NHS Litigation Authority

Risk Management Standards for Acute Trusts

Level 1 Assessment of Northern Devon Healthcare NHS Trust

25th and 26th May 2010
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The comments and findings of the assessment recorded in this report reflect the opinions of the assessor(s) based on the evidence provided by the organisation in relation to the requirements contained in the relevant standards manual. They should not be read as approval or comment in any other context.
1: Executive Summary

On Tuesday 25th and Wednesday 26th May 2010, Det Norske Veritas (DNV) on behalf of the NHS Litigation Authority (NHSLA) conducted a Level 1 assessment of Northern Devon Healthcare NHS Trust.

This assessment was based on the NHSLA Risk Management Standards for Acute Trusts 2010/11. The key findings and recommendations are summarised in this report.

The organisation was assessed against five standards each containing ten criteria giving a total of 50 criteria. In order to gain compliance at Level 1 the organisation was required to pass at least 40 of these criteria, with a minimum of seven criteria being passed in each individual standard. The organisation scored as follows:

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Detailed scores can be found in the organisation’s evidence template which is a separate document that records the evidence reviewed and the compliance awarded at the assessment.

These scores indicate that the organisation was successful in achieving compliance at Level 1 of the standards and as such will continue to receive a 10% discount from their CNST and RPST contributions. The discount will be applied from the beginning of the financial quarter following the date of the assessment visit for the following 24 months thereafter or until such time as the organisation undergoes further assessment.

In accordance with NHSLA and scheme requirements, the organisation will need to be re-assessed against the standards no later than the anniversary date of the last assessment, i.e. by 25th May 2012. Organisations that request an early assessment may choose to be assessed at any time. When an organisation has achieved Level 1 it may apply for assessment at the next level from the following financial year. However, in order to ensure that their systems are embedded, organisations are advised to wait at least 24 months before being assessed at the next level. It is important to note that organisations which perform badly at assessment will drop to a lower level and can potentially drop to Level 0.
Prior to formal assessment the organisation was encouraged to conduct a self-assessment. The organisation’s self-assessment results are depicted below and plotted against the actual assessment results.

Chart 1: Comparison of the organisation’s self-assessment to actual assessment outcome
Overall summary of the organisation’s compliance

Northern Devon Healthcare NHS Trust was successful in demonstrating compliance with the Level 1 requirements of the NHSLA Risk Management Standards for Acute Trusts 2010/11, scoring 46 out of 50.

Key recommendations for the future

The organisation is congratulated on achieving compliance against Level 1 of the NHSLA Risk Management Standards. It was noted, that the organisation had worked very hard to prepare and update the documents required in support of the assessment. However, it is important to remember that whilst a high score has been achieved at Level 1, the content of the documentation is not fully tested until the Level 2 assessment.

The majority of the criteria within the NHSLA Standards require a documented description of a process. Whilst sufficient information was available to achieve compliance at Level 1, a number of documents presented at assessment lacked specific detail of process, and as such, will struggle to evidence compliance at the higher levels. The organisation is therefore advised that prior to further assessment, approved documents should be revised to ensure that where the description of a process is required, that these should be explicit, unambiguous, and clearly reflect practice and the expectations of the organisation. Where a process is described within more than one document there should be clear cross referencing between these. Where insufficient detail of a process has lead to non-compliance, this has been noted within the body of the report.

The organisation is advised that when reviewing its approved documents that it ensures there is a distinct flow to the narrative. Process information that is contained within the duties or monitoring sections of the documents should be removed to allow for a structured flow.

During the course of the assessment, the assessor came across several areas where essential information was captured as a separate document and available on the organisations website, Tarkanet, or in an associated document or appendix which had not been cross referenced or signposted. The organisation is advised that where associated documents are relevant, that these are clearly cross referenced and signposted.

When reviewing any documentation, attention should be paid to ensuring national guidance documents are referenced and that the most up to date version is identified; please see comments in the body of the report.

Several of the criteria within the NHSLA Standards require a documented description of the organisation’s requirements in relation to staff training, as identified in the training needs analysis. The assessor noted conflicting statements within the approved document and the training needs analysis. Any inconsistencies may lead to greater risk and should therefore be amended. Where this has occurred, it has been identified within the body of the report.

Each of the criteria within the NHSLA Standards requires a documented description of a proactive process for monitoring compliance with the minimum requirements. Whilst the organisation has clearly attempted to include detail of how monitoring will occur, for example who will be tasked with this responsibility, when monitoring will be
conducted and the frequency of conducting this, this was not consistent across for all minimum requirements. The organisation is reminded that it is also necessary to detail how gaps in the process will be addressed if deficiencies are identified through the monitoring process and where this will be reported to. The organisation is therefore advised to ensure this detail is included in all documentation at Level 1 to allow progression through the assessment levels and demonstration of the monitoring process at Level 3.

The documentation presented as evidence at the assessment will prove difficult for the organisation to move up the assessment levels for all the reasons described above. It is therefore advisable that prior to booking a higher level assessment, a full and honest self assessment is completed to avoid a subsequent disappointing result. Additional assistance can be obtained via the annual informal visits available to members of the NHSLA schemes; template documents, and a handbook of supporting information which are available at www.nhsla.com/RiskManagement/
2: **Assessment Results**

**Standard 1: Governance**

**Overview**

Effective functioning of the board, managerial leadership and accountability, and the organisation’s systems and working practices will ensure that quality assurance, quality improvement and patient safety are central to the activities of the healthcare organisation. Organisations should apply the principles of sound corporate governance. Board level responsibility for risk management should be clearly defined and there should also be clear lines of individual accountability for managing risk throughout the organisation leading to the board. Organisations should undertake systematic risk assessment and risk management. Risk management should be fully embedded in the organisation’s management processes. All relevant employees, whether permanent or temporary, should be registered with the appropriate professional body and have undergone the required employment checks prior to working within the organisation.

A score of ten out of ten was awarded in this standard.

**Key findings and recommendations**

The organisation is congratulated on achieving full compliance with this standard.

For three criteria within this standard, assurance was taken from the Audit Commission’s ALE KLOE 4.1 scores. The organisation was successful in gaining a Level 2 score against the ALE KLOE requirements for 4.1 in the last 12 months and therefore compliance has been awarded.

1.1.4 **Risk Awareness Training for Senior Management**

1.1.5 **Risk Management Process**

1.1.6 **Risk Register**

1.1.8 **The organisation has an approved documented process for managing the risks associated with paper and electronic health records.**

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.

The organisation provided the *Healthcare Records Policy* (May 2010) in support of this criterion. Whilst the approved document contained sufficient detail to gain compliance at Level 1, the document lacked specific detail in relation to minimum requirement f) ‘process for retention, disposal and destruction of records’; and may prove difficult to evidence at the higher levels of assessment. On further probing, the assessor did see the *Retention and Destruction of Case Notes Guidelines* (undated), which does clearly describe which records are selected for retention or destruction, and how they are identified on the tracking system. Whilst the guideline contained sufficient detail of the process, there was no cross reference or signposting within the
Healthcare Records Policy to the document. The organisation is reminded that associated documents must be approved, dated, and clearly cross referenced.

Additionally, in relation to minimum criterion g) ‘process for monitoring compliance with all of the above’; Section 21.1 refers to an annual periodic review, and states that “The results of the audit will be fed back to the Information Governance Documentation Group”. It is not clear that the audit tool will include monitoring of all the minimum requirements a-f. The organisation is advised to ensure that the monitoring section clearly describes how all of the minimum requirements within the criterion will be monitored.
Standard 2: Competent & Capable Workforce

Overview

The organisation has a responsibility to deliver a safe service to patients by ensuring all staff are appropriately skilled. To ensure that both temporary and permanent staff are adequately equipped to work in a healthcare environment and provide care to patients they must receive training and support, both on initial appointment and on an ongoing basis. By ensuring effective, ongoing training and support, the organisation is promoting the delivery of high quality focused care as well as facilitating staff safety and wellbeing.

A score of nine out of ten was awarded in this standard.

Key findings and recommendations

1.2.1 The organisation has an approved documented process for ensuring the corporate induction arrangements for all new permanent staff.

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.

The organisation provided the Induction Policy (March 2010) in support of this criterion. Minimum requirement c) requires a ‘description of the minimum content of corporate induction programme(s)’. Section 3.2 under the heading of definitions, describes a definition of Corporate Induction. The approved document does not contain a description of the content of the programme; however; the course content is available on the organisations web site known as Tarkanet, which is accessible to all staff, therefore, overall compliance has been awarded. The organisation is advised that there should be clear signposting and cross reference to associated documents, and are strongly advised to ensure that appropriate cross referencing and signposting to associated documents is included when the document is next updated.

Additionally, whilst the approved document contained sufficient information to obtain compliance at Level 1, the document lacked specific detail in relation to minimum requirements d) ‘process for checking that all new permanent staff complete corporate induction’; and e) ‘process for following up those who fail to attend corporate induction’. Both minimum requirements are assessed at the higher levels; the level of description within the approved document at present may prove difficult to evidence at the higher level assessment.

1.2.2 The organisation has an approved documented process for ensuring the local induction arrangements for all new permanent staff.

1.2.3 The organisation has an approved documented process for ensuring the local induction arrangements for all temporary staff.

Compliance was awarded for both criterion; however the organisation is advised to consider the following comments.

As discussed in 1.2.1 above, the level of the detail contained within the Induction Policy (March 2010), contained sufficient information to obtain compliance at Level 1,
but lacked specific detail in relation to processes for the two minimum requirements c) and d) which go forward to the higher levels of assessment in both of these criterion. The organisation is advised that it may prove difficult to evidence these processes at the higher level assessment with the current level of description within the approved document. The organisation may find the Template Document for the Management of Corporate and Local Induction helpful, which is available on the NHSLA website at www.nhsla.com/RiskManagement/.

1.2.4 Supervision of medical staff in training.

Compliance has been awarded for this criterion.

The organisation has met PMETB’s minimum requirements for supervision set out in Domain 6 of the PMETB generic standards for training as determined by the evidence available through the Quality Framework, which includes data from the National Survey of Trainees and Trainers, information from Annual Deanery Reports (ADRs), Annual Specialty Reports (ASRs) and Visit to Deanery Reports.

1.2.5 The organisation has an approved documented process for ensuring a systematic approach to risk management training for all permanent staff.

Compliance was not awarded in this criterion.

The Training and Study Leave Policy (May 2010), presented in support of this criterion appeared to be a document aimed at ensuring staff attend training, and to secure funding for specific courses; it did not include sufficient detail in relation to minimum requirements a) ‘process for developing a training needs analysis which must include all those topics referred to in the TNA Minimum Data Set’, b) ‘process for developing action plan(s) to deliver the training identified within the training needs analysis’, d) ‘process for checking that all permanent staff complete the relevant training programmes in accordance with the training needs analysis’, e) ‘process for following up those who fail to attend relevant training programmes’, and f) ‘process for coordinating training records’. On further probing, the assessor reviewed the Education and Training Strategy 2009 – 2012 (undated), this document also, failed to provide the level of detail required in relation to this criterion, and therefore compliance could not be awarded.

The organisation is strongly advised to review the strategic processes for systematically managing risk management training and ensure that all such processes and organisational expectations are clearly described in the appropriate approved document. Furthermore, all approved documents should be dated, and version control clearly and accurately stated. The organisation may find the Template Document for Ensuring a Systematic Approach to Risk management Training helpful, which is available on the NHSLA website at www.nhsla.com/RiskManagement/.

1.2.7 The organisation has an approved documented process for ensuring that all permanent staff are trained to safely use diagnostic and therapeutic equipment appropriate to their role.

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.
The *Policy for the training and assessment of competency for using medical devices* (April 2010) was reviewed in support of this criterion. The organisation may wish to consider adding additional information in relation to how the inventory of diagnostic and therapeutic equipment used within the organisation is populated, and where the inventory is held to allow for accurate monitoring and assurance that systems and processes are in place and working effectively.
Standard 3: Safe Environment

Overview

It is essential to provide a safe and secure environment in order to facilitate high quality clinical care. The environment should be safe for staff, patients and their visitors in order to prevent accidents, injury and disease. Risk of violence, bullying, harassment, and stress should be managed and minimised and the workplace should be one in which sickness absence can be managed sensibly and effectively.

A score of nine out of ten was awarded in this standard.

Key findings and recommendations

1.3.2 The organisation has an approved documented process for managing the risks associated with sickness absences.

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.

The Sickness and Absence Management Policy (May 2010) was presented in support of this criterion. The level of the detail within the approved document contained sufficient information to obtain compliance at Level 1, but lacked specific detail in relation to processes for the two minimum requirements, e) ‘process for analysing sickness absence data’ and f) ‘arrangements for the organisational overview of sickness absence’, which go forward to the higher levels of assessment in this criterion. The organisation is advised that it may prove difficult to evidence these processes at the higher level assessment with the current level of description within the approved document. Additionally, the organisation is reminded that the monitoring section should include arrangements for the monitoring of all minimum requirements a to f.

1.3.7 The organisation has an approved documented process for managing the risks associated with the maintenance of reusable medical devices and equipment.

Compliance was not awarded in this criterion.

The Management of Medical Devices Policy (May 2010) did not contain a description in support of minimum requirement d) ‘process for checking that calibration of all reusable medical devices is completed within specified time frames’. On further probing, the assessor was informed that the process for calibration of reusable medical devices was performed by a department outside of the Electronics and Biomedical Engineering (EBME) Department and therefore had not been considered for inclusion within the submitted document. For these reasons compliance could not be awarded.

The organisation is advised to ensure that all processes for managing the risks associated with the maintenance of reusable medical devices and equipment, including the processes for calibration are clearly described within an approved document.
1.3.9  The organisation has an approved documented process for managing the risks associated with the prevention and management of violence and aggression.

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.

In regard to minimum requirement d) ‘organisation's expectations in relation to staff training, as identified in the training needs analysis’; Appendix E of the Managing Violence and Aggression Policy (April 2008), contained a guide to available training for managing violence and aggression. The assessor noted that the training identified within Appendix E was different to the training identified as described within the organisational Training Needs Analysis available on Tarkanet.

The organisation is advised to ensure that where expectations of training are described within an approved document, that they accurately correspond to the information provided on the organisations training needs analysis.
Standard 4: Clinical Care

Overview

The care provided within a clinical environment should be of the highest quality. To support this, robust guidelines and policies should be in place for all clinical care procedures. Some of the higher volume and higher risk processes have been selected for assessment by the NHSLA, namely: patient identification, consent, blood transfusion, medicines management and resuscitation. Care should be provided in such a way as to minimise the risk of hospital associated infection. It is particularly important to ensure patients have clear information when undergoing procedures and that accurate information is shared during transfer and discharge. To underpin these care processes, systematic approaches must be in place to ensure there is effective communication between staff, patients and others and that high standards of record keeping are consistent across the organisation.

A score of eight out of ten was awarded in this standard.

Key findings and recommendations

1.4.1 The organisation has an approved documented process for managing the risks associated with the identification of patients.

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.

The organisation may wish to consider including the latest national guidance in relation to patient identification in their Patient Identification Policy which was reviewed and approved (May 2010). References in support of the risk management standards are available in the handbook available on the NHSLA website at www.nhsla.com/RiskManagement/

1.4.5 The organisation has an approved documented process for managing the risks associated with the transfer of patients.

Compliance was not awarded in this criterion.

At Level 1, this criterion contains the following pilot minimum requirement, b) ‘definition of all patient groups’. Whilst compliance against the minimum requirement has been automatically awarded the organisation may wish to consider the following point. The organisation provided the Bed Management Policy (July 2008) in support of this criterion. The classification of patient groups within the approved document was limited, and did not appear to capture those patient groups that are more vulnerable or high risk, including children.

Furthermore, the approved document did not provide sufficient detail in support of minimum requirement c) ‘transfer requirements which are specific to each patient group’. A generic pre transfer form was noted at Appendix C, however, this did not appear to consider groups of patients that may fall within a complex transfer category. Additionally, the document did not contain a description in support of minimum requirement e) ‘process for transfer out of hours’ and for these reasons overall compliance has not been awarded.
The organisation is advised to ensure that the process for managing the risks associated with the transfer of patients are clearly described within the approved document, and particularly for those groups of patients that fall within the high risk, complex transfer category.

**1.4.6 The organisation has an approved documented process for managing the risks associated with medicines in all care environments.**

Compliance was not awarded in this criterion.

Compliance could not be awarded as the approved document, the Medicines Policy, (February 2010), whilst being a very comprehensive and easily navigable document; did not include a description in support of minimum requirement b) ‘process for ensuring the accuracy of all prescription charts’.

When updating the approved document to include the process of ensuring the accuracy of all prescription charts; the organisation is reminded that this minimum requirement is taken forward to the higher levels; and therefore any statement included within the document should be explicit; clearly describing the detail of the process and the responsibilities of those that partake in the process.

**1.4.8 The organisation has an approved documented process for managing the risks associated with resuscitation.**

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.

In regard to minimum requirement f) ‘organisation’s expectations in relation to staff training, as identified in the training needs analysis’; Appendix A of the Resuscitation Policy (December 2008), contained a guide to available training for managing risks associated with resuscitation. The assessor noted that the information regarding levels of training differed from that which was identified in appendix A and that which is available on the organisational Training Needs Analysis available on Tarkanet.

The organisation is advised to ensure that where expectations of training are described within an approved document, that they clearly correspond to the information provided on the organisations training needs analysis.

Additionally, in relation to minimum requirement e) ‘process for ensuring the continual availability of resuscitation equipment’; the approved document did not specify what equipment would be expected to be available in which areas. The lack of description appears to have impacted on the monitoring arrangements in regard to this minimum requirement, as currently the description for monitoring is vague. The organisation is advised to strengthen these areas within the approved document prior to going for assessment at the higher levels.

**1.4.9 The organisation has an approved documented process for managing the risks associated with infection prevention and control.**

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.

As discussed above in 1.3.9 and 1.4.8, the assessor noted that the information regarding levels of training differed from that which was identified in Appendix H of
the Infection Prevention and Control Operational Policy (May 2010), and that which is available on the organisational Training Needs Analysis available on Tarkanet.

The organisation is advised to ensure that where expectations of training are described within an approved document, that they clearly correspond to the information provided on the organisations training needs analysis.
Standard 5: Learning from Experience

Overview

All healthcare organisations should have in place robust systems for the reporting, management and investigation of adverse events (incidents), ill health and hazards, including those that result in no harm, which will help to facilitate organisational learning. Organisations should apologise and explain what happened to patients who have been harmed as a result of their healthcare treatment. Concerns, complaints and claims, when examined in conjunction with all reported adverse events, allow trends to be identified, at both a local and strategic level, and changes to be implemented. This can lead to the prevention or recurrence of incidents, complaints and claims. The sharing of lessons learnt from one service to other areas of the organisation helps to ensure that any system failures discovered during investigations are addressed by the organisation as a whole and pockets of good practice are not isolated. Organisations should consider and implement appropriate external guidance to enable the organisation to operate as safely as possible.

A score of ten out of ten was awarded in this standard.

Key findings and recommendations

The organisation is congratulated on achieving full compliance with this standard.

1.5.2 The organisation has an approved documented process for managing the risks associated with the reporting of all internally and externally reportable incidents.

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.

The Incident Reporting Policy, (November 2007) was submitted in support of this criterion. Whilst the approved document contained sufficient information to gain compliance at Level 1 in relation to minimum requirement c), ‘process for reporting to external agencies’; the organisation is advised that the current level of detail may prove difficult to evidence at the higher levels.

The organisation may wish to consider strengthening the description of the process for reporting to external agencies prior to further assessment.

1.5.5 The organisation has an approved documented process for investigating all incidents, complaints and claims.

Compliance was awarded in this criterion; however the organisation is advised to consider the following comments.

As discussed above in 1.3.9, 1.4.8, and 1.4.9, the assessor noted that the information regarding training differed from that which was identified in Appendix B of the Investigation Policy (May 2010); and that which is available on the organisational Training Needs Analysis available on Tarkanet.
The organisation is advised to ensure that where expectations of training are described within an approved document, that they clearly correspond to the information provided on the organisation's training needs analysis.
Appendices

Appendix A: The NHS Litigation Authority

Background

The NHS Litigation Authority (NHSLA) is a Special Health Authority, which was established in 1995 to administer the Clinical Negligence Scheme for Trusts (CNST) and thereby provide a means for NHS organisations to fund the cost of clinical negligence claims. Almost immediately the NHSLA’s role expanded to cover clinical claims arising from incidents occurring before 1995, known as the Existing Liabilities Scheme (ELS). In 1999 the Liabilities to Third Parties Scheme (LTPS) and Property Expenses Scheme (PES), together known as the Risk Pooling Schemes for Trusts (RPST), were established to fund the cost of legal liabilities to third parties and property losses.

The promotion of good risk management, governance and assurance are integral components of the NHSLA schemes.

Membership of the schemes is voluntary and open to all NHS trusts, NHS Foundation Trusts and PCTs in England. Funding is on a pay-as-you-go non-profit basis, and organisations receive a discount on their scheme contributions where they can demonstrate compliance with the relevant NHSLA Risk Management Standards.

The NHSLA Risk Management Standards for Acute Trusts, Primary Care Trusts and Independent Sector Providers of NHS Care are set out within a single manual containing a number of organisation specific criteria against which the relevant type of organisations are assessed. There are separate standards manuals for mental health & learning disability trusts, ambulance trusts and maternity services.

Further information about the NHSLA can be found on the NHSLA website at www.nhsla.com.

Advice on the standards and general aspects of risk management, and copies of NHSLA publications, can be found on the NHSLA website.

Post assessment reporting

Once the annual assessment cycle is completed, the assessment team will meet to review the overall findings and make recommendations. The team then produces a national overview of risk management activities across England in relation to the standards. This document includes both a summary of the findings and recommendations for improvement.
Benefits of assessment

The standards and assessment process are designed to:

- provide a structured framework within which to focus effective risk management activities in order to deliver quality improvements in organisational governance, patient care and the safety of patients, staff, contractors, volunteers and visitors
- increase awareness and encourage implementation of the national agenda for the NHS
- encourage and support organisations in taking a proactive approach to improvement
- reflect risk exposure and empower organisations to determine how to manage their own risks
- contribute to embedding risk management into the organisation's culture
- reduce the level of claims by reducing the number of adverse incidents and the likelihood of recurrence
- assist in the management of adverse incidents and claims
- provide assurance to the organisation, other inspecting bodies and stakeholders, including patients.

If organisations comply with the standards, they should benefit from the investment in risk management by having fewer claims and will pay lower scheme contributions.

Assessment results and links with other organisations

Results and findings from NHSLA assessments are used in a variety of ways by other bodies. These include the Care Quality Commission, Health and Safety Executive, Monitor, the National Institute for Health and Clinical Excellence and the NHS Counter Fraud and Security Management Service.

Elements of the NHSLA assessment take assurance from work undertaken by auditors on behalf of the Audit Commission and compliance with the Postgraduate Medical Education Training Board (PMETB) minimum requirements for clinical supervision set out in Domain 6 of the PMETB generic standards for training.
Appendix B: Contacts

Assessment/Report enquiries

This report was prepared by Det Norske Veritas on behalf of the NHS Litigation Authority. Any queries regarding this report should be directed to:

General enquiries
nhsla@dnv.com

Address for correspondence:

Det Norske Veritas
Highbank House
Exchange Street
Stockport
Cheshire
SK3 0ET

NHSLA general enquiries

General enquiries
generalenquiries@nhsla.com
Risk management enquiries
riskmanagement@nhsla.com

Address for correspondence:

The NHS Litigation Authority
Napier House
24 High Holborn
London
WC1V 6AZ

Website
www.nhsla.com