

PR-R9-0114-11002

Evaluating the development of medical revalidation in England and its impact on organisational performance and medical practice: overview report

Julian Archer, Karen Bloor, Chris Bojke, Alan Boyd, Marie Bryce, Jane Ferguson, Nils Gutacker, Charlotte Hillier, Kayleigh Luscombe, Tristan Price, Sam Regan de Bere, Abigail Tazzyman, John Tredinnick-Rowe, Kieran Walshe

University of Manchester, University of York and University of Plymouth.

March 2018.

It is an output from independent research commissioned and funded by the Department of Health Policy Research Programme (PR-R9-0114-11002 Evaluating the development of medical revalidation in England and its impact on organisational performance and medical practice). The views expressed in this publication are those of the author(s) and not necessarily those of the Department of Health.

Acknowledgements

This report represents two and a half years of research effort from a multi-institutional team at the Universities of Manchester, Plymouth and York – the team members are listed alphabetically on the front page because there is simply no way to compare people’s respective contributions.

We are all very grateful to the many people at the Department of Health, the General Medical Council, NHS England, and other national agencies and organisations, and across the National Health Service and other healthcare providers in England who gave freely of their time to take part in our research. Particular thanks go to all the Responsible Officers who took part in our surveys and interviews, and to the organisations which agreed to be case studies, and who gave us access to documents, people and meetings for the research.

We also owe a great deal to Hannah Kendrick who was our project manager and kept us organised for the first part of the project, and to Kristin Trichler who joined the project later on to give us administrative support, and was absolutely crucial in helping the team to produce and edit this report and the accompanying working papers.

Kieran Walshe

University of Manchester

March 2018

Executive summary

This report provides a summary and overview of the findings from research commissioned by the Department of Health's Policy Research Programme to investigate the development and implementation of medical revalidation in England, and its impact on organisational performance and medical practice.

The purpose of revalidation, articulated by the Department of Health, General Medical Council, Royal Colleges and other stakeholders in various policy documents from 2007 to 2012, was essentially twofold – to assure patients, the public, employers and others that doctors are up to date and fit to practise; and to improve performance both by dealing with poor performance and improving professional standards and practice overall. The introduction of medical revalidation has been an important opportunity for research which can inform and support policy and practice in health professions' regulation in the UK and internationally. The findings are of interest not just in relation to the medical profession in the UK, but also to other health professions in the UK and to stakeholders in health professions' regulation in many other jurisdictions.

We find that the introduction of medical revalidation has fundamentally changed the way that the medical profession is regulated in the United Kingdom, creating a new tripartite relationship between the General Medical Council, organisations which employ or contract with doctors, and the medical profession (individually and collectively). We describe this as an employer-mediated professional regulatory regime. It has required many healthcare organisations to strengthen (or establish) systems for clinical governance and their oversight of medical performance. Our key findings are:

- Overall, the implementation of medical revalidation and the many organisational and professional changes associated with it has been achieved, at around the costs anticipated by the Department of Health. We found while there was initial resistance to and concern about medical revalidation, that has largely reduced as doctors and healthcare organisations have engaged with its practical implementation constructively, though there is significant residual scepticism about the process and its benefits.
- Revalidation as it was designed has been easiest to implement in quite large healthcare organisations (like NHS trusts) where the capacity and capability for clinical governance already existed or could be provided, and where most doctors have a fairly straightforward employed relationship with the organisation.
- Revalidation has been more problematic to implement in smaller healthcare organisations (like hospices or private healthcare providers which lacked capacity and capability in clinical governance), in primary care (where NHS England area teams have been expected to manage revalidation for very large

numbers of GPs without the supporting governance infrastructures found in NHS trusts) and for doctors whose relationship to organisations is generally more distant or transient.

- The role of “designated bodies” (the formal term for organisations which employ or contract with doctors) and of Responsible Officers has been crucial to the effective implementation of revalidation. Although the regulations give significant statutory responsibilities to Responsible Officers, who are accountable professionally, as doctors, to the General Medical Council, they do not provide for the corporate accountability of designated bodies for revalidation, or provide any powers for the GMC or others to determine which organisations have the capacity to become or remain a designated body.
- Particular areas of concern include the oversight of locum doctors and of doctors working in private practice, and of doctors who move frequently between healthcare organisations. In these groups, it is often not clear who is responsible for appraisal, revalidation and remediation or how these processes should be resourced. The sharing of information about appraisal and revalidation for these doctors between organisations is generally quite limited. Paradoxically, strengthened clinical governance in many healthcare organisations could encourage some doctors to move to these settings where there is less effective oversight of clinical practice.
- Our research finds many examples of changes and improvements in clinical governance and clinical practice reported by Responsible Officers, particularly in relation to doctors whose practice gives cause for concern or where there are problems or concerns about the quality of care. It is less clear that revalidation has had much impact on the majority of doctors whose performance is good, in supporting or stimulating further improvement.
- We describe the model of revalidation implemented to date as generic, by which we mean that the process is intended to be applicable to all doctors regardless of speciality, work setting, prior performance and other characteristics. We think that this “one size fits all” model had the advantage of simplicity, especially in the first cycle of revalidation where relatively little data about the likely outcomes of revalidation was available. However, a generic model is inherently inefficient, and it would be preferable to tailor the future use of revalidation to take greater account of factors such as specialty/service type, work environment/organisation, and prior performance.
- Measuring the impact of medical revalidation quantitatively is difficult, not least because much performance variation does not relate to doctors individually or to organisations. We found no significant changes in a number of quantitative measures of quality attributable to revalidation for a variety of condition/procedure groups. We did find that the likelihood of consultant medical staff leaving the workforce increased significantly as a result of revalidation.

The Department of Health’s own impact assessment from 2012 predicted the costs of medical revalidation conservatively, and was overoptimistic about the benefits to be realised in this first cycle. Some of the benefits predicted are likely only to be measurable over a longer time period than this research allowed.

But, on the basis of current evidence, we cannot demonstrate that medical revalidation as implemented is a cost-effective policy intervention.

The General Medical Council commissioned a review of medical revalidation from Sir Keith Pearson, which was published in early 2017, and has just published an action plan in response to that review. From our research, we would suggest four main areas in which future improvements to medical revalidation might concentrate:

- Healthcare organisations (“designated bodies” as they are referred to in the regulations) are crucial to the effective use of medical revalidation, but they vary hugely in size, capability and capacity, and approaches to medical revalidation. At the moment there is no mechanism for determining what organisations can or should take on this statutory role. In theory at least, any organisation which employs or contracts with a doctor or doctors can be a designated body, though some organisations (NHS trusts for example) are required to be designated bodies by the regulations. Neither the GMC nor the Department of Health seems to have formal responsibility for maintaining a list of designated bodies. We suggest that a central authority should have statutory responsibility for setting the criteria or requirements to be met in order to be a designated body, determining whether an organisation fulfils those requirements, and maintaining the register or list of designated bodies.
- Doctors who do not work in a conventional, employed relationship for one large healthcare organisation or designated body are not well served by the current arrangements for medical revalidation. This includes locums, doctors in private practice, doctors with no “prescribed connection” to a designated body, and arguably doctors in general practice who are all revalidated by NHS England. We suggest that new arrangements for the oversight of doctors in these groups are needed, which take greater account of the relatively limited clinical governance infrastructure around them. It may be that some organisations not currently acting as designated bodies (CCGs or GP federations for example in primary care) should take on that role.
- A substantial amount of information about appraisal and revalidation is collected at an organisational level, but virtually none of it – beyond the revalidation recommendation – is held by the General Medical Council, and information is not reliably shared when doctors move between organisations. In Scotland and Wales there are information systems for appraisal and revalidation (MARS and SOAR) for all doctors in those two countries. We suggest that the use of a single information system could make appraisal and revalidation more efficient for doctors and designated bodies, support information sharing when doctors move from one organisation to another or work for multiple organisations, and make it more feasible for appraisal and revalidation to cover doctors’ whole scope of practice. It would

also help to support doctors who, as noted above, do not work within a single designated body and its clinical governance infrastructure.

- We have noted that the current generic model of revalidation takes little account of differences between doctors' areas of clinical practice or their specialty, organisational context, and prior or current performance. We argued that generic regulatory interventions tend, by their very nature, to be quite inefficient, and we noted that the impact to date of revalidation seems to have been largely at the lower end of the performance continuum. We suggest that revalidation could be made a more flexible process, with greater capacity for designated bodies and their Responsible Officers to be responsive to differences in specialty/clinical practice area, organisational/work context, and performance.

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1. Introduction

This report provides a summary and overview of the findings from research commissioned by the Department of Health's Policy Research Programme to investigate the development and implementation of medical revalidation in England, and its impact on organisational performance and medical practice. It is supported by a number of separate working papers, which report on specific work packages or projects within the research, and which are listed in Appendix A.

This overview report has five main sections. First, it outlines the background to the research, briefly reprising the research aims and questions from the proposal and outlining the four main work packages within the project. There then follow three sections which summarise our findings on the policy aims and underlying mechanisms of medical revalidation; the implementation and processes of medical revalidation; and the impact and cost of medical revalidation in England. Finally, we draw together our conclusions and reflection on the lessons from the research for future directions in medical revalidation.

2. Background: researching medical revalidation

The introduction of medical revalidation has been an important opportunity for research which can inform and support policy and practice in health professions' regulation in the UK and internationally. The central policy problem – how to provide assurance that health professionals are fit to practise throughout their careers and are encouraged as professionals to maintain and improve their standards of practice – is one of great interest not just in relation to the medical profession in the UK, but also to other health professions in the UK and to stakeholders in health professions' regulation in many other jurisdictions.

Medical revalidation was introduced in December 2012 after more than a decade of policy development and debate about how to assure the continuing fitness to practice of doctors in the United Kingdom. Put simply, it requires all doctors in clinical practice to demonstrate on a regular basis that they are up to date and fit to practise in their chosen field and able to provide a good level of care. It involves doctors collecting a portfolio of supporting information about their practice and reflecting upon it, and undergoing an annual appraisal based around the requirements of the GMC's standards set out in Good Medical Practice. Organisations which employ or contract with doctors are required to appoint a medically qualified Responsible Officer, who has a range of statutory responsibilities for the oversight of medical performance, including managing the revalidation process and making a revalidation recommendation to the General Medical Council about each doctor usually once every five years. If a doctor is not revalidated,

they may lose their licence to practise medicine. The introduction of revalidation is perhaps the most fundamental reform to medical regulation of recent years, and it has significantly changed the relationships and lines of accountability between individual doctors, healthcare organisations and the General Medical Council. It is a controversial reform which is still somewhat contested within the profession. There has been a continuing debate about the likely effects or impacts of medical revalidation, and its capacity both to detect and remedy poor performance and to support and encourage wider improvements in performance.

We identified six main research questions to be addressed in this project, which cover the three main themes outlined above – mechanisms by which revalidation could work; the implementation and processes of revalidation; and the impacts and costs of revalidation. The research questions are:

1. What are the main organisational determinants of medical performance, and how is the development of revalidation expected to affect or change those determinants?
2. What is the underlying programme theory (or theories) for the development of revalidation and its incorporation into existing systems for managing medical performance in healthcare organisations?
3. How is revalidation actually implemented in healthcare organisations – and how does this process of implementation reflect or shape the identified programme theory/theories? What are the experiences, lessons and views of key stakeholders in implementation (such as healthcare organisations/leaders, appraisers, appraisees, and other key actors such as educators, professional associations, etc)?
4. How does revalidation influence or change the management of instances of suboptimal medical performance in healthcare organisations?
5. What are the costs of the implementation of revalidation, and how do different models or approaches to implementation affect overall costs and the distribution of costs?
6. What impact do revalidation and related systems have on medical performance? Are levels and variations in performance at an individual or organisational level partly explained by revalidation and related systems for managing medical performance?

We have undertaken our research in four main “workpackages” – subprojects or components of the research, designed to address these research questions. They are summarised in table 1 below, which shows which of the above research questions they address, and what fieldwork and data analysis we have undertaken.

Table 1. Summary of research project workpackages

<p>WP1 – Review of existing research and evidence, and stakeholder engagement (RQs 1, 2)</p>	<p>This work package sought a clear, shared understanding of the mechanisms for revalidation in organisations and their place within wider systems for managing medical performance. It provided a secure theoretical grounding and framework for fieldwork in subsequent work packages. We undertook a review of relevant literature and existing evidence; a policy analysis using documents from 2010 to 2016; and over 70 interviews with key stakeholders in three phases in 2011, 2013 and 2015.</p>
<p>WP2 – implementation of revalidation: national surveys and organisational case studies(RQs 3, 5, 6)</p>	<p>This work package has developed a detailed understanding of the implementation of revalidation in healthcare organisations in England, framed by the programme theories developed in WP1. There were three main fieldwork components of this workpackage: two national surveys of all designated bodies (DBs) in England; the selection of 12 DBs as case study organisations; detailed qualitative research in each case study organisation using interviews and documents.</p>
<p>WP3 – the management of suboptimal medical practice: organisational case studies and cohort study (RQs 3, 4, 6)</p>	<p>This workpackage examined how revalidation and existing mechanisms for managing medical performance are enacted in relation to doctors whose performance is seen as giving cause for concern and whose fitness to practise may be impaired. We used interviews in case study organisations and NHS England, and a cohort study of about 100 cases of concern in primary care.</p>
<p>WP4 – the impact of revalidation on medical performance (RQ 1, 4, 5, 6)</p>	<p>This work package assessed the impact of revalidation in terms of its wider effects on individual and organisational performance, potential unintended consequences and the costs of implementation. We examined the impact of revalidation and related systems for managing medical performance through a quantitative analysis of secondary data sources in NHS acute care looking both at individual level and organisational level effects, and linking to data from the General Medical Council on dates and outcomes of revalidation for consultants. We used multi-level risk adjustment models, difference in difference and interrupted time series analysis.</p>

3. The purpose of revalidation: policy objectives and policy development

The purpose of revalidation, articulated by the Department of Health, General Medical Council, Royal Colleges and other stakeholders in various policy documents from 2007 to 2012, is essentially twofold – to assure patients, the public, employers and others that doctors are up to date and fit to practise; and to improve performance both by dealing with poor performance and improving professional standards and practice overall. In its cost-benefit analysis of the proposed medical revalidation reforms (Department of Health 2012), the Department of Health set out six anticipated benefits:

- Increased public trust and confidence in doctors;
- Improved patient safety, outcomes and quality of care;

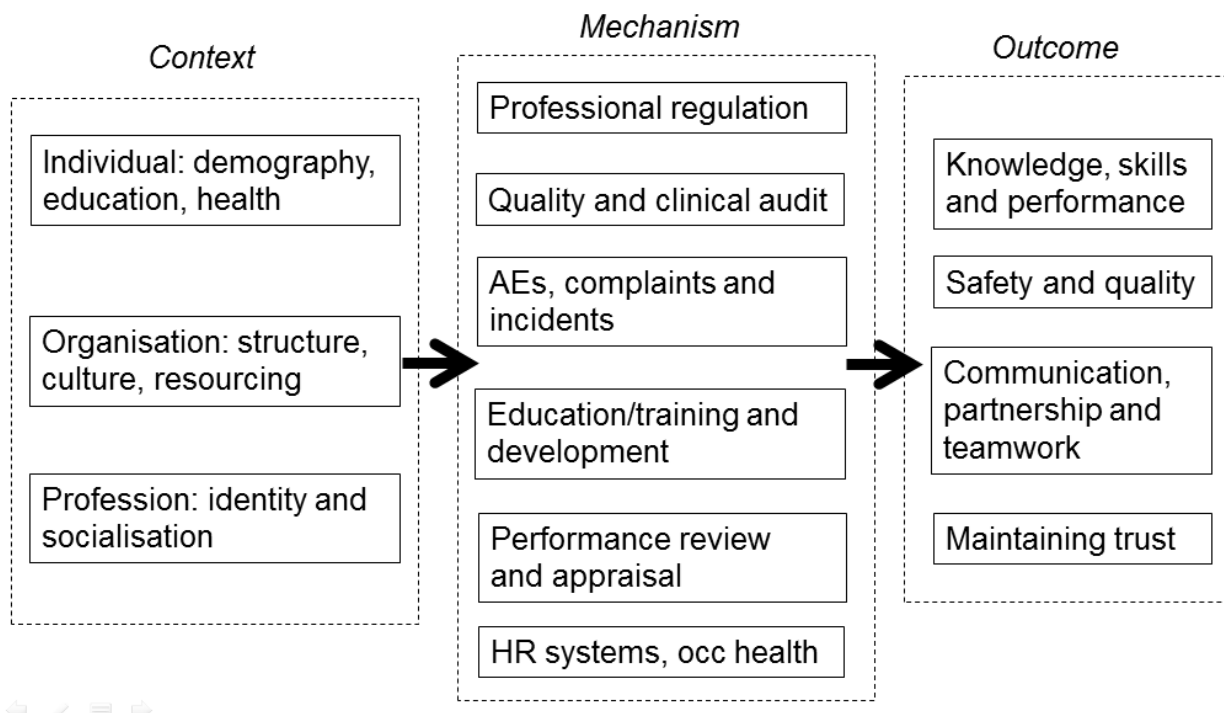
- A reduction in the costs of support for the minority of doctors whose medical practice is poor, through earlier identification of performance issues;
- A reduction in malpractice and litigation costs;
- Improvement in the quality of information about medical care; and
- Supporting positive cultural change in the medical profession.

It is clear that medical revalidation was intended to bring about improvements in medical performance, leading to improved patient safety, outcomes, and quality of care and hence to increased public trust and confidence in doctors, but less clear how those changes were expected to come about. In this section we examine the literature on medical performance and use economic theory to hypothesise how revalidation might change performance; we review the policy literature (reports and other documents from government, the General Medical Council and other organisations) to understand how the policy developed; and we draw on about 70 interviews with key stakeholders who were involved in policy development.

3.1 Revalidation and medical performance: a conceptual model

We undertook a literature review, using the definition of medical performance contained in the General Medical Council's (GMC) guidance for doctors, titled *Good Medical Practice*, which articulates four performance dimensions or domains – knowledge, skills and performance; safety and quality; communication, partnership and teamwork; and maintaining trust. These are the things we regard as “performance outcomes”. We explored the contextual factors which might shape, determine or influence medical performance, and the performance management systems or mechanisms which exist in healthcare organisations, and what evidence there is for how they work or for their impact or effect on medical performance. The resulting model is set out below in figure 1.

Figure1. A conceptual model of medical performance



Our purpose here is to understand how the implementation of medical revalidation might work to change this model of medical performance – what effects revalidation could have on the contexts, mechanisms and performance outcomes outlined in the model.

We conclude that the implementation of medical revalidation is not simply a change to the way the medical profession is regulated. Firstly, it introduces for the first time a formal statutory role in professional regulation for healthcare organisations as employers. By requiring organisations which employ or contract with doctors to appoint a suitably qualified doctor as their Responsible Officer, and giving that person a range of statutory responsibilities concerned with clinical governance including the making of revalidation recommendations to the General Medical Council, the policy effectively extends professional regulation by co-opting the employer to the purposes and processes of regulation, even though the General Medical Council has no formal statutory powers over healthcare organisations. This is a particularly interesting innovation – it effectively creates an employer-mediated professional regulatory regime.

Secondly, the implementation of revalidation requires doctors to undergo an annual process of appraisal (the outcomes of which are used together with other material by the Responsible Officer to make the revalidation recommendation), and the General Medical Council’s detailed guidance on supporting information requirements for appraisal requires doctors to provide information in six areas, and effectively requires healthcare organisations to have systems in place which will produce this information. Again,

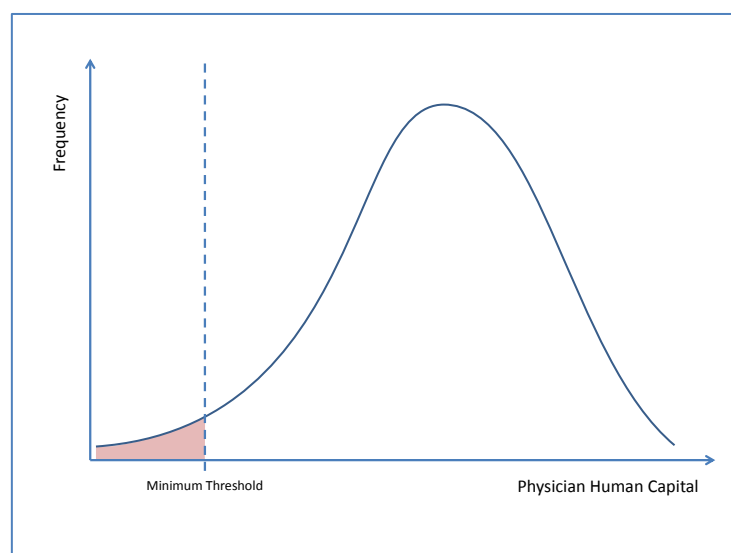
though the General Medical Council has no statutory powers over healthcare organisations, the introduction of revalidation effectively mandates the use of certain organisational systems for managing medical performance.

Measuring changes in medical performance outcomes and then ascribing them to medical revalidation (isolating them from other contemporaneous changes to medical staff training/development, careers, pay and conditions, service organisation, institutional arrangements etc) is rather problematic, not least because the causal chain is difficult to establish. We should be very cautious about attributing such changes to medical revalidation (or conversely concluding if we do not find change that medical revalidation has not worked). Changes in systems and processes, which may be easier both to measure and to associate causally with the introduction of medical revalidation, should be given equal prominence in seeking to understand and evaluate the impact of medical revalidation.

3.2 Predicting the effects of medical revalidation on medical performance

In order to think about how the performance outcomes set out in our model in figure 1 might change with the implementation of revalidation, it is helpful to consider the hypothetical distribution of performance shown in figure 2.

Figure 2. The hypothetical continuum of medical performance



This assumes that performance varies across a continuum (in our example the distribution is slightly skewed with a long tail of lower quality performing doctors). We also suppose that a minimum threshold can be specified such that there should be no doctors practising whose performance falls below this threshold – that is the dotted line on the figure, and the area to the left of that threshold is shaded.

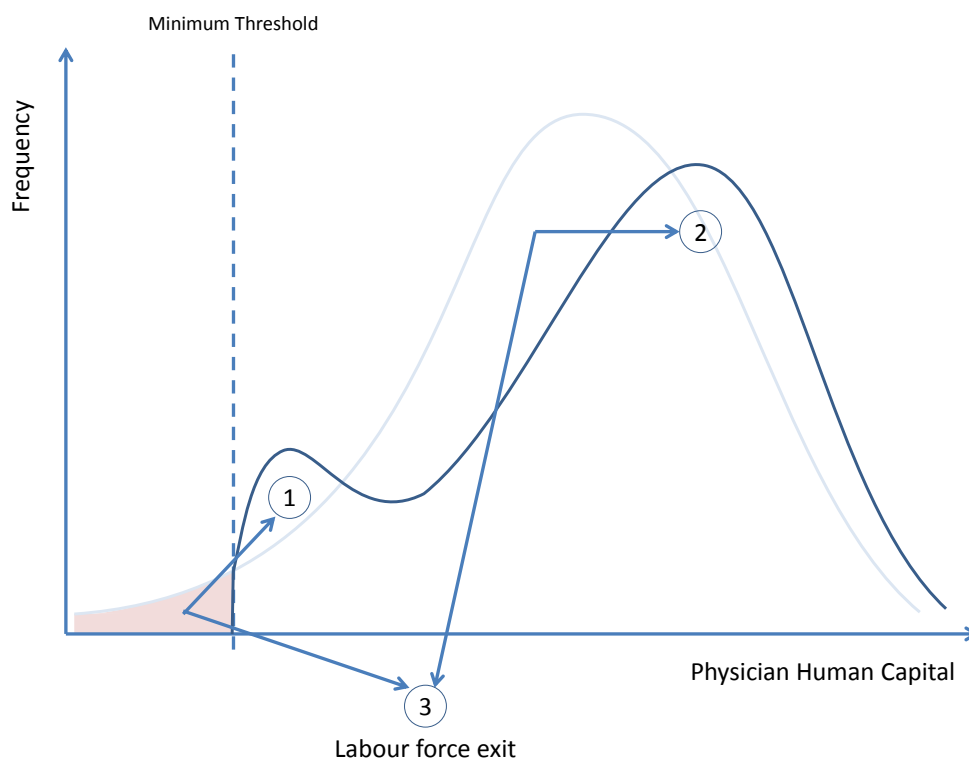
Leaving aside issues like how this threshold should be established, there is a problem in that this distribution will typically be difficult for organisations or regulators to measure. Individual doctors themselves may have a clearer knowledge of where they lie on the continuum, though they too may not have perfect knowledge. Without any knowledge of the distribution of performance, doctors below the threshold would be able to carry on practising.

The process of revalidation, collecting objective evidence on physician performance and training should help regulators form an evidence-based estimate of this distribution. Even if revalidation is sufficiently well designed to capture the whole distribution, however, the simple process of measurement itself may not change the distribution. There might be some intervention that targets those doctors below the threshold such that their performance is increased to a point above the threshold. This might involve further training and would probably incur some costs and take some time to be effective. Nevertheless the impact of measurement plus intervention may be sufficient to change the distribution of physician performance and have a positive impact on the subsequent distribution of patient outcomes. In addition, revalidation could cause doctors in the main body of the distribution to improve their performance. That is, although they are not below the threshold, nor are they perceived as being in any real danger of being below the threshold, it may still cause them to address any limitations identified in their own performance. Thus it is possible the whole distribution may shift to the right rather than just the tail-end of lower quality. Although this shift in distribution may be very small, as it potentially affects the larger group of doctors, the magnitude of impact could be quite large.

Alternatively, some doctors may choose to leave the workforce. This may occur before, during or after the revalidation process. If, for example, doctors have a good idea of their own performance and where they are in relationship to the threshold, then in anticipation of failing to meet the minimum threshold they may choose to leave the workforce. This may include doctors who may be on the 'right' side of the threshold if they are close to the threshold and have imperfect knowledge. Furthermore, the revalidation process itself may impose costs on the individual doctors – time spent on administrative tasks, stress, etc. At the margin, these additional costs may also influence the decisions of doctors to continue in practice or leave. Thus there may be a second impact which affects not necessarily the quality of the medical performance but the quantity.

Figure 3 shows these potential impacts of revalidation on the medical performance: 1) improvement in the tail; 2) general rightwards shift of distribution and 3) a reduction in overall volume via labour market exit from distribution either side of the threshold.

Figure 3. The hypothetical continuum of medical performance after the introduction of revalidation



3.3 Policy development: ambition and realism

We undertook a review of policy documents published from 2010-2016, to seek to understand how the policy on revalidation had been developed before and after the implementation of medical revalidation commenced in 2012. Our review identified 114 revalidation policy documents over this period, including 24 from governmental and parliamentary sources; 23 from the General Medical Council (GMC); 12 from National Health Service (NHS) national agencies; and 55 from the medical Royal Colleges and professional associations. We also interviewed a range of policymakers and senior leaders to understand their views of medical revalidation and its implementation – 71 interviews with 60 individuals were conducted at three points in time: 2011 (n=31), 2013 (n=26) and 2015 (n=14). Interviewees were drawn from the Department of Health, General Medical Council, Royal Colleges, professional associations, employer associations and a range of other stakeholders.

We found that the focus of the policy debate shifted over time from the establishment of revalidation policy and principles in 2010 to the discussions concerned with implementation from 2012 onwards, to a greater focus on impact and evaluation from 2015 onwards, as discourses concerning the revision or refinement of revalidation emerged. As one might expect there were discernible differences between the perspectives of the different stakeholders –the GMC tended to focus on the regulatory statutory function,

government and NHS agencies were concerned with the wider systems of accountability and quality assurance, while the Royal Colleges were primarily interested in issues relating to the quality of care/practice and professional development. These differing perspectives are highlighted because over time we observed a shift in ownership and responsibility for revalidation and its implementation – with the medical Royal Colleges becoming less influential and more marginal to revalidation, and the General Medical Council and, to some extent, the Department of Health and national NHS agencies taking the leading roles in its development and implementation.

We also observed a gradual “drawing in” of the ambitions for revalidation – a narrowing of scope, and some lowering of expectations over time. Before 2012, this was most obviously demonstrated by the decision not to have dual relicensing and recertification arrangements with Royal College set standards and appointed advisors and to move to a more generic and arguably less demanding set of standards for revalidation, but it is also seen in the policy discourse as a shift from ambitions to improve clinical practice across the profession to an increasing focus on getting revalidation established and accepted successfully, albeit with a relatively low bar for this first cycle of revalidation. It is also notable that some difficult or problematic issues in revalidation – for example, the nature of local organisations and Responsible Officers and the way they would enact their role, and the implementation of revalidation for doctors who were not in a straightforward employed relationship with a single organisation such as those in sessional, portfolio or locum roles – were raised early in the policy process and discussed but essentially not resolved, and they resurface as concerns repeatedly over time, including in the most recent review of revalidation undertaken for the GMC in 2016.

We found from our interviews that two discourses were present across the period from 2010 to 2016: professionalism (emphasising formative, development review and improvement drawing on professional traditions of peer review and self-regulation) and regulation (focused more on summative assessment, accountability and meeting performance expectations). However, the nature of the relationship between the two purposes and the way they were described by interviewees changed over time, with the separate discourses converging, and early concerns about actual or potential conflict being replaced by perceptions of co-existence or even co-dependency. It seems that the experience of “doing” revalidation led stakeholders to find they could at least co-exist without too much dissonance in practice. Indeed, some stakeholders began to see the dichotomy between professional and regulatory purposes as somewhat artificial, and to argue that dealing with concerns about poor practice and seeking to improve professional standards were complementary and even co-dependent.

Our interviews suggested that the key actors in revalidation, such as responsible officers and appraisers, had committed to the policy and its implementation but were not always supported by adequate resources

and infrastructure. Cultural resistance and hierarchical boundaries and traditions meant not all doctors were willing to work with others for the purposes of revalidation, and some doctors reportedly felt that revalidation diminished their professional status and positioned them as more like other employees. But again, it seemed that these cultural changes were becoming normalised, in part through new doctors more familiar and comfortable with reflective practice entering the profession.

Most interviewees noted that it was not the principle of revalidation that was in contention but rather the difficulties or challenges encountered in integrating it into working practices. There was evidence that the sense makers of revalidation within organisations were starting to think about how the process of implementation had unfolded, both to highlight problems and to suggest improvements. Revalidation was discussed as “a work in progress”, needing improvement but now accepted by the majority of doctors.

4. Implementing medical revalidation: systems and processes

We conducted an online survey of all Responsible Officers (ROs) in the UK between June and September 2015. We wanted to map how revalidation had actually been implemented by designated bodies (DBs), and how it had interacted with other organisational systems for managing medical performance. We got responses from 374 out of 595 ROs surveyed (response rate 63%). We conducted a second survey of Responsible Officers (ROs) in England between November 2016 and January 2017. This secured responses from 327 of 521 ROs surveyed (response rate 63%). We also conducted a qualitative study of the implementation and running of revalidation across a wide range of 12 case study sites, chosen to represent a range of different NHS and non-NHS organisations. In 2016 and 2017 we undertook a total of 84 interviews with clinical and non-clinical staff involved or connected to revalidation.

4.1 Revalidation: initial implementation

Our first survey found that Responsible Officers believed that revalidation had driven improvements in the use and sharing of information about medical performance within many organisations. This had been principally focused on appraisal as the mechanism whereby information is brought together, considered and used to inform revalidation recommendations. We found that 85% of respondents to the survey perceived that the appraisal system in their designated body had changed; mostly for the better. Improvements in other systems for managing medical performance (continuing professional development/CPD, complaints, quality improvement, significant events/serious untoward incidents, doctors causing concern and fitness to practise) had also occurred, but had been less widespread. Almost half of respondents' designated bodies were reported to have improved their systems in relation to doctors causing concern, and almost 40% were reported to have improved CPD.

Information sharing between organisations and the General Medical Council about doctor performance also seems to have improved, with the GMC's Employer Liaison Service in particular providing better, earlier and more timely access to advice. Over 93% of respondents had contacted ELS advisors, and over 70% of these had found this very useful. It was not clear however that revalidation had driven a similar improvement in information sharing between organisations. Respondents commonly reported difficulties in obtaining performance information about doctors such as locums, who work across more than one DB or about doctors when they move from one DB to another.

We found that the design of revalidation was best suited to larger organisations with a substantial pre-existing clinical governance infrastructure. Smaller designated bodies in particular found revalidation onerous and a strain on their resources and capabilities. Many ROs had added revalidation to their existing leadership responsibilities without having sufficient additional hours allocated to this activity by their organisation.

Very few Responsible Officers wanted to see a reversal of policy on medical revalidation, but many thought it could be made more effective and efficient, and there were some clear and consistent messages about how that might be achieved. Moving from a "one size fits all" single model of revalidation to allow some legitimate and appropriate variation in the way the policy is applied seemed to have widespread support. This could mean differences in the way it worked with organisations with many or few employed doctors; with organisations where there was a close or more distant relationship with employed doctors; with doctors in different fields or specialties due to the clinical content and nature of their work; and perhaps most controversially with individual doctors according to their past and current performance track record.

It was very difficult to answer the question of what impact medical revalidation had had or would have on clinical practice and the quality of medical care from our first survey. There were some early indications that the impact so far was mostly focused on identifying and remediating poor performance, and there was more to be done to ensure that revalidation has benefits and impact for doctors who perform well already.

4.2 Revalidation: making progress

Our second survey in 2016/17 focused on a number of areas of interest, such as quality assurance of appraisals and revalidation, communication between ROs about individual doctors, locum doctors, private practice, patient and public involvement, external revalidation services and outsourcing of revalidation, changes and future improvements to revalidation, and the impact of revalidation.

The quality of appraisals was thought to be dependent on a number of factors, including the appraiser being a medical doctor with formal training in medical appraisal for revalidation. A variety of issues that

may have implications for the quality and consistency of appraisals were identified, such as a perceived lack of consistent guidelines, pressures on resources, appraiser recruitment and retention, information flow and doctor engagement in the process. A number of conditions were thought to be necessary to improve the implementation of appraisal, these included, for example; quality assurance of appraisal process and appraiser, appraisee and appraiser buy in, inclusion of full scope of practice, good resources and administrative support, good appraisal management systems, and a supportive and open culture.

Methods of communication between responsible officers varied and were dependent upon the motive for communication, and substantial discretionary effort on the part of ROs. The Medical Practice Information Transfer (MPIT) form (or similar) was used to communicate information when doctors moved between organisations, but we found a lack of consistency in how frequently it was used and concerns about limitations of the form. ROs reported that they used other channels of communication for more complex cases, or where there were performance concerns.

We found that locum working and private practice represent weak links in the oversight of regulation and clinical governance. Revalidation guidelines had not sufficiently considered the practicalities of implementation in the locum workforce and private practice, leading to ambiguity about who was responsible for overseeing these doctors and some confusion about how to implement the policy. Participants reported poor transfer of information between different settings, and a lack of confidence in the robustness of information provided, making it difficult to oversee the performance of locums and the private practice of doctors. Specifically, locums were highlighted as a point of weakness in systems for communication and for investigating concerns. ROs reported that it was difficult to track and investigate concerns because of the transient nature of locum working. There was ambiguity about who was responsible for reporting information and carrying out investigations, which meant that concerns about locums were sometimes not communicated or addressed and 'low level' concerns were sometimes tolerated and underreported.

There were some similar issues in relation to the private practice of doctors when they worked in other organisations. ROs reported that concerns and complaints were not always communicated to them and were instead dealt with 'in-house'. ROs reported difficulties monitoring private practice due to the poor flow of information and the reliance on organisations and individual doctors to share information. This meant it was difficult for ROs to ensure that revalidation was based on robust appraisals and an assessment of the whole scope of practice for doctors who worked privately.

Respondents reported that there was little or no patient or public involvement (PPI) in revalidation, though where there was some involvement, it was most likely to involve contributions to the development of

patient feedback and governance in revalidation. Some respondents felt that that PPI could contribute to fair and effective revalidation and provide a patient perspective, or a different viewpoint, to medical regulation and the processes surrounding revalidation. However, there were also concerns that PPI was difficult to implement for a number of reasons, such as, recruitment, training and retention of appropriate individuals, a reluctance to see lay involvement encroach on what some saw as a professional domain, the strain it created upon workload and resources, and the limited perceived benefits.

Implementing medical revalidation is more problematic for some designated bodies, particularly smaller ones, and consequently, organisations that provide revalidation services externally have emerged to meet the needs of these organisations and individuals. Some smaller designated bodies reported “outsourcing” the provisions of appraisal and/or revalidation by contracting with another designated body or with individuals to provide these services, and as a consequence, some ROs fulfil this function for more than one organisation. Locum agencies typically used external ROs. Services provided included making revalidation recommendations, dealing with GMC liaison and fitness to practise referrals or doctors causing concern, and organising and undertaking annual appraisals. While outsourcing revalidation made sense for small organisations who lacked the appropriate expertise, there were some disadvantages of outsourcing the RO function including logistical difficulties, lack of strategic and cultural influence of the RO, and a lack of first-hand, real-time knowledge that revalidation is being performed to a high standard.

Respondents described having made incremental revisions and changes to revalidation and appraisal systems. These included, updating policies and procedures and implementing IT systems, as well as changes to roles and responsibilities for ROs. Other changes included the formalisation of decision making groups, and steps to include all groups of doctors in revalidation, particularly those with a more transient or distant connection, such as locums.

In terms of the impact of revalidation, there was a perception that systems such as appraisal, complaints, CPD and audit were more robust and effective as a result of revalidation. Furthermore, doctors’ engagement with these systems was thought to have improved as result of revalidation. However, a minority of respondents remained sceptical about whether revalidation had made an impact on clinical practice and suggested it had created new costs and burdens on doctors when existing systems were already sufficient. While respondents were able to identify how revalidation had impacted systems and engagement, ROs found it more challenging to describe direct impacts on clinical practice, arguing that this was a complex and difficult connection to establish, and that changes were slow to come about. However, some respondents described improvements in knowledge, skills and attitudes or behaviour.

4.3 The role of Responsible Officers and the changing nature of the medical profession

Our findings suggest that the regulatory focus and statutory responsibilities that characterise the RO role mean that those undertaking this work constitute a distinct group of “hybrid professionals”, in that responsibility for monitoring the performance of other doctors within organizations has altered the professional hierarchy, strengthening a divide between ROs as a ‘governance elite’ group and the ‘rank and file’ doctors subject to their oversight.

Establishing whether ROs use their authority within this restructured hierarchy to preserve collective professional autonomy, or whether they operate in support of external standards, acting as a mode of professional self-surveillance interpretable as demonstrating governmentality, is complex. In terms of professional structure, it is apparent that ROs both distinguish the RO role from other managerial work, and that they describe the position of the RO in relation to other groups. Notably, ROs typically described themselves as set apart from and above the doctors whose performance they oversee, and explicitly characterised the relationship between themselves and other medics within their organization in terms of their own authority within that dynamic. However, ROs remain a part of the profession and indeed, their eligibility for the role is contingent upon their membership of the profession. It has been argued that the complex nature of professional expertise renders it necessary for some tasks to be undertaken by those within the profession, and this may be particularly apposite with regards to ‘governance elite’ tasks, with evaluating medical performance likely to be challenging to the profession, making professional qualifications and expertise requisite to achieve credibility in the eyes of other doctors. However, it is also the case that ROs’ status as registered and licensed doctors provides the GMC as regulator with oversight over their performance in the role, through both its FTP procedures and through revalidation itself. ROs’ clinical credentials, therefore, allow them entry to this elite role group but are also the means through which their power is limited, being themselves subject to regulatory authority.

ROs also described their status in relation to wider healthcare management structures in organizations, highlighting that their regulatory responsibilities are conducted in connection with one or more particular organizational contexts. In common, therefore, with purely managerial roles, the RO function is organizationally situated, meaning that experiences of the role are necessarily shaped by the nature of the organization. The way in which ROs make decisions about doctors’ performance, from the information they have access to, through to the administrative or financial support available to them, are all mediated by the organizational context in which the RO operates.

Our findings suggest that the RO has come to embody accountability for medical performance within organisations, balancing authority over rank and file doctors with their responsibilities to the GMC as external regulator. Revalidation, as an on-going process encompassing all doctors, has strengthened regulatory oversight, with ROs being the nexus between the organizational, regulatory and professional spheres.

4.4 Locum doctors: clinical governance and revalidation

Our research on the locum medical workforce suggests that the way locums are employed by the NHS may be problematic and even potentially detrimental for patient safety. Locums reported not receiving adequate induction and experienced poor integration into the organisations where they worked. We found a fairly widespread perception that locums present a greater risk to patient safety. Locums reported that they were often regarded negatively by their colleagues and patients, and were perceived as being less qualified and less capable than other doctors.

Locum doctors were thought to be a greater risk than permanent medical staff by some participants for a variety of reasons, including a lack of confidence in the robustness of the revalidation processes in locum organisations and difficulties overseeing the whole scope of practice for locum doctors. Being on the periphery of revalidation had a number of implications for locums, including confusion about how to enact the policy, a lack of robust recording and transfer of information systems, difficulties achieving the objectives of the policy and a lack of clarity about who was ultimately responsible for locums, including who was responsible for bearing the costs of revalidation. There was also a perception that revalidation in locum settings was of poorer quality than in NHS settings. A lack of robust oversight of locums meant that it was difficult to establish an appraisal record covering the whole scope of practice.

While revalidation was introduced to provide better assurance and oversight of doctors' practice, the policy is perceived to be more applicable and achievable for doctors who are employed largely or wholly by one employing organisation. There was a perception that locum doctors were not fully considered in the development of the policy, and that revalidation was less applicable to locum settings. Locum doctors are expected to revalidate in the same way as doctors who are substantively employed by the NHS; however, findings indicated that locums face a number of challenges achieving revalidation. Participants perceived that locums were less integrated into mainstream clinical practice and experienced barriers to engaging with clinical governance and other developmental activities. Locums, and those working to implement revalidation in locum settings, described difficulties enacting the revalidation policy, such as, collecting the necessary information and engaging in developmental activities required for revalidation. Other difficulties

included poor communication and feedback relating to locum practice, and variable quality of governance and quality assurance. Consequently, while locums were perceived to be higher risk than employed doctors, they were not engaged with revalidation in the same way as doctors working in substantive posts in the NHS.

Furthermore, participants working in NHS organisation reported a lack of robust information from locum agencies. Participants working in the NHS reported that standards of revalidation in locum settings were of poorer quality in comparison to NHS settings and were largely reliant on the probity of the locum, rather than oversight from colleagues or robust collection of information (such as complaints), meaning it was more difficult to establish how safe a locum doctor was. This was accentuated by the ability for locums to change their designated body relatively easily.

4.5 Revalidation and the role of designated bodies

Our research found that employer organisations play an increasingly important intermediary role in the relationship between the GMC and individual doctors, enacting regulatory processes on behalf of the GMC and extending regulatory surveillance and oversight at local level. On the one hand health care organisations have been made accountable for overseeing doctors in a new way, finding that revalidation in practice meant they were in many ways themselves experiencing regulation; the operationalisation of revalidation meant adhering to requirements set out by the GMC, that for many brought substantial changes to governance practice and were potentially costly. On the other hand, they gained new authority and leverage over doctors. The ultimate responsibility for revalidation lay with the individual doctor – but doctors were made more accountable as a result and more reliant on the organisation that employed them. The need for doctors to revalidate and their reliance on organisations to do so thus enabled organisations to legitimately increase their oversight of doctors and bring them into organisational agendas.

The increased reliance of doctors on organisations for support in enacting the revalidation policy was well evidenced by the experience of those who worked outside conventional organisational boundaries, doctors who were not employees, or those who had a relatively transient or distant relationship to their employing organisation. Due to the lack of organisational support available to such individuals the regulatory relationship became increasingly problematic.

Revalidation was experienced as having shifted the regulatory processes ‘upstream’ into the organisational sphere. Having provided an opportunity for organisations to expand their surveillance of doctors’

performance through strengthened mechanisms of accountability and increased requirements to participate in processes of appraisal, the implementation of revalidation was found to have consequently impacted on the position of doctors within the healthcare workforce. In addition to tying doctors more closely into organisations' managerial processes, revalidation was also seen to have brought about some evening out of prior hierarchical differences in approaches to managing different professional groups, positioning doctors more like other employees. This new accountability doctors experienced had been framed, in particular by organisations, the GMC, and doctors in roles contributing to the running of revalidation, as part of their professional obligations, but alongside and perhaps in contrast to an apparent attenuation of professional autonomy and power.

A shared understanding of the aims of revalidation had been established on the whole across the medical profession and by non-clinical staff who were involved in running revalidation systems. Multiple purposes were simultaneously identified by most, specifically: patient safety, the identification and support of struggling doctors and professional accountability. Many reported that that revalidation had helped in some way to meet these aims. Much of the impact attributed to revalidation on the aforementioned factors was discussed as occurring as an indirect result of the policy's introduction by participants. The work revalidation required organisations to do on their pre-existing systems, notably tightening and formalising clinical governance, triangulation of information collected on doctor performance and communication across and between organisation, as well as the increased authority of the RO to manage doctors, were the factors seen as most influential in regards to the introduction of revalidation.

The embedding and acceptance of revalidation was driven by key individuals, specifically the RO and revalidation teams within organisations. These roles were valued and seen as key to the success of revalidation. A two pronged approach was described as being used in organisations by these key individuals to bring about acceptance and ensure all were revalidated; this approach was described as 'carrot and stick' by some of those interviewed. Revalidation teams (the members of whom varied in number and roles across organisations) and ROs provided information, took on the work of making the revalidation process as manageable as possible and voiced the benefits of revalidation in attempts to bring about support and conformity. This approach appeared successful for the most part. However as a last, though seemingly not infrequent, resort the new authority of the RO was described as being used as a stick to bring those not engaging into line. Perceptions of revalidation were described as having gradually improved over time, though not unanimously, with a minority of doctors noted to still be resistant. A generational difference was reported in acceptance of revalidation, with older doctors and those in higher authority positions, presented as more likely to be resistant to revalidation and its peer review. The perceived generational disparity in attitudes towards revalidation was attributed to difference in training and culture.

The impact of revalidation on practice and performance had been thought about and discussed by participants and their colleagues but had not been formally assessed in any organisation. In contrast, organisational systems were or were planned to be appraised and audited by most. Participants' narratives highlighted a conscious move by organisations towards a focus on the quality of their revalidation systems, with assessments and feedback being used to improve them in attempts to make systems more efficient and meaningful. Though no formal assessment of revalidation had been undertaken, most did believe revalidation worthwhile. This view was the result of perceived improvements to organisations and doctors' practice attributed to revalidation. What these improvements were differed across organisations and job roles but can be categorised into eight main areas: continued professional development and keeping doctors up to date; the quality of doctors practice and care delivered; reflection – leading to improvements in patient safety; the quality of appraisal and the appraisal process; improved information recording and flow; communication (within and across organisations); and doctors behaviour to other staff and the likelihood of concerns or behavioural difficulties with a doctor being dealt with.

4.6 Quality and safety systems in healthcare organisations and revalidation

Our case study interviews revealed a clear perception that revalidation has changed the way in which quality and safety data is managed within healthcare organisations. Revalidation has incentivised doctors to access quality and safety data, and at the same time organisations have been incentivised to develop systems for ensuring that all relevant data feeds into appraisal. Notably, the focus here mainly centred on the use of complaints and serious incidents data, with much less of a focus on clinical audit and quality improvement. Importantly, organisations have also developed or maintained systems to ensure that data can inform processes related to safety and performance outside of appraisal. This suggests a recognition that appraisal may be an appropriate forum for quality improvement through reflection on complaints and serious incidents data, but does not negate the need for processes and systems to triangulate that data outside of appraisal to alert organisations to potential patient safety concerns and, relatedly, the identification of poor medical performance.

The case study data shows how the formalisation of appraisal has necessitated the development of systems for improved information flow and communication, especially in larger organisations. IT systems are important for collating data and some organisations are seeking to develop the use of automated systems to bring the data together. However, these systems are limited and real time information on quality and safety data still require personal communication between senior staff. In many cases, the onus of responsibility to bring information into appraisal was on the individual doctor. However, perceived weaknesses in this system have engendered a number of processes within organisations to reduce the reliance on self-reporting. This was through either directing the flow of information directly to the

appraiser, or developing automated systems for collating complaints and serious incidents data in order that they are not reliant on the appraisees finding and presenting the information themselves. Interviewees noted that for both complaints and SUI data it was often unclear, from the data itself, exactly what the doctor's role was within the incident or complaint. The potential for revalidation to impact positively on quality and safety within healthcare organisations, may therefore be dependent on improvements to the way in which quality and safety data around serious incidents and complaints is reported and investigated.

4.7 Revalidation and managing concerns about doctors performance

We noted in section 2 that medical revalidation was expected to result in concerns or problems in relation to medical performance being raised earlier and dealt with more effectively. It was suggested that this would result in fewer formal cases of serious concern (such as those which culminate in a Fitness to Practise hearing following a General Medical Council investigation) and in cases of concern both being identified at an earlier stage and more systematically in healthcare organisations and managed more promptly with better remediation and prevention strategies. We explored this through interviews in our case study organisations, additional interviews in some NHS England area teams, and a cohort study of about 100 anonymised recently closed cases of concerns about general practitioners in five NHS England areas.

We found that in primary care, most concerns are raised as a result of patient complaints, either to the GMC or to NHS England. It was rare for concerns to be raised through the appraisal or revalidation process, apart from a very few concerns that related directly to non-engagement in appraisal or revalidation. Indeed, some interviewees noted their reluctance to see the "safe space" of confidential appraisal used to identify or raise any concerns. Once a concern had been raised, NHS England guidance on how to manage the process was well known and used, though variations in approach were often noted. We found that investigations and further actions (like records audits) quite often uncovered other issues in addition to the original concern, which might suggest that many other issues which could be the cause of concern go unnoticed or unreported in the absence of a patient complaint.

We found most doctors who were the subject of a concern responded quite constructively to the process, accepting the validity of the concern in the main and often seeking out training or other remediation. Those who were compliant in this way tended to see less or no formal action taken as a consequence, even if the original cause for concern involved significant patient harm. When cases were closed, about half involved a recommendation that the case should be discussed at the doctor's next appraisal, though there

was no mechanism for checking that happened. Overall, there was little to suggest that the introduction of revalidation had had much direct effect on the identification and management of concerns.

5. The impact and costs of medical revalidation

Our approach to understanding the impact of medical revalidation was set out in section 3.2 of this report, where we explained how economic theory could be used to generate three hypotheses about changes which we could then test empirically: that we would see an improvement in the tail of the performance continuum; that there would be a general rightward shift in the performance distribution; and that there would be some exit from the workforce from doctors who were either above or below our hypothetical performance threshold (see figure 3). In this section we report on our quantitative analyses directed at testing these hypotheses.

5.1 How much variation in performance measures is attributable to doctors and healthcare organisations

Our first step was to ask how much of the observed variation in performance is attributable to individual doctors, or to the healthcare organisations in which they work. Interventions to improve care quality and reduce variation, such as medical revalidation, operate not just at organisational level but at the level of individual doctors. In the recent past, a number of initiatives have been introduced with the aim of improving hospital specialists' mortality rates through measurement, public reporting and feedback, most notably in cardiac surgery in the UK and US, and in the NHS in England, this has been extended to routine publication of outcome data for consultants (fully-trained hospital specialists) working in various specialities.

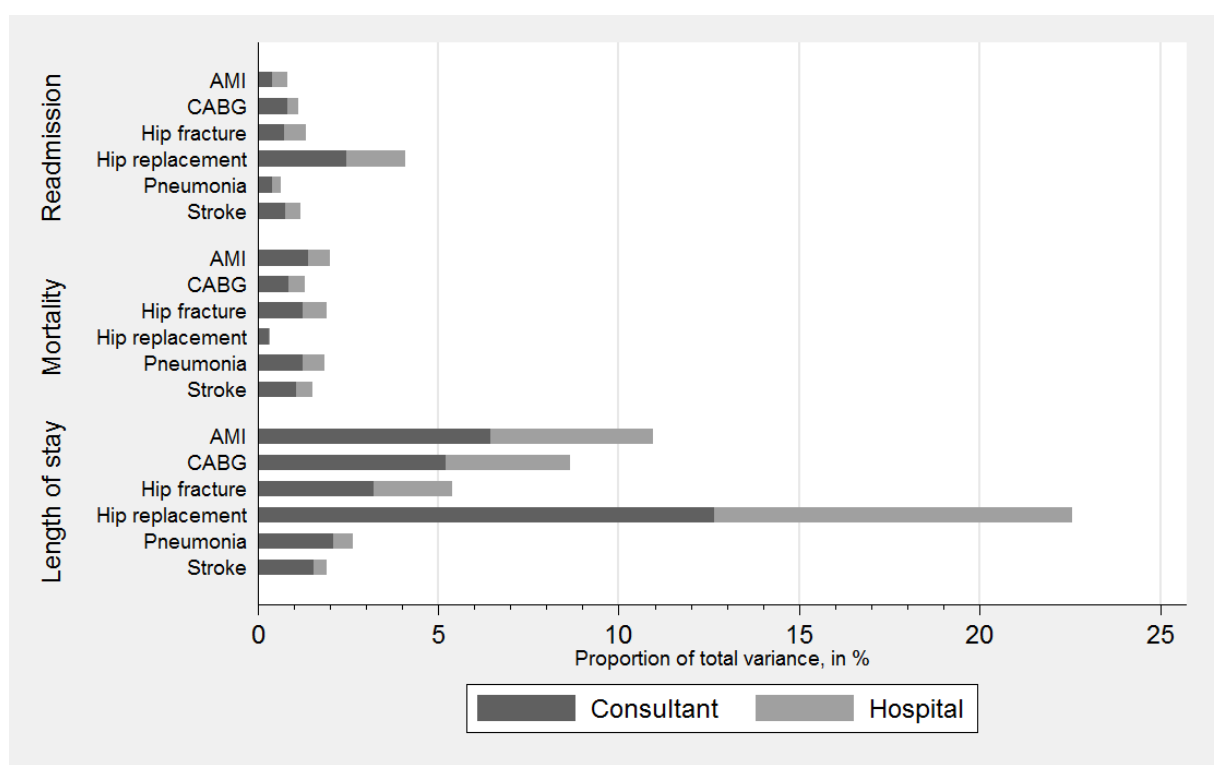
We explored these issues in relation to inpatient mortality, emergency re-admission within 28 days of discharge and inpatient length of stay. The analysis seeks to answer two questions. First, how much variation in observed outcomes can be attributed to individual hospital consultants and how does this compare with the variation attributable to the organisations in which they work? Second, are performance estimates for individual consultants sufficiently reliable to be useful estimates of their true performance?

We used data from Hospital Episode Statistics (HES) on all NHS-funded inpatient care provided in hospitals in England between April 2010 and February 2013. We focused on six conditions/procedures: emergency

admissions for treatment of acute myocardial infarction, acute ischemic stroke, pneumonia and hip fracture; and elective admissions for unilateral primary (i.e. non-revision) hip replacement and isolated coronary artery bypass graft (CABG) surgery. These groups were constructed following US Agency for Healthcare Research and Quality's inpatient quality indicator (IQI) definitions which were recently amended for use in England. Patients were excluded if they were younger than 18 years at the time of admission (<40 years for CABG surgery; <65 for hip fracture) or were living outside of England.

We found, as figure 4 below shows, that except for length of stay after hip replacement, no more than 11% of variation in outcomes can be attributed to doctors and organisations with the rest reflecting random chance and unobserved patient factors. Consultant variation exceeds hospital variation by a factor of 1.2 or more. However, identifying poor performance amongst consultants is hampered by there usually being insufficient numbers of cases per doctor to make reliable estimates of individual performance. Policy makers and regulators should therefore be cautious when targeting individual doctors in performance improvement initiatives, and we should also be cautious in interpreting such indicators of outcome to measure the effects of interventions such as revalidation.

Figure 4. Proportion of variation attributable to consultants and hospitals; case-mix adjusted

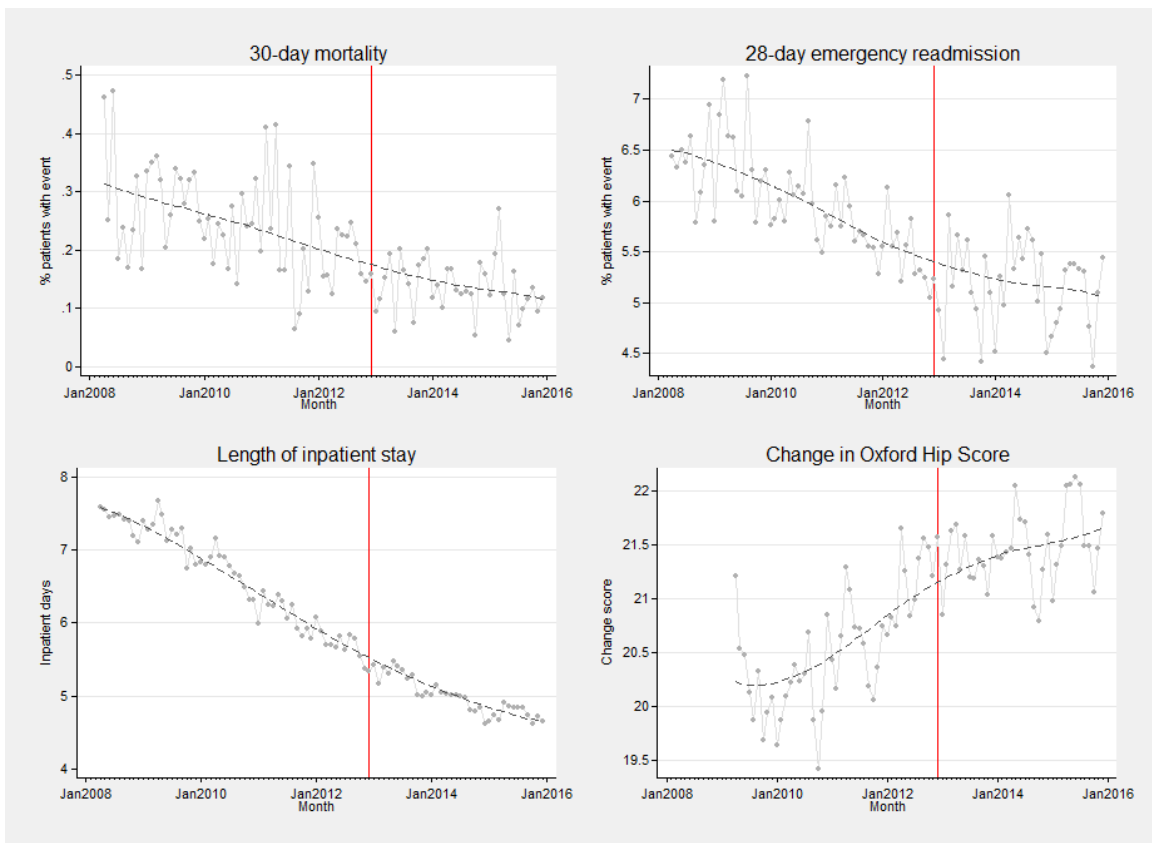


5.2 The effect of revalidation on quality of care

We explored whether hospital consultants' revalidation was associated with any increase in quality of care, as measured by routinely collected indicators. We also explored whether effects vary with previous consultant performance (as measured from 2008-10, before the introduction of revalidation) to illuminate its effect on 'poorly performing' doctors. This retrospective observational study analysed routine administrative data from the English Hospital Episode Statistics (HES) for all NHS patients receiving care in English hospitals during the period 1st April 2008 to 31th December 2015. We focused on six conditions/procedures: emergency admissions for treatment of acute myocardial infarction, acute ischemic stroke, pneumonia and hip fracture; and planned admissions for unilateral primary (i.e. non-revision) hip replacement and isolated coronary artery bypass graft (CABG) surgery. These groups were constructed following US Agency for Healthcare Research and Quality's inpatient quality indicator (IQI) definitions (IQI#12, #14, #15, #17, #19, #20), which were recently adapted for use in England. Patients were excluded if they were younger than 18 years at the time of admission (<40 years for CABG surgery; <65 for hip fracture), were living outside of England, or if information on age, sex or admission details were missing.

Using established measures of safety and quality of care, based primarily on mortality and readmission rates for this set of six conditions/procedures, we found no evidence that revalidation had any effect on the quality of care provided by hospital consultants, either overall or in a sub-group of previously defined 'poor performers'. Although all six of our chosen conditions/procedures demonstrated improvements in mortality over time, these general trends were not affected by revalidation. An example of the graphs for quality measures in one condition/procedure group – hip replacement – is shown in figure 5 below. In each graph the red vertical line marks the introduction of medical revalidation.

Figure 5. Quality measures for hip replacement 2008-2015



The analysis has strengths over and above a traditional interrupted time series. Rather than taking a single intervention point (national introduction of the policy) this analysis uses the fact that revalidation was implemented gradually, and the detail permitted by linking HES data with information from the GMC. Doctors were issued with different revalidation dates and although these were not random we can exploit this variation to estimate robustly the effect of the policy, reducing the risk of confounding by other events. Limitations to the analysis include the imperfect measurement of quality and case-mix adjustment available in routinely collected data. In particular, although HES permits measurement of co-morbid conditions (through secondary diagnosis codes and observation of prior hospital admissions), it is limited in its capacity to measure severity of condition, or clinical details which may affect patient outcomes (e.g. acute myocardial infarction with or without ST elevation).

Our findings are perhaps unsurprising given the relatively small proportion of variation in outcomes that can be attributed to doctors (see section 5.1 above). The findings do not preclude improvements in outcomes resulting in future, as revalidation becomes embedded and potentially changes the culture of medical professionalism, encouraging self-awareness, reflection and continuing professional development, as well as strengthening existing systems of clinical governance. Revalidation is part of a much wider quality assurance system within the NHS, which may be contributing to a general quality improvement as

illustrated by reducing mortality over time as the graph in figure 5 shows. It may also in time contribute to maintaining trust in the medical profession and assuring the public that doctors are up-to-date and fit to practise. At this time, however, we were unable to demonstrate any improvement in quality of care resulting from revalidation.

5.3 The effect of revalidation on the consultant workforce

Preliminary qualitative evidence and theoretical predictions (see figure 3 in section 3) suggested that revalidation may have increased the rate at which doctors leave the profession, so we aimed to explore whether quantitative data supported this assertion.

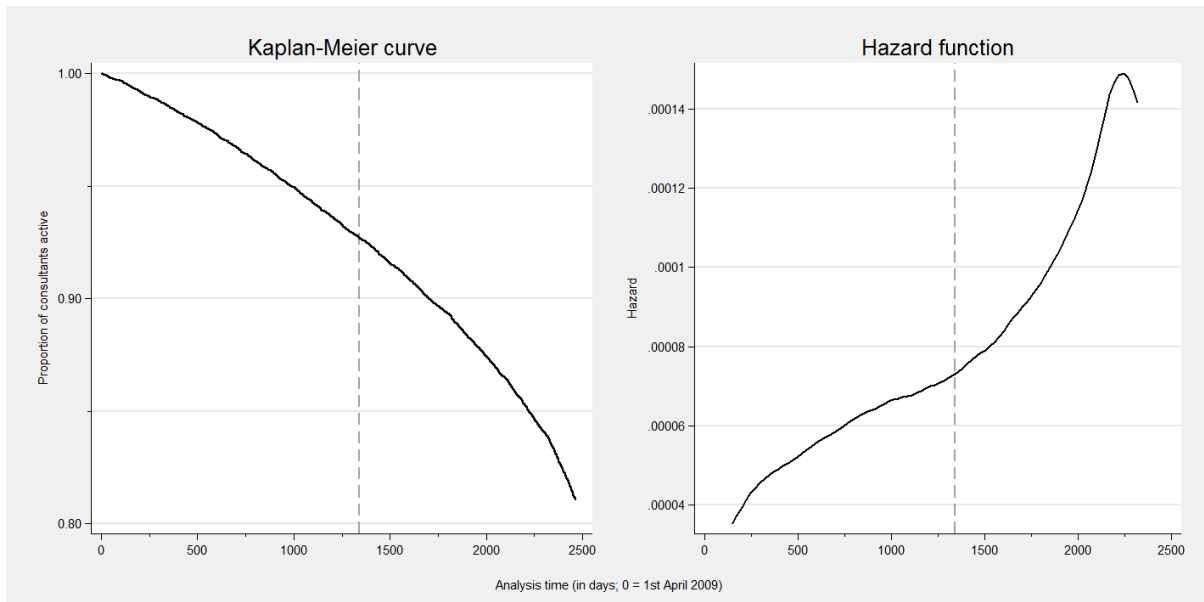
Figures released by the General Medical Council noted that in the three years before the introduction of revalidation (November 2009 to December 2012), 7,994 doctors relinquished their licence to practice, and in three and a half years following its introduction (December 2012 to July 2016) this figure was 33,148 (+256%). It is important to note that this may not be actively practising doctors leaving the profession: many doctors who no longer practice may have kept a licence for various reasons, and they are likely to have been prompted to relinquish this by the introduction of revalidation. From the GMC register there is no way of separating practising clinicians from those who no longer practise but retained a licence.

We analysed activity data from Hospital Episode Statistics (HES) for all consultants in English hospitals from April 2009 to March 2016 (n=19,334). Consultants were deemed to be clinically active at any given date if they took responsibility for at least one full consultant episode (FCE) on this or any subsequent date until the end of the data period (31st March 2016). Consultants were also deemed to be clinically active until the end of the data period if we found them to be employed by an NHS organisation in February 2017 (from the most recent available electronic staff record), which helps to account for absences due to, for example, maternity leave or research leave. Linking HES data with information from the GMC register we estimated semi-parametric Cox models to test whether consultants became more likely to cease clinical activity after the introduction of mandatory revalidation. Crucially, consultants underwent revalidation at different times and we differentiate periods when they were a) not subject to revalidation, b) awaiting a revalidation recommendation, c) after their revalidation had been deferred, and d) after they had received a positive recommendation. We also used difference-in-difference methods to compare the performance (as proxied by 30-day mortality rates) of those who ceased practice and who remained in practice before and after the introduction of revalidation.

19,334 consultants were followed for a total of 44.4 million days. The median follow-up was 2,465 days, around 6.7 years (mean = 2,298 days, 2.3 years). Approximately 17.9% of consultants (n=3,452) ceased to

be clinically active before the end of the data analysis period. Of these, 19.9% (n=689) had received a positive revalidation recommendation prior to exit. Figure 3 shows the Kaplan-Meier survival function and the associated hazard function for the cohort of consultants. The vertical dashed line indicates the introduction of medical revalidation in December 2012.

Figure 6. Kaplan-Meier survival function and hazard function



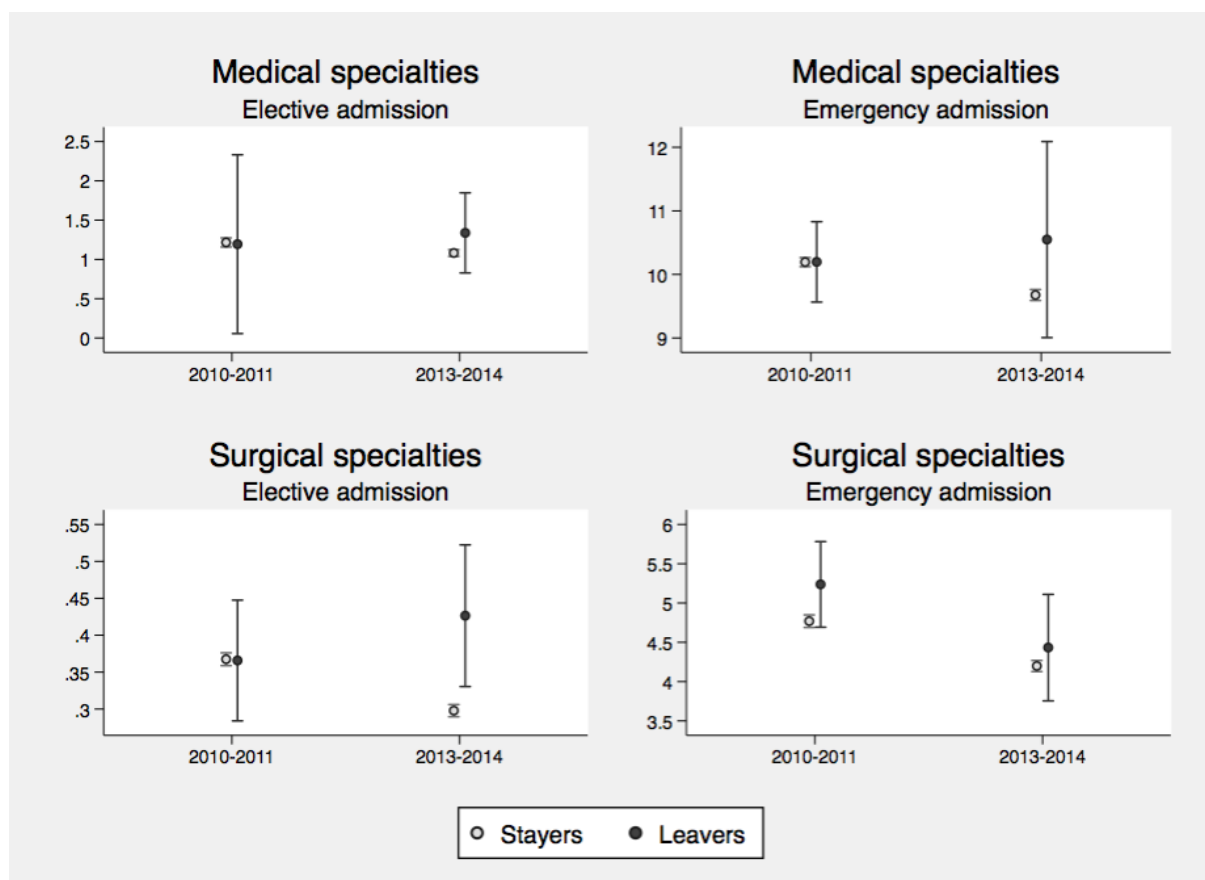
For the cohort as a whole, the proportion of consultants who received a positive revalidation recommendation increased steadily by approximately 1.9% per month after the policy introduction and reached 85.3% by December 2015. ROs issued a recommendation to defer or reported non-engagement for 1,816 consultants, of which 1,278 subsequently received a positive recommendation. The median deferral period was 147 days (interquartile range = 113 to 273).

Consultants that ceased clinical activity before the end of the follow-up period were less likely to have received a positive revalidation recommendation than the overall cohort of consultants in our study (38.2% vs. 86.0%). The proportion of consultants ceasing practice after a decision had been deferred is similar to that measured at the end of follow-up (3.9% vs. 2.0%).

Consultants awaiting their first revalidation recommendation were at higher risk of exit than before they become subject to revalidation (HR: 2.33; 95% CI: 2.12 to 2.57), and the hazard further increased after a recommendation to defer or a report of non-engagement (HR: 3.51; 95% CI 2.71 to 4.55) ($\chi^2(1) = 10.19$; $p=0.001$). A positive recommendation was also associated with an increased risk of exit compared with pre-policy levels (HR: 1.85; 95% CI: 1.65 to 2.06) but the hazard was statistically significantly lower than while awaiting the first revalidation meeting ($\chi^2(1) = 24.36$; $p<0.001$).

Figure 7 shows risk-adjusted 30-day mortality rates for ‘leavers’ and ‘stayers’ before and after the introduction of medical revalidation, by speciality and admission type. . For one group (elective surgical admissions) mortality rates improved over time for patients treated by ‘stayers’ but remained largely constant for patients treated by ‘leavers’, thus suggesting an increasing performance gap between these groups. None of the differences remain statistically significant once we apply a Bonferroni correction to counteract the problem of multiple comparisons.

Figure 7. 30-day mortality rates (95% CI) of stayers and leavers before and after the introduction of medical revalidation



5.4 Revisiting the Department of Health impact assessment for revalidation

To explore the likely costs, cost savings and measurable benefits of revalidation we used as a basis the Department of Health’s impact assessment for revalidation produced in 2012. We reviewed the assumptions made in the DH impact assessment, updating them wherever possible with information that has emerged since these predictions, from our research and from other sources, and we considered areas of uncertainty which may only be determined in the future, over a longer timescale.

The main categories of costs set out in the DH economic model in 2012 were the direct costs of revalidation – essentially the additional time costs of doctors and responsible officers in preparing for and conducting

appraisal and revalidation. Our partner project, funded by the GMC and undertaken by the UMBRELLA consortium, along with this project's surveys of responsible officers (see section 4.1 and 4.2) provide additional information on the actual time spent and the implied costs. Set up and maintenance cost of the regulation system can be estimated from GMC published annual reports. In summary, we found in some instances the original cost estimates were perhaps conservative (particularly in terms of doctors' time spent on appraisal, which DH assumed to reduce following revalidation, and our surveys found to have generally increased), but overall they were not unreasonable.

There are a number of potential benefits of revalidation. The DH case identified as a benefit public assurance in the medical profession but did not make any attempt to quantify it. We reviewed surveys of public trust in professions (data is available annually from Ipsos Mori), which demonstrated trust in the medical profession to be high and largely unchanged over recent years, but this is a small sample and should be viewed with caution.

The main benefits identified by DH related to improving patient safety and improving care quality and patient outcomes. In our project, we estimated improvements in patient safety and hospital quality using a variety of indicators (see section 5.2). DH assumed that 3.7 million patients would benefit by half a day's QALY, which we are unable to substantiate. We used indicators of patient safety and hospital quality created by the US Agency for Healthcare Research and Quality (AHRQ) (see section 5.2), observing these over time. The first revalidation date for each consultant was used as an intervention point with a multi-level interrupted time series approach to attribute any change in trends to the revalidation process. As there were no apparent improvements in estimates of quality or outcomes of care, we did not substantiate the QALY gains that were suggested by the DH impact assessment. Similarly we monitored activity rates per month per consultant from HES data to observe any trends in 'productivity' associated with revalidation, but in a simple interrupted time series analysis (using December 2012 as the intervention point) we found no change attributable to revalidation.

The DH impact assessment makes a number of assumptions around predicted reductions in suspensions and litigation costs. We believe that the lag between an incident and these sanctions is likely to be too long for it to be reasonable to observe benefits within the timescale of this project, so cannot support or refute these assumptions.

In summary, by revisiting the DH impact assessment we found in some instances cost estimates perhaps conservative, but overall not unreasonable. In contrast, we could not support any of the assumed benefits in the DH model, so we find their overall estimate (that benefits would exceed costs within an eight-year timescale) optimistic. There are areas of further potential long-term benefit set out in the DH impact

assessment where there are plausible reasons to expect changes but not within the timescale of this project (e.g. litigation costs, which are highly lagged). These may provide opportunities for future research. But, on the basis of current evidence, we cannot demonstrate that medical revalidation as implemented is a cost-effective policy intervention.

6. Conclusions and reflections

Our research, summarised in this report and described in much more detail in the accompanying working papers, shows that the introduction of medical revalidation has fundamentally changed the way that the medical profession is regulated in the United Kingdom, creating a new tripartite relationship between the General Medical Council, organisations which employ or contract with doctors, and the medical profession (individually and collectively). We describe this as an employer-mediated professional regulatory regime. It has required many healthcare organisations to strengthen (or establish) systems for clinical governance and their oversight of medical performance.

Overall, we find that the implementation of medical revalidation and the many organisational and professional changes associated with it has been achieved. It has been easiest to implement in quite large healthcare organisations (like NHS trusts) where the capacity and capability for clinical governance already existed or could be provided, and where most doctors have a fairly straightforward employed relationship with the organisation. It has been more problematic in smaller healthcare organisations (like hospices or private healthcare providers which lacked capacity and capability in clinical governance), in primary care (where NHS England area teams have been expected to manage revalidation for very large numbers of GPs without the supporting governance infrastructures found in NHS trusts) and for doctors whose relationship to organisations is generally more distant or transient.

We find that “designated bodies” (the formal term for organisations which employ or contract with doctors) and Responsible Officers have been crucial to the implementation of revalidation, though the corporate accountability of designated bodies for revalidation is not well defined. Other areas of concern include the oversight of locum doctors and of doctors working in private practice, and of doctors who move frequently between healthcare organisations. In these groups, it is often not clear who is responsible for appraisal, revalidation and remediation or how these processes should be resourced. Paradoxically, strengthened clinical governance in many healthcare organisations could encourage some doctors to move to these settings where there is less effective oversight of clinical practice.

We found many examples of changes and improvements in clinical governance and clinical practice reported by Responsible Officers, particularly in relation to doctors whose practice gives cause for concern or where there are problems or concerns about the quality of care. But it was less clear that revalidation had had much impact on the majority of doctors whose performance is good, in supporting or stimulating further improvement. Measuring the impact of medical revalidation quantitatively is difficult, and we found no significant changes in a number of quantitative measures of quality before and after the introduction of revalidation for a variety of condition/procedure groups. We did find that the likelihood of consultant medical staff leaving the workforce increased significantly as a result of revalidation. We also found that there were significant differences in performance on mortality between consultants who stayed in and left the workforce after the introduction of revalidation.

The Department of Health's own impact assessment from 2012 predicted the costs of medical revalidation conservatively, and was very overoptimistic about the benefits to be realised in this first cycle. Some of the benefits predicted may only be measurable over a longer time period than this research allowed.

We conclude that the relatively generic, "one size fits all" revalidation model adopted for its introduction had the advantage of simplicity, especially in the first cycle of revalidation where relatively little data about the likely outcomes of revalidation was available. However, this generic model is inherently inefficient, and it would be preferable to tailor the future use of revalidation to take greater account of factors such as specialty/clinical service area, work environment/organisational setting, and prior performance.

Our key findings are:

- Overall, the implementation of medical revalidation and the many organisational and professional changes associated with it has been achieved, at around the costs anticipated by the Department of Health. We found while there was initial resistance to and concern about medical revalidation, that has largely reduced as doctors and healthcare organisations have engaged with its practical implementation constructively, though there is significant residual scepticism about the process and its benefits.
- Revalidation as it was designed has been easiest to implement in quite large healthcare organisations (like NHS trusts) where the capacity and capability for clinical governance already existed or could be provided, and where most doctors have a fairly straightforward employed relationship with the organisation.
- Revalidation has been more problematic to implement in smaller healthcare organisations (like hospices or private healthcare providers which lacked capacity and capability in clinical governance), in primary care (where NHS England area teams have been expected to manage revalidation for very large

numbers of GPs without the supporting governance infrastructures found in NHS trusts) and for doctors whose relationship to organisations is generally more distant or transient.

- The role of “designated bodies” (the formal term for organisations which employ or contract with doctors) and of Responsible Officers has been crucial to the effective implementation of revalidation. Although the regulations give significant statutory responsibilities to Responsible Officers, who are accountable professionally, as doctors, to the General Medical Council, they do not provide for the corporate accountability of designated bodies for revalidation, or provide any powers for the GMC or others to determine which organisations have the capacity to become or remain a designated body.
- Particular areas of concern include the oversight of locum doctors and of doctors working in private practice, and of doctors who move frequently between healthcare organisations. In these groups, it is often not clear who is responsible for appraisal, revalidation and remediation or how these processes should be resourced. The sharing of information about appraisal and revalidation for these doctors between organisations is generally quite limited. Paradoxically, strengthened clinical governance in many healthcare organisations could encourage some doctors to move to these settings where there is less effective oversight of clinical practice.
- Our research finds many examples of changes and improvements in clinical governance and clinical practice reported by Responsible Officers, particularly in relation to doctors whose practice gives cause for concern or where there are problems or concerns about the quality of care. It is less clear that revalidation has had much impact on the majority of doctors whose performance is good, in supporting or stimulating further improvement.
- We describe the model of revalidation implemented to date as generic, by which we mean that the process is intended to be applicable to all doctors regardless of speciality, work setting, prior performance and other characteristics. We think that this “one size fits all” model had the advantage of simplicity, especially in the first cycle of revalidation where relatively little data about the likely outcomes of revalidation was available. However, a generic model is inherently inefficient, and it would be preferable to tailor the future use of revalidation to take greater account of factors such as specialty/service type, work environment/organisation, and prior performance.
- Measuring the impact of medical revalidation quantitatively is difficult, not least because much performance variation does not relate to doctors individually or to organisations. We found no significant changes in a number of quantitative measures of quality attributable to revalidation for a variety of condition/procedure groups. We did find that the likelihood of consultant medical staff leaving the workforce increased significantly as a result of revalidation. We also found that there were significant differences in performance on mortality between consultants who stayed in and left the workforce after the introduction of revalidation.

The Department of Health's own impact assessment from 2012 predicted the costs of medical revalidation conservatively, and was overoptimistic about the benefits to be realised in this first cycle. Some of the benefits predicted are likely only to be measurable over a longer time period than this research allowed. But, on the basis of current evidence, we cannot demonstrate that medical revalidation as implemented is a cost-effective policy intervention.

The General Medical Council commissioned a review of medical revalidation from Sir Keith Pearson, which was published in early 2017, and has just published an action plan in response to that review. From our research, we would suggest four main areas in which future improvements to medical revalidation might concentrate:

- Healthcare organisations (“designated bodies” as they are referred to in the regulations) are crucial to the effective use of medical revalidation, but they vary hugely in size, capability and capacity, and approaches to medical revalidation. At the moment there is no mechanism for determining what organisations can or should take on this statutory role. In theory at least, any organisation which employs or contracts with a doctor or doctors can be a designated body, though some organisations (NHS trusts for example) are required to be designated bodies by the regulations. Neither the GMC nor the Department of Health seems to have formal responsibility for maintaining a list of designated bodies. We suggest that a central authority should have statutory responsibility for setting the criteria or requirements to be met in order to be a designated body, determining whether an organisation fulfils those requirements, and maintaining the register or list of designated bodies.
- Doctors who do not work in a conventional, employed relationship for one large healthcare organisation or designated body are not well served by the current arrangements for medical revalidation. This includes locums, doctors in private practice, doctors with no “prescribed connection” to a designated body, and arguably doctors in general practice who are all revalidated by NHS England. We suggest that new arrangements for the oversight of doctors in these groups are needed, which take greater account of the relatively limited clinical governance infrastructure around them. It may be that some organisations not currently acting as designated bodies (CCGs or GP federations for example in primary care) should take on that role.
- A substantial amount of information about appraisal and revalidation is collected at an organisational level, but virtually none of it – beyond the revalidation recommendation – is held by the General Medical Council, and information is not reliably shared when doctors move between organisations. In Scotland and Wales there are information systems for appraisal and revalidation (MARS and SOAR) for all doctors in those two countries. We suggest that the use of a single information system could make appraisal and revalidation more efficient for doctors and designated bodies, support information

sharing when doctors move from one organisation to another or work for multiple organisations, and make it more feasible for appraisal and revalidation to cover doctors' whole scope of practice. It would also help to support doctors who, as noted above, do not work within a single designated body and its clinical governance infrastructure.

- We have noted that the current generic model of revalidation takes little account of differences between doctors' areas of clinical practice or their specialty, organisational context, or prior or current performance. We argued that generic regulatory interventions tend, by their very nature, to be quite inefficient, and we noted that the impact to date of revalidation seems to have been largely at the lower end of the performance continuum. We suggest that revalidation could be made a more flexible process, with greater capacity for designated bodies and their Responsible Officers to be responsive to differences in specialty/clinical practice area, organisational/work context, and performance.

Appendix A. List of accompanying working papers

The table below lists the sixteen working papers which accompany this overview report. Each working paper is designed to be a self-standing paper, capable of being read and used independently, and each focused on a particular area of interest or concern. Some were produced for our interim report in 2016. A number of them will go on to be published, often in edited form, as academic journal papers, and this is noted as appropriate in the table.

<i>Number</i>	<i>Title</i>
1	How medical revalidation could change medical performance: a literature review and conceptual model.
2	A policy review of the formation and implementation of medical revalidation in England
3	The evolving purposes of medical revalidation in the United Kingdom: a qualitative study of professional and regulatory narratives (accepted for publication in <i>Academic Medicine</i>)
4	The implementation of medical revalidation: an assessment using normalisation process theory (accepted for publication in <i>BMC Health Services Research</i>)
5	Implementing medical revalidation: organisational changes and impacts – findings from a survey of Responsible Officers in 2015 (published as: Walshe K, Bryce M, Luscombe K, Tazzyman A, Tredinnick-Rowe J, Archer J. Implementing medical revalidation in the United Kingdom: findings about organisational changes and impacts from a survey of Responsible Officers. <i>Journal of the Royal Society of Medicine</i> , 2017; 110(1): 23-30. DOI: https://doi.org/10.1177/0141076816683556).
6	Implementing medical revalidation – findings from a survey of Responsible Officers in 2016/17
7	Policing the profession? Regulatory reform, restratification and the emergence of Responsible Officers as a new locus of power in UK medicine
8	Implementing revalidation in the locum medical workforce
9	Reforming regulatory relationships: the impact of medical revalidation on interactions between doctors, employer organisations and the General Medical Council
10	Implementing revalidation – from policy to practice: an assessment using normalisation process theory
11	Revalidation and its impact on systems for quality and safety within organisations
12	Medical revalidation and the management of doctors causing concern
13	Should interventions to reduce variation in care quality target doctors or hospitals? (under

	review by <i>Health Policy</i>)
14	The effect of medical revalidation on patient outcomes and quality of care
15	Does regulation encourage doctors to leave practice? Analysis of routine hospital data in the English NHS following the introduction of medical revalidation
16	Costs and consequences of medical revalidation