

CLINICAL GOVERNANCE

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Editorial: Clinical errors

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Human beings make mistakes because the systems, tasks and processes they work in are poorly designed.

Dr Lucian Leape

Clinical incidents are estimated to affect 10% of hospital patients¹. To date, however, incident reporting has not been systematic or universal in the UK. While many hospitals have put in place a clinical risk management process, the number of incidents they are able to capture is small. There is also no evidence as yet that lessons are systematically learnt from these unfortunate events. Even when lessons are learnt, they are usually confined to the local clinical team and possibly the service they belong to rather than being translated into local organisational learning, let alone influencing the national context. Indeed, the recurrence of many of the known risk factors – such as poor communication, poor supervision, lack of competent staff, poor consent process, non-adherence to policies and procedures and poor record

keeping – demonstrates that appropriate remedial action is either not effective or not applied.

This would seem to indicate that we need a more concerted, national approach to minimising risk to patients and not just a more open reporting system. It remains to be seen whether the establishment of a national incident reporting system will increase the proportion of incidents reported and lead to more effective remedial action. In the work Woloshynowich *et al.* undertook in two London hospitals many untoward events uncovered had not previously been reported¹.

Patient safety has now been given a national focus. The approach has been highlighted in two documents published by the Department of Health: *An Organisation with a Memory*, for which a summary and the implications for the NHS can be found in the September 2000 issue of the *Bulletin*, and the recent *Building a Safer NHS for Patients*, which is dealt with in this issue. These herald major changes in the way adverse events and litigation are handled.

The national incident reporting system is based on anonymous reporting and is managed by the recently created National Patient Safety Agency (NPSA). The NPSA will collect, examine and analyse all incidents, give feedback and identify systems improvements. The information will be disseminated throughout the NHS.

Work on the minimum data set, which covers all aspects of health-care, has already started, as it is being piloted in a number of trusts,

Topics for future issues

- Complaints
- Clinical audit

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as well as in the private sector. The aim of the data set is to get answers to a number of simple questions such as when, where, how and why particular events happened, what action has been taken and what factors would have minimised the impact. This will eventually be rolled out to all NHS organisations in primary, secondary and tertiary care and all adverse events and near misses will have to be reported. The NPSA will also issue guidance to the NHS on root cause analysis to ensure that all factors contributing to the incident have been identified.

Despite these new national systems, health-care organisations will need to continue to encourage reporting and consider local incidents as part of their clinical governance activities. Clinical errors, however, which affect a large number of patients or are deemed serious may be investigated by the Commission for Health Improvement, particularly if lessons are likely to be of value to the wider NHS. In this issue we deal with clinical errors, their investigation and the patient focus agenda.

If you are willing to share your practical experience in any aspect of

clinical governance, we would be pleased to receive your contribution, but remember to highlight the key points in order that everybody can benefit easily from the learning. Topics for future issues will include complaints and clinical audit.

Reference

- 1 Woloshynowich M, Neale G, Vincent C. Adverse events in hospitalised patients: a pilot study and preliminary findings. *Clinical Governance Bulletin* 2000;1(2): 2-3

What will it take to improve patient safety in primary care?

Tim Wilson and Fiona Smith

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- 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.

Medical progress may increase our ability to help patients, but it also increases the potential for harm. Clinicians increasingly appreciate the importance of ensuring patient safety (clinical risk management) – it is not as if it wasn't a problem before, only that their attention seems to have been captured. Despite this, there remains a dearth of understanding of patient safety in primary care, where the overwhelming majority of patient-clinician encounters take place, and this poses a real challenge to the nascent National Patient Safety Agency (NPSA)¹.

The scale of serious harm in primary care is probably of the order of 0.2% per episode of care (compared with 2% per hospital admission, although there are uncertainties regarding the numerator as each admission leads to many episodes of care). For instance, one study (in 1989, of 15,916 mixed computerised and hand-written prescriptions) showed error rates of 3.17%, but none were serious and 1.06% had only a major nuisance factor². However, the volume of consultations in

primary care means that the overall level of patient harm might be high (given 500 million prescriptions annually there would be 1 million significant errors), if uncommon in any one surgery. This causes particular difficulties for primary care, as it is difficult to manage rare events.

Nevertheless, primary care is becoming increasingly complex. Conditions previously in the provenance of the hospital specialist are now firmly established in primary care. Early hospital discharge, the

Box 1. Work for the NPSA: areas for action

Example 1

There are a number of cases in the records of the medical defence organisations that relate to a child putting a hand into a sharps bin on the floor. Although rare, this problem could be easily rectified, now, at no cost.

Example 2

Abnormal blood results can be missed for a number of reasons and recent studies suggest that this may be common⁴. To avoid missing every abnormal result would require a labour-intensive and complicated system of checks. However, how many serious illnesses could be prevented by such a system, including leukaemia? Or would resources be better invested in improving statin prescribing?

Work on behalf of the NPSA could identify cases like the first example and suggest immediate means of rectification. The second example might be highlighted as important, but for action at a later date.

Box 2. The work required of primary care leaders at different levels

National professional leaders should:

- ensure that primary care is well up the agenda of organisations like the NPSA;
- promote safety at every opportunity;
- ensure the right resources are available for safe care;
- demonstrate their human frailties by admitting to mistakes;
- when politicians make mistakes, treat them as they would wish to be treated;
- ensure that the no-blame culture is really that, by ensuring that those who report mistakes are rewarded and immune from disciplinary action.

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'⁵;
- demonstrate that they have patient safety at heart.

Leaders at practice level should:

- use significant event audit to promote safety;
- learn from complaints;
- ensure everyone in the team adopts a reflective style of practice.

prescribing and monitoring of potentially dangerous drugs (such as cyclosporin for skin conditions), the official sanctioning of polypharmacy for patients (such as those with chronic heart disease and diabetes) and the pressure of short consultations are all increasing the risk to patients.

However, what should be done in primary care? In a recent editorial in the *British Medical Journal* it was pointed out that more research is needed³. This is true but waiting for studies will mean that patients will be harmed in the interim. Four other areas need our attention:

- action
- leadership
- individual responsibility
- the involvement of patients and the wider public

Action

Action is needed now. But what? There is already plenty of information about the major areas of harm in primary care, especially in medical defence organisation databases and in complaints systems. Actions that will save lives and can be implemented easily tomorrow need to be identified. The NPSA would be well advised to work with colleagues in primary care to identify these areas

for action (see Box 1). 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.

Leadership

Strong leadership is needed in primary care to promote patient safety. This needs to happen at all levels (see Box 2). It is unreasonable to expect front-line workers to take patient safety seriously until leaders do. Leaders within primary care must be aware that their inaction sends the wrong message to their colleagues and to the public (see Box 3). Leaders in primary care must enable their colleagues to provide a safer service for patients.

Individual responsibility

Everyone in primary care has a responsibility to reduce harm. If we see something is wrong, we should rectify it. This might be a fire door propped open, a slippery patch on the toilet floor or a warning that the drug we are having to prescribe may be incompatible with one that a patient is already taking. Ignoring any one of these could lead to harm – they are all our business. We should also be reflecting on what we do and how we might do it better.

A more difficult issue relates to when we know the performance or action of a colleague is causing harm. Although whistle-blowers have been poorly treated in the NHS, recent legislation and clear guidance from the General Medical Council, for instance, have made acting on poor performance by our colleagues one of our core duties⁶.

Involving patients and public

As the story in Box 3 demonstrates, involving the public and patients is important in reducing harm. This is true from many different perspectives (see Box 4). Involving patients in the detection and reduction of harm is going to make most of those working in health-care feel very exposed. Many feel that the current litigation climate acts as an impenetrable

Box 3. How a PCT can send the wrong message (based on a true story)

A community hospital was struggling to keep nurses. One particular problem was the minor injuries unit. The increasing reliance on agency staff meant that there were times when untrained staff were having to cope with casualties. Quite rightly, the primary care trust (PCT) decided to shut the minor injuries unit. However, this message was not passed on to practices or the public. As a result, an injured child arrived hoping to receive care, but was turned away from the hospital. Not surprisingly this story reached the local newspaper. The PCT decided that the minor injuries unit should remain closed, as there were still insufficient trained staff, but that if people turned up they should be treated. This left both staff and patients in a vulnerable position.

Imagine if the PCT had, at the outset, publicly announced, in the same local newspaper perhaps, that the minor injuries unit had been closed and what alternatives were available. An explanation of what they hoped to do in the future and when could then have been made.

Message. Reducing harm requires admitting problems and involving the public.

Box 4. Patients and public

Patients should:

- be involved in the management of their condition;
- be helped to understand clinical risks;
- be able to give genuinely informed consent.

Patients and the public should:

- help to design local services;
- be informed when significant events have been analysed and problems rectified;
- be encouraged to make constructive use of complaints and suggestions.

barrier to this. However, those who have taken the step, and properly opened up their service to public scrutiny through lay involvement, have found that members of the public are often more supportive and more constructive than expected. The real move towards safer primary care will only come when this happens.

References

- 1 Department of Health. *Building a Safer NHS for Patients*. London: TSO, 2001
- 2 Neville RG, Robertson F, Livingstone S, Crombie IK. A classification of prescription

errors. *Journal of the Royal College of General Practitioners* 1989;39:110–12

- 3 Wilson T, Pringle M, Sheikh A. Promoting safety in primary care. *British Medical Journal* 2001;323:583–4
- 4 Sherwood P, Lyburn P, Brown S, Ryder S. How are abnormal results for liver function tests dealt with in primary care? Audit of yield and impact. *British Medical Journal* 2001;322:276–8
- 5 Pringle M, Bradley CP, Carmichael CM, Wallis H, Moore A. *Significant Event Auditing*. Occasional Paper 70. Exeter: Royal College of General Practitioners, 1995, and <http://latis.ex.ac.uk/sigevent/> (last accessed 3 December 2001)
- 6 Yamey G. Protecting whistleblowers. *British Medical Journal* 2000;320:70–1

Suggestions for the conduct of an investigation

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- When a clinical incident occurs, it is important to determine how serious it is, to ensure that the right type of investigation is undertaken.
- Investigations can take a long time to complete if the problem uncovered is complex. It is therefore helpful to keep a daily record of what happens.
- Because investigations can be traumatic for staff, you need to ensure that you have in place the relevant support mechanisms to deal with their queries and fears.
- Uncertainty generates anxiety among patients. A personal approach (face-to-face meeting) is better at alleviating anxiety and ensures consistency.
- Media interference is unpredictable. You must be ready to deal with press enquiries and have done all necessary preparation to activate a help-line quickly in the case of incidents that affect a large number of patients.
- All health-care organisations should have a clear procedure for dealing with serious clinical incidents, covering the investigation process, communication and reporting, to ensure that there is a consistency of approach.

At the beginning of any investigation into clinical concerns or a clinical incident, it is impossible to tell whether what has happened will eventually be the subject of external scrutiny, for example an investigation by the Commission for Health Improvement (CHI). For our trust, what started as a small study of some recent results unfolded into what we now know to be the biggest review of histopathology in the country. Although the issue of clinical competence remains unanswered, the wider issues surrounding the employment of locum doctors spanned several trusts and the Secretary of State for Health ordered an investigation by CHI. I hope the suggestions made here will be of use to trust managers who are thinking about how to address some clinical concerns and are wondering what the ultimate consequences might be.

Keep a book or a diary

This idea was taken from a clinical governance conference at which a speaker talked about a clinical incident: he held up an exercise book and called it his most valuable asset. When a group of doctors at our trust started to raise questions about the different reporting practice of another

consultant, I found an unused diary and I wrote down everything that had happened on each day. At the time this seemed superfluous, as the dates seemed indelibly ingrained in my memory. However, it was surprising how hazy the chronology became over time. I was particularly grateful for the diary when I was asked to send a copy of the protocol we were using to another trust. In short, the process had been more of an iterative one and since, up until that point, the protocol existed only in my head, the diary was invaluable in transforming a retrospective decision-making process into a protocol.

Set up an incident team

This suggestion was taken from a document on how to investigate cervical screening incidents, but was easily adapted to our circumstances. The purpose of the incident team was to manage, coordinate and progress the review while considering the communication aspects throughout. The team met weekly or occasionally fortnightly over the 18-month review period, always in the same place at the same time (8 a.m. on a Friday morning). As will be mentioned later, the secretarial

support for this meeting provided a turning point in ensuring decisions were recorded and consistency of both note taking and coffee availability! The incident team was made up of the key people involved in the review:

- a clinical expert in the service (i.e. a pathologist)
- the clinical director and manager for the service (i.e. pathology)
- the clinical audit manager (the clinical audit department dropped almost all its other work and took up the role of processing and documenting the information)
- the clinical governance leads (who, in our trust, included both the medical and nursing director, the deputy medical director and the clinical governance facilitator, all of whom were very much needed)
- the trust communications manager (communication was a constant theme, and other health authority communications experts attended at intervals)

External scrutiny was also very important to our review and we found the involvement of a public health consultant from the health authority an asset to our decision making as well as helpful in liaison with other trusts.

The chief executive was a regular attendee at team meetings although did not need to be present at each one.

Plan for media exposure at every stage

Throughout the review of our incident we made successive plans for how we would manage media interest. We took the view that awkward questions from our local press could be asked at any time and we would wish to be honest and not alarmist. This included arranging an 0800 telephone number with BT, which could be activated at a moment's notice. Although initially we thought we would be relying on a paper system to tell us who may be affected, we knew that in time we could arrange this information within a database and would need a room equipped with PCs. The information technology training room was therefore equipped with hands-free headsets and a relay telephone system to enable a large volume of incoming calls to be managed.

Our senior nurse managers and directorate managers were briefed very early on about the possible need to run a help-line and agreed that they between them would take the first 'shifts' in operating it, while recruiting others to relieve them. We produced instructions, in the same format as a major incident card, about who should do what in the event of media interest, as well as draft press releases, letters to patients, teaching packs for those managing the help-line and briefing and scripts for those acting as help-line operators. This information was regularly updated as we became clearer about who was affected in what way.

Brief the board

Briefings to the board on what was happening and how the incident was being managed were given monthly, in the private section of our board papers. The title of the briefing was important since routinely we copy the whole agenda to the Community Health Council (CHC). Although we discussed the review very early on with the Chief Officer of the CHC, we did not wish to put the review into the public arena prematurely, since at that time 60,000 patients could have been needlessly worried.

Involve the key stakeholders

Very early on we talked about the review with the chief officers of the local primary care groups, the CHC and the chief executive of our local private hospital. Therefore it was easier to continue to work in tandem with the CHI investigation. Early copying of all the information CHI sent us, including the terms of reference, was important.

Learn the lessons early and audit the changes

As we went through our review and lessons began to emerge, there was debate about whether to wait for CHI or external bodies to give feedback on what needed to change or whether to update policies, change protocols and then have to change again following external scrutiny. Since CHI looks at what organisations and individuals have learned as a result of what has happened, we felt it was important to learn the lessons early, change the policies,

update the protocols, manage the awareness and where possible audit the changes. There is also a window of opportunity after a clinical incident when staff expect things to change and will exhibit a degree of frustration if nothing does change.

It is obviously not enough just to change the paper documentation: it is necessary to ensure that the changes have happened. The earlier the action plan and audit mechanism are made clear, the more likely the change is to occur.

Don't lose track of patient follow-up

It is easy to concentrate on how to inform the most seriously affected patients; indeed, it is right to think carefully through the process of telling those patients who are most seriously affected about what has happened. However, we found that some of the patients who may be considered to have had fairly minor changes – for example in the information they were given or in the frequency of their follow-up – were some of the most aggrieved and had the most difficulty coming to terms with what happened.

We assumed that those most seriously affected needed to be seen face to face, whereas the large number for whom there were less serious implications could be approached by letter or by their general practitioner. The lesson for us was that everyone would have been more comfortable with a personal approach and certainly consistency is best managed through a personal approach by the same person from the trust.

Allocate secretarial time early

Secretarial time was important in two areas:

- in managing minutes and documenting decisions in the incident team's meetings;
- for CHI's site visit.

In preparing for the CHI investigation, as with a CHI review, it is important to identify a single point of contact (which in our case was the nurse director who led the review). At the same time it was important to allocate secretarial time to the retrieval, collation and indexing of the documents. These documents were similar to those required for a

CHI review, but in addition included documents relating to the investigation and requests for specific audit reports on pathology services and human resource policies.

During the CHI site visit the investigation team split into two and secretarial or administrative support was crucial in the set-up and management of the rooms that were used for the interviews. As a number of matters emerged during the CHI incident team interviews, the original timetable needed rearranging and subsequent appointments had to be rescheduled. Specific administrative time for each room was essential in making this happen, sometimes at a few minutes' notice while managing the disappointment of those waiting. The learning point for us was to allocate separate administrative support to each room, with particular regard to the interpersonal skills of the administrative staff and their ready access to a telephone and telephone directory.

Brief the staff before, during and after interviews

CHI provided briefing information, and we made sure that it was given to every member of staff who was to be interviewed by the investigation.

Personal contact with those about to be interviewed was also important and the director of nursing undertook this. In response to a request, a special incident team meeting was reconvened to allow those people invited for interview to talk about what type of questions CHI might ask and their fears and worries about being interviewed.

Similarly, after the interview it was important that someone was available to meet with those interviewed to ask how it had gone, if there was anything they were still worried about and so on. Perhaps most importantly, as different interview slots were changed, it was important to tell people why the changes had happened, so that they still felt their contribution was valuable and so that their frustrations about spending a lot of time rearranging their clinical work in order to be interviewed by CHI were heard.

Be prepared to suggest what should appear in the report

Each person interviewed by CHI was asked what they wanted to see in the report. Giving some consideration to what would benefit patients or what would assist others who need to carry

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out a similar exercise helped people to influence the final report in a meaningful way.

Conclusions

No one can know whether the exploring of clinical concerns may unfold into a wide-ranging clinical incident necessitating the external scrutiny of a body like CHI. The suggestions above are those which were useful for a trust first undertaking such a review and then preparing for an investigation. Above all, the focus of any review or investigation undoubtedly has to be on what will make a difference to patients.

Lessons from investigations by the Commission for Health Improvement

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- Locum doctors should be subject to the same system of clinical audit and performance monitoring as permanent doctor colleagues.
- In the evolving field of heart and lung transplantation, applying to a small number of very ill patients, the formal amendment of protocols and patient booklets regarding selection criteria is essential, and must be the subject of close multi-disciplinary audit.
- Effective complaints and whistleblowing policies are an essential feature of assuring the quality of patient care.

- Clinical governance is not designed to detect professional misconduct or criminal activity.

A function of the Commission for Health Improvement (CHI) is to investigate serious system failures in the NHS. Such investigations can stem from:

- a request from the Secretary of State for Health in England or the First Secretary in Wales;
- a request from an individual or an organisation;
- the receipt by CHI of information which merits an investigation.

A special process has been developed for the assessment of requests from the public or organisations for an investigation. Whether an investigation is made after such a request is decided by a subcommittee of CHI, on the basis of the following criteria:

- an incident is of great severity;
- there is evidence of high-risk activity;
- there is a pattern of service failure;
- a recurring problem has not been addressed;
- there is evidence of management

or organisation failure which goes beyond a single area or team;

- an investigation by CHI is likely to result in lessons for the whole of the NHS.

An investigation instigated by CHI should meet at least two of these criteria. To date, CHI has received over 350 enquiries or requests to consider an investigation and has recently appointed an enquiries officer to ensure these requests are dealt with in an appropriate and timely way.

CHI does not investigate:

- individual complaints, which should be taken through the NHS complaints procedure, including the Health Service Commissioner (Ombudsman);
- service changes that have been determined by the Secretary of State for Health;
- matters which have been determined by the courts;
- individual complaints about professional misconduct or fitness to practise, which should be referred to the professional regulatory bodies.

Investigations to date

To date, CHI has completed and reported on five investigations. A sixth investigation, regarding breast screening at Charing Cross Hospital and managed by the Hammersmith Hospitals NHS Trust, is at the report writing stage, and a seventh, at the Gosport War Memorial Hospital, Portsmouth, is about to begin. Key areas for learning have been identified in all the investigations but some areas for learning across the whole of the NHS are outlined below from three of these.

The employment of locum consultants

CHI found that a reliance on locum consultants is frequently due to poor workforce planning, particularly in terms of arrangements for covering leave for permanent consultants and in the appointment of new consultants. In some fields such problems are compounded by a chronic national shortage of qualified consultants.

One CHI investigation pointed to a continuing failure by trusts to comply with Department of Health

rules about employing doctors and a duty of care to patients in employing doctors of proven ability to fulfil their responsibilities. This included obtaining references, checking career history, interviewing, and carrying out health checks and induction. CHI concluded that such processes must be reinforced by systematic audit for checking the quality and accuracy of clinical work.

A major problem is that when concerns about the performance or conduct of locum doctors arise, all too often trusts simply terminate contracts or do not re-employ them, without alerting other employers to the problem. There is no system for tracking locum doctors around the NHS to enable employers to check on career history and performance records.

Among other recommendations, CHI proposed that:

- the Department of Health's code of practice on the employment of locum doctors should be strengthened and clarified through greater detail about induction, performance monitoring, occupational health checks and examples of best practice;
- a central system should be established for recording concerns about locum doctors' career history and performance, and this information should be accessible to all employers.

The Department of Health has responded with an initiative for a central agency to support doctors working outside managed organisations. The Royal College of Pathologists has responded with a new protocol for supporting and advising trusts on the performance of consultant pathologists. In response to CHI's concern that trusts fail to report concerns about locums to the General Medical Council, the Council will encourage them to do so through clearer publicity about its services.

Heart and lung transplantation at St George's Healthcare NHS Trust

While written criteria for the selection of patients for heart and lung transplant were broadly in line with those developed by the other six such units in the country, CHI found that in practice patient selection for heart and lung transplant at St George's frequently deviated from

the criteria in a way that was unclear and idiosyncratic.

No formal amendments were made to the transplant protocols to reflect the changes in patient selection nor was there a documented audit of the process for assessing patients for transplant. In addition, CHI found:

- no written documentation on whether or not patient booklets were given to patients or relatives;
- inadequate documentation of risks discussed with patients and relatives, including those patients with increased risk such as serious kidney problems – which did not comply with NHS guidelines on patients' consent for examination and treatment.

Because heart and lung transplant is a constantly evolving field applying to a small number of very ill patients, CHI emphasised that heart and lung transplant programmes must ensure a transparent approach to any changes in selection criteria. This transparency would involve:

- recorded multidisciplinary discussion and agreement of any changes;
- formal amendment of protocols and patient booklets regarding selection criteria, and any changes to these to be the subject of close multidisciplinary audit;
- regular audit and review of outcomes, and the resulting information to be given to patients and relatives.

Additionally, CHI proposed the development of a national format for written information for patients and relatives, such information to be developed with the involvement of patients, relatives and representative organisations.

The case of a general practitioner in Loughborough

This investigation highlighted the importance of effective whistleblowing policies and reported on a culture that did not listen to or treat complaints inquisitively. This was evidenced by a systems failure when, between February 1985 and January 1997, there were 23 occasions when an individual or organisation was aware of a concern or a complaint involving the practitioner involved.

CHI found that the current NHS complaints procedure contributes to a disempowering system for patients and places unreasonable restrictions on them. It lacks independent lay input into the investigation and analysis, and assumes an ability to articulate concerns with a degree of knowledge and perseverance that is unreasonable.

In reviewing clinical governance arrangements in place locally, CHI reported that the primary care group had pushed the boundaries of clinical governance beyond what many may have achieved, evidenced by the willingness of many to learn from the experience of the unacceptable events. Nonetheless, a clear distinction between unintentional poor performance (which clinical governance arrangements should address) and professional misconduct and criminal activity (which clinical governance is not designed to address) is required. CHI concluded

therefore that there remained the potential for professional misconduct to go undetected.

To reduce this risk therefore CHI proposed:

- A clear commitment that patients' interests are central to all activities in the NHS should be demonstrated by the introduction of one complaints system with explicit standards to which all NHS staff must work, and which is clearly understood by those wishing to make a complaint. The system should include lay input into the audit of complaints, and the logging and tracking of anonymous and informal concerns which may be held separately but should be reported in tandem with complaints information.
- Mechanisms for auditing what happens behind the consulting room door – for example, auditing organisation and clinical practice

– should include the patient's perspective.

- Regular audit of critical incident and near-miss reporting should maximise feedback from patients, practitioners and managers.
- There is a need for mechanisms for auditing trust and health authority compliance in establishing whistle-blowing policies.

Discussions are currently taking place with the Department of Health and others in response to these proposals.

Conclusions

Although at an early stage of its development, CHI has been able to identify system failures which need to be addressed at a national level.

Addressing the issues at this level should enable the NHS to develop approaches to assure the quality of patient care.

The audit of cervical cancer: a door to openness and honesty in the NHS

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- All screening is 'low risk' and not 'no risk'.
- Good quality assurance always discovers problems.
- Audit of cervical cancer has resulted in screening recommendations in the NHS Cancer Plan (all women should receive a national information leaflet and informed choice on screening must incorporate an understanding of the potential benefits and harm).
- Following a cultural change, there is now public education that no screening programme will achieve a zero error rate.

In the NHS Cervical Screening Programme, a major way to monitor performance, including both effectiveness and quality, is the audit of invasive cervical cancer. Indeed, since 1996, a mandatory national standard has existed to audit 100% of cases and the findings can be used for both quality assurance (QA) and

quality improvement. An early audit identified system errors (other than women failing to attend for a cervical smear), including incorrect laboratory reporting and inappropriate clinical management¹.

The Leicestershire audit of invasive cervical cancer

The results for this important audit span the period 1992–2000 and relate to over 300 women. Discrepancies in laboratory reporting were identified in over one-third and included both missed abnormalities and inappropriately graded smears. Because of numerous well publicised 'blunders' in cervical screening, there were immediate fears of another failing laboratory. This had to be quickly responded to by the Trent Quality Assurance Reference Centre, as the audit had not identified any one specific causative factor or individual. Furthermore, internal and

external QA spread over several years, backed up by a QA visit, provided no proof of substandard performance. Although numerically high, the percentage and nature of errors were comparable to those already published¹ and known to be occurring elsewhere in the UK.

Despite these errors, it is significant that the death rate from cervical cancer in Leicestershire has fallen by over 33% in the last decade and the errors can account for only 5–10% of overall deaths from cervical cancer.

To tell or not to tell? That was the question

A request to local management for permission to publish the audit findings focused attention on this important question.

Informed members of the medical profession had no doubt as to the preferred way forward^{2,3}. Specifically,

women needed to be informed that undetected disease (false negatives) and mistakenly diagnosed disease (false positives) are an inherent and unavoidable part of any screening programme^{2,3}. As this revelation would create public concern, there would have to be a balancing explanation as to why cervical screening can be successful in the face of these errors. Women would therefore need to be told that cervical cancer can take many years to develop and during this time repeat smears permit previously missed abnormalities to be identified.

Guidance from the General Medical Council was absolute in this area: informed consent should highlight the uncertainties in screening, such as false reports, and patients need to be told if things go wrong and serious harm has been sustained.

Sadly, up to this time, the truth surrounding cervical screening had not been made fully available to the public. A previous Department of Health press release had only referred to false positive reports⁴ and national information leaflets and posters had tended to use restricted information – for example simply stating that cervical screening is not 100% perfect. A patient questionnaire has demonstrated that women were insufficiently informed to provide appropriate consent for the smear test⁵.

For a period of time deliberations occurred between local, regional, Department of Health and ministerial levels. Finally, however, other events brought matters to a conclusion. Tragic medical experiences in Bristol and Alder Hey and the death of a Coronation Street character from cervical cancer, following a 'mix-up' in the local laboratory, provided only one acceptable option, namely that patients must be fully informed about all matters.

On this basis, Leicestershire sensitively informed patients or relatives of the results of the audit and the Department of Health issued a new press release. In the future, all patients with invasive cervical cancer will be given an offer to discuss the outcome of multidisciplinary audit into cervical cancer.

A new information initiative – informed choice

Launched by Lord Hunt, a new national information leaflet is now

available on cervical screening. This addresses misconceptions about the purpose and accuracy of screening and provides honest, clear and balanced information. As well as highlighting the undoubted successes of cervical screening, it also explains that the person reading the slide may occasionally miss abnormal cells.

The future

Despite these major advances in quality, consideration of other issues could achieve even higher standards.

- It must be ensured that consenting women have read and understood the new information leaflet.
- There must be standardised peer review of cervical smears, to avoid context and outcome bias. The findings could be also made available to courts as objective evidence.
- False positive reports and associated increased morbidity require focused attention.
- The multidisciplinary audit of cervical cancer must now address

potential problems that lie outside the laboratory.

- The relationship between screening programme errors, adverse clinical events and reporting to the new National Patient Safety Agency must be clarified.
- Should errors in screening fall under a no-fault compensation scheme?

References

- 1 Slater DN, Milner PC, Radley H. Audit of deaths from cervical cancer: proposal for an essential component for the national screening programme. *Journal of Clinical Pathology* 1994;47:27–8
- 2 National Co-ordinating Network. *Assuring the Quality and Measuring the Effectiveness of Cervical Screening*. Oxford: National Co-ordinating Network, 1994
- 3 Slater DN. False-negative cervical smears: medico-legal fallacies and suggested remedies. *Cytopathology* 1998;9:145–54
- 4 Calman K. Cervical screening programme. Chief Medical Officer outlines new initiatives. Press release. London: Department of Health, 26 January 1994
- 5 Slater DN. Are women sufficiently well informed to provide valid consent for the cervical smear test? *Cytopathology* 2000; 11:166–70

Top tips for dealing with clinical errors

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Below are five top tips on what to do after the discovery of a clinical error.

- The patient needs care. Not only may the original condition still be present, but the patient may have suffered further injury as a result of the error. If possible there should be continuity of care but if the patient has lost faith in the team responsible, an alternative may have to be provided swiftly.
- The health-care professional(s) most immediately connected with the error may need care. The knowledge that a patient has been harmed (irrespective of blame) may have a devastating effect on a junior doctor, nurse or midwife.

They may need to be counselled and occasionally removed from their place of work until they have recovered. Otherwise there is a danger that dysfunctional behaviour may lead to further error.

- The proximal cause of the error (usually an individual health-care professional) may be as much a victim as the patient. Has there been a systems failure? Is there an important remote cause of the error?
- Obtain statements (confined to fact only) from everyone involved, however lowly in the organisation.
- Make sure that information gained and the lessons learned are used to improve quality.

A focus on patient safety – a national approach

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- A mandatory reporting system for adverse events has been established. The National Patient Safety Agency (NPSA) will collate information on adverse events and identify the action needed to reduce risk. Recommendations will be disseminated throughout the NHS.
- Information from different sources (confidential inquiries, complaints, health and safety etc.) will be assimilated by the NPSA to help identify any action required.
- Incentives need to be identified to ensure that all adverse events are reported.
- Health-care organisations need to examine all their adverse events and identify all contributing factors, individual and organisational, so that targeted remedial action can be taken.

A number of investigations by the Commission for Health Improvement (CHI) and the recent publication of the report from the Bristol Inquiry¹ have again identified the need to focus on patient safety and ensure that processes are in place in health-care organisations that are centred on improving patient care while minimising risk and learning from mistakes. A year ago we reviewed in the *Bulletin* the report *An Organisation with a Memory* and its implications for health-care organisations². So what developments have we seen since?

Building a Safer NHS for Patients

The report *Building a Safer NHS for Patients* was published in 2001³. It sets out the next steps in the implementation of *An Organisation with a Memory*. It reiterates the importance of patient safety and of risk-reduction programmes in the overall quality agenda.

The report describes an integrated approach to something that has gone wrong and, as such, clarifies how the mandatory adverse event reporting system differs from other ways of dealing with failures in standards of care and how the various initiatives

need to be linked together for an effective, integrated approach to improving patient safety:

- Adverse events need to be reported and analysed so that lessons can be learnt. A number of reporting channels already exist within any organisation, but adverse events will now also need to be reported to the newly established NPSA. People will be able to report incidents about either their own care or that of another patient.
- Poor clinical performance needs to be identified early and action taken to minimise risks for patients. The National Clinical Assessment Authority (NCAA) will take referrals from employers of doctors in cases where they have difficulty in resolving the issues or when cases are particularly serious; it will carry out an evaluation and provide advice.
- Major service failures must be reported. They will be investigated after discussion between the Department of Health and CHI regarding the type of investigation needed. Organisations themselves will no longer undertake in-depth internal inquiries but will be required to examine the problem in order to inform the above discussion. Service failures that result in harm to a large number of patients or that are of national concern, even if the number of patients affected is small, may be the subject of a public inquiry on the order of the Secretary of State for Health.
- Staff who, for whatever reason, feel unable to report an incident openly must be able to do so in confidence. To this end, a confidential channel must be described in a whistle-blowing policy by every organisation.

Chapter 3 of the report details the new national reporting system; it is about identifying, recording and reporting on incidents, applying standard 'root cause' analyses, examining trends and identifying the lessons to be learnt and ensuring that they are

disseminated to the wider NHS. The importance of an open culture to encourage the reporting of incidents is stressed, as is the need to have a standard format for reporting.

The minimum data set has been designed for the recording of answers to a number of questions, including where, when, how and why an incident occurred as well as what impact the incident had and what action was taken. The minimum data set is currently being piloted by a number of hospitals and it will soon be applied to the whole NHS.

A number of agencies deal with specific types of incidents. Adverse drug reactions are reported to the Medicines Control Agency (MCA), medical devices problems to the Medical Devices Agency (MDA), clinical incidents resulting in litigation to the NHS Litigation Authority (NHSLA), injuries and accidents to the Health and Safety Executive (HSE). Incidents such as suicides as fall under the Mental Health Act Notification and there are also the Confidential Inquiries. The Public Health Laboratory Service deals with infection surveillance and there is a system for the reporting of major transfusion error. To avoid confusion and duplication, there is a need for a standard reporting system and clarity regarding to whom specific incidents need to be reported.

In *An Organisation with a Memory* a number of areas of concern were identified, including spinal injection, harm in obstetrics and gynaecology, medication error and suicides by hanging in hospital. Chapter 4 of this further report deals with the action required in these specific areas.

The report ends with a detailed timetable for action.

Bristol Inquiry report

The recommendations in this report are extensive and comprehensive; they cover many areas, such as keeping patients informed, consent, dealing with patients when things go wrong, patient safety, standards of care, professional competence, children's services and patient involvement. The report also

touches on strengthening the regulation of quality and safety, with the establishment of a Council for the Quality of Healthcare, which will ensure that there is better coordination of the various independent bodies involved in the quality agenda, and a Council for the Regulation of Healthcare Professionals, which will strengthen the system for assuring professional competence.

There are a number of important points as far as patient safety is concerned which are covered in the report:

- Trusts should carefully examine all their adverse events and undertake a thorough analysis, taking into account the individual and the organisational factors surrounding the incident.
- Reporting of adverse events needs to be encouraged and incentives identified. Staff should not face disciplinary action unless a criminal offence has been committed.

- The reporting of adverse events must be covered in staff contracts and in staff induction.
- Patient safety needs to be encapsulated into a policy and clear systems for implementation must be in place (this should be led by a non-executive director).
- The current clinical negligence system should be abolished and replaced by a system of compensation.
- National standards of care need to be developed by the National Institute for Clinical Excellence to ensure that care is appropriate and patient centred. These should take account of patients' perspectives.
- There is a need to include in the education of health-care professionals topics such as communicating with patients, the principles and organisation of the NHS, teamwork and so on.
- Health-care organisations should be validated and revalidated against generic national standards by CHI.

Conclusions

The two reports emphasise the importance of patient safety in the overall NHS quality programme and the need to ensure that the risks of major clinical incidents and service failures are reduced, by taking a systematic approach to analysing what has gone wrong and by ensuring that the lessons are widely disseminated. The successful implementation of the new national reporting process requires sound clinical risk management programmes in every health-care organisation, an understanding by staff of the risk management process, and systematic reporting of incidents. The national approach to patient safety should not, however, deter the wider NHS from taking local action.

Reference

- 1 <http://www.bristol-inquiry.org.uk>
- 2 Ligon M. *An Organisation with a Memory*. Summary and implications for health-care organisations. *Clinical Governance Bulletin* 2000;1(2):3-4
- 3 Department of Health. *Building a Safer NHS for Patients*. London: TSO, 2001

When clinical negligence becomes a crime: implications of medical manslaughter for NHS trusts

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- Health-care professionals will be convicted of manslaughter where their negligence has been sufficiently gross to justify a criminal conviction.
- Where a patient's death resulted from system errors, an individual is less likely to be convicted. However, NHS trusts and their officers may soon face criminal charges in such circumstances.
- Errors should be controlled by imposing effective clinical governance measures to record and facilitate learning from episodes of poor care.

An increase in criminal charges

Criminal charges against health-care staff arising out of criminal negligence were rare before 1990. A paper in the *British Medical Journal*¹

recently described 17 completed cases in which manslaughter charges were brought, involving 21 doctors and several nurses, between 1970 and December 1999. Not all these prosecutions were successful.

Civil and criminal jurisdictions

A patient will bring an action for damages in clinical negligence under the civil jurisdiction of the courts. This involves legal action by one citizen against another following a legal wrong, such as negligence or assault. The remedies granted by the civil courts, such as the High Court and county courts, are generally for financial compensation. To succeed, a case must be proved on the balance of probability.

Courts such as the magistrates' and crown courts, on the other hand, exercise criminal jurisdiction. They

are concerned with wrongs against society as a whole. The police and Crown Prosecution Service will bring criminal actions to court, where guilt must be proved beyond all reasonable doubt. Sanctions include fines or imprisonment.

Criminal negligence

Wrongs such as negligence or assault may be dealt with under either or both jurisdictions. If a surgeon negligently removes the wrong kidney, the patient may bring a civil action for damages. In theory, if there was a sufficient degree of recklessness, the surgeon could also face a criminal charge.

In practice, criminal charges are brought when an unusually serious error has caused a patient's death. If there was gross negligence there could be a conviction of manslaughter.

Gross negligence

Health-care professionals are negligent if they injure a patient while acting in a manner that would be unacceptable to a responsible and logical body of medical opinion skilled in that particular specialty^{2,3}.

To convict on a charge of manslaughter the prosecution must prove that the negligence was gross – that there was such a disregard for the life and safety of the patient that the negligence was serious enough to constitute a criminal offence.

Where there was an express intention to kill a patient, as with Dr Shipman, a charge of murder rather than manslaughter will be brought.

Recent cases

Recently a consultant urologist was charged with manslaughter after a patient of Carmarthenshire NHS Trust died following the removal of his healthy kidney in error. The case has not yet come to trial, but the hospital was the subject of an investigation by the Commission for Health Improvement (CHI)⁴. The CHI recommended improvements to some procedures, such as the marking of radiographs, and called for further work to improve systems for responding to critical incidents.

Another case involved the administration of intrathecal vincristine to a patient at Great Ormond Street Hospital by a registrar anaesthetist, who, with a registrar paediatrician, was charged with manslaughter. At trial in January 1999 the prosecution offered no evidence because an expert witness had realised that system errors were a significant factor in the patient's death and the doctors were acquitted.

Individual or systems failure?

From the latter case it is clear that the existence of systems failures may prevent an individual being convicted of criminal negligence. These might involve NHS trusts, external organisations, or the NHS as a whole. For example:

- in medication errors the problem of confusing packaging has been highlighted⁵;
- a trust may have failed either to train staff effectively or to publish procedures and protocols;
- the NHS itself has been criticised

for failing to prevent repetition over several years of the vincristine incidents.

A hospital is a complex organisation of interdependent individuals working within imposed structures and practices. In these circumstances it is unjust to make an individual solely responsible for the organisation's failure to minimise risk.

Corporate killing

The proposed introduction of legislation to make it possible to bring criminal charges against NHS bodies and their officers reflects the emphasis on systems, rather than individual, error. The availability of a workable charge of corporate killing will make medical manslaughter charges against individuals even less common. Management will find itself criminally accountable for the failings of organisations.

Avoiding criminal responsibility – what can NHS trusts do?

The adoption of clinical governance measures will not only reduce the risk of errors occurring, but will also make it less likely that NHS trusts and their officers will be subject to criminal charges if they have in place effective systems to manage risk.

Trusts should ensure that they properly identify, record and learn

from their own and others' errors. The new national database overseen by the National Patient Safety Agency will impose wider obligations on trusts to work effectively in this way. NHS trusts should have effective processes to recruit capable employees and to ensure that they remain properly trained.

The CHI investigation of Carmarthenshire NHS Trust underlines that procedures merit continual audit and review to ensure that risk is minimised. How many trusts have looked at their systems for marking radiographs in the light of this report? How many trusts have studied other CHI reports or the Bristol Inquiry report⁶ to see how they might improve the quality and safety of care?

Finally, the CHI report illustrates that trusts should respond promptly to critical incidents to ensure that the patients, families and staff affected are supported. Trusts must also be seen to learn from errors by swiftly implementing reforms to reduce the risk of further error.

References

- 1 *British Medical Journal* 2000;321:1212–16
- 2 *Bolam v. Friern Hospital Management Committee*, 1957
- 3 *Bolitho v. City and Hackney HA*, 1998
- 4 Available at the CHI website, www.chi.nhs.uk
- 5 For example, Department of Health. *Building a Safer NHS for Patients*. London: TSO, 2001: 51
- 6 <http://www.bristol-inquiry.org.uk>

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Words, words and more words

Tim Wilson¹ and Carol Haraden²

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The terms **error**, **mistake** and **preventable** are largely unhelpful if your goal is to improve patient care. *Error* and *mistake* both imply someone has done something wrong, when we know that humans will make mistakes roughly 4% of the time in routine tasks. Is it wrong to be human, therefore? To suggest that those who work in health-care should 'try harder' is misguided, unhelpful and has not stood the test of time.

Apparently, we are entering a **no-blame culture**. This means that we can breathe a sigh of relief. Perhaps we should be reassured (although we haven't yet been done so) that reporting mistakes will make us immune from disciplinary action. However, with this right comes a heavy responsibility – safety is everyone's business and we have to do something when we know there is a problem. Failure to do that could and should result in blame.

Significant, critical or adverse events clearly need definition, partly to facilitate their reporting but mainly in order to know what to analyse to reduce future harm. For the purposes of a mandatory national reporting system, everyone involved will need to know what to report and what not to report. This is less important for the purpose of local event analysis: something is an important event if you (or more appropriately your patient) think it is.

Preventable and **non-preventable** adverse events are ambiguous terms. For example, if a patient caused a road crash while taking amitriptyline, would it have been preventable? Yes, although it is not necessarily an unexpected or adverse event. If a patient has a haemorrhage (e.g. admitted with epistaxis) while on warfarin, is this one of the expected and so non-preventable outcomes of the therapy? Possibly, but it is only non-preventable if every possible means has been taken to prevent it (i.e. using the best system for monitoring, education, patient involvement). The boundary between preventable and non-preventable is largely determined by what we deem

acceptable and affordable; although examples at the extremes are obvious (e.g. the first allergic reaction is clearly not preventable), most cases are less clear.

It is unclear whether efforts should be concentrated on investigating **adverse events** or **near misses** (or both). While it is important to learn from events, issues around blame quickly arise (although there is much to be learned from the experience of significant event analysis). Near misses have the advantage of being proactive and less emotive. Lessons from the airline industry suggest that for every event there have been around 300 near misses – this has major implications for the resources dedicated to the collection of data.

Patient safety and **patient harm** are the most useful terms as they simply describe what they are. When we grapple with safety and harm then we are attempting to make the system better. Furthermore, there are

plenty of instances where patient harm can be avoided and we can act on these now.

One component of clinical governance is **risk management**. Why is the medical world talking about **safety** when risk management is the same? After all, both look at the system of care. It is possible that safety is merely a fashionable way to consider risk management. However, risk management does have connotations of risk avoidance, which patient safety does not. Safety *feels* as if it is a whole-system (patient, clinician and management) issue, whereas risk management has sometimes been perceived (by clinicians at least) as a management problem. In this respect it is important that we are entering a period of activity to improve safety, whereas risk management hardly seemed to have any impact. It should be welcomed that leading proponents of the risk management field are in the forefront of the safety movement.

Contributions

Clinical Governance Bulletin is a publication for clinicians and managers working in trusts, health authorities and PCGs and aims to communicate practical examples, pool shared experience and highlight and disseminate best practice on a broad range of issues in health management. Topics covered include the following, with each issue taking one area as its main theme:

- Patient experience
- Clinical effectiveness
- Resource effectiveness
- Communication
- Risk management
- Effective teamwork and learning
- Effective strategy
- Clinical information

Contributions that are practical and relevant to everyday practice are welcomed. They should be 500–800 words in length, with a maximum of five references in Vancouver (numerical) style. Please send your contribution, by post (with floppy disk) or email, to one of the Editors:

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WhoWhatWhere?

Patient safety on the web

National Patient Safety Foundation (NPSF)

<http://www.npsf.org/>

The NPSF is the US equivalent to the NPSA.

Agency for Healthcare Research and Quality – Medical Errors and Patient Safety

<http://www.ahrq.gov/qual/errorsix.htm>

This is also a US organisation.

Australian Patient Safety Foundation
<http://www.apsf.net.au/>

Anesthesia Patient Safety Foundation
<http://www.gasnet.org/apsf/>

The Editors' Choice

National Patient Safety Association (NPSA)

<http://www.npsa.org.uk/index2.htm>

This is the website of a new independent body, the National Patient Safety Agency (NPSA), which was established as a special health authority on 2 July 2001. The NPSA will record adverse events and near misses.

Professor Rory Shaw, medical director at the Hammersmith Hospital, London, has been appointed chairman of the NPSA.

Partnership for Patient Safety
<http://www.p4ps.org/>

'A patient-centred initiative to advance healthcare systems worldwide.'

UCL clinical risk unit

<http://www.patientsafety.ucl.ac.uk>

Provides lists of relevant publications.

Putting the knowledge base to work

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- Knowledge management, like clinical governance, is eminently practical.
- It is important to pay attention both to the application of information technology and to cultural issues.
- A structured approach to knowledge management will map the ways in which knowledge is accumulated and used.

Once the concept has been 'unpacked' from a somewhat esoteric literature, the potential contribution of knowledge management (KM) to the process of continuously improving the quality of health services is readily apparent. KM provides a framework with which organisations can help people to put the 'knowledge base' to work in support of effective health-care.

Information for Health recognised that the introduction of clinical governance and evidence-based practice within the NHS requires:

- improving the access that all staff within the NHS have to information on effective clinical practice and service provision;
- investment in clinical systems and information support services, which support staff in putting evidence into practice.¹

The challenge for the NHS is to look beyond the immediate tasks of facilitating access to information and generating high-quality data. With comprehensive quality improvement at the heart of the agenda, there is a need to look at the broader contribution that KM can make to clinical governance.

KM: a core activity

KM is 'a core activity for the improvement of health and healthcare'², concerned with 'recognising the importance of knowledge and mobilising it in a form that professionals can apply'³. Three core elements of KM are shown in Box 1.

What do we mean by 'knowledge'?

Knowledge encompasses 'theoretical or practical understanding' and 'familiarity gained by experience'⁴. The word is used in three principal ways (see Box 2).

There seem to be two basic kinds of knowledge⁵ that could be managed better to effect improvements in health-care:

- *Explicit knowledge* – the sort that we may 'know about' through the 'body of knowledge' that is articulated and recorded (whether in print or electronically, using text, tables or diagrams).
- *Implicit knowledge* – the kind acquired through personal learning and experience, which is reflected in an individual's capacity for action and which *could* be articulated – but rarely is.

Box 1. Three core elements of KM

Recognise the knowledge component of health-care as an explicit concern in:

- strategy
- policy
- practice

Apply technology and resources to give better access to information²

Support people within a learning organisation committed to:

- sharing best practice
- implementing evidence-based change

Box 2. Knowledge: three different meanings

Know about

Acquainted with, or aware of, facts, methods, principles, techniques, and so on.

Know how

The 'capacity for action': an understanding, sufficient to apply facts, methods, principles, techniques, and so on.

Body of knowledge

Articulated in books, articles, manuals, clinical protocols, computer codes, and so on.

In the face of a myriad of information sources of variable quality, organisations need to look at how health professionals can be helped to search relevant databases. Ensuring access to modern library services should feature in every organization's knowledge strategy.

'Mining' implicit knowledge

Health-care organisations have much to gain from harvesting the implicit knowledge of their staff, but this can be difficult. Pending the application of effortless, intelligent software to 'mine' and share implicit knowledge from willing participants, across electronic 'communities of interest', there is a need to use e-communication in parallel with well established approaches, such as promoting the use of project teams and fostering professional networks (both uni- and multidisciplinary).

Learning from business

Health services are well placed to learn from experience in the business world. Most early work focused on using information technology in a

systematic effort to capture data that could be shared. Projects to bring together clinical guidelines fit into this category, and have an important contribution to make.

Establishing a learning culture

Companies learned the importance of investing time in establishing an ethos by which individuals might 'own' a 'need to know', perceive information seeking as a legitimate activity and be rewarded for sharing knowledge.

Health services that are 'creating an environment in which excellence in clinical care will flourish⁶ should take a broad view of KM from the outset and create an enabling culture in which people can build on previous knowledge, skills and experience, rather than looking to technological solutions alone. 'Soft' techniques that promote person-to-person communication are needed alongside effective dissemination of documented best evidence and best practice.

It is crucial that organisations get to grips with the growing body of evidence on the successful implementation of evidence-based change and organisational development.

Maximising explicit knowledge

There is still work to be done by health services to facilitate access to the published 'knowledge base'. An intranet enables an organisation to deliver knowledge via a corporate memory and a virtual learning centre. It can also be used to help staff navigate the Internet and to signpost high-quality web sources of research evidence, clinical guidelines and biomedical databases.

Table 1. Applying knowledge management within a primary care trust: one approach

KM 'drivers'	Key activities	Examples
Understanding what patients want to know	Public involvement	Patient satisfaction surveys Providing information on services, complaints procedures etc. Providing patient information as leaflets, or as links to websites
Understanding what staff need to know to support their: • work • professional development • research	Ensuring access to: • services • skills • resources	Peripatetic knowledge management service Service-level agreements with library services, information management technology, etc. Support from colleagues with expertise in audit, research, information analysis Access to bibliographic databases
Using knowledge to inform health-care policy	Managing the dissemination of evidence and guidelines Promoting best practice Exploiting information management data	NICE guidelines review group Desktop access to evidence Evidence-based commissioning Information management technology policy Audit cycle
Keeping up to date with changing policy, trends and clinical evidence	Updating services	Communications policy Print and e-newsletters Use of bulletin boards 'Alerting' services (e.g. ZETOC)
Developing an organisational 'memory'	Ensuring access to: • directories • databases • documents	Contacts lists, distribution labels Best practice database, HiMP resources catalogue E-access to PCT policy, protocols, referral guidelines
Embedding best evidence into practice	Collaboration with suppliers and other services Implementing guidelines and promoting best practice	Decision support: protocols and automatic reminders within computer systems Roving primary care development team
Making implicit knowledge explicit	Initiatives to share knowledge	Skills audit; expertise database Special-interest groups, e-fora

Box 3. Locate 'KM' initiatives appropriately

At organizational level

- Intranet
- Knowledge support – for information professionals and information technology staff
- Learning sets, journal clubs
- Discussion fora (both physical and e-networks)

Across a health economy

- Databases of local guidelines, shared care protocols etc.
- e-discussion fora – for distributed staffs
- Research networks
- Opportunities for e-learning

Regionally

- Biomedical bibliographic databases

Nationally

- National electronic Library for Health
- NHS Direct

Adopting a systematic approach

The application of information technology and attention to cultural issues are important 'twin tracks' in KM. However, it is a systematic approach, using a combination of input from a variety of disciplines and technologies, which promises a positive cumulative impact and can deliver sustainable results⁷.

Putting KM into practice

Table 1 illustrates the kind of practical applications that KM may have in health-care, in this case across a primary care trust. The aim is to recognise the diverse knowledge needs of staff and patients, and to identify the key activities through which people can meet these.

The KM 'drivers' shown in Table 1 are generic but effective knowledge strategies must be rooted within the business plan and priorities of the individual organisation. In practice, it will be possible to identify drivers from operational strategies and policies, select specific statements from each, identify associated key activities (giving practical examples) and start to identify and remedy the gaps.

The framework allows an organisation to map the many different ways in which health-care staff generate and manage knowledge, and ensure

that this can be used to better advantage. This process will not only indicate where there may be a need for further KM within the organisation, but may also suggest areas in which it may be helpful to collaborate with partner organisations to develop technological solutions to everyday problems in finding and sharing information.

Certainly, the real challenge may be to engage senior managers in recognising the knowledge dimension of the organisation's work, and to make it explicit in strategies for education, training and development, informatics, research and risk management as well as for clinical governance.

Locating KM initiatives

KM focuses on the needs and assets of the organisation, developing local approaches tailored to meeting the needs of staff and patients. Part of this lies in working, across the widest possible geographical locality, to deliver technological solutions to everyday problems in finding information, and sharing knowledge, rather than risk inadequate investment in parochial information systems.

Box 3 indicates the importance of siting KM initiatives appropriately, in response to local resources and opportunities. These tiers are not mutually exclusive. For example, formal and informal networks operate at all levels yet more could be done to foster knowledge sharing within communities of common interest. Library and information services could be delivered in partnership across a

health economy or by autonomous services at organisational level, subject to an overarching strategy.

Conclusion

Knowledge, including the knowledge of staff (that most valuable resource of all), has been a much neglected resource within the NHS. 'A little neglect may breed mischief'⁸. It might be argued that it is *ignorance*, sheer want of knowledge, which poses the greatest risks for clinical governance. KM is pivotal to the ability of health-care organisations to deliver a first-class service.

References

- 1 Department of Health. *Library Services and Access to Evidence: Information for Health Guidance*, Annex M. London: Department of Health, 1998
- 2 Managing explicit knowledge, National electronic Library for Health, 2001. See : http://www.nhs.uk/nelh/knowledge_management.asp. Page as updated on 15 March 2001
- 3 Wyatt J. *Clinical Knowledge and Practice in the Information Age: A Handbook for Health Professionals*. London: Royal Society of Medicine Press, 2001
- 4 *The Concise Oxford Dictionary*. 1976
- 5 Nickols F. The knowledge in knowledge management (KM). In: *Knowledge Management Yearbook, 2000*. London: Butterworth-Heinemann. See also http://home.att.net/~nickols/Knowledge_in_KM.htm
- 6 *Quality in the NHS. A First Class Service*. London: Department of Health, 1998
- 7 Barclay RO, Murray PC. *What Is Knowledge Management? Knowledge Management Associates*, 1997. See <http://www.media-access.com/whatis.html>
- 8 Preface to *Poor Richard's Almanac*, 1758

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