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Implementing medical revalidation in the United Kingdom: Findings about organisational changes and impacts from a survey of Responsible Officers

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Summary

Objective: To describe the implementation of medical revalidation in healthcare organisations in the United Kingdom and to examine reported changes and impacts on the quality of care.

Design: A cross-sectional online survey gathering both quantitative and qualitative data about structures and processes for medical revalidation and wider quality management in the organisations which employ or contract with doctors (termed 'designated bodies') from the senior doctor in each organisation with statutory responsibility for medical revalidation (termed the 'Responsible Officer'). Setting: United Kingdom

Participants: Responsible Officers in designated bodies in the United Kingdom. Five hundred and ninety-five survey invitations were sent and 374 completed surveys were returned (63%).

Main outcome measures: The role of Responsible Officers, the development of organisational mechanisms for quality assurance or improvement, decision-making on revalidation recommendations, impact of revalidation and mechanisms for quality assurance or improvement on clinical practice and suggested improvements to revalidation arrangements.

Results: Responsible Officers report that revalidation has had some impacts on the way medical performance is assured and improved, particularly strengthening appraisal and oversight of quality within organisations and having some impact on clinical practice. They suggest changes to make revalidation less 'one size fits all' and more responsive to individual, organisational and professional contexts. Conclusions: Revalidation appears primarily to have improved systems for quality improvement and the management of poor performance to date. There is more to be done to ensure it produces wider benefits, particularly in relation to doctors who already perform well.

Keywords

Professional regulation, medical revalidation, quality of care, appraisal, evaluation

Background

The introduction of medical revalidation in 2012,¹ after over a decade of protracted policy development and debate,² has been described as the most important change to the way that medical professionals are regulated in the United Kingdom for 100 years.³ Put simply, it requires all licenced doctors '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'.⁴

Medical revalidation was intended to address longstanding concerns about the accountability of doctors and the quality of medical care, 5.6 which became the subject of close public and political scrutiny following a number of inquiries into major failures. The purpose of revalidation has not always been clear but two main aims have featured – that it should deal more effectively with poor or unacceptable practice, and that it should help doctors to improve their practice. There has been extensive professional scepticism about whether it can achieve these aims, and concern about its costs which were estimated by the Department of Health as £97 million a year. 10

For both doctors and organisations, medical revalidation involves important changes to the way that medical performance is managed and assured. It requires healthcare organisations which employ doctors to introduce some new processes for dealing with issues of medical quality and performance and to consider how these relate to existing processes. Revalidation requires every licensed doctor to be connected to one designated body, which is usually their main employer. They must collect, report and reflect on information about various aspects of their performance through an annual appraisal. Healthcare organisations must, through Responsible Officer, make informed decisions every



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five years about whether to recommend to the General Medical Council that a doctor be revalidated, and thus allowed to continue to practise. This presumes the existence of a number of organisational systems for managing medical performance, such as clinical audit/quality improvement, continuing professional development, incident reporting and investigation, and complaints management. One of the potential impacts of the introduction of revalidation is that it would lead to changes in these systems for managing medical performance and the way they are used.

Both the Department of Health' Policy Research Programme and the General Medical Council¹¹ have commissioned research studies of the implementation of medical revalidation. The General Medical Council has recently commissioned Sir Keith Pearson, Chair of the General Medical Council's Revalidation Advisory Board, to lead a review of revalidation.¹²

Methods

We conducted a survey of all Responsible Officers in the UK between June and September 2015. We collected information about how revalidation has been implemented and what resources have been required, how it has interacted with or influenced appraisal and other organisational systems for managing medical performance, what impact it is perceived to have had on these systems and on clinical practice, and how revalidation recommendations have been made. We also sought the views of Responsible Officers about the implementation of revalidation and their suggestions for improving revalidation in the future.

A significant proportion of Responsible Officers fulfil the role for more than one designated body, so to avoid survey overload, we surveyed each of these Responsible Officers only once about the designated body with the greatest number of doctors. A total of 595 survey invitations were issued to Responsible Officers across the UK, and 374 completed survey responses were received (response rate 63%). The response rate did not differ significantly between the countries of the UK or the different regions within England, or between designated bodies who self-reported higher or lower annual appraisal rates in their returns to NHS England, suggesting the responses were broadly representative of designated bodies generally. There was however a significantly lower response rate (just under 50%) from Responsible Officers responsible for designated bodies with less than 20 doctors and from Responsible Officers for locum agencies.

We analysed numeric and Likert scale data from survey respondents using frequency tables and crosstabulations, identifying statistically significant differences through Chi-square tests. We conducted thematic analyses of free text comments. Themes were identified inductively in relation to each question and then compared across questions in order to identify common, cross-cutting themes.

Results

The role of Responsible Officers

Responsible Officers have statutory responsibility for implementing medical revalidation. We found that a high proportion of Responsible Officers are in very senior, board level roles in their designated bodies (64% were the medical director, 6% were an associate or deputy medical director, 8% were consultants and 17% had other roles such as chief executive, deputy chief executive, postgraduate dean, etc.). On average, Responsible Officers had been working in or with their designated body for 10 years. About 15% of Responsible Officers were responsible for multiple designated bodies, with almost 5% being responsible for three or more designated bodies. They reported spending an average of 5.1 hours a week on revalidation.

Figure 1 provides some illustrative comments from Responsible Officers about their role. First, they emphasise the workload involved for them personally and for colleagues, and the administrative resource commitment required from their organisations (which was not always forthcoming). Second, they comment on the increased authority and hierarchical power which the Responsible Officer role has given them. Some see this positively – as allowing them to address concerns about quality more effectively, and giving them some leverage for change – but others express concern that it changes the professional, collegial relationship they have had with other doctors and that the powers could be misused.

Organisational mechanisms for quality assurance or improvement

We asked Responsible Officers a common set of questions about five mechanisms for quality assurance or improvement which are used in the appraisal or revalidation process: appraisal, complaints, significant events or serious untoward incidents, quality improvement/clinical audit and continuing professional development. We also asked about two mechanisms for dealing with poor performance: arrangements for doctors who give cause for concern and formal fitness to practise referral. We were interested in how institutionalised or embedded these mechanisms were, so we asked about the Responsible Officer's knowledge of each one, about whether there was a written policy

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Figure 1. The role of Responsible Officers.

Workload

- "The revalidation process was conceived and launched many years ago without any significant regard or involvement of those who would have to implement it. That is the role of Responsible Officer often fell to medical directors, who already had a full timetable."
- "It is just one of the tasks that need to be incorporated into an individual's job. It has to be
 prioritised alongside all their other work. Gapped admin posts have been a constraint on the
 implementation of revalidation"
- "Only obstacles are resources; time, energy and costs. I also do not get the impression that the revalidation process was considered in sufficient detail before the launch. Questions are often responded to by saying that there is no answer, but that it will get 'figured out'. This uncertainty leads to time, funds and energy losses. I would have liked to see that the introduction was, and current process is, smoother more business-like, clearer processes and policies, perhaps with more legal input and support."
- "...has added to my usual workload but on the positive side, has given me a framework with which to identify problems and act upon them."

Formal authority, power and hierarchy

- "More work! But actually makes the job easier sometimes as now there is a formal process to tackle problems compared to before-i.e., some teeth!"
- "It has undoubtedly increased my workload, but it allows me a clear justification for the quality work that must be delivered with reference to healthcare professionals"
- "I now have a much stronger grip on the performance and conduct of doctors, and have been able to use the needs of appraisal and revalidation to bring about a number of quality improvements that have benefitted the whole organisation."
- "[there is] some slightly greater engagement with doctors but I think they all now associate the Medical Director with being a policeman/headmaster/oppressor."
- "I became Responsible Officer after revalidation was introduced. It gives the Medical Director a lot of (unwelcome) power."

about it, about compliance by doctors with that policy and about whether the designated body's board received reports about the mechanism. We also asked if each mechanism had changed due to revalidation. The results are shown in Figure 2.

It can be seen that three of these mechanisms – appraisal, complaints and serious untoward incidents – are reported to be well institutionalised with high levels of knowledge about them reported by Responsible Officers, organisations having written policies, high compliance reported with those policies and information about these mechanisms being reported to the organisation's board. However, two – quality improvement/clinical audit and continuing professional development – have generally lower levels of reported institutional embedding. It can also be seen that Responsible Officers also report high levels of knowledge of arrangements for managing concerns and dealing with fitness to practise.

As the graph shows, 82% of Responsible Officers reported that the way appraisals were done had changed due to the introduction of medical revalidation, and 46% similarly reported changes in the arrangements for dealing with doctors causing concern. Between 25% and 40% of Responsible Officers reported changes in the other mechanisms shown in

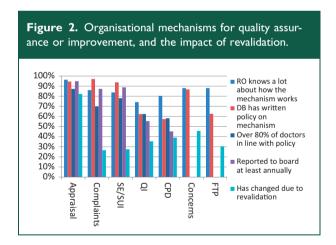


Figure 2. Some examples of their descriptions of these changes are in Figure 3. Across all these systems for quality assurance and improvement, Responsible Officers tended to report that there was greater engagement or participation, that systems were more robust and more formalised, that records of these activities were better kept, that action planning and follow-up in these systems was better and that there was more sharing of information across these systems and within the organisation. Overall, the

Figure 3. Reported changes in organisational mechanisms for quality assurance or improvement due to the introduction of medical revalidation.

- "The appraisal process is much more robust with the introduction of revalidation. The quality is
 continuously checked and improvements made as a result of findings. Our compliance rate has
 improved significantly."
- "Prior to my arrival, all continuing professional development was 'signed off' as appropriate
 by a non-medical member of staff. As Responsible Officer, I now sign off all
 continuing professional development requests, ensuring that continuing professional
 development is appropriate to both the individuals' as well as the organisations overall needs"
- "We have a system that ensures that any complaint activity is not only fed back to the Dr involved - but also to their appraisal. It is part of a corporate information sheet which has to be discussed at appraisal"
- "As an Responsible Officer, I now ask questions about complaints and how they were investigated / resolved that previously I may not have had any knowledge of."
- "Annual appraisal is a powerful reminder to medical staff about importance of engaging within Quality Improvement activities"
- "Learning from audits/ inspections and process improvement initiatives typically leads to
 excellent reflection and very clear Corrective Actions and Plans. These activities are given high
 weighting in 'evidence review'"
- "There is a formal [serious untoward incidents] process to follow now, whereas prior to revalidation there was no one process, and the doctors involved were sometimes not taken to task in the same way as they are now."
- "[Doctors who give cause for concern] It is more formalised and we have a remediation policy
 with more support. We have implemented coaching for doctors for example. We have nine trained
 consultant coaches who coach other consultants as part of a local remediation process. This has
 in my view "saved" careers as well as help doctors improve their skills and so healthcare delivery. I
- "Doctors who give cause for concern: It is a far more robust process now. The linkage with the ELA has helped communication with the General Medical Council."
- "I think perhaps people are more likely to raise concerns about colleagues now than before"
- "1. Less tolerance of doctors not fit to practice; 2. Better understanding of what 'good' looks like;
 3. Colleagues know that raising concerns is part of their duty as a doctor, even about colleagues"
- "We have far more [fitness to practice] cases coming forward and they are exceedingly complex. We have forged a close relationship with our ELA who provides us with an excellent service"

introduction of revalidation had had some wider effects on the way that organisations deal with quality assurance and improvement, particularly in relation to doctors' performance.

About 34% of Responsible Officers reported that there had been more cases of doctors causing concern coming to light since the introduction of revalidation, and 26% of Responsible Officers said there were more fitness to practise case referrals to the General Medical Council. Almost all of the rest said there had been no change in the rates of these cases – only 3% said rates of doctors causing concern or fitness to practise referral had fallen.

Decision-making on revalidation recommendations

The formal revalidation recommendation from the Responsible Officer to the General Medical Council can be to revalidate, to defer revalidation on grounds of insufficient information or an ongoing local process (such as an investigation) or to report nonengagement on the part of the doctor. There is no

option to recommend deferring or withholding revalidation because of the doctor's performance.¹³

We asked Responsible Officers about how they arrived at revalidation recommendations and what recommendations they had made. They reported that information from all the mechanisms for quality assurance or improvement discussed earlier was usually used in these decisions. We found that 88% of Responsible Officers typically reviewed documentation as part of their decision process; with 41% of Responsible Officers reporting that they usually discussed cases with a colleague and 22% reporting that cases were formally reviewed by a committee (Responsible Officers could say they used more than one of these methods, and it was common for Responsible Officers to report that more difficult or complex cases were discussed formally or informally). The Responsible Officer is personally responsible in statute for the revalidation recommendation but 26% of responding Responsible Officers said they, on some occasions, confirmed a recommendation made by someone else, who had typically reviewed the case documentation, etc.

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Figure 4. Challenges in arriving at revalidation recommendations.

- "The definition of concern is broad and ill-defined. I have concerns about several of my colleagues but nothing objective and little in writing. This is not a robust enough evidence trail for action or not giving a recommendation that is positive"
- "Issues that were below the threshold for formal investigation and insufficient to warrant a
 deferral e.g. minor behavioural issues, issues related to the age of the individual but where
 competency was not shown to be materially flawed."
- 'More often than not the concern relates to the quality of the evidence in the Doctors portfolio
 rather than the Doctor per se. Some Doctors whom I have some concern about produce excellent
 portfolios'.
- "Minor behavioural concerns that were addressed at the time but subsequently have escalated
 again. In some doctors they tick all the boxes and can evidence everything that they need to as
 an Responsible Officer you can only really act on the evidence before you and not the "gut reaction.""
- "There are always a few doctors where I and my team spend time discussing the evidence
 because of some concerns. In some instances we have asked the doctor to participate in specific
 educational or improvement activity. We probably now are more inclined to defer if [in] doubt,
 after an experience where we had a positive recommendation and the CQC subsequently visited
 the practice where the doctor worked and discovered very unsafe practice"

The threshold for making a positive recommendation to revalidate seems ambiguous - 28% of Responsible Officers reported that they had made a positive revalidation recommendation while still having residual concerns about a doctor. Responsible Officers can recommend deferral either because they have insufficient information in the portfolio of supporting information (78% reported they had done so about at least one doctor) or because there is some form of ongoing local process such as an investigation (44% had done so again about at least one doctor). The only other option for Responsible Officers is to make a recommendation of non-engagement which can lead to the General Medical Council taking away the doctor's licence to practise and 27% reported making at least one such recommendation.

Responsible Officers commented on the challenges and uncertainties of making revalidation recommendations (Figure 4). First, there was uncertainty about the quality and accuracy of the supporting information in the portfolio from the doctor, and some Responsible Officers expressed reservations about its completeness. Second, there was uncertainty about how or whether to use 'soft intelligence' about the doctor if they had it, especially when the portfolio of supporting information seemed adequate but their personal knowledge of the doctor gave them some cause for concern. Third, there was uncertainty about what recommendation to make in the cases of doctors where there were concerns about their performance but which had not yet triggered any formal process. It seemed that deferral was being used in such cases, though this is not in accordance with the General Medical Council guidance.

Impact on clinical practice and quality of care

We asked Responsible Officers for their views on what impact the various mechanisms for quality assurance and improvement listed earlier (in Figure 2) had had on clinical practice, and their responses are shown in Figure 5. All mechanisms were seen as having little or no negative impact, and while between one-quarter and one-third of Responsible Officers reported that these mechanisms had no impact, between two-thirds and three-quarters reported positive impacts on clinical practice.

Some Responsible Officers gave examples of such changes, of which most (94%) were positive and few (6%) were negative. Positive reported changes related mostly to improved clinical standards, reflective practice, quality assurance and follow-up on instances of poor performance or behaviour. Negative reported changes related to these activities reducing the time doctors had to spend on direct patient care, and them contributing to or causing a less open, supportive or nurturing culture in which doctors might be less willing to raise or share problems.

Improving revalidation

Responsible Officers commented extensively about how revalidation could be improved (Figure 6). First and perhaps most commonly, they saw a need to improve the quality of the annual appraisal process which is central to medical revalidation, through better training for appraisers and more quality assurance. Second, some Responsible Officers believed that there should be greater flexibility to tailor the revalidation model to fit particular organisational or

	A lot worse		A little worse		No change		A little better		A lot better	
	N	%	N	%	N	%	N	%	N	%
Appraisal	0	0%	0	0%	83	23%	212	59%	65	18%
Participation in CPD	0	0%	1	0%	110	35%	145	46%	59	19%
Responses to complaints	1	0%	2	1%	100	30%	171	51%	63	19%
Participation in quality improvement	0	0%	3	1%	70	21%	179	53%	86	25%
Responses to significant events/SUIs	0	0%	1	0%	84	25%	173	51%	83	24%
Actions taken in cases of doctors causing concern	0	0%	0	0%	102	31%	136	42%	88	27%

Figure 5. Impact of mechanisms for quality assurance or improvement on clinical practice.

Figure 6. Responsible Officer's proposals for improving medical revalidation.

- "It is appraisal that is the much more important component, and that training is needed for appraisers to support generation of a high quality appraisal, and a PDP focused on identifying the real development need and followed by action to be taken to meet this in the interest of improved health outcome. The quality of appraisers, their training and assurance is therefore key. [...] Revalidation as a concept should therefore major on the quality of appraisal; having a high quality appraisal should generate an (almost) automatic recommendation for revalidation, in the absence of concerns arising from other sources."
- "A two-tier system would be less onerous for small organisations where the issues are often very
 different and once the structures are in place it is more knowing where to get advice in order to
 ensure consistent decisions made when there are concerns, rather than needing frequent
 network meetings."
- "We need to ensure that doctors are supported and that the pendulum does not swing too far in the direction of an authoritarian or even dystopian future with austere processes and disenfranchised and disillusioned workforce."
- "Communication of revalidation and appraisal history with supporting intelligence re: complaints, claims, SIs and remediation/capability between Responsible Officers needs to be standardised."
- "The variety of ways that appraisal is captured can be problematic and standardisation would be helpful (although difficult to agree). Finding out who a doctor is working for across their whole scope of practice is based upon self-declaration. If employers were made to declare which doctors undertook work for them and this was on GMC Connect [revalidation information system] then it would be easier to contact all employers to get the information necessary to support revalidation."
- "I personally suggest a new category of time-limited provisional or probationary revalidation for
 those who have on-going issues which may or may not be resolved. Responsible Officers should
 have the power to vary RV [revalidation] dates for doctors. This would be especially helpful for
 those approaching retirement.
- "Formal tests of competence starting with a written exam every 5 years. I know exams do not
 test behaviour or the application of knowledge particularly well but if a doctor doesn't have the
 knowledge in the first place s/he certainly cannot apply it!"
- "There is little evidence to suggest that lack of knowledge or skills is a large problem. Generally it
 is poor behaviours and we need a much more robust method of identifying and addressing those
 types of issue."

professional contexts. For example, Responsible Officers in small and non-NHS organisations saw revalidation as onerous, bureaucratic and designed for large NHS organisations. They wanted a lighter touch approach. Third, some Responsible Officers

identified particular difficulties in completing appraisal and revalidation for doctors who moved frequently between organisations (such as locums) or who had portfolio careers across a number organisations. The Responsible Officer in their designated

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body was expected to take account of their performance across the whole of their professional practice, but mechanisms for sharing information between organisations or transferring it between Responsible Officers were not seen as being well developed.

Discussion

Overall, we find that medical revalidation has so far had some important impacts on the way that medical performance is managed and assured – in particular strengthening oversight within organisations (especially those which did not have robust systems in place before) and improving liaison with and communication with the General Medical Council. Of course, our survey is based on self-reports from Responsible Officers and we cannot verify their responses. While our response rate is good, there are some measured differences between respondents and non-respondents which could affect our results, and unmeasured differences could also exist.

We find that revalidation has helped to integrate often diverse sources of information within organisations and has given the Responsible Officer the authority and scope to bring together information on performance and to act upon it. The greatest reported impact has been on appraisal, and many Responsible Officer suggestions for improvement were intended to make appraisal and revalidation work better for doctors who are already performing well. A sizeable minority of Responsible Officers felt that more cases of doctors causing concern had come to light since the implementation of revalidation, and also that there had been more fitness to practise referrals. This is consistent with systems being more robust, but might also be due to Responsible Officers becoming more risk averse, with lower thresholds for raising concerns or taking action.

The introduction of medical revalidation has brought into being the role of the Responsible Officer at organisational level, filled by a senior doctor, with concomitant responsibilities, powers and opportunities. In some designated bodies this seems to be changing relationships between the Responsible Officer and medical colleagues, giving the Responsible Officer greater authority over medical practice. It has also created or strengthened external relationships, between Responsible Officers (in part through the Responsible Officer network meetings they attend) and between Responsible Officers and the General Medical Council.

However, there are concerns about the consistency of medical revalidation within and between organisations and about its coverage, particularly of doctors who do not work predominately in one organisation, but who move between organisations and have portfolio careers. The transfer of information about medical performance between organisations seems problematic. The revalidation model seems to suit large organisations with the capacity to put systems in place but works less well for smaller organisations who employ only a few doctors. The extent to which the Responsible Officer can exercise effective oversight reduces as the 'organisational distance' to the doctor or 'organisational transience' increases. A key challenge would appear to be balancing economies of scale in revalidation systems and administration against the Responsible Officer having a good knowledge of the doctors and organisations they cover and effective means to influence policy and practice in those organisations.

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 seems to have widespread support. This might mean differences in the way revalidation works with organisations having either many or few employed doctors; with organisations where there is a particularly close or particularly distant relationship with employed doctors; with doctors in different fields or specialties, due to the clinical content and nature of their work; and perhaps more controversially with individual doctors according to their past and current performance track record. Many would like to see revalidation made less bureaucratic and time consuming.

Conclusions

It is very difficult to answer the question of what impact medical revalidation has had or will have on clinical practice and the quality of medical care, and more research on this is needed. There are some early positive indications from this survey, and we are exploring both the costs and benefits of medical revalidation further both qualitative and quantitatively in our ongoing research programme. It seems likely that the impact so far is mostly focused on identifying and dealing with poor performance, and there is more to be done to ensure that revalidation has benefits and impact for doctors who perform well already.

Declarations

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