

## Responsible Officer Guidance . Closing the Gap in Medical Regulation

This document is issued by the Department of Health to offer guidance on the new role of the Responsible Officer, to be introduced by (October 2009) as part of the implementation of the government's white paper, *Trust Assurance and Safety*.

The role of managers, both medical and non-medical and systems in healthcare is to provide the best possible context and environment in which clinical professionals of all disciplines can deliver excellent care to patients. The care delivered by doctors licensed by the General Medical Council is almost always of acceptable, and very often high. quality.

The systems by which concerns and early signs of poor practice are identified and their fit with national systems of registration have been reviewed following series of failings and this resulted in the proposals for a system of revalidation for every doctor. Revalidation is to be introduced in October 2009.

The Responsible Officer plays a crucial role in the process of medical revalidation. Introducing the new processes of revalidation and putting Responsible Officers in place has major implications for every doctor and for every healthcare organisation. The new regulations mean that:

- All licensed doctors will be required to relate to a Responsible Officer who, through the organisation's Board and provided that there is no cause for concern about the doctor's fitness to practice, will recommend the doctor to the General Medical Council (GMC) for revalidation.
- All Responsible Officers will be required to make a judgement, as to whether individual doctors should be recommended as fit to practice. This judgement must be founded on the basis of robust, accurate and relevant information about all aspects of the doctor's practice, which has itself been scrutinised through the clinical arm of corporate governance and appraisal processes. It must be sufficient to evidence that their performance meets clinical standards set by the appropriate medical Royal College. If there are concerns about any doctor's fitness to practice, the Responsible Officer will either recommend local remediation or refer the doctor to the GMC.
- All designated healthcare organisations will be required to appoint, resource and support a Responsible Officer, who will be a senior doctor, sitting on the Trust Board.

reference to all healthcare and related organisations employing or contracting with doctors, to all licensed doctors and to all doctors taking on the role of Responsible Officer.

The public, the profession and the NHS have a right to be assured that licensed doctors are fit for purpose. Whilst it is recognised that clinical care in the UK is among the best in the world, the new regulations are designed to help doctors and the organisations in which they work improve the quality of care still further. By providing a framework within which clinical practice and behaviours that are beginning to deteriorate or give cause for concern are identified far earlier than has been the case in the past, the new systems will enable remedial action to be put in place at a stage when it is more likely to be effective.

The role and responsibilities of the Responsible Officer are described in this document as is the requirement for all licensed doctors to relate to a Responsible Officer and the duty of designated healthcare organisations to appoint to and resource the role. The guidance has been produced following the conclusions of a work-stream set up by the Department of Health, as part of the implementation of *Trust, Assurance and Safety*, the results of a consultation on the draft regulations underpinning the role and from contributions of a wide range of clinicians, managers and patient groups.

The guidance has been produced as a collaboration between the Department of Health, the British Association of Medical Managers (BAMM), the Medical Managers Committee of the British Medical Association (BMA) and NHS Employers. The collaboration has sought input at every stage from the Academy of Medical Royal Colleges, the General Medical Council, the British Medical Association and NHS managers.

. This document is designed to provide guidance to 3 key audiences:

- All healthcare organisations in the UK.
- All doctors taking on roles as Responsible Officers
- All doctors licensed with the GMC to practice medicine

Throughout the guidance, reference is made to the principles underpinning a doctor's ethical and professional performance as laid out by the General Medical Council in *Good Medical Practice* (2006). For ease of reference and to set the context these are quoted below.

The duties of a doctor registered with the General Medical Council Patients must be able to trust doctors with their lives and health. To justify that trust you must show respect for human life and you must:

- Make the care of your patient your first concern
- Protect and promote the health of patients and the public

d of practice and care  
knowledge and skills up to date  
within the limits of your competence

- Work with colleagues in the ways that best serve patients' interests
- Treat patients as individuals and respect their dignity
- Treat patients politely and considerately
- Respect patients' right to confidentiality
- Work in partnership with patients
- Listen to patients and respond to their concerns and preferences
- Give patients the information they want or need in a way they can understand
- Respect patients' right to reach decisions with you about their treatment and care
- Support patients in caring for themselves to improve and maintain their health
- Be honest and open and act with integrity
- Act without delay if you have good reason to believe that you or a colleague may be putting patients at risk
- Never discriminate unfairly against patients or colleagues
- Never abuse your patients' trust in you or the public's trust in the profession.

You are personally accountable for your professional practice and must always be prepared to justify your decisions and actions.+

There are differences in the ways in which the reform will be implemented in the 4 countries of the UK. In England, Responsible Officers will undertake a range of duties embracing wider responsibilities of clinical governance. Wales and Northern Ireland will make their own regulations, whilst Scotland is considering what, if any, improvements are needed there and will take forward its own associated guidance and/or legislation.

## 1 Background

1.1 Major changes to the ways in which doctors are regulated was first described in *Good Doctors, Safer Patients*, a report to advise Ministers in July 2006. The reforms were set out in the government's White Paper, *Trust, Assurance and Safety* in 2007.

The reforms were designed to

- support good doctors in improving their practice still further
- identify those doctors giving rise to concern
- encourage early, effective interventions.

1.2 Two key concepts underpin the reforms:

and tighter liaison between the local  
and the GMC, specifically in relation to  
disciplinary and wider clinical governance

systems

- a robust, watertight implementation of revalidation for all doctors by the GMC

The concept of the Responsible Officer, a senior doctor within every managed healthcare organisation, with specific and personal responsibility for the conduct and performance of doctors working in or for the organisation, is a key element in the programme of reform to professional regulation. Legislation in support of this has now been enacted in the Health and Social Care Act 2008.

1.3 Tackling Concerns Locally, a work-stream forming part of the wider implementation of *Trust, Assurance and Safety*, has focused its attention specifically on the first of the two concepts outlined above with recommendations for:

- strengthening local processes to identify and deal with concerns about the performance, conduct of healthcare professionals at an early stage and
- improving coordination between local healthcare organisations and the national professional regulators.

The working group on the role of the Responsible Officer was run in parallel with five other working groups formed the Tackling Concerns Locally work-stream and their work contributed to the thinking behind this guidance. Their remits were:

- Clinical Governance
- Management of information underpinning performance and clinical governance
- General Medical Council (GMC) Affiliates
- Performance lists in primary care
- Death certification

1.4 It is the government's intention that every licensed doctor, regardless of where and how they work, should relate to a Responsible Officer. This includes doctors with portfolio careers, locum doctors, those working in the armed forces and those working in isolation, for example on cruise ships, private nursing homes, or in private general practice and clinics

1.5 The legislation (section 45C(1)) requires every designated organisation to appoint a Responsible Officer. The requirements concerning the role and its functions are set out in the regulations. All doctors will have the right of access to a Responsible officer, so that they may be revalidated. It will be an



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the requirements of legislation and to refuse to

## Section 1 . Guidance for all doctors

### 2 The Doctor's responsibility to a Responsible Officer

2.1 Following the introduction of the new regulations, every licensed doctor will be required by law to relate to a single Responsible Officer of an appropriate, managed healthcare organisation. Every doctor will be required to undergo a process of enhanced appraisal and be able to demonstrate, by production of a portfolio of evidence, that their practice meets:

- standards set by the GMC as laid out in *Good Medical Practice Framework for Appraisal and Revalidation*
- clinical standards as set out by the appropriate Medical Royal College, or Faculty
- expectations of their managed healthcare organisation in safely undertaking the role for which they are employed or contracted.

2.2 Each healthcare organisation will be required to demonstrate that they have in place robust systems for the clinical arm of corporate governance that are fit for purpose and are quality assured. The data fed in to these systems of enhanced appraisal, multi-source feedback and clinical governance, information relating to the doctor's clinical performance, must be assured appropriately validated and reviewed where appropriate and of the highest quality. The information from these systems, which will inform the Responsible Officer's decision-making must be accurate, timely, relevant to the full span of the individual's clinical practice and meet the requirements of the GMC and Royal Colleges and Faculties.

2.3 Every doctor will be required to inform the Responsible Officer of all relevant clinical practice they undertake, both within and without their managed healthcare organisation. All relevant practice means all work undertaken by the individual in his or her role as a doctor, both clinical practice and non-clinical roles such as public health, administration, management and leadership.

## ess and the Responsible Officer

validation is to assure patients, employers, commissioners and colleagues that licensed doctors are up to date and fit to practise. *Trust, Assurance and Safety* describes an approach to medical revalidation involving two key strands:

- Relicensing . to confirm that licensed doctors practise in accordance with the GMC's generic standards in 'Good Medical Practice'
- Recertification . to confirm that doctors on the specialist and GP registers continue to meet the standards appropriate for their specialty

3.2 The core mechanism underpinning these two strands of revalidation which will be managed together by a single set of processes is enhanced appraisal, which has been designed to elicit the necessary information about a doctor's practice, see diagram 1 . information flows in revalidation

[Insert diagram here](#)

3.3 Individual doctors will be responsible for maintaining a portfolio of evidence and supporting information demonstrating maintenance of their specialist skills. Every doctor seeking revalidation will need to ensure that a package of information including a record of enhanced appraisal, is collated for the Responsible Officer to review.

3.4 The enhanced appraisal process will include information from multi-source feedback, CPD portfolios and verified clinical performance information, presented along with any outcomes of investigation of complaints, concerns, patient safety incidents and other available indicators that can be reliably related to the performance of the individual doctor. Evidence confirming that the doctor's performance meets the clinical standards as set out by their respective Royal College or Faculty will be included in their appraisal

3.5 The Responsible Officer will be ultimately accountable for ensuring that the systems of enhanced appraisal, clinical governance and other local relevant evidence are in place and are effective. He or she is also responsible for ensuring that systems are in place to record and collate all the necessary information and for maintaining a record of any practice undertaken by the doctor outside of the organisation.

3.6 The Responsible Officer, having assessed all the information and if appropriate consulted the relevant medical Royal College or Faculty, will take make a recommendation to the Board on whether or not an individual doctor should be revalidated by the GMC. In the occasional circumstance of there being a concern about a doctor, the Responsible Officer must decide whether local processes of remediation are appropriate or whether a referral to the GMC is necessary. It is the Board's responsibility to make the revalidation recommendation to the GMC. The Responsible Officer will be indemnified as a member of the Trust Board for the corporate decisions made about individual doctors.

Where there is cause for concern, the role of the GMC in drawing the case to the attention of the GMC and the GMC's jurisdiction if appropriate. Final decisions, which may affect the ability of a doctor to continue in practice will remain, as at present, the sole responsibility of the GMC.

3.8 All doctors will be required to inform their Responsible Officers of all relevant, clinical and non - clinical, medical practice. Failure to do so may be a fitness to practice issue.

#### **4 Arrangements for relating to a Responsible Officer**

4.1 A doctor should normally relate to the Responsible Officer of the healthcare organisation in which he or she spends the majority of their working week. The principle is that where doctors work in a managed organisation, the organisation will have in place the appropriate systems of enhanced appraisal and clinical governance to support revalidation. Doctors will relate to one Responsible officer only. Each organisation will have only one Responsible Officer.

Providers of healthcare will be required to appoint Responsible Officers. These either

- Provide or arrange for the provision of healthcare by doctors, or
- Employ or contract with doctors

These include:

- NHS hospitals and mental health trusts
- Foundation trusts
- Independent sector hospitals,
- Primary care provider organisations
- Health Boards in Scotland
- Local Health Boards in Wales.
- Health and Social Services Boards in Northern Ireland

Organisations arranging the provision of healthcare, employing or contracting with doctors include:

- PCTs
- Government departments
- Universities

Doctors may also work in other categories of organisations where the requirement for a Responsible Officer is conditional on the organisation's

appropriate clinical governance systems. These

- Locum agencies
- Private sector companies employing doctors, in specialist areas, for example IT, pharmaceuticals
- Private companies who employ doctors to deliver clinical services in non-NHS environments, for example on cruise ships, in aesthetic non-invasive surgery clinics

#### 4.2 Arrangements for doctors in NHS Trusts, Foundation Trusts or independent hospitals

Doctors in acute trusts will relate to the Responsible Officer of that trust. There will be one Responsible Officer per trust and the individual will sit on the trust board. In exceptional circumstances a doctor may make a case for relating to the Responsible Officer of another trust. Such circumstances may include a conflict of interest, family or other personal relationship.

#### 4.2 General practitioners

General practitioners will relate to the responsible officer of the PCT holding the performer's list on which the individual is named. Again, in exceptional circumstances as above, the doctor may make a case to relate to the Responsible Officer of another PCT. Many PCTs are splitting their provider and commissioning functions. In this circumstance the principle remains that doctors relate to the Responsible Officer of the managed organisation in which they work for the majority of their time.

#### 4.3 Doctors working in management roles

All doctors who wish to revalidate with the GMC and maintain their license to practice must relate to a Responsible Officer. This should be the Responsible Officer of their organisation, or in the case of Responsible Officers themselves, the Responsible Officer at the appropriate Strategic Health Authority (SHA), in England. The SHA Responsible Officer will relate to the Chief Medical Officer. Doctors must revalidate in the areas in which they work, rather than in the specialty they originally worked in or practice for a minority of the working week.

#### 4.4 Doctors in training

All doctors in training must relate to the Responsible Officer of the organisation in which they work. All discussions concerning their performance must involve the trainee's Post-graduate Dean.

#### 4.5 Locum doctors

Larger locum agencies, if they are able to demonstrate sufficiently robust systems of clinical governance, may be designated as requiring a Responsible Officer. Doctors working for these agencies will report to that

finding employment through non-designated  
Responsible Officer at another locum agency or at a

#### 4.6 Doctors with portfolio careers

Some doctors hold a number of different roles concurrently. If one role takes up a majority of the doctor's working week then he or she should relate to the Responsible Officer associated with that. If there is no obvious relationship, then the doctor should relate to the responsible officer at the local PCT

#### 4.7 UK doctors working overseas or offshore

Doctors registered in the UK but working as a doctor overseas or offshore should relate to the Responsible Officer of their employing organisation. For example, doctors in military service will relate to the responsible officer for the Defence Medical Services, regardless of where they happen to be. Similarly, doctors at sea working on cruise liners will relate to the cruise company's Responsible Officer. If the company does not have a Responsible Officer a relationship will need to be made with the local PCT.

4.8 External organisations subcontracting the Responsible Officer role will be required to cooperate with the Responsible Officer, allowing access to the organisation and to all relevant records. They must allow the Responsible Officer to attend the Board meetings of the organisation as appropriate

## 5 How to find your Responsible Officer – map

### Section 2 . Guidance for Responsible Officers

## 6 Roles and responsibilities of the Responsible Officer In England, Wales and Scotland

6.1 The Responsible Officer must have regard for Department of Health guidance

6.2 There are two principal processes for which the Responsible Officer has prime responsibility. These are

- processes underpinning revalidation of doctors
- processes underpinning referral of doctors to the GMC should there be doubt concerning their fitness to practice.

and will remain, a matter for the GMC. Decisions  
practise will be taken by the GMC only after the  
been followed.

6.2 The Responsible Officer will be accountable to the Board of the organisation for ensuring there are appropriate systems and processes are to underpin routine monitoring of medical performance and to ensure that poor or deteriorating clinical performance and/or conduct is identified at an early stage in its development. It is the responsibility of the organisation to ensure that these information systems are properly resourced, reviewed and maintained.

6.3 Specifically, the Responsible Officer must ensure that:

- there is an integrated system for monitoring doctors performance, recognising good practice, encouraging and supporting development and learning
- effective systems and processes of enhanced appraisal are in place
- appropriate action is taken to remedy identified areas of weakness
- progress against development plans is monitored

The Responsible Officer has a duty to ensure that the organisation is advised properly of the resource consequences in terms of time, staff and funds needed for enhanced appraisal and for continuing professional development (CPD).

6.4 Medical Royal Colleges and Faculties will offer support to Responsible Officers in terms of evaluating the specialist practice of doctors. The Responsible Officer has a duty to ensure that there is appropriate liaison within the organisation with the Medical Colleges and Faculties to seek their input to the enhanced appraisal process, in terms of specialist practice. . The Responsible Officer has a duty to liaise with the GMC. In England, pending the outcome of a pilot project currently underway, this may be through a regionally . based GMC affiliate. The Responsible Officer will liaise with the GMC on matters in connection with licenses to practice, revalidation, fitness to practice and ethics.

6.5 In the event of concerns being raised about a doctor of a sufficiently serious nature to call into question the doctor's fitness to practice, the organisation will need to consider referral of the doctor to the GMC. Responsible Officers will be accountable for the oversight of these processes. The Responsible Officer is expected to liaise with the GMC in establishing the appropriateness of the referral and will oversee the collation of the relevant information. The Responsible Officer will also be expected to liaise with the appropriate College or Faculty, through the Regional College Advisors for independent advice on the relevant specialist practice.

6.6 The Responsible Officer is also accountable for overseeing the process by which doctors whose practice is supervised and/or limited under conditions imposed by the GMC, are supported. It is the Responsible Officer's

Each doctor in the organisation comply with any requirements by the GMC. It is essential that good arrangements are in place to ensure, for example, that if a doctor is placed within an organisation for remediation, the host Responsible Officer is informed and oversees the monitoring process.

6.7 Whilst the Responsible Officer will under normal circumstances have a personal involvement in and responsibility for referral to the GMC where there is doubt about a doctor's fitness to practice, it is recognised that there may be specific circumstances in which another Responsible Officer should undertake the role. There may be a conflict of interest for the Responsible Officer. For example, a friendship, marriage, a business arrangement outside the organisation or long-standing acrimony. Whilst it is envisaged that these situations will be uncommon, it is important that appropriate governance arrangements are in place.

6.8 Responsible Officers must be able to demonstrate that the monitoring systems are functioning effectively. For example, the Responsible Officer must ensure that the enhanced appraisal system itself is appropriately monitored and that a system of multi-source peer and patient feedback is in place and functioning effectively, as described in *Assuring the Quality of Medical Appraisal for Revalidation*, published by the Revalidation Support Team. See appendix. In the event of concerns about the appraisal process, there should be a clear process in place for these to be raised with the Responsible Officer by the appraisee. It is important to ensure that these processes underpinning the Responsible Officer's decision-making have safeguards and rights of appeal.

6.9 The Responsible Officer does not make the recommendation decision in isolation; they must ensure that the appropriate disciplinary process is followed and that advice is sought from appropriate sources, for example from the medical Royal Colleges and Faculties or NCAS. The Chief Executive is ultimately responsible for ensuring that the recommendations of the Responsible Officer are in line with the organisational governance arrangements.

6.10 The Responsible Officer's responsibilities relate to the local systems, which support local decision-making. For secondary care organisations in England this process is described in *Maintaining High Professional Standards in the NHS*. PCTs in England are advised to follow guidance from the National Clinical Advisory Service. These new arrangements do not in any way affect the right of patients or members of the public to refer cases directly to the GMC.

6.11 Responsible Officers are doctors. It follows that they must each also have a Responsible Officer. In England, the Responsible Officer at the local level will relate to a Responsible Officer at the Strategic Health Authority, who will make a revalidation recommendation or otherwise on their behalf, to the GMC. The SHA Responsible Officer will in turn, relate to the relevant Chief Medical Officer. Scotland, Wales and N Ireland will make their own arrangements for relationships of local Responsible Officers to a Responsible

er, as a doctor, is accountable to the GMC for  
der interests of the patient and the profession

## 7 Additional duties relating to clinical governance for Responsible Officers in England

7.1 The Responsible Officer has a duty to ensure the robust, efficient and reliable functioning of systems of clinical governance.

Clinical governance 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, by creating an environment in which excellence in clinical care will flourish.+

This definition reinforces the concept that, for the great majority of doctors, the focus of clinical governance systems should be on quality improvement, in terms of the quality of care not only as delivered by each doctor but also by the entire team of which the doctor is part .The function of enhanced appraisal, therefore, remains formative . but only after an objective and confident judgement has been made about the quality of the doctor's practice. In by far the majority of cases this judgement will be affirmative, but, in the small number of instances where there is cause for concern, robust processes must be in place to ensure early identification and rapid remedial action.

In addition to the duties outlined above, the Responsible Officer must ensure that doctors are supported by the organisation in their efforts to improve their own performance and the quality of care they provide to patients. They must also ensure that

- Contracts of employment or provision of services (admission to PerformersqLists, for example) are appropriate, effective, robust and designed to safeguard the patient
- Doctorsqperformance and conduct are monitored
- Appropriate, timely action is taken when concerns about shortcomings in performance or conduct are identified

The organisation and individuals have regard to guidance

7.2 The Responsible Officer has a duty to provide professional leadership and to lead the cultural change that must take place in the organisation to support and allow the systems of celebrating and spreading best practice, monitoring clinical performance and reporting concerns when they arise. If the culture does not support honesty, openness and a willingness to rectify and learn from failings, even the most sophisticated technology available will not deliver a system that works. Like any other system and process, the effectiveness of clinical governance is dependent upon the culture and attitudes of the organisation. The Responsible Officer has a major role to play in creating and maintaining that culture

ins when doctors are appointed or admitted to a  
een a number of cases in which patients have  
here a basic check would have revealed issues  
that would have prevented the doctor's registration with the GMC.

7.4 The Responsible Officer will have a statutory responsibility to ensure that there are robust systems within the organisation for

- Undertaking appropriate employment checks for medical appointments
- Obtaining appropriate references and resolving any issues that may arise
- Recording the results of the checking process

7.5 Responsible Officers in England have a broader set of responsibilities relating to the monitoring of conduct and performance of doctors who give rise to concern, but do not require referral to the GMC. It is likely that the systems for monitoring of performance and conduct will be common to both the revalidation and the fitness to practice processes. There will be a range of outcomes and pathways, but broadly, doctors will either be recommended for revalidation, be referred to the GMC or be subject to appropriate local action or remediation to improve the doctor's practice.

7.6 Identifying the concern is merely the start of a process to safeguard patients. It is crucially important that the appropriate action at the appropriate timescale is put in place. The Responsible Officer has a personal responsibility for initiating the action in relation to issues that arise from the conduct and performance of doctors.

These actions may include:

- Initiating an appropriate investigation, with trained investigators separate from the decision-making process
- Co-ordinating with other concurrent investigations into broader systems failure
- Further monitoring
- Sharing information with or seeking information from other healthcare organisations. Other organisations will be expected to share information appropriately
- Excluding the doctor or placing local conditions or restrictions on practice
- Re-skilling, remediation and rehabilitation of the doctor. This may include training and development, mentoring, peer support, coaching or supervision.

External organisations in a subcontracting relationship with the Responsible Officer function will need mechanisms in place locally to deliver the above

Responsible Officers recommendations  
investigation.

7.7 If the investigation identifies a valid concern, the root cause should also be traced. Many cases of apparent poor performance of an individual may in fact be due to a dysfunctional team or a wider organisational system. The Responsible Officer has a duty to initiate action needed to address wider systems or team issues that become clear during the investigation of an individual doctor.

7.8 It is essential that the organisation continually learns and adjusts its systems on the basis of the findings of investigations. The investigation may reveal a system failure, the rectification of which may lie out with the Responsible Officers or organisations immediate control. Issues such as equipment failure, a design flaw, or poorly labelled drugs from the manufacturer, will need action on the part of the Responsible Officer to alert the appropriate bodies . NPSA, MHRA and the manufacturers, in addition to the primary action needed to prevent harm to patients.

7.9 In terms of these wider responsibilities relating to clinical governance, Responsible Officers should have regard to guidance issued by specific organisations only. These organisations include the Department of Health, GMC, NCAS and NPSA.

7.11 The Responsible Officer has a duty to ensure that clinicians delivering the service do so on the basis of the best evidence available on the effectiveness of interventions. This means having regard to NICE guidance, to best practice guidance from recognised sources, to recognised national audits and to local audit of clinical practice. It is the employing organisations responsibility to ensure that clinicians have easy access to best evidence so that they can practice to the highest standards. The onus is on both the clinician and the employer as partners in providing and using best practice guidelines and documentation.

7.13 The Responsible Officer has a duty to ensure that innovation in the organisation is safe, see HSC 2003/11

## 8 Practicalities of the Responsible Officer role

### Case studies from practice

8.1 Dr A has been the senior partner at a large urban practice for 15 years. A local pharmacist contacts the PCTs Responsible Officer after a series of prescribing errors. He reports examples of adult doses being prescribed for children, potential drug interactions which the prescribing GP has overlooked and on one occasion the wrong drug being prescribed. Fortunately these errors had been spotted by the pharmacy and no harm had resulted.

The RO initiates an investigation, which reveals a number of additional concerns relating to documentation, record keeping and communication within

ed suggestions of poor practice but  
ence in prescribing when shown the evidence.  
review the issues in line with the PCT policy on

handling concerns and a programme of supportive education and supervision  
for the individual and the practice was agreed. Dr A was willing to engage with  
this.

A review after 3 months found no further prescribing errors but poor  
documentation of consultations, and a failure to offer chaperones for intimate  
examinations. During this time the PCT received a complaint from a patient's  
husband alleging that Dr A had failed to examine his wife who was  
experiencing chest pain and had failed to initiate appropriate referral or  
investigation. The patient had collapsed and died 48 hours after seeing Dr A  
who had recommended antacids. Dr A refused to cooperate with a further  
investigation. In line with PCT policy the RO set up a formal review panel  
which took the decision to make an immediate referral to the GMC affiliate.

8.2 Dr C is a consultant colo-rectal surgeon who has been in post for six  
years. In line with current practice he has been developing his laparoscopic  
skills with the help of a mentor. Since his appointment he has kept a logbook  
of all operative cases with details of his complication rates and mortality  
figures. He is registered with the Royal College of Surgeons for CPD and has  
acquired more than the required number of credits in each of the last five  
years. He chose to submit his appraisal documentation on line using the  
NHS Appraisal Toolkit three years ago and has had a satisfactory appraisal in  
each of the last five years. He applied for and was successful in his  
application for a Clinical Excellence Award last year.

Dr C undertook a 360 degree appraisal two years ago and received  
complimentary feedback from his colleagues and from patients. He scored  
better than the average for his peer group. Unfortunately earlier this year Dr  
C was implicated in a serious untoward incident when a patient being cared  
for by the specialist registrar he was supervising died unexpectedly. A  
subsequent root cause analysis undertaken by Dr C highlighted inadequate  
clinical supervision as a possible contributory factor. Following the incident Dr  
C wrote a reflective note and included it in his appraisal documentation.

In addition to a number of plaudits, Dr C had two complaints from relatives of  
patients who had been under his care and who had died. In both cases Dr C  
acknowledged that his communication with the relatives could have been  
better and he included reflective notes in his appraisal file. Dr C enjoys  
teaching and has had good feedback from the junior doctors he has taught.  
This is evidenced in his appraisal documentation.

When Dr C is due for revalidation, the Responsible Officer examines the  
appraisal documentation that Dr C has compiled over the previous five years  
and makes a recommendation to the GMC that Dr C should be revalidated.

## 9 Relationships and accountabilities of the Responsible Officer

9.1 The Responsible Officer is a Board-level position. He or she is directly accountable to the organisation's Board, through the Chief Executive. The Responsible Officer also has a relationship with the GMC, in terms of a duty of liaison on matters in connection with licenses to practice, revalidation, fitness to practice and ethics. In England, pending the outcome of a pilot project currently underway, this will usually be through a regionally based GMC affiliate.

9.2 Each locally-based Responsible Officer will be a doctor. They will, themselves, need to relate to a Responsible Officer in order that they may be revalidated. In England, the relationship will be directly between local Responsible Officers and the appropriate SHA Responsible Officer, who in turn will relate to the Chief Medical Officer. This relationship concerns the ability of the local Responsible Officer to demonstrate their competence and fitness to practice in their roles. Scotland, Wales and Northern Ireland will make their own arrangements in this regard.

9.3 Key relationships at the Executive Board level will be with the Chief Executive, Director of Human Resources and Director of Nursing. Within the organisation, the Responsible Officer will relate closely to the organisation's medical management, appraisal and clinical governance infrastructure.

9.4 The Responsible Officer will have a crucial set of relationships with the clinical leads of the various service lines of the organisation. It will be these clinical directors, clinical leads or service line leads in secondary care and PEC chairs, clinical governance leads and clinical service leads in primary care, along with appraisal leads and trainers who will oversee the information processes and flows within the organisation. These individuals will be responsible for collating information on the performance of individual doctors to present to the Responsible Officer. The Responsible Officer will want to ensure that they are properly trained in enhanced appraisal and multisource feedback and are of the highest calibre and integrity.

9.4 The Responsible Officer will liaise with the Medical Royal Colleges and Faculties for information and support regarding specialist practice and recommendations.

## 10 Who should be the Responsible Officer?

10.1 The Responsible Officer is a Board level appointment. Each designated organisation will have only one responsible officer. He or she may devolve some of the wider role of the Board level doctor to an assistant medical director or other medical manager. The decision-making and

Some of the Responsible Officer are the  
members of the Executive Board of the organisation.

10.2 The lead doctor on the Executive Board in most organisations is currently the Medical Director. Decisions will need to be made by the organisation as to how best to deliver the additional duties of the Responsible Officer as well as those carried out by the Medical Director. This may necessitate some restructuring and strengthening of the organisations medical management infrastructure.

### 10.3 Person specification

10.3.1 As an executive member of the board of the organisation, the Responsible Officer is responsible not only for providing leadership to the medical workforce, but also to the board for clinical performance and clinical governance. In some organisations this responsibility will be jointly held with another board member for example the chief nurse.

10.3.2 The Responsible Officer must have practical experience as a senior doctor. He or she must be registered and have a license to practice. The Responsible Officer will be able to demonstrate evidence of personal and professional development through a recognised management and leadership development programme, a postgraduate qualification in management, leadership or clinical governance and practical experience of a role in leadership and management. Specifically, he or she must be able to demonstrate an ability to lead and manage change in complex medical organisations and management. The Responsible Officer must have had practical experience of performance management of colleagues, appraisal processes and audit. He or she must be able to demonstrate the ability to translate findings into remediation and to introduce new policies and strategies throughout an organisation. The Responsible Officer must be able to demonstrate knowledge both of the practicalities of clinical governance and its crucial role in safeguarding quality of clinical care in the NHS.

10.3.3 In terms of special areas of skills and knowledge, the Responsible Officer will need to demonstrate a detailed, accurate and up-to-date knowledge of the law as it relates to medical regulation and of the specific processes underpinning revalidation. He or she will need to be able to demonstrate expert knowledge and skills in enhanced appraisal, quality assurance of appraisal systems and of appraisers, mediation, negotiation, remediation and rehabilitation. The Responsible Officer will need to have an acute grasp on the management and interpretation of information gathered from the various reporting systems underpinning clinical governance. He or she will need to understand how to access the resources of the trust to enable the implementation of the decisions made about individual doctors.

10.3.4 The Responsible Officer will need to be certified in their role as a medical manager and leader. They must be able to demonstrate to the public, to their colleagues and to their organisations that they have the competences, skills, knowledge and attitudes required to deliver this important role. In addition to qualifications, Responsible Officers must be able to demonstrate their on-going development and training, with annual appraisals and

ed set of management and leadership  
professional body or association of medical

10.3.5 The Responsible Officer will need to demonstrate the ability to communicate outside the local organisation, with the GMC, Medical Royal Colleges and Faculties and with the SHA Responsible Officer.

#### 10.4 Competencies

10.4.1 The Responsible Officer must be able to demonstrate a high level of competence in management and leadership if he or she is to be able to deliver the role effectively.

10.4.2 The range of skills, knowledge and behaviours is outlined in competency frameworks for medical leaders. Across the broad competency domains of communication, managing and developing people, managing and developing the business (service), personal effectiveness, understanding the wider context of healthcare and improving quality, the Responsible Officer would be expected to function at the highest levels of competency. There are also competencies specific to the role of Responsible Officer, which will include knowledge of legal and regulatory aspects of revalidation, legal process, GMC process and mediation.

10.4.3 The Responsible Officer will need to demonstrate their competence and the consistency of their decision-making both within their organisation and in terms of the decision-making of peer Responsible Officers. Regular assessments against an agreed set of standards should be undertaken to ensure that his or her decision-making is properly aligned with the regulations, with the GMC and standards set by the appropriate professional body. Peer review with other Responsible Officers should also be undertaken on a regular basis.

#### 10.6 Education and support

10.6.1 Every Responsible Officer will need to undergo initial and on-going education, assessment and support. Initial educational interventions will vary in scale and scope. There are significant differences between those who have been in medical director positions in large complex trusts for many years, with a wide range of experience and a well-developed medical management infrastructure as opposed to those who are taking on the role in an organisations with as yet little or no medical management infrastructure and little experience of clinical governance.

10.6.2 For some, taking on the Responsible Officer role will mean adding on a new knowledge base and a set of skills to an already well-developed and honed medical management competency. For others it will mean a steep and rapid learning curve against a background of organisational change as the necessary structures and processes are put in place.

10.6.3 At a minimum, in addition to education and development in management and leadership required to the level of the medical director, the

to develop the skills, knowledge and behaviours above, broadly:

- The law underpinning medical regulation
- The process of medical revalidation
- Natural justice and other legal processes and principles
- The process underpinning performance management of medical colleagues
- The handling of colleagues about whom there is concern, from investigation through to local remedy or referral to the GMC
- The process of monitoring organisational systems of clinical governance, both in terms of the information output and the rigour of the systems themselves
- The process of monitoring other associated information systems
- The quality assurance and education of appraisers, the quality assurance of systems of appraisal and audit
- The structures of accountability, both within the organisation and externally

10.6.4 Organisations should ensure that their Responsible Officer is facilitated to take part in peer networking and other forms of support and learning, including periodic formal assessment of their performance in the role as feeding in to their own appraisal

## 11 Conflict and its resolution

11.1 Whilst for the most part doctors will relate to the Responsible Officer in a non-confrontational manner, there may be occasions when there is conflict between an individual doctor and the Responsible Officer. This can be as a result of the decisions a Responsible Officer has made about an individual practitioner, or it may be a long-running conflict on an unrelated matter. There may be underlying conflicts of interest, business arrangements or close friendships and marriages.

11.2 It is essential to ensure that there are checks and balances on the decision-making of the Responsible Officer so that where there is a conflict of interest that may sway the process, and thereby potentially cause harm to patients, that this is recognised, made explicit and that other arrangements are put in place. For example, if there is a conflict of interest, a Responsible Officer from another organisation may be sought to handle the revalidation process of the doctor concerned.

11.3 Every Responsible Officer must be a senior, licensed doctor and therefore professionally accountable to the GMC for his or her ethics and

## Section 3 . Guidance for all Healthcare Organisations.

### 12 The responsibilities of the employing organisation

#### (i) In England, Scotland and Wales

##### 12.1 . The duty to appoint a responsible officer

The Secretary of State in the 2008 Act, by regulation, requires that designated bodies nominate or appoint a Responsible Officer.

The unconditionally designated bodies include

- NHS and independent trusts
- PCTs
- Health Boards in Scotland and Wales
- SHA s in England

12.2 Certain other bodies may also be designated to appoint a Responsible Officer subject to their being able to demonstrate robust, quality assured, systems of clinical governance

12.3 If the organisation in which the doctor works is not designated, he or she is required to find a Responsible Officer in an alternative, managed healthcare organisation. The latter organisation may make a financial charge for providing this service.

12.4 It will be an offence for designated organisations to fail to appoint Responsible Officers.

##### 12.5 Resourcing responsible officers

12.5.1 The regulations will require funding to be provided by designated bodies to support the Responsible Officers' functions relating to individual doctors' fitness to practice. Section 120(5) of the 2008 Act enables this to apply equally to the clinical governance functions in England, Wales and Northern Ireland

12.5.2 It is crucial that Responsible Officers are supported at the appropriate level for them to fulfil their role if patient safety is to be improved. In the majority of organisations, the Responsible Officer will be employed by the same healthcare organisation as that which employs the doctors for whom he or she is responsible. The regulations require that the organisation provide the resources needed to carry out the statutory duties.

designated to appoint or nominate a Responsible Officer. If the organisation chooses to provide the function internally, the organisation may choose to provide the Responsible Officer function. The new sections of the 2008 Act enable the responsible officer to be provided with funds to carry out the duties.

12.5.4 Individual medical practitioners who do not work within designated organisations will need to relate to a Responsible Officer of another organisation if they are to be revalidated and therefore able to continue practising. The Responsible Officer's organisation in this circumstance will not bear the cost of providing the service. The designated organisation will be empowered to recover costs from the individual doctor.

12.5.5 The purpose of introducing Responsible Officers is to improve patient safety and quality of care. In order that this may be effected, resources must be made available for the following, by regulation

- Direct salary costs of the Responsible Officer and relevant on-costs
- Medical management infrastructure to support enhanced appraisal
- Support staff . this is essential. The Responsible Officer's role involves a work-load of information gathering and processing that will require a significant team of appropriately trained and skilled staff
- Information systems to allow the collection of data upon which the revalidation and performance management processes depend.

12.5.6 Where organisations are making a charge for providing the responsible officer function to doctors they do not employ or contract with, these charges should be reasonable and related to the marginal costs of providing the service. If the additional work of providing the Responsible Officer function escalates, however, and consumes significant time, then marginal costs will not suffice. A portion of the full costs of the Responsible Officer and the establishment may also be charged.

12.5.7 There are particular resource issues involved with the provision of remediation, re-skilling and rehabilitation. In alignment with NCAS guidance outlined in Back on Track for doctors who are employed by or are in a contractual relationship with an NHS healthcare organisation, an agreement should be reached as part of the remediation action plan on the relative contribution each side should make towards costs. Where an organisation is providing its services to another organisation or to an individual doctor, it would be reasonable to claim the costs in full.

12.5.8 It is also essential that the organisation provides sufficient time in the doctors contract to discharge the duties of the Responsible Officer effectively. The role is complex and demanding. It is likely to require a full-time or almost full-time commitment, depending on the size of the organisation and the level of support for the Responsible Officer. Organisations may have to strengthen and rearrange medical management infrastructures to enable Responsible Officers to deliver these roles.

is a Board level position and should be  
and open competition, with a rigorous process,  
of the individual's competencies.

12.5.10 It is the responsibility of the employing organisation to ensure that the Responsible Officer is properly developed and supported by education, skills training, personal development. The organisation has a responsibility to ensure that he or she takes part in a peer network to ensure sharing of learning, challenge and support in tackling new situations. The learning curve will be steep for all responsible officers and employing organisations must ensure that they are as well supported and developed as possible.

12.5.11 The employing organisation has a responsibility to ensure on appointment that the responsible officer has the competencies as laid out at paragraph 10.4. The competencies of the Responsible Officer against an agreed set of standards must be reviewed on a regular basis, as part of his or her appraisal process. The Responsible Officer's appraisal process could include review by another Responsible Officer from a similar organisation, clinical or academic colleague, with the revalidation recommendation being made by the SHA Responsible Officer

12.5.12 The employing organisation must ensure that patients and other professionals are supported in raising concerns about doctors. This may require organisational and cultural change. The organisation must ensure that it leads the change of culture to create an environment, which enables concerns to be raised early and appropriately, to be handled with skill and sensitivity.

#### **(ii) In England only**

12.5.13 The effectiveness of the Responsible Officer will necessitate timely access to the appropriate information. This means that the employing organisation has a duty to ensure that information systems underpinning the clinical elements of corporate governance and any other relevant processes (for example multi-source feedback) are properly resourced. Much of the data will already be held on systems of clinical governance and the task will be one of collation. It is essential that the staff charged with the responsibility of inputting or collating sensitive data concerning individual clinician's performance are of high calibre, are appropriately senior in the organisation, understand the absolute need for security of the information, are well trained and regularly assessed. They will be expected to work very closely with both those collecting the data and those using it.

12.5.14 Information will also be required from other organisations and individuals. These include

- Other employers, past and present
- All organisations in which the doctor works, including independent practice
- Commissioners of services

Individuals who undertake appraisals of doctors

12.5.15 The information required will relate to concerns about the conduct or performance of individual doctors, information or documents to support revalidation, information from appraisals. Such information may include

- Information on the quality of what the doctor does
- Information tailored to the standards required by the re-certifying body . the relevant Royal College
- Records of complaints about the doctor
- The outcomes of such complaints
- Supportive feedback/letters from patients or colleagues
- The outcome of such complaints
- Multi . source feedback
- Training and CPD activity
- Participation in clinical audit

## Appendix

**A Legislation underpinning medical regulation – and timetable**

**B References – ‘ Good Medical Practice’, ‘Trust ,Assurance and Safety’, ‘Back On Track’, ‘Good Doctors, Safer Patients**

**B Where to go for help – websites, resource list**

**C Responsible Officer model job description**



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