A Review of the
NHSLA *Incident Reporting and Management* and *Learning from Experience* Standards

Assessment Outcomes

April 2003 - March 2004

Background

The NHS Litigation Authority (NHSLA) was established in November 1995, as a Special Health Authority, to administer the "Clinical Negligence Scheme for Trusts" (CNST), a risk-pooling scheme in respect of clinical claims. At this time the NHSLA, via CNST, introduced a series of clinical risk management standards to encourage the promotion of good risk management practices and reduce the number and value of clinical claims.

The CNST standards cover a variety of key risk areas such as advice and consent, health records and induction, training and competence. Incident reporting, now assessed under CNST Standard 1: *Learning from Experience*, is central to the management of all risks. This standard not only considers the volume and severity of incidents reported but that all staff are expected to report, including medical staff (an area which is still poor in some trusts), that incidents are graded according to severity and that training is given to staff responsible for the grading. In addition, the standard also addresses the management of any incident investigations and how the trust implements lessons learned.

It is probably true that the CNST standards were the first set of clinical risk management standards that included the assessment of how well NHS organisations were reporting clinical incidents. Back in 1995, only a minority of trusts were actually reporting and recording clinical incidents. This was due to a variety of reasons including the culture and acceptance that clinical incidents were to some degree 'expected' side effects or complications to treatment. Such an approach was coupled with a general acceptance by the public that 'doctor knows best'. Today, of course, a more knowledgeable and probing public demand a great deal more from the NHS.

From 1 April 1999 the NHSLA's responsibilities were further expanded to include non-clinical claims under the "Liabilities to Third Parties Scheme" (LTPS) and "Property Expenses Scheme" (PES), known jointly as the Risk Pooling Schemes for Trusts (RPST). As a result, the NHSLA risk management standards now include the reporting of all non-clinical incidents too, especially those relating to staff accidents. Learning from experience in relation to all types of incidents, complaints and claims, continues to be an important element in all the NHSLA risk management standards i.e. CNST General, CNST Maternity, RPST and those specifically designed for PCTs and Ambulance Services which combine elements of clinical and non-clinical risks.

Although voluntary, all NHS Trusts and Primary Care Trusts (PCTs) are members of CNST and virtually all are members of RPST and pay contributions to these schemes. Trusts' CNST contributions are determined by the number of Whole Time Equivalent clinical staff they employ and the types of specialties provided. Higher risk specialties, in particular Obstetrics, attract the greatest contributions. Members are encouraged to comply with the standards not only so they will receive a risk management discount on their scheme contributions but to also encourage good risk management practices. Compliance with the standards is assessed at least 2-yearly via a robust independent assessment process which includes a document review and site visit.

2003/04 Assessment Results

The last financial year ended with the highest level of compliance against the NHSLA risk management standards.

CNST General

Level	No. of Trusts
0	14
1	198
2	51
3	6
Total	269

During 2003/04 the number of CNST General Level 0 trusts fell by 74% whilst the number of trusts at Level 2 rose by 28%, with the widespread uptake of the additional support and training made available to trusts by the NHSLA in relation to the standards having the intended positive effect on assessment outcomes.

CNST Maternity

Level	No. of Trusts
0	20
1	108
2	24
3	1
Total	153

2003/04 was the first year of formal assessments against the new CNST Maternity standards and by the end of the year all qualifying trusts had been assessed against these separate standards. Within each trust, the levels attained in the CNST Maternity assessment were generally lower than those achieved in the CNST General assessment, a reflection of the depth of the assessment, the fact that the standards are comparatively new, and that many maternity risk managers are new in post.

RPST

Level	No. of Trusts
0	41
1	228
Total	269

The number of trusts achieving RPST at Level 1 continued to rise in 2003/04 to the point where 85% were compliant. Of the remaining non-compliant trusts, it is anticipated that a large number will achieve success at RPST Level 1 during the current year. Assessments against RPST Levels 2 and 3 have not been introduced pending a review of the NHSLA approach to standards and assessments.

PCTs

Level	No. of Trusts
0	205
1A	98
Total	303

All 303 PCTs were assessed against the Level 1A requirements of the new PCT standard for the first time in 2003/04, with around one third demonstrating compliance. The results were encouraging and reflect the pattern which emerged during the early stages of the CNST and RPST standards for NHS Trusts. It is anticipated that the results will dramatically improve following the next round of assessments, which are taking place during 2004/05.

NHSLA Incident Reporting Requirements

The NHSLA has never sought to impose a single incident reporting system on trusts. In the context of incident reporting, the role and strength of CNST and now RPST has been to raise awareness, educate and promote good practice, and after years of encouraging and supporting trusts in this area, real progress (albeit slow), is now being seen.

A political imperative of the NHSLA is that it is the outcome that is prescribed and not the means to achieving it. Consequently it is not so much the computer system but the effectiveness of its use that is important and this varies considerably from trust to trust. Some trusts may be using more than one system for their risk management, claims and complaints handling respectively. Most computer systems do have the capacity now to address all aspects of risk management, including complaints and claims management, but are dependent on the level of the software package purchased by the trust and inevitably this is linked into the resources available at the time. In practice, the majority of all trust incident reporting systems are paper based, i.e. information is gathered using a form completed in the clinical area and then entered onto the computer centrally. Although time consuming, central data entry does ensure co-ordination and consistency at an appropriate level, allowing a trust-wide perspective of all incidents so that action can be taken immediately.

The CNST clinical risk management standards are well established in trusts. They have achieved recognition at many levels both within and outside the NHS, and are increasingly seen as providing a reliable and authoritative measure of the risk management practices in place within trusts. Most importantly, they are recognised as the clinical negligence indicators for clinical governance by NHS organisations and contribute towards the NHS performance (star) ratings. Compliance with the CNST standards promotes local ownership of risk management policies from trusts, whilst the independent assessment of each trust against the standards, and the award of a discount from scheme contributions, provides the incentive to comply and perform well.

Before the introduction of the RPST Risk Management Standard, the adverse incident reporting requirements were contained within CNST, and therefore related exclusively to patient safety (clinical) incidents. Since 2003 however, the requirement for trusts to have an incident reporting system in place has been covered by Criterion 4 of the RPST Risk Management Standard: *Incident Reporting and Management*. In accordance with the current NHS move towards the convergence of all risks, this standard looks at the systems in place across the organisation for both clinical and non-clinical incidents and ensures that common management techniques are

used across the whole organisation. The standard requires that there is '….an agreed process for reporting, managing, analysing and learning from adverse incidents….in accordance with NHS guidance'.

The CNST General Clinical Risk Management Standards continue to deal specifically with patient safety incidents within Standard 1: *Learning form Experience,* which requires that patient adverse incidents and near misses are reported in 50% of all specialties at Level 1, and 100% at Levels 2 and 3. The effectiveness of any of these systems is demonstrated at Levels 2 and 3 of the CNST assessment. CNST Standard 2 assesses the *Response to Major Clinical Incidents,* which contains further references to incident reporting. The CNST Maternity Standards also look at patient safety incidents occurring within the Obstetric specialty in Standard 2: *Learning from Experience.*

Criterion 2: *Incident Reporting and Management* of the NHSLA Risk Management Standard for PCTs requires that organisations have an agreed process for reporting, managing, analysing and learning from adverse incidents in place, in accordance with NHS guidance. Criterion 4: *Incident Reporting and Management* of the NHSLA Risk Management Standard for the Provision of Pre Hospital Care in the Ambulance Service contains the same requirement. (As formal assessments against this standard only began in April 2004, data for Ambulance Services in 2003/04 is included in the CNST General standards.)

Assessors only look for the minimum data required to satisfy the standard being assessed at the time. This means that many trusts may therefore have incident reporting systems operating beyond that required by the standards.

Status of Incident Reporting in Trusts 2003/04

Following the publication of *An Organisation with a Memory* in 2000, the NHSLA was able to provide the Department of Health with detailed information on trust compliance with the then current CNST incident reporting and management standards to inform the work of the National Patient Safety Agency. This *Review of the NHSLA Incident Reporting and Management and Learning from Experience Standards* updates this data by providing information on the outcome of assessments in relation to these standards, conducted as part of all CNST General, CNST Maternity, RPST and PCT assessments in 2003/04 (Appendices A – D).

CNST

The CNST General Clinical Risk Management Standards consist of seven core standards against which trusts are independently assessed. In addition, there are standards for adult mental health and ambulance services, which are applicable only to trusts that provide such services. Since April 2003, trusts providing maternity services have also been assessed against the separate CNST Maternity Clinical Risk Management Standards.

Every trust must be assessed against the standards at least once in any two year period and within 12 months of merging with another trust. CNST compliance is valid for a maximum of two years, and a trust can only be assessed once in any scheme year (April - March). If a trust fails to achieve compliance with the Level 1 standards, an annual assessment is required.

NHS trusts which achieve compliance with the standards are entitled to a discount from their CNST contribution for the following 2 financial years.

The discounts are:

Compliance at Level 1	10%
Compliance at Level 2	20%
Compliance at Level 3	30%

The NHSLA publishes information on assessment results on both an individual basis (Factsheet 4 on the NHSLA website www.nhsla.com is updated monthly) and aggregate basis, and provides copies of assessment reports in confidence to those bodies that have a statutory right to see them.

Within each standard, there are individually numbered criteria. A numerical score is assigned to each criterion. The standards are assessed progressively and each criterion is allocated to one of three levels:

- Level 1 criteria represent the basic elements of a clinical risk management framework.
- Levels 2 and 3 are more demanding. Many are concerned with the implementation and integration into practice of policies and procedures, monitoring them and acting on the results. These levels also require staff to have a good understanding of clinical risk issues.

A trust will be assessed as complying with the standards at a particular level if the following minimum scores are achieved:

Level 1 75% of the total score available for Level 1 criteria, in every standard.

Level 2 90% of the total score available for Level 1 criteria, in every standard, and 75% of the total score available for Level 2 criteria, in every standard.

Level 3 90% of the total score available for Level 1 criteria, in every standard, and 90% of the total score available for Level 2 criteria, in every standard, and 100% of the total score available for Level 3 criteria, in every standard.

Guidance behind the rationale for each criterion and the assessment process is provided within the CNST manual. The "verification" section details the evidence the assessor needs to see in order to confirm compliance.

Assessment at a selected level only addresses criteria included in that or a lower level. Criteria relating to higher levels are not assessed at that time.

Evidence in support of a criterion must be in place and effective at the time of assessment. Draft documentation, planned or proposed systems that have not been implemented, are not admissible at an assessment.

CNST General Clinical Risk Management Standards – Appendix A
Standard 1: *Learning from Experience*

The *Learning from Experience* standard is one of the core standards within the CNST General standards. The standard focuses on how the trust ensures that lessons are learnt and patient care is improved through the effective reporting of adverse incidents and near misses. This standard also considers external confidential reviews and lessons learnt from claims and complaints handling.

The *Learning from Experience* standard examines how the trust is overcoming the barriers that exist and encouraging staff to report incidents so that lessons can be learnt through analysis, dissemination of the findings, and implementing change. Another essential element is to learn

from events external to the trust and to ensure that essential findings and recommendations of the Confidential Enquiries are considered and implemented.

The standard is divided into ten criteria in total. Two of these are assessed at Level 1, with six criteria being assessed at Level 2, and a further two at Level 3.

Level 1

Criterion 1.1.1 Patient adverse incidents and near misses are reported in 50% of all specialities.

Trusts address this criterion very well, with evidence of reporting of various types of clinical incidents from all staff groups. A full score is only awarded if medical staff are participating in the system. A few organisations do have some difficulty in providing evidence that medical staff are reporting.

Criterion 1.1.2 Summarised patient incident reports are provided regularly to relevant bodies for review and action.

Some trusts are able to demonstrate that an analysis of trends for all reported patient adverse incidents is produced for the appropriate clinical risk management group, that there is a trust-wide perspective of patient adverse incidents, and that lessons are learnt and shared across the organisation. However, many trusts do have difficulty in providing evidence that reports produced clearly demonstrate analysis of themes and trends, and that any lessons learnt are communicated throughout the organisation.

Level 2

Criterion 1.2.1 Clinically related events are reported as they occur and before claims are made.

This criterion is generally addressed well by trusts, with clear evidence provided that an incident form has been completed at the time of the incident and that a system is in place where incident reports identify the potential for complaint or litigation. Those few trusts which do not comply with this criterion usually fail due to the lack of a robust system.

Criterion 1.2.2 There is evidence of management action arising from patient adverse incident reporting.

Compliance with this criterion is achieved by the trust demonstrating that is has in place a systematic approach to learning from individual incidents and that changes, when necessary, are implemented and monitored to ensure sustained improvement. This criterion is generally addressed well, as evidence of incident investigation at local level is seen and original incident report forms often indicate action taken and whether further investigation is required. Trusts are also able to demonstrate that there is effective liaison between claims managers and risk managers. Those trusts that have difficulty in complying with this criterion usually are unable to provide evidence that there are clear links between the incident being reported and subsequent action taken.

Criterion 1.2.3 Patient adverse incidents and near misses are reported in 100% of all specialities.

Trusts address this criterion very well, with evidence of reporting of various types of clinical incidents from all staff groups. A full score is only awarded if reporting is in 100% of all specialities and all professionals are reporting. A few organisations do have some difficulty in providing evidence for all specialities and that all professionals are reporting.

Criterion 1.2.4 In the interest of patient safety, openness and constructive criticism of clinical care is actively encouraged.

To enable an organisation to comply with this criterion, a uniform policy needs to be in place which applies to all staff, which makes it clear that openness and constructive criticism within and between professionals is encouraged. Full compliance is awarded if the trust has an appropriate policy and evidence is provided that this is distributed to all staff. Many trusts are able to provide a suitable policy, which is often the "Whistle Blowing" policy. However, difficulties can arise in providing evidence of distribution to all staff.

Criterion 1.2.5 Examples of two changes which reduce risk as a consequence of complaints can be demonstrated.

In this criterion the organisation is expected to demonstrate that, following the investigation of complaints where changes which will reduce risk are identified, these are considered and implemented. Compliance with this criterion is achieved well by most trusts as they are able to demonstrate that changes in practice, where required, are both considered and implemented. The difficulty some trusts have in complying with this criterion is that they are unable to clearly demonstrate that changes have taken place.

Criterion 1.2.6 The Trust applies the advice in the National Confidential Enquiries.

To comply with this criterion, a systematic approach to reviewing the findings of all of the National Confidential Enquiries within the organisation is required. A large percentage of trusts are able to comply with this criterion by demonstrating that they have a systematic approach to all enquires and that the Trust Board/ Governance Committee receives a report demonstrating that reviews are undertaken. The problem for some trusts is ensuring that all National Confidential Enquiries are considered regardless of service provision.

Level 3

As only a small percentage of trusts have been assessed at Level 3, it is not possible to provide a meaningful analysis or identify any trends.

Criterion 1.3.1 All clinical staff receive training in patient adverse incident reporting.

To comply with this criterion, the organisation must produce evidence that a training needs analysis has taken place for all clinical staff, and that training programmes for all grades of staff, including medical staff, are in place.

Criterion 1.3.2 Examples of five changes which reduce risk as a consequence of complaints can be demonstrated.

Like criterion 1.2.5, in this criterion the organisation is expected to demonstrate that, following the investigation of complaints where changes which will reduce risk are identified, these are considered and implemented.

CNST Maternity Clinical Risk Management Standards – Appendix B
Standard 2: *Learning from Experience*

Where appropriate, the CNST Maternity standards are linked to the CNST General standards, reflecting the trust-wide approach to the management of risk. The CNST Maternity standards also contain a specific standard on learning from experience. Prior to the publication of the current April 2004 CNST Maternity manual, this standard was reviewed, and those criteria that are either assessed as part of the CNST General assessment or as part of an RPST assessment were removed to prevent duplication of the assessment process. The information in this Review document relates to the criteria in the August 2003 manual, which were assessed in 2003/04.

Level 1

Criterion 2.1.1 A system is in place for reporting adverse incidents and near misses in all areas of the maternity service.

Generally, this criterion is well addressed. Although evidence is seen of all staff groups within maternity units reporting adverse incidents and near misses, as with the CNST General criterion it is noted that the level of reporting from medical staff is lower in some units than would be expected.

Criterion 2.1.2 The incident form gathers significant data about the event.

Most maternity units do well in this criterion. The criterion looks at the information gathered on the incident form to ensure that details of those involved in the incident and the location are recorded.

Criterion 2.1.3 The incident report form contains clear guidance on its completion and any subsequent action required.

This criterion assesses the guidance given to staff on the completion of incident forms and the guidance on actions to be taken following an incident. As with criterion 2.1.2, this is well addressed by maternity units.

Criterion 2.1.4 Summarised adverse incident reports are provided regularly to the Maternity Services Risk Management Group for review and action.

Following the first year of assessing maternity units, this appears to be the criterion within the *Learning for Experience* standard that maternity services find the most difficult to achieve. The verification for this criterion asks that there are regular reports of the incidents that occur within the service, which in general most units were able to provide. However, the verification also asks that there is an analysis of the data gathered to ensure that relevant lessons are learnt from the information, and this is an area in which a number of units were unable to demonstrate compliance. The final point of verification for this criterion asks for Board reports showing that the trust Board are aware of incidents occurring within the maternity service. Again, this was an

area where some units where not able to demonstrate compliance, suggesting that the trust Board is not provided with an overview of all incidents occurring within the service.

Criterion 2.1.5 The maternity service implements the trust policy on the relationship between incident reporting and disciplinary action.

This criterion is well addressed by maternity services, with most not only following the trust incident reporting policy and procedures but also replicating this within their risk management strategy. Evidence is also seen of the proactive use of supervision of midwives following reports of clinical incidents.

Level Two

As the financial year 2003/04 was the first year of formal CNST Maternity assessments, only a limited number of trusts applied for assessment at Level 2, with 24 achieving compliance. As a result, although most of the Level 2 criteria were well addressed by trusts, it is difficult to comment with confidence on how maternity units are complying with these requirements.

The following criteria are those assessed at Level 2, and generally maternity units found these to be more challenging. In particular, the findings at assessment suggest that although maternity units may, for example, be making changes in practice following the report of incidents, they find it difficult to show evidence demonstrating these changes.

Criterion 2.2.1 The maternity service has a strategic approach to the management of adverse incidents that might lead to a claim or litigation.

Criterion 2.2.2 There is evidence of lessons learned and action arising from adverse incident reporting.

Criterion 2.2.3 The maternity service applies the board approved trust policy for managing serious untoward incidents.

Criterion 2.2.4 The maternity service can demonstrate changes in practice which reduce risk, in response to complaints.

Criterion 2.2.5 All professional staff receive guidance and training in adverse incident reporting.

Criterion 2.2.6 The service considers and applies the recommendations made in the National Confidential Enquiries.

Level Three

At present the manual only contains one criterion at Level 3:

Criterion 2.3.1 The service audits its practice against the advice in the National Confidential Enquiries, and implements changes accordingly.

At the end of the 2003/04 financial year, only one trust had been assessed at Level 3 of the CNST Maternity standards. Thus, it is not possible to accurately describe how this criterion is

being addressed. However, it is expected that more maternity units will achieve Level 3 during the current financial year.

RPST Risk Management Standard – Appendix C

The Liabilities to Third Parties Scheme (LTPS) and Property Expenses Scheme (PES) were established in 1999, to provide a means for NHS Trusts to fund the cost of legal liabilities to third parties and property losses, and to encourage and support the effective management of risk and claims. The risk management standard that supports these schemes is known as the Risk Pooling Schemes for Trusts (RPST).

The RPST Standard consists of eight criteria which are identical to the Department of Health's former core Controls Assurance Risk Management Standard. It provides a framework that will help trusts to focus their risk management systems effectively, thereby improving patient care, the safety of employees and organisational governance.

The standard is designed to:

- be measurable
- be achievable
- increase risk management awareness
- improve standards of care and the effectiveness of systems within the organisation
- embed risk management into an organisation's culture
- reduce the level of claims
- ensure that members' contributions equitably reflect their standards of risk management
- be capable of progressive development
- contribute to the development and implementation of governance

Every trust will normally be assessed against the RPST Standard at least once in any two year period and within 12 months of merging with another trust. However, pending the outcome of an ongoing review of the NHSLA standards and assessments, RPST assessments have been suspended for all but Level 0 Trusts (who are required to be assessed every year until compliance is achieved) during 2004/05. RPST compliance is usually valid for a maximum of two years. A trust can only be assessed once in any scheme year (April - March). Trusts which are assessed as complying with the standard are entitled to a discount from their LTPS and PES contributions for the following two financial years. The discount for compliance at Level 1 is 10%. A trust may not apply for assessment at CNST General or CNST Maternity Level 3 if Level 1 has not been achieved in the RPST Standard.

Each criterion is scored out of 100%. A trust will be assessed as complying with the Level 1 requirements if it scores 75% of the total score available in every criterion. Level 1 focuses on corporate ownership of risk through effective policies and procedures. In some cases the trust may be achieving the objective of the requirement through an alternative, but equally effective, route. In such cases, provided that adequate evidence is produced to demonstrate that the objective of the requirement is being met, the assessor can give the appropriate credit. In assessing a trust's performance against a particular requirement, it is sometimes possible for the assessor to award a partial compliance if progress towards full compliance is demonstrated. Where this is possible, the accompanying score sheet will allow such an entry. However, unlike CNST, no score is awarded for a partial compliance, as their purpose is solely to act as an indicator that the organisation is making progress towards full compliance. Evidence in support of a requirement must be in place and effective at the time of assessment. Draft

documentation, or planned or proposed systems which have not been implemented, are not admissible.

Criterion 4: *Incident Reporting and Management*

This requires that an agreed process for reporting, managing, analysing and learning from adverse incidents is in place, in accordance with NHS guidance.

Level 1

4.1 There is a Board approved policy/procedure for recording, reporting and managing incidents.

4.1.1 A documented procedure for the reporting, and management of all incidents exists.
4.1.2 A Board minute evidences that the procedure has been Board approved.
4.1.3 An annual review date is applied to the procedure.

The Board should have formally approved the procedure for recording, reporting and managing incidents. A Board minute should be available evidencing approval of the procedure. In order to maintain an up to date document, the incident reporting procedure should be reviewed on at least an annual basis. The date when the procedure was initially approved and adopted by the Board should be displayed on the front sheet of the procedure. Trusts normally do well with this set of requirements. Where a trust has failed, it is normally because they produce as evidence a draft procedure or a procedure that has not been Board approved.

4.2 The policy/procedure is based upon a standard definition of incidents.

4.2.1 There is a clear and concise definition of all incidents including the terms near miss/hazard within the document, which takes into account national requirements.

The incident reporting procedure must have clear definitions of standard terms including: incident, accident, near miss, hazard, dangerous occurrence, significant event etc. and must take into account all national requirements. The National Patient Safety Agency (NPSA), Medicines and Healthcare products Regulatory Agency (MHRA) and RIDDOR all have specific definitions which should be included within the policy/procedure. Where trusts fail this criterion it is often because the definitions are either very clinically or very health and safety focused and do not represent the full range of incidents that could occur within the organisation.

*4.3 The policy/procedure promotes a positive and fair blame approach towards incident reporting***.**

4.3.1 The incident reporting procedure clearly describes the organisation's approach towards positive and fair blame incident reporting.
4.3.2 The incident reporting procedure cross-references other significant documentation such as the whistle-blowing policy.

The reporting of incidents should form an integral part of the organisation's risk management strategy and as such should be supported by an open and objective culture of learning from incidents. The Board should promote a non-punitive approach to incident reporting, with an explanation of how the organisation perceives the term 'non-punitive'. This statement should be detailed in the incident reporting procedure and could also be described within the Risk

Management Strategy. The incident reporting procedure should include cross-references to other significant documentation, which relate to the reporting of incidents and concerns. These might include serious incident procedures, MHRA procedures, etc. In particular the incident reporting procedure should reference the 'whistle-blowing policy' as a further means of reporting concerns. When a trust fails this criterion it is most often because there is no reference to a fair blame reporting procedure, but this is now very rare.

4.4 All reported incidents and causal factors are classified and categorised in accordance with a standardised classification scheme.

4.4.1 There is an approved, published classification scheme that deals with the full range of potentially reportable incidents and their potential causes and takes account of national requirements.

The incident reporting procedure and/or the incident reporting guidelines must clearly set out the approved, published classification scheme that deals with the full range of potentially reportable incidents and their potential causes, taking into account any relevant national requirements. Where a trust fails this criterion it is normally because the procedure has a basic set of cause codes which only deal with clinical or health and safety issues.

4.5 The policy/procedure states that all incidents must be reported promptly and an incident form completed.

4.5.1 The document describes the timescales for the reporting of all incidents both to local and central management.
4.5.2 The timescales for reporting incidents are linked to an initial severity grading and to external reporting requirements.
4.5.3 The organisation can demonstrate that incidents are reported to relevant external stakeholders in accordance with their reporting requirements.
4.5.4 The organisation has a training programme for incident reporting.

The trust incident reporting procedure should be clear on the need to report all incidents promptly and to complete an incident report form. It is expected that the incident reporting procedure will clearly describe the timescales for the reporting of all incidents both to local and central management. Most organisations require immediate verbal reporting of incidents to local management with form completion occurring within twenty-four hours. Timescales for the reporting of incidents vary from organisation to organisation. Where serious injury or death has occurred or there was potential for serious injury or death, reporting should be immediate. The timescales for reporting must be linked to an initial severity grading and to external reporting requirements. The methods for the reporting of incidents should be clear and simple to use. The incident form should be completed as soon as possible either following the event or following notification of its occurrence. To ensure that the organisation is fulfilling their role, the timescales should be linked to the severity grading given at the time of reporting. Finally, it is expected that there is an appropriate training programme for incident reporting available to all members of staff. New starters should receive training on incident reporting at both central and local induction whilst existing members of staff should have access to update courses.

Where a trust fails this criteria it is most commonly because the procedure does not contain clear guidance on reporting to external stakeholders, although reporting to the Health and Safety Executive under RIDDOR is almost always included. In relation to training, trusts are

very good at providing training on incident reporting as part of their induction courses but are not so good at providing on-going training for existing staff.

4.6 The policy/procedure states that management actions and preventative measures taken must be recorded.

4.6.1 The incident reporting procedure requires managers to take immediate actions and the incident form(s) allows for this detail to be recorded.
4.6.2 The incident reporting procedure includes clear guidance on the types of immediate actions that managers may be required to take and is linked to severity grading.
4.6.3 The incident reporting procedure contains cross-references to policies/procedures, which contain instructions on immediate actions to be taken.

Whilst the Chief Executive has overall responsibility for risk management within the organisation, managers equally have a responsibility for the management of risk within their own directorate or service. Following every incident, whether a near miss or an incident resulting in injury, all managers must take and record immediate and/or preventative actions. This directive should be clearly laid out in the incident reporting policy/procedure under management responsibilities and must be an integral part of managers' job descriptions. The incident reporting form must allow for the recording of actions taken by managers. The incident procedure should include clear guidance on the types of immediate actions that managers may be required to take which in turn must be linked to the severity grading. The incident reporting procedure should clearly detail and cross reference to policies/procedures which contain instructions on immediate actions to be taken e.g. medication error incidents. Where a trust fails this criterion it is normally because the procedure does not include a cross reference to policies/procedures which contain instructions on immediate actions to be taken.

4.7 All reported incidents are graded according to severity of outcome and potential future risk to patients and/or the organisation.

4.7.1 The incident reporting procedure requires all incidents to be graded according to severity of outcome, as soon as possible after the incident.
4.7.2 The incident policy/procedure clearly describes the grading system and those responsible for grading.
4.7.3 Training is provided for those responsible for applying gradings.
4.7.4 There is clear evidence of gradings being applied as soon as possible after the incident.

The incident reporting procedure requires all incidents to be graded according to severity of outcome, as soon as possible after the incident. The grading system and those responsible for grading must be clearly described within the procedure. Evidence showing that training is provided for those responsible for applying gradings should be available. Ideally, those completing the incident reporting form should carry out gradings. Where a trust fails this criterion it is often because the organisation is using more than one grading system e.g. a letter based system for clinical incidents and a numerical system for non-clinical incidents. This prevents the trust from accurately analysing their full range of incidents as this information cannot easily be combined.

4.8 A policy/procedure on incident investigation and root cause analysis is in place that contains a clear protocol to be followed.

4.8.1 The incident reporting procedure includes clear guidance on incident investigation and root cause analysis.
4.8.2 The guidance clearly details who is responsible for incident investigation and root cause analysis and when.
4.8.3 The incident reporting procedure requires incidents to be regraded following investigation.
4.8.4 The guidance requires the level of the investigation to be linked to the incident grading.
4.8.5 The guidance clearly details when external agencies need to be involved in the investigation process.
4.8.6 Training is provided for those responsible for incident investigation.

The incident reporting procedure must provide clear guidance on both incident investigation and on root cause analysis. It must clearly state who is responsible for incident investigation and root cause analysis and when. Documentation should show that, following incident investigation and the implementation of action/preventative measures, incidents are routinely regraded. Guidance within the incident reporting policy should clearly set out when external agencies need to be involved in the investigation process and also make clear reference to the training that is provided to those responsible for incident investigation. The grading of all incidents should be undertaken a soon as is possible following the event. Where a trust fails this criterion it is most often because the organisation has a basic investigation procedure that does not contain detail on the root cause analysis of incidents. A number of trusts are currently developing investigation procedures including root cause analysis which incorporate incidents with complaints and claims.

4.9 For serious adverse incidents that could have an impact upon staff, patients or the public the policy/procedure requires them to be advised.

4.9.1 The organisation can demonstrate compliance with CNST General Standard 2 (Response to Major Clinical Incidents).
4.9.2 The incident reporting procedure is explicit about responsibility for informing staff and the public.
4.9.3 The incident reporting procedure requires any information given to staff and the public to be documented.
4.9.4 The incident reporting procedure is explicit that those directly affected by the event must be notified before the media.

To achieve compliance in this criterion the organisation will need to demonstrate compliance with CNST Standard 2: *Response to Major Clinical Incidents*. The incident reporting policy/procedure needs to be explicit that an appropriate individual is responsible for informing staff, patients or the public following any adverse event. Those directly affected by the incident must be notified before the media and where relevant permission should be sought before families are notified. In all cases it is important that accurate records are kept of information given to staff and the public. Where a trust fails this criterion it is normally because the focus is solely on informing the patient and the procedure does not cater for staff or visitors.

4.10 All incidents are reported on standard forms, which may be paper-based or electronic, and which captures a minimum dataset of information in accordance, where relevant with NHS guidance.

4.10.1 Standard forms exist for the reporting of all incident types.

4.10.2 Clear guidance on form completion has been produced and is available to all staff and referenced within the incident reporting procedure.
4.10.3 The incident form allows near misses to be reported.
4.10.4 The form(s) gathers significant data about the incident which, at the least, is in accordance with the minimum data set outlined by the NPSA.
4.10.5 The incident report form(s) state clearly that fact only and not opinion must be recorded.
4.10.6 The incident form states clearly that when any serious incident including those to patients has occurred, reporting is immediate irrespective of time of day.

In order for the organisation to receive information on incidents promptly, standard forms should exist, covering all types of incident. The organisation should consider the use of a single incident reporting form, allowing all types of incidents to be recorded including clinical incidents and near misses. To assist staff in completing an incident form, clear guidance should be attached to the incident reporting pad or book and referenced within the incident reporting policy/procedure. The form should be designed to gather significant data about the event and include the minimum data set outlined by the NPSA. The form should clearly state that fact not opinion should be recorded and that when a serious incident occurs, including those to a patient, reporting is immediate. Where a trust fails this criteria it is normally because the organisation is using a form that does not contain all the key information described above. Occasionally, a trust may fail this criterion where a large number of different forms are being used to collect information.

NHSLA Risk Management Standard for PCTs – Appendix D

The PCT Standard provides a framework to help PCTs focus their risk management systems effectively, thereby improving patient care, the safety of employees and organisational governance. At Level 1A the standard consists of ten criteria reflecting potential clinical and non-clinical risks to the organisation, including those for higher risk clinical services, maternity and adult mental health, which are only applicable to PCTs that provide such services. Level 1 focuses on corporate ownership of risk through effective policies and procedures, with assessment at Level 1A comprising an off-site review of key risk management documents. Every PCT in England was assessed against the PCT Standard at Level 1A between October 2003 and March 2004.

Each criterion is scored out of 100% and a PCT is assessed as complying with the Level 1A requirements if it scores 75% in every criterion. Compliance at Level 1A is rewarded by a 5% risk management discount from contributions to all NHSLA schemes i.e. CNST, LTPS and PES. The principles of assessment are similar to CNST and RPST, and like these assessments, evidence in support of a requirement must be in place and effective at the time of assessment. Draft documentation or planned or proposed systems which have not been implemented are not admissible.

Criterion 4: *Incident Reporting and Management*

This requires that an agreed process for reporting, managing, analysing and learning from adverse incidents is in place, in accordance with NHS guidance.

Level 1A

1A2.1 *There is a Board approved policy and procedure for recording, reporting and managing incidents.*

1A2.1.1 A documented procedure for the reporting and management of all incidents exists, which has been Board approved.

Where a PCT has failed this requirement it is usually because the policy has not been Board approved although it may be in use within the organisation.

1A2.2 *The incident reporting policy and procedure contains the following:*

1A2.2.1 Definitions of all incidents.
1A2.2.2 A description of the incident reporting culture within the organisation.
1A2.2.3 Timescales for reporting to local and central management for all types of incident (including serious).
1A2.2.4 Guidance for managers on the types of immediate actions that may be required in the event of an incident for all types of incident.

Where a PCT has failed this requirement it is often because the incident reporting policy defines only certain types of incident, e.g. clinical, rather than a full range. Alternatively, although the policy may state the requirement for immediate action to be taken, it may not provide information on what that immediate action may comprise.

1A2.3 *Requirements for grading are included in the incident reporting policy.*

1A2.3.1 The requirement for incidents to be graded in the policy states it should occur 'as soon as possible after the event'.
1A2.3.2 Responsibility for grading is defined in the policy.

1A2.4 *The organisation has the ability to collect and collate relevant information relating to incidents.*

1A2.4.1 Standard form(s) exist for the reporting of all types of incident.

Failure in this requirement may relate to the PCT using old forms from previous organisations or from using forms that do not capture all types of incident e.g. only using a clinical incident form or a health and safety form.

1A2.5 *The incident report form(s) contain the following (if more than one incident form is used in the PCT, all forms must contain the element to be compliant).*

1A2.5.1 Individual identifiers for the person the incident happened to (e.g. patient, visitor, contractor or staff name).
1A2.5.2 Description of the incident (e.g. fall, drug error, etc.).
1A2.5.3 The incident form allows near misses to be reported.
1A2.5.4 Immediate action taken.
1A2.5.5. Equipment involved.
1A2.5.6 Witnesses (name and contact details)
1A2.5.7 Name and grade of the person completing the form.
1A2.5.8 A statement that 'if the event is serious, it should be reported immediately'.
1A2.5.9 A statement that 'fact not opinion should be recorded'.

The most common elements for PCTs to omit from the form relate to the equipment involved in the incident and the need for the immediate reporting of serious incidents.

Conclusion

The effectiveness of any incident reporting system is dependent on the information and data that is collected and how this is used by the trust. Influencing this process is the inherent culture of the organisation as a whole. For an incident reporting system to be effective, lessons to be learnt, and practice to change accordingly, the trust must promote and encourage its staff to report clinical incidents and near misses. The trust's stance on the relationship between incident reporting and disciplinary action must be quite clear to all staff, and the promotion of an open and fair approach to incident reporting needs to be actively encouraged. Staff are asked whether they feel comfortable reporting incidents as part of their interviews at a Level 2 CNST assessment.

There needs to be good feedback to all staff, and in particular to those who report, on the actions taken by the trust following an incident report. This ensures that staff feel involved in the process, can appreciate the benefits, and will continue to report incidents – avoidance of the 'black hole' syndrome. Staff also need to be aware of the type of incidents to report in order for them to participate fully, and clinical staff training in patient safety incident reporting is a requirement of the NHSLA standards.

All of the above requirements are to be addressed through the trust's incident reporting and management policy/procedure document, which is thoroughly reviewed as part of the RPST/PCT assessment process. Good incident reporting and management practices can only be achieved through effective communication at all levels within the organisation, which is the lynchpin to the effectiveness of all incident reporting systems. It should also be noted that incident reporting is such a fundamental element that any meaningful assessment of a trust's risk management system must incorporate a review of the incident reporting arrangements. There is clear evidence that the reporting of all types of incidents within NHS organisations has gathered momentum rapidly since the late 1990s. One of the reasons for this is certainly the work undertaken by the assessors, who not only assess trusts in relation to their compliance with the standards but also provide advice and guidance and encourage networking and the sharing of notable practice.

The NHSLA has an established network of relevant contacts with all NHS Trusts and PCTs, and delivers an ongoing educational programme to promote good risk management practices, comprising seminars, workshops, visits to individual trusts and sharing of notable practice. In addition, the NHSLA also produces various risk management publications, including the *NHSLA Review*. Over the years, these various forms of advice and support have been used to further promote the importance of effective incident reporting and management systems within the NHS.

CNST General assessments carried out in 2003/04 **APPENDIX A**

Number of Trusts assessed: -
Level 1 142
Level 2 34
Level 3 2

Standard 1 : Learning from Experience
The trust proactively uses internal and external information to improve clinical care

		%		
		Compliant	Partial	Non - Compliant
1.1.1	Patient adverse incidents and near misses are reported in 50% of all specialties.	96%		4%
1.1.2	Summarised patient incident reports are provided regularly to relevant bodies for review and action.	61%	34%	5%
1.2.1	Clinically related events are reported as they occur and before claims are made.	97%		3%
1.2.2	There is evidence of management action arising from patient adverse incident reporting.	91%		9%
1.2.3	Patient adverse incidents and near misses are reported in 100% of all specialties.	88%	9%	3%
1.2.4	In the interests of patient safety, openness and constructive criticism of clinical care is actively encouraged.	79%	18%	3%
1.2.5	Examples of two changes which reduce risk as a consequence of complaints can be demonstrated.	97%		3%
1.2.6	The trust applies the advice in the National Confidential Enquiries.	79%	15%	6%
1.3.1	All clinical staff receive training in patient adverse incident reporting.	100%		
1.3.2	Examples of five changes which reduce risk as a consequence of complaints can be demonstrated.	100%		

CNST Maternity assessments carried out in 2003/04 **APPENDIX B**

Number of Trusts assessed: -
Level 1 132
Level 2 27
Level 3 2

Standard 2 : Learning from Experience
The maternity service proactively uses internal and external information to improve clinical care.

		%		
		Compliant	Partial	Non - Compliant
2.1.1	A system is in place for reporting adverse incidents and near misses in all areas of the maternity service.	89%	9%	2%
2.1.2	The incident form gathers significant data about the event.	90%	8%	2%
	Patient identifiers			
	Date, time and location			
	Description of the incident			
	People involved and others present (staff and patient identifiers)			
	Equipment failure and to whom reported			
	The provision of any first aid to non-patients			
2.1.3	The incident report form contains clear guidance on its completion, and any subsequent action required.	88%	11%	2%
	Fact only and not opinion must be recorded.			
	When unexpected death or serious injury has			
	occurred reporting is immediate, regardless of time of day			
	“Near misses” are to be reported.			
2.1.4	Summarised adverse incident reports are provided regularly to the Maternity Services Risk Management Group for review and action.	48%	46%	5%
2.1.5	The maternity service implements the trust policy on the relationship between incident reporting and disciplinary action.	98%		2%
2.2.1	The maternity service has a strategic approach to the management of adverse incidents that might lead to a claim or litigation.	96%		4%
2.2.2	There is evidence of lessons learned and action arising from adverse incident reporting.	85%		15%
2.2.3	The maternity service applies the board approved trust policy for managing serious untoward incidents.	93%		7%
2.2.4	The maternity service can demonstrate changes in practice, which reduce risk, in response to complaints.	93%		7%
2.2.5	All professional staff receive guidance training in adverse incident reporting.	93%		7%
2.2.6	The service considers and applies the recommendations made in the National Confidential Enquiries.	85%		15%
2.3.1	The service audits its practice against the advice in the National Confidential Enquiries, and implements changes accordingly.	100%		

RPST assessments carried out in 2003/04 **APPENDIX C**

Number of Trusts assessed = 153

Criterion 4: Incident Reporting and Management

An agreed process for reporting, managing, analysing and learning from adverse incidents is in place, in accordance with NHS guidance.

		%		
		Compliant	Partial	Non - Compliant
4.1	**There is a Board approved policy/procedure for recording, reporting and managing incidents.**			
4.1.1	A documented procedure for the reporting, and management of all incidents exists.	96%	2%	2%
4.1.2	A Board minute evidences that the procedure has been Board approved.	69%	0%	31%
4.1.3	An annual review date is applied to the procedure.	82%	0%	18%
4.2	**The policy/procedure is based upon a standard definition of incidents.**			
4.2.1	There is a clear and concise definition of all incidents including the terms near miss/hazard within the document, which takes into account national requirements.	82%	13%	5%
4.3	**The policy/procedure promotes a positive and fair blame approach towards incident reporting.**			
4.3.1	The incident reporting procedure clearly describes the organisation's approach towards positive and fair blame incident reporting.	88%	8%	4%
4.3.2	The incident reporting procedure cross-references other significant documentation such as the whistle-blowing policy.	75%	10%	15%
4.4	**All reported incidents and causal factors are classified and categorised in accordance with a standardised classification scheme.**			
4.4.1	There is an approved, published classification scheme that deals with the full range of potentially reportable incidents and their potential causes and takes account of national requirements.	89%	4%	7%
4.5	The policy/procedure states that all incidents must be reported promptly and an incident form completed.			
4.5.1	The document describes the timescales for the reporting of all incidents both to local and central management.	69%	22%	9%
4.5.2	The timescales for reporting incidents are linked to an initial severity grading and to external reporting requirements.	81%	10%	9%
4.5.3	The organisation can demonstrate that incidents are reported to relevant external stakeholders in accordance with their reporting requirements.	91%	0%	9%
4.5.4	The organisation has a training programme for incident reporting.	80%	12%	8%
4.6	**The policy/procedure states that management actions and preventative measures taken must be recorded.**			
4.6.1	The incident reporting procedure requires managers to take immediate actions and the incident form(s) allows for this detail to be recorded.	86%	7%	7%
4.6.2	The incident reporting procedure includes clear guidance on the types of immediate actions that managers may be required to take and is linked to severity grading.	59%	14%	27%
4.6.3	The incident reporting procedure contains cross-references to policies/procedures, which contain instructions on immediate actions to be taken.	46%	8%	46%

Criterion 4: Incident Reporting and Management - continued

		%		
		Compliant	Partial	Non - Compliant
4.7	**All reported incidents are graded according to severity of outcome and potential future risk to patients and/or the organization.**			
4.7.1	The incident reporting procedure requires all incidents to be graded according to severity of outcome, as soon as possible after the incident.	64%	17%	19%
4.7.2	The incident policy/procedure clearly describes the grading system and those responsible for grading.	79%	9%	12%
4.7.3	Training is provided for those responsible for applying gradings.	67%	9%	24%
4.7.4	There is clear evidence of gradings being applied as soon as possible after the incident.	76%	0%	24%
4.8	**A policy/procedure on incident investigation and root cause analysis is in place that contains a clear protocol to be followed.**			
4.8.1	The incident reporting procedure includes clear guidance on incident investigation and root cause analysis.	66%	18%	16%
4.8.2	The guidance clearly details who is responsible for incident investigation and root cause analysis and when.	74%	16%	10%
4.8.3	The incident reporting procedure requires incidents to be regraded following investigation.	58%	0%	42%
4.8.4	The guidance requires the level of the investigation to be linked to the incident grading.	76%	0%	24%
4.8.5	The guidance clearly details when external agencies need to be involved in the investigation process.	38%	20%	42%
4.8.6	Training is provided for those responsible for incident investigation.	61%	14%	25%
4.9	**For serious adverse incidents that could have an impact upon staff, patients or the public the policy/procedure requires them to be advised.**			
4.9.1	The organisation can demonstrate compliance with CNST Standard 2 (Response to Major Clinical Incidents).	95%	0%	5%
4.9.2	The incident reporting procedure is explicit about responsibility for informing staff and the public.	46%	16%	38%
4.9.3	The incident reporting procedure requires any information given to staff and the public to be documented.	44%	0%	56%
4.9.4	The incident reporting procedure is explicit that those directly affected by the event must be notified before the media.	54%	0%	46%
4.10	**All incidents are reported on standard forms, which may be paper-based or electronic, and which captures a minimum dataset of information in accordance, where relevant with NHS guidance.**			
4.10.1	Standard forms exist for the reporting of all incident types.	97%	0%	3%
4.10.2	Clear guidance on form completion has been produced and is available to all staff and referenced within the incident reporting procedure.	85%	5%	10%
4.10.3	The incident form allows near misses to be reported.	90%	1%	9%
4.10.4	The form(s) gathers significant data about the incident which, at the least, is in accordance with the minimum data set outlined by the NPSA.	96%	0%	4%
4.10.5	The incident report form(s) state clearly that fact only and not opinion must be recorded.	89%	0%	11%
4.10.6	The incident form states clearly that when any serious incident including those to patients has occurred, reporting is immediate irrespective of time of day.	77%	0%	23%

PCT assessments carried out in 2003/04 **APPENDIX D**

Number of PCTs assessed = 303

Criterion 2: Incident Reporting and Management

An agreed process for reporting, managing, analysing and learning from adverse incidents is in place, in accordance with NHS guidance.

		%	
		Compliant	Non - Compliant
1A2.1	**There is a Board approved policy and procedure for recording, reporting and managing incidents.**		
1A2.1.1	A documented procedure for the reporting and management of all incidents exists, which has been Board approved.	76%	24%
1A2.2	**The Incident Reporting Policy and Procedure contains the following:**		
1A2.2.1	Definitions of all incidents.	86%	14%
1A2.2.2	A description of the incident reporting culture within the organisation.	82%	18%
1A2.2.3	Time scales for reporting to local and central management for all types of incident (including serious).	58%	42%
1A2.2.4	Guidance for managers on the types of immediate actions that may be required in the event of an incident for all types of incident.	61%	39%
1A2.3	**Requirements for grading are included in the Incident Reporting Policy.**		
1A2.3.1	The requirement for incidents to be graded in the policy states it should occur 'as soon as possible after the event'.	60%	40%
1A2.3.2	Responsibility for grading is defined in the policy.	76%	24%
1A2.4	**The organisation has the ability to collect and collate relevant information relating to incidents.**		
1A2.4.1	Standard form(s) exist for the reporting of all types of incident.	91%	9%
1A2.5	**The incident report form(s) contain the following:**		
	If more than one incident form is used in the PCT, all forms must contain the element to be compliant.		
1A2.5.1	Individual identifiers for the person the incident happened to (e.g. patient, visitor, contractor or staff name).	92%	8%
1A2.5.2	Description of the incident (e.g. fall, drug error, etc).	87%	13%
1A2.5.3	The incident form allows near misses to be reported.	88%	12%
1A2.5.4	Immediate action taken.	90%	10%
1A2.5.5	Equipment involved.	76%	24%
1A2.5.6	Witnesses (Name and Contact Details).	88%	12%
1A2.5.7	Name and grade of the person completing the form.	86%	14%
1A2.5.8	A statement that 'if the event is serious, it should be reported immediately'.	62%	38%
1A2.5.9	A statement that 'Fact not opinion should be recorded'.	82%	18%