# Review of compliance

## Mid Staffordshire NHS Foundation Trust

<table>
<thead>
<tr>
<th>Region:</th>
<th>West Midlands</th>
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| Location address: | Stafford Hospital  
                Weston Road  
                Stafford  
                ST16 3SA |
| Type of service: | Acute service |
| Date the review was completed: | December 2010 |

**Overview of the service:**  
Mid Staffordshire NHS Foundation Trust was authorised as a foundation trust on 1 February 2008. It operates and manages two hospitals, Stafford Hospital and Cannock Chase Hospital, as well as providing a number of outreach services in the community. It provides medical and surgical services in a range of specialities and has a specialist centre for rheumatology, serving a wider geographical area that includes Sutton Coldfield and North Birmingham.
Summary of our findings
for the essential standards of quality and safety

What we found overall

We found that Mid Staffordshire NHS Foundation Trust was not meeting all the essential standards. Improvements are needed to ensure that people receive services that meet the essential standards of quality and safety.

The summary below describes why we carried out the review, what we found and any action required.

Why we carried out this review

We carried out this review because concerns were identified in relation to:
- Management of medicines
- Supporting workers
- Assessing and monitoring the quality of service provision

How we carried out this review

We carried out an initial review of the information we already held about this provider that was relevant to the concerns that had been identified. This included the findings of our review of compliance of the trust with all sixteen of the essential standards of safety and quality published in October 2010. We also asked the provider for additional information relevant to the areas of concern. The information available did not provide us with sufficient evidence to reach a judgment on the issues identified.

We subsequently carried out an unannounced visit on 15 November 2010 to collect further information. We based our review at one of the two locations registered under the Health and Social Care Act 2008, Stafford Hospital. We talked with staff and checked some of the provider’s records in a number of areas of the trust, including theatres, maternity services and surgical ward areas. The concerns that prompted this review related to the management and monitoring systems within the trust. We therefore did not observe how people were being cared for or talk with people who use services as part of the review on this occasion.

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What we found about the standards we reviewed and how well Mid Staffordshire NHS Foundation Trust was meeting them

Outcome 9: People should be given the medicines they need when they need them, and in a safe way

- Overall, we found that improvements are needed for this essential standard.

The trust has systems in place to support the right patient receiving the right medicines at the right time, but there are gaps in compliance with these systems. The auditing of medicines management processes is incomplete and there are few examples of change as a result of this. The competence of staff to administer and handle medicines is not routinely checked or monitored and relies on self declaration and re-assessment after incidents or errors have occurred. These issues impact on the safe management of medicines in the trust.

We have assessed this as a moderate concern. This level of concern is unchanged from our review of compliance during the summer of 2010. At the end of November, the trust provided us with a report to show how it is going to achieve and maintain compliance with this outcome. We will evaluate the suitability of this action plan following this review.

Outcome 14: Staff should be properly trained and supervised, and have the chance to develop and improve their skills

- Overall, we found that improvements are needed for this essential standard.

We assessed the trust’s arrangements for monitoring the training and competence of staff. We found the trust has processes in place for identifying staff training needs and monitoring the extent to which these have been met through attendance at training or competence assessments. It recognises these need to be updated and integrated and the monitoring needs to be extended, so that it can be assured that staff receive the learning and development they need to carry out their roles and keep their skills up-to-date.

The trust has focused on improving staff attendance at annual mandatory training and about 90% of staff had attended this day, up to 30 September 2010. The trust has asked staff to assess whether or not they feel competent to use generic nursing equipment and 93% of the responses indicated that staff either did not need to use the items or felt competent to use them.

The trust has assurance that most staff have attended mandatory training days and feel competent to use the equipment they need. There are also examples of training and competency assessments taking place which are not recorded in the central system for monitoring training. The trust therefore has insufficient assurance that staff receive all the training they need.

We assessed this outcome as a moderate concern overall during the summer of 2010 because the trust had also not put a comprehensive supervision system in
place. We therefore did not remove the condition made at the time of registration, requiring it to ensure that supervision and appraisal systems were in place. At the end of November, the trust provided us with a report to show how it is going to achieve and maintain compliance with this outcome. We will evaluate the suitability of the action plan following this review.

**Outcome 16: The service should have appropriate systems for gathering, recording and evaluating accurate information about the quality and safety of the care, treatment and support the service provides, and its outcomes.**

- Overall, we found that improvements are needed for this essential standard.

We assessed some of the trust’s systems for assessing and monitoring the quality of its services and identifying, assessing and managing risks. When we reviewed the trust’s compliance during the spring of 2010, we found that it had made good progress in developing its systems for assessing and monitoring the quality of its services but these were not yet fully embedded. It had provided sufficient assurance of compliance that the condition of registration could be removed.

During this review of compliance, we found that these systems were not fully documented, integrated or embedded. This creates a risk that the trust does not have full assurance as to the quality of its services and whether or not it was appropriately identifying, assessing and managing any risks. However, we have assessed this as having a low impact on people using the service because assessing and monitoring systems are in place but the likelihood of it occurring is possible, because they are not fully integrated or embedded. This means it is a minor concern. This is an increased level of concern from our review of compliance during the summer of 2010. We are requiring the trust to send us a report about how it is going to achieve and maintain compliance with this essential standard.

**Action we have asked the service to take**

We have asked the provider to send us a report within 28 days of them receiving this report, setting out the action they will take to improve. We will check to make sure that the improvements have been made.

**Other information**

In our previous review, published in October 2010, we found that improvements were needed for the following essential standards:

Outcome 9: People should be given the medicines they need when they need them, and in a safe way

Outcome 14: Staff should be properly trained and supervised, and have the chance to develop and improve their skills

Outcome 17: People should have their complaints listened to and acted on properly
We also suggested that some improvements were made for the following essential standards:

Outcome 1: People should be treated with respect, involved in discussions about their care and treatment and able to influence how the service is run.

Outcome 4: People should get safe and appropriate care that meets their needs and supports their rights.

Outcome 7: People should be protected from abuse and staff should respect their human rights.

Outcome 10: People should be cared for in safe and accessible surroundings that support their health and welfare.

Outcome 11: People should be safe from harm from unsafe or unsuitable equipment.

Outcome 12: People should be cared for by staff who are properly qualified and able to do their job.

Outcome 13: There should be enough members of staff to keep people safe and meet their health and welfare needs.

Outcome 21: People’s personal records, including medical records, should be accurate and kept safe and confidential.

Please see our previous review report for more information.
What we found
for each essential standard of quality
and safety we reviewed
The following pages detail our findings and our regulatory judgement for each essential standard and outcome that we reviewed, linked to specific regulated activities where appropriate.

We will have reached one of the following judgements for each essential standard.

**Compliant** means that people who use services are experiencing the outcomes relating to the essential standard.

A **minor concern** means that people who use services are safe but are not always experiencing the outcomes relating to this essential standard.

A **moderate concern** means that people who use services are safe but are not always experiencing the outcomes relating to this essential standard and there is an impact on their health and wellbeing because of this.

A **major concern** means that people who use services are not experiencing the outcomes relating to this essential standard and are not protected from unsafe or inappropriate care, treatment and support.

Where we identify compliance, no further action is taken. Where we have concerns, the most appropriate action is taken to ensure that the necessary improvements are made. Where there are a number of concerns, we may look at them together to decide the level of action to take.

More information about each of the outcomes can be found in the *Guidance about compliance: Essential standards of quality and safety.*
Outcome 9: Management of medicines

What the outcome says

This is what people who use services should expect.

People who use services:
- Will have their medicines at the times they need them, and in a safe way.
- Wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf.

What we found

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<td>There are moderate concerns with outcome 9: Management of medicines</td>
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Our findings

The purpose of this review was to look at how medicines in the trust are managed and how the trust responds to medicines related incidents when they occur. We also looked at the understanding of both staff and the accountable officer within the trust of the role of the controlled drugs accountable officer with regard to the Safer Management of Controlled Drugs Regulations 2006.

We reviewed the information held in the quality and risk profile of the trust. There was information that reflected potential issues in the quality of information shared with patients about their medicines. The concerns that prompted this review related to the management and monitoring systems within the trust so we did not include this element in our review.

We had reviewed the trust’s compliance with this outcome during the summer of 2010. We identified moderate concerns because there were inconsistencies in prescribing practice and the standard of record keeping on the wards identified in audits completed. At the end of November, the trust provided us with a report to show how it is going to achieve and maintain compliance with this outcome. We will evaluate the suitability of this action plan following this review.

The trust has range of policies, procedures and clinical guidelines in place to ensure that medicines are prescribed and given to people safely. The trust’s Medicines Management Policy applies to all staff who prescribe, administer, dispense and
supply medicines, to include controlled drugs. The policy was last updated in September 2010. The policy describes the expected principles of practice to be followed by staff involved in the management of medicines. There are also Medicines Management Codes in place which support implementation of the policy. The codes describe the day to day operation of the policy, including the prescribing, administration and recording of medicines interventions.

The trust's management processes for ensuring that policies and guidance continue to support staff to maintain the safe management of medicines are not adequate. There was evidence of working policies and procedures being in place for a number of years without any evidence of review to ensure they remain up to date and consistent with published guidance. We found that the trust's Medicines Management Policy referred to specific training that staff in one clinical area were required to undertake but that staff working in this area were unaware that it was specified in the policy. Nursing and medical staff we spoke with told us that all trust policies were accessible through the trust intranet. The majority of nursing staff we spoke with confirmed that they followed identified practice in the management of medicines, to include controlled drugs, but that they were not aware of the supporting written guidance provided in the Medicines Management Codes.

The trust has systems in place to ensure that newly recruited nursing and medical staff have the competency and skills needed to handle medicines, including controlled drugs, safely. Medicines management training is a mandatory area of training for newly qualified nursing staff and junior doctors. We talked with nursing and medical staff who confirmed that medicines management was included in the induction programme for new staff. The training and nursing managers we talked with explained that the competence of newly qualified nursing staff is assessed during their first week in the trust through completion of a workbook and observation of practice on the wards. Additional training in intravenous (IV) drug administration and controlled drugs is then undertaken. Nursing staff we talked with confirmed this level of training and assessment had taken place and considered they felt confident to administer medicines, in line with the trust policy, following this training. A junior doctor described being supported in a range of ways including their consultant educational supervisors, pharmacists and a new electronic prescribing teaching package. The pharmacy programme provided includes training on the British National Formulary (BNF) and a medicines management module looking at prescribing through the review of case studies.

The trust has a range of ongoing support mechanisms in place to support staff in the safe management of medicines. All nursing staff we met with spoke positively about the level of pharmacy support provided on the wards and in theatres. All staff working on the wards confirmed that pharmacy staff attend the wards every day to review stocks, review medicines records, complete a reconciliation of medicines for patients and provide advice and guidance to staff. Nursing staff confirmed they could access supervision and support as they needed through nursing key trainers in medicines management in place on the wards and through the practice development team. Nursing staff also confirmed that they could access medicines management study days on request.

The ongoing assessment of competence in medicines management in the trust is
principally based on responding to concerns and errors, rather than a proactive ongoing programme to ensure that staff are competent to carry out their roles. The trust’s processes do not ensure that ongoing training needs and competencies in medicines management are routinely checked or monitored. There was no evidence of any formal programme of ongoing medicines management training for nursing staff. There were related areas of competency training, such as IV drug administration and the use of syringe drivers that are subject to mandatory updates for nursing staff. Ward managers we talked with described continued observation of nursing practice as part of the management of the ward but there was no formal requirement to assess nursing competencies relating to the management of medicines on an ongoing basis unless linked to a specific concern. There was evidence that the trust has processes in place linking performance and competency concerns to training and reassessment, but the approach across different professional groups is not consistent. There is a clear performance management process after a medication error. The Head of Pharmacy outlined the working arrangements to manage concerns with the practice of medical staff in the management of medicines, including junior doctors. These arrangements are currently not formally documented and remain under discussion with the medical director through the reports received by the clinical risk group and patient safety group.

The trust uses temporary staff on an ongoing basis on the wards. Nursing staff we talked with told us that it would be usual for qualified bank and agency staff to be involved in medicines administration. The risk and patient safety team confirmed that there has been an emerging trend in medication incidents involving agency staff. The quarterly medication incident report June to Sept 2010 reflects a number of medication incidents involving agency staff. A review of competencies and suspension from the agency cover list had been noted as actions taken in response to these incidents, with ongoing monitoring undertaken by the bank staffing team. The trust provided evidence of the induction and competency assessment process that bank staff are required to complete. The Practice Development Team confirmed that all agency staff are required to complete a workplace induction checklist before starting work on a ward for the first time, which includes confirmation of competency to undertake IV drug administration. Where the ward manager has concerns with the competency of an agency worker, information on competencies can be requested from the supplying agency.

The trust has a range of mechanisms in place for the reporting, monitoring and review of medicines incidents, including those relating to controlled drugs. Ward level incident data is reviewed and changes in practice identified as a result shared through meetings at ward and directorate level. All nursing and medical staff we talked with described receiving feedback and awareness of changes in practice being implemented following an incident. The Safe Medication Practice Group (SMPG) reviews all medication incidents reported and the learning identified. The annual report on medication incidents for 2009/10 reported a total of 403 adverse incidents reported in the trust. This was a significant increase on 339 incidents reported in 2008/2009 but no evidence of reasons for the increase or the action taken in response has been provided. The trust provided some evidence of learning from incidents reviewed but it was not always clear which actions had been completed. SMPG had not reviewed any medication incidents data and analysis for the current year 2010/11 since receiving the annual report for 2009/10 in May 2010.
This means there has been no ongoing timely review of issues identified through incident reports received by SMPG. Serious untoward medication incidents and related action plans are also reviewed and monitored in detail by the trust clinical risk group (CRG). There is a clear record of actions agreed that the group then monitor at each meeting to ensure completion or ongoing review whilst actions remain outstanding.

SMPG also has a role to ensure that medicines alerts received are implemented in the trust. The trust has a management and monitoring process in place to implement and act upon the recommendations in alerts issued. We followed an example of a medicines safety alert which led to new clinical guidance being developed in response and staff training being delivered to support its implementation under the coordination of the SMPG. We identified another medicines alert that was significantly overdue for completion and the trust was unable to confirm the reasons for this. This means that the process in place does not always ensure that recommendations for change are implemented.

There has been some integration of the role of the controlled drugs accountable officer within the governance arrangements of the trust. The use of controlled drugs is monitored through the routine reporting processes of the trust including the SMPG and CRG. The designated accountable officer is the chair of the clinical risk group although attendance at recent meetings has not been consistent. There was no evidence of direct reporting of incidents relating to the safer management of controlled drugs to the accountable officer in the trust. Nursing and medical staff we talked with were not generally aware who the controlled drugs accountable officer for the trust was, or the scope of that role. The Head of Pharmacy confirmed that they would discuss specific controlled drugs incidents with the accountable officer on a case by case basis. There has been ongoing engagement of the trust in the sharing of concerns in the management of controlled drugs through the Head of Pharmacy’s relationship with the Staffordshire Controlled Drugs Local Intelligence Network. We discussed the role of the controlled drugs accountable officer (AO) with the post holder by telephone conversation as part of this review. In that, he confirmed that operational AO responsibilities are delegated to the Head of Pharmacy, and that controlled drugs incidents would be discussed at the Local Intelligence Network though there were no reportable incidents at the last meeting. In the trust, these are brought to his attention, and that of the trust board, by reporting from the CRG. Another duty of the AO is to produce standard operating procedures for handling of controlled drugs. These are included within the Medicines Management Codes which describe the day to day operation of the Medicines Management Policy.

There was limited evidence of results from the systems of audit supporting the monitoring of the safety of medicines management in the hospital and examples of change as a consequence of this. There were medicines management audits taking place but these were not always consistent with the audits outlined in the Medicines Management Policy. Medicines audits do not form part of the trust wide clinical audit programme. Nursing staff and the Head of Pharmacy confirmed that operational compliance with the Medicines Management Policy is monitored daily through the pharmacist reviews completed on the wards. All nursing staff we talked with confirmed that a minimum of once daily, and in some places twice daily, controlled
drug stock checks take place on the wards. Any management and prescribing issues identified are followed up with medical and nursing staff at the time of the visit. The Head of Pharmacy confirmed that outcomes of the daily monitoring are not routinely formalised in writing or as an incident report.

The trust presented an overview of formal ward based audits completed or scheduled in 2010 across the wards and departments of the trust in response to our request for evidence of ongoing monitoring activity taking place. The information reflects that an annual audit of general medicines management arrangements in wards and departments takes place alongside a biannual audit specific to the management of controlled drugs. The information reflected that there was only one general medicines management audit outstanding out of 44 auditable areas in the trust. However, 24 out of 44 of auditable areas did not complete the controlled drugs audits scheduled in the first half of 2010. All controlled drugs audits scheduled since June 2010 to date had been completed. The Head of Pharmacy and nursing staff on the wards confirmed that outcomes from these audits had been discussed at ward level to agree improvements required but there had been no mechanism to report outcomes from these audits into the governance processes of the trust. This impacted on the ability of the trust to evidence that outcomes and learning from audit activity are considered and shared in a systematic and trust wide basis.

Our judgement
The trust has systems in place to support the right patient receiving the right medicines at the right time, but there are gaps in compliance with these systems. The auditing of medicines management processes is incomplete and there are few examples of change as a result of this. The competence of staff to administer and handle medicines is not routinely checked or monitored and relies on self declaration and re-assessment after incidents or errors have occurred. These issues impact on the safe management of medicines in the trust.

We have assessed this as a moderate concern. This level of concern is unchanged from our review of compliance during the summer of 2010. At the end of November, the trust provided us with a report to show how it is going to achieve and maintain compliance with this outcome. We will evaluate the suitability of this action plan following this review.
Outcome 14: Supporting workers

What the outcome says

This is what people who use services should expect.

People who use services:
• Are safe and their health and welfare needs are met by competent staff.

What we found

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<th>Our judgement</th>
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<td>There are moderate concerns with outcome 14: Supporting workers</td>
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<th>Our findings</th>
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<td>The purpose of this review was to look at the arrangements the trust has to ensure that people who use services are cared for and treated by staff who are given appropriate support, properly trained, supervised and appraised. We therefore assessed the trust’s arrangements for monitoring the training and competence of staff.</td>
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<td>When we registered the trust under the Health and Social Care Act 2008, we registered it with a condition for this outcome, requiring it to ensure that supervision and appraisal systems were in place and were recorded.</td>
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<td>We reviewed the trust's compliance with this outcome during the summer of 2010. We identified areas in which the trust had made good progress, which included attendance at induction and the corporate mandatory training day; in ensuring that staff are appraised; and in promoting whistleblowing. We had minor concerns because the trust had not provided any information about how it was assured staff receive all the training they need, and we had moderate concerns because it had not put a comprehensive supervision system in place. This meant that overall, although we recognised the progress the trust had made, we had a moderate level of concern for this outcome and we did not remove the condition made at the time of registration.</td>
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suitability of this action plan following this review.

We reviewed the information we hold about this outcome in the quality and risk profile of the trust. Three quarters of this information relates to the findings of the national staff survey, with the other data items relating to specific education or training issues or sickness absence. There is information that reflects concerns from the findings of the last staff survey but as this was undertaken in the autumn of 2009, the findings are no longer necessarily a reflection of the trust’s current position. We therefore considered that this information did not fall into the scope of this review. The next national staff survey is currently being conducted and the quality and risk profile will be updated with these findings when the reports are published.

During our visit on 15 November 2010, we looked at the trust’s arrangements for monitoring the training and competence of staff. Trust staff showed us their analysis of the training needs for all roles. They explained that information about essential training requirements had been put into the computer system that holds staff records, so that each member of staff's record showed essential training needs. They explained that information about courses staff attended to meet these training needs is also recorded on the same system. The trust can therefore report on essential training needs and the extent to which they have been met. These reports can provide information at a range of levels, from trust, through division, directorate and department, to individual. The trust provided us with a copy of a report that showed this.

Trust staff explained that not all training information was being held in this way and gave an example of training about dementia, which is held on a separate spreadsheet. We also met with maternity services managers who explained that they had a maternity services training needs analysis. Trust staff explained that information about staff competence to use equipment or perform certain procedures was also held separately and by different people. This means that, although the trust is able to monitor that staff receive the learning and development opportunities they need to carry out their role and keep their skills up to date, this cannot be done in a consistent way from a single system. This creates a risk that some training may not be monitored and some training needs may not be met.

Trust staff explained that the training needs analysis had been done about a year ago and needed to be updated so that it reflected the current training needs for staff roles. This would mean that, for example, the training about dementia would be included in the analysis. They explained that the training needs analysis also needed to be extended to ensure that core competences (also known as essential skills) are included. These relate to the use of generic nursing equipment, intravenous drug administration, oral drug competence for registered general nurses, and observations competences for healthcare support workers. They explained that the staff records also needed to be updated so that all the training needs are held in them. When the training needs analysis and staff records have been updated by 31 March 2011, the trust will have a complete picture of all the mandatory and essential skills training that is required for each role. Trust staff explained that information about other, more specialist, training and skills will continue to be maintained within service areas.
Trust staff explained that there has been a significant focus on improving staff attendance on the mandatory training days, at which a number of annual training needs are met, and reports on this are presented to the board each month. About 90% of staff had attended this day, up to 30 September 2010. This is a significant improvement on the 58% attendance up to 18 December 2009, reported at the end of January 2010. As outlined above, trust staff explained that they were able to provide reports on the take up of other types of training and provided us with a copy of a report that showed the extent to which training needs in 13 mandatory areas had been met. The percentages varied significantly between mandatory areas but overall, 60% of the training needs had been met. (The percentage of needs that had been met did not vary greatly between the different divisions.) Trust staff explained that they are extending the reporting about training in order to do more to assure themselves that staff are receiving the training they need to carry out their roles and keep their skills up-to-date. They will begin providing management reports monthly from January 2011.

Trust staff gave us a copy of the self-declaration statement of competence in the use of generic nursing equipment that staff were asked to complete during their induction. The form reminds staff that they should seek education if they are in any doubt about their competence to use equipment and asks them to consider four questions before declaring competence. These relate to knowing the purpose of the equipment and any contra-indications for use, feeling confident to use it safely, knowing what to do if there are any problems and being aware of health and safety and infection prevention issues. The self-declarations are also signed by the ward managers. We also saw a copy of the log compiled by the practice development unit that identified the items of equipment, whether or not staff needed to use them and whether or not they felt competent in their use. The self-declaration statements had been completed by 866 staff working in 53 clinical areas. 93% of the responses indicated that staff either did not need to use the items or felt competent to use them. Trust staff explained that ward managers were responsible for ensuring that staff received the training they required and that the self-assessments needed to be reviewed so that they were up-to-date and any training needs that were still outstanding could be met. This is an example of how staff competence is assessed on appointment and how assurance of competence is reported upwards to the practice development unit. Trust staff said that, by 31 March 2011, this information will be included in the staff records with the other mandatory and essential skills training.

Trust staff explained that they have a system of ‘key trainers’ for areas of clinical practice such as cannulation and venepuncture, intravenous drug administration, tissue viability and manual handling. Trust staff explained that key trainers receive initial training, followed by annual update training, and have a responsibility for cascading information to their colleagues and assessing their competence. One of the staff we talked with was a key trainer for a specific area of clinical practice on her ward and she explained how this worked in practice. She described how she had had her annual training in August 2010, after which she was approved to continue in this role. She explained that she had details of the staff who were competent in this area of clinical practice and that she would be reassessing their competence as their review dates arose. Information about this would be passed to the practice development midwife who in turn would report the information to both
the relevant maternity services governance group and the training and development
department. This is an example of how staff competence is routinely assessed at
ward level and how assurance of competence is then reported upwards to both the
clinical service and the training managers. By 31 March 2011, this information for
the core competences will be included in the staff records with the other mandatory
and essential skills training.

A few staff we talked with said they were aware of some occasions on which junior
staff were asked to provide cover in different clinical areas but did not feel
competent to do this and were uncomfortable about expressing their concerns. They
said that the more senior staff in their own clinical area were being supportive to
them.

We also looked specifically at training and assessment of competence in medicines
management and our findings are described in outcome 9.

Our judgement
We assessed the trust’s arrangements for monitoring the training and competence
of staff. We found the trust has processes in place for identifying staff training needs
and monitoring the extent to which these have been met through attendance at
training or competence assessments. It recognises these need to be updated and
integrated and the monitoring needs to be extended, so that it can be assured that
staff receive the learning and development they need to carry out their roles and keep
their skills up-to-date.

The trust has focused on improving staff attendance at annual mandatory training
and about 90% of staff had attended this day, up to 30 September 2010. The trust
has asked staff to assess whether or not they feel competent to use generic nursing
equipment and 93% of the responses indicated that staff either did not need to use
the items or felt competent to use them.

The trust has assurance that most staff have attended mandatory training days and
feel competent to use the equipment they need. There are also examples of training
and competency assessments taking place which are not recorded in the central
system for monitoring training. The trust therefore has insufficient assurance that
staff receive all the training they need.

We assessed this outcome as a moderate concern overall during the summer of
2010 because the trust had also not put a comprehensive supervision system in
place. We therefore did not remove the condition made at the time of registration,
requiring it to ensure that supervision and appraisal systems were in place. At the
end of November, the trust provided us with a report to show how it is going to
achieve and maintain compliance with this outcome. We will evaluate the suitability
of this action plan following this review.
Outcome 16: Assessing and monitoring the quality of service provision

What the outcome says

This is what people who use services should expect.

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.

What we found

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<td>There are minor concerns with outcome 16: Assessing and monitoring the quality of service provision</td>
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The purpose of this review was to look at some of the trust’s systems for assessing and monitoring the quality of its services and identifying, assessing and managing risks.

When we registered the trust under the Health and Social Care Act 2008, we registered it with a condition for this outcome, requiring it to ensure that governance and audit systems to assess and monitor the quality of service provision were in place across all services.

We reviewed the trust’s compliance with this condition during the spring of 2010 and found that the trust was able to demonstrate that it had governance and audit systems in place across all services. We also found that the trust had made good progress in engaging clinicians and developing effective clinical audit, but that this was not yet fully embedded. We reported that the trust needed to monitor those areas to ensure the arrangements became embedded. We found that the trust had provided sufficient assurance of compliance that the condition of registration could be removed.

When we undertook our planned review of compliance during the summer of 2010, we did not seek any additional evidence because we had reported on this outcome.
in July 2010, when the registration condition was removed.

We reviewed the information we hold about this outcome in the quality and risk profile of the trust. The information relates to a range of issues including clinical audit and incident reporting. There is information that indicates potential issues in the timeliness of responding to centrally issued alerts and participation in or reporting on some national audits. This indicates that the trust's arrangements for assessing and monitoring the quality of service provision may not be sufficiently robust.

The trust has a corporate governance structure, which is published on its website. This shows a number of committees reporting to the trust board, including a healthcare governance committee. The healthcare governance committee has three sub-groups, covering patient care, patient safety and patient experience. Each of these has a number of groups that focus on specific issues such as clinical audit and clinical risk. There are also governance meetings for the different directorates. This structure means that there are opportunities for quality and safety issues to be discussed across the trust (at the sub-groups, for example) and within clinical services (in the directorate governance meetings).

Trust staff gave us copies of the minutes of recent meetings of the clinical risk group, which showed that serious incidents were being reviewed and action plans were developed to make improvements. The group also reviewed corporate and clinical risks. This indicates that the trust's arrangements are being implemented.

During our 12 month review of the progress that the trust had made in implementing the recommendations of the Healthcare Commission's investigation report, we found that the surgical, clinical support services and facilities divisions all had governance meetings, as did each of the three directorates in the medical division (emergency care, acute medical specialties and out-patient services). All groups met monthly to discuss patient quality in their services, audits, clinical incidents, complaints, risks and staff training.

During our visit on 15 November 2010, we met with the maternity services managers who explained how this worked in practice, by describing their clinical governance arrangements to us. They explained that there is a maternity services governance meeting, which reviews information about a range of issues including the experiences of people who use services, clinical practice, training and incidents. They therefore oversee the quality and safety of maternity services and take action to introduce improvements and address shortfalls. They explained how they integrate with the wider trust governance arrangements by giving an example of their clinical practice group. They explained that they consider clinical policies and guidelines relevant to their services. They therefore have the authority to approve these documents if they are specific to maternity services but other groups have to approve these documents if they cover other services as well. They gave us a copy of a report that the maternity services clinical practice group had just presented to the maternity services governance meeting, showing liaison with colleagues across the trust and the different approval routes. They explained that maternity services staff sit on a number of other groups but they felt that they were not fully integrated with the wider trust governance arrangements. This creates a risk that different decisions might be made in different parts of the trust.
All the staff we talked with were clear that they would find the most recent copies of the policies and procedures that they need on the trust’s intranet. They also reported that they were told when these were updated. This indicates that staff are clear about where they can find policies and procedures when they need them and reduces the risk that different staff will be using different policies and procedures across the trust.

On 13 and 14 October 2010, the NHS Litigation Authority (NHSLA) assessed the trust against its risk management standards for acute trusts at level 1. At this level, trusts are only required to demonstrate that the process for managing specific risks has been described in approved documents. The outcome of the assessment was that the trust did not pass sufficient criteria to gain compliance at level 1. The NHSLA has recognised that the trust’s recent focus has been on improving the delivery of care to people who use services and implementing revised governance arrangements, rather than documenting the arrangements and processes to manage risk. This therefore created a difficulty with the level 1 assessment, which is document based. The trust has been offered an improvement period, during which it can rectify the areas of non-compliance. There will be a reassessment against the governance standard and its criteria in mid January 2011 and, assuming compliance is achieved, a reassessment of all the other standards and their criteria before the end of March 2011. This means that the trust’s process for managing specific risks has not been sufficiently described in approved documents.

We also looked at audits of medicines management and reporting of medicines management incidents and our findings are described in outcome 9.

Our judgement
We assessed some of the trust’s systems for assessing and monitoring the quality of its services and identifying, assessing and managing risks. When we reviewed the trust’s compliance during the spring of 2010, we found that it had made good progress in developing its systems for assessing and monitoring the quality of its services but these were not yet fully embedded. It had provided sufficient assurance of compliance that the condition of registration could be removed.

During this review of compliance, we found that these systems were not fully documented, integrated or embedded. This creates a risk that the trust does not have full assurance as to the quality of its services and whether or not it was appropriately identifying, assessing and managing any risks. However, we have assessed this as having a low impact on people using the service because assessing and monitoring systems are in place but the likelihood of it occurring is possible, because they are not fully integrated or embedded. This means it is a minor concern. This is an increased level of concern from our review of compliance during the summer of 2010. We are requiring the trust to send us a report about how it is going to achieve and maintain compliance with this essential standard.
Compliance actions

The table below shows the essential standards of quality and safety that were reported as **not being met** during our review of compliance, published in October 2010. The trust has provided us with an action plan report to show how it is going to achieve and maintain compliance with these essential standards. We will evaluate the suitability of the action plan following this review.

<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>13 Management of medicines</td>
<td>9</td>
</tr>
<tr>
<td>Assessment or medical treatment for persons detained under the 1983 Act.</td>
<td></td>
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<tr>
<td>Surgical procedures</td>
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<tr>
<td>Diagnostic or screening procedures</td>
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<tr>
<td>Maternity and midwifery services</td>
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<td></td>
</tr>
<tr>
<td><strong>How the regulation is not being met:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are inconsistencies in practice and the standard of record keeping on the wards.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>The outcome for people that should be achieved:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>People who use services are assured that medicines are prescribed and documented accurately.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment of disease, disorder or injury</td>
<td>23 (1) Supporting workers</td>
<td>14</td>
</tr>
<tr>
<td>Assessment or medical treatment for persons detained under the 1983 Act.</td>
<td></td>
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<td>Surgical procedures</td>
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<tr>
<td>Maternity and midwifery services</td>
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</tr>
<tr>
<td><strong>How the regulation is not being met:</strong></td>
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</tr>
<tr>
<td>The trust has not put a comprehensive supervision system in place that is monitored and reviewed.</td>
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<tr>
<td><strong>The outcome for people that should be achieved:</strong></td>
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</tr>
<tr>
<td>People who use services are assured that staff can talk through any issues about their role, or about the people they provide care, treatment and support to.</td>
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</table>

CQC should be informed in writing when these compliance actions are complete.
The table below shows the additional essential standard of quality and safety that **is not being met**. Action must be taken to achieve compliance.

<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>10 Assessing and monitoring the quality of service provision</td>
<td>16</td>
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<tr>
<td>Assessment or medical treatment for persons detained under the 1983 Act.</td>
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<tr>
<td>Surgical procedures</td>
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<tr>
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<td></td>
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<tr>
<td>Maternity and midwifery services</td>
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</tbody>
</table>

**How the regulation is not being met:**
We assessed some of the trust’s systems for assessing and monitoring the quality of its services and identifying, assessing and managing risks. When we reviewed the trust’s compliance during the spring of 2010, we found that it had made good progress in developing its systems for assessing and monitoring the quality of its services but these were not yet fully embedded. It had provided sufficient assurance of compliance that the condition of registration could be removed.

During this review of compliance, we found that these systems were not fully documented, integrated or embedded. This creates a risk that the trust does not have full assurance as to the quality of its services and whether or not it is appropriately identifying, assessing and managing any risks. However, we have assessed this as having a low impact on people using the service because assessing and monitoring systems are in place but the likelihood of it occurring is possible, because they are not fully integrated or embedded. This means it is a minor concern. This is an increased level of concern from our review of compliance during the summer of 2010. We are requiring the trust to send us a report about how it is going to achieve and maintain compliance with this essential standard.

The provider must send CQC a report that says what action they are going to take to achieve compliance with this essential standard.

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

The provider’s report should be sent to us within 28 days of this report being received.

CQC should be informed in writing when these compliance actions are complete.
What is a 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 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, called *Guidance about compliance: Essential standards of quality and safety*.

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

When making our judgements about whether services are meeting essential standards, we 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 or compliance actions, or take enforcement action:

**Improvement actions**: These are actions a provider should take so that they maintain 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.

**Compliance actions**: These are actions a provider must take so that they achieve 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.

**Enforcement action**: 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.
### Information for the reader

<table>
<thead>
<tr>
<th><strong>Document purpose</strong></th>
<th>Review of compliance report</th>
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<tbody>
<tr>
<td><strong>Author</strong></td>
<td>Care Quality Commission</td>
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<td>The general public</td>
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### Care Quality Commission

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<tr>
<td><strong>Telephone</strong></td>
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<td><strong>Email address</strong></td>
<td><a href="mailto:enquiries@cqc.org.uk">enquiries@cqc.org.uk</a></td>
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</tbody>
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