SECTION TEN
RISK MANAGEMENT

This section considers:

- controls assurance processes across the PCT
- systems and processes to ensure that all clinical risks are proactively identified, monitored, analysed and managed
- the need for patients and their carers to be actively involved in the identification and management of clinical risks
- promoting a staff culture that promotes the identification of adverse events and near misses
- learning from complaints, adverse event reporting and other forms of pro-active risk identification.

The challenge of keeping patients safe

Ensuring the safety of everyone that comes into contact with health services is one of the most important challenges facing health care today, not just in the UK, but worldwide. The Department of Health's response to the recent inquiry into children's heart surgery at Bristol Royal Infirmary — Learning from Bristol placed the safety of NHS care and learning from adverse events at the heart of the The NHS Plan.

The National Patient Safety Agency, established in 2001, has a key role in implementing this agenda, and will run a new national system for reporting, analysing and learning from adverse incidents involving NHS patients.

Two things, therefore, lie at the heart of a Board and a PEC's clinical governance statutory duty of quality in relation to all aspects of a PCT's current care provision. These are:

- proactive identification of clinical risks
- initiation of a concerted and systematic strategy to minimise them, to monitor them and to learn from them.

Thorough, effective and on-going clinical risk management is one important driver of many other technical aspects of clinical governance (e.g. clinical audit, clinical effectiveness). It establishes an essential foundation upon which future service improvements can be based; it needs to be built into the commissioning and partnership arrangements that PCTs develop within their local health economies.

'Nothing is more important than the safety of our patients.'

Kizer, 2002

Key learning from the pilot programme

All PCTs rightly accord significant priority to the management of risks, but many are still reactive rather than pro-active in the identification, management and minimisation of clinical risks, not least in relation to dentistry, and optometry.

PCTs would welcome national action to:

- raise the profile of risk in primary care
- foster greater understanding of the characteristic ways that evidence of safety can be generated and clinical risk minimised (such as the engagement of patients and carers as active partners in the process).

Across all PCTs in the pilot programme, the section on Clinical Risk Management was the third highest scoring at 5.7 on the progress scale (range 4 to 7.1).

More recently formed PCTs were likely to find this a significantly more challenging issue than those that had a longer to embed controls assurance processes and a risk-sensitive culture. The 25 PCTs under a year old when they completed the questions scored an average of 5.2 whilst the remainder scored an average of 6.

REFLECTION

To what extent are patients, staff, the PCT itself, currently 'quality protected'? What evidence is there to support your view?

No PCTs were complacent about this issue. Many believed that they had made considerable progress in embedding a 'culture of safety' in the organisation and in promoting the reporting and learning from serious untoward incidents. However, responses to key questions about the evidence of the safety of care (located in Section 9) demonstrated that robust and concrete 'intelligent information' about the safety of provided and commissioned services is still extremely difficult for Boards and PECs to generate or obtain.

Many PEC members also recognised the need to engage patients and their carers more actively in the process of risk identification and management, not least in relation to life style and informed concordance with treatment issues.

Overall, there was a desire to be more pro-active in the identification and management of all aspects of risks, both to patients and to the organisation, and most PCTs recognised that the breadth and the depth of their overall clinical and managerial

expertise in these areas needed to be significantly extended. They were able to identify a number of factors that promote or inhibit effective risk management, and these are included in the Checklist at the end of this section.

Quality protects

Boards and PECs of PCTs need to devote sustained time and attention to ensure that quality and patient safety remain at the forefront of the primary care agenda.

'Strong leadership is needed in primary care to promote patient safety. It is unreasonable to expect front-line workers to take patient safety seriously until leaders do.'

Wilson and Smith, 2001

In social care, the Department of Health introduced the 'Quality Protects' initiative in order to protect the most vulnerable infants and children. This drew to the attention of staff at all levels within the organisation the critical correlation that exists between quality and safety. Over and above the key protection from harm that quality affords to the service user, it has not been widely recognised that it also:

- protects the individual professional from adverse criticism,
- protects her or his organisation from damage to their reputation
- protects the service as a whole from damage to reputation and from the hostile scrutiny of the media.

If quality is to be built into primary care, the decisions and actions of all staff and of service users need to be informed by clinical governance and an active concern for safety needs.

'Although the majority of patient care occurs in general practice, little is known about patient safety there.

Action is needed now to reduce harm to patients – a list of priority actions for safer care should be developed.

Leadership is required to support safer care and to show a serious intent to reduce harm.

Individual responsibility is needed from everyone – safety is not someone else's business.

Involving patients (and the wider public) is the most important way in which to improve safety and share understanding of risk.'

Wilson and Smith, 2001

Clinical risk management and Controls Assurance

Controls Assurance is concerned with identifying and managing the risks that confront an organisation. It straddles all of the Governance responsibilities of an NHS Trust, and lays a solid foundation upon which continuous improvement and service redesign can safely be based.

'Corporate governance is the system by which an organisation is directed and controlled, at its most senior levels, in order to achieve its objectives and meet the necessary standards of accountability and probity. Effective corporate governance, along with clinical governance, is essential for a Primary Care Trust (PCT) to achieve its clinical and quality and financial objectives.'

Corporate Governance Framework for Primary Care Trusts, August 2002

It is also important to recognise the other aspects of governance (Information and Research) that need to be brought together into one integrated governance agenda (see Section 3 for a fuller discussion of this issue).

Controls Assurance is an overarching and unifying process that deals with the risks that are attendant upon all of these areas of activity and is:

'designed to provide evidence that NHS bodies are doing their reasonable best to manage themselves so that they meet their objectives and protect patients, staff, the public and other stakeholders against risks of all kinds.'

Controls Assurance Unit, 2002

NHS Trusts provide this evidence of assurance by having in place clear systems and processes that routinely and systematically embed risk identification and risk management into all aspects of:

- financial, organisational and clinical planning
- implementation
- commissioning
- monitoring, evaluation and review.

Evidence from these processes must routinely be scrutinised by Boards. Where this scrutiny confirms the robustness of these systems, the CEO of the organisation is able to fulfil her/his statutory duty to complete a Statement of Internal Control (SIC).

'From 2001/2002 all NHS Chief Executives will sign SICs, which will form part of the statutory accounts and annual report. To provide this Statement, Boards need to be able to demonstrate that they have been properly informed through assurances about the totality of their risks, not just financial, and have arrived at their conclusions based on all the evidence presented to them. ... ... such a Statement puts responsibility for the system of internal control unequivocally at the Board table.'

Department of Health, 2002a

The scope and complexity of the PCT agenda mean that Boards and PECs must take decisive action to ensure that the evidence presented to them is robust and wide-ranging and that the collection of this evidence is supported by appropriate expertise.

'Taking stock, at any one point in time, of all these activities and their connection, or not, to key risks is a substantial but necessary task ..... A common starting point is a structured risk identification and assessment exercise involving Board members and senior managers .....In particular, consideration should be given to the establishment of a multi-disciplinary assurance team that has wide-ranging senior representation. Such a team, with internal audit support, can be the focus for building the assurance framework that begins the process of integrating healthcare governance across the organisation.'

Department of Health, 2002a

This integrated governance and the purposeful use of intelligent information that underpins it will become the focus of scrutiny of the new Commission for Health Audit and Inspection (CHAI).

The specific form of governance arrangements will, however, vary from organisation to organisation.

'Every organisation will need to design its own framework, which will relate to the delivery of its own objectives within the context of an understanding of the principal risks that the organisation faces.'

Department of Health, 2002a

Regardless of the shape and form of these arrangements, it is essential that they generate robust information. This may be through a specific committee and through the clear allocation of operational responsibility and accountability for risk management to named individuals. This demands not only clarity but reasonableness in the delegation of primary responsibility for risk identification and management within a PCT.

'To make sure that new guidance and directives are implemented means identifying the most appropriate person to action them, without the workload becoming unmanageable for any single individual.'

NHS Litigation Authority, 2002

PCTs face a particular challenge because of the nature and the extent of their inherited clinical management infrastructure.

'The literature assumes a complex secondary care model, with dedicated staff like risk and claims managers. However, PCG/PCTs may find it worth while to appoint such officers, to implement organisation wide strategies.'

O'Rourke, 2002

The Board and PEC must find sustainable processes and structures to generate robust forms of risk management information and they must scrutinise the outcomes on a regular basis. They must also maintain a clear record of lessons learned and actions that are required and occur as a result of this scrutiny.

REFLECTION

What evidence exists of a solid and secure foundation of Controls Assurance in place across the full range of the PCT's activities?

What Boards must do

'The Board ensures that there are proper and independent assurances given on the soundness and effectiveness of the systems and processes in place for meeting its objectives and delivering appropriate outcomes.'

Governance Standard (criterion 6)

How Boards can take this forward

- Structured risk identification at Board level linked to objectives
- Assessment of significant risks taking into account controls and other management assurances
- Identification and coordination of independent assurance and other review functions
- Ongoing Board monitoring of the effectiveness of the resulting Assurance Framework

Such a process will support a Board in making a fully informed Statement on Internal Control that sets out the achievements in the embedding of risk management and the work that remains to be done.

Department of Health, 2002a

'Reasonable' assurance

Absolute assurance is not a realistic goal for any form of assurance system – whether financial or clinical.

'A Board [should] fully debate and map the connections linking organisational objectives, risk and the range and effectiveness of existing assurance reporting. In doing so it will be important to establish the principle of reasonable rather than absolute assurance and to establish a consensus on what 'reasonableness' means for the organisation... it will also become clear to individual Board members, if it was not before, that assurance, whatever its source, will never be a guarantee that offers absolute certainty.'

Department of Health, 2002a

Active engagement with and the careful balancing of complex risk lie at the heart of the care process. Clinical risk management processes and systems are designed to provide to patients, to professionals and to organisations 'reasonable' assurance that due and prudent attention has been given to minimising inescapable risk.

This is in no sense an argument for complacency. Recent and proposed changes in the law have placed the responsibility for safety upon organisations and their systems, rather than concentrating solely on the behaviour of individual employees.

Clinical risk management is, inescapably, a corporate concern.

Clinical risks in primary care

The publication of An Organisation with a Memory signalled a renewed emphasis upon safety across the NHS and made it clear that action needed to be taken at local level to embed a 'culture of safety'.

> 'In combination, the introduction of clinical governance and the expansion of controls assurance beyond purely financial risks provide a strong impetus for the further development of comprehensive local risk assessment and risk management systems.'
>
> *Department of Health, 2000*

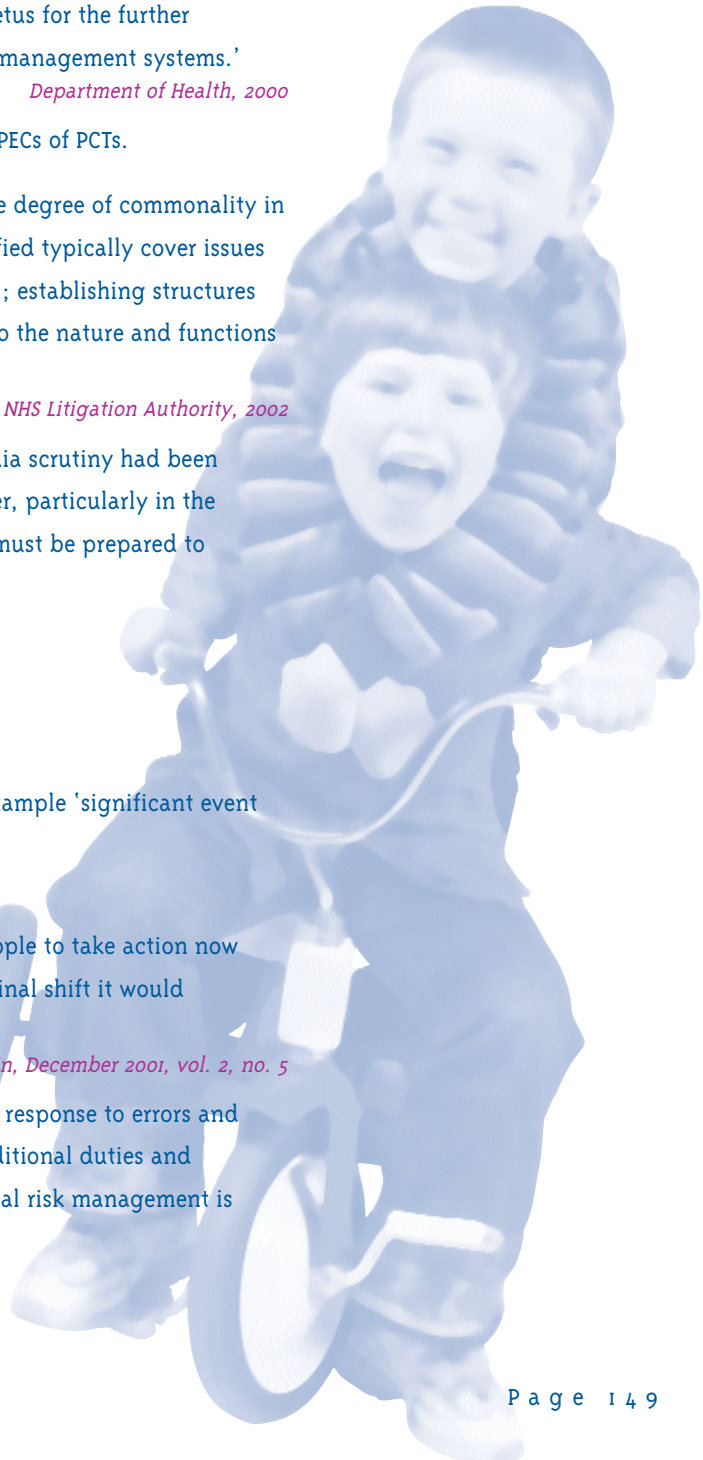
This has direct and immediate implications for the Boards and PECs of PCTs.

> 'The risks facing PCTs are wide-ranging, although there is some degree of commonality in terms of the major risks currently facing PCTs. The risks identified typically cover issues associated with the development of any new organisation (i.e.; establishing structures and frameworks for activity) together with risks which relate to the nature and functions of PCTs themselves.' (10)
>
> *NHS Litigation Authority, 2002*

Hitherto, most professional emphasis and most public and media scrutiny had been directed at risks, failures and errors in the acute sector. However, particularly in the shadow of Shipman, Green and others, those who govern PCTs must be prepared to withstand equal scrutiny.

> 'Leaders at the level of the primary care trust should:
>
> - support their colleagues in promoting safety;
> - encourage and reward the reporting of errors;
> - promote well validated methods of analysing events, for example 'significant event audit';
> - demonstrate that they have patient safety at heart.
>
> The importance of this in reducing harm and encouraging people to take action now cannot be underestimated in terms of the cultural and attitudinal shift it would engender.'
>
> *Clinical Governance Bulletin, December 2001, vol. 2, no. 5*

Leaders should also promote a just culture by their appropriate response to errors and near misses. In the wake of altered patterns of care and the additional duties and responsibilities that PCTs have inherited, this attention to clinical risk management is timely.



'Primary care is becoming increasingly complex. Conditions previously in the provenance of the hospital specialist are now firmly established in primary care.'

Clinical Governance Bulletin, December 2001, vol. 2, no. 5.

This poses a particular challenge for primary care since the

'great majority of available information and evidence on adverse events in the NHS, and in the health care sector generally, relates to hospital-based care. We have also stressed that this report and its conclusions are nevertheless of equal relevance to primary care, in particular to Primary Care Groups and Primary Care Trusts as developing organisations.'

Department of Health, 2000

More recently, researchers have challenged the assumption that there is an acute shortage of research data – rather they emphasise that the data has not been recognised or acted upon.

'There is already a surfeit of knowledge that is not being put into action.'

Wilson and Sheikh, 2002

Recent work by the Wisdom Centre at Sheffield University has underlined the extent of the primary care risk management agenda.

'Potentially hazardous areas for primary care seem to be:

- **Failure to examine**
- **Failure to visit**: Delay or failure to visit produces about a third of complaints to FHSAs. It is the doctor's responsibility to decide if a visit is indicated, even if the caller is seeking advice and does not specifically request a home visit.
- **Minor operations**: (failure to document fully or send appropriate samples for histology; infection afterwards)
- **Informed consent**: In primary care, this has often been informal and implicit. For more interventionist procedures explicit consent may be needed.
- **Communication**: failure to keep patients adequately informed if outcomes are likely to be poor; failure to explain setbacks; failure to inform fully of complications and side effects.
- **Drug and prescribing errors**
- **Medical records**'

O'Rourke, 2002

Given the nature and the scope of these issues it is clear that, the management and minimisation of risk, like clinical governance itself, is not just the business of doctors, or other professional staff. It is the duty of all members of the PCT community – from reception staff to Board members – and is now enshrined in the professional duties of NHS managers.

'I will make the care and safety of patients my first concern and act to protect them from risk.'

Department of Health, 2002b

Similarly, to widen the capture of risk related clinical data, the 'Yellow Card Scheme', has now been extended to a wider range of professional groups.

'The Medicines Control Agency has now extended its suspected adverse drug reactions scheme (the Yellow Card Scheme) to all nurses adding around 333000 NHS Professionals to the scheme....The scheme accepts reports from doctors, dentists, coroners, pharmacists, nurses, midwives and health visitors. It plays an important role in identifying drug safety issues and preventing harm.'

CEO Bulletin Issue 143 Nov 2002

REFLECTION

What evidence is there to indicate that staff across the PCT feel a sense of responsibility for risk management and for patient safety?

Evidence from litigation of 'high risk' activities

Scrutiny of litigation claims proceeding from adverse incidents in General Medical Practice also provide important indicators of high risk activities. The results are shown in Table 10.1.

Table 10.1 Indicators of high-risk activities

Delays in diagnosis, principally	55% of claims*
missed malignancies	
missed conditions requiring surgery	
missed meningitis and pneumonia	
Medication errors	25% of claims
Management of pregnancy	10% of claims
Other procedures and interventions	20% of claims

*Approximate percentage of total indemnity paid out. Total value of payments in the latest 2 year period is £16.9 million.

Source: Derived from Medical Protection Society and Medical Defence Union
Also published in An organisation with a memory

A quarter of these errors relate to prescribing actions or outcomes.

'About 1.5 million prescriptions are written by general practitioners in England every day and a further 0.5 million in hospitals daily. The standard of prescribing of drugs is generally high but it is inevitable that errors will occur. When this happens, patients can be harmed, sometimes seriously.'

Department of Health, 2001

Two initiatives offer significant opportunity to manage and minimise risk:

- the introduction of the medicines management programme in PCTs, set out in the Government's *Programme for Pharmacy in the NHS*
- the integration of community pharmacy services with those of the PCT

Particular safeguards may need to be considered for 'dispensing practices' (often in rural areas) that may not have the additional safeguard of scrutiny from a trained pharmacist.

Common medication errors resulting in litigation claims

- Incorrect or inappropriate dosage
- Wrong drug
- Administration error (correct medication wrongly administered)
- Contra-indicated medication (e.g. patient given medication which reacts badly with another drug or condition)
- Prescribing and dispensing errors (e.g. prescribing or dispensing an incorrect drug with a similar name to the intended medication)
- Failure to monitor progress
- Failure to warn of side-effects
- Repeat prescribing without proper checks
- Over-reliance on computerised prescribing
- Prescribing unlicensed drugs

Source: Derived from Medical Protection Society and Medical Defence Union
Also published in An organisation with a memory

REFLECTION

What activities has the PCT identified that are likely to generate risk?

What evidence is there of systems and processes in place to monitor and manage these risks?

The activity launched by the NPSA to pilot adverse incident reports with a number of PCTs highlighted the following concerns:

'Drug Administration error
Delayed OPD referral
Lost specimens
Messages not passed
Out of date vaccine administered'

Corbett-Nolan, 2002

Learning from adverse events, serious untoward events (SUIs) and near misses

Some confusion may currently arise from the use within the national and international professional literature of different terminology to describe potentially avoidable 'risk active' clinical situations or incidents. These are generally referred to as 'near misses' (borrowing terminology from the airline industry). This section will regard all of the former categories (i.e. 'adverse incidents, serious untoward incidents, or 'sentinel events') as being risk active and therefore demanding a risk management response.

As *An Organisation with a Memory* pointed out, adverse events provide a rich source of learning for the NHS in relation to the prevention or minimisation of clinical risk. Although the situation is changing rapidly, adverse event reporting has traditionally been least developed in primary care. This is paradoxical, as it is here that most patients are seen. There are

- more than 250 million GP consultations
- 26 million dental consultations

- a hitherto uncalculated number of community nursing episodes of care.

This absence of focus on and within primary care compounds system-wide weaknesses in current NHS incident reporting systems

'There is no standardised, operational definition of 'adverse event' which would be easily understood by all NHS staff.

The coverage and sophistication of local incident reporting systems, and the priority afforded to them by NHS Trusts, varies widely. Incident reporting in primary care is largely ignored.'

Department of Health, 2000

In part this reflects the difficulty of co-ordinating and embedding adverse event activity across the discrete practices that make up PCTs.

'There is very little evidence about the capacity of primary care organisations, down to the level of individual practices, to learn actively from failures, but the general caveats we have highlighted about lack of systematic dissemination and follow-up of lessons apply at least as strongly in primary care as they do in the hospital sector.'

Department of Health, 2000

In part also problems in progressing adverse incident reporting and learning reflects the absence of robust systems, structures and management capacity in many PCTs.

'Primary care faces particular challenges in developing and maintaining effective local incident risk reporting systems, not least because it has lacked some of the organisational structures to support such systems.'

Department of Health, 2000

In order to address this issue, a number of SHAs have begun to develop guidance and structures to bring coherence and consistency to generating and sharing data.

For example, in the SHA in Bedfordshire and Hertfordshire has used existing national guidance to develop a common definition of 'serious untoward incidents' for use by all NHSTs in their area.

'What is a Serious Untoward Incident?

A serious untoward incident is any unexpected event, occurring on an NHS site or elsewhere whilst in NHS funded or regulated care involving:

- NHS patients, relatives or visitors
- Staff, students undertaking clinical or work experience and/or their tutors
- Contractors, equipment, building or property that
  - caused death (including suicide) or serious injury or was life threatening
  - contributes to a pattern of sustained reduction in standards or care
  - involves a hazard to public health, including major toxic contamination or radiation hazard.'

Bedfordshire and Hertfordshire Health Authority, 2002

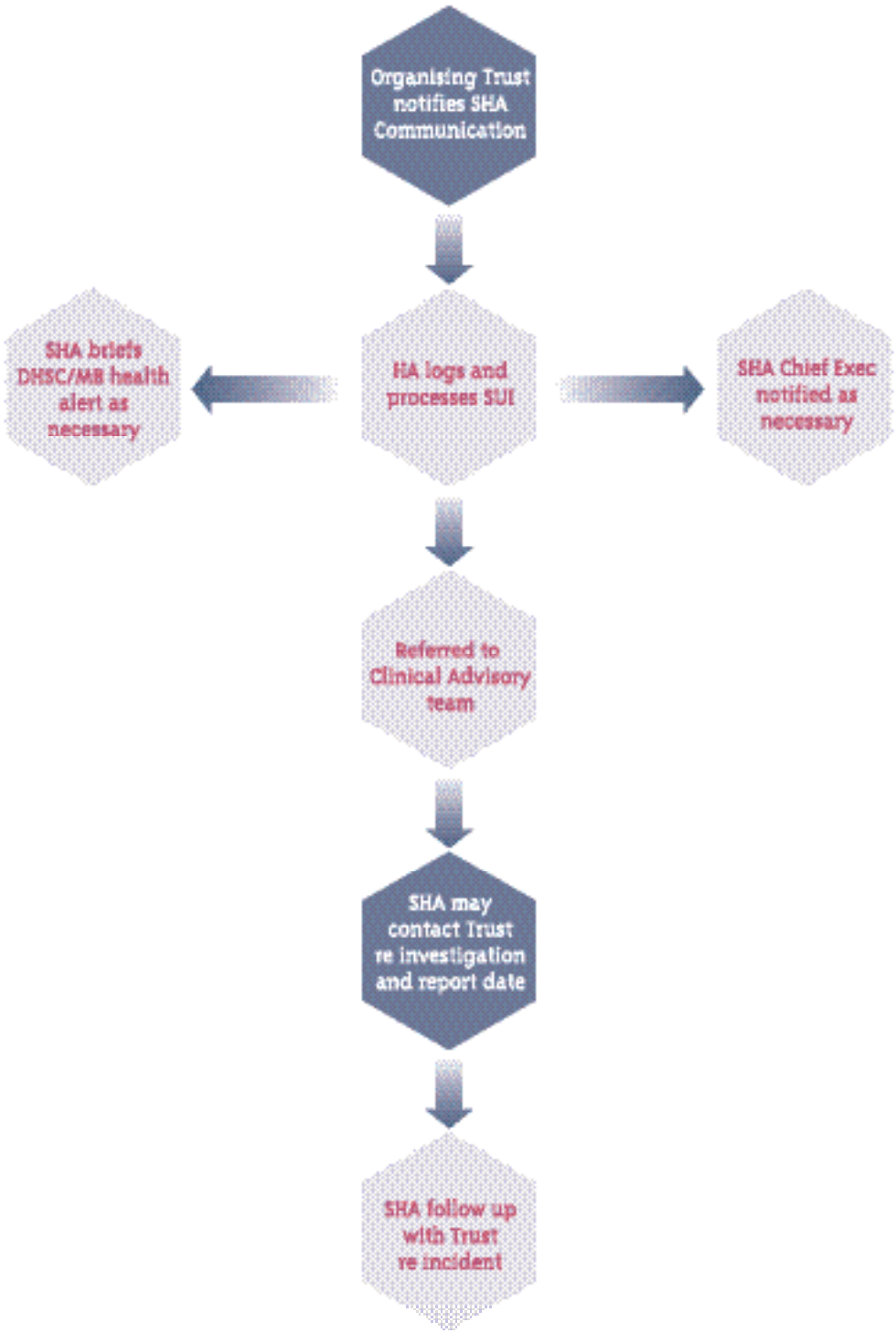
REFLECTION

What evidence exists of the steps the PCT has taken to establish clear systems for SUI/adverse incident reporting for all groups of staff?

Excluded from this definition are adverse outcomes reasonably associated with routine NHS activity, such as major surgical procedures or radiotherapy treatment.

The SHA has gone on to develop a model for reporting and follow-up action procedure and process.

Bedfordshire and Hertfordshire Health Authority, 2002



Systematic reporting for adverse events and near misses

These regional and local initiatives complement the national work led by the National Patient Safety Agency (NPSA). The NPSA has already begun collecting and analysing key information from local organisations and from other sources – providing relevant and timely feedback to organisations and clinicians to help them improve patient safety. Following on from piloting of this system in 28 hospitals and primary care units, the reporting system will undergo further testing and development in early 2003 prior to being implemented across the NHS from April 2003.

By collecting and analysing data on adverse events, the agency will be able to identify trends and patterns of avoidable adverse events, provide feedback to organisations to enable them to change their working practices, help develop models of good practice and systems solutions at national level and support ongoing education and learning.

PCTs, as with other NHS organisations, will increasingly be required to report adverse events and near misses to the National Patient Safety Agency as a matter of course.

In order for them to do so, Boards and PECs must ensure they have well-understood and effective systems in place for reporting and learning from adverse events, as well as systems for implementing relevant patient safety alerts and other guidance from the NPSA.

The key characteristics of such systems is that they should facilitate and support:

'• reports by individual members or teams of staff to management for action;

- reports by organisations to the new national body and, where appropriate, other agencies responsible for specific reporting schemes;
- reports by individual members of staff or teams of staff directly to the new national body in some circumstances (including a confidential channel of reporting);
- reports by patients and carers to the new national body.'

Department of Health, 2001

REFLECTION

What evidence is there to indicate that the PCT has established open and effective channels for patient complaints?

Are complaints scrutinised and SEAs routinely undertaken of key complaints? Do the Board/PEC ensure that action is taken to address significant shortcomings or problems that they uncover?

Patient Involvement in identifying and managing clinical risks

There is a danger that in thinking about 'risk' some organisational controls assurance processes are reflexively more concerned with the minimising risk to the organisation than with preventing possible harm to patients.

Particularly in primary care, the overwhelming majority of the risks to which patients are exposed are invisible to clinicians and the PCT. Many of these risks proceed from macro-lifestyle and environmental factors that can only be addressed through pro-active health promotion measures supported, where appropriate, by screening regimes.

Other risks, however, proceed from ongoing life style choices made by individual patients that counteract or undermine the treatment process, sometimes in ignorance of the risks generated, and sometimes in the face of clear and effective clinical advice.

Similarly, much preventable harm occurs, and a significant proportion of the total NHS drug budget is wasted, because the rates of concordance with treatment that are routinely achieved are less than 50% (Section 15 addresses this aspect of clinical effectiveness in more detail).

As they set about tackling these issues, it is important that PCTs recognise and find ways to unlock the potential improvements in safety and in treatment outcomes that can be achieved through working more closely and more imaginatively with local communities and patients themselves.

'Involving the public and patients is important in reducing harm.'

Clinical Governance Bulletin, December 2001, vol. 2, no. 5

The Loughborough Investigation report identified a number of ways in which the public could have been protected if more systematic and sustained attention had been given to concerns raised, over time, by patients and staff. The report called for

'explicit and consistent and mandatory policies in primary care for:

- the logging and tracking of anonymous and informal concerns to facilitate the identification of a pattern of potential concerns. Such a system to be held separately, but reported in tandem with, other complaints information.
- evaluation of complaints and untoward incidents, maximising feedback from patients, practitioners and managers.
- regular audit of organisation practice, for example, patient appointment systems, and regular audit of clinical practice, for example, critical incident and near miss reporting and analysis.'

Commision for Health Improvement, 2001

Boards and PECs need to have in place robust systems that make it easy for patients (and especially vulnerable groups) to register complaints or concerns. They must routinely and sensitively analyse the data and consider the outcomes.

'Overall, we believe that information from complaints is under-exploited as a learning resource.

Department of Health, 2000

Commissioning and clinical risk management

PCTs need to identify and minimise PCT-wide clinical risks. Through their commissioning processes, they must pay explicit attention to the ways in which risks are identified, managed and minimised by the organisations that deliver care on their behalf. They also have to pay particular attention to any risks that may occur at points of transition within the patient 'journey'.

Feedback loops must be in place to enable them to share learning, key risk and risk management issues.

The role of the NHS Litigation Authority

The NHS Litigation Authority (NHSLA) is a Special Health Authority, established on 21 November, 1995. Its principle task is to administer schemes set up under section 21 of the NHS and Community Care Act 1990 to allow NHS bodies to pool the cost of injury, loss or damage to property and liabilities to third parties arising from carrying out their functions. It is an essential source of expertise, information and guidance on the prevalence and the management of clinical risks.

Historically, it has focussed primarily upon the acute sector; but with the growing importance and centrality of primary care it has now assumed a significant and central role so far as PCTs are concerned.

The Authority produces a set of standards for the identification and management of risks. The performance of each NHST is measured against these standards. The better the performance of an organisation, the lower the premium that it pays to insure its corporate and clinical risks.

Hitherto there have been two sets of broadly compatible standards in operation:

- those developed by CNST and
- those developed by the Risk Pooling Schemes for Trusts (RPST).

In order to provide a single and unified approach to standard-setting, these standards will be united from April 2003.

'These standards will comprise relevant criteria from both the existing CNST and RPST standards and introduce new criteria specific to the activities of PCTs. All supporting guidance, examples of the verification etc. will be appropriate to PCTs.'

NHS Litigation Authority, 2002

Once they have been published. All PCTs will be assessed against the Level I standards during 2003/2004. Until these new standards become available, much can be learned from scrutiny of the principles that underlie both of these frameworks.

Current RPST standards suggest a staged process of engagement with the risk management agenda.

'Step 1 – Self-Assess

Step 2 – Support from the Board

Once the PCT has completed a self-assessment and determined its compliance or otherwise against the criteria, this information needs to be shared with the Board via the Board sub-committee(s) with overall responsibility for risk management. They must ascertain whether or not they feel that the organisation is in a position to achieve a successful outcome at the formal assessment. Not only does this approach gain support from the Board but also, more importantly, it portrays the importance of risk management to the rest of the organisation.'

NHS Litigation Authority, 2002

Current CNST standards identify 7 standards against which the performance of a Trust is judged:

'Standard 1: Learning from experience

Standard 2: Response to Major Clinical Incidents

Standard 3: Advice and Consent

Standard 4: Health Records

Standard 5: Induction, Training and Competence

Standard 6: Implementation of Clinical Risk Management

Standard 7: Clinical Care'

NHS Litigation Authority, 2002

'**General Principles to consider when applying the standards**

Consistency – It is essential the PCT has a consistent approach across the trust to clinical risk management.

Policies – If a policy of system from a previous trust is to be used, as a short-term measure, it must be formally adopted by the PCT, in order to ensure ownership throughout the whole organisation. Of equal importance, is to ensure policies are accepted by all clinicians concerned. CNST would suggest all policies are systematically reviewed and amended to ensure they reflect the arrangements in the new organisation.

Communications – Given the size and disparity of individual PCTs, communications is potentially a huge risk area. Good communication between the constituents of the PCT is essential. The CNST and RPST standards, if adopted trust-wide, would aid effective communications.

Service Level Agreements – Several PCTs contract out for certain services such as incident reporting and staff training to other organisations via service level agreements. There may be a host organisation providing a particular service for several PCTs in one locality. Whatever the agreement, the PCT is ultimately responsible for ensuring the service provider regularly reports progress and areas of concern. All service level agreements should be reviewed at least annually or more frequently if service provision changes. As an example, if your PCT relies on another organisation to provide induction, how do you know all clinicians employed by your organisation, have received a corporate induction? In undertaking baseline assessments, the assessors found PCTs were not always able to demonstrate they could check this out with inaccessibility to the host organisations data being the main reason. Or, there were delays in sending training or induction records back to the PCT.'

NHS Litigation Authority, 2002

'**The Structural Building Blocks of a Clinical Risk Management System**

The RPST standards identify a number of important structural components that need to be in place in order to manage clinical risk.

3.1 There is a Board sub-committee(s) with responsibility for overseeing all aspects of risk management.

The RPST standard requires that Boards of PCTs should ensure they have a sub-committee, or sub-committees, for overseeing risk management within their organisation.

3.2 The role and responsibilities of the committee(s) responsible for overseeing risk management activities is/are clearly defined to ensure that any separations of clinical, financial and organisational risks are kept under review.

3.3 The Chief Executive and the designated Executive Directors with responsibility for specific aspects of risk management should be members of the committee.

There is at least one Non-Executive Director as a member of the committee.'

NHS Litigation Authority, 2002

In addition they specify that 'All identified risks are systematically assessed and prioritised' Risk Management System (Core Standard) 2001 and that there must be 'an organisation-wide risk register that is populated by data representing all known risks'. Helpful Guidance is provided in the model Risk Register database on the Controls Assurance Support Unit website.

PCT Boards and PECS need to immediately engage with the new standards once they are published.

The way forward

Figure 10.1 The learning circle

As clinical governance becomes embedded in all aspects of an organisation's activities, so the incidence of unidentified or unmanaged risk should diminish.

'Over time, we would expect the development of clinical governance in all health care organisations within the NHS to reduce the likelihood of service failure. An important part of this local process will be the further development of risk management programmes, an approach which is already well underway.'

Department of Health, 2000

Like clinical governance itself, risk management is the business of every member of the PCT community, and of patients and their carers. The more actively all of them embrace this responsibility – and the more responsive the organisation and its leaders are to the concerns or improvements they identify – the safer the total environment and experience of care will become.

'Experience and research studies suggest that safety is likely to be a strong feature of **an informed culture**, which has four critical sub-components

A **reporting** culture: creating an organisational climate in which people are prepared to report their errors or near-misses. As part of this process data need to be properly analysed and fed back to staff making reports to show what action is being taken;

A **just** culture: not a total absence of blame, but an atmosphere of trust in which people are encouraged to proved safety-related information – at the same time as being clear about where the line is drawn between acceptable and unacceptable behaviours. An example is the airline safety system which we discuss later in this chapter;

A **flexible** culture: which respects the skills and abilities of 'front line' staff and which allows control to pass to task experts on the spot; and

A **learning** culture: the willingness and competence to draw the appropriate conclusions from its safety information system, and the will to implement major reforms where their need is indicated.'

Department of Health, 2000

REFLECTION

To what extent is the PCT culture one that encourages the identification of risk and of error?

What evidence is there of learning and change as a result of adverse incidents?

One significant characteristic of a 'learning culture' is that it understands the importance that systems as well as individuals play in generating error and risk.

'Systems-thinking is the only route to definitive risk-reduction solutions.'

Department of Health, 2001

In primary care this will require a subtle and imaginative approach to the analytic task.

'The systems perspective tells us we must look beyond individual mistakes or bad luck to understand important problems. We must look beyond personalities and events. We must look into the underlying structures which shape individual actions and create the conditions where types of events become likely.'

Senge, 1994

A number of telling conclusions can be drawn from the detailed analysis that has occurred of clinical negligence in the NHS in Wales.

'A significant contributor was the incidence of potentially avoidable errors by clinicians and others, associated with administrative, communications, or wider systems issues, as opposed to strictly clinical judgment or technical error.

Such 'non-clinical' errors ranged from breakdowns in communication – between clinicians, patients and non-clinicians – to straightforward administrative failings such as losing patient records.'

National Audit Office Wales, 2001

Root cause analysis in primary care

The Welsh bear out those from commercial and technical fields of study, where there has been significant investment in risk identification and management.

'Extensive study in the non-health field has shown that with most unintended failures there is usually no single explanatory cause for the event. Rather there is a complex interaction between a varied set of elements, including human behaviour, technological aspects of the system, socio-cultural factors and a range of organisational and procedural weaknesses. Systematic study of these issues in the health care field is sparse, but available evidence suggests a similarly complex pattern of cause and effect relationship.'

Department of Health, 2001

Within a complex and interdependent system such as health care, it is unlikely that errors will result exclusively from actions that occur within the boundary of any one organisation. The analysis of causative factors needs to be comprehensive and system – rather than organisation – based.

Although not yet widely applied to or in primary care, root cause analysis provides one important analytic tool. It can be a fundamental component of an effective significant event audit that can help unlock the learning that too often remains concealed when errors occur.

'**Key features of a thorough root cause analysis**

- determination of the human and other factors most directly associated with the event, and the processes and systems related to its occurrence;
- analysis of the underlying systems and processes through a series of 'why' questions to determine where redesign might reduce risk;
- identification of risk points and their potential contributions to the event;
- determination of potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.'

Joint Commission on the Accreditation of Healthcare Organisations, USA

REFLECTION

Are there people in the PCT community who have expertise in significant event audit and root cause analysis?

Can the PCT call upon help and support from other parts of the local health economy to help them learn from adverse events?

Priorities for action

Now that you have finished reading through this section, please identify three priorities for the PCT in relation to the identification and management of clinical risks and relate them to the Checklists below.

1

2

3

Checklist: Factors that inhibit effective risk management in primary care

Need for a common and primary care appropriate 'risk vocabulary'
'Thin' professional literature on risk in primary care
Resource constraints/ inherited infrastructure • Level of organisational maturity • Dealing with the after shocks of merger and cultural collisions • Staff shortages leading to stress, overload error risk • Complexity of employment/contractual arrangements • PCT responsibility significantly greater than power within current contractual arrangements with all independent contractors
Absence of infrastructure and systems to translate clinical and other risk data into 'intelligent information'
Invisibility of many primary care risks
Life style issues
Invisibility of absence of concordance with treatment
Insufficient attention to transition risks
Risks attendant upon commissioned as well as provided services
Proliferation of non-aligned inspection regimes' information demand overload

Checklist: Factors that promote effective risk management in primary care

Integrated Governance
Explicit ownership of Clinical Risk Management Agenda by Board and PEC
Explicit attention to risks to communities and patients as well as to the organisation
Clear strategy for the pro-active identification, management and minimisation of all of these risks
Clear delegated lead responsibilities and authority for strategy implementation to named individuals and groups
'Passionate' ownership of safety within all professional and other staff groups
Pro-active patient and carer engagement in risk identification and management
Effective and lean systems to promote and evidence CRM
Supportive and trusting staff culture
Clinical supervision, accountability and support
Collaborative inter-organisational working
Managed transitions
'Intelligent external scrutiny'

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Joint Commission on the Accreditation of Healthcare Organizations, USA.
www.jcaho.org

Resources

Centre for Risk and Crisis Management (CRaCM) is at the University of Liverpool:
Email: denis.smith@liverpool.ac.uk

Commission for Health Improvement – CHI's aim is to improve the quality of patient care in the NHS.
www.chi.nhs.uk

Controls Assurance Support Unit
www.casu.org.uk

Making Amends: proposals about the way the NHS deals with medical negligence cases
www.doh.gov.uk/makingamends/cmoreport.htm

National Patient Safety Agency
www.npsa.org.uk

NHS Litigation Authority (NHSLA)
www.nhsla.com

National Audit Office
http://www.nao.gov.uk/publications/workinprogress/clinical_governance.htm

Wisdom Centre at Sheffield University includes a virtual conference on clinical governance.
www.shef.ac.uk/uni/projects/wrp/cgmenu.html

Rating the PCT's current stage of development

Please rate the PCT's current stage of development in relation to the following questions.

Remember to use the Response Sheet provided for your answers.

10.1 To what extent is there a strategy proactively to identify and minimize clinical risks to patients?

10.2 To what extent is particular attention paid to the risks confronting vulnerable or marginalized people?

10.3 To what extent is there a strategy proactively to identify and minimize risks to staff?

10.4 To what extent are patients and their carers actively involved in the identification and management of clinical risks?

10.5 To what extent are patient complaints systematically analysed to identify and eliminate risks?

10.6 To what extent does the PCT culture promote the identification of and learning from serious untoward incidents or near misses?