities in the PCT. The previous medical director and previous chief executive have said that they were both under the impression that the

pharmaceutical adviser had continued to provide advice after October 2005. The previous chief executive told us that he "would have been expected to be informed if the pharmacy adviser was not employed or unable to continue to provide the advice agreed".

The pharmacy adviser did not provide written feedback to the trust but told us that she advised the previous medical director that the trust needed "advice around storage, training for staff, to match the packet sizes of drugs with the patient group directions", that they could not "over label original packs of drugs, as this was in breach of pharmaceutical regulations" and "gave some general advice about need for a PGD policy to cover writing and development of new PGDs, need for regular pharmacist input in this area and suggested developing a standard template for all PGDs".

It is documented in the minutes of the August 2005 meeting of the risk and clinical governance committee that the previous medical director reported: "The controlled drugs policy has been approved and the adviser confirmed that the system operated in supply services with regard to the storage and logging of drugs was entirely satisfactory. The issue of labels on drugs was under discussion. This had no effect on patient safety." The previous medical director told us that he has no recollection of the pharmacy adviser making any comments "regarding training and storage" but recalls "a statement from the pharmacist to the effect that the existing medicine policy was broadly acceptable" and that she was "happy with the existing PGDs, although there was some discussion about development of future PGDs". The pharmacy adviser has clarified that she was not involved in the formal approval of the policy for controlled drugs and did not comment on the safety of patients.

The minutes of the meeting of the trust's board held in September 2005 state that the trust has purchased pharmaceutical advice "which has not recommended any major changes in current operating procedures". Both executive and non-executive members of



the trust's board told us that they felt that they had been assured the trust was receiving advice from a pharmacist about the management of medicines, and that the previous medical director was responsible for this area, although they acknowledged they were not experts in this area.

## Controlled drugs: morphine sulphate injection

Controlled drugs are governed by the Misuse of Drugs Act 1971. In the National Prescribing Centre guidance (February 2007), it states that ambulance organisations should have a licence to possess morphine. (This was not stated in an earlier edition of the guidance.)

The trust was first issued with morphine sulphate injection in 2004, for use only by doctors. Following a change in the regulations for medicines in January 2004, paramedics were allowed to carry ampoules of morphine sulphate. In September 2005, the trust gave approval for morphine sulphate injection to be administered by paramedics. This was because the drug nalbuphine (used to treat moderate to severe pain) was no longer being manufactured and the trust needed to find an alternative drug to use.

The previous medical director told us that the approval of paramedics to administer morphine sulphate injection was met with reluctance by some of the executives, while he and the previous clinical services manager advocated that paramedics should be allowed to use it. Eventually it was agreed that the trust would allow them to administer morphine. The local ambulance paramedic steering committee had responsibility for clinical approval of the introduction of morphine sulphate injection and the production directorate had responsibility for the operational implementation, overseen by the executive committee. The policy for controlled drugs was discussed regularly at the production directorate meetings.

On 1 November 2006, the trust contacted the Home Office asking for clarification about whether or not it was required to have a

licence for the storage, possession and administration of controlled drugs by ambulance paramedics. The Home Office told the trust on the phone that that it was required to obtain a licence. However, the following day the trust received an email from the Home Office stating that "...in accordance with the Misuse of Drugs Regulations 2001: Group Authority issued to NHS Ambulance Paramedics ...a separate licence to the Group Authority is not required".

In December 2006, the trust's acting medical adviser applied to the Home Office for a licence to possess and supply controlled drugs. The trust received a licence in January 2007 to possess drugs listed in schedules 2 and 4 of the Misuse of Drugs Regulations 2001. This included morphine sulphate and diazepam. The licence required the trust to make an annual return to the Home Office by the end of each February.

When we asked why the trust had not applied for a licence earlier, the previous medical director told us that the advice they received was that they did not need a licence "...probably on the basis that they were covered by the Group Authority". This is reflected in the minutes of the risk and clinical governance committee, August 2005, where the previous medical director reported that the pharmacy adviser from South Western Staffordshire PCT had approved their policy for controlled drugs and that their management arrangements were satisfactory.

The pharmacist from Mid Staffordshire General Hospitals NHS Trust, who supplied the trust with its drugs, did not know if the trust was required to have a licence. It is the responsibility of the supplier to check if an organisation is required to have a licence to ensure it can lawfully supply the controlled drugs.

During the course of this investigation, we contacted the Home Office to clarify the precise position as to whether ambulance trusts were required to have a licence to possess and supply controlled drugs to registered paramedics. Initially, we were told this was a requirement. However, shortly afterwards, the Home Office told us that it was

not a requirement and that the trust did not have a licence. However, the trust had already provided us with a copy of its licence.

The Home Office has confirmed that “ambulance paramedics were first authorised by the Home Office to supply controlled drugs under a group, or blanket licence, issued in January 1993. The licence covered diazepam...”. Following an application from the Joint Royal Colleges Ambulance Liaison Committee, “an updated Home Office group licence was issued in January 2001 to cover NHS ambulance paramedics to supply, by way of administration, both diazepam and morphine sulphate injection to a maximum strength of 10mg. In November 2003, the licence was amended to increase the amount of morphine sulphate injection to a maximum strength of 20mg and again, in April 2007, to include morphine sulphate oral as well as injection”.

The Home Office has stated that the trust was therefore automatically “covered under the provisions of the group licence to hold diazepam and morphine, and would not have required specific licences for these drugs. They would, however, have required ones to enable them to hold any other drugs controlled under Schedules 2-4 of the Misuse of Drugs Regulations 2001. The application for licences to possess and supply controlled drugs, dated 10 December 2006, included a number of drugs not covered by the group licence”. However, the Commission has become aware that another ambulance trust has been given different information, from the Home Office, about the requirement for them to have a licence to hold morphine and diazepam. Our Controlled Drug team will be seeking further clarification from the Home Office through the National Controlled Drugs Group on this issue.

The approval of paramedics to administer morphine sulphate injection presented the trust with a number of security issues that it needed to consider, such as storage of the drug in the trust, ambulances and CPO cars, recording of usage, and the potential risks to staff who carried morphine.

Morphine sulphate injection was stored in each of the three bases in secured cupboards. It was checked out to each paramedic individually. There is evidence that when paramedics first started administering morphine sulphate injection, some of them were storing ampoules in their personal lockers or taking it home with them once they had finished their shift. In November 2005, the trust’s board approved the allocation of funding for individual safes for the storage of morphine.

At the end of each shift, paramedics returned any unused ampoules to their personal safe. The individual safes were located within a main cupboard, which was locked. Only the paramedics had access to the cupboard and their individual safe. The senior manager had access to the cupboard where the safes were located, but did not have access to the individual safes. Therefore, if the trust wanted to know the total number of ampoules of morphine sulphate injection it would have had to call in all the paramedics and ask them to open their individual safes. The trust’s policy for the management of controlled drugs was not updated to reflect the introduction of individual safes.

Paramedics were required to record on the patient report form (documentation used by ambulance staff to record details about the patient and the care and treatment they provided to the patient) if morphine sulphate injection was administered. Each paramedic had a separate book in which they recorded the running total of morphine sulphate injection checked out to them and the morphine sulphate injection they administered. Once the paramedic had used all the ampoules of morphine sulphate injection, the book was presented to the trust and the paramedic received new ampoules. During interviews, staff demonstrated a good awareness of this process.

The Group Authority to National Health Service Paramedics, November 2003, allowed paramedics “serving or employed at any approved ambulance station to possess diazepam and/or morphine sulphate injection

(to a maximum of 20mg)". The trust's policy for controlled drugs stated that paramedics could hold up to 40mgs (4x10mg ampoules). In November 2006, the trust contacted the Home Office and was told: "Ambulance paramedics... may possess and supply for the purposes of administration morphine sulphate injection to a maximum of 20mg." The Medicines and Healthcare products Regulatory Agency has clarified that the limit applies to the amount paramedics can supply to an individual patient, not to the stocks the paramedic can hold.

Another issue that arose shortly afterwards was that paramedics and community paramedic officers (CPOs) were handing over parts of used ampoules of morphine sulphate injection to the ambulance staff who were transporting the patient. On occasion, several ambulance staff may be sent to a call (CPOs do not usually transport patients) and if, for example, a CPO was the first to arrive at an incident, they may administer some morphine sulphate injection to the patient but not necessarily use the full amount in the ampoule. They would then give the ampoule to the ambulance staff transporting the patient to hospital.

Information was circulated to all staff, in the clinical routine instructions in November 2005, outlining the action that staff should take; that is any remaining morphine sulphate injection should be discarded and the paramedic transporting the patient should use their own morphine. Discarding of morphine sulphate injection should, where possible, be witnessed and documented in the patient report form. This was circulated on 1 November 2005. Two weeks later, further information was circulated reminding staff that morphine sulphate injection was issued to and recorded to individual state registered paramedics and that "issue of morphine sulphate injection to another state registered paramedic from his/her own stock is prohibited".

### **Audit and random checks of the usage of morphine sulphate injection**

In the minutes of the production meeting held on 20 July 2006, it is documented that "with

morphine sulphate injection being issued to staff all over, the trust needs to do random checks to reduce risk of loss". Area managers were responsible for enforcing this and were expected to carry out random checks either once a month or once every two months. When asked how the trust audited compliance with the policy and how the random checks were carried out, the trust provided information about audits carried out in May and June 2007. The information is a series of spreadsheets detailing the number of morphine sulphate injection ampoules issued, the number used and the outstanding balance. There is no written information accompanying the numbers and it is difficult to interpret the information.

### **Other controlled drugs**

The trust had also approved its paramedics, technicians and community first responders (CFRs) to possess and administer midazolam (a schedule 4 controlled drug useful for sedation and used by ambulance services to treat patients suffering from fits) by the buccal (cheek) route. As a controlled drug, it is subject to additional controls under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001. Paramedics, ambulance technicians and CFRs do not have the authority to possess this drug for use on their own initiative. If a patient was in possession of their own individual prescribed supply it could be administered by paramedics, ambulance technicians and CFRs in accordance with the prescription. Authorisation to possess this drug can only be granted by the Home Office. An organisation, such as the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) would have to make an application to the Home Office for a change in the regulations to allow ambulance staff to possess and administer midazolam. In November 2006, the trust informed staff that paramedics and technicians were not to use midazolam and asked them to return any ampoules they may have.

Ambulance technicians and community first responders were also administering diazepam

to patients. In the clinical routine instructions, dated 6 November 2006, it states that they "...should use rectal diazepam for fitting episodes..." The Medicines and Healthcare products Regulatory Agency clarified (in an email dated 24 October 2006 to West Midlands SHA) that the trust could not supply diazepam to technicians and CFRs. If CFRs and ambulance technicians attend a patient who requires diazepam and the patient has their own prescribed supply, they can administer the drug in accordance with the prescription. They are not authorised under medicines legislation to make the decision to supply or administer diazepam to a patient on their own initiative.

The previous medical director has told the Commission that controlled drugs were "not supplied directly to the staff concerned, instead ambulances were equipped with a standardised quota of medication, much like a medical cupboard on an Accident and Emergency Ward". Advice sought from the Home Office on behalf of the trust in May 2007 by the SHA states: "The authority that allows paramedics to possess, supply and administer morphine and diazepam does not extend to technicians and therefore ambulances crewed only by technicians should not carry controlled drugs."

During the course of the investigation, it became apparent that staff believed it was acceptable practice for technicians to administer diazepam without an awareness of the legal requirements. We informed the trust about this practice and the trust has now stopped it.

## Drugs administered by CFRs

Until late 2006, CFRs were allowed by the trust to administer the following medicines and controlled drugs:

- oxygen
- aspirin tablets
- salbutamol nebulisers (a medicine used to treat asthma)
- glyceryl trinitrate spray (a medicine used to treat angina)

- a mixture of oxygen and nitrous oxide taken via a face mask used to relieve pain
- liquid paracetamol (used to treat post febrile convulsions in children)
- glucagon injection (a hormone made in the pancreas that raises blood sugar levels. It can be given by injection to treat severe hypoglycaemia)
- naloxone (a medicine given as an injection used to counter the effects of overdosing on opioids)
- adrenaline 1:1000 injection (a medicine used to treat an immediate and severe allergic reaction to a substance, for example food or medicines)
- diazepam (a controlled drug used to treat epileptic fits)
- midazolam (buccal – a controlled drug useful for sedation and to treat epileptic fits)
- ipratropium bromide (a medicine used to treat asthma)
- budesonide (a medicine used to treat asthma).

The medicine that CFRs used most frequently in 2005/2006 was oxygen, on 1,139 occasions. Ipratropium bromide and budesonide were the least used (zero occasions). Diazepam and midazolam were administered on four and three occasions respectively.

The previous medical director told us that CFRs could use the same medicines that ambulance technicians were allowed to use. This decision was made by the previous medical director, "the previous chief executive and senior paramedics in the service". The previous chief executive has commented that "the range of drugs used by CFRs were only extended following the change in their training and to bring their clinical capability in line with ambulance technicians". They were only expected to use controlled drugs for life threatening situations and then only on the advice and authority of a trust doctor. He also told the Commission that at least one CFR was medically qualified and some were trained nurses.

As far as the previous medical director was aware, the pharmacists who supplied the trust with their medicines were aware that CFRs were using the medicines supplied; it was common knowledge within the county of Staffordshire. Compared with other ambulance trusts, the trust allowed their CFRs to administer the widest range of medicines and controlled drugs.

In July 2006, the trust's acting medical adviser, who previously worked as a doctor for the out-of-hours service, wrote to the Medicines and Healthcare products Regulatory Agency (MHRA) asking for advice about the legality of some of the medicines and controlled drugs that the CFRs were administering. The medicines were:

- adrenaline 1:1000 for use in life threatening anaphylaxis
- glucagon for use in diabetic hypoglycaemic episodes
- liquid paracetamol for the use in children post-febrile convulsion
- oxygen
- a mixture of oxygen and nitrous oxide
- salbutamol nebulas 2.5mg for life threatening asthma
- glyceryl trinitrate (GTN) spray for ischaemic chest pain
- diazemuls PR / buccal midazolam for epileptic fits.

The letter also included information about the role of CFRs and stated that they "have all undergone extensive training to administer, but never supply, a limited range of prescription only medications".

The response of the MHRA was that as CFRs were trained, worked on behalf of and were accountable to the trust, they were able to access the medicines as part of the trust. The MHRA said that the CFRs could administer adrenaline 1:1000 and glucagon (these are parenteral medicines and may be administered by anyone in a life threatening emergency). The response went on to say

"medicines legislation does not address the administration of non parenteral medicines so there is nothing to prevent CFRs administering the remaining products listed in your letter", but the MHRA did advise that there "should be guidance in place relating to the use of medicines and the trust should take responsibility for the CFRs' activities/training". The response confirmed that only specified health professionals could use patient group directions (PGDs — see page 29).

In August 2006, concerns were raised by representatives of staff about the legality of the trust supplying CFRs with diazepam and midazolam. They were further discussed at the partnership board in September 2006 and it was agreed that a review of the medicines being administered by CFRs should be carried out. At the next partnership board meeting, the issue was discussed again. Questions were asked about the legality of the CFRs administering certain medicines and about the status of the CFRs, for example whether they were recognised as healthcare professionals and whether or not their training was accredited by a national organisation. To answer these questions, it was agreed that specialist advice from pharmacists was needed.

The West Midlands SHA commissioned a review of the use of medicines by the trust, in particular the medicines used by the CFRs, PGDs and controlled drugs.

On 17 October 2006, the chief executive of the West Midlands SHA wrote to the trust asking for confirmation that the CFRs were complying with the legal framework for medicines. The letter informed the trust that an urgent review of the trust's policies and procedures on the authorisation for use, supply and storage of medicines to CFRs and controlled drugs would be carried out.

On 18 October 2006, the acting chief executive of the trust wrote to the CFRs informing them that the trust was withdrawing seven of the 13 medicines and controlled drugs they were administering. The trust withdrew the medicines and controlled drugs because it was unable to provide indemnity to CFRs who the trust considered may have been operating

outside the legal framework of the safe and secure handling of medicines.

The following medicines and controlled drugs were withdrawn: ipratropium bromide, diazepam, entonox, glyceryl trinitrate, midazolam (buccal), budesonide and salbutamol. The CFRs were still allowed to administer adrenaline 1:1000, glucagon, naloxone, aspirin, paracetamol, and oxygen.

In an email to the West Midlands SHA dated 24 October 2006, the MHRA clarified that the trust could not supply diazepam to technicians and CFRs.

On 26 October 2006, the acting chief executive wrote to the SHA confirming that they had withdrawn the above medicines and controlled drugs.

The CFRs also contacted the MHRA and were advised, in an email dated 6 November 2006, that “the administration of medicines for injection is restricted. If not self administered they should only be administered by an appropriate practitioner or a person... acting in accordance with the directions of such a practitioner”. The MHRA also advised that there was an exemption from this restriction for a list of specific medicines that can be administered by anyone for the purpose of saving a life in an emergency situation. Glucagon and adrenaline were examples of medicines on the list. The MHRA also advised that the “trust’s clinical governance arrangements relating to the use of medicines, documentation etc do need to be sufficiently robust”.

The issue was discussed at the trust’s board meeting in November 2006. The chairman of the trust, the chief executive of West Midlands Ambulance Service, acting chief executive, regional pharmacists and a representative from the SHA met with representatives from the CFR schemes and agreed that a ‘working group’ would be established.

The review of the trust’s use of medicines, which included the policies and procedures on the authorisation for use, supply and storage of medicines to CFRs and controlled medicines, was completed in November 2006. The review states that “...they were informed

that CFRs within SAS have access to a range of medicines including prescription only medicines”. This is followed by a list of the medicines and drugs that includes diazepam stesolid and midazolam. The review confirmed that the trust was not allowed to supply either midazolam or diazepam to CFRs as they are controlled drugs and subject to additional controls under the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations.

The review also found that many of the protocols related to medicines were not always dated and it was unclear when or if they had been reviewed. One of the main concerns was that it was not clear from the protocols to whom they were applicable: CFRs, technicians or paramedics. Potentially, this meant that CFRs could practise widely using trust policies that were not meant to be applicable to them. In relation to the trust’s clinical protocols, they were all dated 2001, there were no review dates and it was unclear which groups of staff they applied to. The review made a number of recommendations including:

- an urgent independent assessment of the training for CFRs and their assessments with regard to medicines
- the trust ensures it develops appropriate procedures approved by the trust board for developing, reviewing, approving and signing off PGDs
- the trust secures authoritative and consistent pharmaceutical advice
- the pharmacy advisers who carried out the review felt that the biggest issue for the trust was the lack of consistent pharmaceutical advice.

The assessment of the training provided to CFRs and the assessments related to medicines were completed in January 2007.

The assessment found that training on prescription only medications, glyceryl trinitrate, salbutamol and entonox, involved presentations about the medicines, but did not include information about potential side effects and the management of these. There was little information about decision-making or

differential diagnosis (distinguishing between diseases of similar character by comparing their signs and symptoms) in relation to the administration of the medication. Assessment for the administration of medications was by a multiple-choice questionnaire, consisting of 30 questions of which only four related to the above medications.

The assessors commented that the CFRs were “highly motivated and professional in attitude and performance” and recommended that the trust defined the role of CFRs in the immediate management of medical emergencies, developed a clear scope of practice for the CFRs and a reassessment of CFR training to meet the expected scope of practice. The review recommended that the trust should reintroduce salbutamol, entonox, glyceryl trinitrate and use according to JRCALC guidelines and that the CFRs should discontinue using naloxone. It was recommended that the CFRs could continue to use adrenaline 1:1000 but that it should be used according to JRCALC guidelines and only for life threatening anaphylaxis.

Glyceryl trinitrate, salbutamol and entonox were reintroduced in January 2007 under revised standard operating procedures reflecting the JRCALC guidance.

This issue and the resulting action caused a lot of unrest and uncertainty among the CFRs. They were concerned about the implications of this on their role and how it would affect the care they provided to patients. They felt the CFR schemes had been working very well for seven years and they could not understand why this was happening. They were unaware that they had been administering medicines and controlled drugs that they were not legally entitled to and were worried about the implications of this for them personally and professionally. Such was the furor about the withdrawal of the medicines and the drugs that it was even debated in the House of Commons. There was a suggestion that some of the schemes may not be prepared to continue.

From the perspective of most of the CFRs we spoke to, once the legal issues were explained to them, they appreciated why the trust was so concerned and understood the need for more

robust governance arrangements to be put into place.

## Supply of medicines to CFRs

The assessment noted that CFR schemes were supplied with medicines by paramedics and community paramedic officers from individual ambulances or paramedic cars. The assessment recommended that the trust introduce a process that enabled effective monitoring of the medicines that CFRs were administering. The trust accepted this recommendation and introduced a standard operating procedure outlining a new process for issuing medicines to CFR schemes. This was drafted in November 2006 and although it still has “draft” stamped on it, from discussions with CFRs there is evidence that it has been implemented.

Under the new process, introduced in 2007, each CFR scheme obtained their medicines from the trust’s supplies department and was required to keep a register of the medicines used. The medicines were kept in the “responder bag”. The bag was held by whichever CFR is on call and passed on at the change over.

## Patient group directions (PGDs)

PGDs were first introduced in the trust in 2002. The original PGDs were written by the previous medical director. They were taken from the National Electronic Library for Health (the PGDs on this site are examples only and still need to be ratified locally). The out-of-hours medicines management committee had a list of medicines that were required to be available from the out-of-hours service and the medicines on the PGDs were based on this list.

The previous medical director explained that when the first PGDs were being developed, he was working part time at the trust as the medical adviser. He was based in Oxford and relied on email and post to circulate copies of the PGDs.

The trust developed PGDs for a range of medicines including amoxicillin (an antibiotic),

## Patient group directions

Patient group directions (PGDs) are written instructions for the supply or administration of named medicines in defined clinical situations to groups of patients who may not be individually identified before presenting for treatment.

Only specific groups of registered health professionals can supply or administer medicines under a PGD. These include nurses, midwives, health visitors, pharmacists, radiographers and ambulance paramedics. They can only do so if they are named individuals on a list maintained by a trust. A PGD must be signed by a senior doctor (or, if appropriate, a dentist) and a senior pharmacist, both of whom should have been involved in developing the PGD. It must also be authorised by the employing authority such as an NHS trust or PCT.

A PGD must contain the following information: the date the direction comes into force and the date it expires, a description of the medicine to which it applies, the health professionals who may supply or administer the medicine, the signature of the doctor or dentist and a pharmacist, the clinical condition or situation to which the direction applies, a description of those patients excluded from treatment under the direction and information about the records to be kept for audit purposes. The employing authority is also required to keep a list of all staff who have been trained and are competent and authorised to use each PGD. (Health Service Circular 2000/026).

codeine phosphate tablets (a schedule 5 controlled drug used to relieve pain) and prednisolone (a steroid) and haloperidol (an antipsychotic drug).

One of the early PGDs was for ondansetron. The PGD was approved by the local ambulance paramedic steering committee. Ondansetron is only licensed for use in the management of nausea and vomiting following chemotherapy and for the prevention and treatment of nausea and vomiting following surgery. If the trust used this medicine for conditions other than those specified, it would be operating outside the terms of the licence and would be liable for any adverse incidents that occurred. It is also a requirement that the patient is informed that the medicine is being used outside of its licence. The trust stopped using this drug in early 2007 and now uses another medicine to treat nausea and vomiting.

Further PGDs were introduced when the trust took on responsibility for the out-of-hours service. Response to calls for the service was provided mainly by the community paramedic officers. For them to provide appropriate and

effective treatment to patients, it was necessary for them to administer a range of medicines not included on the JRCALC list of medicines for paramedics. PGDs enabled them to do this.

Although the PGDs appeared to be consistent in format with the guidance contained in HSC 2000/206, some contained only the electronic signature of the previous medical director. Others included the name, but not the signature, of the pharmacist from the former South Western Staffordshire PCT, who told the Commission that she was not aware of this. She had been asked to attend a meeting in May 2006 to sign some PGDs but had been unable to attend the meeting. When asked about this, the previous medical director said that he had included the name of the pharmacist on the PGD because he was unaware that she had stopped working for the trust in October 2005. He was not working in the trust in May 2006 but had included the pharmacist's name to be signed off by the doctor who had taken over this responsibility.

A pharmacist from Queen's Hospital Burton NHS Trust also signed some PGDs. He had not



attended any meetings where the PGDs were discussed and had received them in the post to sign.

The pharmacist told the Commission that initially he refused to sign them. The trust approached him again saying that no one else would do it for them and he signed them reluctantly. The PGDs looked reasonable, he felt sympathetic towards the trust and that he thought it was better that someone signed them. He understood from the trust that they were keeping a record of which staff had been trained to use the PGDs. More recently, in March 2007, he was asked to sign approximately five more PGDs, which he did. We showed him a PGD dated April 2006 that contained his name (but not his signature). The pharmacist said that he had never seen this PGD. Prior to 2007, the last time he had signed a PGD was in 2004.

Other PGDs were not signed and it was unclear which ones had been distributed to staff. The trust provided eight versions of the PGD for codeine phosphate tablets, developed between January 2004 and April 2007. The only versions provided by the trust that were signed by all the designated people are the first and most recent versions. The first one, which was issued in January 2004 and expired on 1 February 2006, was signed by the medical director, the previous chief executive and the pharmacist at Queen's Hospital Burton NHS Trust. The most recent one, dated April 2007, was signed by all the designated people.

The trust intranet and internet had different versions of PGDs. For example, the PGD for codeine phosphate on the intranet (as at 25 April 2007) came into force on 1 October 2005 and expired on 1 October 2007. It includes the names of the previous chief executive, previous medical director and the pharmacist from South Western Staffordshire PCT, all unsigned. The trust's internet had a PGD for the same drug (as at 3 July 2007) which came into force on 1 February 2004 and expired on 1 February 2006. It included the names of the previous medical director, previous chief executive and the pharmacist from Queen's Hospital Burton NHS Trust, all unsigned.

We have been unable to establish a defined process for the development, approval and review of PGDs. There is evidence that in February 2004, PGDs were presented to the risk and clinical governance committee. It is recorded in the minutes that they were presented "for information at this stage". In June 2004, they were tabled at the local ambulance paramedic steering committee "for information only". In an email, dated 7 July 2006, from the acting medical adviser to a trust doctor, information about a proposed process is described. It states that "the PGDs will be circulated to the doctors, the assistant director of production and the consultant cardiac nurse for comment. They will then be taken to the executive directors, both of the out-of-hours service drugs committees meeting and the joint medical directors meeting. They will then be passed onto training etc".

In 2004, the trust provided some training for community paramedic officers (CPOs) on the use of PGDs. Staff who were interviewed told us they had some understanding of PGDs. Concerns about how the trust introduced drugs were raised at the team leaders' meeting in 2004, and the minutes of the production meeting held in October 2004 state that "a number of paramedics have raised concerns regarding the accessibility of documentation for guidelines of administration of new drugs".

Interviews with staff as part of this investigation indicate that some staff felt that drugs were introduced before they had received training about them. Staff told us that they were "... not adequately trained in providing these patients with antibiotics and... carried drugs without knowing how to properly use them or knowing their long-term effect" and "they often tend to get the paperwork about a drug first before they are trained on it". Although the trust was able to provide evidence that some of the CPOs had attended training on PGDs, they were unable to provide records of staff who had been trained and approved to work under PGDs. The previous chief executive has commented that staff were not expected to administer any drug for which

they had not received training and if they had any concerns they could contact one of the doctors for advice.

In July 2006, one of the trust doctors undertook a review of the PGDs. From the report of this review, it seems that the trust was planning to develop more robust PGDs. However, in October 2006 the joint director of clinical performance noted that the “most of the PGDs had expired in late 2005 or early 2006”.

There is also very little evidence that the trust carried out any formal audit that staff were complying with the PGDs.

The trust has provided copies of patient therapeutic guidelines (PTGs). These were written in August 2006 and appear to have been written as guidelines for drugs that could be given by technicians and CFRs. This was about the same time that the trust asked for confirmation from the Medicine and Healthcare products Regulatory Agency that PGDs could only be used for registered health professionals in accordance with Health Service Circular 2000/2006.

In a later review of the trust’s arrangements for clinical governance, in March 2007, it was noted that the trust did not have a contractual arrangement with a pharmacist for advice and recommended that the trust should appoint a pharmacist.

## Labelling of drugs

The labelling of drugs to be dispensed is governed by the Medicines Labelling Regulations 1976 as amended. The regulations state that any medicine dispensed must bear the name of the person for whom it is to be administered, the name and address of the person who is supplying the medication, date of dispensing, directions for use, the dosage form and any essential warnings. These requirements do not apply to medicines supplied under a PGD. However, for the trust to fulfil its duty of care to patients, there should be some labelling to enable identification, ensure safe administration and avoid misuse/overdose of medicines or drugs.

In relation to PGDs, the trust did not purchase packs of medicines containing the required amount of the medicine to be administered or supplied as per the PGD. It would have been more costly, and instead the trust bought standard packs that contained more doses than they intended to give the patient (that is, for which there was a valid instruction in the PGD). The senior pharmacist from Mid Staffordshire General Hospital NHS Trust told us that, when the trust was asked why they continued to over-label packs of drugs, he was told it was too expensive to buy packs containing the required amount of medicines.

The previous chief executive disputes this, commenting that “the cost of supplying drugs to out-of-hours patients was not significant”. This meant that patients often received more doses than necessary and more doses than indicated on the label. For example, in the case of diazepam, the standard packs contain 28 tablets and the paramedics were allowed to supply patients with packs of 28 tablets. Yet, the PGD states that diazepam 2mg is “taken three (3) times per day for a total of two days”. We were told that paramedics told patients to destroy the remaining 22 tablets, although this is not included in the PGD.

The trust sought advice from Mid Staffordshire General Hospitals NHS Trust about how to label the drugs they were issuing to patients as part of the out-of-hours service. The trust developed a template for labelling drugs that included all of the appropriate information, except for the address of the trust.

The issue of labelling medicines was discussed at the risk and clinical governance meeting in November 2004, and the GP who had lead responsibility for the out-of-hours service confirmed that the practice of labelling and splitting packs of drugs would be reviewed. In the minutes of the risk and clinical governance meeting held in February 2005, the medical adviser (who later became the medical director) confirmed that the trust had sought pharmaceutical advice and that the packs would not be “tampered with in future”, that is they would not split the packs of drugs.

In September and October 2005, there was further discussion about this issue at the clinical meeting for the out-of-hours service, which included the pharmacy adviser from South Western Staffordshire PCT. The pharmacy adviser informed the trust that they had two options, “to use the Stoke product or use a ‘sausage label’” (in other words, buy pre-packaged medicines or use a standard label). The previous medical director summarised that the medicines can “be either properly labelled with no patient information or not properly labelled and patient information available”, and that the “format will be dealt with by” the pharmacy adviser. When asked about the overlabelling of drugs the previous medical director said that he sent a request to the supplies department asking them not to do this, which was repeated at a later date.

There is some evidence that the trust was splitting packs of medicines. In October 2006, the trust advised staff that they were not permitted to split packs of drugs and that this should only be done by a pharmacist.

The pharmacist from Mid Staffordshire General Hospitals NHS Trust and the pharmacist from South Western Staffordshire PCT were aware that the trust was labelling and splitting packs of medicines. The pharmacist from the PCT told us that she was under the impression that the labelling was going to stop and that the trust was going to buy the correct size packs of medicines to be administered.

During an unannounced visit to the trust, in June 2007, we observed packs of medicines that did not have labels on them and other packs that had labels without the necessary pharmaceutical information or essential warnings. The labels were applied to the boxes in a number of different ways.

## Other issues

The trust used a database to record, on a monthly basis, medicine and medical gases (such as oxygen and entonox) that were issued

to each of its three bases. The information was used to forecast requirements and reduce wastage. The database was comprehensive and it would be possible to see if one ambulance base was ordering larger quantities of a drug or medicine than previously. From the information provided, it seems that the database was used more for financial planning and stock control purposes than as an audit tool for checking which drugs and medicines staff were using.

The trust has supplied a list of “drugs for out-of-hours GPs”. However, we were told that “every doctor was requesting something new”. For example, one trust doctor ordered magnesium sulphate (a medicine used to treat a rapid heart rate, premature labour and to prevent fitting in toxæmia of labour), not included on the list “drugs for out-of-hours GPs”, in pre-filled syringes. The minimum order for these was 100 syringes. Only one doctor used the drug, and only one syringe was used before they went out of date.

There was no agreement in place between the trust and Mid Staffordshire General Hospitals NHS Trust about which medicines would be supplied, or in what amount. The trust was supplied with whatever medicines it ordered. There was no system in place to highlight if the trust was ordering large quantities of a particular medicine or whether it was legal to do so.

Although the trust provided training on PGDs to CPOs, there is little evidence of other more general training for staff on the management of medicines. The lack of training was evident in the staff’s approach to medicines in the team leader minutes for March 2005, it is documented that staff would take drugs from the depot, including the safe, without signing for them. The production minutes for August 2004 state that there is a discrepancy in the number of drugs on the ambulances and that “it is always the same drugs that are missing”.

The supply services manager was responsible for ensuring the trust had an adequate supply of medicines. He was also responsible for the storage and labelling of drugs. He received

Figure 1: Example of medicine stock sheet in the out-of-hours cupboard in the trust's headquarters

Obtained during OBOOS

FRUSEMIDE

DATE	IN/OUT	AMOUNT ISSUED	BALANCE	C/SIGN	
23/12/06	OUT	4 x 50mg	21	513	
24/12/06	<del>OUT</del>	1	20	3385	
6/01/07	OUT	3	23	378	
10/01/07	IN	10	30	510	
12/01/07	MIX	2	28	394	OUT OF DATE REFERENCE
14/01/07	OUT	1	26	378	
17/01/07	OUT	2	24	501	
23/1/07	OUT	1	23	394	
30/1/07	OUT	2	18	518	
31/1/07	OUT	1	13?	513	
7/2/07	OUT	1	22	3911	
7/2/07	OUT	2	20	378	
10/2/07	OUT	5	13	580	ONLY 13 NOT 13.
10/2/07	OUT	1	12	393	
15/2/07	OUT	1	11	385	
29/3/07	OUT	1	25	310	
4.4.07	<del>IN</del>	2	20 amp	Restock	incorrect stock
5.4.07	IN	20 amp	36amps	Restock	incorrect stock
12.4.07	Stock	CHECK	35amps	1 MED	MISSING
15.4.07	OUT	1 Amp	33amps	1 MED	MISSING
20.4.07	Stock	CHECK	34amps		
20/4/07	out of	date in stock	33 Amps		
2/5/07	OUT	1 out	24 IN STOCK		
3/5/07	OUT	2	22?	524	
5-5-07	Stock	CHECK	19		
6-5-07	OUT	2	17	518	
12-5-07	OUT	1	16	525	
20-5-07	OUT	1	24	378	
26-5-07	OUT	1	23	393	
20-05/07	OUT	3	20	378	
1. 06.07	OUT	1	19	382	

very little training from the trust for this aspect of his role and relied on advice from the medical staff, the external pharmacists and the GP with lead responsibility for the out-of-hours service. When asked if he had ever been informed of any concerns about how the medicines for the out-of-hours service were labelled, he replied that he only heard of concerns in relation to one incident.

A range of medicines was kept at each base. Staff were required to sign a sheet when they took supplies of medicines (other than controlled drugs), although they did not record the batch number of the medicines they were taking out. This meant that in the event that a drug was recalled, the trust would know which depot the drugs had gone to, but they would not know which patient had received the medicine.

The West Midlands SHA was concerned about the amount of diazepam that was being administered by the trust's staff. Compared with other trusts, now known as localities, that made up West Midlands Ambulance Service NHS Trust, the amount was significantly higher. For example, the number of diazepam 2mg oral tablets administered by ambulance staff working for the trust during 2005 and 2006 was 17,360, compared with 308 for the Hereford and Worcester locality. The other localities, Birmingham, Black Country and Shropshire and Coventry and Warwickshire, do not administer diazepam 2mg tablets.

Diazepam can also be administered rectally, and again the numbers were significantly higher for the trust when compared with West Midlands Ambulance Service NHS Trust. The trust administered it 1,410 times, compared with 453 times by the Hereford and Worcester locality, and 849 times by the Birmingham, Black Country and Shropshire locality.

The trust carried out an investigation into the usage of diazepam and concluded that it was difficult to draw a conclusion because not all of the localities were administering diazepam in tablet form, and that a clinical view "needs to be established to the practice of leaving a complete box of 28 tablets with the patient".

For diazepam that was administered rectally, the trust concluded that the variance was due to different treatment regimes but the figures "tend to support a more vigorous treatment regime within the Staffordshire locality".

During an unannounced visit in June 2007, the Commission observed that it was recorded in the register for controlled drugs there were four ampoules of fentanyl, yet there were no ampoules in the safe for controlled drugs. When asked about this, we were told that the ampoules had been transferred to another depot to be destroyed. The trust was not aware that the entry in the register should have said that the drugs had been transferred and the balance recorded as nil.

Figure 1 shows that on a number of occasions there were discrepancies in the recording of the number of boxes of frusemide, and there is no indication that any action had been taken. We found similar discrepancies for other medicines.

Other observations during the visit were:

- The stock levels, in the medicines cupboard, of adrenaline 1:1000 and 1:10,000 did not correspond with the level recorded on the medicines stock sheet.
- The stock sheet for adrenaline 1:10,000 showed a reference "?40 gone??".
- The balance column was incomplete for many of the medicines on the stock sheet.
- It was highlighted on many of the stock sheets that medicines were missing.
- In the drugs register it was recorded that two boxes of codeine phosphate tablets were missing. We raised this with a senior manager at the trust who agreed to look into it. The manager said that while staff are restocking drugs they are often tasked to respond to a call and do not always have time to complete the paperwork.
- There were no labels on boxes of diazepam tablets and when this was raised with staff they were unaware that there should have been labels on the boxes. They had assumed that the manufacturing information leaflet inside the box was sufficient.

In a list of written concerns presented by representatives of staff, in February 2007, to the chief executive of West Midlands Ambulance Service NHS Trust, there is reference to the number of “out-of-hours drugs missing”.

From October 2006, the trust used the West Midlands Strategic Health Authority regional pharmacy adviser for informal pharmaceutical advice. In April 2007, the trust secured formal pharmaceutical advice

## Findings of fact

- The current accountabilities for the management of medicines are clear, but have not been in the past.
- The management of medicines was discussed at a number of committees but without robust or appropriate advice.
- The trust’s method for disposing part used ampoules of morphine sulphate injection did not comply with the requirements of the Environment Protection Act 1990.
- Prior to October 2006, the trust did not receive or obtain consistent robust pharmacy advice.
- Labelling of medicines by the trust requires a manufacturer’s licence to cover assembly.
- Medicines administered and supplied under PGDs were not always labelled in a consistent and safe manner.
- The trust allowed paramedics to supply medicines outside of the terms of the PGDs. For example, patients were supplied with 28 tablets of diazepam instead of six.
- PGDs were used for non-registered groups of staff; this is a breach of the medicines regulation.
- Two of the PGDs had the names of professionals who did not have any knowledge that their name was on the PGD.
- The trust permitted CPOs to supply medicines using PGDs that were not signed or that included the name of pharmacists who were unaware of the PGD. This did not meet the requirements of the medicines legislation.
- By supplying midazolam (buccal) to paramedics, technicians and CFRs, the trust did not meet the requirements of the legislation for controlled drugs.
- By supplying diazepam to CFRs and technicians, the trust did not comply with the legislation for controlled drugs.
- Compared with other ambulance trusts, the trust allowed CFRs to attend a greater range of calls and administer a wider range of medicines and controlled drugs.
- The trust allowed CFRs to administer medicines that were inappropriate for their experience and remit.
- There was little evidence of any audit of compliance with the policy for controlled drugs or with PGDs.
- The training on medicines provided by the trust was not comprehensive.
- There was a lack of knowledge and awareness among staff about the importance of compliance with medicines legislation and legislation for controlled drugs.
- The trust did not have robust governance arrangements in place for the management of medicines.
- There was a lack of clarity about the requirements for an NHS ambulance trust to have a licence to possess controlled drugs.

# The process for introducing new equipment

## Sources of evidence

- Interviews with current and former staff
- Minutes of internal and external meetings, including those of the risk and clinical governance committee, the local ambulance paramedic steering committee and the trust's board
- Various external clinical reports about equipment
- Trust clinical reports

One of the concerns raised by the West Midlands SHA was the trust's process for introducing new equipment. These related to equipment used to assist with cardio pulmonary resuscitation (CPR). CPR is a method of artificial breathing and circulation when the natural heart action and breathing have stopped.

The trust was very clear that its main purpose was to save as many lives as possible and to be at the "forefront of advances in resuscitation care". To achieve this, the trust was keen to be an early implementer of new equipment that improved the chances of resuscitating patients who had had a cardiac arrest.

The previous clinical services manager told us he was responsible for introducing new clinical equipment, with support from the previous medical director. The previous medical director told us that, from May 2005, he was responsible for the introduction of new equipment and that, before this, it was the director of production. The trust's standard operating procedure stated that the field operations manager was responsible for introducing new clinical equipment.

The trust did not have an equipment committee and the previous medical director

told the Commission that he was "not convinced" that having such a committee "was a better system or gave better patient outcomes". The standard operating procedure referred to the fact that a project manager should be nominated as responsible for introducing new equipment and establishing a project group, and that staff should be properly trained in the use of the equipment.

## Automated gas-driven chest compression device

In June 2004, the trust began a trial of an automated gas-driven chest compression device for use in the routine management of cardiac arrest. The potential benefit of this type of device was that it would improve the flow of blood to the coronary arteries during CPR and hence increase the flow of blood through the brain.

The device had a CE mark that showed it was in accordance with the Medical Devices Regulations 2002. A CE mark is a declaration by the manufacturer that the product meets all the appropriate provisions of relevant European directives. Essentially, it means that the device is fit for purpose. However, this does not necessarily equate with robust evidence of clinical and cost effectiveness.

The previous clinical services manager noticed in 2003 that there was a decrease in the number of times the trust had achieved a return of spontaneous circulation (ROSC). ROSC is a term used to denote the regaining of heart function, following treatment, in a person who has had a cardiac arrest. We were told that the trust was concerned about the effectiveness of the CPR being carried out by the ambulance crew and community paramedic officers. It is very difficult, and tiring, to maintain effective CPR over a long

period, especially for ambulance crew who are standing in a vehicle that is travelling at speed through traffic.

The automated gas-driven chest compression device was seen as a solution to these problems. The trust's board discussed it in June 2004 and gave approval for four devices to be trialled. It was introduced under the equipment appraisal standard operating procedure. The paper presented to the trust board contained information about the device and stated that four devices had been loaned to the trust.

The device was driven by oxygen. Oxygen was used because it was already carried on ambulances. If the trust was to use compressed air instead, it would mean putting additional cylinders on the ambulance and increasing the weight the ambulance had to carry. The device had already been used on a patient who had had a cardiac arrest and the ambulance staff attending the patient had found it "effective and useful". The paper stated that community paramedic officers would receive training and be given supporting information. Detailed information about the use of the device would be collected to assess its effectiveness.

In September 2004, the local ambulance paramedic steering committee was informed that the device was being trialled.

We were told that staff working in the local accident and emergency (A&E) departments were not involved in discussions about introducing the device. Some consultants working in A&E felt there should have been more discussion. They also expressed concerns about the device and the type of patients on whom it was being used. The previous chief executive told us that he had given an information session about the device to nursing staff from a local A&E department. The previous clinical services manager told us that he circulated information about the device to all the local acute trusts and that a presentation about the device was given at a local conference hosted by the trust.

At the meeting of the trust board in November 2004, it was reported that the device was essential for all cardiac arrests. In February 2005, the trust's board approved in principle a proposal to buy further devices and, by May 2005, all ambulances were equipped with the device. However, it was reported at the executive management committee meeting on 17 October 2005 that "there is currently no evidence of improvements since the introduction of the equipment". The previous chief executive told the Commission that although there was not an increase in the total ROSC number, there was evidence of an increase in ROSC in certain groups of patients.

The trust carried out a risk assessment before introducing the device and judged that it should not pose a risk to patients, but that consideration should be given to how the device should be stored on the ambulance. The trust believed that this type of device could reduce some of the risks faced by the ambulance staff when carrying out CPR in a moving ambulance. It would also enable staff to focus on other aspects of resuscitation.

The training for staff consisted of a presentation and a practical demonstration. The presentation did not include any information about circumstances when the device should not be used. Although all staff should have received training before using the device, 23 out of the 35 staff we asked felt that they had not received sufficient training on using the device, and in some instances had only received training after they had been using the device for two or three years. Some staff received training from their colleagues and described it as an initial, brief explanation.

The trust used a training programme provided by the manufacturer, but it became apparent that staff needed more information than was included in the programme. The previous clinical services manager acknowledged that the training could have been better and that sometimes staff used the device inappropriately. In 2005, the trust planned to include the training in the annual skills development day, but there is no reference of this happening until 2006/2007.



The previous medical director described the device as a “particularly easy piece of equipment to use and was taught to use it in a few minutes”. He also said that he “confirmed that staff were being trained in using it”, and reassured himself about the training by “speaking to crews and gathering soft intelligence”. The previous chief executive commented that staff were not expected to use this device until they had received training in how to use it.

According to the previous medical director, after discussions with “academics and the manufacturers of the device”, it was decided that it could be used during defibrillation. This is when a high-energy electrical impulse is used to stop a fast abnormal heart rate. The shock restores the heart’s normal rhythm. Stopping the device for any significant length of time before defibrillation reduced the chances of a successful defibrillation. The trust has provided guidelines dated 2005 with “draft” written across the pages. The guidelines state that defibrillation can be performed while the device is in use.

In June 2007, the trust informed staff that the device should not be used on elderly frail people or women who are pregnant, and that it should be switched off when defibrillation is being carried out. The previous chief executive told the Commission that the information about “its use on heavily pregnant females was not available when the device was first issued”.

During an earlier external review, in March 2007, of the trust’s arrangements for clinical governance, a concern was raised about the increase in the level of oxygen in the atmospheric air while the device is being used. The normal level is 21%. The trust carried out a number of tests that showed that there was a slight increase, up to a maximum level of 24.1%. This varied according to whether the ambulance was stationary or moving, and whether the ambulance was ventilated.

In May 2007, the trust informed the Health and Safety Executive (HSE) about the results of the test. The HSE’s view was that the safe working level of atmospheric oxygen is 23% and this is

confirmed by the European Industrial Gases Association. The HSE were satisfied that the device was safe to use as long as a number of conditions were applied: that the device was used in a ventilated area, that potential sources of ignition, such as defibrillation, were identified and avoided, and that the trust should consider using an alternative gas, such as air, to drive the device.

In February 2007, the Medical Healthcare products Regulatory Agency issued an alert notice about the device, following reports of inadequate ventilation in patients who are not intubated (that is, without a tube to help breathing), damage to lungs and raised levels of oxygen in the atmosphere where the device is powered by oxygen.

The trust confirmed that the above information had been shared with staff. During the time that the device has been in use, we were told that no major concerns had been raised by ambulance staff. The trust contacted all coroners in Staffordshire asking for any information about any unusual chest trauma following use of the device and the previous medical director told us that “no one came back with any concerns”.

The University of Birmingham was asked to review the literature on this type of device and offer an opinion on its effectiveness. They concluded that based on the current evidence it should be “considered experimental, and should not be used outside properly randomised controlled trials” or in “special circumstances agreed by the relevant authorities”. The previous chief executive commented that this type of device is used throughout Europe and its value is well recognised, and that the view of Birmingham University is “nonsense”. He told the Commission that “the benefits of the device are clear in the Healthcare Commission-directed national audit of hospital cardiac arrest data for the years 2004, 2005 and 2006, which show that Staffordshire outperforms all other ambulance services in the number of patients per million population who survive an out-of-hospital cardiac arrest to reach hospital alive”.

In June 2006, the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) issued a briefing paper on the device, saying that it supported the need for research into its effectiveness. It acknowledged that devices were already in use in some ambulance trusts. It recommended their continued use only in the context of an approved trial, or in special circumstances agreed by the relevant organisations, for example for patients for whom recovery using traditional CPR methods had been shown to be very low. JRCALC could not recommend the introduction of further devices at the time.

The National Research Register has no record of any clinical trials for this type of device.

### Impedance threshold device

In May 2004, the trust introduced an impedance threshold device. This is a valve that limits air entry into the lungs during CPR. In May 2004, the trust's board was informed that the trust was using it in an "equipment evaluation phase" and the trust had been chosen as the only pre-hospital evaluation site in the world.

Information about the device is included in the clinical report for April 2004 to March 2005. It states that it was used on 503 patients who had suffered a cardiac arrest, and ROSC was achieved in 134 of these.

A report presented to the risk and clinical governance committee in October 2005 states: "We have proved the benefits of the impedance threshold device when used in isolation in cardiac arrest...".

In 2006, the previous medical director became aware of potential problems with the device while he was working in another ambulance trust. When he returned to the trust in July 2006, he informed them of the problems. In August 2006, the trust issued a notice to all staff that the device was to be withdrawn. The concerns were that the device may cause iatrogenic pulmonary oedema – this is a collection of fluid in the tissues of the lungs induced inadvertently by a physician, surgeon, medical treatment or diagnostic procedure.

The acting medical adviser contacted JRCALC about the concerns and use of the device. The response from JRCALC, in October 2006, was that although it was not aware of any additional evidence about this concern, "without clear and objectively supported proof of patient benefit" the cost of the device would be difficult to justify. It was suggested that a controlled trial of the device be undertaken. The trust had submitted two papers supporting the efficacy of the device. However, both were co-authored by the person who had developed the device. JRCALC recommended that a truly independent assessment was needed.

At the trust's board meeting in December 2006, the joint director of clinical performance reported that JRCALC could not support the impedance threshold device being reintroduced until a formal research evaluation had been completed. This conflicts with the paper submitted to the risk and clinical governance committee in October 2005, which states that the trust had "introduced innovative and well researched adjuncts to improve survival from cardiac arrest" and refers to the automated gas-driven chest compression device and the impedance threshold device.

Neither of the devices described were recommended in guidelines issued by the Resuscitation Council (UK).

Both the previous medical director and chief executive have commented that the American Heart Association recommends both devices. The American Heart Association supports the use of the automated gas-driven chest compression device on the basis that it allows better and more frequent compressions – particularly in long arrests where endurance is a factor. However, as yet there is little evidence of the benefits to patients.

The trust made efforts to collect information on the use and effectiveness of both of these devices by asking ambulance staff to record on the patient report form whether they had used these devices. However, there were occasions

when ambulance staff did not document that they had used the equipment.

The information that the trust collected was related to the outcome of cardiac arrest following the use of the devices. This was done by looking at the number of times return of spontaneous circulation (ROSC) was achieved following a cardiac arrest. The clinical report for 2004/2005 included the number of cardiac arrests and whether or not the automated gas-driven chest compression device was used. In the governance report submitted to Shropshire and Staffordshire SHA in 2006, the trust stated that since the introduction of the automated gas-driven chest compression device throughout the service, although there had been less cardiac arrests, the number of ROSCs had increased by 45%.

Information about both of these devices was presented to the trust board in March 2006. The information includes “positive feedback” from ambulance staff who highlight the “vastly increased effectiveness of CPR”.

## Mechanical ventilator

In 2005, the trust introduced a new ventilator. This is a mechanical device used to inflate and deflate the lungs, providing the force needed to deliver air into the lungs. We asked how the ventilator was introduced to the trust and were told that it was on an “evaluation basis”. The previous clinical services manager told us that he was on holiday when it was introduced and when he came back, he “found it on his desk”. The previous chief executive has told us that “the equipment was trialled and approved before the clinical services manager took up his appointment”. Initially the ventilator seemed fine, but soon afterwards they found it had a number of technical problems, which may have compromised the safety of patients. Once the problems were identified, the trust consulted with “some of the world’s leading authorities in cardiac arrest survival” and the

decision was taken to withdraw the ventilator from use.

The problems were reported to the risk and clinical governance committee in October 2005. The previous clinical services manager told us that the trust reported the problems to the Medicines and Healthcare products Regulatory Agency.

When asked about these devices, the previous medical director said that “the trust was innovative and open to new technologies”. He said the trust had carried out audits on equipment and “acted on what they found”. He also said that there was a lot of equipment the trust had not introduced because there was not the evidence to prove its effectiveness.

## Findings of fact

- There is no reference to the role and responsibilities of medical staff for the introduction of new clinical equipment in the standard operating procedure.
- The trust introduced equipment that was not always proven to be clinically effective or efficient.
- The trust chose to withdraw some equipment due to concerns about the lack of evidence underpinning its safety and efficiency.
- Once problems with equipment were identified, the trust took appropriate action to inform the relevant organisations.
- Staff did not always receive adequate training on how to use new equipment, or information about the potential risks and contraindications.
- Risk assessments carried out on new equipment have not always been rigorous or comprehensive.

# The management of community first responders

## Sources of evidence

- Interviews with community first responders
- Interviews with current and former staff
- Minutes of community first responder meetings
- Minutes of the trust's board, production, the joint working group and the executive management committee
- Other reviews of the community first responders
- The trust's response to the Healthcare Commission's survey of community first responders

In this chapter, we examine the trust's management of community first responders (CFRs) and how the trust assured itself that the service they were delivering was safe and effective.

During the course of our investigation, we realised that there was a distinct lack of national information about CFRs. We therefore undertook a national survey of CFR schemes in NHS ambulance services in England. We published our findings, *The role and management of community first responders*, in December 2007.

CFRs are primarily lay people who volunteer to respond to some medical emergencies on behalf of an ambulance trust. They provide immediate assistance and treatment until the arrival of an ambulance paramedic or technician. The trust described their role as "to respond within their designated area of operations and provide emergency life support until the arrival of the ambulance service resources".

CFRs work independently or in pairs. They are not a replacement for an ambulance or

community paramedic officer and they do not transfer patients to hospital. The amount of training and the type of calls they respond to varies from one ambulance trust to another. All ambulance trusts, except one, have CFRs.

In August 2006, staff representatives raised serious concerns about the medicines and controlled drugs that the trust allowed its CFRs to administer to patients. The concerns were first raised with the chief executive of West Midlands Ambulance Service NHS Trust and again at the meeting of the Partnership Board in September 2006. The concerns, and the response of the trust to them, triggered a review of training for CFRs and of the drugs they were administering. This review helped inform our decision to carry out this investigation.

## The introduction of CFRs to the trust

The trust introduced CFRs in 1999. It was not the first ambulance trust to do so. CFR schemes were initially introduced in the more rural areas of the county. The intention was to provide a prompt emergency service for communities that ambulances could not reach so quickly, and to improve the outcomes for patients where the speed of the first intervention can be critical, especially those with chest pain or having a cardiac arrest. It was not the intention to assign them to calls for the GP out-of-hours service. They were to be used in addition to, rather than instead of, ambulance staff.

At the time of our investigation, the trust had 25 CFR schemes and 315 trained CFRs. Another 79 were being trained. The majority of the schemes were in rural areas, although some were being introduced in more built up areas.

All of the schemes received financial support from their local community and responded to calls within their community boundary. Occasionally they were asked to respond to calls outside this.

The trust gave talks to communities within Staffordshire, explaining how they could establish their own CFR scheme. Representatives from local communities would sometimes approach the trust to ask about setting up a scheme. For a CFR scheme to be established, it had to have support from a local elected authority such as the parish council. This would organise public meetings to see if there was enough support within the community. Once the scheme had local approval, the trust would be approached.

Schemes had to be self-financing. They raised money in a variety of ways, including sponsorship from local companies and fund-raising events.

The number of hours provided by each scheme varied, although many of them strived to provide cover for 24 hours, seven days a week. Some schemes were unable to do this due to the number of CFRs in their scheme, or where many of the CFRs had full-time jobs. The trust did not place any requirement on schemes to provide cover for a minimum number of hours.

Some schemes had “buddies”, who received some training, but not to the level of a CFR, and accompanied CFRs on calls to help with navigation, carrying equipment or looking out for the arrival of the ambulance.

## Accountability and management structure

Responsibility for CFRs sat within the production directorate and they were ultimately accountable to the director of production.

The trust had two CFR coordinators/trainers, who covered schemes in the north and south of the county. They were trained paramedics who coordinated and delivered the training for CFRs and were the CFRs’ main contacts on a day-to-day basis. They were available to

provide support for CFRs if they had attended distressing incidents.

Each CFR scheme had its own management structure. Although there may have been slight variations, each usually consisted of a coordinator. More recently, in 2007, some schemes had a person responsible for recording the medicines used and ensuring they were replaced. The scheme coordinator sometimes carried out this latter role.

There was also an association of Staffordshire community first responders, chaired by a CFR.

Until 2007, the trust did not have any formal agreement outlining the working arrangements between the trust and the CFRs. In 2007, the trust drafted and consulted CFRs on a volunteer agreement for all CFRs to sign. This contained information about the role of the CFR, training, and insurance for CFRs and their vehicles. The HR directorate implemented the agreement and all CFR schemes signed it.

The trust held quarterly CFR project meetings, attended by representatives from the trust, including executive directors and the previous chief executive, the CFR coordinators/trainers and scheme coordinators. Issues relating to CFRs were also discussed at the production meetings, directorate governance meetings (previously the operational team meeting) and meetings of the executive management committee. The trust produced a quarterly report detailing all the schemes, new schemes and training programmes. The CFR working group was established in 2006, in response to the concerns about the drugs the CFRs were administering. Information about the number of schemes and the areas they covered was shared at the trust’s board meetings.

## The recruitment of CFRs

The trust had for some time provided guidance on how to establish a CFR scheme. This was revised in 2004 and again in 2007 and covered recruitment, training, equipment, legal aspects and insurance, documentation and finance.

The trust’s managers were not involved in recruiting CFRs to a scheme. This was usually

done by the coordinator for the scheme, often in partnership with the parish council. People were recruited in several ways, for example through local free papers or by word of mouth. Any person in the community could apply but they had to:

- hold a driving licence
- be physically fit to carry out the role
- be prepared to meet the commitment for training and responding to calls
- have a good knowledge of the local area
- have no criminal record (since 2002, the trust carried out a Criminal Records Bureau check for each CFR, at no cost to the scheme)
- be able to maintain confidentiality about the patients and incidents that they attend.

The trust checked the driving licences of CFRs. An upper age limit of 70 was agreed in 2003. There was no guidance about a lower age limit but, when interviewed, some CFRs said that they consider how mature the person is. They gave an example of a CFR who was under 21 – the scheme coordinator ensured that they received sufficient support and that they were always accompanied to incidents by another CFR. Other schemes set a lower age limit of 21, as they had difficulty obtaining vehicle insurance for anyone younger.

## Training for CFRs

The trust's coordinators/trainers were responsible for organising and delivering training. Other organisations such as the fire and police services and staff from local hospitals were also involved. Training took place in either the trust's training centre or local community venues.

The original training was based on the Health Care Support Worker course and was accredited as a level 3 vocational qualification. However, some CFRs found this too demanding and time consuming. The previous chief executive was aware that this was causing anxiety among some CFRs and was concerned about the amount of theory included in the

training. In the minutes of the community responder project meeting for June 2005, it is documented that he hoped that a more practical type of training could be undertaken.

The training, which was not accredited, consisted of weekly three-hour sessions for 25 weeks, two formal assessments at weeks 13 and week 25, and a driving exercise. Training was provided to schemes rather than individuals and all members of the scheme had to attend all the sessions. If a CFR missed a session, they were expected to attend it another time, for example by joining another scheme for the session. The training took place in the evenings and at weekends. CFRs were also required to spend five shifts on an ambulance, observing. There was a final exercise that they had to pass, involving various scenarios. The final assessment was intended to confirm that the scheme was ready to operate and could last up to 16 hours over a weekend.

The trust maintained that the course was “to the exacting standards of the Health Care Support Worker course”. This was questioned in an earlier review of the training for CFRs, carried out by West Midlands Ambulance Service NHS Trust. Most Health Care Support Workers roles are there to support or assist healthcare professionals, whereas CFRs work autonomously, assessing the patient and initiating treatment. The course does not have a regulatory body and does not result in a qualification.

The trust also claimed that CFRs were trained to roughly the same level as ambulance technicians. This claim is not substantiated, as technicians are required to spend eight weeks at an accredited training centre undertaking an Institute of Health Care Development training course with approximately 320 student/tutor contact hours, compared with 75 contact hours for CFRs. Ambulance technicians are also required to complete a period of assessed supervised practice of at least a year. However, the trust did provide more training for CFRs than other ambulance trusts.

The training included a series of PowerPoint presentations and practical demonstrations. Subjects included code of conduct, anatomy, physiology and conditions of the respiratory and cardiovascular system, cardio pulmonary resuscitation, traumatic injuries, wounds and haemorrhage, paediatric life support and medical emergencies.

We were told that CFRs were assessed to see if they could safely drive an ambulance. Some CFR schemes have considered undertaking additional driving training at their own expense. However, they are waiting for guidance from the trust about which course would be most suitable.

In terms of ongoing support, the CFR coordinators/trainers were available for advice. The CFRs could also contact the trust's doctors and other staff working in the emergency operating centre for advice. Schemes offered a range of support for CFRs. An experienced CFR would partner a newly trained CFR in attending calls. Some coordinators arranged time for the scheme members to meet, to review and discuss calls they had attended. CFRs commented that they had a good relationship with community paramedic officers and most ambulance staff, and were happy to discuss cases with them.

The CFR coordinators/trainers were also responsible for ongoing training. They provided a range of updates for CFRs and were responsible for keeping them informed of any changes in policies or procedures. The scheme coordinators kept a record of attendance at these events. The CFRs had access to the clinical routine instructions, routine instructions and the trust's intranet. CFRs commented that the trust had established an email group for the scheme coordinators.

## Equipment

Each CFR scheme was responsible for buying its own equipment – this had to be compatible with the equipment used by the trust. The trust provided advice and an equipment list that included thermometers, breathing equipment, bandages, blankets, a defibrillator

and protective clothing. Each scheme relied on financial support from its community to buy the equipment.

Schemes were also required to buy their own vehicles. The trust carried out a maintenance check on the vehicles before they could be used in responding to calls.

CFRs were not required to wear a uniform, but some of them chose to wear navy overalls with the trust insignia. (Ambulance staff wear green overalls.) The guidance to CFRs provided by the trust states that if CFRs choose to wear a uniform, this must identify the wearer as a responder and not as an ambulance paramedic or technician. While on duty, CFRs were also required to wear a fluorescent jacket and carry their trust identity card.

## Calls attended by CFRs

CFRs arranged their own rota for when they would be on call. They were not obliged to respond to calls all the time.

The trust's guidance did not specify which calls CFRs could attend – it merely referred to "emergency calls". Once the CFRs had completed their training, the trust issued each scheme with a pager, which was held by the CFR who was on call. They were paged automatically to attend any call within their area when they are available to respond. Staff told us that CFRs once did, but no longer, attend motorway incidents due to concerns about their personal safety. All calls attended by CFRs should be backed up by an ambulance dispatched at the same time. However, in the past this has not always happened. There was evidence of delays in dispatching ambulances and of CFRs cancelling ambulances that were on their way to attend the call. The trust took action in response to these incidents.

CFRs were attending some follow-up calls for the GP out-of-hours service but this has now stopped.

CFRs respond to any emergency calls within their area. At the same time that the trust dispatches a CFR, they also dispatch either a community paramedic officer (CPO) or an

ambulance crew. Once the CFR has arrived at the scene, they confirm their arrival either by phone or radio. The trust told us that this procedure had been in existence since CFRs were introduced. We were told of instances where CFRs were asked to attend calls in neighbouring areas and occasionally outside the county border into Cheshire and Merseyside. The previous chief executive has commented that CFRs could also respond if asked to do so by their local GP or a member of their community. The issue of being asked to respond by a member of their community was discussed at the CFR meeting in December 2006 and they were advised that they must inform the emergency operating centre if this happened.

The trust provided information about the type and number of calls attended by CFRs. These included suicide attempts, chest pain, miscarriage, traumatic injuries, road traffic accidents, assaults and rapes. The majority were to people with breathing problems, chest pain or traumatic back injuries. The number of calls that each scheme attends is variable and can be as little as two or three calls per week. We were told of an example where one CFR was not sent to any calls for two months. CFRs were aware of the effect this may have had on them maintaining their skills.

When asked about what is expected of them when they attend calls, CFRs told us that it varied and quite often their role is about providing reassurance. There was very little they could do if, for example, if they were attending someone who was in early labour or miscarrying, except provide reassurance and try to keep the person calm until the ambulance arrived.

Calls attended by CFRs are included when the trust calculates its response times for submission to the Department of Health. There was some confusion among staff about whether or not they were included, but it has been confirmed that they are. The guidance states that "for the purpose of the eight-minute standard (Category A), an emergency response may be by an emergency ambulance... or an approved first responder

equipped with a defibrillator, dispatched and accountable to the ambulance service" (The Information Centre, 2006). However, the trust states that in terms of the number of calls attended by CFRs, even if they do not meet the eight-minute response time, it would not have an impact on their performance ratings. Between April 2006 and March 2007, the trust received 159,485 emergency calls and CFRs were sent to 4,371 of those calls.

## Documentation used by CFRs

CFRs were required to complete a patient report form for every patient they attended. This contained personal information including the name, address and date of birth of the patient. The patient report form was handed to the ambulance crew when they arrived. If the CFR and the ambulance crew arrived at the same time, then the ambulance crew initiated the form.

There were three copies of the form and the trust became aware that the CFRs were retaining the third copy. They did this in case they were asked to give evidence in the event of a clinical incident.

The trust informed them that they should not be retaining the third copy. The CFRs queried this, and the trust advised them that it did not comply with Caldicott guidance for NHS organisations on the protection and use of confidential health information. Also, patient report forms are held by the trust and the CFRs can access them should they need to.

In June 2007, the trust introduced a new standard patient report form which includes an extra carbon sheet that does not record the patient's name or address. The CFRs are allowed to keep this copy for their records.

## The use of blue lights and other sirens

The trust was the only one in England that allowed all CFRs to use 'blue lights' and sirens when responding to calls, without having undertaken advanced driving instruction. In 2004, it is documented in the minutes of the



training joint working group that CFRs should drive within the speed limit. In October 2006, in the absence of written guidance from the trust, the CFRs drafted guidance for the use of blue lights and sirens. This stated that the CFRs could drive to a maximum of 20 miles per hour above the speed limit, and go through red lights. The guidance was agreed by the trust.

When we first raised serious concerns about CFRs using blue light and sirens without training, in December 2006, we were told that the previous chief executive had discussed it with the Chief Constable of Staffordshire at the time, but that nothing had been documented.

Previously, in July 2001, the trust carried out an assessment of the potential risks to CFRs working in rural areas of the county. This covered risk of accident or injury, the impact of the weather and road conditions, and training for drivers. In relation to the training for drivers, the document stated that, as CFRs used their own vehicles, there were “no special driving needs required” and “CFRs as all drivers should drive within their own competence”. It also stated that “pre-1981 ambulance personnel have never undertaken driving courses” for blue lights and sirens. There was no reference to the risk to CFRs of using blue lights and sirens without having received any additional driver training. Nor was there any specific reference to the risk faced by members of the public. One of the conclusions of the assessment is that, since CFRs are generally expected to respond to calls only in their own area, the “use of blue lights should not be required”.

The assessment concluded that “the risk of driving based against the duty of care for other road users is of medium risk” and that this “assumption” was based on the fact that many CFRs were located in rural areas and only responded within their own area; therefore “the use of blue lights should not be required in responding”. The assessment states that blue lights are useful in protecting the CFR and the patient if they are on exposed roads and that “blue lights are fitted to act as a beacon to guide ambulances to remote farms”.

The trust’s view was that using blue lights and sirens alerted other drivers to the presence of CFRs. CFRs had a similar view. They found blue lights and sirens helpful because they warned other vehicles of their presence and would allow them to pass. CFRs also said that blue lights were useful in assisting ambulances to find locations in rural areas. One CFR told us that they used their “common sense” and did not always put the siren on. For example, if they were driving through a village in the middle of the night, they would not use the siren as it would wake everyone up. They stressed that the aim was to get to an incident as soon as possible but also as safely as possible. They felt this was a “grey area” and said they would welcome more training.

In January 2007, the trust issued “Guidance to the Establishment and Operation of a Community First Responder (CFR) Scheme in Staffordshire”. This advised CFRs “to proceed... with due care and attention for themselves and other road users .....using blue lights and sirens provides no authority to drive recklessly or endanger life...”. They were told to leave the blue light flashing to help the ambulance crew or helicopter locate the scene.

At the meeting of the trust board, in April 2007, it was agreed that CFRs who were currently using blue lights and sirens could continue to do so, but they must comply with the Road Traffic Act, abide by the Highway Code and not exceed the speed limit. New CFRs would not be allowed to use blue lights and sirens until the issue had been resolved and the trust would write to the Chief Constable seeking his advice on this issue.

In the minutes of the integrated governance and performance committee meeting held in July 2007, it is documented that a letter had been sent to the Chief Constable and the CFRs had been notified they could not exceed the speed limit. Therefore, there was no need for them to use blue lights and sirens.

Section 19 of the Road Safety Act 2006 amended section 87 of the Road Traffic Regulation Act 1984. Prior to this amendment, section 87 provided that vehicles being used for fire and rescue authority, ambulance,

police or serious organised crime agency purposes are not subject to any statutory provisions imposing a speed limit, if observance of the limit would be likely to hinder their use for the purpose for which they are being used on that occasion.

The substituted section provides that the exemption from speed limits does not apply unless the vehicle is being driven by a person who has satisfactorily completed a course of training in the driving of vehicles at high speed, provided in accordance with regulations under the new section, or is driving the vehicle as part of such a course. Subsection 3 of the new section enables regulations to be made about courses of training in the driving of vehicles at high speed. So far, no regulations have been issued setting out the requirements for such courses. However, in terms of health and safety law, an employer who expected their staff to drive with blue lights and sirens would normally require their staff to complete a training course in order to do this safely.

In relation to the use of blue lights, the Road Vehicles Lighting Regulations 1989 state that “no vehicle, other than an emergency vehicle, shall be fitted with a blue light or special warning lamp...”. For a vehicle to be classified as an emergency vehicle they must be constructed or adapted in some way to carry sick or injured people. This was reinforced in the Court of Appeal decision in *Norman Aston v Crown Prosecution Service* (2005).

Ambulances comply with this description.

The previous chief executive told us that “every response vehicle used by CFRs had to be prepared to carry a patient” and that many were four-wheel drive and had stretchers fitted so that they could respond off-road and move patients to the ambulance waiting at the roadside. However, the trust has clarified that “not all CFR schemes possess 4x4 capabilities and some of the vehicles that are 4x4 capable do not possess any ability to transport patients due to their internal specification”. The schemes that do have 4x4 capability “are more often than not supported by a CPO in a 4x4 ambulance response vehicle”. The potential occasions where CFRs may transport patients

from isolated areas to a waiting ambulance include adverse weather conditions.

## Insurance for CFRs

CFRs are covered by the NHS Litigation Authority scheme for clinical negligence and third party liability, provided they act within the law and stick to the trust’s policies and procedures. The trust did not provide insurance for loss of earnings and recommended to CFR schemes that they took out their own insurance to cover personal injury and loss of earnings. From interviews with CFRs, schemes have taken out additional insurance for their vehicles and insurance for personal accidents.

## Audit of CFR practice and interventions

Although the trust had collected information about the number and type of calls attended by CFRs, and the number of times they administered medicines and controlled drugs, this information had not been used to review or assess the work they undertook. In January 2007, the trust introduced a “skills form” to audit the medicines that CFRs were administering and the types of interventions they were applying. CFRs are required to complete and submit a copy to the trust on a monthly basis and retain a copy for their own records.

## Evaluation of the role of the CFR

Although the trust’s CFRs were established in 1999, the trust had not carried out an evaluation of their role. Any information about how the role had affected patient care had never been collated. This particularly surprises us, since CFRs had been awarded commendations for their actions. Lack of time and resources were put forward as reasons for why the role had not been evaluated. Any evaluation that was undertaken would have also had to consider the perspective of the local community. From the information provided by CFRs and from members of the public, it would seem that the schemes are

highly valued by their local communities. The fact that they continue to support them and finance them is an indicator of this.

## Findings of fact

- The trust has been using CFRs, mainly in rural areas, since 1999.
- The trust only recently introduced a formal agreement for CFR schemes.
- Information about the number of CFR schemes was provided to the trust's board.
- The trust has not undertaken a risk assessment or issued guidance about the type of calls/incidents that CFRs should attend.
- Calls attended by CFRs are included in the trust's calculation of its response times which are declared to the Department of Health.
- CFRs have in the past attended calls for the GP out-of-hours service.
- The trust provided training, including update training, for CFRs.
- Compared with other ambulance trusts, the trust provided the most training for its CFRs.
- The trust did not ensure that CFRs were fully compliant with Caldicott guidance and patient confidentiality has, in the past, been breached.
- The trust allowed CFRs to drive using blue lights and sirens without providing written guidance for them.
- The trust allowed CFRs to drive over the permitted speed limit without providing training for them to do this and put them at risk of incurring penalty points for breaking the speed limit.
- Despite the Commission first raising concerns in December 2006 about CFRs using blue lights and sirens, the trust has only recently developed a training proposal for CFR blue light response.
- No evaluation of the CFR role has been undertaken since it was introduced in 1999.

# The management of staff, and training and education

## Sources of evidence

- Interviews with current and former staff
- Minutes of internal meetings, including production meetings, team leaders' meetings, HR meetings and meetings of the trust's board
- Clinical governance action plans
- Previous reports and assessments on the governance arrangements of the trust
- Standard operating procedures provided by the trust
- The trust's intranet, website and surveys of staff

This chapter covers the working conditions for staff, the support available to help them carry out their jobs effectively, and the training and education provided by the trust.

Responsibility for the management of staff was shared between the human resources (HR) directorate, the scheduling team and the area managers, who sat within the production directorate. The director of HR was a member of the trust's board and there were a number of forums where staffing issues were discussed, for example, the field operations staff liaison committee, the quarterly staff liaison committee and the education and training committee.

In the model of delivery used by the trust, the role of the scheduling team was seen as crucial. It was responsible for day-to-day work schedules, mapping out annual leave in advance, managing requests for annual leave and other time off work, and monitoring levels of sickness. The role of HR was to manage the recruitment and induction of staff.

## The management of sickness

The trust had consistently high levels of sickness and the ambulance staff providing the emergency service had the highest rates. The rate of sickness was on average around 8% (April 2004 to December 2006). Staff working in the emergency service had the highest rate of sickness, at times above 10%. The rates of sickness were frequently discussed at the staff liaison committee and the risk and clinical governance committee, and were reported to the trust's board where it was discussed by both the executive and non-executive directors.

The scheduling team managed short-term sickness and HR managed long-term sickness. The scheduling team would inform the area managers if staff were off sick. The team would ask the HR directorate to send out return to work letters, which would require the member of staff to attend an interview with their area manager. Staff were themselves responsible for arranging these interviews and the area managers were responsible for conducting them. The scheduling team informed HR about staff who were absent due to long-term sickness. If people were off only for a day, it was felt that HR did not need to be kept "in the loop".

When we asked whether the trust had tried to establish why the levels of sickness were high, we were told that the trust "had never got to the root cause of why staff were off sick". The trust did undertake some analysis. It found that in the majority of instances where staff had taken more than three days off sick, it was due to an injury from lifting or transferring patients. However, there is no evidence that this led to increased training on the moving and transferring of patients.

The trust had a "managing attendance policy" which was revised in 2006. This used the

Bradford scoring factor, which measures attendance by assessing frequency and duration of absence. It shows whether an individual's sickness record is made up of a few, or many, spells of short and/or long term duration.

At the trust's board meeting in April 2006, in response to a question from one of the non-executive directors, the acting chief executive said that historically the trust had been lenient with regard to the management of sickness, but would be addressing it more "rigorously". Staff told us that in 2006 there was a huge increase in the number of return to work letters sent out. In August 2006, 366 letters were sent, yet there was a poor uptake of interviews, with only 172 interviews undertaken. Depending on the person's score, the letter may have mentioned that the person would have been subject to disciplinary action.

Some staff felt the trust's management of sickness was inappropriate. We heard reports of one person who was visited at home by two senior members of staff to verify that the person was sick. Visiting staff at home is not included in the managing attendance policy. This was discussed at the meeting of the trust's board in December 2006, where it is documented that "there was a feeling that now the trust was proactively managing sickness, staff perceived it as bullying".

The trust's managers acknowledged that the return to work letters did not have the desired outcome. This was partly attributed to the fact that the interview should have been carried out by the area manager, who may not have had enough time to give it the attention it deserved. It was also the responsibility of the staff who had received the letters to arrange the interview.

If staff became unwell while they were on duty, there were three options available to them: see one of the trust's doctors, see a community paramedic officer, or go to an appropriate hospital. The policy stated that staff "had the right to refuse these options, but Control must be notified of this and you are advised before leaving to speak to the area manager". We were told that staff were discouraged from refusing the three options.

In 2007, the chair of the trust's audit committee requested a review by the internal auditors of the rates of sickness. This found that there was no evidence of "systematic abuse of the sickness system, but there were some areas for improvement".

Also in 2007, the trust changed the method for calculating sickness from "hours lost" to "days lost", as per guidance from the Department of Health. This resulted in a decrease in the recorded rates of sickness. Comparison indicates that the "days lost" figures are about 80% of the "hours lost" figures, so there was a reduction in the rates of sickness. Although the rates of sickness were not as high, they were still high when compared with the other localities that made up West Midlands Ambulance Service NHS Trust.

## Disciplinary procedures

The Commission was told that HR were not routinely involved when disciplinary action had to be taken against staff. Although the trust had a procedure, it was not often used. This was because the previous chief executive did not believe in initiating the disciplinary procedure unless it would result in the dismissal of a member of staff. He did not think that the policies enabled the evidence to be gathered for disciplinaries and that in many cases the disciplinary procedure was not necessary. He has commented that "managers were not good at managing disciplinary procedures and HR, whose responsibilities was to advise managers prior to disciplinary action being taken were often reluctant to do so". He believed that staff did not come to work "to intentionally do wrong" and that as long as staff always acted in the best interest of the patients, there was nothing they "couldn't do to save a life".

Some managers found this approach frustrating, as there were occasions when they felt it necessary to discipline a member of staff and were unable to do so. One senior manager said that initiation of the disciplinary procedure required the approval of the previous chief executive.

This does not mean that staff were never disciplined. The disciplinary procedure was used six times in 2004/2005, nine times in 2005/2006 and 12 times in 2006/2007. This increase has been attributed to a lower tolerance of some behaviours that may once have been acceptable.

We were also told of a single time when a member of staff, without having been formally disciplined, was told they were “sacked” and sent home. The next day, they received a phone call asking why they were not at work. This was not documented in their HR record.

Another member of staff told us that the previous chief executive had once gone to an A&E department to “fire two staff who had stayed with a child”. Half an hour later, he reversed the decision. The previous chief executive has commented that he went to talk to two members of staff who refused to answer telephone or radio messages, but not to sack them. They both “apologised and learned their lesson”. The view of one member of staff was that “there are not many people at Staffordshire that haven’t been sacked... they laugh about it, but they know it’s not right and it would not be in other services”.

Some told us they were threatened with disciplinary action if there were delays in handing patients over in A&E. The trust allowed 15 minutes for the handover to take place.

## The system for appraisal

Appraisal systems allow staff to discuss formally their professional role and clinical practice, to improve on good performance and to recognise poor performance at an early stage.

The trust’s records show that in 2005/2006, 65% of staff received an appraisal. However, interviews with staff indicate that appraisals were not carried out on a regular basis and some said that they had never had one.

Training on how to carry out an appraisal was available to managers. Due to the demands of the service, this was done on an ad hoc, one-to-one basis. There was a view held by some managers that staff should have their appraisal

in their own time. One manager commented: “They cannot take people off the road as the patient comes first” and “staff won’t come in their own time and therefore they won’t get done.”

The appraisal system was intended to include discussion about the staff performance record, focusing on average activation time (defined at the time of the investigation as the time from determining the response needed to the time the response is actually mobile), average response time, average on scene time, average transport to hospital time, average hospital turn around time and their Bradford sickness score. While all this information is relevant, it may at times be outside the control of the ambulance crew. Staff told us that they felt it was very statistically orientated and there was insufficient focus on professional or personal development.

In 2003, the trust introduced the career development plan (CDP). This was a competency model with statistical targets that staff had to achieve to progress through the organisation. Staff had to submit a portfolio of evidence to the career development committee demonstrating that they had achieved the competencies. The committee included representatives from HR, the scheduling team and staff generally. In order for people to progress, they had to spend some time working in the emergency operating centre (EOC). This enabled them to gain experience in handling calls for both the emergency service and the out-of-hours service and ensuring the appropriate response was dispatched.

The main concerns that staff had about the CDP were that it was inflexible and they had to spend long periods in the EOC. Working in the EOC meant there were long periods when ambulance staff were not responding to emergency calls. More than half who were asked about the time they spent in the EOC expressed dissatisfaction in terms of their interest and motivation. They were concerned that it had a detrimental effect on their clinical skills and they were not kept up to date with changes such as the introduction of new equipment or drugs. Once they went back to responding to emergency calls, they were

expected to bring themselves up to date with any changes. Only four of the staff who were asked this question were positive about their experience of working in the EOC. The trust was aware of these concerns, which were documented in the minutes of the distribution meeting in October 2006.

The previous chief executive has commented that “all staff who successfully completed their level of training in the EOC were supportive of the system. Those who did not were not and usually became... shop stewards”.

### Working conditions for staff

Delays in handing patients over in A&E was an ongoing problem for the trust (although they are not the only ambulance trust to face this problem). For ambulance trusts, delays in A&E may result in fewer ambulances available to respond to calls from patients.

While the trust was very clear that it had a duty to patients who were waiting for a response to their call, ambulance staff were faced with the dilemma of leaving a patient unattended in A&E in order to respond to patients who may be waiting.

Managers told us that rather than having a number of ambulance crews waiting in A&E, they would tell one crew to hand their patients over to another crew to look after. We were told that staff would do this on some occasions, particularly if it was coming near to the end of their shift, while on other occasions they would refuse. The reason they gave was that they were personally responsible for the patient until they handed them over to A&E staff. The trust would sometimes send a manager or a community paramedic officer to the A&E department to take responsibility for the patients, freeing up the ambulance crew to respond to incoming calls. It was also not unusual for the previous chief executive to go to the A&E as well.

Some staff told us they had been “told off” for exceeding the 15-minute hand over period or that they had been repeatedly paged, in one instance up to 12 times, while they were waiting to hand over a patient. Some told us they were threatened over this issue. One of the problems

was that staff were often paged by a number of managers: their area manager, the manager in the emergency operating centre and senior managers. It was not unknown for staff who had been delayed in A&E to be called to the trust headquarters to account for themselves.

The ambulance staff may have had good cause to be concerned about the trust’s approach to managing this difficulty. The minutes of the team leaders’ meeting for November 2004 stated: “Once again staff are not complying with the request from Control to leave receiving hospital departments after being at hospital for an excessive amount of time... Some staff are claiming they have not received the pager message... If staff wish to please themselves and not do as requested, there will be unpleasant consequences.” In the weekly production minutes there are a number of references to this issue, for example: “If crews still refuse it can be taken down the disciplinary procedure for refusing a direct instruction.”

Some staff said they would find it difficult to raise concerns about their working conditions. One person who expressed dissatisfaction with the area in which they were working was told that “it would be down the road for ...” if they did not want to work in that particular area of the trust.

Ambulance staff often attend very traumatic incidents, sometimes in potentially dangerous areas, and they are expected to deal with sad situations. When asked about the support they received, the response was variable. Some said that “down time” following a call out to a traumatic incident had reduced, mainly due to the increased demand for the service. Others said they were satisfied with the support they received.

The trust had access to occupational health services and some staff were aware of this. The standard operating procedure for staff support, welfare and counselling was written in 1999 and the contact details are out of date. In the staff survey for 2006, the trust had the lowest percentage of all ambulance trusts, at 14%, for respondents who said they had access to counselling services.

The commission was told that many staff worked beyond their contracted hours, although they were paid for the hours they worked. There was also an expectation that they would be on call for long periods. Until recently, the trust did not have an on-call roster. There was an expectation that staff, including managers, would be available to respond in order to “potentially save lives”.

We were told that unless managers called in to say they were not on call, it was assumed that they were. It was not documented anywhere that this was a requirement. Instead, it had evolved through custom and practice.

We were told of instances when the trust had shown compassion for staff and supported them in taking time off, for example if a relative was ill.

In the Commission for Health Improvement Clinical Governance Review (2003), there is reference to the number of additional hours that staff were working. The review recommended that the trust should “quantify how much work staff and volunteers are undertaking in their own time to assess the likely impact should this time be removed and manage potential health and safety risks”. This recommendation was not included in the action plan that the trust developed following the review and it seems that staff and managers were still working beyond their contracted hours, albeit being paid to do so.

Ambulance staff in the trust were grouped into teams of 10 and previously had team leaders to cascade information and perform team administration. When the community paramedic role was introduced in 2000, it was meant to incorporate aspects of the previous team leader role. However, the community paramedic officers (CPOs) were based in rural areas and essentially worked on their own, sometimes only meeting up with colleagues at incidents. The impact of this included an increase in management responsibilities for the area managers, who were more frequently at depots for the ambulance staff. Team leader study days were initially attended by CPOs or other team representatives, but these gradually petered out and it was difficult for the CPOs to cascade the information.

As regards ambulance technicians, once they have completed their training they are required to complete at least a year of assessed and supervised practice. Some staff said that this support was not available to them. In June 2005, the lack of availability of mentors for newly qualified technicians was raised at a meeting of the distribution team. It is documented that newly-qualified technicians “appear to be working without a more experienced member of staff. Serious concerns were raised in the meeting about this matter”.

The head of HR told us that, in theory, the CPOs should have looked after the technicians and paramedics, but the “system that was being operated didn’t allow them to do the role”. The previous chief executive partly attributed this to the changes brought about by Agenda for Change. The reduction of staff hours and extra pay for overtime required ambulance trusts to recruit more technicians. At the same time, paramedics were being taken off ambulances to work as CPOs to cover the work generated by the GP out-of-hours contract.

The results of the staff surveys for 2003, 2004, and 2005 showed a significant decrease in the percentage of staff who reported that they worked in teams and had support from their line manager. In the survey for 2006, the trust had the highest percentage among ambulance trusts of staff (17% of those who responded) who were very dissatisfied with the support they received from their immediate manager.

## Communication with staff

A key form of communication with staff was via the trust’s intranet. In 2005, it was noted that not all staff had access to the intranet. This subsequently improved and intranet access was available at bases and standby posts. Clinical information was distributed through clinical routine information sheets (CRINS) and other information through routine information sheets (RINS). Staff raised a concern about the number of abbreviations used in the RINS, making them difficult to read, but this does not appear to have been resolved.



## Medical staff employed for the GP out-of-hours service

In May 2004, the trust began to provide some aspects of the GP out-of-hours service for the area of south west Staffordshire, and in December 2004 for the rest of south Staffordshire. The contract for the service states that the service provider needed to “have a GP available during the out-of-hours period to whom patients will be referred, to attend home visits... provide medical advice and support to community paramedic officers”. It was noted that the PCT would provide the GP from 6.30pm to midnight and the trust would provide GP cover after midnight.

The trust had difficulty recruiting GPs to provide this service. The previous chief executive told us that this was because the “GP contract was nearing agreement and would reward GPs massively, bringing their earnings to over £100K per annum without any unsocial hours. The PCTs would only allocate £75K for GPs to work predominantly unsocial hours”. However, in July 2004 it employed a GP to have lead responsibility for the service. The post holder was expected to provide cover in the emergency operating centre and attend internal and external meetings.

The other doctors recruited to take on this role were not GPs and were not on the PCTs Performers List, although some of them had experience of working in primary care in other countries. The National Health Service (Performers List) Regulations (August 2004) state that it is a requirement that “doctors providing primary care services” are on a PCT Performers List. Under the Personal Medical Services Agreement Regulations 2004, it is a requirement that “any doctor performing medical services under this (the OOH) contract must be a general practitioner”. From January 2005, there was also a requirement that “where it is clinically appropriate, patients must be able to have a face-to-face consultation with a GP, including where necessary, at the patient’s place of residence” (Department of Health, *National quality requirements in the delivery of Out-of-Hours services*, January 2005).

South Staffordshire PCT commented that the PCT understood the doctors employed by the trust were not employed as GPs and were not on the PCT Performers List, but were working as “medical practitioners”. Their understanding was that the initial guidance was not thought to preclude non-GP doctors, and that home visits by a GP were not a requirement.

South Western Staffordshire PCT, and subsequently South Staffordshire PCT, hosted the service level agreement in the south of the country. A previous chief executive of one of the PCTs has commented that, when the PCTs became aware of the guidance, they asked the trust to take action to resolve the matter, but that the trust did not pursue it with “appropriate priority”. The current chief executive of South Staffordshire PCT told us that in mid-2005 the chief executives from the previous PCTs had several meetings with the previous chief executive of the trust to discuss the issue of cover by GPs. Some of these discussions are described as “heated”. At the trust’s board meeting in May 2005, the director of distribution stated that “clarification of the wording regarding clinical coverage by doctors was required in respect of the GP OOHs service SLA”.

The job descriptions for the doctors are titled “Out of Hours Doctors, Control Centre” (August 2004) and “Out of Hours Doctor” (November 2005). Both state that the first principle duty is to provide emergency medical care to trust patients. Later versions of the job description are titled “Trust GP OOH & Urgent Care Doctor”. The focus of the job descriptions is very much on emergency care, with very little reference to primary care.

Although some cover after midnight was arranged and a GP from South Western Staffordshire PCT took on the role for a short period, the issue of the role and qualifications of the doctors employed by the trust was ongoing. As late as 2006, the issue was still being discussed. At the trust’s board meeting in November 2006, the acting medical adviser stated that the doctors needed to be “GPs on the GP register”. The chief executive of West Midlands Ambulance Service NHS Trust agreed

that although there was no regulation stipulating the qualifications of doctors employed by ambulance trusts, in the absence of any regulation it was best to apply the “nearest regulation”, which was that the doctors should be GPs. In late 2006, the trust employed a new cohort of doctors who were trained as GPs and were on the PCTs Performers List.

In May 2005, the GP who had lead responsibility for the GP out-of-hours service left the trust. We were told that the way the roster was organised, it was difficult for the GP to attend all the internal and external meetings that she was required to attend. It was also difficult for the doctors to meet as a group. The same GP subsequently returned in November 2006 to the same position.

When reviewing the details of the trust doctors on the General Medical Council register, we found some inconsistencies. For example, the registration number provided by the trust did not match one individual’s registration number on the GMC website.

## Findings of fact

- Accountabilities for staffing were shared.
- The HR function was restricted.
- The approach to appraisal did not encourage or enable staff to develop their professional and clinical skills.
- The trust did not evaluate the impact of the career development plan on staff or the service.
- The trust did not implement a standard disciplinary process.
- The trust was unable to meet the requirements of the service level agreement with the PCTs for the GP out-of-hours service.
- When recruiting doctors to cover the GP out-of-hours service, the trust did not always take into account the NHS regulations.
- There was confusion about the role and experience of the doctors required for the GP out-of-hours service.

- The issue of GP cover after midnight was an ongoing issue between the trust and the PCTs.
- There was an expectation that staff would work in excess of their contracted hours on a regular basis.
- Some staff found it difficult to raise concerns.

## Training and education

### Accountability and structure

The trust had a dedicated training department and employed a head of training. The head of training had been absent due to long-term sickness and an acting head of training was appointed in late 2006. Prior to this, a paramedic was seconded to the role for a few months “as a stop gap” appointment.

There were four clinical tutors who were all accredited by the Institute of Health Care Development (IHCD). This is the awarding body for the Ambulance Service Association. The awards are the training standard for those employed by NHS Ambulance Services, and are operated throughout the UK. The IHCD Paramedic award entitles the holder entry onto the State Register for Paramedics operated by the Health Professions Council.

The trust had a training strategy for 2002-2005, and information about training was included in the strategic direction for 2004-2007. The business plan for 2006/2007 included a list of courses that the trust planned to run each month.

Over the last few years, executive accountability for training and education has changed a number of times. Initially, the director of HR had responsibility and training and education sat within HR. In 2005, responsibility was moved to the previous medical director and sat within the clinical services department. When the previous medical director left the trust in March 2006, responsibility moved to the acting chief executive and finally back to the director of HR.

We were told that the reason it was transferred out of HR was the increased work generated for

HR by Agenda for Change (the system introduced to provide fairer and more responsive pay and career structures for NHS staff). However, the previous medical director told us that there were several reasons why responsibility was transferred to him. These included concerns about the training in performing cardio pulmonary resuscitation and also in risk management. The previous chief executive also told us that training “suffered from inadequate management from HR and the training manager which resulted in poor record keeping...”.

We were told that under the previous medical director, there was some confusion about the role of the trainers and the management of the team. We were told that the trainers would develop training packages for staff but before they had the time to roll them out, they would be asked to change them. However, the previous medical director has commented that it was standard practice for him to review the training packages and, where the information was inaccurate, to make the necessary changes.

The main forum for discussion about training and education was the training joint working group.

## Resources for training

The budget available for training was variable. For 2003/2004, it was £200,000; a year later, it was £400,000. For 2005/2006 and 2006/2007, the trust provided a statement saying there was no defined budget and costs must be met from “efficiencies”. Some staff told us that there was some ring fencing of money for training but, if there was an increase in operational activity, the money would be taken to provide the additional resources. Other staff said that the budget for training always came out of the overtime budget and if there was an increase in overtime then resources for training were decreased. It was evident from the trust’s business plan for 2005/2006 and 2006/2007 that increased operational activity with no additional funding for it had an adverse effect on maintaining the training programme.

## Training provided by the trust

The training provided by the trust included the annual skills development (ASD), the Health Care Support Worker course and training to become a paramedic or an ambulance technician. Both the paramedic and technician courses were accredited by the IHCD. Other training was on an ad hoc basis and in response to specific requests, such as a member of staff returning to work after a long absence or issues arising from a clinical incident.

## Mandatory training

Staff were required to attend ASD days. The aim of these was to inform staff about any new drugs or protocols and mandatory training on clinical skills. The 2003 Commission for Health Improvement Clinical Governance Review states that “the trust has extended the annual skills day for paramedics and technicians to four days per year” and that staff were positive about being taken for training as teams.

This was changed, to taking staff off for training on an ad hoc basis rather than as a team, because it was considered more economical. It is unclear when this actually happened. The trust has provided information about the ASD days from 2001 until 2006/2007 and they vary in duration from two to three days.

In the minutes of the weekly production team meeting, there was regular mention of the ASD day being cancelled because of operational demand. In 2005, a technician course, a paramedic course and a health care support worker course were all cancelled due to high operational demand. There is evidence of an increasing number of staff unable to access ASD training in each financial year. In 2006/2007, only 30 staff completed it.

There was also insufficient provision built into the training plan for enough ASD days for all staff to attend. In 2005/2006, just four weeks were allocated.

ASD training was not “protected training time” for staff. Staff either attended during working time or were paid at overtime rates to attend in

their own time. Staff who attended during working time were required to wear their uniform and go with their vehicle, as they were considered to be on call. Although this did not happen on a regular basis, there were occasions when both the instructor and staff were called out and the study day had to be cancelled. The previous chief executive told us that he never “sanctioned any reduction in training”.

The scheduling team was responsible for allocating staff to attend an ASD day, but it was not clear, from the staff we spoke to, who was responsible for ensuring that staff attended.

## Training to become a technician and paramedic

There were mixed messages from the IHCD regarding the adequacy of the training, provided by the trust, to become a technician. The course included topics that were not on the IHCD list. In 2003, a report from the external verifier states that “the technician course does not comply with the modules D, E, and F for the sessions included”. Later in the report, it states that “overall the centre appears to meet all the standards set by the IHCD”. The course was run over six weeks, whereas in other ambulance trusts it varied between seven and 12 weeks. The IHCD recommended that the trust “should give greater consideration to extending the course to allow for a greater learning experience”. It was agreed that the prior learning that technicians acquired on the Health Care Support Worker course, which took three weeks to complete, would be incorporated into the accreditation for the technician course.

There were no validation visits from the IHCD between November 2003 and March 2005. In March 2005, the external verifier’s report confirms that the issues with the length of the technician course had been resolved.

In terms of other training, there is an expectation and a requirement that all professional staff will keep up to date with changes in clinical practice. NHS organisations are expected to support their staff in achieving this. Staff reported that they did not receive support, either financial or in time, to undertake

additional training provided by external organisations.

## Training provided for community paramedic officers (CPOs)

The Commission for Health Improvement Clinical Governance Review published in 2003 highlighted that, although training had been provided to support the role of the CPO, it did not cover all aspects of their role. The report recommended that a structured training programme be developed in liaison with local NHS organisations. This was discussed at the risk and clinical governance committee in May 2005. The previous medical director said there was no funding to provide the extended training recommended in the review. Although they received some training, the CPOs raised concerns about its adequacy.

In 2004, when the trust took on the GP out-of-hours service, the CPOs undertook the majority of home visits required as part of this service. This reinforced the need for additional training for them.

The training provided for CPOs to undertake aspects of the out-of-hours service focused on the additional medicines and drugs they would be expected to administer. They did not receive training on how to manage patients in primary care generally. The trust did not have a list of competencies, other than for the administration of some drugs, that CPOs were expected to be assessed on before they could attend calls for the GP out-of-hours service. An annual skills development course for CPOs was only run twice. The latest training records provided by the trust show that 48 CPOs had not attended training on the medicines and drugs used for the GP out-of-hours service. However, an appraisal of this service found that the training provided for CPOs was appropriate for their role.

The GP with lead responsibility for the GP out-of-hours service acknowledged that the CPOs were not adequately trained to attend calls for that service, and described the training as “sparse”. More recently, the trust has provided additional training for CPOs and is currently working on an analysis of their training needs.

The previous medical director told us that it was never intended that CPOs should deal with all the calls for the GP out-of-hours service and they were not expected to replace GPs. They were the “information collecting arm of the duty doctor”. They were not expected to manage complex cases and part of their role was to assess which patients could be left at home and seen by their GP the next day, and which patients had to be admitted to hospital.

## Non-clinical training

Between April 2004 and December 2006, the trust did not provide training in management skills “due to financial pressures”. We were told that there had been no “structured management development programme since 1994”. Staff were expected to undertake this in their own time. The trust has confirmed that it did support some staff to undertake leadership training in 2002/2003.

Some of the managers commented that they had not been given appropriate training or support to undertake the managerial aspects of their role. This issue was raised at the training joint working group twice in 2005. However, the response was that this type of training could not be offered as the trust had to focus on clinical training. There was not enough time or funding. Staff acknowledged that this type of training would be useful and some had undertaken it in their own time and paid for it.

The previous chief executive told us that the trust “supported and sponsored eight undergraduates paramedics at Warwickshire University”. However, the trust has confirmed that it did not sponsor eight undergraduate paramedics at Warwick University. The trust provided practical placements for “foundation paramedic degree students from Coventry University, but did not provide academic support”.

Very few staff had received training on how to investigate incidents or complaints. Initially we were told that staff had received training, but the training focused on how to write a report rather than how to carry out an investigation.

## Training records

Concern about the robustness of the training records is documented earlier, in October 2005, by the previous medical director at the training joint working group. Yet, there seems to have been little improvement. The records provided by the scheduling department during our investigation are not fully accurate. There are a number of sections not completed and they do not correspond with the records of training provided by the training department. The trust had problems providing evidence about which CPOs had attended training.

## Findings of fact

- Accountability for training and education changed a number of times during the period covered by the investigation.
- There was little long-term planning for training and education and the trust did not have a fixed training budget.
- There was not sufficient capacity built into the model of delivery to provide protected training time for staff within their contracted hours.
- Staff were not always provided with adequate training to carry out their role.
- The training for the CPOs to respond to calls for the GP out-of-hours service was limited to the medications they would be administering.
- Training was not always delivered in a timely manner.
- Opportunities for staff to access management training were limited.
- The training records of staff are not fully accurate.
- There was a disparity between the increasing role of ambulance staff and the services provided by the trust, and the funding available to train staff.

# Clinical governance and the management of risk

## Clinical governance

### Sources of evidence

- Interviews with current and former staff
- Minutes of internal and external meetings, including meetings of the risk and clinical governance committee, the local ambulance paramedic steering committee, the research and development committee and the clinical steering committee
- Clinical governance action plans
- Previous reports and assessments on the governance arrangements of the trust
- Standard operating procedures provided by the trust
- The “lifeline” form and the incident form
- Serious untoward incident reports
- Clinical negligence scheme for trust reports

Clinical governance is the system by which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. All NHS trusts are responsible for ensuring that clinical governance principles, processes and systems are embedded within the trust’s board and across the organisation. These include, among other things:

- ensuring that the trust has in place systems to ensure safe, high-quality care and that clinicians conduct regular clinical audits
- developing an open culture, where incidents are reported and lessons are learned

- monitoring trends in key clinical quality and clinical outcome measures
- maintaining a focus on continuous, demonstrable improvement in the quality of the experiences of patients and in healthcare outcomes.

### Accountability and structure

The trust’s philosophy was that clinical governance was rooted in its model of delivery and that quality assurance was incorporated into how the trust operated on a daily basis. The trust believed that everyone had a role in clinical governance.

The previous chief executive had executive responsibility for clinical governance until he left the trust in March 2006. He was supported in this by the director of production. The Commission was told that the previous medical director was responsible for preparing the annual clinical governance report.

In March 2006, the acting chief executive took over responsibility until the chief operating officer was appointed in March 2007. In November 2007, the joint director of corporate services took over responsibility for integrated governance, health and safety, and the management of risk.

Different managers were given lead responsibility for the different components of clinical governance. For example, the assistant director of production was responsible for the management of non-clinical risk and the control and prevention of infection, and the patient liaison manager was responsible for complaints and the patient advisory and liaison service. However, these managers reported to different executive leads: taking the same example, the assistant director of production reported to the director of production while the

patient liaison manager reported directly to the chief executive.

The risk and clinical governance committee was responsible for overseeing clinical governance in the trust. It reported to the trust's board and met only four times a year. The members included the previous chief executive (who also chaired the meeting), the director of operations (production), the director of operations (distribution), two non-executive directors and the medical adviser.

Other staff on the committee were the previous clinical services manager, the patient liaison manager, the assistant director of production, a senior doctor for the GP out-of-hours service and a staff representative. Representatives from HR and training and education were not members, but there is evidence of their attendance at some of the meetings.

There were a number of other committees where clinical governance issues were discussed. Some of these existed only for a short period. For example, the research and development committee existed from May 2005 until December 2005 and was then incorporated into the clinical steering group, which existed between December 2005 and July 2006.

In November 2006, the risk and clinical governance committee was suspended. One non-executive director felt that the meetings were more to do with process than looking in detail at the issues. It was agreed that a new committee would be introduced, chaired by a non-executive. As a result, the integrated governance and performance committee was established in February 2007.

### **GP out-of-hours service**

The GP who had lead responsibility for the GP out-of-hours service was also responsible for the arrangements for clinical governance for this service. When she left the trust in May 2005, the previous chief executive and the previous medical director took over this responsibility.

The minutes of the risk and clinical governance committee, held in November 2004, state that an out-of-hours clinical governance sub-committee would be formed. However, this did not happen and in the minutes of the August 2005 meeting it is stated that the out-of-hours sub-committee would be incorporated into the proposed clinical steering committee.

The trust has provided a document, titled "Out of Hours – Procedures For The Improvement of Clinical Governance". It is not dated, but provides an overview of the arrangements for clinical governance for the out-of-hours service. These include a list of meetings where out-of-hours issues were to be discussed, including the daily operations meeting and the daily out-of-hours review at 8.30am each morning. Calls to the service during the previous 12 hours were discussed at the daily review.

The trust attended the out-of-hours medicines management committee, which was an external committee run in conjunction with a local PCT.

### **Local ambulance paramedic steering committee**

Representatives from the trust attended the local ambulance paramedic steering committee. Part of the remit of this committee was the validation of paramedic training, which is a requirement laid down by the Institute of Health Care Development.

This committee was chaired by a consultant anaesthetist from the University Hospital North Staffordshire NHS Trust. The trust suspended this committee in June 2005, citing as the reason the pending regionalisation of ambulance services. The minutes of the August 2005 risk and clinical governance committee state that, with the introduction of the daily clinical meetings, the local ambulance paramedic steering committee was retrospectively approving decisions already taken by the trust.

The trust subsequently decided to merge the local ambulance paramedic steering committee with the research and development committee to form the clinical steering committee.

## Findings of fact

- Responsibility for clinical governance was shared among the executive team and managers.
- There was a range of central and local committees where clinical governance was discussed.
- Some of the committees were short-lived and attendance was limited.
- The clinical governance arrangements for the GP out-of-hours service were fragmented.

## The management of clinical incidents and risks

The trust's annual report for 2005/2006 stated that risk management was embedded in the core principles of the trust and described it as the "matching of supply to demand". It went on to say that the principal risk for the trust was "any imbalance between supply and demand", and that the structures for the management of risk were "well embedded" throughout the trust.

The risk management policy, introduced in 2000, was regularly reviewed. The previous chief executive had responsibility for the policy and the director of production was responsible for issuing and amending the policy.

We were told that responsibility for the management of risk was shared between the assistant director of production, who was responsible for the management of non-clinical risk and the prevention and control of infection, and the risk manager, who was responsible for the management of clinical risk and health and safety. If the risk manager was informed of a clinical incident, he referred it to the previous medical director or the previous clinical services manager. He

also worked closely with the assistant director of production.

In addition, he was responsible for the trust's risk register. Reporting on the risk register and clinical and non-clinical risk was a standing item at the risk and clinical governance committee. Each directorate was responsible for identifying risks, which they then referred to the risk manager. He assessed what was already in place and what other measures were needed to reduce the risk.

## Training in the management of risk

Training in the reporting of incidents and the management of risk was provided by the risk manager. It was included on the annual skills development (ASD) study day that all staff had to attend and was given a one-hour slot. Information about the training has been provided for the year 2005/2006. The syllabus covers a number of areas including the management of accidents, reporting of injuries and reporting of adverse incidents. It is not clear if all of these areas were covered during the ASD day, given that only an hour was allocated to the subject. Training on root cause analysis methods for investigating incidents was limited. Only the patient liaison manager had received this training.

## Clinical incidents

Staff are required to report incidents where something has gone wrong, or could have gone wrong, with the care of patients. The analysis of such incidents should lead to lessons being learned and the risk to patients reduced. Serious incidents have to be reported to the strategic health authority and incidents affecting the safety of patients must also be reported to the National Patient Safety Agency.

The trust has provided copies of its incident report form and its "lifeline" form. The incident report form is dated October 2002 and is labelled draft. It states that it is designed to replace all other types of form for reporting incidents, that it is to be used for staff accidents, near miss incidents, violence,



abuse and clinical incidents, and that it should be submitted to the line manager.

The lifeline form was used by staff to report incidents anonymously (although staff could include their details if they wanted to). It was sent to the medical director or left in designated boxes in the three bases. It had a section for the description of the incident and a list of contributing factors such as lack of protocol, equipment fault or wrong drugs or equipment.

Details of incidents submitted using the lifeline form were reported on a quarterly basis to the risk and clinical governance committee. Serious untoward incidents were reported to the trust board. When asked, some staff were confused over which form to use when reporting an incident. The lifeline form seemed to be used most often. It is unclear whether any staff reported incidents using the incident report form. When asked, some said that they preferred to report incidents anonymously. There was a feeling that they would be “blamed for the incident” or they were “grassing up” their colleague. One of the directors said that staff felt more comfortable reporting incidents anonymously.

The trust’s clinical governance report for 2004/2005 stated that a large number of changes had been made as a result of lifeline forms, including changes to clinical protocols, training and equipment.

Between April 2004 and December 2006, the number of incidents reported monthly using the lifeline form varied from zero to 24. Many of them related to health and safety issues such as injury from lifting a patient or the collapse of a stretcher. There is evidence of the trust making improvements to equipment as a result of concerns raised in this way.

Many staff told us that they did not think the lifeline forms were a useful route for communicating concerns. There was little or no feedback once a form had been submitted.

## Investigating incidents

We were given conflicting information about which member of staff was responsible for

investigating incidents. We were told that the severity of the incident determined who would carry out the investigation. Area managers were responsible for investigating less serious incidents and the risk manager and the assistant director of production would investigate the more serious ones.

We were also told that the risk manager was responsible for carrying out investigations into clinical incidents. The previous medical director told us that the patient liaison manager was responsible for coordinating investigations into clinical incidents. This included collecting information from all the people who had been involved in an incident and discussing it with the previous chief executive.

When we asked why the risk manager did not carry out this role, we were told that the risk manager was busy preparing the trust for the clinical negligence scheme for trusts’ assessment and managing the risk register. The patient liaison manager was described as the “lynch pin” for investigations into clinical incidents and that the assistant director of production investigated incidents that were not of a clinical nature. Neither the area managers nor the assistant director of production had received training in how to investigate incidents.

## Serious untoward incidents

Serious untoward incidents were reported to the risk and clinical governance committee, the trust board and to the strategic health authority. Between April 2004 and December 2006, there were 33 serious untoward incidents reported, relating to delays in transferring patients, stolen drugs and keys for the drug store going missing.

There is some evidence of learning from these incidents. For example, the trust carried out reviews following two incidents: one a delay in transferring a child from a ward to an intensive care unit and the other a delay in responding to a child suffering from an asthma attack. In the first incident, the trust carried out a review independently of the acute trust. The acute trust told us that they

would have welcomed the opportunity to have jointly reviewed the incident but they were not given the opportunity. The previous chief executive told us that the acute trust showed “little interest in reviewing the matter themselves or jointly with ourselves”. In the second, the review was carried out by external experts and overseen by the strategic health authority. The trust accepted the report and implemented the recommendations.

A more recent serious untoward incident, in October 2006, involved the failure to transport a person complaining of chest pain to hospital. The ambulance staff who initially responded to the call carried out an assessment and gave the person some advice. The person died very shortly (within minutes) after the ambulance staff had left. The person had had a heart attack. An incident form was not initially completed but the matter was reported to the acting medical adviser and a statement was taken from the attending crew “in the event of a problem”. The family of the person who died contacted the trust to complain and this triggered an investigation into the incident.

The trust responded to the complaint and, in November 2006, a senior manager initiated an investigation. In the investigation report, it is documented “that no further action needed to be taken”. The trust wrote to the family and included a report “addressing their concerns” and a list of actions they intended to take. The report acknowledged that the person should have been transported to hospital and that the assessment carried out by the ambulance staff was not of an acceptable standard.

The family were unhappy with the response from the trust and the trust subsequently sought an external review of the incident. The external review found a number of failings in the care provided to the person and in the trust’s system for investigating clinical incidents and complaints. It described the system as “very disjointed, with no evidence of a managed process” and recommended that the trust developed a “training programme that prepares first line managers to conduct investigations”.

In February 2007, it was alleged that the previous medical director, while working as a duty doctor at the trust, was asked by an ambulance crew to advise on the treatment of a patient with symptomatic tachycardia. This is rapid heart rate causing symptoms or side effects. The treatment advised was outside the scope of practice for paramedics. Initially the trust was not aware that this was an incident and it was not until the joint director of clinical performance became aware, later the same day, of what had happened, that an investigation was commenced. The trust has asked an external expert to review this incident and is in the process of setting up a capability hearing. A report on the incident is still under discussion and as yet the outcome has not been finalised.

We were told that at the same time that this was recognised as an incident, the paramedics were told that they would receive commendations for their actions.

What is concerning about both of these examples is that the trust did not initially recognise them as incidents. There were also a number of flaws in the initial investigation and management of the incidents.

## Clinical negligence scheme for trusts

In 2005, the trust was unsuccessful in achieving level 1 in the clinical negligence scheme for trusts (CNST) assessment. The assessment found that the trust was weak in a number of areas, including the reporting of

### The clinical negligence scheme for trusts

This scheme is managed by the NHS Litigation Authority. It handles negligence claims made against NHS bodies in England. The cost of meeting claims is met through contributions from trusts. Trusts in the scheme are regularly assessed against a series of standards for the management of risk. These standards include three levels, with level 1 being the lowest. As a trust successfully meets each level, its contributions are reduced.

incidents and training for staff in the management of risk. This was reported at the trust board meeting in April 2005.

The previous chief executive described the assessment method as “tick a box if evidence is produced” and that “no allowance is made for individual ambulance trusts and their different ways of working”. The trust viewed the assessment process as “intensively bureaucratic”. The options were to decline any reassessment, or invite a reassessment against revised criteria that included the trust’s performance against the national response times. At the trust’s board meeting in June 2005, the chairman stated that “the failure to achieve level 1 did not reflect well on the trust” and asked for a meeting to be held and for a further report at the next board meeting.

The risk and clinical governance meeting in August 2005 discussed the assessment. The previous chief executive eventually acknowledged that in some areas the assessment was justified, such as the reporting of incidents, training in risk management and induction of staff. The trust was eventually reassessed and achieved level 1 in February 2006.

## The ‘make ready’

This is a system where at the start of each shift every ambulance crew is supplied with a vehicle that has been cleaned and restocked with medicines and equipment by ambulance fleet assistants. This means that ambulance staff are ready to respond to calls as soon as they arrive on duty. It also removes the need for staff to familiarise themselves with where everything is stored each time they use a vehicle and reduces the risk that equipment or medicines may be out of date or not replaced. However, the trust was including controlled drugs with the medicines carried by ambulances, which was not acceptable for ambulances crewed only by technicians.

## Findings of fact

- Responsibility for the management of risk was shared and it is unclear who was

responsible for investigating clinical incidents.

- Clinical risk and non-clinical risk were not integrated.
- There was some training for staff on the management of risk, but little training on how to investigate an incident.
- There was more than one system for reporting incidents.
- Staff preferred to use anonymised incident forms to report incidents.
- Not all incidents were investigated or even recognised.
- There is evidence that investigations carried out following incidents were not always robust.

## The management of clinical audit and clinical effectiveness

Clinical effectiveness can be defined as “the extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are intended to do – that is, maintain and improve health and secure the greatest possible health gain from available resources” (NHS Executive, 1996). It is a key component of clinical governance.

Clinical audit improves the care of patients through regular systematic review of practice against standards, guidelines and policies. Where indicated, changes are implemented at an individual team or service level and further monitoring is used to ensure that the change has resulted in improvement in the care provided.

As part of their arrangements for clinical governance, all trusts should have a clinical audit programme.

The previous clinical services manager had lead responsibility for clinical effectiveness and clinical audit until he left the trust in the middle of 2006. He was supported in his role by a community paramedic officer, who was responsible for collating data.

During the course of our investigation, we asked to interview the current manager for clinical audit. However, the person nominated by the trust was not the manager for clinical audit, rather he was a paramedic seconded to do clinical audit. He had not received any training for the role, although he had spent two weeks working with the previous paramedic who had been seconded to the role. He received support from the clinical governance manager.

The trust did not have a clinical audit programme or a clinical effectiveness plan, although there is some high level reference to clinical audit in the trust's strategic and business plans. For example, in the strategic plan for 2004 to 2007 it states: "To improve clinical audit to measure the performance of the trust in the provision of pre-hospital care to patients."

The focus of clinical audit was on the key outcome measure of the return of spontaneous circulation (ROSC) and also on the number of patients who received pre-hospital thrombolysis. This is the breaking down of a blood clot in an artery or vein using medical treatment, used for patients who have had a heart attack. The joint director of clinical performance commented that the trust collected "a lot of data" and that it "focused on two conditions (ROSC and thrombolysis)".

Information about these audits was submitted to the board on a regular basis. The trust has very high success rates in these areas, and carried out more pre-hospital thrombolysis than any other ambulance trust in England.

The equipment used by the trust when responding to a cardiac arrest recorded the actions taken by staff. These showed when the cardiac arrest occurred and when ROSC was achieved. The trust separately recorded how often they achieved ROSC before transferring a patient to hospital and how often there was ROSC on arrival at hospital.

There was concern from some staff working in local accident and emergency departments about patients who had been recorded as having a pulse on arrival but who did not have a pulse once the automated gas-driven chest

compression device was removed. One consultant told us that "there could be cases where they have measured a pulse in the patient five miles from the hospital and then when the patient arrives in hospital... the pulse has gone".

When asked about the trust's figures for ROSC, the previous clinical services manager was confident about the accuracy of the number recorded. He was confident that no one would report a ROSC achieved solely by the use of the automated compression device. If anything, he said, the trust tended to err on the side of caution and did not include some of the cases.

The definition that the trust used for ROSC has been questioned. In the 2004/2005 clinical report, the trust states that "unlike the Utstein template" the trust includes patients "who have been deemed as not for resuscitation". (Cardio pulmonary resuscitation is not to be initiated if breathing stops or the heart stops beating.) These patients would not normally

#### Utstein templates

These are templates and guidance for each of the various categories of patients upon which a trust may wish to report cardiac arrest data. They can be sub-divided into:

- the Utstein Template for Out of Hospital Cardiac Arrest
- the Utstein Template for In Hospital Cardiac Arrest
- the Utstein Template for Paediatric Cardiac Arrest.

be included in a report on cardiac arrests and would therefore inflate the numbers of cardiac arrest seen.

A review of the 2004/2005 clinical report found a number of flaws in the information presented about the number of patients who had a cardiac arrest and the number of patients who had a ROSC at hospital. The report had included patients who were terminally ill and expected to die, or where a community

paramedic officer had attended to confirm death. This resulted in an artificial inflation of the number of patients reported to have had a cardiac arrest. It did not, however, alter the number of reported ROSCs on arrival at hospital.

There were also a number of data errors in the executive summary. For example, the percentage of patients who had a ROSC on arrival at hospital was 24% as stated in the report. However, this represented 223 patients, not 509 as stated in the report. The review also commented on the absence of an “unequivocal uniform definition of ROSC across the trust”.

In addition, the review commented on the number of patients who received thrombolysis. Eighteen people received this treatment while they were in cardiac arrest “presumably under direction from a doctor” and the review stated that this information should have been reported separately, since inclusion of them in the overall figures for patients who received thrombolysis artificially inflated the figures and prevented meaningful comparison with other ambulance trusts.

The trust has carried out very little audit for other medical conditions.

## GP out-of-hours service

In the document titled “Out of Hours – Procedures For The Improvement of Clinical Governance”, it states that there is “too little audit at present for out of hours” and that the “lack of robust evidence-based outcome points for audit remains a problem”. The summary concludes that audit remains a key area to be addressed.

The trust audited its compliance with national standards for taking calls, and carried out surveys to assess the satisfaction of patient who had used the service.

## Findings of fact

- The trust did not have a programme for undertaking clinical audit although some audit was carried out.

- Responsibilities for clinical audit were not always clear.
- Resources for clinical audit were limited.
- The range of clinical audit carried out by the trust was limited.
- It is unclear if the trust was always using the nationally agreed definition of ROSC.

## The management of complaints

The patient liaison manager was responsible for managing complaints from patients and the public. She reported to the chief executive and also managed the patient advisory and liaison service (PALS). The Department of Health guidance on the management of complaints and PALS recommends that these functions should be managed separately.

Quarterly reports on complaints were submitted to the trust’s board and were a standing item on the risk and clinical governance committee. The trust received 72 complaints for 2005/2006 and 89 informal concerns were raised through PALS. The majority of complaints were about response times for the accident and emergency service and the attitude of staff. For the GP out-of-hours service, the complaints were mainly about the provision of GPs. Action taken by the trust included retraining of staff, counselling of staff and reviewing protocols.

In 2005, the trust received a number of complaints from GPs about the GP out-of-hours service. A previous review of the service found that the trust refused to investigate complaints from patients when raised via their GP. The trust would only respond to complaints that came directly from patients. The previous chief executive told us that the GPs did not provide enough information for the trust to investigate the complaint further and that they did investigate complaints made by patients.

## Engagement with the local community

The trust has a high profile in the local community and was very good at keeping the

public informed about its work and future plans. In 2005/2006, the trust held 221 public relation events and there were over “4,000 media exposures of the trust’s activities”. Meetings of the trust’s board were held at various locations around the county and the majority of the discussions took place during the public part of the meeting. The trust encouraged visits from local councillors and representatives from parish councils.

During the course of the investigation, we spoke to a number of patients and relatives who had experience of using the ambulance service. Patients and relatives also wrote to us. The majority of people had positive things to say about their experience and about the staff and the trust generally.

There were a few people who had had concerns. These related to the attitude of staff and the care they had received. Only three comments were specifically about community first responders and these were generally positive. One concern was about the use of blue lights and sirens disturbing the residents in a village.

## Findings of fact

- The trust had a combined complaints and PALS function contrary to guidance from the Department of Health.
- The complaints manager reported directly to the chief executive.
- Complaints were reported to the board.
- The trust did not always respond appropriately to complaints received from GPs.
- Patients were generally positive about their overall experience of the trust.

## The management of policies and protocols

The trust relied heavily on the intranet to communicate with staff and over the years produced a large number of standard operating procedures (SOPs) and clinical guidelines. The risk manager was also

responsible for transferring SOPs and guidelines onto the intranet. When new guidelines or SOPs were added, the old ones were not taken off. The previous chief executive has commented that the trust internet or intranet “was not the source for current protocols” and that if there was any confusion about protocols, staff could contact one of the trust’s doctors. He also said that the training department was responsible for the production of clinical protocols and amendments. Its failure to do this was “another reason that training was put under the direct management of the medical director in 2005”.

The Commission was told that, in 2007, there were 4,500 information sheets for staff on the intranet, including seven different guidelines for how to carry out thrombolysis. As new information and guidelines were being produced, no one had ever deleted the old ones. We were also told that new SOPs were sometimes implemented before all staff had received training on them. The previous medical director told us that “no member of staff was expected to adhere to a new SOP until they had been trained in it. Until then, their standard of care would be assessed against the previous SOP”. In 2007, we found a number of versions of guidelines related to the same drug. The trust is now addressing this.

## Findings of fact

The trust did not have an effective process for ensuring that up-to-date policies and procedures were communicated to staff.

# Leadership and management

## Sources of evidence

- Interviews with current and former staff of the trust and the strategic health authority.
- Interviews with stakeholders
- Minutes of meetings of internal trust committees, the board and the executive management committee
- Previous reports such as the Commission for Health Improvement's *Clinical Governance report 2003*
- Annual health check results
- Report on practices in the emergency operating centre
- Press releases
- The trust's website

## Style of leadership and culture of the trust

To understand how the problems with the trust's management of medicines and its working relationship with other NHS organisations began, it was necessary to consider the style of leadership and the culture of the organisation.

The Commission for Health Improvement's clinical governance review in May 2003 described the leadership as "strong" and the management style as "robust and vigorous".

In our investigation, we found there was a shared belief among staff at all levels of the trust that the "patient" and "saving lives" were the priorities for the trust. We were told that saving and protecting lives was the philosophy that underpinned everything the trust did.

The previous chief executive was in post from 1992 to March 2006. Senior staff within the

trust described him as a "charismatic leader", a "very dominant force", "a benevolent dictator", and "having all of the problems associated" with this style of leadership. They said that he set high standards and that staff strived to meet them. He was very direct and exerted a lot of influence over managers and executives. We were told that staff referred to him as "the dad" of the family. A few staff told us that if he had a disagreement with you one day, it would be forgotten the next. One manager described the culture of the trust as "difficult" and that it was very "military in style".

We heard examples of the previous chief executive showing compassion but equally, examples of subtle bullying. For instance, although it was not explicit there was an expectation that if there was a sudden increase in activity, staff who were off duty would return to work. We were told there "were lots of demands placed on managers", and it could be "draining".

However, many staff spoke with admiration, and on occasion affection, about the previous chief executive and his focus on providing the best service possible for the patient. Many were proud of what the trust had achieved and attributed much of it to his drive and vision. A few senior staff felt that when he left the trust, it lost its "clinical focus" and that the patient was no longer at the heart of everything they did.

There is no doubt that a lot was expected of staff, but the previous chief executive also acknowledged their contribution. Commendations were distributed on a regular basis to staff, sometimes at a public ceremony.

The relationship between the previous chairman and previous chief executive was described as very good and close. The

previous chairman, although not 'hands on', knew a lot about how the trust operated. The new chairman was not familiar with the ambulance service, but did have a good understanding of how the public sector worked. The relationship between the previous medical director and previous chief executive was also described as very close.

All of the non-executive directors were impressed with the trust and described the staff as hard working and dedicated. Each non-executive was partnered with an executive director to gain an understanding of that particular aspect of the service. The non-executives occasionally met as a group before board meetings and they would keep in touch by phone and email. There was a view from some members of the board that it was not really operating as a board should, that "it was perhaps a little too cosy". This was attributed to the fact that the trust was performing so well. It was described as the best performing ambulance trust in the country and had a great deal of support from the local community.

The appointment of the new chairman in April 2005, and a new non-executive director in December 2004, changed how the board worked. Some of the managers felt that the non-executives began to look more closely at information.

The previous chief executive believed it was important that the non-executives had an understanding of how the service was delivered and they were encouraged to go out on calls with the ambulance staff. However, he was clear about the boundaries of their role and had no hesitation in making his view clear if he felt they were becoming too involved in day-to-day operations.

During the consultation about the proposed merger between the four ambulance services that then existed within the West Midlands, the trust was described as being very aggressive in opposing the merger. The previous chief executive put out strong statements about the number of lives that would be lost if the merger went ahead. He was publicly critical of other ambulance trusts, going as far as to

name trusts that he thought were not performing as well. The chairman asked him to refrain from this. Eventually, he toned his speeches down.

There were similar issues about the previous medical director. His behaviour at a public meeting was described as "quite surprising".

The behaviour of both of them may have caused unnecessary and unfounded alarm among the public. When asked about this, the previous medical director said that he behaved professionally but felt he had a duty to speak out because he was concerned that "lives were going to be lost". By making his concerns known, he said he was complying with General Medical Council guidance that a doctor's duty is to "make the care of (your) patient your first concern".

The previous chief executive described his style as identifying where the problems were, and being there to manage them. This might be in the trust or in another trust or responding to calls. It was not about managing from a distance. He told us that a leader needs to be where he can be most effective, be seen by his staff..."and that he never needed to appear when the director of production or the medical director had took control of a problem" but that he did "with other executive or senior managers". He took his responsibility as chief executive very seriously and believed that he was accountable for everything. He said he would not describe it as a "command and control style".

His view was that the ambulance service is not a 9 to 5 service and it was inappropriate to try to manage it as though it were. This was reflected in both the structure and management culture of the trust and fits in with the philosophy of their model of operation. In the model, all managers are seen as "operational and everything else, board meetings, data entry, interviews etc come a distant second to managing the service to the advantage of the patient".

It was not only the previous chief executive who was directly involved in the day-to-day management of the service. The other



executives and senior managers would respond to calls as demand increased. Staff were expected to leave meetings (including external meetings) and the emergency operating centre to go out on calls. We were told of one meeting where three members of the trust left to respond to calls.

The trust was keen to embrace new technology and practices that would improve patient care. But there was a sense that “things” moved too fast and the trust made changes “very quickly and staff didn’t always understand the rationale behind the changes”. One senior manager said the trust was like a “train” that needed to stop at the “station to fill up and consolidate rather than push on relentlessly”.

The previous medical director said that “things moved quite quickly and they always used to laugh that, if you went on holiday for a week, when you came back something would have changed”.

There was a perception from external stakeholders that the trust was insular. The view of one member of staff, when asked if the trust benchmarked themselves against other trusts, was that there was no point “as they are not as good as us”. However, the previous medical director told us that the trust did benchmark itself against other trusts including “Wiltshire, Wales, Lincolnshire and South Yorkshire”. A view put forward by an external stakeholder was that the trust had “a lack of humility” and that “everything they do, they think is right”. This was reinforced in a paper submitted to the risk and clinical governance committee in October 2005, which stated that “clinical governance within the service is very strong and our high clinical standards are the envy of every other UK ambulance service”.

A review of the GP out-of-hours service carried out in 2007 described the trust as taking an “independent view of NHS requirements (including regulations)” and that they “adopt them to the extent that they consider warranted by their local circumstances”. Although this was an “interesting approach, it is not tenable within an NHS service”.

Although the operational manual stated that continuous quality improvement was achieved through “empowerment and development of staff at every level in the identification of solutions to problem areas”, it was difficult to see how this was translated into practice. Some managers felt that previously they were not given permission to make decisions and it was only recently that they have been allowed to “manage”.

## Management arrangements

Over the 10 years prior to mid-2000, the trust had had a relatively stable management and executive team. Many of the senior managers and directors had been in post or worked in the trust for a number of years.

The previous chief executive had a background in military service and when he took up his post, he applied the knowledge he had gained from his military experiences. He told us that he placed great importance on the staff who delivered the service ensuring they had the necessary equipment to do the job. He also understood the importance of being able to match resources with demand. His experience of working with nurses and doctors in the military had made him recognise the importance of having a doctor in an ambulance service. The trust was one of the first ambulance services to appoint a doctor. Some of the other directors, senior managers and medical staff also had experience of working in military service.

The trust had always employed medically qualified staff. In recent years, the trust appointed a doctor to the post of director of distribution. In May 2005, the then medical adviser became the medical director and deputy chief executive. Although he attended the trust’s board meetings, he was not a member of the trust’s board. We were told, by the previous chief executive, that this was because it meant another executive director would have had to give up their board position. He had been employed in the trust since 1999, mainly in the role of medical adviser or medical director, although for a short period he was the field operations manager.

The previous medical director managed 13 staff: nine trust doctors, the security and risk manager who had lead responsibility for the management of risk, the emergency planning officer and the training officer. He was not on the General Medical Council register of specialist practitioners or on the register of GPs. He worked closely with the previous clinical services manager.

In July 2004, the trust recruited a GP to lead the GP out-of-hours service. However, in 2005 she left the trust. She told us that the way the role was structured meant that she was unable to fulfil all its requirements and the relationship with the medical director proved to be difficult. She returned to the trust in November 2006 as the lead doctor for the out-of-hours service, but due to serious illness was off sick from May 2007.

In October 2004, the director of distribution transferred to work as a GP for the out-of-hours service because of differences with the previous chief executive. He returned to the post of director of distribution in September 2006. In October 2004, the trust recruited a director of distribution, who transferred in October 2006 to West Midlands Ambulance Service NHS Trust before returning in March 2007 as the chief operating officer for the trust.

## Meeting and committee structure

The previous chief executive had introduced daily operations meetings which took place in the afternoon. They were attended by executive directors, senior managers from production and distribution, the medical director and the doctors who were covering the GP out-of-hours service. The purpose of the meeting was to review activity over the previous 24 hours, address any problems that had arisen and anticipate any problems for the day ahead.

There were also weekly executive meetings on Friday afternoons. These focused on activity and any associated issues. The previous chief executive attended both of these meetings. Production and distribution staff also had their own weekly meetings.

The executive management committee met monthly and focused on business planning for the trust. Any information that was going to the trust board was first discussed at this meeting. We were told there was considerable debate and discussion among the executives at this meeting.

There was a daily meeting between the doctors about the out-of-hours service. Again, this was an opportunity to review calls from the previous evening, discuss the treatment provided and make any changes, for example to clinical guidelines, that might be necessary. It covered cardiac arrests, any deaths and any calls related to children.

The audit committee, chaired by a non-executive director, met monthly and the risk and clinical governance committee met quarterly.

There is evidence that all of these meetings were well attended by staff.

The trust's board meetings were held in various local community venues. The majority of them were held in public. Private sessions were held if, for example, there was an item that referred to an individual member of staff. The trust's philosophy was that it wanted as much information as possible to be available to the public. The trust's website contained all minutes of the board meetings, associated papers and its response times to calls.

The minutes of the risk and clinical governance meetings were a standing item on the board agenda and clinical issues such as the introduction of the GP out-of-hours service were regularly discussed.

The previous chief executive believed that the non-executives should have access to same information as the executives. The information they received for board meetings included a great deal of data. The non-executives were expected to read and analyse this. The board papers were described as "thick and full". Some of the non-executives asked for the format of the information to be changed, as they found there was too much detail and it took a lot of time to read and interpret.

Initially, the executive directors were reluctant to do this, as it would mean producing two lots of information, one for the executives and one for the non-executives. This would take time and resources. However, in late 2006, the format was changed and the information was presented in a way that was easier to understand.

The non-executive directors felt they had been given information about the automated chest compressor. They confirmed that they did ask questions and were reassured by the previous chief executive and previous medical director that it was safe to use. The management of medicines was more likely to be discussed at the risk and clinical governance committee.

## Arrangements at strategic level to assure safety and the quality of services

### Ambulance performance targets

Each year, all ambulance trusts are required to submit a KA34 to the Department of Health. The KA34 is the annual national ambulance statistical return for activity and performance. The submission is based on calls and responses to both of the categories, A and B. There is guidance for how the report is to be completed.

In 2007, concerns about delays in ambulances attending calls where CFRs had first attended were brought to the attention of the chief operating officer and the chief executive of West Midlands Ambulance Service NHS Trust. They commissioned a review of practices within the emergency operating centre for recording calls and dispatching ambulances, and to identify whether this had any impact on how the trust reported performance against the ambulance performance targets. The review found a number of areas where the trust was not compliant with the KA34 guidance.

The trust did not use the national classification of A, B and C. Instead, they used priority 1 (P1) defined as 'life threatening emergency', priority 2 (P2) defined as

'emergency', and priority 3 (P3) defined as 'urgent'. The trust did not have an equivalent for category C, and these calls were coded as P2 calls. P1 and P2 calls were treated the same, requiring an eight-minute response. The use of P1, P2 and P3 meant that it was difficult for the trust to assign the calls to the Department of Health advanced medical priority dispatch system (AMPDS) code. The department's set list identifies which AMPDS codes fit within each of the A, B and C classifications. Trusts are expected to use these lists.

A number of calls that the trust categorised as P1 actually corresponded with the category B classification. Treating both P1 and P2 calls as requiring an eight-minute response may have resulted in resources being diverted from life threatening incidents.

Between 1 April 2006 and 28 February 2007, 27% of 999 calls had not been coded in line with national guidance using AMPDS. For some calls, the trust started coding using AMPDS but then aborted this before the response was completed. These calls were recoded manually and retrospectively by staff working in the emergency operating centre. Once a call has been received and coding has started, it should not be stopped until the response has been completed.

One concern raised was about the length of time CFRs waited for back up from an ambulance or community paramedic officer. When a CFR is asked to respond to a call, an ambulance crew should also be asked to attend at the same time. The review found that on occasions there had been delays between when the CFR was asked to respond and when the ambulance was sent. It also found evidence that CFRs, once they had arrived at a call and carried out an assessment, were contacting the control room and standing down the ambulance. Between 1 April 2006 and 28 February 2007, CFRs attended 3,939 calls. Of these, 237 were not backed up by an ambulance.

In October 2006, the trust issued a standard operating procedure to ensure that the

manual reprioritisation of calls stopped. Yet there was evidence that this was still happening. Priority coding for some calls had been changed manually after the event. Calls that had started as 999 calls had subsequently been downgraded at various stages.

The review considered that the trust's approach to prioritising calls was more likely to be a case of custom and practice, rather than a deliberate attempt to manipulate the data. Staff had "inconsistently applied the rules on a regular basis".

Despite all of this, the review found that the response times by the trust were very good and in fact may have been better if they had adhered to the KA34 guidance.

The review identified areas in the operational arrangements and practices that needed to improve to ensure that the trust complied with the KA34 guidance. While it concluded that the trust would find it difficult to create a 2006/2007 KA34 report for quarters 2 to 4 that would comply with the national guidance, the KA34 was subsequently accepted by the Information Centre. The review contained 12 actions, which we have been told the trust has now implemented.

When asked about the review, staff acknowledged that the trust made a decision not to have category C calls and that there were delays in sending ambulances when CFRs had responded to a call. One view put forward was that the trust had not taken the guidance for completing the KA34 seriously.

## Compliance with core standards

The Healthcare Commission's annual health check assesses NHS organisations on many aspects of their performance. The assessments are based on a range of data gathered throughout the year, including information about whether they are meeting the targets and standards set by the Government. Trusts have to complete a declaration stating whether or not they are compliant with the core standards.

For 2005/2006, the trust declared that it was compliant with all but one of the 24 core standards. For core standard C9 relating to the management of records, the trust declared that it had insufficient assurance about whether or not it was compliant. The declaration was signed by the executive and non-executive directors of the trust.

In the declaration for 2006/2007, the trust declared that it had insufficient assurance for five of the core standards. They were:

- C2 – following national child protection guidelines
- C4a – systems to reduce the risk of healthcare-acquired infection
- C4d – systems to ensure that medicines are handled safely and securely
- C5b – ensuring that clinical care and treatment is carried out under supervision and leadership
- C5d – healthcare organisations must ensure that clinicians participate in audits and review of clinical practice.

When we asked about what had changed in the trust to make it change its declaration on compliance with these standards, a director told us that the trust had taken a different approach to completing the declaration for that year. She told us that there was not enough evidence to support the declaration made in 2005/2006, but the trust had since implemented stronger mechanisms by which to assure itself of compliance. More time was spent discussing the declaration for 2006/2007 and the trust had taken more time to "dot the 'i's and cross the 't's".

## The strategic health authority

In 2002, strategic health authorities (SHAs) were created to manage the local NHS on behalf of the Secretary of State. Each SHA is responsible for developing a strategic framework for its local health and social care community and managing the performance of NHS healthcare providers (other than foundation trusts) within its geographic boundaries.

The trust was part of the Shropshire and Staffordshire SHA until July 2006 when the SHAs were reconfigured, and it became part of the West Midlands SHA.

## Monitoring of the trust's performance

The Commission was told that the previous SHA's performance monitoring for the trust focused heavily on finance and performance targets (in other words response times) for ambulances.

The trust was performing very well against the performance targets. In fact, it was exceeding them. From the perspective of the previous SHA, the trust was achieving what it was supposed to achieve. This, coupled with the view of the previous chief executive as a strong leader, meant that the trust was not challenged by Shropshire and Staffordshire SHA.

In terms of clinical governance, the trust submitted a clinical governance plan to the SHA each year as required. The previous SHA was responsible for chairing a patient safety and quality group, which reviewed trends in serious untoward incident submitted by trusts. All trusts were expected to report into this group and the trust was efficient at reporting serious untoward incidents to the SHA.

The previous SHA also had a clinical governance network and ran events to bring together all organisations. We were told that the trust's attendance was patchy, but it was their prerogative whether or not to attend.

The one area that did cause the previous SHA some concern was the GP out-of-hours service. Following an incident in 2005, the previous SHA commissioned a review of the service and monitored progress against the actions arising from the review.

There were two incidents related to transfers between hospitals. The view of the previous SHA was that responsibility was shared between the trust and the acute trust. It was how the trust responded to these incidents that made the previous SHA aware that the trust was not working in a cooperative manner

with other organisations. The previous SHA was concerned about this, as similar concerns had been highlighted in the Commission for Health Improvement clinical governance review. It seemed that the trust had not taken this issue seriously. Because of the incidents, the previous SHA instigated mid-year performance reviews of the trust, which was unusual for a three star trust.

The previous SHA acknowledged that the trust did investigate incidents. However, it questioned how self-critical the trust was.

It was felt that the trust did have good intentions in terms of patient care, but there was less certainty that the "checks and balances" were in place.

## Primary care trusts

Primary care trusts (PCTs) covering all parts of England receive budgets directly from the Department of Health. Since April 2002, PCTs have taken control of commissioning local healthcare, while strategic health authorities monitor performance and standards. In October 2006, PCTs were reorganised and merged.

North Staffordshire PCT was formed on 1 October 2006 following the merger of Newcastle-under-Lyme PCT and Staffordshire Moorlands PCT. Prior to this, Newcastle-under-Lyme PCT was the lead commissioner for emergency ambulance services for the north of Staffordshire.

South Staffordshire PCT was formed on 1 October 2006 following the merger of four PCTs: Burntwood, Lichfield & Tamworth PCT, Cannock Chase PCT, East Staffordshire PCT and South Western Staffordshire PCT. Prior to this, South Western Staffordshire PCT was the lead commissioner for emergency ambulance services for the south of the county.

The merger of North Stoke and South Stoke PCTs formed Stoke On Trent PCT in 2006.

South Western Staffordshire PCT hosted the service level agreement (SLA) for the ambulance contract. The recently formed South Staffordshire PCT now holds the SLA.

A director of a PCT told us that, historically, commissioning had been unsophisticated. The PCTs received the usual contract monitoring information regarding performance targets and, if there were any issues with the information, they felt they could pick up the phone and talk to the trust about it. They also received the routine information about the financial contract.

The PCT did not receive any other information about the quality of the emergency service provided by the trust. Although they said it was rare to get a complaint about the emergency service, they acknowledged that perhaps less attention was paid to the trust because “the figures all look ok”, so the contract was relatively easy to monitor.

## Findings of fact

- The trust had a relatively stable executive and management team from its establishment until 2005.
- The chief executive had a clear vision for the trust.
- The medical director was not a member of the trust’s board.
- The leadership of the trust did not empower staff to manage or make decisions.
- The leadership style was inconsistent.
- The information provided for non-executive directors was too detailed and was difficult to interpret.
- The trust did not comply with the Department of Health guidance for completion of the KA34 for the year 2005/2006.
- The trust had not always sent an ambulance at the same time as asking a CFR to respond to a call.
- The trust had manually altered the priority of some calls.
- The previous SHA and PCTs were reassured because the trust was performing well against the national targets for ambulance trusts.

# Joint working arrangements with local health community partners

## Sources of evidence

- Interviews with current and former staff
- Interviews with current and former staff from PCTs
- Interviews with staff in local acute trusts
- Minutes of meetings including meetings of the trust's board and the risk and clinical governance committee
- Previous reports – the Commission for Health Improvement's Clinical Governance Review 2003,
- Independent reviews of the out-of-hours service
- Incident reports
- Correspondence between the trust and South Staffordshire Local Medical Committee

In considering the joint working arrangements with its local health community partners, we have focused on the interface with local accident and emergency departments and the GP out-of-hours service.

The Commission for Health Improvement's clinical governance report (2003) recommended that the trust should work more closely with other NHS organisations "to improve external perceptions of the trust [and] develop a shared understanding of each other's need...".

## Accident and emergency departments

The main interface between the trust and local accident and emergency (A&E) departments was during the handover of patients. As previously discussed, this was an ongoing problem for the ambulance trust, causing much anxiety for staff. The trust transported

patients to a number of A&E departments. During the investigation, we interviewed staff at University Hospital North Staffordshire NHS Trust, Queen's Hospital Burton NHS Trust, Mid Staffordshire General Hospitals NHS Trust and Good Hope Hospital (part of the Heart of England NHS Foundation Trust).

The trust had an escalation policy that promoted leaving patients in A&E if there were any delays in the handover. This policy had gone past its review date. It notes that "the trust is not funded to provide a patient minding service at hospitals or to wait longer than 15 minutes and that 999 calls always take priority over looking after patients in hospital".

A flowchart was attached for ambulance staff to follow if they were unable to hand over within 15 minutes. The policy advises staff to leave the patient on the stretcher and inform the staff in A&E that they are leaving. They could also leave patients with other ambulance staff who were also waiting to hand over and the trust would try to send support for the ambulance staff. The previous chief executive told us that when the trust was not busy and "could allow staff to stay at hospitals for over an hour, they would do so".

Many staff that we interviewed talked about the difficulties in handing over patients in A&E, mainly related to delays. Although the CHI clinical governance report highlighted the need to work with local acute trusts to resolve the problem, some staff felt it had either not been addressed at all or had been addressed but not very successfully.

Delays in handing over patients was an area of contention between the trust and some A&E departments. The problem was not unique to the trust. We were told about staff leaving patients in A&E before they had handed them over to a member of A&E staff. Some A&E

staff talked about how the trust, on some occasions, tried to work with them to manage the situation, while on other occasions the trust would threaten to put tents up in the car park to receive the patients. This would, however, be unworkable as there would be no more A&E staff available beyond those already on shift. The previous chief executive told us that when hospitals informed them that they could not accept any more patients, they would deploy their “resources to provide warm dry shelter if necessary outside such hospitals, until different hospitals could be found to receive the patients”. They found the situation would change and the relevant hospitals would be able to receive patients.

One acute trust had set up meetings with the trust to try to look at peaks in demand and see how both trusts could work together to manage them. They reached an agreement where, if there was more than one ambulance crew waiting to hand over in A&E, one of the crews would take responsibility for the patients, freeing up the others to respond to calls.

The same acute trust had also worked with the trust in conducting a pilot project looking at triaging patients who had minor injuries. Triage is the system of prioritising patients in an emergency when there is a great number of injured or ill. The project also involved local GPs. The aim was to consider the best way to manage patients who had a minor injury. The site for the project was the primary care centre attached to the acute trust.

Another acute trust had sought legal opinion about who was responsible for the patient once they arrived in A&E. They were advised that the acute hospital had some responsibility. The acute trust had tried to introduce an arrangement whereby the trust would send someone to care for the patients and free up the ambulance staff, but this was not always adhered to. The trust was described as “aggressive and verbally intimidating” and it was felt that personalities were inhibiting discussions taking place.

Delays in handing patients over were referred to in the trust’s annual report for 2005/2006. The average turn around time at A&E was

15.59 minutes. Although delays happened on 1,550 occasions, the report states that “this was a substantial reduction on 2004/2005”.

## Patient transport service

The patient transport service was also an area of contention for some of the acute trusts. Three of the four trusts that we spoke to thought that this service took in the ambulance trust’s priorities. There had been concern about delays in the transfer of very ill patients either between trusts or within a trust. One example was a patient who was acutely unwell and needed specialist care at another hospital. They asked the trust to transport the patient and had to wait over three hours before this was done.

There were also examples of delays in transferring patients who attended hospital on a regular basis. One acute trust told us that there were “daily battles” trying to get patients transported and it was difficult to get information about the level of activity for this service, although the trust kept saying that it was increasing. There was a view that the trust did not treat the acute trust as a customer, and told them that they had other “priorities”. The previous chief executive told us that there were major problems with the contract because the acute trust asked for more patients to be transported than was agreed in the contract.

In terms of complaints from patients about this service, sometimes the trust would respond to complaints that involved the acute trust but would not copy it into the response. To overcome this, a joint procedure was developed and we were told that the trust did adhere to it.

## Incidents and complaints

There was little evidence of the trust working jointly with other NHS organisations to respond to complaints and incidents. We were told of one occasion where the trust was reluctant to provide information about a transfer involving a patient who died. The



acute trust was unsure about the treatment the ambulance staff had provided and the family of the patient had some questions. It was documented in the minutes of the risk and clinical governance committee that the previous medical director refused to discuss the case with the consultant in the A&E department of the acute trust. The previous medical director refutes this allegation.

We were also told of an incident involving the previous chief executive who, because of his behaviour, was asked to leave A&E and was escorted out by a security officer. The trust completed an incident form and sent it to the strategic health authority, but there is no evidence that any action was taken. The previous chief executive told us that he went to the A&E to check up on a patient. He was not happy with the way the patient was being resuscitated and he “expressed his views calmly to the doctor in charge”. He left the A&E immediately he was asked to do so, and informed the chief executive of the trust and received a full apology.

Despite all of this, the acute trusts were generally positive about the paramedics, technicians and some of the managers. They felt they worked well with the paramedics and technicians and appreciated they were often faced with a difficult decision about whether or not to leave a patient. They were also positive about some of the managers and directors, whom they felt had latterly developed better working relationships with the acute trusts.

One suggestion put forward by a staff member in an acute trust was that the two national targets (the ambulance response times target and the A&E waiting time target) should be integrated. This would promote joint working between trusts and avoid unnecessary tension.

## GP out-of-hours service

In 2000, the Carson Review was published. This had been commissioned by the Department of Health following concerns nationally, raised by the Health Service Commissioner (the Ombudsman), about GP out-of-hours services.

The review included 22 recommendations, which were all accepted by the Department. It also identified some core quality standards to which all GP out-of-hours services should be delivered in the future. The Department asked that all providers of GP out-of-hours services achieve compliance with the standards by March 2004. The standards were reviewed in 2004 and then re-cast as the National Quality Requirements from 1 January 2005.

During 2002 and 2003, a new contract for GPs was negotiated which allowed them to opt out of responsibility for providing out-of-hours care from 1 April 2004. Where GPs opted out, responsibility passed to their PCT. By 1 January 2005, 90% of GP practices nationally had transferred arrangements for GP out-of-hours services.

The trust described taking on the out-of-hours service as an innovative way of getting involved in primary care, that it was a good opportunity and would bring in additional revenue for the trust.

The service was provided outside normal GP hours, from 6.30pm to 8.00am Monday to Friday, and 24 hours over the weekend and bank holidays. It was located in the emergency operating centre and staffed by paramedics and call takers. The service was overseen by a senior paramedic and one of the trust’s doctors.

The service provided:

- call handling for patients who called their GP’s surgeries out of hours
- telephone triage by a paramedic using approved integrated access management software
- medical advice to callers on how they could treat common ailments at home
- home visits by community paramedic officers
- management of the appointments systems for the five primary care centres
- referral to specialist services such as mental health services.

The previous chief executive told us that, at a meeting held in January 2004, it was agreed

that visits by CPOs could lead to other options such as a visit by a GP. It was also agreed that the ambulance trust, through the employment of GPs, “will cover the red-eye service and that in order to attract GPs employment may need to be on a 24x7 shift basis”.

Initially, all the PCTs jointly commissioned the out-of-hours service. When the PCTs were reconfigured in October 2006, South Staffordshire PCT took over lead responsibility for the contract arrangements.

Prior to May 2006, the reports provided by the trust to the PCTs did not include information about all of the national GP out-of-hours service quality requirements. The reports were mainly about activity. From May 2006, the reports covered all of the quality requirements as well as information about activity

There were four main concerns about the service:

- The trust’s IT system, which did not comply with the Department of Health’s specifications but which the PCTs agreed to accept.
- Home visits by GPs between midnight and 8am – initially there was some confusion about whether or not the trust had agreed to provide this.
- Information provided to GPs.
- Contract arrangements – no service level agreements were signed in the first year but letters of agreement were in place.

We were told by the previous chief executive of South Western Staffordshire PCT that there were extensive discussions between the trust and the Department of Health about the IT system, which did broadly meet the requirements. The PCT was given an assurance that any problems could be overcome.

The provision of GP cover after midnight was a contentious issue between the trust and the PCTs, along with the fact that the doctors employed by the trust were going out on emergency calls. It was felt that the emergency service was being subsidised by the GP out-of-hours service.

There is also evidence that CFRs were attending follow-up calls for the out-of-hours service. This decision had not been agreed with the PCTs.

However, the feedback from the patients who used the service was generally complimentary. The PCTs also felt that the service offered by the trust was better than the previous arrangement.

Audits carried out against the national standards for taking calls showed the trust’s performance had consistently fallen below the national standards. Against the national standard that no more than 5% of calls should be abandoned after 30 seconds, the trust performance varied between 10% and 25%. Against the national standard that 100% of calls should be answered within 60 seconds, the average call waiting time was two to two and a half minutes.

In December 2006, the trust worked hard to improve its performance for call taking and has had some success. They had reduced the rate of calls abandoned to below 5% for the first time, and the average call waiting time was 39 seconds.

An external appraisal of the service was carried out in March 2006 and found the care provided to be satisfactory. Although it was positive about the role and the training of community paramedic officers, it commented that while the experience and training of the medical staff supported the delivery of an effective service for patients with emergency problems, it was less “suited to the management of more chronic and complex problems” and in this respect was not comparable to the service that would be provided by an experienced GP.

The previous medical director told us that although he agreed in principle with the decision for the trust to take on the service, he believed that the problem was that the trust did not have enough resources. He described it as a “bridge too far”, that they had “struggled” with the introduction of new drugs from a control (meaning the arrangements for the supply of medicines) point of view, and that “they couldn’t get the paperwork right in training”. Another senior manager also felt that the service was not adequately resourced.

The previous medical director told us that the trust asked the PCTs for extra resources but, because they had financial difficulties, they were unable to give the trust any additional money for the service. However, South Staffordshire PCT told us that in response to a request from the trust, some additional resources were agreed and the movement of resources within the contract was agreed.

## Relationship with GPs

A GP was involved in helping the trust develop some of their guidelines for the out-of-hours service, and there was a liaison group, which included GPs and the previous medical director of the trust, that met monthly in the early stages of the trust taking over the service.

There were some difficulties between the trust and South Staffordshire Local Medical Committee (LMC), which felt the trust was not listening to its concerns about the GP out-of-hours service. The LMC told the Commission that their main concern was about the lack of “vocationally trained GPs to provide home visits”. The previous chief executive told us that, until the trust took on the GP out-of-hours service, “relationships with the LMC were excellent”. The main issue was about the salary being paid to the doctors employed by the trust; the LMC were unhappy with the amount being paid.

An extract from a letter sent, in September 2005, by the previous medical director to East Staffordshire PCT, shows that the relationship was difficult: “Following a string of erroneous adverse incident reports by PCT employees, the trust has unfortunately no option but to pare down investigation precipitated by PCT employees which we now classify as vexatious adverse incidents.” The letter goes on to say: “Given that the trust provides a service for the public of Staffordshire, the trust will only investigate patient complaints...”.

We were also told that GPs considered they received a quick response from the trust if they needed an ambulance for a patient who had taken ill in the surgery.

We were told that recent changes in the medical leadership in the trust and support from the current SHA has brought about improvements in the working relationship.

## Findings of fact

- The trust had not worked effectively with the local acute trusts to resolve the problems identified in the Commission for Health Improvement clinical governance report (2003).
- Until May 2006, the monitoring arrangements for the GP out-of-hours service did not include information about all of the national quality requirements.
- The out-of-hours service initially provided by the trust was not compliant with national guidance.
- Until recently, the trust did not have an effective working relationship with the local medical committee in south Staffordshire.

# Conclusions

This report is set against a backdrop of significant change in the NHS ambulance service, including the reconfiguration of ambulance trusts from 31 to 12 in 2006. During the investigation, the trust was in a continual state of change: new doctors were appointed, joint directors were being appointed with West Midlands Ambulance Service NHS Trust, (WMAS) and policies and procedures were also being aligned with WMAS. This all culminated in October 2007 when the trust merged with WMAS.

## The concerns

We were notified of serious concerns in August 2006. We made some initial inquiries and identified further serious concerns. The trust was unable to convince us that it had the capacity to address the problems and establish why they had arisen. As a result, we launched a formal investigation.

## The management of medicines

The management of medicines management is a complex area, and expertise is required to ensure that medicines legislation and regulations are interpreted and applied correctly. NHS trusts should have robust governance arrangements in place, and staff need to have an appreciation and understanding of the legal requirements and the seriousness of non-compliance.

The trust took the practice of paramedics administering morphine seriously and there was considerable debate about some of the risks associated with this. However, the trust did not give due consideration to all of the potential risks. There was too much focus on the potential risk of abuse of morphine by staff, rather than looking at all the potential risks of paramedics administering morphine.

Staff were not given fundamental information about the management of controlled drugs, hence their practice of handing over part used ampoules of morphine to ambulance staff.

When the trust took on the GP out-of-hours service in May 2004, this introduced a whole new range of drugs for the trust to manage, and for community paramedic officers to supply and administer. This was a new service for the trust, indeed for ambulance trusts in general, and the trust should have secured robust and ongoing pharmacy advice at an earlier stage.

The previous medical director was working part-time as the medical adviser, and given his time restrictions, it was at best unrealistic, and at worst potentially dangerous, of the trust to believe it could develop and introduce patient group directions (PGDs) with the resources they had access to. This was happening at the same time as the trust agreed to allow paramedics to administer morphine, thus increasing the need for pharmaceutical advice.

In relation to the PGDs, the efforts by several pharmacists to assist the trust, although well intentioned, were misguided. They did not ask enough questions about the PGDs they signed, the medicines they supplied, and were too easily assured by the trust about the governance arrangements for the management of medicines.

The PGDs were confusing, too many versions were in circulation and there was no version control. The trust did not audit staff compliance with the PGDs and training for staff was not thorough, with some staff receiving no training at all.

Community first responders (CFRs) administered a greater range of medicines and drugs than in other ambulance trusts,

yet a review found the training on medicines they received was limited. The trust supplied its CFRs with drugs that contravened legislation for controlled drugs and allowed them to administer medicines that were outside their remit. This was a potential risk to the safety of patients and also to the CFRs, who were operating outside the law.

When concerns were raised about the range of medicines and controlled drugs the CFRs were administering, the trust was unable to assure the current SHA, staff or CFRs that it complied with medicines legislation or that the CFRs had received sufficient training. This issue caused considerable anxiety to individual CFRs and such was the level of concern about the withdrawal of the medicines and the drugs, it was discussed in the House of Commons. The CFRs sought advice, independently of the trust, from the Medicines and Healthcare products Regulatory Agency, and there was a suggestion that some CFRs might withdraw their services.

Missing and unaccounted for medicines were not unusual. During an unannounced visit to the trust, we found the medicines cupboards in disarray. When senior managers were asked about missing medicines and drugs, they did not seem to appreciate the seriousness of the situation.

The trust sought advice from different pharmacists but the advice was not comprehensive or robust. There seems to have been a misunderstanding between the trust and pharmacists about their role and expectations, a lack of sharing of information, all of which resulted from a failure to spend time discussing and agreeing requirements and resources.

The nature of their work often means that ambulance trusts are faced with unique problems. However, they are still required to ensure they comply with medicines legislation. The trust did not have robust arrangements in place for the management of medicines and has breached medicines legislations and regulations. In doing so, it put the safety of patients and staff at risk.

## Introduction of new equipment

There is no doubt that the trust wanted to provide the best possible care for patients and recognised the role of new technology in helping to achieve this. The trust was very open about the equipment it was introducing and it had discussions with some experts about the equipment. However, the trust should have spent more time discussing and trying to engage the support of local health partners when introducing new or pioneering equipment. Failure to do so has resulted in ongoing tension with some of the local acute trusts.

It is a significant omission that the standard operating procedure for introducing new equipment made no reference to the role of medical staff, or indeed the clinical services manager in this area. The clinical services manager and the previous medical director clearly had some responsibility for introducing new equipment.

The trust did not always provide adequate training or sufficient information for staff, or carry out comprehensive risk assessments, prior to introducing equipment. This resulted in some clinical equipment being used inappropriately and on groups of patients that it should not have been used on. Once concerns or problems were raised, however, the trust did take appropriate action.

Although we have not found any evidence of harm to patients, and while equipment such as the automated gas-driven chest compression device may reduce risks for staff, the benefits for patients have yet to be established.

When introducing innovative and relatively unproven clinical equipment, the trust should have given more consideration to engaging experts in research to help it obtain the necessary evidence to prove the benefits to patients. Failure to do this has resulted in missed opportunities, and potential damage to the reputation of the trust.

## The trust's management of community first responders

It is clear that improving the care provided to patients was the key reason the trust introduced CFRs. Although in many ways the CFR schemes were a success, there were some flaws in the trust's management of them.

Some of the problems may have arisen from the fact that the trust perpetuated the belief that the role of CFRs was broadly equivalent to that of ambulance technicians. Although the trust provided more training for CFRs than other ambulance trusts, this was not comparable to the training for ambulance technicians. The way in which CFRs carry out their role is also different to that of ambulance technicians. This blurring of roles had the potential to cause tension between the two groups.

While there is no doubt about the commitment and motivation of the CFRs, it is questionable whether the trust should have allowed them to attend all emergency calls and, for a short time, calls for the GP out-of-hours service. We have already established that the CFRs were allowed to administer medicines and drugs that were outside their remit and expertise. This put the CFRs, and the patients they attended, at risk.

Allowing CFRs to use blue lights and sirens when driving and to exceed the speed limit, without providing the necessary driving instruction, potentially jeopardised the safety of CFRs and other drivers.

When we first voiced our concerns about this practice, the trust was initially reluctant to put any constraints around CFRs using blue lights and sirens.

At some point the trust seems to have lost sight of the fact that as volunteers and without a formal agreement, the CFRs were not bound by the same terms and conditions as staff employed by the trust. This gave them the power to seek their own advice on issues, for example in relation to the withdrawal of some of the medicines and controlled drugs they

were administering. They also had the power to withdraw their services.

What began as a volunteer service providing care and treatment to discrete groups of patients, almost mushroomed into a parallel ambulance service, which had the power to potentially disrupt the service provided by the trust. In allowing the role of CFRs to develop in the way it did and without a formal agreement, the trust found itself in a situation that was very difficult to manage and unwittingly put the good working relationship between the CFRs and the trust at risk.

## The management of staff and training and education

From 2003, there had been a gradual reduction in the resources and support staff needed to carry out their jobs. In 2004, the trust took on responsibility for providing some aspects of the GP out-of-hours service and at the same time there was an increase in demand for the emergency service. Community paramedic officers played a key role in the out-of-hours service, resulting in the expansion of their role and requiring them to learn new skills. Staff and managers were consistently working long hours, albeit with payment.

There was confusion about the role and experience of the doctors required for the GP out-of-hours service. The service provided by the trust was not always compliant with NHS regulations.

The increased demand on the service made it even more imperative that staff were not delayed in handing over patients in accident and emergency, which led to increased pressure on staff and managers. The way the managers handled this was at times inappropriate, and served only to increase the pressure on staff and on themselves without necessarily resolving the problem.

Managers were not always allowed to manage. Where it was felt there was a deficit in their skills or knowledge in a particular area, responsibility was taken away from them

rather than the skills gap being addressed. Similarly, if a department was not functioning, the responsibility was transferred elsewhere. This may have been the correct decision in the short term if the intention was to address the underlying problems, but this does not seem to have happened.

There was a gradual reduction in the education and training provided by the trust. It provided little or no support for staff to attend external training or specialist management training. This lack of training in management skills may have contributed to the ineffective way managers addressed some issues, such as how they carried out disciplinaries and managed delays in accident and emergency.

## The trust's arrangements for clinical governance and the management of risk

The arrangements for clinical governance and risk management had remained relatively unchanged for a number of years.

The main forum for clinical governance, the risk and clinical governance committee, met only four times a year. It had a huge remit, not helped by the fact that there was not a separate committee responsible for risk management. It was unrealistic to think that all the items on the committee's agenda could have been given the attention they required, and the committee should have considered meeting more frequently.

The trust did try to introduce other committees to look at governance in specific areas, for example the GP out-of-hours service, but it was unsuccessful.

The system for managing clinical risk was fragmented. A number of staff were involved, formally or informally, in investigating incidents yet very few had received any training from the trust in how to carry out this role. Staff were reporting incidents using anonymised forms and their comments suggest a perception that a blame culture existed. If more managers had been given training on how to carry out investigations,

this may have helped dispel some of the staff's concerns.

Given that this was a trust that wanted to be innovative and at the forefront of introducing new equipment, the arrangements for clinical governance should have been more robust.

The number of information sheets and versions of guidelines on the intranet suggests that the trust could not keep up with the number of changes it was introducing. This was confusing for staff and potentially dangerous for patients.

The structure for governance was changed in early 2007 with the introduction of the integrated governance and performance committee. The committee is chaired by a non-executive director and meets monthly.

## Leadership and management

The leadership style of the trust was very 'hands on'. In some ways it is to be commended that senior managers, executive directors and the previous chief executive would make themselves available to respond to calls and "go to where the problems were". On some occasions, this may have been helpful; on others, it seems to have exacerbated what was already a difficult situation. It also possibly reinforced the perception of a lack of confidence in the ability of managers. It is also difficult to see how the executive directors had time to fulfil their obligations as directors, and accounts for why many of them consistently worked beyond their contracted hours.

The trust had a relatively stable executive and non-executive team. Although the previous medical director was also the deputy chief executive and not a member of the trust's board, he was involved in much of the decision making about new clinical equipment and the management of medicines. He was also the only director who had a clinical background.

When the new chairman was appointed in 2005, the dynamics of the board began to change. For example, despite the previous chief executive's view that the clinical

negligence scheme for trusts assessment was just a “tick box assessment”, the new chair recognised that it was important for the trust to be successful in the assessment and successfully challenged this view.

Although there had been earlier requests, it was not until late 2006 that the trust changed the format for information for board meetings. While it can be difficult getting the balance right between giving too much and too little information to non-executive directors, the trust should have responded earlier to the request by the non-executives for clearer, less detailed information. If the information had been presented in a more meaningful way, it may have enabled the non-executives to be more questioning and challenging about some of the decisions the executive directors were making. Equally, the non-executives should have persisted with this request.

The trust was very open about its intentions and what it was trying to achieve. The trust’s board, previous SHA and PCTs did not sufficiently question or ask the right questions about how the trust was balancing the requirements to meet the Department of Health’s response times targets, be at the forefront of new technology and introduce new services, while at the same time reporting a reduction in resources and an increase in demand for the service. There was complacency at strategic level, brought about by the trust’s continued ability to meet the Department of Health’s targets. If there had been more rigorous questioning and challenge, it may have been recognised earlier that the achievements, and the pace the trust was operating at, were not sustainable.

### Joint working arrangements with local community health partners

There was clearly some tension between the trust and local acute trusts, much of it generated because of delays in handing patients over in accident and emergency. The trust is perhaps not alone in this. However, some of the behaviour by senior staff served only to exacerbate the situation. Despite this

issue being identified in 2003, the trust seems to have taken little action to address the problem.

The language used in some correspondence with PCTs could also be described as antagonistic. There were problems between the trust and the PCTs when the trust took on responsibility for some aspects of the GP out-of-hours service. The service provided by the trust was not always compliant with NHS regulations. Although the trust was trying to be innovative and work in partnership with PCTs to solve a serious local problem, it is another example of the trust not securing the necessary expertise or taking the time to consider the implications for training, and the additional demands it would place on the service.

### Overall conclusion

The trust was keen to be innovative, and to be at the forefront of embracing new practices and technology, in order to improve the care provided to patients. While this is to be commended, and the Commission would not wish to stifle innovation in the NHS, the pace of innovation was too quick. Being innovative requires expertise and resources and it is clear that, despite at times requesting expertise, this was not always available to the trust. Innovation also brings risk and the trust did not always anticipate the risks or manage them as well as it could have done.

There were occasions when the trust should have paused and taken time to consolidate what it had already achieved, rather than rushing to embrace the latest piece of equipment. However, despite these serious problems, the trust and staff were committed to improving the care and treatment it provided to patients.



# Developments since the investigation was announced

There have been changes at the trust since the investigation was announced in January 2007.

## Changes of management arrangements

In October 2007, the trust merged with West Midlands Ambulance Service NHS Trust and is now one of four localities that make up the trust. It is known as the Staffordshire locality. Starting in November 2006 and leading up to the merger, the following joint directors were appointed:

- director of clinical performance
- director of finance, planning, and performance management
- director of human resources and organisational development
- director of information management and technology
- director of corporate services.

The majority of the previous executive directors and some of the senior managers have left the trust. Those who have stayed, have different responsibilities.

West Midlands Ambulance Service NHS Trust is in the process of introducing a new, more locally based, management structure with the aim of improving leadership and communication with ambulance staff.

## Clinical leadership

West Midlands Ambulance Service NHS Trust has appointed a medical adviser for each of the four localities, including Staffordshire, that make up the trust. The advisers are supported by a team of clinical managers led by the regional head of clinical services.

West Midlands Ambulance Service NHS Trust has a part-time pharmacy adviser, who provides advice across the trust, including the Staffordshire locality.

## Changes to services provided by the trust

The contract for the GP out-of-hours service was put out to tender in 2007, before the merger. The former Staffordshire Ambulance Service NHS Trust submitted a bid to retain the contract but was unsuccessful. The contract will transfer to an alternative provider as determined by South Staffordshire PCT.

# Recommendations

The Healthcare Commission considers the findings of this investigation to be extremely serious, and to constitute a significant failing on the part of Staffordshire Ambulance Service NHS Trust, which, although committed to improving the quality and expanding the range of services provided, failed to protect the interests of patients and staff.

We are mindful of the fact that, in October 2007, Staffordshire Ambulance Service NHS Trust ceased to exist and its services became the responsibility of West Midlands Ambulance Service NHS Trust. Our recommendations, therefore, relate to West Midlands Ambulance Service NHS Trust, which we refer to here as “WMAS”.

We expect WMAS to consider all aspects of this report. Here we highlight areas where action is particularly important.

## Clinical governance and the management of risk

Risk management is a key component of improving patient care and is a central part of an organisation’s strategic management. The WMAS board must satisfy itself that there is an effective framework in place to monitor the quality of care and the safety of the services provided by WMAS, and that it receives information that enables it to assess whether WMAS is compliant with national standards and other regulatory requirements.

Before introducing any significant new services, practices or equipment, WMAS must carry out robust assessments of potential risk to the safety of patients and ensure there is clear evidence demonstrating the benefits to the care of patients. It must also take into account the need for any additional training and education that may be required.

WMAS must review its arrangements for reporting, investigating and learning from incidents, to ensure that they are effective and clearly understood by all staff.

## Management of medicines

WMAS must ensure that it has robust arrangements in place for the management of medicines, including sufficient and appropriate expertise from specialist advisers.

It must continue to align its policies and practices for the management of medicines, and ensure that good practice is consistently applied across the organisation and that all staff are aware of their responsibilities.

## Community first responders

WMAS must carry out a review of the training, education, support and governance arrangements for its community first responders (CFRs), to ensure that they are able to carry out their role safely and effectively. This must include the use of blue lights and sirens by CFRs. Findings and actions from this review must be clearly communicated to the CFRs.

## Training and education

WMAS must take the necessary steps to ensure that staff attend mandatory training and education. This must include specific training on the management of risk.

WMAS should, where appropriate, provide access to mentoring and coaching for managers, to help develop skills in leadership and to encourage staff to adopt new ways of working.

## Communication

WMAS must ensure that it has effective methods of communicating with staff, to ensure they are up-to-date with new working practices and developments within the trust.

## Joint working arrangements with local acute trusts

In partnership with local acute trusts, WMAS must develop procedures to assist the timely handover of patients in accordance with their needs, and ensure that ambulances are available to respond to other emergency calls.

## National recommendations

All NHS ambulance trusts must read this report, review their services in light of the findings and, where appropriate, take the necessary action. In particular, they must ensure their boards receive information that enables them to assess if users are receiving a high quality, safe service that complies with national standards and other regulatory requirements and identifies potential areas of risk.

Any NHS ambulance trust that expands the range of services it provides, to include for example GP out-of-hours services, must carry out comprehensive risk assessments to identify any potential risks to the safety of patients. It must ensure there is clarity about the scope of the service it will provide and it must adhere to national and professional guidelines related to the service.

When introducing any significant new services or practices, NHS ambulance trusts must take into account the need for additional training and education that staff may require, and ensure this is provided.

NHS ambulance trusts must ensure that their arrangements for the management of medicines comply with legislation for medicines and controlled drugs, and that they have robust governance arrangements in place to assure and monitor compliance.

The Department of Health needs to liaise with the Home Office to clarify the circumstances in which NHS ambulance trusts require a licence to possess and supply controlled drugs to registered paramedics.

When introducing new equipment, NHS ambulance trusts must carry out robust assessments of potential risks to the safety of patients and ensure there is clear evidence demonstrating the benefits to the care of patients.

All NHS ambulance trusts must ensure that CFR schemes are properly managed, supported and audited, and are in line with the national guidance recently agreed by the NHS ambulance service Chief Executive group.

Commissioners of NHS ambulance services should ensure that they, and ambulance trusts, have systems in place for monitoring and reporting on the quality and safety of services.

# Appendix A: The Healthcare Commission's criteria for an NHS investigation

The Healthcare Commission works to improve the quality of healthcare provided by the NHS and the independent (private and voluntary) sector. One of its functions is to investigate serious failures in NHS services.

## What will the Healthcare Commission investigate?

The Healthcare Commission will investigate allegations of serious failings that have a negative impact on the safety of patients, clinical effectiveness or responsiveness to patients. This may include:

- a higher number than anticipated, or unexplained, deaths, serious injury or permanent harm, whether physical, psychological or emotional
- events that put at risk public confidence in the healthcare provided, or in the NHS more generally
- a pattern of adverse effects or other evidence of high risk activity
- a pattern of failures in service(s) or team(s) or concerns about these
- allegations of abuse, neglect or discrimination against patients.

Other failings with less serious effects on patients' safety may be subject to a review. In determining whether to investigate, the Healthcare Commission will consider the extent to which local resolution, referral to an alternative body, or other action might offer a more effective solution.

The Healthcare Commission does not investigate:

- a complaint that has not been pursued through the NHS complaints procedure or the Healthcare Commission's independent stage, unless it raises an immediate concern
- individual complaints about professional misconduct
- changes to service configurations
- matters being considered by legal process
- specific matters already determined by legal process.

This does not preclude the Healthcare Commission from investigating circumstances surrounding such matters, particularly if there are general concerns about patient safety or suggestions that organisational systems are flawed.

# Appendix B: The investigation team

**Margaret McGlynn**  
Investigation Manager  
Healthcare Commission

**Janet Watkinson**  
Chief Pharmacist  
Hitchingbrooke Healthcare NHS Trust

**Kate Thornton**  
Senior Investigations Analyst  
Healthcare Commission

**David Whiting**  
Director of Operations  
East Midlands Ambulance Service NHS Trust

**Graham Johnson**  
Consultant Emergency Medicine/Clinical  
Director Urgent Care  
Leeds Teaching Hospitals NHS Trust

**David Whitmore**  
Senior Clinical Advisor to the Medical Director  
London Ambulance Service NHS Trust

**Dr Nina Moorman**  
General Practitioner  
Formerly partner at Whiteladies Medical  
Group, Bristol

Additional advice was provided by:

**Gillian Arr-Jones**  
Head of Pharmacy  
Healthcare Commission

**David Griffiths**  
Ambulance and Emergency Care Sector Lead  
Healthcare Commission

**Professor David Haslam CBE**  
National Clinical Advisor to the Healthcare  
Commission

The team was supported by:  
Senior legal advisor: Rona Nicoll  
Investigation Officer: Nicola Hepworth  
Investigation Analysts: David Harvey,  
Benjamin Young and Sarah Davis  
Investigations coordinators

We would like to thank the Medicines and  
Healthcare products Regulatory Agency for its  
advice in relation to medicines management.

## Appendix C: Interviews

The investigation team conducted a total of 193 interviews. Of these, 106 interviews involved former or current trust staff. Some people were interviewed more than once.

The investigation team was in contact with 46 stakeholders (members of the public or members of external organisations associated with the trust). They were interviewed face-to-

face or by telephone, either as a result of contacting the investigation team or in response to an invitation from the team. Seventeen stakeholders contacted the investigation team in writing. The following tables show a breakdown of those interviewed and those who contacted the team.

<b>Trust staff, former trust staff and community first responders interviewed</b>
Chief executive and executive directors, including medical director and associate directors
Chairman and non-executive directors
Joint directors
Managers, including senior and clinical managers
Paramedics and community paramedic officers
Technicians
Trainers and community first responder coordinators
Volunteer car drivers
Call takers
Medical staff and nursing staff
Pharmacy adviser
Staff-side and union representatives
Coordinators and administrative staff
Community first responders

<b>Stakeholders interviewed</b>	
Patients and relatives	15
Current and former staff	9
Other	4

<b>Stakeholders who contacted the investigation team in writing</b>	
Patients and relatives	15
Members of Parliament	1
Other	1

<b>Outside organisations interviewed</b>	
Acute trusts	4
Strategic health authorities	2
Primary care trusts	4

# Appendix D: Sources of information

- Interviews and correspondence with patients, relatives and carers
- Interviews and correspondence with current and former trust staff, including joint directors of West Midlands Ambulance Service
- Interviews with organisations in the health community, including local primary care trusts, West Midlands Ambulance Service, West Midlands Strategic Health Authority, UHNHS, Good Hope Hospital NHS Trust, Burton Hospital NHS Trust and Mid Staffordshire General Hospitals NHS Trust
- Information and guidance from the Department of Health
- Road Traffic Regulation Act 1984 and Road Safety Act 2006
- Notices, alerts and advice issued by the Medicines and Healthcare products Regulatory Agency, the Home Office, the ASA and the Joint Royal Colleges Ambulance Liaison Committee
- Interviews and correspondence with Members of Parliament
- Observations at the trust's emergency operation centre, depots and make-readies
- Minutes of trust meetings and board reports, including meetings of the trust board, the executive management committee, the risk and clinical governance committee, the integrated governance and performance committee, the local ambulance paramedic steering committee, the clinical steering committee, the research and development committee, the doctors' out-of-hours committee, production, distribution, the partnership board, team leaders, the locality management committee, the medicines management committee, the field operations staff liaison committee, the health and safety committee, the operational team, the training joint working group and executive training group, the executive staff liaison group, community first responders and community first responders working group
- Relevant trust policies and standard operating procedures with particular reference to thrombolysis, the Emergency Rule, introduction of new equipment, child protection and protection of vulnerable adults, Caldicott, data protection and version control, information governance, AMPDS, procurement, incident reporting, risk management, staff welfare and counselling, sickness, grievances, disciplinary action, career development, risk management training, internal and external training, whistle-blowing and hospital turnaround
- Documentation relating to the trust's management of medicines including patient group directions, controlled drugs policy and other drugs protocols, medicines and pharmacy advice, accountabilities, GP formulary, audits and reports on the loss of drugs
- Clinical governance documentation, such as the risk register, terms of reference for the risk and clinical governance committee and the integrated governance committee, and relevant job descriptions
- Information on the trust's patient advice and liaison service, incident and complaints reporting procedures and structure
- Information on relevant complaints, including reports by independent review panels
- Information on relevant incidents, including reports of serious untoward incidents



- Lifeline and incident forms, including serious untoward incidents
- Details of grievance actions taken
- Risk assessments carried out by the trust
- Risk alerts issued by the trust
- Self-assessments, audits and position statements by the trust
- Systems status management handbook
- Clinical routine instructions issued by the trust
- IT arrangements, reports, policies and plans for the trust
- Organisational, management and reporting structures
- Job descriptions and person specifications of trust staff including doctors, nurses, community paramedic officers, CPs, technicians, paramedics, call-handlers, managers, directors and the chief executive
- Details of the trust's community first responder arrangements, including their management, training, policies and procedures and audits, for example guidance to the establishment and operation of a CFR, the CFR volunteer agreement, CFR standard operating procedures for drugs and the re-introduction of drugs, recruitment guidance, standard operating procedures for training CFRs, risk assessment, driving guidance and CFR activity
- Documentation and correspondence provided by the trust relating to whole-time equivalent staffing numbers, leavers, vacancies, appraisals, the trust's career development pathway, sickness levels, anonymised disciplinarys, the annual training plan, training strategy 2002-2005, the training budget, accreditation of training, external training offered and training content, and attendance numbers, (planned and actual), for induction, mandatory training, technician training, paramedic and CPO training, and non-clinical training
- Commission for Health Improvement clinical governance review into Staffordshire Ambulance Service NHS Trust, May 2003
- The Healthcare Commission's annual health check and star rating system for 2004/2005, 2005/2006 and 2006/2007
- Findings from the Healthcare Commission's 2005 and 2006 national surveys of staff and patients in the NHS
- The level 1 clinical negligence scheme for trusts' assessments of the trust in February 2005 and February 2006.
- Clinical governance review of the trust by Dr Richard Fairhurst, 2007
- Reports and analyses of various aspects of the trust's operations including the report on the trust's emergency operation centre by West Midlands Ambulance Service, the trust's provision of out-of hours-services by Dr Faye Wilson and the Independent Police Complaints Commission report on a serious untoward incident
- Correspondence between the trust and local acute trusts and primary care trusts regarding pharmacy advice
- Application to the Home Office for a controlled drugs licence and subsequent licence
- Royal Pharmaceutical Society, Medicines, Ethics & Practice: A Guide for Pharmacists and Pharmacy Technicians, 2007
- National Prescribing Centre guidance, 2007
- Hospital Pharmacists Group, The safe and secure handling of medicines: a team approach, March 2005 (a revision of the 1988 Duthie report)
- The trust's partnership arrangements, including action plans, joint protocols and service level agreements with West Midlands Strategic Health Authority (previously Staffordshire and Shropshire SHA) and provider organisations including primary care trusts and acute trusts for the provision of services.
- Copies of minutes of meetings, papers, plans and correspondence from primary care trusts and strategic health authorities

# Appendix E: List of parenteral medicines that can be administered by paramedics for the immediate necessary treatment of sick or injured persons

- Diazepam 5 mg per ml emulsion for injection
- Succinylated Modified Fluid Gelatin 4% intravenous infusion
- Prescription only medicines containing one or more of the following substances but no other active ingredient:

Adrenaline Acid Tartrate

Amiodarone

Anhydrous Glucose

Benzylpenicillin

Bretylium Tosylate

Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution)

Ergometrine Maleate

Frusemide

Glucose

Heparin Sodium (Note: administration is only allowed for the purpose of cannula flushing)

Lignocaine Hydrochloride

Metoclopramide

Morphine Sulphate

Nalbuphine Hydrochloride

Naloxone Hydrochloride

Polygeline

Reteplase

Sodium Bicarbonate

Sodium Chloride

Streptokinase

Syntometrin

Tenecteplase

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## Healthcare Commission

Finsbury Tower  
103-105 Bunhill Row  
London  
EC1Y 8TG

Maid Marian House  
56 Hounds Gate  
Nottingham  
NG1 6BE

Dominions House  
Lime Kiln Close  
Stoke Gifford  
Bristol  
BS34 8SR

Kernel House  
Killingbeck Drive  
Killingbeck  
Leeds  
LS14 6UF

5<sup>th</sup> Floor  
Peter House  
Oxford Street  
Manchester  
M1 5AX

1<sup>st</sup> Floor  
1 Friarsgate  
1011 Stratford Road  
Solihull  
B90 4AG

Telephone 020 7448 9200  
Facsimile 020 7448 9222  
Helpline 0845 601 3012

Email [feedback@healthcarecommission.org.uk](mailto:feedback@healthcarecommission.org.uk)  
Website [www.healthcarecommission.org.uk](http://www.healthcarecommission.org.uk)

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