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 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 multidisciplinary 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 management[1].

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 published[1] 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,