Tackling Concerns Locally

Report of the working group

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Tackling Concerns Locally

Report of the working group

Professor Jenny Simpson OBE,
Chair of the working group on Tackling Concerns Locally

Contents

Department of Health response to the working group's recommendations

1. The working group "Tackling Concerns Locally", chaired by Jenny Simpson, is one of seven working groups set up to carry forward implementation of the programme of reform of professional regulation set out in the white paper Trust, assurance and safety. The Department is most grateful to Professor Simpson, and the members of her working group and its various subgroups, for bringing their experience, enthusiasm and commitment to this task.

The remit of the working group

2. The vast majority of healthcare professionals are committed to doing their best for their patients, day in day out. There are however a small number who are struggling to maintain consistently high standards, whether because of health or personal problems or a deficiency in their training and experience. Within this a tiny minority practice to an unacceptable standard that may lead to harm for patients.

3. Dealing with these issues requires action at both local and national levels, and close coordination between local and national systems. The remit given to the Tackling Concerns Locally (TCL) working group was to advise on how local systems could be strengthened to enable healthcare organisations to identify and deal with those healthcare professionals whose performance, conduct or health could put patients at risk. The working group's report sets out the principles of best practice in this area and sets it in the context of an overall framework of clinical governance which seeks to promote continuous improvement in the quality of care. The report particularly emphasises the importance of early identification of concerns, coupled with access to remediation to enable healthcare professionals wherever possible to address and overcome these concerns and to get their career back on track.

The Department's response

4. The Department of Health warmly welcomes the analysis and recommendations of the working group's report, and of the three subgroup reports which are published in parallel[1].

5. Some of the recommendations in the main TCL report, and in the report of its Clinical Governance subgroup, are addressed to healthcare organisations. They set out the basic principles of clinical governance and in particular those aspects which are relevant to handling concerns over professional performance. The Department warmly commends these recommendations to NHS and other healthcare organisations, and will

[1] Report of the Clinical Governance subgroup (Department of Health, February 2009); report of the Information Management subgroup (Department of Health, February 2009); report of the Performers List subgroup (Department of Health, February 2009). Copies of all three reports are available on the DH website at [web address]

in due course be updating and promoting guidance in these areas as recommended by the working group.

6. The remaining recommendations in the TCL report and in the three subgroup reports are addressed to the Department itself and to other national organisations. They fall broadly into the following areas (see table 1 below):

i *General principles.* The report asks the Department to review and update existing guidance on all aspects of "tackling concerns locally", and to promote best practice through training events, networking, and (in relation to PCTs) the performance management framework. The Department accepts these recommendations and will be commissioning guidance and training packages during the remainder of 2009.

ii *Identifying concerns.* The report calls for further support for patients and professionals who want to raise a concern about the performance or conduct of a health professional. The Department has already begun discussions with relevant patient and professional organisations and intends to bring forward firm proposals later this year. Work on developing quality indicators at the level of the individual healthcare professional or healthcare team will be taken forward as part of the more general development of clinical indicators proposed in *High quality care for all*[2].

iii *Handling concerns – new options.* A number of new options for handling concerns in primary care have been identified in the report of the Performers List subgroup. The Department accepts these recommendations and will in due course bring forward draft regulations and guidance. Modified proposals for "recorded concerns", first proposed in the Chief Medical Officer's review of medical regulation *Good doctors, safer patients*[3], will be modelled as part of the pilots of the "GMC affiliate" concept and final decisions taken in the light of the outcome of these pilots and further discussion with interested parties.

iv *Handling concerns – information management.* The Department will, as recommended by the Information Management subgroup, develop and publish guidance on best practice in handling information relating to concerns over the performance, conduct and health of health professionals. This will form part of the suite of guidance referred to above.

One particular aspect is the sharing of information between healthcare organisations. The Department will consult during 2009 on draft regulations, and associated guidance, to bring into effect the "Duty of cooperation" described in Section 121 of the Health and Social Care Act 2008.

A scoping study of the IT options to support information management [is underway][will commence shortly] and the Information Management will reconvene to advise the Department further once this has been completed.

v *Locum and sessional practitioners.* The Department welcomes the recommendation of the Performers List subgroup that PCTs should actively support locum practitioners on their Performers List in exchange for a commitment to working a

[2] *High quality care for all: final report of the Next Stages Review* (Department of Health, September 2008)
[3] *Good doctors, safer patients* (Department of Health, July 2006)

certain number of days in the PCT area; and will discuss with interested parties how such arrangements could be promoted.

In other cases (and in particular in secondary care) the Department agrees with the recommendation of the Information Management subgroup that locum agencies should be encouraged to exercise clinical governance oversight for locum practitioners on their books. In the case of doctors, this would be through the appointment of an appropriate Responsible Officer.

The Department notes the proposal of the Performers List subgroup for a single national list of sessional staff and will consider this further with the national regulators.

vi *Primary care: the Performers List arrangements.* The Department agrees with the Performers List subgroup that the Performers List arrangements should be retained for doctors, dentists and optometrists, subject to the proposed improvements set out in the report. The Department will issue detailed guidance and standard forms as part of the suite of guidance referred to above, and will consult on amendments to the Performers List regulations including the proposed right to an oral hearing in removals cases.

Among other improvements to current arrangements the Department will

– seek to improve the operation of Performers List arrangements across national boundaries

– commission further work on remediation in primary care, including a pilot study on the options for clinical placements; and

– review arrangements for update training for practitioners returning to practise in the UK after a break in service.

vii *Assessment and review.* The Information Management subgroup have called on the Department to convene a stakeholder working group to review and refine its recommendations no later than two years after implementation. The Department agrees and considers that it would be sensible to review progress of the whole "Tackling Concerns Locally" work programme no later than two years after its various elements are in place. On current plans, this review would take place in around 2012.

Table 1

Tackling Concerns Locally: recommendations to the Department of Health and other national organisations

Summary of recommendation	Specific recommendations
General principles	
Update and disseminate guidance on handling concerns	Main TCL recs 6,7 CG subgroup recs 6-8 and 11 PL subgroup *passim* (see below)
Develop training packages/ competency frameworks	CG subgroup rec 9 PL subgroup recs 49b, 59
Use assurance framework or other performance management levers to encourage PCTs to build capacity	Main TCL rec 8 CG subgroup rec 10 PL subgroup rec 60
Identifying concerns	
Development of quality indicators at level of individual or individual team	Main TCL rec 1
Further support for patients and professionals in raising concerns	Main TCL recs 2, 3 CG subgroup rec 12
Handling concerns - new options	
Model possible use of recorded concerns	Main TCL rec 5 PL rec 40
Additional options for PCTs in Performers List cases (wider use of conditions, formal warnings, voluntary retirement)	PL recs 26, 32, 39, 44
Handling concerns - information handling	
Issue guidance on best practice in information handling	IM subgroup recs 1-8, 12 a & b PL subgroup rec 13-14, 19, 38b
Issue regulations and guidance on information sharing ("duty of cooperation")	IM subgroup recs 9-11, 13-14
Scoping study, then early decision on options for IT support in storing and collating information	IM subgroup rec 15 Main TCL recs 4, 9 PL subgroup recs 10, 11, 14, 38a, 42, 50
Locums	
PCTs to support sessional and locum practitioners on their list in return for a commitment to a reasonable volume of work in the PCT area	PL subgroup rec 51
Locum agencies to be invited to exercise CG oversight over practitioners on their books	IM subgroup rec 12c PL subgroup rec 52
Consider single national list of sessional performers	PL subgroup rec 54

Summary of recommendation	Specific recommendations
Performers List arrangements	
Retain Performers List subject to improvements	PL rec 1
Issue and disseminate detailed guidance and standard forms on operation of PL arrangements	PL recs 2, 4, 7-8, 12-13, 16-17, 18, 20-21, 23-28, 29-30, 32-37, 39, 41, 43-44, 45-49a, 52-53
Amendments to PL regulations	PL recs 24-26, 31, 32-33, 39, 41, 46, 48
Improve operation of PL arrangements across national boundaries	PL recs 55-56
Further work on remediation in primary care (placements, indicators for success, funding models)	PL recs 61-63
Develop guidance on how to apply PL principles when break in NHS service; review provision for update training after a break in NHS service	PL recs 3, 64
Review	
Review and refine recommendations no more than 2 years after implementation	IM subgroup rec 16

Covering letter from the chair of the working group

The Rt Hon Alan Johnson MP
Secretary of State for Health
Department of Health
Richmond House
79 Whitehall
London SW1A 2NS

5 December 2008

Dear Alan

TACKLING CONCERNS LOCALLY: REPORT OF THE WORKING GROUP

I have pleasure in attaching the report of "Tackling Concerns Locally", one of seven working groups set up last year to advise on implementation of the programme of reform to professional regulation set out in the government's White Paper *Trust, assurance and safety*.

Our group was tasked with advising on the steps needed to strengthen clinical governance processes in local healthcare organisations in order to identify, and deal effectively with, concerns over the performance, conduct and health of healthcare professionals. Our report therefore complements the report which Ian Kennedy sent you [earlier this week][last week] on the steps needed to strengthen and improve the transparency of the processes used by the national regulators.

Our report sets out the general principles required for all sectors and all professions, and then deals with some of the specific elements (information handling, the use of information from death certification) and the application to specific sectors (primary care) and professions (the medical profession). The main report is supported by reports from three of our subgroups dealing respectively with clinical governance, information management, and the review of the Performers List system.

Although our advice is primarily addressed to the Department the main report, and the report of the Clinical Governance subgroup, contain some important and urgent messages for healthcare organisations. I therefore hope that you will agree to early publication of the suite of reports.

I would like to express my enormous thanks to all those who have contributed to this exercise – above all to the members of my working group and the chairs and members of the six subgroups; to colleagues who have contributed to our thinking by submitting ideas and papers and by responding to the two surveys we carried out; and to those who have attended conferences and workshops, including the meeting of the National Reference Group earlier this year, and who have helped us to test out our emerging thinking.

With best wishes

Yours sincerely

Jenny Simpson
Chief Executive
British Association of Medical Managers

Executive summary

1. The Tackling Concerns Locally working group is tasked with taking forward one of the workstreams of the programme of reform to professional regulation launched by the government's White Paper *Trust, assurance and safety.* Our concern is with

   – strengthening the local processes for identifying and dealing with concerns over the performance, conduct and health of healthcare professionals

   – improving coordination between local healthcare organisations and the national professional regulators.

   This report gives a broad overview of our work to date; further detail is given in the reports of three subgroups which are published in parallel, and in the other publications of this workstream listed in Annex B.

2. Our report begins (chapter 2) with a broad overview of the concept of clinical governance, which has been defined as "a framework through which healthcare organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care". This framework includes not only specific processes and structures but also an organisational culture in which all members of the organisation take joint responsibility for quality and safety, and in which the contribution of patients and the general public is welcomed. The specific processes concerned with poor performance should be seen in this wider context. In particular, this chapter emphasises

   – the need to address any wider, systemic problems which may be affecting the performance of individual health professionals

   – the need to pick up signs of deteriorating performance at the earliest possible stage and to take early action, offering additional training or remediation, reskilling and rehabilitation wherever this would be effective.

3. The following chapter (chapter 3) sets out the key principles of best practice relating to the four key processes required to identify and deal with performance issues:

   – identifying issues, including supporting patients and fellow professionals who wish to raise a concern

   – investigation

   – deciding what action is needed

   – access (where appropriate) to remediation, reskilling and rehabilitation.

   These principles are intended to be generic across all professions and all sectors of healthcare.

4. Chapter 4 discusses three of the specific recommendations for the medical profession set out in the review of medical regulation *Good doctors, safer patients*. The chapter

   – reviews the main proposals of a consultation paper on "responsible officers" (locally-based senior doctors, with specific responsibility for overseeing the performance and conduct of doctors working for the healthcare organisation) published in July 2008

- describes the basis of the two pilots which began in September and October 2008 of the concept of "GMC affiliates" (regionally based officers or associates of the General Medical Council (GMC) who will support and advise responsible officers)
- sets out modified proposals for the "recorded concern" (a voluntary agreement between a doctor and a healthcare organisation recognising a source of concern, linked to a plan for remediation, reskilling or rehabilitation). Because of the widespread misunderstanding of the original concept we suggest renaming this as an "agreed statement of concern".

5. Chapter 5 addresses the handling of information to support the processes described in previous chapters. It

- summarises the information which should be held at local level and the safeguards over access to the information
- discusses some particularly sensitive issues such as the use to be made of concerns which have not been articulated as a formal complaint ("soft information")
- discusses the tests which a healthcare organisation should apply before sharing information about a healthcare professional with another organisation
- reviews the options for storing and sharing information, including the relative advantages of localised and centralised systems.

6. Chapter 6 considers the particular issues for healthcare professionals working in primary care and in particular reviews the operation of the "Performers List" arrangements, under which primary care doctors, dentists and optometrists must be accepted onto the list of a Primary Care Trust (PCT) before they can offer NHS services. We concluded that these arrangements still provide a useful safeguard but that steps should be taken to improve the consistency and flexibility of their operation.

7. Chapter 7 reviews progress in piloting and implementing the new arrangements for death certification first proposed in *Learning from tragedy*, an overview of the Government's response to all the recommendations from the Shipman Inquiry. Better information from death certificates will be valuable for both public health and clinical governance purposes.

8. Chapter 8 summarises the action that needs to be taken centrally to promote good practice in all these areas and outlines the timetable for implementation. Our key recommendations and conclusions are summarised in Chapter 9, which is reproduced below.

Key messages for healthcare organisations

9. One of our key recommendations is that the Department of Health should commission a refresh of existing guidance on clinical governance, in particular those aspects which relate to identifying and handling concerns over the performance, conduct and health of healthcare professionals. We expect this guidance to be published and disseminated in the course of 2009. In the meanwhile, the key messages for healthcare organisations can be summarised as follows:

General principles

1. Boards of healthcare organisations should take responsibility for developing a culture of continuous quality improvement and for maintaining and resourcing effective clinical governance structures and processes, including those needed to identify and handle concerns over professional performance, conduct and health.

2. These processes should actively encourage the participation of patients and the general public.

3. Healthcare organisations should aim to identify concerns about health, conduct or professional performance at the earliest possible stage and to intervene quickly to safeguard patients and, where possible, help the professional to get their career back on track.

4. Healthcare organisations should be alert to the possibility that apparently poor individual performance could be the result of wider systems problems, and take action as required.

Processes for identifying problems with performance, conduct or health

5. People who wish to raise concerns – whether patients, carers or other members of staff including trainees – should be encouraged to do so and supported throughout the process; organisations should act swiftly on concerns and provide regular feedback to those raising the concern.

6. Healthcare organisations should establish systems for collating and analysing information from a variety of sources relating to potential early signs of poor performance, conduct and health; and should regularly review this information in order to identify clusters and trends.

Processes for investigating and acting on concerns

7. Healthcare organisations should ensure that they have clear processes and the capacity and skills to investigate concerns over professional performance, conduct and health. This may involve pooling resources or bringing in external expertise, especially for smaller organisations.

8. Following an investigation, a clear decision must be taken by a transparent and fair process which protects patients while respecting the rights and needs of the healthcare professional. Healthcare organisations should ensure that they have the structures, processes and capacity to achieve this.

9. Healthcare organisations should develop a robust, quality assured and resourced strategy for remediation, reskilling and rehabilitation where this is appropriate. There should be access to remediation for all professions. Remediation plans should be tailored to the needs of the individual with integral arrangements for clinical placements, supervision, monitoring and return to normal clinical practice.

Supportive strategies

10. Subject to Parliament, healthcare organisations will be required to nominate or appoint "Responsible officers" with specific responsibilities for the local clinical governance arrangements relating to the performance, conduct and health of doctors. We expect to introduce this requirement in the final quarter of 2009. In the meanwhile, healthcare organisations should consider what further support is needed to medical directors or other senior officers who are already carrying similar responsibilities.

11. Subject to the result of pilots now underway, the GMC will establish a network of "GMC affiliates" to support responsible officers, to help them to improve the consistency of local decisions, and to improve the liaison between local and national processes.

12. Reforms to death certification will improve the quality and accuracy of certification, provide greater protection for the public, and improve public health surveillance.

Recommendations for the Department and other national organisations

Recommendation 1: We endorse the proposal in *Good doctors, safer patients* that the Department should work with the Royal Colleges and professional organisations to develop and disseminate clinical indicators relating to individual healthcare professionals for use both in secondary and primary care [para 3.6].

Recommendation 2: We recommend that the Department should take forward with the national regulators and with NHS bodies, and in consultation with patient and professional groups, the further steps needed to support patients and colleagues in raising concerns about a healthcare professional as identified by the clinical governance subgroup. This will include confidential advice and clearer signposting for those considering raising a concern; support in articulating the concern, including advocacy support for vulnerable people; and support as the concern is progressed, for instance for people invited to give evidence at disciplinary hearings [para 3.11, para 8.12]. In the particular case of concerns relating to doctors which have been referred to the GMC for consideration, the GMC affiliates might have a particular role in liaising with the patient or carer raising the concern and ensuring that they have access to appropriate support.

Recommendation 3: A part of the action arising out of the previous recommendation, the Department should consider what redress or support could be made available to patients who have raised a concern relating to patient safety and who are not satisfied that it is being investigated with an appropriate degree of independence.

Recommendation 4: We recommend that the Department should commission a review of analytical tools for collating and analysing information on the performance and conduct of healthcare professionals and should consider whether further steps are needed to stimulate the market [para 3.13].

Recommendation 5: We recommend that the modified version of the "recorded concern" described in para 4.12 should be modelled as part of the GMC affiliate pilots [para 4.13].

Recommendation 6: We recommend that the Department of Health should commission and disseminate an update of the guidance on identifying and handling concerns about healthcare professionals, consulting relevant stakeholders and authors of existing guidance. The aim should be to generate a coherent and accessible body of guidance in this area [para 8.8].

Recommendation 7: We recommend that DH should set up or commission a web portal on which all relevant guidance (any newly-commissioned guidance and existing guidance from bodies such as the National Clinical Assessment Service) can be readily found [para 8.8].

Recommendation 8: We recommend that DH should invite SHAs to work with PCTs to set in place adequate systems for the early identification and effective handling of issues of poor professional performance, conduct and health in primary care contractor organisations [para 8.11]

Recommendation 9: We recommend that DH should make an early decision on the options for developing a centralised database to hold information on concerns about performance, conduct and health, following the scoping study which the Department is commissioning. If the decision is taken that this is not feasible or would pose too much risk, then we recommend that the Department should discuss with the national regulators the alternative model of holding a core of information on the national register for each profession [para 8.16].

1 The professional regulation reform programme

1.1 This is the report of the Tackling Concerns Locally working group, which is tasked with taking forward one of the seven work streams of the programme of reform to professional regulation launched by the government's White Paper *Trust, assurance and safety.* This introductory chapter sets out the background, describes the task given to our group, and explains how we organised our work.

The changing nature of clinical practice

1.2 The current framework for the regulation of healthcare professionals date back to the middle of the nineteenth century. At that time, the majority of healthcare professionals worked in single practice and the main concern of legislators was to enable patients to distinguish between those professionals who were properly qualified from those who were not. The solution was to invite each of the main healthcare professions to set up a register of qualified practitioners and to define the criteria and processes for admitting practitioners onto the list and (where necessary) removing them. There was an implicit assumption that a healthcare professional, once trained, would maintain their skills; but unless some very serious incident occurred they would stay on the professional register for life.

1.3 Clinical practice today is very different. The pace of change in clinical practice means that it is no longer safe to assume that all healthcare professionals will be able to maintain and update their clinical skills. New roles – in some cases, new professions – are emerging to meet changing demand. The great majority of healthcare professionals now work in clinical teams, many of them in managed organisations, and communication and teamworking skills are increasingly as important as clinical skills. There is a much greater acceptance of the principle that it is the team or organisation as a whole which has accountability for the quality of services, not just the individual clinician[1]. We return to this theme in the next chapter.

1.4 Public and patient expectations are also changing. Many patients are no longer prepared to act as passive recipients of healthcare from an authoritative healthcare professional, but are looking for a more equal dialogue in which they play their part as "co-producers" of their own health[2]. When clinical errors occur – as inevitably they do in an activity as complex and intrinsically risky as healthcare – patients do not necessarily want to sanction the organisation or individual that has harmed them, but they do want a clear explanation of what went wrong and an assurance that lessons have been learnt for the future[3].

1.5 These changes mean that, inevitably, fundamental questions have been asked about the nature and purpose of professional regulation. In response, the professional regulators have updated their codes of practice[4] and have increasingly added lay membership to their governing councils[5]. The concept of periodic "revalidation" of a clinician's fitness to practise – a periodic test that he or she has maintained the skills required for their current area of practice – was put forward in the Merrison report[6] and, more recently, plans developed to implement it in some of the healthcare professions[7]. But the basic structure of professional regulation has remained unchanged, and – for some critics at least[8,9] – progress has been all too slow.

The Shipman Inquiry and related inquiries

1.6 The position was changed radically[10] by a series of high-profile events which came to public attention in the 1990s – the excess mortality in paediatric cardiac cases at Bristol Royal Infirmary, the serial murders of Harold Shipman, failures in appointments processes in the case of Richard Neale, boundary violations in the cases of Clifford Ayling, William Kerr and Michael Haslam. In each case the same questions were raised – why did those in authority not realise earlier what was going on, and if they had realised earlier did they have the power to take effective action to protect patients? The resulting public inquiries produced a series of authoritative reports which have radically shaped the direction of healthcare policy in this century. For the purpose of this paper, our main concern is with the fifth report of the Shipman Inquiry[11], which made recommendations about the monitoring of doctors, about complaints and concerns, and about the role and processes of the General Medical Council (GMC); and with the related recommendations of the Ayling[12] and Kerr/Haslam[13] inquiries.

The reviews of medical and non-medical regulation

1.7 The government responded by setting up reviews of medical regulation, under the Chief Medical Officer for England Sir Liam Donaldson, and of non-medical regulation, under the then Director of Workforce Andrew Foster, and their reports were published for consultation in July 2006[14].

1.8 Following consultation, the government's final proposals were set out in a series of three documents published in February 2007. The White Paper *Trust, assurance and safety*[15] set out the overall principles for reform of professional regulation. *Safeguarding patients*[16] gave the government's formal response to the individual recommendations of the Shipman Inquiry's 5th report and to the reports of the Ayling, Neale and Kerr/Haslam inquiries. *Learning from tragedy*[17] summarised all the action which the government is taking in response to the various reports of the Shipman Inquiry and also set out some new proposals on death certification, responding to recommendations in the Inquiry's 3rd report (see chapter 7 below). Together, these three documents define the scope of the programme of reform on which the government has now embarked.

1.9 Some of the key principles of the reform programme which are of particular relevance to this report are as follows:

i the protection of patients and the general public should be the overriding priority;

ii this protection requires an even closer cooperation between local healthcare organisations – responsible for the day-to-day monitoring of the performance, conduct and health of healthcare professionals and for the immediate response to any issues which may arise – and the national professional regulators, responsible for maintaining the national register;

iii continuing fitness to practise should no longer be assumed (in the absence of any concerns) but should be demonstrated through an effective, periodic process of revalidation rooted in annual peer appraisal;

iv however, these additional safeguards should be introduced in a way which minimises any adverse impact on the normal processes of healthcare, makes best use of scarce resources, and affirms and supports the vast majority of healthcare professionals who strive to provide safe and effective care for their patients;

v reforms should be carried out with the support and assent of professionals and the general public.

The implementation programme

1.10 Implementation was launched at a major national conference in June 2007[18], involving patient organisations, the national professional regulators and other professional organisations, and healthcare organisations. It was decided to set up seven working groups, each with broad stakeholder membership, to advise on implementation of different aspects of the programme (see box 1 on the following page).

1.11 Our workstream, “Tackling Concerns Locally”, is concerned with

– strengthening the local processes for identifying and dealing with concerns over the performance, conduct and health of healthcare professionals

– improving coordination between local healthcare organisations and the national regulators.

Our formal remit, and the membership of our working group, are given at Annex A. Because each country of the United Kingdom is separately responsible for the organisation of its healthcare system our recommendations relate in the first instance to England only. However, we

expect that the Devolved Administrations will wish to consider applying broadly similar principles[a] in their healthcare systems.

Box 1 Implementing the reforms to professional regulation: the seven working groups

Enhancing confidence in the healthcare professional regulators – including considering the size and composition of their councils, the strategic role of the councils, and accountability to patients, the general public and Parliament

Extending professional regulation – advising on the criteria to determine whether emerging health care roles should be regulated, and making recommendations about existing non-regulated healthcare roles

Medical revalidation – the principles and next steps for implementing the revalidation of doctors in the United Kingdom, with enhanced annual appraisal complemented by additional evidence on specialist skills

Non-medical revalidation – developing general principles, applicable to all the professions other than doctors, for a new system of appraisal and revalidation

Tackling concerns nationally – advising on the establishment of an independent body to adjudicate (i.e. to judge and make final decisions) on medical fitness to practise cases brought before the General Medical Council

Tackling concerns locally – coordinating a series of reforms which will strengthen local arrangements for identifying poor practice among healthcare workers and taking effective action to protect patients and the public

Health for health professionals – piloting and evaluation of referral services for doctors and dentist, and development of an integrated national strategy for the health of all health professionals.

Structure of this report

1.12 We agreed at an early point in our discussions to structure our work round the model shown in figure 1 and described more fully in chapter 3. This model identifies the following elements which local healthcare organisations need to have in place in order to handle issues of professional performance, conduct and health:

- a culture which encourages learning and reflection on current practice, supported by systems to assess and raise standards of professional performance including giving early warning of any possible problems

[a] Regulation of (most of the) healthcare professions is a reserved matter, i.e. decisions taken in the UK Parliament apply throughout the UK. Organisation of health services is devolved, i.e. decisions are taken separately in each administration. However, because some of our recommendations hinge on the interface between local clinical governance processes and the national professional regulators, it will be helpful if the local processes are broadly similar in each part of the UK.

– systems to guide and support patients, carers and fellow professionals in raising concerns;

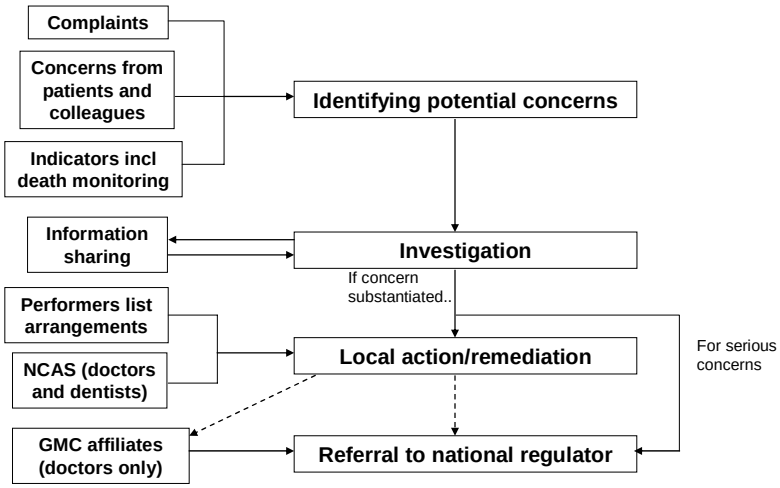
– investigations which are thorough, objective and have an appropriate degree of independence;

– fair and transparent processes for making decisions on any action to be taken following investigation, including the possibility of referral to the national professional regulator;

– ready access to remediation, retraining and rehabilitation.

Figure 1

Tackling concerns – a possible framework



1.13 We agreed to set up six subgroups to take forward our work. One subgroup, the Clinical Governance subgroup, considered the model in its entirety and has developed principles of good practice relating to all healthcare professions and to all sectors. The other subgroups have considered particular elements of the model (the role of information, death certificates as one potential source of information), the application to particular sectors (the Performers List subgroup for primary care contractors), and the particular recommendations in *Trust, assurance and safety* relating to the medical profession (the Responsible Officer and GMC Affiliate subgroups).

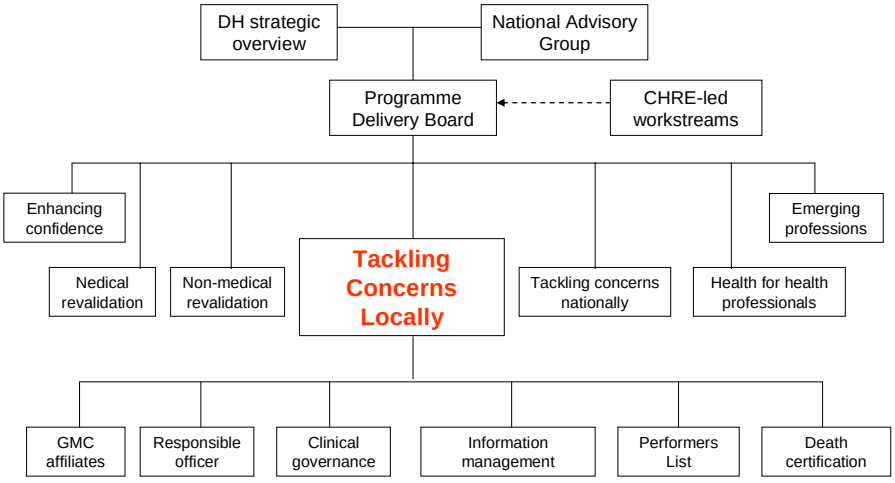
1.14 This report follows a very similar structure. Chapter 2 sets out some further background to the concept of clinical governance and its relation to recent developments in the understanding of clinical leadership and accountability. Chapter 3 summarises the recommendations on best practice of the clinical governance subgroup. The recommendations of the remaining subgroups follow in chapters 4-7. Chapter 8 outlines our proposals for taking the changes forward, including proposals for dissemination of good practice guidance. Chapter 9 summarises those recommendations in this report which are addressed to the Department of Health and other national organisations.

1.15 In parallel, we are publishing the reports of three of our subgroups: the Clinical Governance, Information Management and Performers List subgroups. These set out further detail on the recommendations and best practice principles summarised in this report. A consultation document on responsible officers – in effect, an interim report from the responsible officer subgroup – was published in July[19].

1.16 A complete list of publications from this work stream, and other closely related publications, is at Annex B; the recommendations from the three subgroup reports are reproduced at Annex C.

Figure 2

Professional Regulation and Patient Safety Programme: governance arrangements



2 Clinical governance

2.1 The concept of clinical governance was first described in *The new NHS – modern, dependable* in December 1997[20] and has been elaborated in a series of subsequent publications[21]. It has been defined as "a framework through which healthcare organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care"[22] . This framework includes not only a number of specific *processes* and *structures* but more generally an organisational *culture* in which every member of the organisation – managers and administrative staff as well as healthcare professionals – takes joint responsibility for the quality and safety of the healthcare services provided.

Leadership and accountability

2.2 The concept of clinical governance is thus very closely linked to developing ideas about leadership and accountability in the healthcare professions. As noted in chapter 1, many healthcare professionals have traditionally worked in a one-to-one relationship with patients, within a philosophy which emphasised accountability to the individual patient and to the codes of good practice defined by the profession's own national regulator[b]. Clinical practice is now very different, with many healthcare professionals working as part of a multi-disciplinary clinical team, often in large and complex organisations. There is also an increasing realisation of the need to balance the requirements of the individual patient with those of larger populations, especially given the conflict between budgetary constraints and the increasing availability of very expensive treatments. Finally, the relatively new science of evidence-based healthcare emphasises the need to balance the clinician's judgement on the treatment which may be best for the individual patient with evidence on which interventions can be shown to work for patients in general.

2.3 In this new context, clinical governance emphasises the importance of a *collective*, rather than individualistic, approach to ensuring clinical quality. High quality and safe healthcare is not just the responsibility of individual clinicians – although that of course remains vitally important – but also of clinical teams working within agreed protocols and guidelines on safe practice and supported by systems which have been designed to be as resilient as possible[23]. Adverse clinical events are in many cases the result not primarily of errors by individual clinicians, but of weaknesses in the underlying systems[24,25]. The response to a clinical error should be to investigate the "root cause" and fix any problems in the wider system, not to search for an individual to scapegoat[26]. Quality is a core responsibility of the board of the healthcare organisation, which should take responsibility for the structures and processes needed to secure quality and should receive regular reports on key quality indicators.

[b] The major exception of course is nursing, which in secondary care has for many years been organised on a team basis with clear leadership structures.

2.4 Patients and the general public also have a key role to play in clinical governance. Feedback from patients on individual incidents – usually in the form of complaints or concerns – has always formed, at least in theory, one source for quality improvement. This feedback remains vitally important and much work is needed to improve the responsiveness of the complaints system in both health and social care so that organisations can truly "make experiences count".[27] But the involvement of patients and the general public should be much deeper than this. Current guidance[28] emphasises the need to seek proactively the views of patients and the public on where services need improving and to involve lay people in all the structures and processes of clinical governance.

2.5 These newer insights have major implications for the concepts of clinical accountability and clinical leadership. In this more complex environment, clinicians are not just accountable to their individual patients or to the national regulator; they are also accountable to the local clinical team, to the organisation in or for which they work, and to the wider population which it serves. And clinical leadership means leading not merely by the more traditional means – teaching and mentoring, research, development of national standards of good practice – but also taking responsibility for developing the local structures, protocols and guidelines within which clinical quality can be assured and improved.

Quality improvement and quality assurance

2.6 The standard definition of clinical governance quoted above includes implicitly elements of both quality improvement and quality assurance. (For the purpose of this report, clinical quality assurance can be defined as the structures, processes and culture which seek to ensure that standard best practice is applied so as to minimise the risk of adverse events; clinical quality improvement seeks new ways of delivering clinical services in ways that improve health outcomes and/or the overall quality of the patient experience. The distinction is not clear cut but is generally accepted as useful.)

2.7 This report focuses on issues of poor performance, conduct and health in individual healthcare professionals. It covers therefore only a small part of the broader issues that come under the heading of clinical governance, specifically of that part of clinical governance which relates to quality assurance. It is worth emphasising two points at the outset:

i issues which manifest themselves in the performance or conduct of individual healthcare professionals may nevertheless be symptoms of broader problems in the team or organisation. Clinical governance processes designed to deal with issues of performance and conduct need to be always open to the possibility of these wider, systemic, problems;

ii quality assurance is only one part – arguably the less important part – of clinical governance. The more important part is to focus all members of the healthcare organisation on improving the quality of services,

within a governance framework which ensures that risks are managed and the impact of changes assessed. It would be a tragedy if the processes put in place to identify and deal with poor performance acted in a way which discouraged this sort of structured search for quality improvement.

We believe that the approach taken in this report, and set out in more detail in the recommendations of the Clinical Governance subgroup, are consistent with these important principles.

Handling poor performance – the need for early intervention

2.8 The experience of clinical directors and directors of education suggests that, where healthcare professionals begin to show serious manifestations of poor clinical performance or unacceptable behaviour, the warning signs were available at a much earlier stage in their career[29]. Traditionally, in some professions at least, there has been a reluctance to tackle issues of poor performance – for a variety of reasons: because of the underlying philosophy of clinical autonomy; because of a culture in which it was not considered appropriate to voice concerns about a colleague; because, once performance has deteriorated too far, it is likely to be too late to attempt remediation; because formal disciplinary processes tend to be very costly and protracted. However, the high profile cases referred to in chapter 1 are a reminder of the potentially disastrous consequences of failing to act on early signs of problems. In contrast, early intervention can often help healthcare professionals to get their career "back on track" without any adverse effects on patient care[30].

2.9 This report therefore starts from the basic premises that

i annual appraisals and clinical governance monitoring systems need to be sensitive enough to pick up the early signs of deteriorating performance, conduct and health at the earliest possible stage. Similarly, staff with concerns over a colleague should be encouraged to come forward as early as possible to share their concerns;

ii where concerns are substantiated, healthcare organisations should act as quickly as possible, with the aim of protecting patients by addressing systemic issues and offering additional training or remediation, reskilling and rehabilitation wherever this would be effective;

iii nevertheless, healthcare organisations should not shirk their responsibility to refer healthcare professionals to the national regulator where local interventions have failed to address the problems or where a serious issue of fitness to practise emerges.

3 Key principles of best practice

3.1 This chapter describes the key principles of best practice in those elements of clinical governance which relate to issues of poor performance, conduct and health of healthcare professionals. It takes into account the findings of two surveys of the current state of awareness in the NHS of the relevant principles of clinical governance, one relating to the handling of complaints and concerns[31] and one relating to access to remediation, reskilling and rehabilitation[32]. Further details are given in the report of our Clinical Governance subgroup (see Annex B).

3.2 As already noted in chapter 1, our underlying model (figure 1) involves the four stages of

- identifying issues
- investigation
- deciding on what action is needed
- access (where appropriate) to remediation, reskilling and rehabilitation

and this chapter is structured round these four themes[c]. We emphasise again that the boards of healthcare organisations should take responsibility for ensuring that the organisation has appropriate structures, processes and resources in all four areas, within an overall clinical governance structure committed to ensuring and improving quality.

3.3 As elsewhere in this report, the model described is generic across all professions and sectors of healthcare, and should be considered alongside specific arrangements for specific professions such as the statutory supervision of midwives. Frameworks describing the application of the general principles of clinical governance to particular sectors have been developed by the Clinical Governance subgroup and are available on the DH website[33].

Identifying issues

Annual appraisal

3.4 Arrangements for enhanced annual appraisal are being discussed in the parallel work by the working groups on medical and non-medical revalidation (see box in para 1.10). Where appraisal is working well, it can be one of the

[c] For ease of exposition, this chapter is written on the assumption of a healthcare professional working in a managed environment in which there is an identifiable clinical governance function reporting to a senior (clinical) manager with the authority to initiate action where required. The particular circumstances of the primary care contractor professions (GPs, general dental practitioners, optometrists and community pharmacists) are discussed in chapter 6 below. A number of other healthcare professionals, eg podiatrists and speech and language therapists, often work in environments in which there is no effective local clinical governance structure; in these cases the national professional regulator may need to exercise directly some of the functions which in this chapter are ascribed to the local healthcare organisation.

most effective ways of identifying problems at an early stage[d]. It is therefore vitally important that

i appraisal systems should be well resourced and both the systems and the individual appraisers should be quality assured

ii the appraiser should have access to relevant information such as information from multi-source feedback, performance data, and any complaints, concerns or adverse events involving the healthcare professional.

Routine monitoring of performance data

3.5 The report of the Next Stages Review, *High quality care for all*[34], has emphasised the crucial importance for healthcare organisations of regular monitoring of the quality of the care they provide. Most of these indicators at present relate to the performance of whole organisations or clinical teams. However, in some specialties it may in due course be possible through suitable risk-adjustment methods to derive reliable indicators at the level of individual clinicians; and in any case healthcare organisations should always be alert to the possibility that the outcomes of a whole clinical team is being affected by the poor performance of one individual.

3.6 At present the development of practitioner-level indicators is in its infancy, and there is relatively little experience in the use of indicators at the level of the team or organisation to detect concerns over the performance of individual clinicians. We therefore **endorse the proposal in *Good doctors, safer patients* that the Health Departments should work with the Royal Colleges and professional organisations to develop and disseminate suitable sets of clinical indicators for use both in secondary and primary care**. Some work is already underway for the related purpose of revalidation[35] and (at the level of the clinical team or GP practice) for registration with the Care Quality Commission[36] and for accreditation[37]. Healthcare organisations should also ensure that they have the capacity and skills to make use of such indicators for the regular monitoring of performance data and for the detection of trends and outliers.

Adverse events and other individual incidents

3.7 As already noted (para 2.3) individual adverse events – clinical errors leading to harm to patients or "near misses" – will in many cases be due to wider systemic problems, not to a deficiency on the part of the professional. However, a pattern of adverse events may well indicate a problem that needs to be addressed. In any case, it is important that any healthcare professional involved in a serious adverse event should be supported and helped to learn from the incident.

[d] Appraisal of course has a much wider function – for most healthcare professionals, the purpose of the appraisal interview is to enable the professional to reflect on how they can improve current practice, ie the appraisal process is developmental rather than judgemental.

3.8 Healthcare organisations should also be alert to any incidents of a non-clinical nature – for instance, probity issues – which may indicate an underlying problem of conduct or health.

Supporting patients and colleagues in raising concerns

3.9 Concerns from patients and from colleagues can be one of the best sources of early warning that the conduct or performance of a healthcare professional is slipping below acceptable standards. However, as the Shipman Inquiry [11] noted, the traditional culture in healthcare did not until very recently encourage clinicians to express concerns about colleagues, either through a misplaced sense of loyalty or through a belief that it was someone else's responsibility. And patients (and colleagues in subordinate roles or employees) often feel too vulnerable or disempowered to raise their concerns, or are concerned at the personal consequences that might result.

3.10 The clinical governance group considered these issues and has proposed the following principles of good practice:

1. **Support is needed at all stages for those raising concerns or making formal complaints.** The crucial stages are

   – advice ("signposting") on the options for raising concerns;

   – support in formulating the complaint or concern, including advocacy support for vulnerable individuals;

   – support in the subsequent stages in the handling of a concern, for instance if the person raising the concern is subsequently asked to give evidence at a local or national hearing.

   Support is needed for both patients and colleagues (including trainees and non-clinical staff) raising concerns, although the precise form of support needed may be different in each case.

2. **Opportunities to raise concerns should be optimised**, eg through the use of multi-source feedback and patient rating surveys.

3. **Clear explanation of the processes involved should be provided at the outset.**

4. **There should be formal procedures in place for colleagues to raise concerns** with a written policy in each healthcare organisation. This should include the option of raising concerns with a responsible person outside the normal work setting or line of command.

5. **Concerns should be treated with due seriousness** and appropriately clarified and investigated; as with formal complaints, the healthcare professional should be made aware of the nature of the concern and given the opportunity to comment.

6. **Advocacy, support and signposting should be provided for those who wish to raise concerns.** Additional capacity and expertise is

needed to offer support to vulnerable patients or in complex cases, while building on the support already offered by existing successful services.

7. **The professional regulators should provide support for potential witnesses.** The regulators already provide support with the practical details of hearings such as information about the process and expenses, but there is a need to explore what additional support could be providing without compromising the regulators' impartiality. Further publicity should be given to the witness support schemes operated by the professional regulators[38].

3.11 Some of these principles will require action by DH or the national regulators.

Bringing the information together

3.12 To maximise the chance of early identification of performance issues, the information from all these sources – annual appraisals, adverse events, routine performance data, complaints and concerns – must be brought together in a structured way which enables clinical management to take an informed overview. The information subgroup have considered the sort of information that should be available to healthcare organisations and the safeguards on access, but have not discussed in depth the sort of tools needed to analyse the data, to detect patterns and outliers, and to flag up issues of concern.

3.13 We are aware of a number of commercially available software packages which claim to provide this kind of overview of qualitative and quantitative data, and (in a rather different context) the Healthcare Commission have also pioneered the use of tools to interrogate this kind of dataset[39]. **We recommend that the Department should commission a review of these analytical tools and should consider whether further steps are needed to promote their development.** This could perhaps be combined with the scoping study of IT to support clinical governance and revalidation referred to in the chapter on the information subgroup (see para 5.12 below), and informed by the work of the Revalidation Support Team to develop suitable tools to support revalidation.

3.14 Once the information has been collated, with appropriate analytical and IT support, we recommend that it should be reviewed by a senior clinician with the authority to initiate further action as needed. This review should be undertaken as part of the periodic revalidation process, and more frequently as needed (for instance, as a result of a concern expressed at an annual appraisal interview or receipt of complaint suggesting serious cause for concern).

Investigations

3.15 Guidance on good practice in carrying out investigations of professional conduct and behaviour has been published by the National Clinical Assessment Service (NCAS) for both primary and secondary care[40] and guidance on handling performance issues in secondary care, and on

investigations more generally (for instance, investigations of Serious Untoward Incidents), is available from other sources[41]. The Clinical Governance subgroup reviewed this guidance. In addition, the Council for Regulation Healthcare Excellence (CHRE) carried out a separate consultation process, at the Department's request, in order to establish what standards would be required of local investigations in order that the national regulators could refer to their findings of fact without having to duplicate the investigation. The findings of the CHRE consultation have been incorporated in the subgroup's recommendations.

3.16 The subgroup concluded that good practice in carrying out investigations of concerns over professional performance, conduct and health could be summarised in the following principles:

1. The overriding objective should be to protect the safety of patients and the public.

2. Healthcare organisations should draw up **clear policies for local investigation** in partnership with all stakeholders, signed off at board level. This should include an initial assessment of whether the case can be handled internally or should be referred to the national regulator; and whether there are any underlying health issues for the healthcare professional or systems issues for the organisation.

3. The investigation process must be **fair, consistent and objective** and retain the confidence of the person raising the concern, the healthcare professional and other stakeholders. The complainant should have the right to seek an independent review and there should be a means of redress if, despite representations, the complainant is not satisfied with the way in which the investigation is being carried out. All decisions must be based on the best available evidence and thorough records must be kept.

4. The **scope and context of the investigation** must be clearly defined at the outset. The investigators should seek out the evidence and establish the facts, not make any formal decision. If material comes to light which calls into question the initial terms of reference, the investigation should be suspended until the terms of reference can be reviewed.

5. Investigations should be **properly resourced**. An initial assessment should be made of the resources required and employers should ensure that the investigation is carried out by staff with appropriate seniority, experience and training and that there are no conflicts of interest.

6. Healthcare organisations must be rigorous in **working to agreed timescales**. If delays are unavoidable the reasons must be communicated to all parties.

7. **People raising concerns or making complaints should be supported and kept informed** throughout the process, including referral to available sources of advice, support, guidance and advocacy.

8. Similarly **the healthcare professional under investigation** should be supported, kept informed of progress of the case and given the opportunity to comment, contribute and take independent advice at all appropriate points. Healthcare organisations should bear in mind that this can be a very stressful experience for the healthcare professional, and consider offering mentoring support or access to specialised health services (see para 3.17 below, principle 7).

9. Healthcare organisations need to decide who else, in the organisation or outside, needs **to be informed about the investigation and its progress** (see chapter 6 for the views of the information subgroup on the related issue of informing other organisations).

10. Healthcare organisations should **seek expert external advice when appropriate** including occupational health assessment, recording when they have done so and how it has contributed to their decision making. This is particularly important when it becomes apparent that the organisation does not have the capacity or expertise to deal fairly with the case.

The decision-making process

3.17 Once the investigation has established the facts, an entirely separate process is needed to decide what action (if any) is needed. Guidance on this process is again available from DH, NCAS and other sources[42]. The Clinical Governance subgroup concluded that the key principles could be summarised as:

1. **A decision must be made**, recorded and relevant parties informed.

2. There should be **complete separation between the investigation and decision making processes** – those who are take part in the decision making stage should have had no involvement in the initial investigation (and no close relationship with the investigator).

3. The decision making process must be seen to be **fair, impartial, consistent and timely**. All staff involved in decision making should be appropriately trained, supported and resourced. Organisations should consider formalising the process, for instance by use of a “Decision making group” as recommended by NCAS[43]. Organisations also need to consider how to bring both lay input into the process and representation from the profession of the subject of the investigation.

4. **Expert input should be brought in where necessary**, including where appropriate a health assessment, input from professional peers on

options for mentoring and remediation, or input from NCAS (for doctors and dentists) or other professional bodies[e].

5. **A range of options should be considered, based on the specialty and circumstances of the individual healthcare professional**. This could vary from further training or reskilling, through a range of intermediate options such as formal warnings, additional supervision or conditions on practice, to more formal sanctions including in the most serious cases referral to the national regulator. Decisions should take into account both the individual circumstances and the organisational factors which may have impacted on the performance issue.

6. **Organisations should consider their own learning and make appropriate changes.** This should include changes both to alleviate an existing situation and to ensure there is no similar occurrence.

7. **Individuals should be encouraged to seek out support and self refer for help.** In relation to health problems, the "Health for Health Professionals" working group is developing a national strategy and a self-referral service, for doctors and dentists in the first instance, is being piloted in London[44].

8. **Healthcare professionals should have the right to appeal against any decision made**, except for decisions to refer cases to the national regulator[f], to the police, or to the NHS counterfraud service**.** The appeal panel should be completely independent of the original decision making process, although individuals involved in the latter may be asked to present. One model would be to use a panel of three members, including a member of the relevant profession or specialty and a lay member (eg a non executive director where appropriate). Healthcare organisations may wish to set up reciprocal arrangements with another organisation to provide unbiased members for the panel.

Remediation, reskilling and rehabilitation

3.18 Chapter 2 (paras 2.8-2.9) has emphasised the need for early intervention when concerns emerge over the performance or conduct of a healthcare professional, with the aim wherever possible of remediation, reskilling or rehabilitation. However, the survey carried out by the Clinical Governance subgroup has revealed wide variations between healthcare organisations in the extent to which they are able to offer access to such services. We strongly endorse the subgroup's view that, in appropriate circumstances, remediation offers a far better option both for the healthcare professional concerned and for patients than the alternative options which could result

[e] NCAS will be offering a similar service in relation to pharmacists from April 2009, and possibly in the longer term for other healthcare professions.

[f] The professional regulators are responsible for the criteria and processes for determining when an issue requires referral to their fitness to practise processes. Once the healthcare organisation has decided to consult the regulator over a possible referral, the decision making responsibility transfers in effect to the regulator. Patients, carers and other interested parties may of course take a case directly to the regulator whether or not the healthcare organisation considers that a referral is needed.

from formal disciplinary processes. The subgroup proposes the following principles of best practice, which build on the widespread experience of NCAS in this area and its guidance document *Back on track*[45]. These principles are supported by the remediation working group of the Academy of Medical Royal Colleges, which expects to complete its own report during the first part of 2009.

1. Remediation must ensure **the safety of patients and the public** while aiming to secure

   – the **well being of the healthcare professional and the wider team**,

   – the **robust delivery of services** based on agreed patient care pathways, and

   – **consistent competence of the healthcare professional** across the entire scope of their practice.

2. There should be **lay and patient input into the quality assurance and delivery of remediation**. This could for instance involve a "lay champion" of healthcare professional performance at the level of the Trust board. Also, patients under the care of a professional undergoing remediation should be informed of his or her status (as the Information Management subgroup have also recommended – see para 5.4).

3. PCTs and healthcare providers should maintain an **available and accessible, quality assured process of remediation for all professional groups** as an integral part of their local performance processes. A senior executive team member of the organisation should be responsible for the implementation and quality assurance of these processes and there should be regular reports to the board on the progress of individual practitioners. Self-referral by practitioners should be encouraged.

4. Decisions on remediation should be based on evidence using **validated tools for assessment of performance, conduct and health**. This would include assessment of behaviour at work, functioning in the clinical team, clinical competence, feedback from patients, assessment of the work and organisational environment, and any underlying health issues.

5. Remediation should be **personalised to the individual healthcare professionals and their learning style**, with explicit goals and timescales that are proportionate to the risks to patient safety. The possible need for a clinical placement away from the normal place of work should be considered. Resource needs, and the relative contribution of the healthcare organisation and the professional for funding, should be agreed out the outset.

6. **Remediation should be of high quality.** All involved in providing remediation should be competent in relation to the process as a whole and expert in their own field. There should be clear, accurate and comprehensive documentation of all processes and meetings. Processes should respect confidentiality both of patients and of the professional.

7. The performance of the professional during and following remediation should be **monitored by quality assured methods** focussing on the attainment of planned goals. A designated individual should be appointed by the healthcare organisation to oversee and support the professional both during remediation and during the transition back to unsupervised practice at the end of the remediation process. The responsible person should regularly review whether the plan still adequately protects patient safety or whether other action (eg referral to the national regulator) is necessary.

8. The **work environment for remedial placement should include adequate, quality assured supervision by a named individual.** The environment should reinforce the values of patient centred care. The relative responsibilities of the placement supervisor and of the individual responsible for the general oversight of the practitioner (see principle 7) should be clearly specified, including an agreed system for reporting any concerns arising out of the placement.

9. There should be **training and support for the whole clinical team working with the professional undergoing a remedial placement** while maintaining confidentiality over discussions between the professional and those responsible for oversight of the process.

10. All those involved in the remediation process should **uphold the NHS commitment to equality and recognition of diversity**.

11. **Remedial training and reskilling must be adequately and appropriately resourced**. Healthcare boards must have a senior member responsible for the resourcing and operation of performance procedures who can make the case for investment in remediation, including sufficient capacity for clinical placements. This will involve effective partnership working with postgraduate Deaneries/higher education institutions approved by the relevant regulatory bodies, and with other local healthcare organisations.

12. Healthcare organisations should **define success criteria and learn from experience**.

Links between handling concerns and revalidation

3.19 This chapter has set out proposals for best practice in handling concerns, or clusters of concerns, relating to individual healthcare professionals. It is essentially a reactive process, although as emphasised the intention should always be to intervene as quickly as possible with additional support and

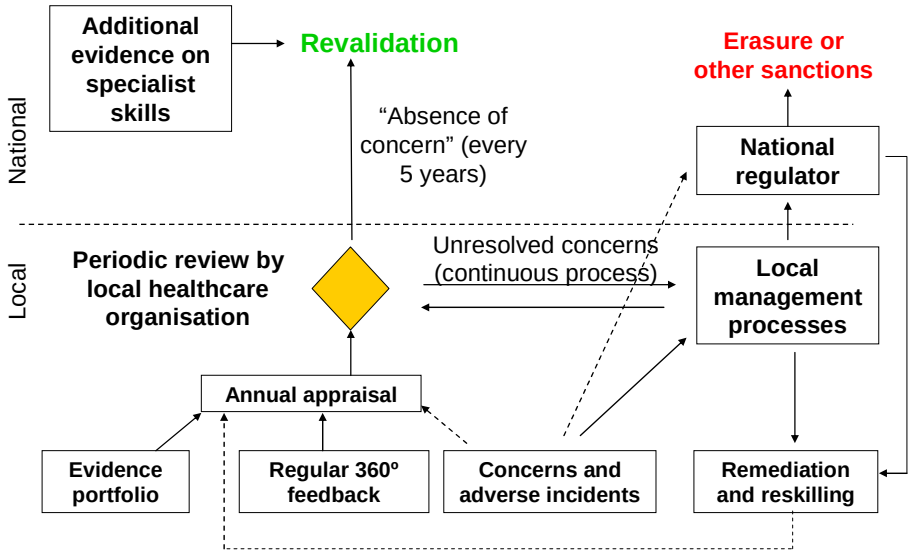
training once there is an indication that a professional's performance or conduct may be slipping below acceptable standards.

3.20 In contrast, revalidation is intended as a systematic, pro-active process in which a healthcare professional has to demonstrate at periodic intervals that he or she has maintained and updated the skills necessary to a particular area of clinical practice. Revalidation should ideally be driven by the professional, with support from their professional body, on the basis of a portfolio of evidence which has been carefully accumulated throughout the revalidation cycle and reviewed through regular appraisal or other appropriate means.

3.21 In practice, the two types of process need to be closely linked (see figure 3). Whatever material the professional presents to support the process of revalidation needs to be complemented by evidence from the employer or local contracting organisation[g] that there are no outstanding concerns. Of course, the employer/contracting organisation should not wait until the end of the revalidation cycle before acting on the concerns – that would completely negate the objective of intervening at the earliest possible stage. Nevertheless, the periodic revalidation cycle provides the opportunity to bring together the positive evidence on reflective learning, and the evidence on the absence of specific and unresolved concerns, in a way that enhances the assurance to patients of the practitioner's continued fitness to practise.

Figure 3

How it all fits together



[g] See the footnote to para 3.2 – for some professionals working outside managed clinical governance the reference to an employer or contracting organisation will not apply, and information on concerns is likely to be held directly by the national professional regulator.

4 Particular issues for the medical profession

4.1 This chapter discusses three of the specific recommendations for the medical profession in *Good doctors, safer patients* and *Trust, assurance and safety.* There are no immediate plans to generalise these recommendations to other health professions, though the Department will no doubt wish to keep policy under review in the light of experience in implementing them for doctors.

4.2 Para 1.9 has emphasised the importance of the close cooperation of local healthcare organisations and the national regulator in dealing with issues of professional performance and conduct. *Good doctors, safer patients* suggested that this close relationship could be promoted by setting up a network of "GMC affiliates" – both medically qualified and lay – who would be based in local health communities. The affiliates would

- promote good practice in local investigations and in the use of local decision-making processes
- have the authority to act on behalf of the GMC in the less serious fitness to practise cases such as those meriting a "recorded concern" (see below), and
- refer the more serious cases onto the GMC's central fitness to practise machinery.

After consultation, *Trust, assurance and safety* set out a modified proposal in which GMC affiliates based in Strategic Health Authority (SHA) regions or parts of regions provide advice and support to local "responsible officers", senior medical staff of PCTs, hospital trusts, and other local healthcare organisations. Our working group, through its Responsible Officer and GMC Affiliate subgroups, has taken forward the development of these concepts.

Responsible officers

4.3 Primary legislation relating to responsible officers was included as Sections 119-120 of the Health and Social Care Act 2008[53]. The legislation allows ministers through regulations to require healthcare organisations to appoint a senior doctor known as a "responsible officer" with specific duties for monitoring the performance and conduct of doctors under the oversight of the organisation, and for liaison with the GMC over revalidation and fitness to practise procedures. These aspects of the legislation (Section 119) apply throughout the UK. A further section (Section 120) allows ministers in England, Wales and Northern Ireland to give additional duties to responsible officers relating to clinical governance more generally.

4.4 Much of the detailed legislation will be set out in regulations, and the main task of the Responsible Officer subgroup was to advise on the principles on which the draft regulations will be based. Their conclusions are set out in a consultation paper which was published in July 2008 (see Annex B).

4.5 Much of the subgroup's discussion was taken up with the question of which organisations should be required to have Responsible Officers (ROs) in their own right, and the linked issue of how to ensure that every doctor in the UK can relate to an RO. The subgroup's conclusions are summarised in figure 4 below. In brief, the subgroup advise that

i every healthcare organisation employing doctors as doctors should have an RO[h];

ii PCTs should provide the RO function for all doctors on their Performers List, including locum GPs;

iii federations of self-employed doctors are encouraged to apply to provide the RO function for their members, subject to demonstrating appropriate clinical governance capability (eg a system allowing oversight of complaints and concerns from patients and fellow professionals; access to appraisal and remediation).

The subgroup were unable to reach a firm conclusion on the appropriate arrangements for locum doctors in secondary care. One option floated in the consultation paper is for locum agencies to appoint an RO, subject as with federations of doctors to demonstrating appropriate clinical governance. The subgroup agreed that, if a locum doctor was unable to find an RO through a locum agency or other route, in the last resort they should be able to look to the PCT of their GMC-registered address for the RO function.

4.6 The subgroup confirmed that, in many organisations, the natural choice for the RO would be the existing medical director, who would in any case need to take responsibility for the RO function. However the subgroup did not feel that the regulations should be prescriptive on this point, especially as there is no statutory requirement for PCTs (unlike hospital trusts) to have a medical director; and in large trusts there might be a need for more than one RO. The subgroup recognised that medical directors had many responsibilities, of which dealing with issues of poor performance is only one; the subgroup have therefore outlined the resources, including support staff and IT systems, on which the RO should be able to draw. It is worth emphasising that the RO's primary responsibility is for the clinical governance systems needed to handle revalidation and to identify and deal with performance issues, not with each individual piece of casework – although the RO would be expected to be broadly aware of all concerns over doctors in the organisation, and to become personally involved in the most serious cases including those involving referral to the GMC or a recommendation against revalidation. A quality assured system of appraisal (see para 3.4), with effective appraisers

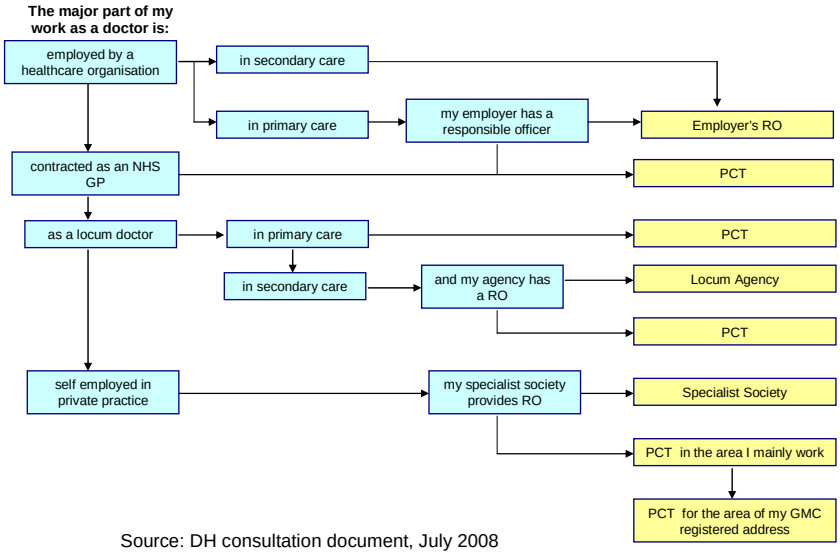
[h] The legislation allows one organisation to "hire in" a senior doctor from another organisation to act as its RO; this may be particularly helpful for organisations employing only a few doctors.

identifying and reporting early signs of problems, would take much of the weight off the RO.

4.7 There have been some concerns that the RO will be subject to conflicts of interest or will have too much power over the future of individual doctors. The subgroup emphasised that ROs remain accountable to the board of their organisation, and that decisions on disciplinary issues are taken with the authority of the board. As a matter of good practice all significant decisions should be taken by a properly constituted subcommittee of the board rather than by any individual acting on their own (see para 3.17, principle 3). In addition, ROs are professionally accountable to the GMC in their own right.

Figure 4

How do I find my responsible officer (RO)?



Source: DH consultation document, July 2008

GMC affiliates

4.8 *Trust, assurance and safety* made clear that the concept of GMC affiliates would be piloted before full-scale rollout in England[i]. The main task of the GMC Affiliate subgroup has therefore been to develop the details of the pilot sites and to design and commission an external evaluation.

4.9 GMC affiliates will be piloted in two SHA areas: in the Camden, Enfield and Haringey areas of the London SHA; and in the West Yorkshire part of the Yorkshire and Humberside SHA. In each case, the "lay affiliate" will be a trained GMC case worker[j]. For the London pilot the medical-qualified affiliate

[i] The Scottish Executive, the Welsh Assembly Government and the Northern Ireland Assembly will await the results of the pilots in England before deciding whether to implement the GMC affiliate concept in their countries.

[j] Some members of the subgroup felt that this would depart significantly from their understanding of the original concept of the lay affiliate. The subgroup accepted that, in order to achieve the main aims of the pilots as described in *Trust, assurance and safety* without too much delay, it would be necessary to choose affiliates who were already experienced in GMC processes. The evaluation team will be invited to comment on the skills, experience and attributes needed for the lay affiliate if a decision is taken after the pilots to proceed to national implementation.

will be a GMC case examiner, but for the Yorkshire pilot the affiliate will be the Deputy Regional Director of Public Health. This will enable the pilots to gauge reactions to a variant of the original proposal in *Trust, assurance and safety* in which the medically-qualified affiliate is part of the local health community, rather than a locally-based member of the GMC staff. The pilots will run for a period of 12 months starting in September/October 2008, with an interim evaluation after 6 months and a final evaluation at the end of the project.

4.10 Since medical revalidation will not begin until 2011-12 except in some limited pilots, the scope of the GMC affiliate pilots is limited to the handling of concerns over performance and conduct and will focus in particular on cases which are (or might under previous arrangements have been) referred to the GMC. The key evaluation domains will be

- the model and process
- the perception of those involved
- cost-effectiveness of the new arrangements
- the availability and use made of data.

The pilots will also seek to model the potential use of recorded concerns, as discussed below.

Recorded concerns

4.11 The concept of the "recorded concern" was first introduced in *Good doctors, safer patients*. It was originally envisaged as a possible sanction which the GMC affiliates could administer for cases which would otherwise have been referred to the GMC's central fitness to practise machinery. It is essentially a documented recognition of an issue of concern about performance, conduct or health which requires addressing; one particular feature is that it can only be issued with the agreement of the doctor involved. *Good doctors, safer patients* envisaged that, if the doctor was unwilling to accept a recorded concern, the case would then normally be referred on to the GMC.

4.12 We have had extensive discussion of this concept, both in individual subgroups and in a specially-convened subgroup with membership drawn from across the subgroups. It is fair to record that there remains considerable concern over the concept, both whether it would in practice be useful as an addition to the options already available at local level, and whether it could be administered in a way that was fair both to doctors and to patients. Although we have not achieved a consensus, the Department has suggested that recorded concerns are most likely to be of value in the following, slightly modified form:

i the "recorded concern" should always form part of an agreed package of remediation, reskilling and rehabilitation to help the doctor address the perceived area of concern. The involvement of NCAS and/or the local Deanery may be helpful in drawing up this package;

ii recorded concerns should not be seen as an alternative to referral to the GMC's fitness to practise procedures, but as an option for areas of concern which do not yet put the doctor's fitness to practise into question but could do in the future if not addressed now. In other words, the recorded concern is seen as a form of early intervention to address issues of performance, conduct or health before they become sufficiently entrenched to require referral to the GMC;

iii recorded concerns should therefore be seen as part of the spectrum of options available to the local healthcare organisation, not as the lowest form of sanction available to the GMC. The recorded concern should therefore be proposed by the RO after a fair process in which the doctor would have the opportunity to express his/her views. As originally envisaged in *Good doctors, safer patients* the doctor would be free to reject the recorded concern.

It may be helpful to use a slightly different term to describe this modified concept, eg "agreed statement of concern", especially as the original concept has been widely misunderstood.

4.13 **We recommend that this concept should be "modelled" as part of the GMC affiliate pilots**. Cases involving performance, conduct and health issues will be handled by the local healthcare organisation on advice from the GMC affiliate (where sought) using the options currently available. However, a suitable sample of these cases (augmented if necessary by other recent cases in the pilot areas) will be anonymised and reviewed to determine whether a recorded concern would have been a useful option. The results of the reviews will be collated and fed back to DH which will then consult further on whether to proceed further with the concept.

5 Information handling

5.1 This chapter summarises our recommendations on the information relating to performance, conduct and health which should be available to local healthcare organisations for clinical governance purposes; the safeguards over access to such information; the conditions under which information could be shared between healthcare and other organisations; and the IT implications. Details are in the report of our Information Management subgroup (see Annex B).

Information to be available locally

5.2 The Shipman Inquiry's 5th report recommended that healthcare organisations should maintain datafiles on all information likely to be relevant "for clinical governance purposes" and that the Department should issue guidance on the content of these datafiles. The subgroup's proposals are summarised in box 2 below[k]. Broadly speaking, this information can be regarded as related to the four functions in our generic model – "triggers" suggesting the possible existence of a performance or conduct issue, information from investigations, outcomes of the decision making process, and information relating to remediation and reskilling.

Box 2: recommended categories of information to be held locally

- information obtained or verified at the time of initial recruitment, including references and Criminal Records Bureau (CRB) checks (in future, Independent Safeguarding Authority (ISA) checks)
- clinical audits undertaken (broad nature, outcomes and learning)
- any clinical quality indicators which are agreed by the relevant professional body to give a fair indication of the performance of the individual or clinical team
- summary outputs of annual appraisals
- complaints and concerns from patients, carers, fellow professionals and trainees (nature of the complaint or concern, outcome, learning)
- adverse events where performance on the part of the professional was a contributory factor (nature, resulting harm, results of root cause analysis)
- clinical negligence claims (nature, current status, final outcome)

[k] For primary care contractors, the full dataset would be held by the contractor and a subset by the PCT.

Box 2 (continued)

- information on health issues which may affect professional performance
- learning needs and training undertaken, in particular any remedial training
- investigations or internal disciplinary processes (nature of allegation, status, outcomes)
- informal and formal warnings, including (for doctors) recorded concerns (subject to the outcome of the further discussions on this issue)
- local agreements on conditions on practice
- referrals to the national regulator (nature of allegation, status, outcomes including any conditions imposed by the regulator)

5.3 The subgroup considered at length the extent to which "soft" information should be recorded as part of this dataset. "Soft" information was defined for these purposes as "a statement of concern about an identifiable healthcare professional which has not been articulated as a formal complaint or as part of a formal process such as the summary record of an appraisal interview". The majority view of the subgroup was that healthcare organisations should always take seriously – and act on – any soft information which, if true, implied a threat to patient safety. "Acting on" the information should include a thorough investigation, a record on the database, and the opportunity for the healthcare professional involved to comment. Information which was not confirmed through investigation should be reviewed after 5 years (or if later the next revalidation cycle) with a presumption of removal from the database if no similar concerns had subsequently been raised.

5.4 The subgroup also considered the extent to which patients and the general public should have access to information about individual healthcare professionals, in particular information about allegations or investigations underway. This raises difficult issues about the balance of public interest, for instance ensuring that patients are kept informed about the skills and competence of the professionals treating them, while still allowing professionals undergoing remediation to undertake some clinical activity. The subgroup concluded that

i patients and the general public should not be told of the *details* of any current allegation/concern being investigated, although it may sometimes be necessary to confirm that an investigation is underway;

ii if it is judged necessary to place conditions on the healthcare professional during the investigation, patients and the public should be told about the nature of the conditions;

iii patients and the public should be told about the outcome of investigations where either (a) the investigation was already public knowledge, or (b) the outcome results in a finding that requires some

remedial action on the part of the individual professional. The consultation exercise carried out by NCAS in preparing the framework *Back on track*[46] found that patients were strongly supportive of remediation programmes and would be content to continue to be treated by a healthcare professional undergoing an agreed programme of remediation or reskilling.

Sharing information between organisations

5.5 One of the lessons learnt from, in particular, the Ayling Inquiry was the importance of sharing concerns between organisations when a professional is employed concurrently (or consecutively) by more than one organisation. The government has therefore taken powers, through the Health and Social Care Act 2008, to enable ministers (in England and Wales) through regulations to impose a "duty of cooperation" on healthcare and related organisations. This duty would require organisations

- to share information which could indicate that a healthcare worker may be a threat to the health and safety of patients,
- to respond to requests for information about healthcare workers, and
- to agree on any action needed to protect patients and the public.

5.6 Details of the duty (and of accompanying safeguards) will be set out in regulations and guidance, drawing on existing guidance such as that relating to patient-identifiable information[47], and the Department of Health will be consulting in due course on draft regulations and guidance. The information subgroup has however set out some broad principles which the Department proposes to adopt in drafting the regulations. The key principle is that a healthcare organisation, before sharing information or seeking information from another organisation, should apply the following tests:

- could the information already in the healthcare organisation's possession, once fully investigated, indicate that the healthcare worker is likely to pose a risk to patients or the general public;
- does the information come from a source which the organisation has reason to believe is reliable, and/or is supported by other information;
- is the other organisation likely to be in a position either (a) to take immediate action to protect patients from the risk of harm, (b) to provide information relevant to the investigation?

5.7 These tests are most likely to be fulfilled when a healthcare professional is working simultaneously for two or more healthcare organisations (for instance, a GP who is also employed by a commercial out of hours agency, or a nurse who also works for an agency). Slightly different considerations apply when a healthcare organisation becomes aware that one of its healthcare professionals is seeking to move to a new organisation. In these circumstances the subgroup suggests that

- the current organisation should share information on current concerns about performance and conduct only if there is judged to be an immediate threat to patient safety;

- other information held on file should be transferred to the new organisation once the appointment process has been completed.

5.8 The subgroup has also suggested some safeguards which should be applied whenever a healthcare organisation is considering sharing information about one of its healthcare professionals. The proposed safeguards are already good practice but would be reinforced through regulations and guidance.

IT implications

5.9 The Shipman Inquiry recommended that, for doctors, a national database should be set up containing all information relating to a doctor's fitness to practise – in effect, an enhanced version of the GMC's register with additional information from local systems. This would be particularly useful for doctors such as locum doctors who move frequently between healthcare organisations, and would ensure that (subject to suitable safeguards) relevant information would always be accessible to the current employer or contracting organisation.

5.10 The Information Management subgroup considered whether similar arrangements should apply in principle to all healthcare professionals, and compared the advantages and disadvantages of this "centralised" model against the alternatives of

- a fully localised model (information is held only at the local level and transfers between healthcare organisations when a healthcare professional moves) and

- a mixed model (detailed information is held locally but a core of information is held on a central database).

The subgroup also considered how far the Electronic Staff Record (ESR), if suitably enhanced, could meet the requirements.

5.11 The subgroup was attracted to the central solution but recognised that there were potential risks. It recommended that any IT solution should meet the following criteria:

i it must be capable of applying to professionals in primary care and (if possible) to professionals working in private or non-NHS practice;

ii it must be capable of synthesising information about all aspects of a professional's practice, including professionals with a "portfolio" of different clinical practice;

iii there must be safeguards on access, with "keys" which can be set either locally or nationally depending on the nature of the information;

iv there must be provision for continuous updating of the core clinical governance dataset, with clear responsibilities for data validation and data integrity;

v for locum professionals, the system must allow 24/7 access to the clinical governance dataset to staff in individual provider units to whom the locum applies to work.

5.12 We understand that DH is shortly to commission a scoping study to investigate the technical options for meeting the information needs both of clinical governance and of revalidation, including enhancements to the ESR. The information subgroup will reconvene to review its recommendations once this scoping study has reported.

6 Particular issues in primary care: the Performers List system

6.1 This chapter considers the application of the principles set out in the three previous chapters to healthcare professionals working in primary care. These healthcare professionals are, typically, not employed by an NHS healthcare organisation. Some are self-employed, or working in small professional partnerships; others are employed by commercial organisations such as the pharmacy chains. They provide professional services to NHS patients through contracts between the partnership or commercial organisation and the local primary care organisation (in England, the PCT).

6.2 Since 1999 GPs and general dental practitioners who wish to provide services to NHS patients have been required to apply to join a "Performers List" maintained by the PCT. The Performers List system enables the PCT to seek additional assurance that each individual healthcare professional providing services through its contracts, including locum practitioners, are fit for purpose; and to take action if it perceives a threat to patient safety. These arrangements have recently been extended to the General Optical Service.

6.3 It has often been asked whether these safeguards are necessary, in addition to the safeguards provided by the national regulator and by the contracts (which enable PCTs to take action if the services provided under contract are not of adequate quality). *Good doctors, safer patients*[14] proposed a review of the Performers List arrangements and terms of reference were drawn up in 2006. DH subsequently decided that this review should be carried out under the overall direction of the Tackling Concerns Locally working party, because of the strong overlap with the issues considered in the rest of the workstream.

6.4 Further details can be found in the report of our Performers List subgroup (see Annex B).

The case for retaining local lists

6.5 Chapter 3 has reviewed the elements of a wider clinical governance system needed to identify and deal with concerns over performance and conduct. Ideally, these elements should be found in all healthcare organisations, including primary care contractors; in practice, the position is very variable as the NAO found in their recent survey[48]. The Shipman Inquiry recommended that patients with complaints and concerns about GPs should have the right to take their concern direct to the PCT, and that PCTs should have oversight

of all concerns raising "clinical governance" issues in relation to GPs in their area.

6.6 In England, PCTs have (under the Health and Social Care Act 2008) a duty to seek continuous quality improvement in the services they commission on behalf of their patients. For contracts with secondary care providers, PCTs can discharge this duty by seeking assurance about the clinical governance systems in place, and by monitoring key measures of service quality and outcome. For primary care, developments such as the "federated" model recently proposed by the Royal College of General Practitioners (RCGP)[49] may provide a way forward in the longer term; in the meanwhile, PCTs may reasonably feel that they need a more direct means of assuring the quality of each of the practitioners providing care.

6.7 For these and related reasons, the Performers List subgroup concluded that PCTs should retain the responsibility for monitoring the conduct and performance of each primary care practitioner providing care to NHS patients, and for taking any action needed if there is a threat to patient safety. The Performers List system provides a means of discharging this responsibility.

Potential improvements

6.8 The subgroup however agreed that there was considerable potential for improving the operation of the Performers List system, in particular to improve the consistency of decisions taken by different PCTs. Some of the key recommendations are as follows:

i more detailed national guidance should be provided to promote greater consistency, fairness and transparency both over initial admissions to the list and over the processes leading to possible suspension or removal from the list, with greater clarity over the safeguards for the practitioner;

ii SHAs in England should consider the potential advantages of the model adopted in Wales and in some parts of England, with a central agency carrying out basic tasks of administration and checking of information. PCTs should also consider the advantages of pooling resources for investigations, while retaining the final responsibility for decisions on admissions, suspensions and removals;

iii once a practitioner is admitted to the Performers List of a PCT, the PCT should promote access to training[l], appraisal and where necessary remediation and reskilling;

iv in turn, the practitioner should inform the PCT of all relevant employment, provide up-to-date contact details, and (for locum practitioners) commit to providing a minimum number of sessions for the PCT's population;

[l] It is already a contractual requirement for PCTs to provide access to appraisal for all GPs.

v the process of moving to a new PCT should be made simpler by the use of standardised files of personnel and performance information, including a certificate of the checks carried out at initial admission;

vi the regulations should be amended to make explicit that practitioners have a duty to report clinical negligence claims relevant to performance. Clear guidance should be issued to cover the stage at which claims should be reported and the safeguards for practitioners;

vii PCTs should be able to suspend a practitioner with immediate effect (rather than after 24 hours as at present) subject to convening a panel within a reasonable period to confirm the suspension;

viii PCTs should keep suspensions under review and should have the option, at suspension hearings, of allowing the practitioner to return to practice subject to conditions;

ix the option of imposing conditions on practice should be extended to grounds of "unsuitability", not just inefficiency or fraud as at present. Conditions should be designed to be developmental, not punitive;

x PCTs should have the power to issue formal warnings to practitioners, for instance as a preliminary to imposing conditions. These warnings should be notified to the national regulator and should remain on the record indefinitely;

xi remediation and reskilling is an important option for practitioners in primary care (as in secondary care) and more work is needed on the options for finding suitable placements for independent practitioners undergoing remediation.

Use of the national registers to provide access to information

6.9 The subgroup was clear that responsibility for admissions to the Performers List, and for disciplinary options such as suspension, conditions and removals, should remain with PCTs. However, there is a strong argument for information on PCT decisions to be more widely accessible (subject to suitable safeguards), eg to other PCTs where a practitioner may seek to work. We understand that the national professional regulators would in principle be content for the national registers to be used for this purpose. The subgroup made the following recommendations in this area:

i DH should discuss with the national professional regulators the feasibility of holding information from local Performers Lists. Further discussion is needed on the precise information to be held (eg on reasons for refusing admission to the List) and on the safeguards on access;

ii in particular, information on all decisions taken by the PCT in its management of the list, including decisions to suspend practitioners,

imposing conditions or issue formal warnings, should be notified to the regulator in a standard format and available to bona fide enquirers;

iii DH should discuss with the regulators whether it would be feasible to develop a single national list of locum/sessional staff, identifying the PCT to whose Performers List they are currently admitted.

7 Death certification and reform to the coroners system

7.1 The Shipman Inquiry's 3rd report proposed radical change to the arrangements for certifying deaths and for referring cases to the coroner. These recommendations fall within the ambit of our working group to the extent that information on deaths, in particular unexpected deaths, is one of the potential "triggers" which could alert healthcare organisations to poor performance – or, in extreme cases like Shipman's, to the deliberate intention of harming patients. An analysis carried out by Professor Richard Baker on behalf of the Shipman Inquiry[50] showed not only that the overall mortality rate for Shipman's patients was high but that certain features of these deaths – for instance, the proportion taking place in patients' homes – were highly unusual.

7.2 The Shipman Inquiry's proposals for reform of the coroner service are being taken forward by the Ministry of Justice[51] and a bill is being introduced in the current session of Parliament.

7.3 Proposals for a new approach to death certification in England and Wales were outlined in *Learning from tragedy*, the summary of the government's response to the Shipman Inquiry, and set out in more detail in a consultation paper in July 2007[52]. In brief, the government's proposal is to introduce a single system of effective medical scrutiny applicable to all deaths (including deaths in hospital) that do not require a coroner's post mortem or inquest. The scrutiny will be undertaken by an independent "Medical Examiner" attached to the clinical governance team in the PCT. The Medical Examiner would be able to refer individual cases to the coroner, but in addition information from death certificates would be captured and analysed in order to identify any unusual clusters or trends. This information would be combined with other clinical governance information as described in previous chapters. An overview of the proposed process for death certification is given in figure 5.

7.4 The response to last summer's public consultation was generally very supportive. The vast majority of respondents supported the proposed introduction of a process of secondary certification of deaths that are not referred to the coroner, and for this scrutiny to be undertaken by appropriately qualified Medical Examiners. Work is now proceeding to prepare the legislative basis for the new arrangements, as part of the bill described in para 7.2.

7.5 The subgroup is directing and supporting work on a number of activities, including:

- design of the improved process of death certification and review / development of the associated forms and procedures;
- development of guidance for Medical Examiners on the proportionate and effective scrutiny of Medical Certificates of Cause of Death;
- development of guidance on the role of the Medical Examiner in providing medical advice to Coroners and in working with NHS colleagues to support clinical governance;
- development of guidance on the appointment, independence and accountability of the Medical Examiner and on the local support and infrastructure they require; and
- design and development of accredited materials required to train and assess new Medical Examiners and their support officer.

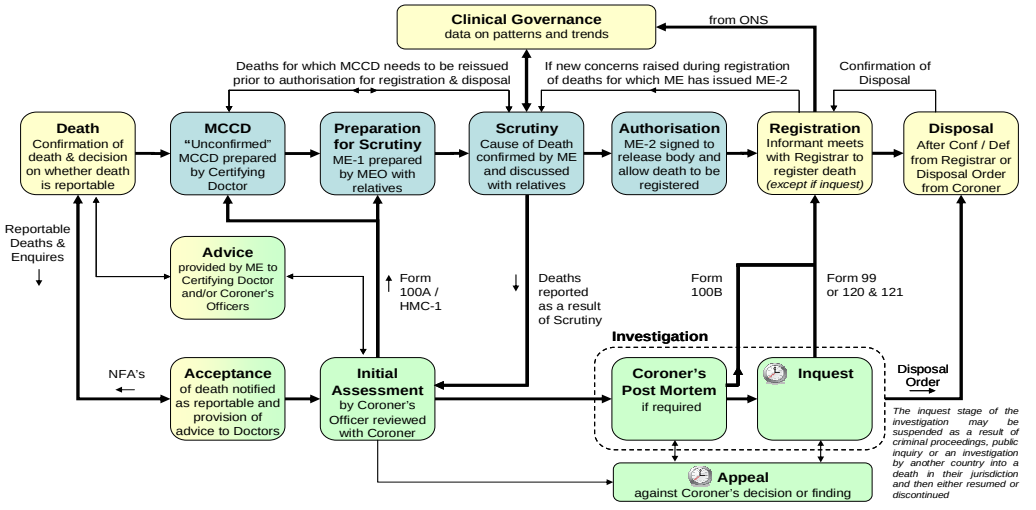
7.6 Some features of the proposed new process of death certification are being tested and evaluated in a pathfinder pilot established in March 2008 in Sheffield. Early findings from this hospital-based pilot have been positive, and the interim report concludes that

> "including a Medical Examiner in the process improves quality and accuracy of the MCCD [Medical Certificate of the Cause of Death] and provides a better service to bereaved families".

The interim report[53] from the Sheffield pilot is available online [www.doh.gov.uk/tcl], and further pilots are taking place in other locations during 2008/09, beginning in Gloucester in December 2008.

Figure 5

Overview of Proposed Process for Death Certification



Note: ME is an abbreviation for Medical Examiner. MEO is an abbreviation for Medical Examiner's Officer. ME-1 is the proposed name of the form used as the Application for Disposal and the ME-2 the Medical Examiner's Authorisation to Release Body and Register Death. The Certifying Doctor holds on to the original MCCD until a copy has been scrutinised by the ME and the cause of death has been confirmed and discussed with relatives, s/he then gives the original to the informant to deliver to the Registrar.

8 Taking forward the recommendations

8.1 This report has surveyed a broad range of developments in those aspects of clinical governance relevant to the performance, conduct and health of individual healthcare professionals. Some of these developments will require legislative change before they can be fully introduced; others are more a question of disseminating and promoting best practice; others will require further investment in IT systems. This chapter sets out our proposals for taking these developments forward, in particular where action falls to the Department of Health (DH) or other national organisations, and gives an outline timetable.

Legislation

8.2 Legislation will be required for the introduction of responsible officers, the duty of cooperation, the new arrangements for death certification, and some of the proposed changes in the Performers List arrangements; and possibly also for the introduction of GMC affiliates and recorded concerns.

Responsible officers

8.3 As noted above, the legislative basis for responsible officers and the duty of cooperation has already been laid by the Health and Social Care Act 2008. The DH has recently consulted on outline proposals for responsible officers[19]. Following this consultation, DH will now prepare and consult on draft regulations and guidance, with the intention of laying the regulations before Parliament later in 2009 and bringing them into force by the end of 2009. This timeline is related to the timeline for the introduction of medical revalidation as set out in the report of the medical revalidation working group[54].

Duty of cooperation

8.4 The basis on which DH proposes to implement the “duty of cooperation” is outlined in the report of our Information Management subgroup (see Annex B). DH will now prepare and consult on draft regulations and guidance and expects to bring these provisions into force by April 2010.

Death certification

8.5 Legislation on the proposed new system of death certification is now before Parliament[55]. DH will then prepare and consult on draft regulations and guidance and expects to bring these provisions into force by the end of 2011.

Performers List arrangements

8.6 Some of the changes to the Performers List arrangements proposed by the Performers List subgroup will require amendment to regulations. Details are given in the report listed in Annex B. DH envisages consulting on these changes in spring 2009 with the intention of bringing them into effect by spring 2010.

GMC affiliates

8.7 It is not clear at this stage whether any specific legislative basis will be needed for GMC affiliates, especially if (as in the original model) they will be appointed as GMC officers. The GMC already has broad powers to determine the internal structures needed to discharge the functions laid on it by Parliament. We will review the position in the light of the outcome of the pilot projects. If any change is needed, it can be achieved through secondary legislation.

Guidance products

8.8 Apart from the guidance needed to implement specific new duties such as responsible officers, our subgroups have identified the need to update, or in some cases fundamentally rewrite, a number of pieces of guidance. This includes guidance on

- supporting patients and fellow professionals in raising concerns over professional performance, conduct and health
- carrying out investigations
- the operation of the Performers List system and the decision-making process in primary care
- remediation, reskilling and rehabilitation.

We are aware of the need to avoid burdening NHS and other healthcare organisations with excessive volumes of guidance. We **recommend that the Department of Health should discuss with NHS Employers, the NHS Confederation, the British Association of Medical Managers, the National Clinical Assessment Service (NCAS), the professional regulators and other stakeholders the most useful way in which a coherent body of guidance in this area could be commissioned and disseminated**. We also **endorse** the recommendation of the Clinical Governance subgroup that DH should set up or commission a web portal on which all relevant guidance (any newly-commissioned guidance and existing guidance from bodies such as NCAS) can be readily found.

8.9 Ideally, any new guidance should be available by the autumn of 2009 to support the introduction of responsible officers and medical revalidation.

Workshops, networking and awareness raising

8.10 Many healthcare organisations are aware of the principles of good practice in this aspect of clinical governance, and are already putting them into effect; others are not, especially where there has been a loss of experience and expertise as a result of restructuring. A series of workshops run by NCAS in the winter of 2007-08 were extremely successful in raising awareness. We therefore warmly **endorse** the recommendation of the Clinical Governance subgroup that DH should commission a further series of workshops to promote good practice in the identification and handling of concerns over professional performance and conduct, and should work with SHA clinical quality leads and others to promote networking among relevant NHS staff. These workshops should take place during 2009 and should be linked to any specific training planned by DH for new responsible officers.

8.11 We also **endorse** the proposal of the Clinical Governance subgroup that SHAs should work with PCTs to ensure that they have appropriate capacity and capability in this area.

Support for patients, carers and members of staff

8.12 The Clinical Governance subgroup has identified a need for additional support to patients, carers or professionals wishing to raise a concern (see para 3.11). This would include confidential advice and clearer signposting for those considering raising a concern; support in articulating the concern, including advocacy support for vulnerable people; and support as the concern is progressed, for instance for people invited to give evidence at disciplinary hearings. The precise forms of advice and support are likely to be different for the different groups. We **recommend** that DH should take this forward with the national regulators and with NHS bodies, in consultation with patient and professional groups.

8.13 There is a specific issue relating to patients who have raised a concern and are not satisfied that the investigation proposed by the healthcare organisation is sufficiently independent to be credible (see para 3.16 principle 3). At present, it is not clear what redress a patient would have in these circumstances, other than an appeal to the Ombudsman or a judicial review. Patient representatives on our working group felt very strongly that a patient who had in good faith drawn attention to a potential risk to patient safety should not have to bear all the burden of ensuring that it is properly investigated. We **recommend** that, as part of the action under the previous paragraph, DH should review what redress or support for patients could be offered in these circumstances. In the particular case of concerns relating to doctors which have been referred to the GMC for consideration, the GMC affiliates (see para 4.2) might have a particular role in liaising with the patient raising the concern, explaining how the concern will be handled, and ensuring that they have access to appropriate support.

Information systems

8.14 Further work is needed to develop indicators of the clinical performance of individual clinicians (see para 3.6) and tools for bringing together and interrogating all available information about performance, conduct and health (para 3.13). DH expects to be able to take forward these recommendations in the first half of 2009.

8.15 The information subgroup has discussed (paras 5.9-5.12) the need for further development of IT systems to hold information relevant to professional performance and conduct and to ensure that this information is readily available (subject to appropriate safeguards) wherever a healthcare professional seeks to work in the NHS. One possible option would be a centralised database, possibly supplemented by more detailed information held at local level. The Performers List subgroup has made a related proposal in relation to decisions about admission to the Performers List (para 6.9), suggesting that a core dataset should be reported to the national regulator and held on the register.

8.16 As noted in chapter 5, DH is commissioning a scoping study to consider the options for providing IT support for handling concerns over professional performance and conduct, including enhanced use of the Electronic Staff Record (ESR). **We look to see early progress with this study**, so that a decision can be made without too much further delay on whether to pursue the option of a centralised database. If the decision is taken that this is not feasible or would pose too much risk, then we **endorse** the recommendation of the Performers List subgroup that DH should discuss with the national regulators the alternative model of holding a core of information on the national register for each profession.

The overall timetable

8.17 The overall timetable which we propose is summarised in the table below:

Work stream	Key tasks	Dates
Clinical Governance	Commissioning service specific guidance	Spring 2009
	Workshops for dissemination of proposals	Spring to autumn 2009
	Provision of additional support for (a) patients, (b) colleagues in raising concerns	Beginning spring 2009
	Further development of indicators of individual clinical performance	First half of 2009
Responsible Officers	Consultation period (ends) Consultation on draft regulations and guidance	Oct 2008 Quarter 1 2009

Work stream	Key tasks	Dates
	Final version of regulations and guidance Implementation	Quarter 2 2009 Quarter 4 2009
GMC affiliates	Pilots begin Mid term evaluation Final evaluation report and decision whether to roll out nationally	Sept/Oct 2008 April 2009 Nov 2009
Recorded concerns	Model potential use (as part of GMC affiliate pilots) Further discussion and decision	Spring/summer 2009 Autumn 2009
Managing Information	Regulation and guidance on the "Duty of Collaboration": – consultation on draft regulations – final versions – implementation	 Quarter 2 2009 Q3-Q4 2009 April 2010
	Scoping study on IT options for handling and sharing information	Q1-Q2 2009
	Assessment of systems for analysing trends and clusters	Q1-Q2 2009
	Review IT options	Quarter 2 2009
Performers List	Consult on draft changes to regulations Commission guidance Implement new regulations	Spring 2009 Spring 2009 Spring 2010
Death certification	Introduce Bill to Parliament Consult on regulations/guidance Implement	Dec 2008 2009/2010 end 2011

9 Recommendations and conclusions

9.1 The recommendations and conclusions of this working group are summarised below. In addition, **we endorse** the recommendations in the separate reports of the Clinical Governance, Information Management, and Performers List subgroups listed at Annex C.

Key messages for healthcare organisations

9.2 One of our key recommendations is that the Department of Health should commission a refresh of existing guidance on clinical governance, in particular those aspects which relate to identifying and handling concerns over the performance, conduct and health of healthcare professionals. We expect this guidance to be published and disseminated in the course of 2009. In the meanwhile, the key messages for healthcare organisations can be summarised as follows:

General principles

1. Boards of healthcare organisations should take responsibility for developing a culture of continuous quality improvement and for maintaining and resourcing effective clinical governance structures and processes, including those needed to identify and handle concerns over professional performance, conduct and health.

2. These processes should actively encourage the participation of patients and the general public.

3. Healthcare organisations should aim to identify concerns about health, conduct or professional performance at the earliest possible stage and to intervene quickly to safeguard patients and, where possible, help the professional to get their career back on track.

4. Healthcare organisations should be alert to the possibility that apparently poor individual performance could be the result of wider systems problems, and take action as required.

Processes for identifying problems with performance, conduct or health

5. People who wish to raise concerns – whether patients, carers or other members of staff including trainees – should be encouraged to do so and supported throughout the process; organisations should act swiftly on concerns and provide regular feedback to those raising the concern.

6. Healthcare organisations should establish systems for collating and analysing information from a variety of sources relating to potential early signs of poor performance, conduct and health and should regularly review this information in order to identify clusters and trends.

Processes for investigating and acting on concerns

7. Healthcare organisations should ensure that they have clear processes and the capacity and skills to investigate concerns over professional performance, conduct and health. This may involve pooling resources or bringing in external expertise, especially for smaller organisations.

8. Following an investigation, a clear decision must be taken by a transparent and fair process which protects patients while respecting the rights and needs of the healthcare professional. Healthcare organisations should ensure that they have the structures, processes and capacity to achieve this.

9. Healthcare organisations should develop a robust, quality assured and resourced strategy for remediation, reskilling and rehabilitation where this is appropriate. There should be access to remediation for all professions. Remediation plans should be tailored to the needs of the individual with integral arrangements for clinical placements, supervision, monitoring and return to normal clinical practice.

Supportive strategies

10. Subject to Parliament, healthcare organisations will be required to nominate or appoint “Responsible officers” with specific responsibilities for the local clinical governance arrangements relating to the performance, conduct and health of doctors. We expect to introduce this requirement in the final quarter of 2009. In the meanwhile, healthcare organisations should consider what further support is needed to medical directors or other senior officers who are already carrying similar responsibilities.

11. Subject to the result of pilots now underway, the GMC will establish a network of “GMC affiliates” to support responsible officers, to help them to improve the consistency of local decisions, and to improve the liaison between local and national processes.

12. Reforms to death certification will improve the quality and accuracy of certification, provide greater protection for the public, and improve public health surveillance.

Recommendations for the Department and other national organisations

Recommendation 1: we endorse the proposal in *Good doctors, safer patients* that the Department should work with the Royal Colleges and professional organisations to develop and disseminate clinical indicators relating to individual healthcare professionals for use both in secondary and primary care [para 3.6].

Recommendation 2: we recommend that the Department should take forward with the national regulators and with NHS bodies, and in consultation with patient and professional groups, the further steps needed to support patients and colleagues in raising concerns about a healthcare professional as identified by the Clinical Governance subgroup. This will include confidential advice and clearer signposting for those considering raising a concern; support in articulating the concern, including advocacy support for vulnerable people; and support as the concern is progressed, for instance for people invited to give evidence at disciplinary hearings [para 3.11, para 8.12]. In the particular case of concerns relating to doctors which have been referred to the GMC for consideration, the GMC affiliates might have a particular role in liaising with the patient or carer raising the concern and ensuring that they have access to appropriate support.

Recommendation 3: as part of the action arising out of the previous recommendation, the Department should consider what redress or support could be made available to patients who have raised a concern relating to patient safety and who are not satisfied that it is being investigated with an appropriate degree of independence.

Recommendation 4: we recommend that the Department should commission a review of analytical tools for collating and analysing information on the performance and conduct of healthcare professionals and should consider whether further steps are needed to stimulate the market [para 3.13].

Recommendation 5: We recommend that the modified version of the "Recorded Concern" described in para 4.12 should be modelled as part of the GMC affiliate pilots [para 4.13].

Recommendation 6: We recommend that the Department of Health should commission and disseminate an update of the guidance on identifying and handling concerns about healthcare professionals, consulting relevant stakeholders and authors of existing guidance. The aim should be to generate a coherent and accessible body of guidance in this area [para 8.8].

Recommendation 7: We recommend that DH should set up or commission a web portal on which all relevant guidance (any newly-commissioned guidance and existing guidance from bodies such as NCAS) can be readily found [para 8.8].

Recommendation 8: We recommend that DH should invite SHAs to work with PCTs to set in place adequate systems for the early identification and effective handling of issues of poor professional performance, conduct and health in primary care contractor organisations [para 8.11]

Recommendation 9: We recommend that DH should make an early decision on the options for developing a centralised database to hold information on concerns about performance, conduct and health, following the scoping study which the Department is commissioning. If the decision is taken that this is not feasible or would pose too much risk, then we recommend that the Department should discuss with the national regulators the alternative model of holding a core of information on the national register for each profession [para 8.16].

Glossary and abbreviations

Adverse incident	An event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage.
Boundary violation	Range of situations in which actions and feelings are allowed to enter into a professional relationship which is supposed to operate in the interests of the patient/ client, and which, by virtue of the patient/client's vulnerability, is inherently unequal.
Clinical accountability	The process by which individual healthcare professionals have the ability, responsibility and authority for actions in relation to the care they provide.
Clinical governance	A framework through which healthcare organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care.
Clinical leadership	The process by which individual healthcare professionals can drive service improvement and the effective management of teams to provide excellence in patient/client care.
Devolved administrations	The Governments of Scotland, Wales or Northern Ireland to which legislative powers have been given.
GMC affiliate	Regionally based officers or associates of the GMC who will support and advise responsible officers.
Multi source feedback	A tool to provide a sample of attitudes and opinions of colleagues (and patients) on clinical performance and professional behaviour.
Peer appraisal	A method by which the performance of an individual is measured by a colleague rather than by a line manager.
Performers List	Lists of primary care contractors (doctors, dentists and optometrists) held by the primary care organisation in order to assure the suitability and quality of those who undertake clinical services in their area.
Professional regulation	A system designed to ensure the patient can trust that the care they receive from individual health care professionals will meet certain minimum standards of safety and quality.

Recorded concern	A voluntary agreement between a doctor and a healthcare organisation recognising a source of concern, linked to a plan for remediation, reskilling or rehabilitation.
Rehabilitation	The supervised period and activities for restoring the practitioner to independent practice – by overcoming or accommodating physical or mental health problems.
Remediation	Supervising and monitoring the implementation of the individual practitioner's strategy to redress the aspects of underperformance identified and agreed by the detection, diagnosis and assessment processes.
Reskilling	Provision of training and education to address identified lack of knowledge, skills and application so that the practitioner can demonstrate their competence on those specific areas.
Responsible officer	Locally based senior doctors with specific responsibility for overseeing the performance and conduct of doctors working for healthcare organisations.
Revalidation	A periodic test that a healthcare professional has maintained the skills required for their current area of practice.
Serious untoward incident	Any incident of a serious nature that has or may have impacted on care provision including incidents affecting direct clinical care as well as organisational issues.
Significant event audit	A process in which individual episodes are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care, and to indicate changes that might lead to future improvements
Soft information	A statement of concern about an identifiable healthcare professional which has not been articulated as a formal complaint or as part of a formal process such as an appraisal interview.

Abbreviations

BMJ	British Medical Journal
CHRE	Council for Healthcare Regulatory Excellence
CRB	Criminal Records Bureau
DCA	Department for Constitutional Affairs
DH	Department of Health
ESR	Electronic Staff Record

FHSAA	Family Health Services Appeal Authority
GMC	General Medical Council
ISA	Independent Safeguarding Authority
MCCD	Medical Certificate of the Cause of Death
MoD	Ministry of Defence
NAO	National Audit Office
NCAS	National Clinical Assessment Service
NHS FT	National Health Service Foundation Trust
NPSA	National Patient Safety Agency
ONS	Office for National Statistics
PCT	Primary Care Trust
RCGP	Royal College of General Practitioners
RCN	Royal College of Nursing
RO	Responsible Officer
SHA	Strategic Health Authority
TCL	Tackling Concerns Locally

Annex A: Membership and remit of working group

Membership

Simpson, Jenny (Chair)	British Association of Medical Managers
Baker, Edward	Guys and St. Thomas' NHS FT
Barber, Janice	Hempsons Solicitors
Barnett, Steve	NHS Employers
Beddoe, Tony	Community Health Council Wales
Bourne, Vanessa	Patients Association
Bown, Stephanie	Medical Protection Society
Chambers, Ruth	Staffordshire University
Davies, Therese	Royal Free Hampstead NHS Trust
Dunlop, William	Joint Medical Consultative Committee
Giltrow, Jackie	Royal Pharmaceutical Society of Great Britain
Hamer, Ian	General Optical Council
Haslam, David	Healthcare Commission
Johnson, Bethan	Welsh Assembly Government
Jones, Emyr Wyn	Doncaster and Bassetlaw NHS FT
King, Janet	Frimley Park Hospital FT
Longdon, Trish	Health Service Ombudsman
Mishra, Padmini	Scottish Executive
Mortimer, Alexandra	Department of Health
Old, Peter	National Clinical Assessment Service
Philip, Paul	General Medical Council
Russell, Alan	British Medical Association
Russell, Douglas	Tower Hamlets PCT
Scott, David	British Medical Association
Walsh, Peter	Action Against Medical Accidents
Woods, Paddy	Department of Health, Social Services and Public Safety, Northern Ireland
Young, Lynne	Royal College of Nursing
Secretariat:	
Chukwunyere, Blessing	Department of Health
Dobson, Charles	Department of Health
Todd, Karen	Department of Health
Warner, Lucy	Department of Health

Remit

To consider the proposals for improving local systems for dealing with concerns about professional performance and behaviour in the two publications *Trust, Assurance and Safety* and *Safeguarding Patients.*

In particular:

- To review and update current guidance on clinical governance, in particular in relation to the identification and subsequent handling of possible poor professional performance
- To inform the review and development of systems for collecting and using information on health professionals relating to standards of clinical practice, complaints, investigations and disciplinary measures
- To inform the project to develop the “Responsible Officer” concept and establish more explicit competencies and accountability for the role of medical directors in England
- To inform the development and piloting of a UK network of GMC Affiliates, initially at a regional level in England and subsequently (subject to the outcome of the pilots) at a national level in Scotland, Wales and Northern Ireland
- To inform the review of the current Performers List arrangements in England to consider whether or not they are being used effectively
- To inform the development of improved arrangements for death certification
- To assess the impact of all recommendations on equality and diversity
- To ensure that recommendations are sensitive to the relevant differences in the healthcare systems of England, Scotland, Wales, and Northern Ireland.

The group will liaise as necessary with other working groups and establish its own sub-groups where it thinks fit to examine detailed matters.

Annex B: Key publications

Inquiry reports

Shipman Inquiry 5th report *Safeguarding patients: lessons from the past – proposals for the future* (TSO, December 2004)

Neale Inquiry *Independent investigation into how the NHS handled allegations about the performance and conduct of Richard Neale* (TSO, August 2004)

Ayling Inquiry *Independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling* (TSO, September 2004)

Kerr/Haslam Inquiry *Independent investigation into how the NHS handled allegations about the conduct of William Kerr and Michael Haslam*, Cm 6640 (TSO, July 2005)

Relevant government publications

Coroner reform: the Government's draft bill – improving death investigation in England and Wales (Department for Constitutional Affairs, June 2006)

Good doctors, Safer patients: proposals to strengthen the system to assure and improve the performance of doctors and improve the performance of doctors and to protect the safety of patients (DH, July 2006)

Learning from tragedy, keeping patients safe: *overview of the Government's action programme in response to the recommendations of the Shipman Inquiry* (DH, February 2007)

Safeguarding Patients: the Government's response to the recommendation of the Shipman Inquiry's fifth report and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries (DH, February 2007)

Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century (DH, February 2007)

Other publications from the Tackling Concerns Locally working group

Improving the Process of Death Certification (DH, July 2007)

Responsible officers and their duties relating to the medical profession (DH, July 2008)

Tackling concerns locally: report of the Clinical Governance subgroup (DH, December 2008)

Tackling concerns locally: report of the Information Management subgroup (DH, December 2008)

Tackling concerns locally: report of the Performers List subgroup (DH, December 2008)

Annex C: Recommendations of the subgroups

Clinical Governance subgroup

Recommendations for the NHS

1. a. boards of healthcare organisations should take responsibility for developing a culture of continuous quality improvement and for maintaining effective clinical governance structures and processes;
   b. clinical governance and quality assurance should be built into every contract and agreement for delivery of healthcare across all disciplines and health settings and resourced appropriately;
   c. the principles for best practice outlined in the chapters of this report should be adopted to ensure effective identification, clarification, investigation and decision making processes in relation to concerns over the performance, conduct and health of healthcare professionals.

2. a. the clinical governance lead in each healthcare organisation should ensure that robust communication systems are set up and maintained allowing information about all individual health professionals' performance to be collated and fed to those responsible for appraisal and performance management.
   b. a lead in each independent contractor work setting should have oversight of clinical governance processes including feeding information to the Primary Care Trust (PCT) communication system and collating concerns. This responsibility should be specified in the contract with the PCT.

3. All Trusts and PCTs should take steps to develop a strategy for implementing recommendation 8 of *Safety First*[56] [ie to ensure that patients and carers play an integral part in all initiatives to introduce a patient safety culture change within the NHS].

4. The clinical governance/patient safety lead in each Strategic Health Authority (SHA) should review the networking arrangements for clinical governance leads between and within organisations, ensuring that all staff know where they can go for help within the SHA if they meet a problem outside their current experience, and sharing expertise and resources.

5. All healthcare organisations that do not already take part in consortium or networking arrangements for the provision of clarification, investigation and assessment, and subsequent reskilling or remediation, should review their potential advantages**.**

Recommendations to the Department of Health and other national organisations

6. The Department should work with the National Clinical Assessment Service (NCAS), the Council for Healthcare Regulatory Excellence (CHRE) and other stakeholders to review and update the most useful parts of the existing guidance, ensure that they are applicable to all healthcare professionals, and reissue revised guidance through the web portal described below. As part of this review, some pilot work should be commissioned to explore how recommendation 8 of *Safety First* can best be implemented and guidance produced on best practice in this area.

7. The Department should arrange to create a single web portal so that all the relevant facilitatory material is conveniently available in one place. The NCAS 'toolkit' might form a suitable basis that could be generalised to all healthcare professionals.

8. The Department should work with NCAS and other potential providers (including Royal Colleges such as the Royal College of Nurses (RCN)) to set up a networking website dedicated to clinical governance staff involved in the detection and management of healthcare professional performance, conduct and health issues. Individual cases would not be discussed except in an anonymised format.

9. The Department should work with NCAS and SHAs in promoting a further series of regional or sub-regional workshops where learning about the need for expert investigation/ assessment of concerns is generalised to all healthcare professionals and healthcare settings. This would among other things promote the development of local networking and could be used to explore the potential of more formal consortium arrangements, as in our previous recommendations.

10. The Department should invite SHAs to work with PCTs to set in place adequate systems for the early detection, identification and effective handling of issues of poor professional performance and conduct and health, and to promote best practice.

11. The national professional regulators, working with the Revalidation Support Team, should set out a national quality assurance framework for appraisal of healthcare professionals, for regional and local implementation. The quality assurance framework would cover:
    - the quality of selection, training and development of appraisers
    - a generic job description / person specification for the appraiser/lead appraiser role
    - structures and processes in Trusts/ PCTs for the relicensing element of revalidation, specifying communication links between clinical governance and complaints/concerns, appraisal, CPD, local performance procedures etc
    - the quality control process for appraisers
    - support for appraisers.

Supporting patients and healthcare professionals wishing to raise a concern

12. We recommend that:

a. The Department should consider how a confidential telephone helpline could best be provided to give advice and guidance to patients wanting to raise a concern or make a complaint

b. dedicated support for vulnerable patients or patients with complex needs should be commissioned to assist them in understanding their options and navigating through local and national processes

c. all regulatory and professional bodies should provide support to those expressing concerns or making complaints - information on these processes and services should be provided at the outset

d. consideration is given to what additional support should be provided to health professionals and other staff to raise concerns about health professional colleagues and to raise awareness about the helpline service provided by Public Concern at Work

e. the Department should review what redress or support could be offered to patients who have raised a concern and are not satisfied that the investigation proposed by the healthcare organisation is sufficiently independent to be credible.

Information Management subgroup

1. DH should issue guidance to healthcare organisations on the information to be held on the performance, conduct and health of healthcare professionals. The main categories of information that should be held are:

– information obtained at the time of initial recruitment
– clinical audits undertaken
– relevant clinical quality indicators
– outcomes of annual appraisals
– complaints and concerns from patients, carers, fellow professionals and trainees
– adverse events resulting from the performance of the health professional
– clinical negligence claims
– information on health issues which are likely to affect performance
– training needs and training undertaken, in particular any remedial training
– investigations or internal disciplinary processes
– informal and formal warnings
– local agreements on conditions on practice
– referrals to the national regulator.

2. The level of detail needed will differ between secondary and primary care; PCTs will only need summary detail on some items, as set out in Table 1 of the report.

3. Different individuals within healthcare organisations should have different levels of access to information (Table 2 of the report). Patients and the general public should have

access to objective measures of the professional's conduct and performance, but not to details of complaints and investigations in train. The individual healthcare professional should have access to all information relating to himself/herself and should have the opportunity to correct errors of fact and/or to record comments.

4. Healthcare organisations, on receiving "soft" information about a healthcare professional, should consider whether it is information of a kind which, if true, would suggest a threat to patient safety. ("Soft information" for this purpose is defined as a statement of concern about an identifiable healthcare professional which has not been articulated as a formal complaint or as part of a formal process such as the summary record of an appraisal interview.) If the statement of concern passes this test,

i the allegation should be investigated as thoroughly as the nature of the allegation allows,

ii the healthcare professional should be informed and given the opportunity to respond and, if they wish, have their comments recorded,

iii the allegation should be recorded with a note of the source, the conclusions of the investigation and any subsequent action.

5. Where the allegation is confirmed and results in further action the information should be retained indefinitely; in other cases the information should be retained for a period of 5 years (or until completion of the next revalidation cycle if later) and then reviewed with a presumption of destruction unless there have been further concerns of a similar kind, or at the request of the health professional.

6. We endorse the recommendation of the Shipman Inquiry that primary care contractors should be required to notify the PCT of all clinical negligence claims. We define "claims" in this context as claims reaching the stage of letter before action and/or issue of proceedings, and all claims settled whether or not there is a formal admission of liability.

7. Healthcare organisations should consider carefully the balance of interest in deciding what information to give to patients and the general public about investigations and their outcomes. In general, we suggest that patients and the general public should not be told of the *details* of any current allegation or concern being investigated. They should be informed of any *conditions* placed on the healthcare professional during the investigation, and of the *outcome* of investigations where either (a) the investigation was already public knowledge or (b) the outcome is an adverse finding, including a finding leading to conditions on practice or the need for some remedial action on the part of the individual professional.

8. A person raising a concern about a healthcare professional should always be kept informed of the progress and outcome of the investigation.

9. A healthcare organisation investigating a complaint or concern about a healthcare organisation should consider whether any other organisation could be in a position either (a) to take immediate action to protect patients from the risk of harm, (b) to provide information relevant to the investigation.

10. In considering these questions, the organisation should consider whether (a) the information, once fully investigated, could indicate that the healthcare worker is likely to pose a risk to patients or the general public, and (b) whether the information comes from a source which the organisation has reason to believe is reliable, and/or is supported by other information.

11. If a healthcare professional is applying for a job with a new healthcare organisation, the current organisation should share information on current concerns about performance, conduct and health only if there is judged to be an immediate threat to patient safety. Other information held on file should be transferred to the new organisation once the appointment process has been completed.

12. Unless or until a centralised database with information relating to performance, conduct and health is established, local healthcare organisations should collate the necessary information for healthcare professionals who are employed by them or contracted to provide services to them. For locum practitioners in primary care, PCTs should maintain an oversight of such information for practitioners on their Performers List. For other locum practitioners, locum agencies with appropriate clinical governance arrangements should be invited to exercise this oversight and should take responsibility for transferring this information onto a new employer, PCT or locum agency when the practitioner transfers to new employment.

13. The organisations which will be required to share information about healthcare professionals, under Section 121 of the Health and Social Care Act 2008, should include those listed in para 3.16 of the report.

14. Additional safeguards in sharing information about concerns over the performance, conduct and health of healthcare workers should include

i promotion of culture of corporate responsibility for patient safety which seeks wherever possible to identify systems failures rather than scapegoating individuals;

ii a presumption that individuals who recognise deficiencies in their conduct or performance will be offered remediation and reskilling wherever this is likely to be cost-effective;

iii a presumption that individual healthcare workers will be told at the earliest possible stage of any allegations against them and given the opportunity to have their side of the story recorded;

iv considering whether the information to be shared needs to include person-identifiable information, and if so seeking patient consent;

v ensuring that shared information on unverified allegations and on investigations currently underway is kept in strict confidence in the organisations receiving the information as well as the originating organisation.

These safeguards should be reinforced in the guidance to accompany regulations laid under Section 121.

15. Our provisional view is that information on the performance, conduct and health of healthcare professionals should be stored on a central database and made available (subject to suitable safeguards) to relevant employers or contracting organisations, or (for locum practitioners) organisations using their services. Any technical solution should meet the following criteria:

i it must be capable of applying to professionals in primary care and in private or non-NHS practice;

ii it must be capable of synthesising information about all aspects of a professional's practice;

iii there must be safeguards on access, with "keys" which can be set either locally or nationally depending on the nature of the information;

iv there must be provision for continuous updating of the core dataset, with clear responsibilities for data validation and data integrity;

v for locum professionals the system must allow 24/7 access to staff in individual provider units to whom the locum applies to work.

We propose to review this recommendation, and the alternative options, once DH has completed a scoping study of the options for providing the information required for revalidation and for handling concerns the options for providing the information required for revalidation and for handling concerns.

16. DH should convene an appropriate stakeholder working group to review and if necessary refine all the recommendations in this report no later than 2 years after implementation.

Performers List subgroup

General

1. The Performers List system should be retained, but improvements made to improve its effectiveness. The following recommendations will make it more effective.

Admissions to the Performers List

Initial admission to the list

2. The tests for admission to a list should be complementary to the requirements of the national regulators. The standard information to be provided to PCTs and regulator should be coordinated so that, as far as possible, an applicant provides each piece of information once only. Similarly if PCTs require additional information in connection with a particular application they should liaise with the regulator to minimise the burden on the applicant.

3. Before admitting a practitioner to its Performers List a PCT should normally ensure that there is a satisfactory and complete record of appraisals. The Department should give guidance on how this principle should be applied where there has been a break in relevant experience (for instance, for a practitioner returning from work overseas or from a career break); one option would be to invite the Postgraduate Deanery to assess the relevance of the recent experience.

4. PCTs need to develop a greater consistency in decision making processes. This could be achieved through a combination of more detailed national guidance and improved networking and learning.

5. We consider that there are strong advantages to the model adopted in Wales and in some parts of England, in which a central agency carries out the routine administration and information checking and provides appropriate professional advice, whilst responsibility for decision making remains completely with the local Health Board/PCT. The Department should encourage all SHAs in England to see how far similar arrangements could be adopted.

6. A suite of standard forms should be introduced for the initial application process, including application forms and proformas for references, to facilitate the carrying out and recording the results of reference checks on applications and to record reasons for refusal or conditional entry. Some elements of the forms would be specific to each profession and other elements generic. Forms should be available in electronic format eg as Word documents. The forms developed by the Welsh Common Services agency (see examples at Annex C) may provide a useful model.

7. The Department should discuss with the Criminal Records Bureau (CRB) how (a) CRB checks could be expedited and (b) greater consistency achieved over what information should be included.

8. There should be a formal induction process to help new performers settle into local health economies. This would be tailored to the needs of the individual but would typically cover both local and (for those who had not previously worked in primary care in the UK) national elements.

9. Once a Performer has been admitted to the Performer's List, the PCT has an obligation to provide access to training and appraisal support. In turn, the Performer has an obligation to inform the PCT of all relevant employment and to provide up-to-date contact details, in particular an effective address, at all times.

Recording and sharing information

10. The Department should explore with the regulatory bodies the feasibility of using their professional registers as repositories for information from local Performers Lists. The objective would be to collate individual lists into a virtual, web based, national list. PCTs should however, retain disciplinary powers and make the final decision on acceptance and removal from the list, and the imposition of conditions. PCTs would also need to be responsible for updating the information.

11. Core personal and career information should be held on the central register of the regulatory body and be made available to potential employers and, to a lesser degree, the public. Further discussion is needed on what categories of information would be freely available and on the safeguards on access to more sensitive information.

Moving to a new PCT

12. Each new PCT needs to assure itself that the practitioner meets the criteria for admission to the list, but there is scope for streamlining processes by use of standardised information and by improving consistency in the approach of different PCTs to the admission process.

13. PCTs should issue a certificate in a standardised format confirming the information checks that they have carried out as part of the admission to a Performers List. As and when revalidation is introduced, this could be developed into a "certificate of good standing" stating that there are no outstanding concerns over the practitioner's performance. Practitioners could apply for an up to date certificate from their current PCT when they move to a new employer or PCT, with a view to cutting down the information to be verified on each occasion.

14. PCTs should develop a standardised file for each practitioner that would hold both personnel and performance information. A copy of the file should be sent to the new PCT on transfer.

15. To reduce time lags on transfers, and as a general principle, PCTs should move towards storing and providing information in secure electronic files, integrated with the electronic staff record.

16. There are issues for post-registration trainees taking up positions as independent practitioners, especially those moving around the UK. The Department should explore whether some form of "holding arrangement", with the health professional admitted to a Performers List on an interim basis pending further checks, might be helpful.

17. Further guidance is needed on the frequency and transferability of any CRB checks required for Performers List purposes.

Maintaining and updating the list

Revalidation

18. The Department should consider issuing guidance to PCTs on how to assess the continuing suitability and efficiency of practitioners who only maintain occasional practice, especially those who have retired only on grounds of ill health. In doing so the Department should seek advice from the working groups on medical and non-medical revalidation.

Identifying concerns: responsibility to report clinical negligence claims

19. The wording of regulation 9(1)(h) is ambiguous and should be amended to make explicit that practitioners on the Performers List have a duty to report clinical negligence claims, at the stage of proceedings issued or claim settled (whichever is the earlier), as for other issues which are potentially relevant to their suitability as a performer. Further work is needed to determine the precise circumstances in which this would apply. Clear guidance would need to be issued to cover

- the sort of claims that should be reported
- the tests which PCTs should apply to deciding whether the information should be retained
- the nature of the information to be held on file
- the handling of borderline cases
- the need for PCT staff to seek professional advice in assessing the significance of individual claims, especially for professions where the PCT had no in-house expertise
- the right of the practitioner to comment and for the comment to be held on file together with details of the claim.

It should be made clear that the information is being collected only to help identify patterns suggesting poor performance, and that the number of clinical negligence claims is not in itself a reliable indicator.

Investigations

20. The Department should set out more clearly how the current guidance documents interlink, including the guidance issued by NCAS, the National Patient Safety Agency's "risk management" tool and relevant aspects of the DH guidance on disciplinary processes for employed doctors *Maintaining High Professional Standards*; and should reissue or update the relevant guidance documents. A national workshop might be a good way of launching a new initiative to improve standards of investigations and to determine what new guidance was needed. It would be helpful if any new guidance could:

- emphasise the need for a clear separation between staff carrying out investigations and the subsequent decision-making process
- clarify the role of PCTs in practice development and practice support, across all the contracting professions
- clarify the interface between *Maintaining High Professional Standards* and the Performers List, in particular in relation to professionals who are directly employed by PCTs
- concentrate more on dealing with the practical aspects of disciplinary procedures, with an emphasis the practicalities and processes rather than the theory
- deal with interface between Performers List management and contract management
- help PCTs manage the sessional performers on their list.

21. Investigating officers should have appropriate access to all relevant documents and records, including patient records, to allow them to conduct an investigation based on all the facts. There should be robust mechanisms to protect patient confidentiality. The Department should consider further what barriers there may be to achieving this and clarify in guidance how, and when, patient consent should be obtained to allow access to their records.

Suspension

22. PCTs should report all suspensions to the national regulator and subsequent handling should in normal circumstances reflect decisions taken by the regulator.

23. There should be a duty on the PCT to consider the impact on the performer of suspension and provide support e.g. a mentor.

24. The current requirement for a twenty-four hour period of notice of suspension, in circumstances requiring immediate action to protect patients and the public, is illogical. The regulations should be amended to enable PCTs to suspend immediately if circumstances warrant it, subject convening a panel within a reasonable period to confirm the suspension. The practitioner should have the right to attend the panel.

25. The practitioner should have a right of appeal to the Secretary of State, in practice a body directed to exercise the function, against decisions to suspend or to confirm immediate suspensions. The appeal would be on paper and there would be no further hearing.

26. PCTs should have the option, at suspension hearings, of imposing or confirming suspension or of allowing the practitioner to resume practice subject to interim conditions pending completion of the investigation and any subsequent full hearing.

27. . When a practitioner is suspended from clinical work but wishes to continue to undertake non-clinical activities related to healthcare, the PCT should draw up an agreement with the practitioner and/or his or her primary care provider (eg GP practice) clarifying the activities which can be undertaken.

28. PCTs should be encouraged to keep suspensions under review and to conduct a formal review at any stage, if appropriate before the 3-month point.

Removal from the list

29. The Department should seek advice from professional bodies, the Colleges and national regulators on what standards of performance health professionals should maintain in order to be suitable to remain on a Performers List.

30. If a PCT decides to remove a performer from its list it should, as a matter of routine, ask the FHS Appeals Authority to consider a national removal. The FHS Appeals Authority (FHSAA) should inform the PCT of its decision and explain its reasons in those circumstances where a national removal is not considered appropriate.

31. The requirement that a PCT must remove a performer from its list if he or she is sentenced to a term of imprisonment of over six months is inflexible and should be reviewed, in discussion with the national regulators.

Conditions

32. PCTs should be able to impose conditions on the grounds of unsuitability as well as inefficiency or fraud.

33. The distinction between conditional inclusion and contingent removal should be ended.

34. DH should discuss with the regulatory bodies the best way of disclosing to PCTs, and other appropriate organisations, information relating to conditions imposed on health professionals. This must be balanced against the reasonable rights of health professionals to privacy, especially in health cases.

35. PCTs should give further consideration to designing conditions which can be effectively monitored in all situations.

36. Conditions imposed by PCTs should be designed in the first instance to protect patients and, if appropriate, to provide practitioners with the opportunity to remedy weaknesses.

37. Conditions should be clearly worded so that both the PCT and the practitioner know what is expected.

38. Information on conditions should be recorded on the professional register and available to bona fide inquirers. The PCT should decide on a case by case basis how far they should take more proactive steps to inform patients and the general public of any conditions imposed on a professional's practice. The normal presumption should be that patients have a right to know about any conditions on practice which could potentially affect their treatment.

Warnings

39. In general, PCTs should have the power to issue formal warnings to practitioners, for instance as a preliminary to imposing conditions. The PCT should review the position as needed, and at least after an interval specified in the warning itself. The Department should develop guidance and examples of good practice on the use of such warnings, the circumstances in which they might be used and how and when they should be reviewed.

40. For doctors, more consideration is needed as to whether PCTs should be able to issue formal warnings in their own right (under the Performers List arrangements) in addition to proposing "recorded concerns" to be agreed with the doctor.

41. The Department should develop an appeal mechanism, at least for the more serious warnings.

42. Formal warnings should be notified to the national regulator and to the other bodies listed in Regulation 16. They should be held on file indefinitely, as a safeguard in case the behaviour giving rise to the warning was subsequently repeated.

Financial penalties

43. The working group did not consider that the power to levy financial penalties would add effectively to the remedies available to PCTs to protect patients in cases of poor performance. Financial penalties (withholdings) are of course a legitimate remedy for any failure by contractors to meet contractual requirements. It would then be up to the contractor to take action with the relevant employee.

Voluntary retirement

44. Retirement, with voluntary erasure from the national register, should only be allowed with robust regulatory safeguards to ensure that inefficient or unsuitable practitioners could not use it to avoid disciplinary action or to attempt subsequent re-entry to the register. PCTs following this course should lodge full papers with the national regulator making clear the nature of the unresolved concern. This approach should never be used in cases where there is *prima facie* evidence of actual harm to patients.

Panel hearings – potential removal cases

45. Guidance should stress the need for a reasonable degree of separation between the staff involved in the investigation of the facts and the panel members. It is for instance good practice to have a non-executive board member on the panel. However, it is an important principle that the panel is empowered to take decisions on behalf of the PCT; the PCT's board should therefore formally delegate responsibility to the panel.

46. Where there is a dispute over facts, the Performer should have the right to an oral hearing in which he/she can be represented and can cross-examine the presenting officer (but, at the PCT's discretion, not other witnesses). If the facts are not in dispute, the practitioner should have the right to make representations but not to cross-examine. DH should issue guidance on the procedures for such hearings.

47. Panel hearings should be recorded and transcribed in case there are disputes over the facts in later proceedings.

48. As at present, there would be a right of appeal to the FHSAA that would take into account the issues discussed at the panel hearing.

49. Panel members and chairs should have training to give them the skills needed to conduct hearings effectively and fairly. The Department should explore with regulatory bodies, medical defense organisations and the FHSAA how their experience in relation to performance issues could be shared with PCT staff.

Recording the results of PCT decisions

50. All decisions taken by the PCT in its management of the Performers List, including decisions to suspend practitioners, impose conditions, or issue formal warnings, should be notified to the national regulator and the NHSLA in a standardised format. Further discussion is needed on what information should be publicly available and what should be disclosed only in response to bona fide inquiries, e.g. from other healthcare organisations.

Sessional and locum staff

51. PCTs should consider actively supporting sessional and locum practitioners on their list in exchange for a commitment to a reasonable volume of work within the PCT and to keeping the PCT informed of other temporary employment. This should include

- access to appraisal, continuous professional development, and where necessary remediation
- supporting their information needs
- ensuring access to NHS IT systems.

52. Locum agencies should provide CPD and performance management for staff they provide to healthcare organisations, or ensure that staff have access to appraisal and CPD through other means. PCTs should regularly check that all the locum and sessional staff on their list have appropriate access to appraisal and CPD.

53. The Department should clarify where the responsibility lies for investigating complaints or incidents when a sessional or locum practitioner is temporarily employed in a PCT other than the host PCT.

54. The Department should have discussions with the regulators to see whether it would be practical to have a single national list of sessional staff, e.g. the GMC for doctors.

Cross border issues

55. If a professional performs largely in one country, he/she should undergo a single appraisal in that country, with an appropriate contribution from secondary employers in other countries. The MoD system might be a good model for how this could work.

56. The Department should consider whether there should be a period of grace, perhaps three months, to allow appropriate checks to be completed when a professional who is on the Performers List of one country moves permanently to another.

Capacity building in PCTs

57. PCTs need to retain individual responsibility for identifying possible cases of poor performance ("triggers") and for final decisions. There are however advantages in pooling resources between PCTs to build a specialised team with skills in investigation, and this model should be commended to the NHS. SHAs, for example, could provide a source of local advice to help PCTs.

58. It would be helpful for the Department to issue more detailed guidance, including model timelines for resolving cases and an indication of the resources required.

59. The Department should commission work on competencies related to the PCT's Performers List management responsibilities and promote the development of one-off and continuing training.

60. SHAs' performance management of PCTs should take account of the quality of their management of the Performers Lists.

Remediation, reskilling and rehabilitation

61. The Department should commission further research on the indicators for success in remediation.

62. The Department should commission further work on the typical costs of remediation and on funding options, including shared funding between the PCT and the practitioner, the possible role of the medical defence or other insurance organisations, and the possible links to the current ill health retirement scheme. Where there seems little likelihood of successful remediation, practitioners should be prepared to meet the full costs of any further remediation.

63. More work is needed on the options for finding suitable placements for independent practitioners undergoing remediation and how local Deaneries and equivalent organisations could help in this process.

64. The Department should review the provision for update training for practitioners returning to practice after a career break or work outside the UK.

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