## Review of compliance

### Mid Staffordshire NHS Foundation Trust

#### Stafford Hospital

<table>
<thead>
<tr>
<th>Region:</th>
<th>West Midlands</th>
</tr>
</thead>
</table>
| Location address:| Mid Staffordshire NHS Foundation Trust  
Weston Road  
Stafford  
ST16 3SA |
| Type of service: | Acute service                  |
| Regulated activities provided: | Treatment of disease, disorder or injury  
Surgical procedures  
Diagnostic or screening procedures  
Maternity and midwifery services |
| Type of review:  | Responsive review               |
| Date of site visit (where applicable): | 29/3/10, 31/3/10, 9/4/10, 13/4/10, 22/4/10 |
| Name of site(s) visited (where applicable): | Stafford Hospital |
| Date of publication: | July 2010                      |
Information for the reader

<table>
<thead>
<tr>
<th>Document purpose</th>
<th>Review of compliance report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Care Quality Commission</td>
</tr>
<tr>
<td>Audience</td>
<td>The general public</td>
</tr>
<tr>
<td>Further copies from</td>
<td>03000 616161 / <a href="http://www.cqc.org.uk">www.cqc.org.uk</a></td>
</tr>
<tr>
<td>Copyright</td>
<td>© Care Quality Commission 2010. This publication may be reproduced in whole or in part, free of charge, in any format or medium provided that it is not used for commercial gain. This consent is subject to the material being reproduced accurately and on proviso that it is not used in a derogatory manner or misleading context. The material should be acknowledged as CQC copyright, with the title and date of publication of the document specified.</td>
</tr>
</tbody>
</table>

Care Quality Commission

<table>
<thead>
<tr>
<th>Internet address</th>
<th><a href="http://www.cqc.org.uk">www.cqc.org.uk</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone</td>
<td>03000 616161</td>
</tr>
<tr>
<td>Email address</td>
<td><a href="mailto:enquiries@cqc.org.uk">enquiries@cqc.org.uk</a></td>
</tr>
</tbody>
</table>
| Postal address   | Care Quality Commission  
|                  | Citygate  
|                  | Gallowgate  
|                  | Newcastle upon Tyne |
|                  | NE1 4PA |
Introduction to our review of compliance

By law, providers of certain adult social care and health care services have a legal responsibility to make sure they are meeting essential standards of quality and safety. These are the standards that everyone should be able to expect when they receive care.

The Care Quality Commission (CQC) has written guidance about what people who use services should experience when providers are meeting essential standards. This is called *Guidance about compliance: Essential standards of quality and safety*.

CQC licenses services if they meet essential standards and we will constantly monitor whether they continue to do so. We formally review a service when we receive information that is of concern and, as a result, decide we need to check whether it is still meeting one or more of the essential standards. We also formally review services at least every two years to check whether they are meeting all of the essential standards in each of their locations. Our reviews include checking all the available information and intelligence we hold about a provider. We may seek more information by contacting people who use services, public representative groups and organisations such as other regulators. We may also ask for more information from the provider, and carry out a site visit with direct observations of care.

When we make our judgements about whether services are meeting essential standards, we will decide whether we need to take further regulatory action. This might include discussions with the provider about how they could improve. We only use this approach where issues can be resolved quickly, easily and where there is no immediate risk of serious harm to people.

Where we have concerns that providers are not meeting essential standards, or where we judge that they are not going to keep meeting them, we may also set improvement actions, compliance actions or take enforcement action:

<table>
<thead>
<tr>
<th><strong>Improvement actions</strong></th>
<th>These are actions a provider should take so that they <em>maintain</em> continuous compliance with essential standards. Where a provider is complying with essential standards, but we are concerned that they will not be able to maintain this, we ask them to send us a report describing the improvements they will make to enable them to do so.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compliance actions</strong></td>
<td>These are actions a provider must take so that they <em>achieve</em> compliance with the essential standards. Where a provider is not meeting the essential standards, but people are not at immediate risk of serious harm, we ask them to send us a report that says what they will do to make sure they comply. We monitor the implementation of action plans in these reports and, if necessary, take further action to make sure that essential standards are met.</td>
</tr>
<tr>
<td><strong>Enforcement actions</strong></td>
<td>These are actions we take using the criminal and/or civil procedures in the Health and Adult Social Care Act 2008 and relevant regulations. These enforcement powers are set out in the law and mean that we can take swift, targeted action where services are failing people.</td>
</tr>
</tbody>
</table>
How this report is presented

On page 5 below, there is a summary that shows whether the essential standards about quality and safety that were checked during this review of compliance are being met. The section on each outcome is set out in this way:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>XX: The outcome number and title</td>
<td>Whether the service provider is compliant, or whether we have minor, moderate or major concerns about their compliance</td>
</tr>
</tbody>
</table>

Following the summary, there is a detailed section on the outcomes for each of the essential standards that we looked at. The evidence that we used when making our judgements for each one is set out in the following way:

Outcome XX (number):
Outcome title

Details of the outcome, taken from our Guidance about compliance: Essential standards of quality and safety.

What we found for the Outcome

Our judgement

Our judgement about whether the <service/provider> meets the outcome described in the Guidance about compliance: Essential standards of quality and safety, or whether there are minor, moderate, or major concerns in relation to compliance.

Our findings

A summary of the evidence and findings used to reach our judgement, related to regulated activities as appropriate.

At the end of the report you will find details of:

- Any improvement and/or compliance action(s) that the service provider should make to maintain or achieve compliance with the essential standards of quality and safety.
- Any formal enforcement action that we are taking against the service provider.
Summary of findings for the essential standards of quality and safety

The table below shows the judgement that we reached for each of the essential standard outcomes that we reviewed.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>4: Care and welfare of people who use services</td>
<td>Minor concern</td>
</tr>
<tr>
<td>11: Safety, availability and suitability of equipment</td>
<td>Minor concern</td>
</tr>
<tr>
<td>13: Staffing</td>
<td>Compliant</td>
</tr>
<tr>
<td>16: Assessing and monitoring the quality of service provision</td>
<td>Compliant</td>
</tr>
</tbody>
</table>

Summary of key findings:

- The purpose of the visit was to assess the trust’s progress with the five registration conditions that ‘expired’ on 1 April 2010. The sixth condition will be reviewed in August. The assessment was undertaken as part of the 12-month progress review which was carried out during March and April 2010. This review involved observations in the clinical areas, and interviewing patients, carers and staff.

- In line with the registration condition on outcome 4, we set out to determine whether the trust has implemented procedures for managing patients admitted as emergencies. The A&E department has strong clinical leadership and is adequately staffed and equipped. Patients have good access to A&E consultants. We found that the procedures for managing surgical emergencies had improved. However, there has been little improvement in managing the time patients remain in the A&E department. Flows through the hospital are impacting on A&E and this needs further improvement. The trust also needs to undertake further work to streamline the arrangements for patients attending as medical emergencies. Since the visit, the trust has stated that a focus on the whole system has improved the performance against the four hour target. It was agreed that the trust had provided sufficient assurance of compliance and that this condition could be removed. However, a minor concern exists and improvement action is required by the trust. We will review progress again in August 2010.
• We placed two registration conditions on outcome 11 at registration. In line with the first we set out to determine whether the trust has a system to ensure all medical equipment is in working order and if a maintenance programme in place. We found that the trust has processes in place to ensure that equipment is maintained, however these are not well co-ordinated and the assurance framework required to effectively demonstrate and monitor compliance with this regulation is still developing. In addition, we observed patients who were at risk of developing pressure sores but who did not have access to pressure relieving devices. Staff also raised concerns about access to pressure relieving equipment. The trust must ensure that sufficient pressure relieving devices are routinely available and since our visit the trust has stated that this has been addressed. We will follow this up in August 2010. It was agreed that the trust had provided sufficient assurance of compliance and that this condition could be removed. However, a minor concern exists and improvement action is required by the trust. We will review progress again in August 2010.

• In order to review compliance with the second registration condition on outcome 11 we set out to determine whether clinical staff who use medical equipment have been trained and are competent to operate that equipment. We found that the trust has good systems in place to ensure that staff are appropriately trained in using equipment specific to their role. It was agreed that the trust had provided sufficient assurance of compliance and that this condition could be removed.

• In order to review compliance with the registration condition on outcome 13, we set out to determine whether the trust has recruited to its vacant nursing posts and whether it has sufficient staff to meet the dependency levels of patients on the wards. We found that the trust has made very good progress in recruiting to its vacant posts. Examination of the trust's nurse to patient ratios indicates that the numbers of nurses are now sufficient to ensure that patient needs are met. In some areas there are high numbers of nurses being absent due to sickness and the trust needs to continue to tackle this. We also spoke with patients to determine whether the increase in number of nurses had made an impact on their experiences. The majority of patients we spoke to confirmed that it had. It was agreed that the trust had provided sufficient assurance of compliance and that this condition could be removed.

• In line with the registration condition on outcome 16 we set out to determine whether the trust has implemented governance and audit systems, to assess and monitor the quality of service provision, across all services. The trust was able to demonstrate that it has governance and audit systems in place to assess and monitor the quality of service provision across all services. We found that the trust has made good progress in engaging clinicians and developing effective clinical audit, but this is not yet fully embedded. The trust needs to monitor these areas to ensure that the arrangements do become embedded. However, it was agreed that the trust had provided sufficient assurance of compliance and that this condition could be removed.
What we found for each essential standard of quality and safety

The section below details the findings and our regulatory judgement for each essential standard and outcome that we reviewed, linked to specific regulated activities where appropriate.

Further detail about each of the outcomes described below can be found in the Guidance about compliance: Essential standards of quality and safety.
Outcome 4: 
Care and welfare of people who use services

People who use services:
- Experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights.

This is because providers who comply with the regulations will:
- Reduce the risk of people receiving unsafe or inappropriate care treatment and support by:
  - assessing the needs of people who use services
  - planning and delivering care, treatment and support so that people are safe, their welfare is protected and their needs are met
  - taking account of published research and guidance
  - making reasonable adjustments to reflect people’s needs, values and diversity
  - having arrangements for dealing with foreseeable emergencies.
What we found for Outcome 4

Our judgement

There are minor concerns with Outcome 4: Care and welfare of people who use services

Our findings

Patients have very good access to senior doctors in A&E. Consultants spend a large proportion of their time in the department, and are readily available to provide patient care, and supervision to more junior staff. The hospital ambulance liaison officer for West Midlands Ambulance Service NHS Trust has been in the post for about a year and is well integrated into the department, providing liaison between ambulance crews and A&E staff and giving advice to the trust about ambulance service issues and practices.

The A&E department is separated into majors and minors. The decision making doctors (consultants and middle grade doctors) are primarily based on the majors whilst the minors is supported by the use of clinical protocols, identifying what clinical action should be taken in specific cases.

The four-bedded area in the A&E department is now being more formally used as an observation unit. The trust had developed a policy to clarify the use of this area although, at the time of our visit, this had not been formally approved. The observation unit is under the management of A&E. Admissions are made with the consent of A&E’s decision-making doctors, and for a maximum of 24 hours only. The admission criteria are: minor head injury (not awaiting scan); awaiting psychiatric assessment; occupational therapy assessment; and intermediate care team. However, we found that acute medical patients were still admitted to the area, due to bed capacity issues. Use of the observation unit needs clarifying further to reduce unnecessary risks to patients.

The trust has opened a surgical assessment unit and all stable patients attending A&E with surgical problems are transferred to the unit. The percentage of eligible patients transferred to the unit from A&E has steadily increased, from 52% in November 2009 to 81% in February 2010. The unit is managed by the surgical division and is open between 8am and 10pm. It has facilities for 10 patients and is staffed with experienced nurses. Patients are rapidly seen and well managed and about a third of patients are discharged home rather than being admitted to a ward. The assessment unit has made a good impact on the care that surgical patients receive.

Despite the number of improvements that have been made in A&E over the last 12 months, there has been little improvement in managing the time that patients remain in the department. There is still a marked drive to admit, discharge or transfer patients in the last 10 minutes before the four-hour waiting target is breached. There also appears to be an over-reliance on the use of A&E to house patients who fall between acute medical or surgical conditions and ‘level 2’ high dependency cases. We found two patients who had
remained in A&E for a protracted period of time; they may have benefited from being moved to a level 2 high dependency facility sooner. The trust has recognised the need to improve the effectiveness and efficiency of discharge from its wards in order to improve the flows through A&E (and the acute medical unit). A project has begun since our visit and early feedback indicates this has had a positive impact on flows through A&E.

We were told that direct admission to the acute medical unit (AMU) is meant to occur for patients referred by their GP. However, when we visited in March 2010, the trust had an outbreak of norovirus (an infectious diarrhoea and vomiting bug). A number of wards had been closed to admissions during this period, and it had not been possible to fast track GP referred patients because the space for this dedicated activity was taken up by medical patients requiring admission. We were also provided with documentation describing the admission process for patients referred by their GP, and who do not arrive by ambulance. These show that patients should register with the A&E reception and be triaged by a nurse in A&E before being admitted to the AMU. This implies that admission is not direct to AMU and this needs clarifying as part of the project to improve flows through A&E.
Outcome 11: Safety, availability and suitability of equipment

People who use services:
- Are not at risk of harm from unsafe or unsuitable equipment (medical and non-medical equipment, furnishings or fittings).
- Benefit from equipment that is comfortable and meets their needs.

This is because providers who comply with the regulations will:
- Make sure that equipment:
  - is suitable for its purpose
  - is available
  - is properly maintained
  - is used correctly and safely in line with manufacturers’ instructions
  - promotes independence
  - is comfortable.
- Follow published guidance about how to use medical devices safely.
What we found for Outcome 11

Our judgement

There are minor concerns with Outcome 11: Safety, availability and suitability of equipment

Our findings

Equipment maintenance
The trust has continued to develop its systems to ensure that new equipment is purchased appropriately and that all equipment is appropriately maintained. The trust has a preventative maintenance log of when planned maintenance should be carried out. However, there is no rolling replacement programme for larger items of equipment as reflected in the corporate risk register of 20 April 2010. During our visit, staff pointed out that some anaesthetic machines were coming to the end of their useful life. Since then, the trust has told us that nine new anaesthetic machines have been ordered, and some of these have already been delivered to the trust.

The policy on management of medical devices has been revised and is awaiting ratification. This includes comprehensive information about processes for the appropriate procurement, maintenance, replacement and disposal of medical devices. A medical devices group has been newly formed to oversee implementation of the policy. It first met on 18 May 2010.

In all areas visited, including A&E, staff commented generally that there was ready access to equipment. However, we found some patients, who had been assessed as being at risk of developing pressure sores, not having the appropriate pressure relieving mattress or device. Staff said that access to this equipment was sometimes an issue. In April a review of pressure relieving equipment was commenced with an anticipation of the need to purchase additional pressure relieving equipment. Since the site visit the director of nursing has stated that there is a process in place to rent pressure relieving equipment in the interim.

In our observations in clinical areas, we found that individual items of equipment had been checked, and included relevant information such as the registration number, the date the appliance was next due to be tested, and a ‘do not use after’ date. The viability of some equipment is tested via audits.

The adverse incident reporting policy outlines the process for investigating incidents relating to equipment. Adverse incidents involving medical devices are reported to trust board. It is envisaged that key performance indicators will be developed by July 2010 to provide board assurance of compliance in the maintenance of equipment and medical devices. The trust needs to strengthen its assurance processes for maintaining and managing equipment and medical devices.
Staff competence in use of equipment

The trust has taken steps to ensure that equipment is used correctly and it can show that the majority of clinical staff are competent to use medical equipment. All nursing staff need to demonstrate they are competent in using the equipment before they are allowed to use it. A training programme is in place to support the development of competencies for nurses and this is closely monitored.

A baseline audit was undertaken to determine the competency of ward staff in use of 16 specified pieces of equipment. The audit demonstrated that 88% of nurses were competent on all pieces of essential ward equipment. This resulted in the development and introduction of a medical devices training plan to address the shortfall in skills identified. The information is held centrally on a database and used by the practice development team for monitoring nursing staff competencies. Separate information is held for doctors and for laboratory staff. The trust also runs mandatory training for clinical staff to raise awareness about their own responsibilities in using medical devices, including accessing training for the safe use of devices and reporting faulty equipment. Overall, 73% of staff had attended this training.

Staff reported that they were confident in using equipment in their clinical areas. There is a process for reporting faulty equipment (including during ‘out of hours’) and staff also told us they were aware of the process.

The risks relating to specific equipment are discussed by the trust’s board and at divisional clinical governance meetings, including clinical incidents and serious untoward incidents.
Outcome 13: Staffing

People who use services:
- Are safe and their health and welfare needs are met by sufficient numbers of appropriate staff.

This is because providers who comply with the regulations will:
- Make sure that there are sufficient staff with the right knowledge, experience, qualifications and skills to support people.
What we found for Outcome 13

Our judgement

The provider is compliant with Outcome 13: Staffing

Our findings

The trust has made significant progress in recruiting nursing staff. At 27 March 2010, it had an overall nursing vacancy rate of around 7%. This ranged across clinical areas from about –24% (i.e. overstuffed) to +17%. In four of the five clinical areas with a vacancy rate of more than 10%, appointments had been made but people had not yet taken up their posts. The trust projected that, with effect from 12 April 2010, the overall nursing vacancy rate would be about 5%. The trust has been closely supported by the SHA on nursing and workforce development issues.

The trust has an effective approach to covering vacancies. Where senior posts such as ward manager are vacant, the relevant matron focuses on that ward, supported by ward nurses ‘acting up’, until the new post holder is able to start. The trust has also changed its use of bank and agency staff: from 30% bank and 70% agency to 70% bank and 30% agency. This was reported following the September 2009 visit, and has been sustained.

The trust is undertaking a detailed examination of the nurse to patient ratios on the wards to ensure that the numbers of nurses match the needs of the patients. It is using tools developed by the Association of UK University Hospitals (AUKUH). This is a long-term project and the study has been completed twice so far (in September 2009 and January/February 2010). The trust increased budgeted establishments on the wards by 10.32 wte between the two studies. The findings of the January/February study indicate that the staffing numbers are generally about right and the trust intends to repeat the study later in 2010.

Absence due to sickness is high in some clinical areas and the trust needs to continue to tackle this. The average sickness rate (reported as 5.86% at 27 March 2010) is near the target sickness rate, but rates range from 0% to around 15% across the trust.

We sought direct feedback from 51 patients during the site visit to determine impact of staffing on patient experience. This included observation of the written care plans and of direct care being provided on medical and surgical wards. Staff interactions across the wards and departments visited was good. Patients told us that they understood the plan for their care. Call bells were generally accessible and where assistance was required, staff were responsive. Patients confirmed that where they needed it, assistance was being provided at mealtimes. Patients were observed to have water close to hand.
Outcome 16:
Assessing and monitoring the quality of service provision

People who use services:

- Benefit from safe quality care, treatment and support, due to effective decision making and the management of risks to their health, welfare and safety.

This is because providers who comply with the regulations will:

- Monitor the quality of service that people receive.
- Identify, monitor and manage risks to people who use, work in or visit the service.
- Get professional advice about how to run the service safely, where they do not have the knowledge themselves.
- Take account of:
  - comments and complaints
  - investigations into poor practice
  - records held by the service
  - advice from and reports by the Care Quality Commission.
- Improve the service by learning from adverse events, incidents, errors and near misses that happen, the outcome from comments and complaints, and the advice of other expert bodies where this information shows the service is not fully compliant.
- Have arrangements that say who can make decisions that affect the health, welfare and safety of people who use the service.
What we found for Outcome 16

Our judgement

The provider is compliant with Outcome 16: Assessing and monitoring the quality of service provision

Our findings

The trust has aligned its governance and reporting frameworks with the five key themes of its strategic vision: Creating a culture of caring; Seeing zero harm as its target by keeping patients safe; Listening, responding and acting on what patients and the community tell the trust; Supporting its staff to become excellent; giving responsibility but holding to account as well; Continuing to do what the trust needs to do to satisfy its regulators. The board meetings, weekly executive team meetings and healthcare governance committee (HGC) meetings are structured in line with these themes.

The trust has further developed its local governance arrangements at a divisional level. All groups meet monthly to discuss patient quality in their services, audits, clinical incidents, complaints, risks and staff training. In addition, monthly cross-divisional clinical governance meetings provide a mechanism for sharing learning across the divisions. The trust gave us evidence of improvements that have been made following incidents and feedback from patients, including complaints.

The trust now has a systematic process, involving all clinical directors, for monitoring and reviewing all patient deaths. The trust’s board receives data on mortality and other clinical outcomes on a monthly basis and the scrutiny of this information has improved. Mortality data is also discussed both at divisional clinical governance meetings and at the trust’s healthcare governance committee.

Clinical audit is led by the medical director and clinical staff reported being involved in audit activities. The structure for audit includes staff with responsibility for clinical audit (including a clinical lead in each of the eight clinical directorates) and groups at which audits and their findings are discussed. The extent to which clinical audit is embedded within the trust’s services and structures is variable. Some services, such as obstetrics and gynaecology, reported a long history of clinical audit. A&E has a more recent history of audit and audit is still developing in the surgical division. The trust now takes part in national audits and this enables them to compare their performance with that of other trusts.

At ward level, arrangements are in place to monitor the quality and safety of services and make sure that action is taken when risks are identified. Each ward is expected to undertake a monthly audit of its performance against a number of indicators. These include daily checking of controlled drug counts; daily checking of the ward resuscitation trolley; monthly hand hygiene audits; infections rates; and patient risk assessments in respect of slips/trips/falls, whether they need pressure relieving devices to prevent pressure sores, and nutritional requirements. Ward sisters are expected to produce action plans, which
must also be displayed, to quickly address any failings. Matrons hold ward sisters to account for making sure any necessary improvements are made.
Improvement actions

The table below shows where improvements should be made so that the service provider **maintains** compliance with the essential standards of quality and safety.

<table>
<thead>
<tr>
<th>Regulated activity</th>
<th>Regulation</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of disease, disorder or injury</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>Surgical procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic or screening procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternity and midwifery services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Why we have concerns</td>
<td></td>
<td>The outcome for people that should be achieved</td>
</tr>
<tr>
<td>The trust has demonstrated that it has procedures for managing patients attending as emergencies. Therefore the specific condition relating to regulation 9 may be removed. However this area remains a minor concern for the following reasons:</td>
<td></td>
<td>• An improvement in managing the time that patients remain in A&amp;E.</td>
</tr>
<tr>
<td>• There has been little improvement in managing the time that patients remains in A&amp;E.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Flows through the hospital are impacting on A&amp;E and this needs further improvement.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• There also needs to be improved governance of patients requiring a level 2 high dependency facility.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>We will re-assess regulation 9 as part of a planned review in August 2010. This review will include a request for an update on the trust’s progress against actions arising from the 12 month follow up review.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>11</td>
</tr>
<tr>
<td>Why we have concerns</td>
<td></td>
<td>The outcome for people that should be achieved</td>
</tr>
<tr>
<td>The trust has not adequately demonstrated that it has a</td>
<td></td>
<td>• An improvement in availability of and access to appropriate</td>
</tr>
</tbody>
</table>
The provider must send CQC a report about how they are going to maintain compliance with these essential standards.

This report is requested under regulation 10(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

The report should be sent within 28 days of this report being received.

CQC should be informed in writing when these improvement actions are complete.