EXPLANATORY MEMORANDUM TO

THE MEDICAL PROFESSION (RESPONSIBLE OFFICERS) REGULATIONS 2010

2010 No. 2841

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The purpose of this instrument is to establish the role of the responsible officer, who will be concerned with the evaluation of doctors' performance. Organisations designated under these regulations will have a duty to appoint a senior doctor to the role of responsible officer. The responsible officer will have duties relating to the evaluation of the fitness to practise of doctors in the organisation, and in England will have additional functions relating to the monitoring of the conduct and performance of doctors.

2.2 These new regulations are designed to help doctors and the organisations where they work to further improve the quality of care provided to patients. They seek to raise the already high standards of the overwhelming majority of professionals, whilst ensuring that the small number of staff who are not able to meet those standards are swiftly identified and then dealt with fairly and effectively and, where appropriate, are supported to get back on track.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1. None

4. Legislative Context

4.1 This instrument relates to the wider reform of the regulation of healthcare professionals to assure good medical practice following the Chief Medical Officer's report of inconsistencies in local arrangements in *Good Doctors, Safer Patients*, July 2006[1]. The instrument is made under powers in the Medical Act 1983 as amended by the Health and Social Care Act 2008, and some additional powers in that 2008 Act.

4.2 Since November 2009 a doctor must have held a licence to practise medicine. It is planned that this licence should be renewed every 5 years in a process known as revalidation. The details of the revalidation process have not yet been finalised, but it is envisaged that a doctor's responsible officer will make a recommendation to the General Medical Council on the doctor's fitness to practise as part of the revalidation process. The General Medical Council has

[1] Good Doctors, Safer Patients, Department of Health, 14 July 2006 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137232

recently held a public consultation on the system of revalidation[2] and they will determine the revalidation process following the outcome of this consultation. The Department of Health is running ten pilots in England that will examine the process of revalidation and the information that needs to be collected through the appraisal process and how this will support recommendations on fitness to practise to the General Medical Council.

4.3 These regulations give senior doctors in certain organisations (designated bodies) functions for specified doctors that will ensure doctors are regularly appraised and where there are concerns about a doctor's fitness to practise they are investigated and, where appropriate, referred to the General Medical Council. In England, where the concerns are below the level that the General Medical Council considers a fitness to practise issue, responsible officers will investigate, identify the cause and take the appropriate action to bring the doctor back on track. This policy should achieve an increase in public and professional confidence in the regulation of doctors.

4.4 Responsible officers are being introduced now, ahead of the revalidation process, to give them the necessary time and training to prepare for supporting the new process within their organisations.

5. Territorial Extent and Application

5.1 Parts 1 and 2 of the regulations apply to England and Wales and Scotland. Part 3 (additional responsibilities of responsible officers) applies to England only.

6. European Convention on Human Rights

The Parliamentary Under Secretary of State for Public Health (Anne Milton MP) has made the following statement regarding Human Rights:

"In my view the provisions of the Medical Profession (Responsible Officers) Regulations 2010 are compatible with the Convention rights."

7. Policy background

- ***What is being done and why***

7.1 Following the Shipman Inquiry, the Chief Medical Officer undertook a review of the arrangements in place for medical regulation. His report *Good Doctors, Safer Patients* in July 2006 identified inconsistencies in the way organisations managed concerns about doctors and particularly when they were referred to the General Medical Council. This was described as a 'regulatory gap'. The report set out proposals to strengthen the systems for assuring good medical practice and protecting patients.

[2] Revalidation: The Way Ahead, The General Medical Council, March 2010 http://www.gmc-uk.org/doctors/licensing/5786.asp

7.2 A public consultation[3] was held from July 2006 to November 2006 on the proposals set out in *Good Doctors, Safer Patients* and received over 2000 responses, the majority of which were supportive of the proposals for change in healthcare professional regulation. This consultation informed the programme of reform set out in the Government's White Paper *Trust, Assurance, and Safety: The Regulation of Healthcare Professionals in the 21st Century* in July 2007[4].

7.3 The White Paper *Trust, Assurance, and Safety* set out that doctors will relate formally to a responsible officer in the organisation where they work. The White Paper envisaged that this officer would liaise with the General Medical Council over the fitness to practise of individual doctors and oversee local systems for dealing with issues of doctors' performance and conduct. The resulting primary legislation, the Health and Social Care Act 2008[5], made provision, amongst other things, for the role of the responsible officer. This instrument establishes this responsible officer role.

7.4 The Health and Social Care Act 2008 made provision (by the insertion of new powers in the Medical Act 1983) for designated bodies to nominate or appoint a responsible officer with responsibilities relating to the evaluation of the fitness to practise of doctors with a prescribed connection to the body. This instrument sets out these responsibilities for England, Wales and Scotland. The organisations that this instrument designates in having a duty to nominate or appoint a responsible officer can be broadly summarised as:

- organisations that provide healthcare;
- organisations that set standards and policy for the delivery of healthcare; and
- some specialist organisations which employ or contract with doctors.

The instrument sets out the prescribed connections between individual doctors and the organisation which appoints the doctor's responsible officer.

7.5 Section 120 of the Health and Social Care Act 2008 made provision for additional responsibilities of responsible officers in England, Wales, and Northern Ireland relating to local systems of clinical governance. This instrument sets out these additional responsibilities for England only.

7.6 The Department of Health has held two public consultations on the regulations for the role of responsible officer (see paragraphs 8.1 and 8.2 below). The first consultation in 2008 received 126 responses and the second consultation in 2009 received 117 responses. Both public consultations helped inform the development of the responsible officer regulations including which organisations should be designated to nominate or appoint a responsible officer, and the duties and responsibilities of the officer.

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[3] Healthcare professional regulation: Public consultation on proposals for change, Department of Health, July – November 2006
http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_062974

[4] Trust, Assurance, and Safety, Department of Health, 21 February 2007
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946

[5] The Health and Social Care Act 2008
http://www.opsi.gov.uk/acts/acts2008/pdf/ukpga_20080014_en.pdf

7.7 The regulations aim to provide the basis for consistent action by setting clear functions and responsibilities for responsible officers. By setting out how responsible officers cooperate with the General Medical Council they help to bridge the 'regulatory gap'.

7.8 NHS Professionals Ltd (which falls within paragraph 20(a) of the Schedule) is a unique organisation. It was established as a Special Health Authority to be the NHS's own locum agency. As a special health authority it was not able to tender for inclusion on the NHS PASA framework agreement referred to in paragraph 20(b) of the Schedule to the regulations. However it is no longer a special health authority and so is not covered by paragraph 16 of the Schedule; it therefore needs to be listed separately.

7.9 The Independent Doctors Forum (paragraph 24 of the Schedule) represents doctors who work outside the usual structures but who provide healthcare directly to patients. It approached the Department to undertake the role of responsible officer for its members. It has been designated as it is considered by the Department to have appropriate arrangements in place for appraisal and clinical governance that support the role of a responsible officer.

7.10 Where surgical procedures for the purpose of religious observance , such as circumcision, are carried out or supervised by a medical practitioner the procedures are part of the practitioner's medical practice. That practice is regulated by the General Medical Council and organisations that provide such services are designated in line with other organisations where the healthcare is provided by doctors (paragraph 26(1)(c)]of the Schedule). As the responsible officer role relates only to doctors, the designation excludes organisations that use only non-medical staff to carry out the procedures.

7.11 Some insurance policies such as holiday insurance provide medical services as part of the cover. The organisations that provide such services on behalf of the insurance company are providing healthcare, though the doctors they employ are a distinct category of healthcare provision. Such organisations have the same responsibilities to ensure they provide quality care and their doctors are supported in improving that care. Such organisations are covered by paragraph 38 of the Schedule to the regulations.

7.12 Employers have responsibilities for the appraisal and development for their staff. Primary care organisations and Deaneries have similar responsibilities in terms of doctors on their Performers Lists and postgraduate trainees respectively. Other organisations that are designated do not have those responsibilities and, usually, any costs are incurred by the individual doctor. Regulation 14(3) recognises these arrangements and provides for organisations to recover the costs related to the role of the responsible officer, for example for undertaking appraisals for those doctors who are not employees, postgraduate trainees or on a Performer List. For example membership organisations such as Faculties who are funded through the subscriptions of members will be able to recover the costs from those members that have a connection to under Regulation 10.

8. Consultation outcome

8.1 The first public consultation on the role of responsible officers was held between July 2008 and October 2008. There were 126 responses to this consultation and the Department's response document was published in May 2009[6].

8.2 The second public consultation on the responsible officer draft regulations and guidance ran between August 2009 and October 2009. The consultation audience included Primary Care Trusts, independent healthcare providers, Royal Colleges, private companies in the pharmaceutical industry, and individual doctors. There were 117 responses to the consultation and the Department has made a number of changes based on the key issues raised:

- a locum doctor will have a prescribed connection to a designated body, and relate to a responsible officer, as there were concerns that this group of doctors was not supported by the regulations;
- an appearance of bias will also be cause to nominate or appoint a second responsible officer (as well as a conflict of interest), as there were concerns that the provisions for addressing conflicts of interest were unduly biased in favour of the designated bodies; and
- doctors in postgraduate training will relate to the responsible officer in their postgraduate medical deanery.

The Department's response to the consultation is available on the Department's website[7].

9. Guidance

9.1 The Department has published guidance alongside this instrument. The document is designed to provide guidance to all doctors, doctors taking on the role of responsible officer, and the organisations designated to nominate or appoint a responsible officer. The guidance will also be relevant to doctors who work in different settings and across a number of organisations to understand which responsible officer they relate to under the regulations. A copy of the guidance document is available on the Department's website[7].

10. Impact

10.1 The impact on business, charities or voluntary bodies is limited to designated organisations employing or contracting with one or more licensed medical practitioners. Further details are set out in the impact assessment.

10.2 Following the implementation of this policy it is estimated that there will be around 975 responsible officers across England, Scotland and Wales. It is

[6] Response to the consultation on responsible officers and their duties relating to the medical profession, Department of Health, May 2009
http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098851

[7] http://www.dh.gov.uk/en/Managingyourorganisation/Workforce/Professionalstandards/ProfessionalRegulationandPatientSafetyProgramme/TacklingConcernsLocally/ResponsibleOfficers/index.htm

expected that these will be existing staff, such as Medical Directors, and many of their functions are those that should already be carried out in most organisations. The average annual cost is estimated to be £22m but it is worth noting that this estimate is of economic impact and includes (non-financial) opportunity costs.

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on the OPSI website.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 The Impact Assessment details the provisions set out for small businesses in the section Cost of Appointing a Responsible Officer on Small Firms on page 22. The instrument allows for a doctor to be nominated or appointed as the responsible officer for more than one designated body. This enables small organisations to share one responsible officer and incur costs that are proportionate to their responsibilities.

12. Monitoring & review

12.1 The instrument aims to improve local systems of assuring good medical practice and to bridge the regulatory gap between local healthcare organisations and the General Medical Council.

12.2 A measurable outcome will be a reduction in the number of referrals to the General Medical Council where issues of concern of doctors' fitness to practice are identified earlier and handled at a local level. Currently about one third of all referrals are not fitness to practise issues and are returned to employers for local action with no further national action. A closer relationship between the national regulator and employers should reduce these cases and improve the efficiency with which they are managed.

12.3 This policy and this instrument will be reviewed as part of the review of the implementation programme of the White Paper *Trust Assurance and Safety* currently planned for 2011.

13. Contact

Michael Wright at the Department of Health Tel: 02079721323 or email: michael.wright@dh.gsi.gov.uk can answer any queries regarding the instrument. Alternatively Blessing Chukwunyere at the Department of Health Tel: 02079721283 or email: blessing.chukwunyere@dh.gsi.gov.uk.

Title:	Impact Assessment (IA)
The Medical Profession (Responsible Officers) Regulations 2010 - IMPACT ASSESSMENT	**IA No:** 5000-RC
	Date: 28/05/2010
Lead department or agency:	**Stage:** Final
Department of Health (NHS Medical Directorate)	**Source of intervention:** Domestic
Other departments or agencies:	**Type of measure:** Secondary legislation
	Contact for enquiries: Michael Wright 0207 972 1323

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Over the past decade there has been increasing evidence that current clinical governance arrangements for addressing concerns about the conduct and performance of doctors can be improved in order to protect patient safety. A so called 'regulatory gap' has been identified in the handling of poor performance of doctors between local employers and the General Medical Council (GMC). Addressing the current issues requires a national solution that only government can provide.

What are the policy objectives and the intended effects?

The policy objectives are to:
- bridge the 'regulatory gap' in the regulation of doctors to ensure effective handling of any poor professional conduct and behaviour;
- achieve consistency of approach; and
- ensure local clinical governance and national regulatory actions are proportionate, effective, fair and focused on patient safety.

Intended Effects: Improved patient safety and enhanced public and professional confidence.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

Introduce a responsible officer role, to evaluate the fitness to practise of doctors in designated organisations delivering healthcare, and those with a role in setting policy and standards for healthcare. This option would focus on public protection, patient safety and service quality and would apply as follows:
(1) in England, Scotland and Wales – the responsible officer role will relate to the evaluation of fitness to practise;
(2) in England only – the responsible officer will have additional functions relating to clinical governance; and
(3) Northern Ireland will prepare their own regulations, which are expected to be broadly similar.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	2011 (See PIR Plan)
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes (See PIR Plan)

Ministerial Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister: ***Anne Milton*** ..... Date: ***17th July 2010*** .....

Summary: Analysis and Evidence

Policy Option 1

Description:

Introduce a responsible officer role, to evaluate the fitness to practise of doctors in designated organisations delivering healthcare.

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** >£0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	1	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£26m		£21.9m	**£192.4m**

Description and scale of key monetised costs by 'main affected groups'

OPPORTUNITY COST - The training costs and salary costs of responsible officers carrying out their tasks of skills checking, coordinating investigations and strengthening clinical governance systems. These will fall on public, private employers of doctors and designated organisations contracting with doctors. We also anticipate that earlier detection and action by responsible officers will enable cases to be managed at a lower cost and in time a smaller proportion of cases to be referred on to the GMC. The costs presented are net of these benefits.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	1	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	16.4		£16.4m	**£155.9m**

Description and scale of key monetised benefits by 'main affected groups'

As more cases are detected earlier, responsible officers will be able to use remediation to improve the performance of doctors. This is expected to lead to an improvement in health outcomes, which can be estimated as a £16.4 m annual benefit. Other significant benefits from the policy (explained below under "key non-monetised benefits") are difficult to quantify but are expected to have a significant positive impact on health outcomes.

Other key non-monetised benefits by 'main affected groups'

Better protection of patients and public through strengthened clinical governance arrangements; earlier identification of problems before cases escalate; some downstream savings e.g. in litigation costs; greater transparency over disciplinary processes with positive impact on quality of care.

Key assumptions/sensitivities/risks **Discount rate (%)**

Assumptions: (1) Current levels of medical performance and conduct have been correctly estimated (2) Responsible officers' incentives will not lead to excessive assessments

Risks: (1) Failure of complementary policies (2) Obstructions to remediation (3) Effect on small firms (4) Overzealous behaviour from responsible officers leading to an unnecessary increase in assessments.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	**AB savings:**	**Net:**	**Policy cost savings:**	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			01/01/2011		
Which organisation(s) will enforce the policy?			Designated Bodies		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	Yes/No	Yes/No

Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	Yes	28
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	28
Small firms Small Firms Impact Test guidance	Yes	28
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	28
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	28
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	28
Human rights Human Rights Impact Test guidance	No	28
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	28
Sustainable development Sustainable Development Impact Test guidance	Yes	28

1 Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

References

No.	Legislation or publication
1	Medical Act 1983 (as amended by The Health and Social Care Act 2008) http://www.opsi.gov.uk/acts/acts2008/pdf/ukpga_20080014_en.pdf
2	*Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* (The Stationery Office, February 2007)
3	Consultation on the role of responsible officer, July – October 2008: Department of Health http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098851
4	Consultation on the responsible officer draft regulations and guidance , August – October 2009: Department of Health http://www.dh.gov.uk/en/Managingyourorganisation/Workforce/Professionalstandards/ProfessionalRegulationandPatientSafetyProgramme/TacklingConcernsLocally/ResponsibleOfficers/index.htm

Evidence Base

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	£4.1	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
Annual recurring cost	£21.9	£21.9	£21.9	£21.9	£21.9	£21.9	£21.9	£21.9	£21.9	£21.9
Total annual costs	£26	£21.9	£21.9	£21.9	£21.9	£21.9	£21.9	£21.9	£21.9	£21.9
Transition benefits	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
Annual recurring benefits	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4
Total annual benefits	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4	£16.4

* For non-monetised benefits please see summary pages and main evidence base section

Evidence Base (for summary sheets)

Problem under consideration

1. Over the past decade, there have been significant patient, public and professional concerns about the capacity and capability of local and national systems to address concerns about the conduct and performance of healthcare professionals.

2. The White Paper, *Trust, Assurance and Safety: The Regulation of Health Professionals in the 21st century*[2] reviewed recent developments in the processes available to healthcare organisations and national regulators to identify and deal with such concerns. The White Paper concluded that further steps were needed to:

   a. enhance public confidence in the competence of the health professions;
   b. enhance confidence of the professions themselves that individual cases of apparent poor performance will be handled fairly, with the intention wherever possible of enabling individuals to remedy agreed defects; and
   c. bridge the 'regulatory gap' between healthcare organisations responsible for local handling of performance issues, and national health professional regulators.

3. According to *Good Doctors, Safer Patients* (DH 2006)[3], "the anecdotal evidence is that chief executive officers of Primary Care Trusts have concerns that a small number of general practitioners within their jurisdictions may not be truly fit for purpose"[4]. Similarly, Chapter 3 of that publication gives a summary of the findings of the inquiries into Ayling, Neal and Kerr/Haslam, which highlights how failures in the conduct, monitoring and performance management of doctors led to adverse outcomes.

4. In the same publication a 'regulatory gap' between the GMC and the employers of doctors is identified as follows: "Some doctors fall between these two stools, being judged as not 'bad enough' for action by the regulator, yet not 'good enough' for patients and professional colleagues in a local service to have confidence in them. There is thus a significant 'regulatory gap' and it is this gap that endangers patient safety." (paragraph 27, Summary Chapter).

5. The study *Patient safety incidents in British hospitals: preliminary retrospective record review*[5] presented a retrospective analysis of 1,014 medical and nursing records from two acute hospitals in England. They found 10.8% of patients experienced an adverse incident, of which around half (5.2% of all patients) were judged to have been preventable. 66% of patients who experienced an adverse incident had minimal impairment or recovered within one month; 19% of patients developed an injury or complication that resulted in moderate impairment, 6% developed a permanent impairment and for 8% it contributed to death. Overall, 48% of adverse events were judged preventable with ordinary standards of care. The study does not provide the breakdown of the proportion of serious adverse events that were preventable. The sample size is small and the focus is on errors by any healthcare professional rather than just doctors, and on incidents in an acute care setting rather than over the whole healthcare sector. However, these figures provide a useful estimate of the actual standard of practice that the policy is meant to address.

6. A further issue to be addressed is the under-reporting of incidents. In the National Audit Office's (NAO) *A Safer Place for Patients: learning to improve patient safety*[6], NHS Trusts estimate that on average 22% of incidents go unreported. The incidents reported are mainly medication errors and incidents leading to serious harm caused by healthcare professionals. These figures were obtained from a survey with responses from 201 NHS Trusts but should be taken with caution as they refer to cases caused by all staff types rather than just doctors. However, they are a good

2 'Trust Assurance and Safety' – The Regulation of health professionals in the 21st century (The Stationery Office, February 2007)

3 Good doctors, safer patients (Department of Health, July 2006)

4 Chapter 10, paragraph 20.

5 "Patient safety incidents in British hospitals: preliminary retrospective record review" Charles Vincent, Graham Neale and Maria Woloshynowych, BMJ, March 2001, 322:517-519" available at: http://www.bmj.com/cgi/content/full/322/7285/517?ijkey=df2d184bc4ed409208fbbabb72320d0f78757339

6"A Safer Place for Patients: learning to improve patient safety" NAO 2005 http://www.nao.org.uk/publications/0506/a_safer_place_for_patients.aspx

indication of the scope of the problem that responsible officers and other policies stemming from the White Paper *Trust, Assurance and Safety* aim to tackle.

The proposals in this impact assessment (IA) specifically relate to the medical profession; other parts of the reform programme announced in *Trust, Assurance and Safety* are relevant to all the healthcare professions.

7. At present, the GMC has no specific powers to instigate an investigation unless the matter is reported to it or it learns of a concern from a public source (e.g. a newspaper article). The White Paper, drawing on earlier proposals in the Chief Medical Officer in England's review of medical regulation, proposed introducing a system of locally based GMC officials known as "GMC affiliates", linked to "responsible officers" in individual healthcare organisations. The GMC affiliates would provide support to local healthcare organisations in addressing emerging concerns about doctors and independently quality assure local revalidation processes, thus acting as an interface with the GMC nationally and filling the 'regulatory gap'. The role of the GMC affiliate has been piloted and its implementation is subject to the outcome of GMC and Department of Health discussions alongside further testing. Responsible officers will be under a statutory duty to cooperate with the GMC.

8. The primary legislation to create the statutory role of responsible officer in regulations is contained in the Medical Act 1983, as amended by the Health and Social Care Act 2008. Provision for the additional functions relating to clinical governance of responsible officers in England are contained in the Health and Social Care Act 2008.

9. The main provisions of the regulations apply in relation to England, Scotland and Wales, enabling the Secretary of State through regulations to require specified healthcare organisations (designated bodies) to appoint a responsible officer with prescribed responsibilities in relation to the evaluation of doctors' fitness to practise, and to liaise with the GMC. Regulations will also give responsible officers additional responsibilities relating to clinical governance more generally, e.g. in relation to appointments processes. These regulations will apply only in England.

Rationale for Government Intervention

10. From the evidence presented above, it is evident that the current clinical governance arrangements can be improved in order to reduce the number of adverse events that endanger patient safety as well as the proportion of incidents that are not reported.

11. Responsible officers, liaising with and professionally accountable to the GMC, will help to address the 'regulatory gap', ensuring effective handling of cases involving apparent poor professional conduct and behaviour. Revalidation will be a specific example of evaluation of fitness to practise and responsible officers will play an important role in implementing future proposals for revalidation in a cost effective and appropriate way. The responsible officer and the GMC will work together to ensure consistency of approach and ensure that actions relating to the regulations are proportionate, effective, fair and focussed on patient safety. In addition, in England, the responsible officer will have statutory duties relating to clinical governance.

Policy Objectives

12. The objectives are to:

a. Enhance public confidence;
b. Enhance confidence of the profession in the regulatory system; and
c. Bridge the 'regulatory gap'.

13. This IA is published alongside the draft regulations and guidance laid before Parliament. The draft regulations designate certain healthcare organisations as being required to nominate or appoint a responsible officer. They also prescribe the functions of responsible officers in two areas: i) In England, Scotland and Wales functions relating to the evaluation of the fitness to practise of doctors (regulatory functions) and ii) in England only additional functions relating to the monitoring of conduct and performance (clinical governance functions). In particular, the document sets out proposals for:

a. determining which organisations are required to nominate or appoint responsible officers (in relation to England, Scotland and Wales);
b. connecting individual doctors to an appropriate responsible officer (in relation to England, Scotland and Wales);
c. requirements for appointing responsible officers (in relation to England, Scotland and Wales);
d. the functions of responsible officers in relation to the Medical Act 1983, as amended by the Health and Social Care Act 2008 (in relation to England, Scotland and Wales);
e. additional functions for clinical governance more generally (in relation to England only);
f. resources (in relation to England, Scotland and Wales); and
g. ensuring compliance (in relation to England, Scotland and Wales).

Intended Outcomes/Effects

14. The primary strategic aims for this policy are focused on patient safety and on delivering quality in healthcare and high professional standards among those who provide that care. The responsible officers will evaluate doctors' fitness to practise and will help to raise the already high standards of the overwhelming majority of professionals, whilst ensuring that the small number of staff who fall below standards are swiftly identified and dealt with fairly and effectively.

15. The intended outcomes support the achievement of the policy objectives as follows:

- Enhance public confidence

Having a responsible officer nominated or appointed in; England, in each NHS Trust, Foundation Trust, PCT and SHA; Scotland, in each Health Board; Wales, in each Local Health Board; and in a range of other organisations where licensed doctors are employed. Organisations will provide an easily identifiable individual in their organisation who is answerable for performance concerns about doctors. Responsible officers will be responsible for the systems needed to identify problems early and to respond to concerns raised by either fellow professionals or patients, and will be personally involved in overseeing the most serious cases. The introduction of responsible officers should also indirectly improve the quality of care. Firstly, by acting early and managing cases of poor practice as they arise so that they are not allowed to continue. Secondly, the extra scrutiny and increased likelihood of poor practice being detected and acted upon should provide the incentive for doctors to avoid such performance issues. This focus on fitness to practise, with resulting improvements in quality of care, and the knowledge that systems exist for this purpose and that a senior easily identifiable member of the organisation has oversight should enhance public confidence.

- Enhance confidence of the profession in the regulatory system

We expect that the responsible officer will be a respected senior doctor – usually the medical director – who will be an integral part of the organisation's senior clinical leadership and its clinical governance structures. This local focus should mean that the majority of concerns can be dealt with swiftly and effectively and there should be fewer inappropriate referrals to the GMC. Professional confidence will be enhanced by having a senior doctor with local knowledge who understands the professional, clinical and regulatory implications and who is able to initiate change in the organisation as a whole where cases reveal systemic failings.

- Bridge the 'regulatory gap'

The introduction of responsible officers is an integral part of a series of reforms, which will strengthen local arrangements for identifying poor practice among medical practitioners. This will fill the perceived 'regulatory gap' identified in the White Paper. In doing so it should help to ensure that cases of professional misconduct are addressed consistently, fairly and effectively. Responsible officers will be required to work with the GMC as set out in the regulations and will be aided by the introduction of GMC affiliates subject to policy decision.

Preferred Policy Option

16. The preferred option will designate certain organisations that employ or contract with doctors and deliver healthcare, including organisations with a role in setting policy and standards for the delivery of healthcare, as requiring a responsible officer.

17. As well as the baseline do-nothing option, the consultation IA also considered an option that involved designating all employers of licensed doctors on the Register to nominate or appoint responsible officers.

18. The preferred option was chosen as it reduced the likelihood of risks to public health, and did so at a lower cost than the extended option where all registered doctors whether they worked in healthcare or not would be nominated.

19. It will apply as follows:

- in England, Scotland and Wales – the responsible officer role will relate to the evaluation of fitness to practise;
- in England only – the responsible officer will have additional functions relating to clinical governance; and
- Northern Ireland will prepare their own regulations, which are expected to be broadly similar.

20. The regulations set out a Schedule of 'designated bodies' that are the organisations that will be required to have responsible officers. Regulation 4(2) and Part 1 of the Schedule lists bodies that are always required to have responsible officers, for example NHS hospitals. Regulation 4(3) and Part 2 of the Schedule list bodies that will be required to have responsible officers only while they employ or contract with doctors. This part of the Schedule also includes those locum agencies in England and Wales, who are on the Buying Solutions framework (formerly NHS PASA). It does not include organisations that do not provide healthcare services, such as universities, research companies and insurance companies. In Scotland, locum doctors will be expected to relate to the responsible officer in the appropriate Health Board.

21. It is expected that senior doctors who fulfil the necessary criteria and already have an overall responsibility over these issues (such as medical directors in NHS Trusts) will be nominated or appointed within each organisation as responsible officers. Although in many organisations senior doctors do currently have responsibilities relating to the fitness to practise of doctors, this policy will address the so-called 'regulatory gap' by giving them statutory responsibilities, and ensuring that they have the necessary resources to carry out their duty in this respect.

22. In order to support compliance with this policy, the regulations provide the option for the Secretary of State to nominate a responsible officer for a designated body where the designated body has failed to nominate or appoint a responsible officer or in the case where the nominated responsible officer does not meet the conditions stipulated in the regulations. There will be no particular checks of compliance such as inspections by another organisation to ensure that organisations have complied with the law.

23. The preferred option is expected to achieve the policy objectives while minimising the costs of doing so. It will closely align with the system regulation under the Care Quality Commission and with the implementation of the NHS Next Stage Review.

Risks and benefits

24. The proposed policy is part of a programme intended to enhance the confidence of the public and the profession in professional regulation and to bridge the so-called 'regulatory gap' between local employers and the national regulator. Although it builds on and formalises best practice already undertaken by good medical directors, there are still risks that the policy may not be seen to be successful if there are high profile cases of individual failures.

25. Changes in other policies, such as revalidation, will impact on the responsible officer because they are closely linked and in some aspects complementary. Lack of success in these policies could be attributed to responsible officers. Furthermore, although every effort has been made to

assess this policy in isolation, failure in complementary policies could reduce the benefit from responsible officers or at least obstruct any additional benefits.

26. Remediation is necessary to enable the expected increase in cases detected by the responsible officers to lead to improved patient outcomes. If anything prevents this remediation from taking place, it might reduce the benefits that we envisage. An issue that has become apparent through the consultation responses is that there is a great deal of uncertainty in the healthcare sector as to how to define remediation and what constitutes best practice. Several responses also indicated concerns about funding increased remediation.

27. The Department is developing work on remediation with a focus on the following tasks:

- confirming the definition of remediation;
- defining the principles of remediation best practice (validating the principles set out in the Tacking Concerns Locally (TCL)-Clinical Governance Sub-Group Report);
- commissioning additional research to include:
  - mapping current remediation provision in England at local/regional/national level;
  - mapping current levels of usage in England at local/regional/national level;
  - mapping where current responsibility lies for funding remediation;
- producing an analysis of where there are gaps in the provision of remediation in England at local/regional/national level;
- evaluation of the cost-effectiveness of remediation based on systematic data collection on the impact of remediation upon practitioner performance and upon incidence of adverse events; and
- commissioning analysis to understand the potential impact of revalidation on remediation; and collecting and sharing examples of best practice in the NHS and independent sector.

28. This should help to build an understanding of the issues surrounding remediation and their interface with responsible officers and revalidation policies.

29. Regulation 8 ("nomination or appointment of one person as responsible officer for two or more designated bodies") sets out the provision for small organisations to contract with another organisation for the time of a responsible officer, if they are unable to appoint a responsible officer due to costs. This provision reduces the burden on small organisations.

30. The main benefits of this policy are discussed below. We expect to see benefits from improved local processes that deal more effectively with poor performance in doctors. Earlier intervention, providing remediation, re-skilling and rehabilitation bringing doctors back on track to the benefit of patients, doctors, and employers should increase the confidence of the profession in the regulatory process and avoid the costs associated with the protracted national disciplinary process. The increased scrutiny on and improved management of the conduct of doctors is expected to result in improved patient safety, better quality of care and improved public confidence.

Costs and Benefits

31. Before going into the detailed analysis of the costs and benefits of the preferred option, the following aspects have to be examined:

- overlap of costs and benefits with those of other policies; and
- scope of responsible officer policy.

<u>Overlap of costs and benefits with those of other policies</u>

32. Costing the proposals in this consultation document poses certain problems because the introduction of responsible officers is one of an interlocking series of reforms to professional regulation and it is difficult to attribute costs and benefits to any one reform.

33. The responsible officer IA covers the impact of setting up the systems for appraisal and maintaining them, including training and quality assurance, as well as, in England, dealing with

investigations that arise outside of appraisal, which would include applying remediation where appropriate.

34. The impact of conducting appraisals, assessing evidence and making recommendations to the GMC on doctors' fitness to practise will be assessed under the Revalidation IA. Revalidation is the process by which doctors would demonstrate on a regular basis that they remain fit to practise. It would feature an annual cycle of appraisals with a re-licensing process for all licensed doctors every five years. The expected benefits from this policy will be similar and complementary to those of the introduction of responsible officers. These will include an increase in public confidence in professional regulation, improvement in the quality of care as well as the confidence of doctors in the regulatory system. This policy is currently being piloted and plans to implement it are subject to the outcome of that piloting.

35. The Department of Health is also preparing a proposal, through regulations, to create a broad duty on healthcare organisations in England to share information on healthcare workers' performance and conduct where this is needed to protect patient safety (Duty of Cooperation). Like responsible officers and revalidation, this policy's ultimate aim is to improve clinical governance and through that to improve quality of care, patient safety and public confidence.

36. Responsible officers and revalidation policies are aimed only at doctors, whereas Duty of Cooperation covers all healthcare workers. The mechanisms by which they pursue this are also different: Duty of Cooperation policy specifically attempts to join up the information on the conduct and performance of healthcare workers that is already available but is held by different organisations.

37. In terms of improving doctor performance and conduct, the effects of these three different policies are expected to be complementary. This IA assesses the effect of the proposed responsible officer regulations independently from any other policy to ensure there is no double counting.

Scope of responsible officers policy

38. The regulations will give responsible officers functions in two areas as follows:

- Under the Medical Act 1983 as amended by the Health and Social Care Act 2008, regulatory functions will relate to evaluation of fitness to practise of doctors and will include ensuring that the processes to support this are in place, including appraisals and other information sources, and will also require close working with the GMC. This part of the regulation will apply to England, Scotland and Wales. Northern Ireland will make their own regulations and IA. These functions will be costed for England, Wales and Scotland; and

- Under the Health and Social Care Act 2008, the responsible officer in England will have additional functions including a duty to ensure the robust, efficient and reliable functioning of systems of clinical governance in accordance with a clinical governance framework for healthcare organisations. This is in relation to ensuring that appropriate action is taken when concerns about medical practitioners' conduct or performance are raised. Wales and Northern Ireland will make their own regulations. The impact of these additional functions of the responsible officers is costed for England only.

39. In summary, this IA covers both aspects, with some costs and benefits being assigned to the clinical governance aspects of the introduction of responsible officers, in which case the costings will only cover England, and others assigned to professional regulatory responsibility, in which case the costings will cover England, Wales and Scotland.

Data used to inform cost and benefit analysis and confidence intervals.

40. As part of the consultation process, we have sought to improve the evidence base for the cost benefit analysis by consultation with stakeholders and circulating a questionnaire on the policy to a sample of 16 medical directors.

41. This questionnaire included questions dealing with the baseline: "How are concerns about the conduct and performance of doctors investigated?", "What are the different paths an investigation

can take?", and "What is the cost for each different path?". The questionnaire also included questions on the estimated impact that the introduction of responsible officers would have on the investigation of such concerns, and the cost of such an investigation

42. For simplicity, we have decided against using confidence intervals. Instead, we based assumptions on central estimated figures. To test the robustness of the conclusions a sensitivity analysis explores the possibility of changing an important assumption.

Preferred Option's costs and benefits

Benefits

Bridging the 'regulatory gap'

43. In the current system, the employer and the regulator (GMC) deal with poor medical performance separately. The current risks identified by the Chief Medical Officer for England in *Good Doctors Safer Patients*[3] of doctors falling between these two stools, being judged as not 'bad enough' for action by the regulator, yet not 'good enough' for patients and professional colleagues in a local service to have confidence in them, should be reduced. Responsible officers should help processes to be followed through completely by coordinating with the GMC.

44. Under this new policy, responsible officers will have the statutory duty to cooperate with the GMC. Furthermore, responsible officers will provide a unique port of call at a local level for medical performance issues. The increased organisational clarity as well as the fact that responsible officers would be adequately trained and in touch with all the relevant stakeholders should help breach the 'regulatory gap'.

45. Post-implementation information on under-reporting as well as the number of suspensions and adverse incidents will be key variables to estimate whether the policy has been effective in bridging this gap.

Better quality of care

46. As set out in the "Problem under consideration" section, there is currently evidence of a significant number of avoidable adverse events for patients, as well as evidence of significant under-reporting of incidents. The introduction of responsible officers will be likely to result in an increase in the number of cases of conduct and performance issues identified and, more importantly, addressed (although, as explained below in paragraph 48, the proportion of serious cases would be expected to decrease). The responsible officer will be an identifiable port-of-call for conduct and performance issues and so will be likely to attract a greater number of reports of concern about these issues than the same senior doctor or medical director would have done before the introduction of the policy.

47. At present around 1.5% of doctors in England have concerns raised about them that require investigation every year. Responses to our questionnaire indicated that the introduction of responsible officers might lead to an increase of 27.5% in this proportion, up to 1.9% of all doctors (see the "Investigating referrals" section of the cost analysis for more detail on these figures, as well as Flowcharts 1-2 and Table 1).

48. This increase in the number of cases detected would lead to problems being addressed before they escalate to the level where they would involve referral to the GMC under fitness to practise procedures and the doctor being suspended under current arrangements (often after a major adverse event). Therefore, the proportion of serious cases would be expected to decrease. This should be reflected in an increase of the proportion of cases solved through local remediation and a decrease in the proportion of cases that are subject to extended versus standard assessments, as well as a reduction in the likelihood and magnitude of future adverse events.

49. At present around 20% of investigations result in remediation. Remediation can consist of different measures (training, counselling, etc.) aimed at improving the performance of the investigated doctor in specific areas. Remediation can help doctors with insufficient skills regain an acceptable level and those with conduct issues to tackle them before fitness to practise

concerns appear. It can be particularly appropriate, if applied effectively, for those doctors who may be currently in the so-called 'regulatory gap'. The increased scrutiny arising from the appointment of responsible officers will lead to greater opportunity for supporting doctors. This earlier intervention is estimated to increase the proportion of investigations that result in remediation from an initial level of 20% to around 25% because of cases being detected earlier (see the "Investigating referrals" section of the cost analysis for more detail on these figures, as well as Flowcharts 1-2 and Table 1). This increase in remediation activity is dependent on other factors, including resourcing, that are beyond the scope of this policy. This issue is discussed in the third point under "Risks and benefits".

50. Cases should require shorter assessments because they are detected earlier but also because responsible officers would be appropriately trained and would be able to handle cases more effectively. The responses to our questionnaire suggested that the proportion of standard assessments (versus longer and more expensive extended assessments) would increase by around 17%, from the original 60% to a proportion of 70% of all cases after the introduction of the policy.

51. The early detection and increase in investigations described above should lead to a general improvement in the skills level, conduct and general performance of doctors that come under investigation, because any poor practice will be more likely to be recognised and remedied. Although the number of directly affected doctors per year is relatively small (1.5% of all licensed doctors before the introduction of the policy and 1.9% afterwards), each doctor is likely to provide healthcare for a relatively large number of patients (for instance, the average number of patients per GP is around 1800), so the number of patients likely to benefit would be large.

52. The two studies quoted in the "Problem under consideration" give an idea of the scope for improvements in both quality of care and reporting levels.

53. Furthermore, the greater level of scrutiny, (and also the revalidation process when it is implemented) should act as a strong incentive to avoid poor practice. According to principal/agent theory in economics, the performance of doctors should improve when the level of performance monitoring increases. This is difficult to quantify with any accuracy, even more so because of the difficulty of assigning benefits between overlapping policies as discussed above.

54. Although there is little evidence that doctors would necessarily respond to negative incentives in this way, there is evidence that other forms of feedback do have an effect. Grol's review of the literature[7] led him to conclude that "face to face instruction, assessment, and feedback by well respected peers - combined with practical support - seem to be particularly effective in improving the quality of care." To support this, a study on the influence of observation on community health workers' practices found evidence of a decrease in the frequency of treatment errors when workers "were not observed, but knew they were being studied" (Rowe et al. 2006)[8]. It is therefore reasonable to suggest that the possibility that a respected doctor might identify and act upon a medic's areas of poor practice would encourage them to maintain minimum acceptable standards. These incentives would be expected to affect all doctors, not only those under investigation.

Both these factors are expected to lead to an improvement in quality of care and patient safety.

7 "Implementing guidelines in general practice care." R Grol - British Medical Journal, 1992

8 "The influence of observation and setting on community health workers' practices", Rowe et al, International Journal for Quality in Health Care 2006 18(4):299-305

Quantifying improvements in quality of care and patient safety

55. The scale of the expected increase in the proportion of cases caught early, fall in the proportion of cases requiring an extended assessment and increase in remediation suggests that the improvement in quality of care and patient safety would be significant.

56. Out of all these effects, the effect of the increase in remediation in the public sector is the only one we are able to quantify in money terms. As explained above, remediation consists of any measure (training, counselling, etc.) aimed at improving the performance of the doctor in question in specific areas. We expect that the policy would increase the number of doctors that undergo remediation in two different ways: a) as cases are detected earlier, before they escalate, a greater proportion of them are expected to be at a stage suitable for remediation; and b) as more cases are detected, the responsible officer will be able to apply remediation to cases which would have remained undetected before.

57. Respondents to our questionnaire believed that increased scrutiny of the conduct and performance of doctors resulting from the introduction of responsible officers will result in an initial increase in more doctors requiring some form of remediation. According to the responses, their criteria for applying remediation would be the same as with the current system but the difference is that more cases would be detected.

58. National Institute for Clinical Excellence (NICE) assesses the cost of a marginal 'quality adjusted life years (QALY)'[9] to the NHS at £25,000 each. If the NHS allocates its funds efficiently, we would expect that currently £25,000 spent on remediation would lead to a 1 QALY improvement on the population. If we assume that senior doctors who are appointed responsible officers will have the same criteria when deciding whether to apply remediation as they did before, then we would expect that each £25,000 spent on remediation will produce at least 1 QALY. Additional applications of remediation could in fact constitute intra-marginal interventions. This means that their benefits could be greater than 1 QALY for each £25,000, as remediation would be applied to cases where currently remediation is not applied not because it is deemed inefficient, but rather because the specific conduct or performance issue has not been detected.

59. The additional public sector expenditure because of increased remediation (according to the assumptions presented in the Costs section below) is quantified as £6,851,222. This would represent £6,851,222/£25,000 = 274 QALYs.

60. It is estimated that the general public value one QALY at £60,000, and therefore the opportunity cost of public funding in terms of QALYs should be monetised at £60,000 each QALY to obtain its true value. Therefore the minimum impact of the increase in remediation would be valued at 274 QALYs*£60,000 = £16,442,933.

61. The validity of this estimate is subject to whether the propensity of senior staff to apply remediation is affected by the introduction of the policy or not. If responsible officers face incentives to be overzealous and apply remediation beyond what would be the optimal point, each additional £25,000 spent on remediation will be expected to produce less than one QALY.

62. Although the response to the consultation is encouraging in this respect, whether this assumption is valid should be one of the key points to be determined in an eventual post-implementation policy review.

63. It should be noted that the above refers only to the impact of increased remediation on the public sector only. We do not have an estimate for the opportunity cost impact of increased remediation on the private sector. The private sector providers that are commissioned by the public sector would be expected to produce a similar opportunity cost of healthcare spending, but there is no information on the opportunity cost of private sector spending. Those additional benefits are not quantified.

9 The quality-adjusted life year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived. It is used as a means of assessing the value for money of a medical intervention.

Central estimate: £16.4m

64. This represents only a small part of the total benefits in terms of improved healthcare outcomes that can be expected from the introduction of responsible officers. The effect of the improvements to doctor skills and conduct is currently the object of research by the Department of Health as part of the Revalidation IA. When this research is completed, it may be possible to put a numerical value to the total impact of responsible officer policy on patient safety and quality of care.

Deviation from assumptions

65. Because of the strong assumptions that underpin the analysis above, it can be useful to explore what the outcome would be if they were to be relaxed.

66. In terms of the benefits, perhaps the crucial assumption is that responsible officers will face the same incentives to investigate a case as a current medical director or senior doctor faced with a similar case. However, the very fact of appointing medical directors responsible officers and giving them responsibilities over performance and conduct issues is likely to have an effect over the incentive structure they face. Whether this increases benefits as well and to what extent will depend on whether these additional investigations are justified or not.

67. The implications of relaxing this assumption on costs and benefits is discussed in the section "Addressing concerns".

68. Because the benefits are realised by early intervention and then managed through the clinical governance elements of the functions of responsible officers these benefits have been costed for England only.

Benefits from responsible officer training

69. As explained below in "Responsible Officer Training", new responsible officers will receive training relevant to their duties. For responsible officers in England and Wales, the Department of Health is proposing to provide core training initially. Scotland is planning to provide this training independently. The training is intended to focus on the principles and competencies required for the responsible officer role, such as strengthened appraisal systems, the principles of investigation, the law surrounding revalidation, fitness to practise and equality. This will enable all responsible officers to acquire the necessary competencies whether they are experienced medical managers or are relatively new to the role.

70. This training should improve the effectiveness and efficiency in the performance of the responsible officers' duties, helping to improve the management of incidents as well as the setting up of structures and systems connected to appraisal. It is therefore expected that both the management of concerns and the setting up of appraisal procedures will be fairer, more consistent and effective with trained responsible officers.

71. This impact is difficult to quantify for Scotland and Wales. For England it can partly be quantified through the decrease in the proportion of cases that are assessed through a standard assessment versus an extended assessment (see the section on "Assessing cases"), which is expected to increase from 60% to 70% of all cases. As this increase is expected to arise from the earlier detection of poor performance it is difficult to know how much is due only to the provision of training.

Enhanced confidence of the profession in the regulatory system

72. The introduction of responsible officers would increase doctors' confidence that their professional performance will be considered fairly and evaluated on the basis of solid evidence and their own testimony. The consistency of decision making that responsible officers would bring to the process would further reduce the uncertainty doctors face when concerns are raised about their conduct and performance because they would know that the same clear and fair process would be followed every time. Responsible officers would have received appropriate training and over

time develop valuable experience in dealing with performance and conduct issues (this could be reinforced by revalidation policy).

73. Inappropriate referrals to the GMC are detrimental to doctors because they are stressful and can tarnish long-term reputations undeservedly. Responsible officers should reduce the number of cases inappropriately referred to the GMC, the percentage inappropriately investigated and therefore further enhance the confidence of the profession.

74. We assume that the percentage of all investigated cases referred to the GMC by designated bodies would fall from around 5% to around 3.7%, because of the projected fall in the proportion of cases subject to extended investigations. This will be partly due to the fact that cases will be detected earlier before they escalate, and partly to a decrease in the percentage of inappropriate referrals to the GMC.

Enhanced public confidence

75. Patients and the public in general would be likely have greater trust in the medical profession as a result of the policy. Improved quality of care and increased patient safety would decrease the likelihood of adverse events, as discussed above. It would also promote positive patient experiences whenever complaints are made. A discussion with a patient representative has suggested that any wider gains outside of those mentioned above would depend on how aware patients are of the policy. Similarly, the fact that referrals to the GMC may decrease may be balanced out in the public opinion by the fact that ordinary investigations will increase.

76. Therefore, the bulk of gains in public confidence can be expected from the avoidance of high-profile adverse events. To quantify this effect it would first be necessary to estimate the likelihood of an adverse event large enough to cause large-scale anxiety on public opinion. As these adverse events are rare by nature, estimating their likelihood is difficult in itself. A suitable proxy in this case might be the number of doctor suspensions or of doctors struck off the medical register every year (see the Suspensions section below). Evidence on the effect of the likely outcomes of the preferred option would still be necessary to quantify this benefit. It is therefore included as qualitative benefit.

Costs

77. The costings below are based on English data, however it may be possible to extrapolate some of this information to Scotland and Wales. There are 151,070 doctors on 'head count' basis currently practising in England (source: OECD Health Data 2009, figures for 2007, available at http://www.oecd.org) that will be overseen by around 900 responsible officers (estimated from the types of organisations referenced in the regulations). We estimate there will be around 21 in Wales and 54 in Scotland, adding up to a total of 975 responsible officers overall. Out of the total, we estimate that 49% of all responsible officers will be in the public sector and 51% in the private sector. We will use this ratio to split training costs between public and private sectors (see the section on training costs below for more details).

78. However, as 128,210 doctors, 85% of the total, work for the NHS, we expect that most responsible officer activity will actually take place in the NHS. We will use this ratio to split the total estimated cost of the policy between the private and public sectors for costs that are related to volume of investigations.

79. Based on experts consulted, the total annual salary for each responsible officer is estimated to be in the range of £125,000 to £200,000, so we have used a central estimate of £160,000 for these calculations. We assume that band 6 and band 4 administrators supporting responsible officers (amongst other duties) will be respectively £30,000 and £20,000. Non-salary costs for each employee of 30% of total salary are also assumed.

80. Responsible officers are assumed to be medical directors or senior doctors currently working in each organisation who will devote a proportion of their working time to responsible officer duties. The cost of performing these duties will be reflected by the foregone working time they would have dedicated to their medical or managerial duties.

Similarly, the administrators are assumed existing administrators in the organisation who dedicate some of their working time to supporting the responsible officer.

81. For the NHS and other public organisations providing healthcare, the opportunity cost of re-allocating money to meet the responsible officer policy requirements will lead to an additional social cost. NICE assesses the cost of a QALY to the NHS at £25,000 each. Hence, the opportunity cost of £25,000 of Department of Health funding is one QALY. However, it is estimated that the general public value one QALY at £60,000, and therefore the opportunity cost of public funding in terms of QALYs should be monetised at £60,000 each QALY to obtain its true value.

82. This applies to all public spending required for an option, whether from the Department of Health budget, from local authorities or from other Government Departments. It should be noted that, while these additional opportunity costs of public spending are monetised, they do not correspond to actual financial costs for the organisations involved.

83. The opportunity costs of the private sector are difficult to quantify beyond the salary costs. We do not have an estimate for the opportunity cost impact of increased spending due to the policy by the private sector. The private sector providers commissioned by the NHS would be expected to have a similar opportunity cost of healthcare spending to that of the public sector. There is however no information on the opportunity cost of purely private sector spending. If this increase in costs was passed through to NHS commissioners, then the opportunity costs of increased spending would be the same as in the public sector. If the costs are passed on to paying patients, then the opportunity costs will be in terms of business lost for the independent health sector and a reduction in the consumer surplus of private patients.

Those additional costs are not quantified as part of this IA.

Skills checking when doctors are initially appointed

84. Based on an assumed turnover of 10.5% (based on the NHS Information Centre annual staff census figures from 2006/07[10]) there would be around 15,862 new appointments each year. Based on the responses to our questionnaire, we estimate it currently takes around 6 hours of "Agenda for Change" band 4 staff and around 1 hour of a senior doctor's time to check their skills. This skills check would not necessitate the presence of the doctor whose skills are being checked.

85. The additional resources required for this task due to the introduction of responsible officers would vary across the NHS. It would depend on the extent to which NHS organisations are already carrying out these checks, in line with current guidance from NHS Employers in England. We assume that the introduction of responsible officers would result in an average increase of 20% in the amount of band 4 staff time and 30% in the amount of senior doctor time involved in this work. (This relies on information from Kings College London suggesting that half of the time required for band 4 staff will consist of process arrangements which would be unchanged by the policy).

86. The calculations unfold as follows:

- Band 4 additional cost, central estimate: 10.5% doctor turnover * 151,070 doctors in total * (6 hours per doctor *20% increase because of the introduction of responsible officers) * (salary of £20,000 +30% of salary as on-costs) / (35 hours per week * 44 weeks per year) = £321,367

- Responsible officer additional cost, central estimate: 10.5% doctor turnover * 151070 doctors in total * (1 hour per doctor *30% increase because of the introduction of responsible officers) * (salary of £160,000 +30% of salary as on-costs) / (35 hours per week * 44 weeks per year) = £642,734

10 http://www.ic.nhs.uk/statistics-and-data-collections/workforce/nhs-turnover/medical-staff-turnover-2006-2007

87. As explained above, 15% (£145,888) of the cost would correspond to independent healthcare sector organisations and 85% (£818,213) of the cost would correspond to public sector healthcare organisations.

88. As set out at the beginning of the costs section, the cost imposed on public organisations is assumed to have an additional opportunity cost. The opportunity cost in terms of QALYs foregone will be equal to £818,213/£25,000 = 33 QALYS, which, valued at £60,000 each, will give us a total opportunity cost of £1,963,711.

Central estimate: £2.1m a year

This benefit relates to the clinical governance aspect of the introduction of responsible officers and therefore applies to England only.

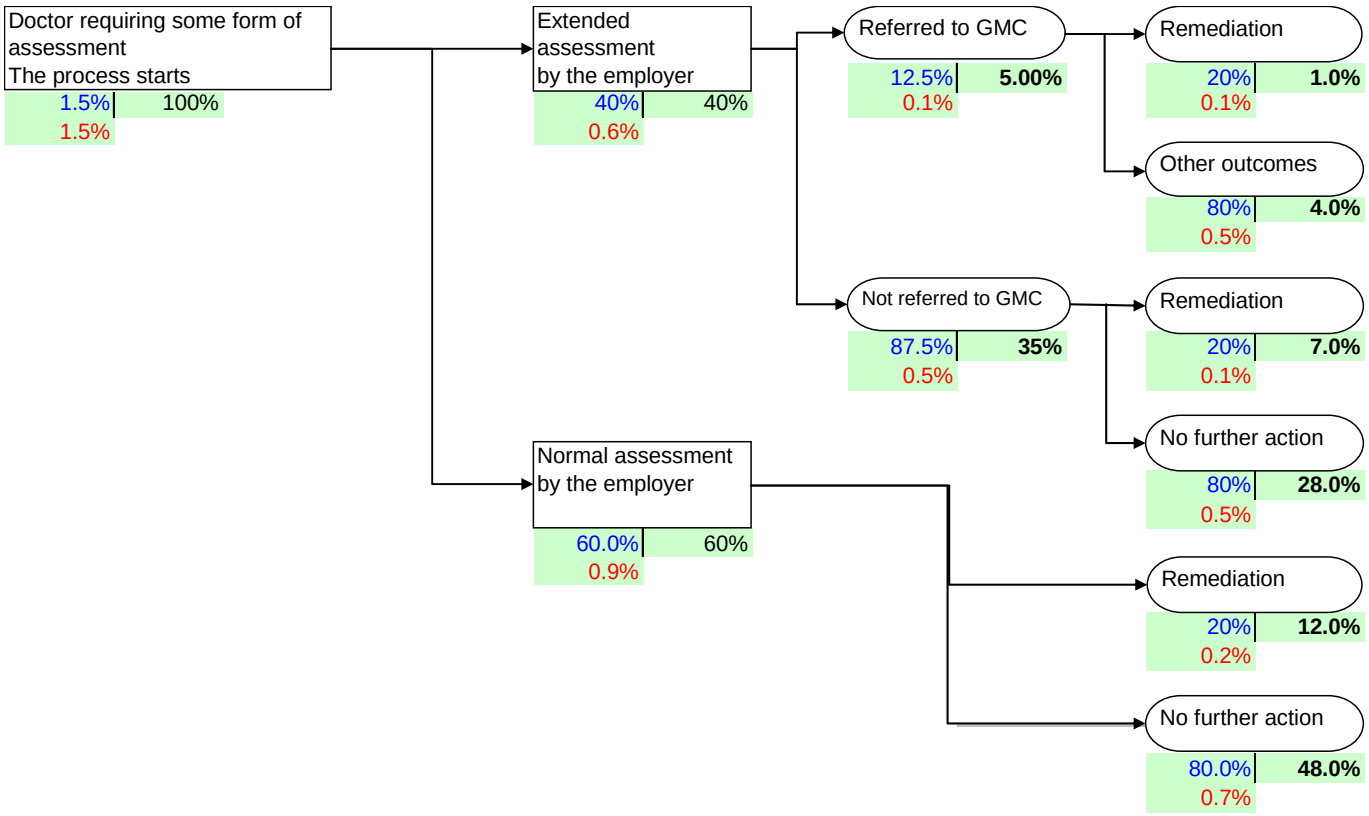
Assessing cases

89. Modelling the potential impact of responsible officers on the flow of assessments requires simplifying assumptions. This is partly because cases are managed on an individual basis and can therefore take a variety of pathways and partly because we do not have all the necessary information. Flowchart 1 below gives a broad representation of the process. Cases are subject to a normal or extended assessment before either being referred to the GMC, undergoing remediation or it being decided that no further action is required. The tables embedded within it also show the current flow of cases through the process.

90. Estimates in this section are based on our questionnaire responses obtained from a sample of NHS medical directors as well as several meetings with stakeholders as part of the consultation process.

91. Based on the questionnaire responses, we estimate that around 1.5% of doctors are subject to some form of assessment each year. This equates to roughly 2,266 cases. On average 0.5% of practising doctors are referred to the National Clinical Assessment Service (NCAS) each year and these are only the most serious cases, so 1.5% seems a plausible proportion for the total of doctors investigated. Of these cases, we estimate that 40% would require an extended assessment with the remainder only requiring a normal assessment. 20% of all assessments (normal and extended) result in some form of remediation and 12.5% of extended assessments result in onward referral to the GMC.

Flowchart 1: The referral process before the introduction of responsible officers



The key below shows the meaning of the percentages in the shaded areas of the flow diagram.

The **percentage of all referred doctors** that follow through to this stage.

The **percentage of the previous stage** that follow through to this stage.

The **percentage of all doctors** that follow through to this stage.

Table 1 below shows the change in the flow of cases caused by the introduction of responsible officers. As explained above in the "Better quality of care" section, we assume responsible officers would have the effect of increasing the number of detected cases by around 27.5%. This assumption was informed by the responses to our questionnaires as well as conversations with several experts, which suggested the proportion of doctors about whom concerns are investigated would increase by 25% to 30%. From this, we take the central estimate of 27.5%.

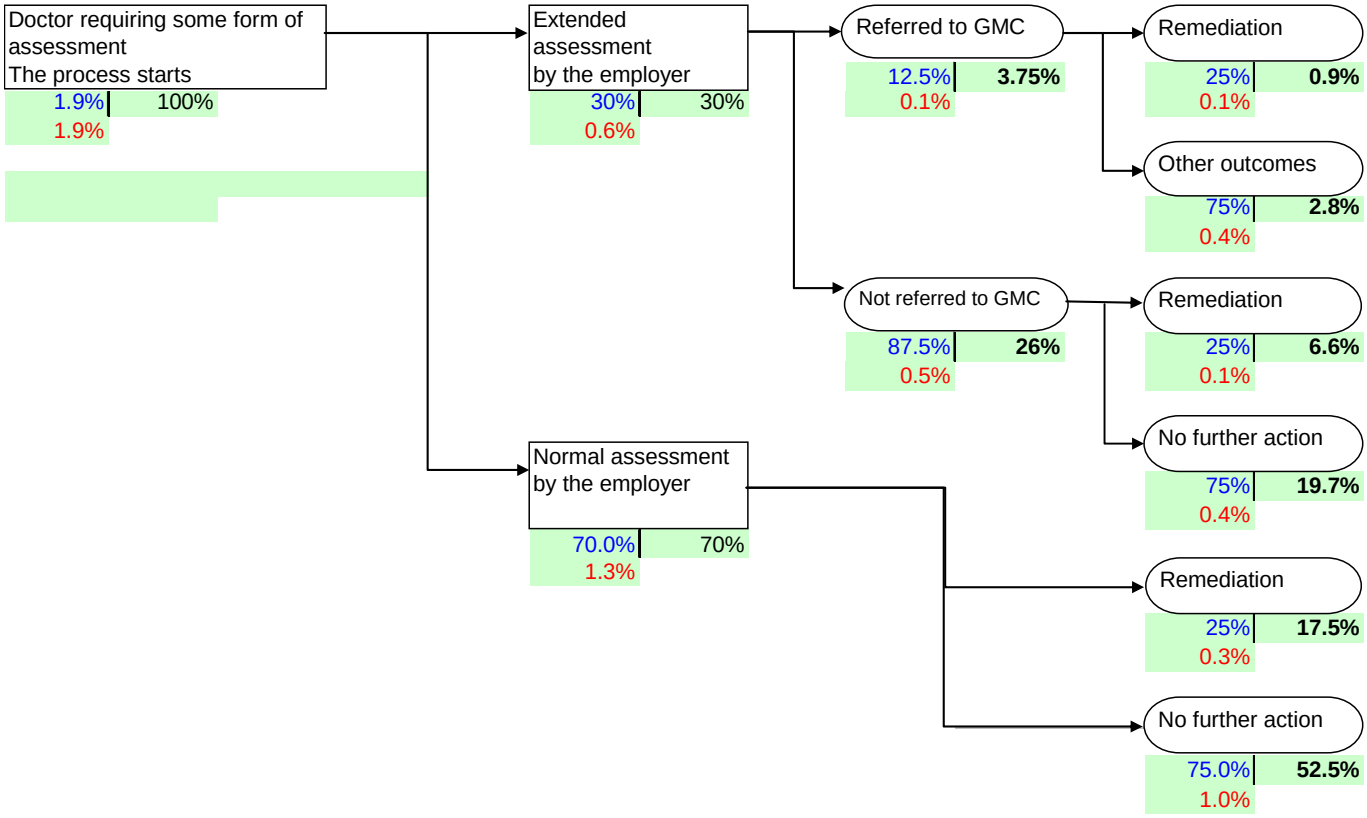
Questionnaire responses concerning the effect of the policy on the proportion of extended investigations that are referred on to the GMC were very diverse and difficult to aggregate into one coherent view. Several responses indicated that they thought this proportion would decrease by 33%, but an equivalent number thought the policy would have no effect. Finally, several responses indicated that this proportion was likely to increase in the short term while existing under-performing doctors were tackled before settling down at a lower level. We therefore assume no change because there are no grounds to make an assumption in either direction.

Table 1: Estimated changes caused by responsible officers

	Increase/decrease	Central estimate
The percentage of doctors being requiring some form of assessment	Increase	27.5%
The percentage of cases that are subject to a standard investigation (vs. an extended one)	Increase	17%
The percentage of cases resolved with some form of remediation	Increase	25%

Flowchart 2 below shows the flow of referrals through the different paths after the introduction of responsible officers. This can be contrasted with flowchart 1.

Flowchart 2: The referral process after the introduction of responsible officers



The key below shows the meaning of the percentages in the shaded areas of the flow diagram.

The **percentage of all referred doctors** that follow through to this stage.

The **percentage of all doctors** that follow through to this stage.

The **percentage of the previous stage** that follow through to this stage.

Based on the questionnaire responses, we estimate that the time required to carry out:

- a normal assessment would be around 3 ½ days of Agenda for Change band 6 administrator and 1 day of the responsible officer; and
- an extended assessment would require 8 ½ days of band 6 administrator and 3 days of the responsible officer.

In addition to the extra time spent by staff, local remediation would cost an average of around £30,000 per doctor referred (assuming a mix of interventions varying from short interventions at £4,000 and NCAS programmes at £90,000. Referral to the GMC would result in a further cost of £4,000 to the local healthcare organisation, £12,000 for investigation by the GMC, and £50,000 for formal hearings in 9% of cases.

Table 2: Cost of each referral outcome in addition to the extra time spent by staff

Referral outcome	Cost	Assumption
Local remediation	£30,000	Summary of questionnaire responses by a sample of Medical Directors
GMC preliminary investigation	£4,000 (Employer) £12,000 (GMC)	Summary of questionnaire responses by a sample of Medical Directors. GMC figure derived from information provided by the GMC.
GMC formal hearing	£50,000	Formal hearings will occur in 9% of cases.

Combining these assumptions results in estimates of the net additional cost of £8,806,012.

As explained above, 15% (£1,332,531) of the cost would correspond to independent healthcare sector organisations and 85% (£7,473,481) of the cost would correspond to public sector healthcare organisations.

As set out at the beginning of the costs section, the cost imposed on public organisations is assumed to have an additional opportunity cost. The opportunity cost in terms of QALYs foregone will be equal to £7,473,489/25,000 = 299 QALYS, which valued at £60,000 each will give as a total opportunity cost for the public sector of £17,936,355.

Central estimate: £19.3m a year

Assumptions on responsible officer incentives

92. It is assumed in the calculations above that a responsible officer will have the same tendency to investigate a referral or to apply remediation as a current medical director or senior doctor faced with a similar case. The only difference is assumed to come from the greater number of referrals brought to his or her attention through the greater visibility of the role (abstracting from any cases flagged up through the revalidation process, which will be evaluated separately). This is supported by the responses to the questionnaire and seems reasonable given that the regulations do not envisage any changes to these criteria.

93. However, the very fact of designating a medical director to be a responsible officer could have an effect over the incentive structure they face. Under the preferred option, responsible officers will be given a clear responsibility to tackle performance and conduct issues in their organisation. A responsible officer would therefore be likely to face increased incentives to detect and remediate cases, whether because of a sense of duty towards the new obligations or because any adverse events may reflect badly on their performance.

94. This additional responsibility may make responsible officers more likely to investigate referrals or apply remediation.

The evidence presented above on current under-reporting of incidents suggests that an increase in the incentives of responsible officers to investigate may not necessarily have a negative impact. Indeed, current under-reporting may be due to some extent to existing incentives not to investigate. Therefore, increasing the incentives to investigate may balance this existing bias and lead the level of investigation closer to the optimum point. In this case, the increase policy costs would be accompanied by additional benefits.

95. If at present the propensity of senior doctors to investigate referrals and apply remediation is close to optimal, then an increase in incentives could lead responsible officers to be overzealous and investigate beyond what would be optimal. This could represent for example, spending a lot time investigating non-serious cases, or applying a disproportionate amount of remediation. In that case, each additional £25,000 spent on investigation and remediation will be expected to produce less than one QALY. In this case, the benefits from additional investigation and remediation may not offset the costs.

96. The risk that the incentives of responsible officers would lead to excessive investigations should be monitored after implementation. The number of investigations and cases leading to remediation after the introduction of responsible officers should be a key variable to examine. However, while increased investigations certainly increase costs, whether they increase benefits to a similar extent will depend on the outcome of these investigations. This will be partly dependent on whether the implicit assumption on the current medical performance and conduct is correct. This is explored in the following section.

Assumption on current medical performance and conduct

97. The calculations presented above assume that the percentage of doctors subject to an assessment would increase from a base of 1.50% to 1.90% due to the introduction of responsible officers.

98. Together with the assumption that responsible officers would face the same incentives to investigate concerns or apply remediation, this increase in assessments assumes an underlying standard of medical performance and conduct that is below that which is currently observed. It assumes that currently there is under reporting and that introducing responsible officers would lead to bring to light already existing cases that are not currently investigated.

99. Given that both the current standard of medical performance and the number of unreported cases can only be estimated (and the same applies to the proportion of those unreported cases that can actually be brought to light by appointing medical directors and other senior doctors to be responsible officers), it may be useful to explore the solidity of this assumption.

100. The two studies quoted in the section "Problem under consideration" give an idea of the scope for improvements in both quality of care and reporting levels.

Because of the uncertainty linked with any estimates related to poor practice and under-reporting it is advisable to explore the possibility of the impact on costs and benefits of relaxing this assumption.

Sensitivity analysis

101. As an upper band, it is useful to look at what would be the increase in cost if the introduction of responsible officers was to lead to an increase of 300% in the proportion of doctors being assessed, instead of the 27.5% increase derived from the questionnaire responses. As a result of this increase, 6% of all doctors would be investigated after the implementation of responsible officers, instead of the currently assumed 1.9%. Such an increase would be most likely in the first one or two years after implementation, when the increased scrutiny could be expected to lead to more investigations. This may be through over-reporting by responsible officers, responsible officers uncovering lower standards of medical performance and conduct than expected, or dealing with a backlog in performance and conduct issues not addressed by the current system.

102. Using the same method as in the calculations above but assuming that the introduction of responsible officers would lead to 6% of doctors being investigated, the cost of introducing responsible officers would be around £166 m per year over the public and private sectors from investigating referrals over the first few years of implementation.

103. It should however be noted that, if this huge increase in investigations is motivated by the current under-reporting, the benefits in terms of the policy would also be expected to hugely increase, particularly in terms of quality of care. We would expect that in this case, benefits would be of £110.8 m, leading to net costs of £55 m per year.

However, if the increase in the number of investigations were instead motivated by over-reporting by responsible officers, the additional benefits would be far smaller.

104. When reviewing the effects of this option after implementation, it will be necessary to examine the apparent effects of responsible officers on the number of cases investigated, as well as the composition of those cases in terms of the gravity of the errors uncovered. This may help to understand whether the assumption does hold in practice and if it does not, which is the most likely cause.

Suspensions

105. The effect of the introduction of responsible officers on the total level of suspensions apart from those resulting from the GMC fitness to practise panels is difficult to ascertain. On one hand, we assume that a greater number of cases would be detected (the *volume* effect), but on the other, the proportion of investigated cases that result in suspensions would be expected to fall as cases

are detected earlier and doctors would have incentives to improve their performance (the *composition* effect).

As explained under "Assessing referrals" we estimate 2,266 doctors are investigated every year (1.50% of all doctors). This would be expected to increase by 27.5% because of the introduction of responsible officers and constitutes the *volume* effect.

We estimate that currently the proportion of cases that result in suspension is 17%, based on the central assumption that 1.50% of doctors are investigated and there are 389 suspensions per year (GMC figure for 2008) from 151,070 active doctors in England.

106. As also explained above, the introduction of responsible officers is likely to change the proportion of cases investigated that result in suspensions and this change would constitute the *composition* effect. We do not have an assumption on the magnitude of this decrease, but if the total number of suspensions were to stay the same, the proportion of investigations that result in suspension would have to fall from 17% to around 13.5%.

With no hard evidence on which of these two effects is stronger, the direction and magnitude are left un-quantified and should be revisited when the policy is reviewed.

Cost of appointing a responsible officer on small firms

107. The impact of the policy would fall more heavily on small organisations if no provision were made because not all costs vary according to the size of an organisation. The questionnaire and consultation responses do indeed suggest that the additional cost from additional investigations on smaller firms would not be proportionally higher than on larger firms.

108. However, the cost of appointing a responsible officer could be greater for designated bodies that do not already employ a doctor that fulfils the requirements to be nominated or appointed as the responsible officer. In this case, they would need either to nominate a doctor outside of their organisation or employ a new doctor in order to comply with the regulations. The total cost of employing an appropriate doctor is in the range of £125,000 to £200,000 on-cost figures, but the net additional cost to the organisation would be potentially smaller because they would benefit from all the other work that doctor would do.

109. Locum agencies within the NHS framework agreement are designated and an expert consulted estimated that only about 7.5% of them employ any full-time doctors that could be nominated as responsible officers, so the impact on them could be significant if no provisions are made. 94% of these 53 agencies are small or micro size (less than 50 and 10 employees respectively) and 6% are of medium size (50 or more employees). It is clear that smaller agencies that do not already employ a senior doctor suitable for being nominated or appointed would face the whole cost of appointing a full time responsible officer if no special provisions were made.

110. This is why provisions have been made that should reduce the impact of the policy on small organisations for whom employing a doctor to appoint as the responsible officer would impose too great a burden. The relevant legislation is:
- Regulation 8 : "A single person may be nominated or appointed as the responsible officer for two or more designated bodies"
- Regulation 14 : "Each designated body must provide its responsible officer with the sufficient resources necessary to enable the officer to discharge their responsibilities for that body under Regulations 11 and 13".

111. From these regulations, we anticipate that organisations could have two alternatives to appointing a responsible officer that could reduce the burden on them. They could pay a larger organisation to provide a responsible officer, i.e. through nomination, or they can employ a doctor on a part-time basis in order that they can be designated the responsible officer.

If organisation 'A' chooses to act in accordance with Regulation 8 that is, to contract with another organisation 'B' for the costs of a responsible officer's time, we could expect that organisation 'B' would be neither inclined nor disinclined to provide an responsible officer because they would be no better or worse off either way.

112. There are financial and non-financial ways of making larger organisations inclined to help smaller counterparts in this way. Larger organisations might choose to provide responsible officer time to smaller ones because of business linkages or strong network relationships. A desire to preserve vendor-client relationships could provide the incentive for a large firm to help. Alternatively, decision-makers within both organisations could have developed relationships through networks so that the decision takes on a more inter-personal (rather than simply inter-organisational) dimension.

113. If these non-financial incentives are not enough to induce the larger organisation to provide responsible officer services to the smaller one, the latter could introduce financial incentives. Any additional payment beyond the minimum of covering costs would make larger organisations better off if they choose to provide a responsible officer than if they do not. Although this suggests that the additional cost need only be very small, the larger organisations may try to benefit more from the agreement by charging more.

114. The maximum that they could charge would be the cost to small organisations of employing a new part-time doctor to be the responsible officer. If they go beyond this small organisations would choose to employ a new doctor on a part-time basis, since this would leave them better off.

115. Given the small number of firms affected, the likelihood of strong non-financial links and the fact that any financial incentives to provide doctors would be effectively capped by the cost of appointing a part-time doctor, it is reasonable to assume that the cost for a small firm of obtaining an responsible officer's time would be similar for a small firm and a larger organisation.

When the policy is reviewed, it will be necessary to examine available evidence to confirm whether this assumption still holds.

Responsible officers training

116. In order to support the introduction of the role of responsible officers effectively, the Department of Health is developing the training support framework for the responsible officers in England and Wales. This will enable all responsible officers to acquire the competencies whether they are experienced medical managers or are relatively new to the role. Those taking up the role of responsible officer will need to ensure that they are effectively trained. He or she must be able to demonstrate to the public, their colleagues and to their organisation, 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 assessments of performance.

117. The training support framework will include a competence framework along with curriculum for training that will provide the basis for understanding the role of responsible officer by employers, those taking up the role and by training organisations.

118. The programme will be developed in conjunction with providers and users following the consultation. We anticipate the training will take no more than two days.

119. Scotland is planning to organise training for responsible officers in Scotland and the details of the training programme will be announced in due course. For the purposes of this IA it is assumed that these costs are similar to those in England and Wales and therefore the total cost of training based on the estimated number of responsible officers is reflected in the calculations below.

<u>First year</u>

120. According to early contacts with training providers, the cost of training in the first year is assumed to be around £650 per responsible officer for two days of training. This includes an assumed volume discount from the training providers. In subsequent years, the cost of training per responsible officer is assumed to increase up to £1000 for two days. A turnover of 10.5% is also assumed, as above.

If all responsible officers are trained in the first year, the direct costs for that year will be for around 975 responsible officers * £650 = £633,750.

121. Apart from the direct cost of training, there will also be an opportunity cost due to the time taken away from work by responsible officers to receive training over two days:
Responsible officer additional cost, central estimate: 975 responsible officers in total * two working days (14 hours) * (salary of £160,000 +30% of salary as on-costs) / (35 hours per week * 44 weeks per year) = £1,843,636.

122. In the first year subject to Ministerial approval, the direct costs of training will be faced by Department of Health, whereas the indirect costs of training will be faced by both the private (51% of the cost) and public (49% of the cost) sector. This split is in proportion to the split between the number of responsible officers in the public and private sectors, as the costs of training will be faced by each organisation that employs responsible officers, independent of the number of doctors each responsible officer oversees.

The total private sector cost will be £1,843,636*51%= £940,254.

As set out at the beginning of the costs section, the cost imposed on public organisations is assumed to have an additional opportunity cost. The opportunity cost in terms of QALYs foregone will be equal to (£633,750+£1,843,636 *49%)/£25,000= 61 QALYS, which valued at £60,000 each, will give as a total cost including opportunity costs for the public sector of £3,689,116.

Subsequent years

123. In subsequent years, the direct training costs will be 10.5% turnover * 975 responsible officers * £1000 = £102,375.

The indirect training costs will be: responsible officer additional cost, central estimate: (10.5 turnover * 975 responsible officers in total) * two working days (14 hours) * (salary of £160,000 +30% of salary as on-costs) / (35 hours per week * 44 weeks per year) = £193,582

The total private sector cost will be 51%*(£102,375+£193,582)= £150,938.

As set out at the beginning of the costs section, the cost imposed on public organisations is assumed to have an additional opportunity cost. The opportunity cost in terms of QALYs foregone will be equal to 49 %*(£102,375+£193,582)/£25,000 = 6 QALYS, which valued at £60,000 each will give as a total opportunity cost for the public sector of £348,045.

Year 1 Central estimate:£4.6m a year
Subsequent years' central estimate: £0.5m a year

This cost relates to the Regulatory Responsibility aspect of the introduction of responsible officers and therefore applies to England, Scotland and Wales.

Further training may be required either as a refresher or to address issues that arise, but this has not been costed because we do not know the extent of this or how it will be managed. It is not likely to add to the overall costs by a significant amount.

Ensuring quality of appraisal systems

124. The responsible officer would have to ensure that his or her healthcare organisation has a cohort of trained appraisers, that doctors undergo annual/regular appraisal and that the organisation has a system that collects the evidence needed for appraisals. In many organisations, these systems will already exist. The additional workload will relate to ensuring the systems are able to capture the information needed for a fair appraisal.

Nearly all the NHS organisations and majority of the Independent Healthcare providers will already have appraisal systems in place, so the costs are likely to be very small.

Costs of compliance

125. As explained in the "Option description" section, there will be no particular checks of compliance such as inspections so costs will only occur where cases are brought against organisations.

126. The regulations provide the option for the Secretary of State to nominate a responsible officer for a designated body where the designated body has failed to nominate or appoint a responsible officer or in the case where the nominated responsible officer does not meet the conditions. Organisations providing healthcare will have to show that they have appropriate clinical governance systems in place, when registering with the Care Quality Commission.

127. Responsible officers will be licensed doctors and, as such, they will be subject to the same disciplinary regime as any other doctor. They will also have to show how they comply with the GMC's Good Medical Practice for their whole practice, including their role as responsible officer. Responsible officers will also be monitored by their own responsible officer, which should help compliance.

128. Finally, the visibility of the role is likely to give a further incentive for compliance.

We expect that these factors and the last resort of nomination by the Secretary of State will result in organisations and responsible officers themselves complying with the legislation.

129. Compliance with this option would be further strengthened by the adoption of revalidation requirements. With the introduction of revalidation, there will be greater pressure on organisations to ensure that they have a responsible officer to make recommendations on fitness to practise. Organisations that do not appoint a responsible officer will not be able to take their doctor employees through re-licensing. Failing to appoint a responsible officer would therefore be unsustainable because doctors would try to leave in order to keep their license. Clearly, significant changes to expected rules on revalidation processes could cause compliance issues with responsible officer policy. This should be considered if and when changes are made.

Total cost impact

130. According to the calculations above, we estimate that in the first year the total cost will be £26m. Thereafter, we estimate that the total annual cost will be £21.9m per year.

The Present Cost of the project over 10 years and assuming a discounting rate of 3.5% is £192.4m.

Year 1	**Total (£m)**
Skills checking	£2.1
Additional investigation	£19.3
Responsible officers training	£4.6
Total	**£26**

Subsequent Years	**Total (£m)**
Skills checking	£2.1
Additional investigation	£19.3
Responsible officers training	£0.5
Total	**£21.9**

These represent central estimates. Due to the wide margins of uncertainty around the parameters that contribute to these calculations it is difficult to estimate meaningful ranges. The sensitivity analysis conducted below give an idea of the impacts of extreme parameter values.

Net benefits

Year 1	Year 1 (£m)	Subsequent years (£m)
Total Costs	**£26**	**£21.9**
Total Benefits	**£16.4**	**£16.4**

This table shows the quantified costs and benefits. The present benefit of the project over 10 years and assuming a discounting rate of 1.5% appropriate for discounting QALY gains) will be £155.9m.

We expect the net benefits of the policy to be positive, as the benefits shown above are only a fraction of the expected improvement in quality of care and health outcomes as a result of the policy.

Poor practice or misconduct by doctors results in some form of harm for the patients involved. This harm can theoretically be converted into a QALY value, which enables the estimate of a monetary value using the estimated value for a QALY (£60,000).

131. As explained in the "Problem under consideration", the study *Patient safety incidents in British hospitals: preliminary retrospective record review*[11] found 10.8% of patients experienced an adverse incident; of which around half (52 % of all adverse incidents) were judged to have been preventable. These adverse incidents caused permanent impairment in 6% and contributed to death in 8% of cases.

132. In terms of the percentage of incidents that go unreported, according to the NAO's *A Safer Place for Patients: learning to improve patient safety*[12], NHS Trusts estimate that on average 22% of incidents go unreported. These are mainly medication errors and incidents leading to serious harm.

133. According to the "Hospital Episode Statistics: Headline figures, 2008-09"[13] in that year there were 16,232,579 finished consultant episodes. From these figures it can be estimated that that year there were a total of around 1,082,172 incidents of which 238,078 went unreported.

134. The figures above are based on NHS hospital (and independent sector commissioned by the NHS) records alone and therefore the total number of incidents in the health care sector as a whole will be higher.

135. Responsible officer policy has the potential to increase the reporting rate as well as reduce errors and incidents presented in these studies and therefore has the scope to produce significant QALY gains. As explained above, this would happen through two main channels. The first is an increase in the number of cases where remediation is considered appropriate, due to responsible officers being able to detect more cases than current systems. The benefits of £16.4m per year shown above represent a minimum estimate of this effect that is likely to underestimate its total benefit.

136. The second is an improvement of the quality of healthcare provided by healthcare professionals, due to increased scrutiny and improved performance management. This effect has not been quantified but could be significant.

The benefits of even a relatively small rise in the quality of care and patient safety would be sufficient to justify the costs of the policy.

The scale of both costs and benefits is uncertain and depends on several assumptions. While there seems to be sufficient evidence that there is scope to improve the performance and

11 "Patient safety incidents in British hospitals: preliminary retrospective record review" Charles Vincent, Graham Neale and Maria Woloshynowych, BMJ, March 2001, 322:517-519"

12'A Safer Place for Patients: learning to improve patient safety' NAO 2005 http://www.nao.org.uk/publications/0506/a_safer_place_for_patients.aspx

13 http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=193

conduct of doctors and that there is a 'regulatory gap' that should be closed, the size of this gap is by nature difficult to ascertain.

137. We have explored the possibility that the quality of care and patient safety is much lower than our central estimate. We have also explored the possibility of responsible officers receiving additional incentives to investigate doctors beyond the central estimate in this IA. If only the former is true or if both are true, the policy could have increased costs but also far greater benefits than envisaged in this IA.

138. The main remaining risk identified is that, if only the latter is true and responsible officers are incentivised to investigate beyond what would be the optimal point, and, in fact, the 'regulatory gap' is smaller than currently thought, the costs of the policy could outweigh the benefits. The risk is that the net impact of bringing these 'regulatory gap' cases to light and attempting remediation would yield QALYs that cost more than £25,000, therefore leading to fewer benefits for this expenditure than would be expected from alternative uses by the NHS.

139. This risk should be the focus of monitoring and reviewing of the policy when it is evaluated as part of a wider evaluation of revalidation (part of the Professional Standards Programme) in 2011 (this date is subject to review).

Reviewing the policy

140. A series of Pathfinder pilots on revalidation are currently underway. These include a pilot in the West Midlands to focus on the role of responsible officers in the revalidation process. The pilot will also examine responsible officers duties in regards of setting up appraisal systems as well as making sure that appraisers and appraises are matched up and that the relevant information from the organisation is provided. Therefore, the outcome of these pilots will provide an early indication of the impact of this aspect of the responsible officer regulations.

141. The policy as a whole will be evaluated as part of a wider evaluation of revalidation (part of the Professional Standards Programme). This is currently proposed for 2011 but this date is subject to review.

142. When the policy is reviewed and evaluated, the evolution of variables such as percentage of doctors investigated, percentage of investigations resolved in remediation, percentage of suspended doctors and general indicators of doctor performance should be analysed to check whether the assumptions presented here do hold and whether the performance of doctors has improved as expected.

143. Despite the fact that it will be difficult to disentangle the cause for any improvement (as discussed above, policies like Revalidation and Duty of Cooperation pursue similar objectives), a sustained worsening of some of these indicators, such as the percentage of suspended doctors might indicate the policy has not had the intended effect.

144. A first risk to monitor will be the number of investigations. If there is no increase, this could be interpreted as a failure of the policy, as this would mean that the level of under-reported cases had not been eroded.

145. Of particular interest will be the indicators that can shed some light on the effect of the policy on the incentive structure of responsible officers, whether the policy gives responsible officers incentives to detect and remediate cases beyond what would be the optimal point, yielding QALYs that cost more than £25,000.

146. As discussed in the "Assumptions on responsible officer incentives" section this risk is mitigated to some extent by several factors. However, it should still be monitored as part of the post-implementation evaluation.

147. Remediation is one of the main mechanisms through which responsible officers are expected to improve quality of care and therefore its use should also be monitored after implementation. The Department is currently leading a working group on remediation that will perform an evaluation of the cost-effectiveness of remediation based on systematic data collection on the impact of

Specific Impact Tests

A: Competition Impact Assessment

1. The creation of the role of responsible officer will only have marginal effects on competition. The proposals have been deliberately framed to minimise the impact on smaller healthcare organisations (see evidence base).

B: Small Firms Impact Test

2. The Small Firms Impact Test is included in the evidence base.

C: Legal Aid Test

3. The primary legislation allows for the possibility of enforcement of some of the requirements against either individuals or organisations. However, we are not proposing to create offences where it would be necessary to take formal enforcement action against individuals. The proposals in this document will therefore have no implications for legal aid.

D: Sustainable Development

4. The legislation creates a role within organisations that enhances the confidence of the public and the profession in the system of professional regulation, and bridges an existing 'regulatory gap'. As such, it will contribute to the following principles of sustainable development: ensuring a strong, healthy and just society and promoting good governance.

5. The role of responsible officer will be held by a senior individual in an organisation, one with the power to raise issues at board level ensuring that processes and consideration of issues is built into the governance process. By having a clear role in legislation, responsible officers will build confidence with the public that the systems to protect them are strong and healthy. We expect that medical directors, who understand the local issues, will fill the role in the main. They will build the confidence of the profession in a system that will be seen to be just.

E: Carbon Assessment

6. There will be no impact on carbon emissions and greenhouse gases.

F: Other Environment

7. There will be no impact on other environment.

G: Health Impact Test

8. This policy is designed to protect the health and safety of the public by enhancing the processes that will identify poor conduct and performance by doctors.

H: Equalities – (Race, Disability and Gender)

9. See separate Equalities Impact Assessment below (annex: 2)

I: Human Rights

10. We consider the Medical Profession (Responsible Officers) Regulations 2010 will not engage or restrict individuals' rights under the Human Rights legislation. For information relating to equality issues see the Equality Impact Assessment (annex: 2).

J: Rural Proofing

11. We do not believe the policy will impact differently on different communities or doctors in rural communities, although piloting and research is taking place to test this belief.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review];

The policy will be evaluated as part of a wider evaluation of revalidation (part of the Professional Standards Programme).The review date is currently expected in 2011 but is subject to the timetable for the introduction of revalidation.

Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]

The responsible officer policy will be reviewed to ensure that the regulations are operating as expected and whether the policy objectives are being met.

Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]

The review approach and rationale will be set at a later date as part of the wider evaluation of revalidation (part of the Professional Standards Programme).

Any post-implementation analysis should evaluate the evolution of variables such as percentage of doctors investigated, percentage of investigations resolved in remediation, percentage of suspended doctors and general indicators of doctor performance should be analysed to check whether the assumptions presented in the Impact Assessment do hold and whether the performance of doctors has improved as expected. It will also examine the pattern of trends in relation to these variables.

Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]

The baseline against which changes will be measured will be determined at a later date as part of the wider evaluation of the reform of regulation of healthcare professionals within the Professional Standards Programme.

Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]

Objectives of the policy on responsible officers need to be considered in the light of the objectives of the wider programme. These are:

a. Enhance public confidence;

b. Enhance confidence of the profession in the regulatory system; and

c. Bridge the regulatory gap.

The success criteria will be determined as part of that review.

They are however likely to include an evaluation of whether variables such as percentage of doctors investigated, percentage of investigations resolved in remediation, percentage of suspended doctors and general indicators of doctor performance have evolved as expected.

Despite the fact that it will be difficult to disentangle the cause for any improvement (as discussed above,

policies like Revalidation and Duty of Cooperation pursue similar objectives), a sustained worsening of some of these indicators, such as the percentage of suspended doctors might indicate the policy has not had the intended effect.

Of particular interest will be the indicators that can shed some light on the effect of the policy on the incentive structure of responsible officers, whether the policy gives responsible officers incentives to detect and remediate cases beyond what would be the optimal point, yielding QALYs that cost more than £25k.

Remediation is one of the main mechanisms through which responsible officers are expected to improve quality of care and therefore its use should also be monitored after implementation. The Department is currently leading a working group on remediation that will perform an evaluation of the cost-effectiveness of remediation based on systematic data collection on the impact of remediation upon practitioner performance and upon incidence of adverse events. The results will be highly relevant to the post-implementation review of responsible officers policy.

Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]

Revalidation pathfinder pilots, which commenced in April 2010 include aspects of the responsible officer role and the training of responsible officers. An independent evaluation is being planned. The findings of these pilots will help to inform any future review of the responsible officer policy.

Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]
Not applicable