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Reviving clinical governance? A qualitative study of the impact of professional regulatory reform on clinical governance in healthcare organisations in England

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ABSTRACT

Background: Until recently, processes of professional regulation and organisational clinical governance in the UK have been largely separate. However, the introduction of medical revalidation in 2012 means that all doctors have to demonstrate periodically to the regulator that they are up to date and fit to practise, and as part of this process doctors must engage with clinical governance activities in the organisations in which they work.

Objective: To explore how the recent implementation of medical revalidation has affected the arrangements for clinical governance in healthcare organisations in England.

Design: Thematic analysis of interviews with 62 senior clinicians and non-clinicians in management or senior administrative roles, from a range of healthcare organisations in England.

Results: Revalidation has engendered changes to clinical governance systems, resulting in: increased doctor engagement with clinical governance activities; new or improved systems for access to clinical governance data for doctors and leaders within healthcare organisations; and more leverage – through the Responsible Officer role – to enforce engagement with clinical governance. Organisational context has been an important mediator of the impact of revalidation on clinical governance.

Conclusion: Revalidation has increased alignment between systems for organisational and professional oversight and accountability, resulting in increased scrutiny of clinical practice. However, it is still a matter of conjecture whether this will in turn lead to improvements in medical performance.

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1. Introduction

In the UK and globally, the last three decades has witnessed a marked increase in the oversight of healthcare organisations and the doctors that work within them [1]. This shift has been driven by a variety of factors including market liberalisation, pressures

on the delivery of public services, and changing societal expectations towards the medical profession as a result of regulatory failure [1–3]. In the UK, regulatory failures and subsequent public inquiries have had a particularly prominent role in shaping policy developments (see Fig. 1) [4–7]. This paper explores how these reforms have played out in the UK, and particularly focuses on the development of and interaction between systems for professional and organisational regulation.

1.1. Organisational regulatory reform and the introduction of clinical governance

In the late 1990s exceptionally high mortality rates after paediatric cardiac surgery were identified at the Bristol Royal Infirmary in Southwest England [4,5]. The Bristol scandal led to a landmark

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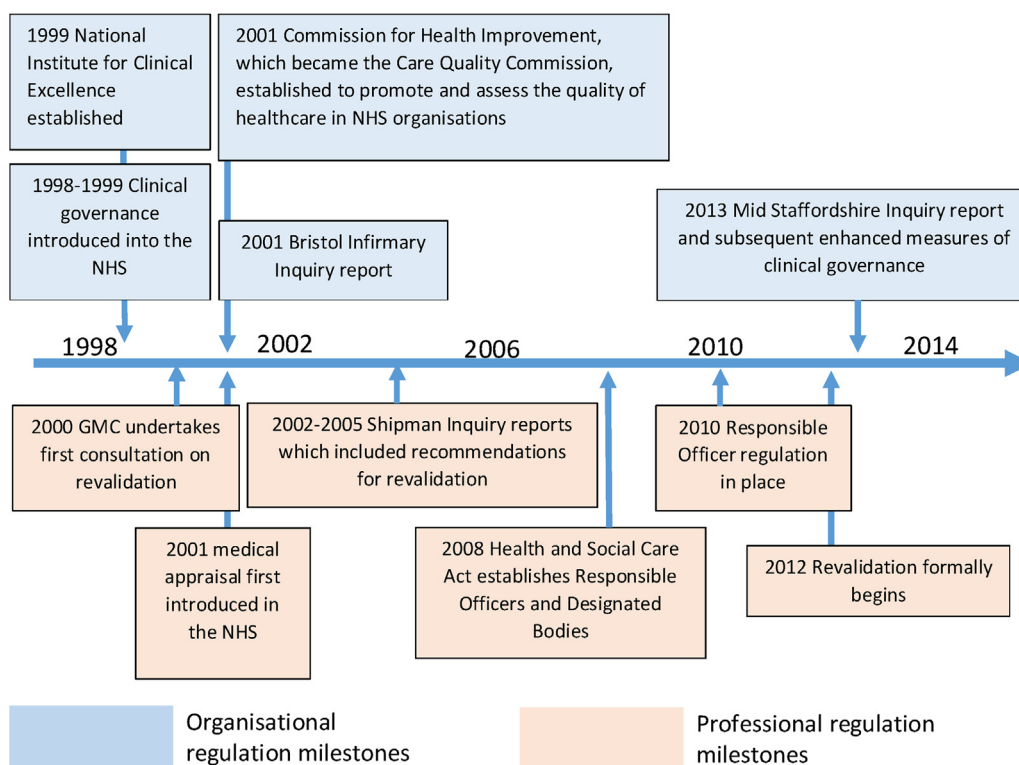


Fig. 1. Timeline of key milestones in organisational and professional regulatory reform.

public inquiry and did much to change public, political and professional opinions about the need for effective oversight and scrutiny of the quality of healthcare [4,5]. In response, the UK government enhanced the level of organisational accountability in the NHS, specifically through the introduction of clinical governance. Clinical governance was based on the concept of corporate governance and entailed many of the same features, in particular the requirement for NHS organisations to have a chief executive and a board which would be responsible for implementing quality improvement systems [6]. However, clinical governance covered a range of activities and was defined by the Department of Health in broad terms: “a system in which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which high standards will flourish” [8]. This included developing systems for reporting and dealing with patient complaints and serious incidents, and conducting clinical audit against nationally recognised standards.

In order to set and monitor standards for clinical governance, the government created new regulatory agencies: the National Institute for Clinical Excellence (NICE), which set out guidelines to reduce variations in the standard of NHS treatment, and the Commission for Health Improvement (CHI), which had the power to monitor and assess NHS organisations [9,10]. CHI’s oversight of clinical governance has continued through its successor organisations, first the Healthcare Commission, and now the Care Quality Commission (CQC) [11].

However, less than a decade after the introduction of clinical governance in the NHS, gross failings of care over a period of five years were identified at Mid-Staffordshire NHS Foundation Trust [12]. The subsequent public inquiry highlighted the inadequacies of clinical governance arrangements in the Trust [13–15]. This resulted in the introduction of additional measures related to the reporting of complaints and safety data, the monitoring of staffing levels, and increased powers of oversight for the CQC [11].

1.2. Professional regulatory reform and the introduction of medical revalidation

The introduction of clinical governance in 1999 did not in itself change the regulatory arrangements for UK doctors [7]. However, the Bristol Royal Infirmary Inquiry had highlighted inadequacies in the regulatory processes for ensuring that doctors remained fit to practise [5]. In 2005 the Inquiry into Harold Shipman, the GP who murdered at least 215 of his patients [3], criticised the UK medical regulator, the General Medical Council (GMC), on the grounds that it had “focused too much on the interests of doctors and not sufficiently enough on the safety of patients” [16]. This led to a review of medical regulation by the then Chief Medical Officer, Sir Liam Donaldson [17], and to reforms of the GMC. The Shipman Inquiry also added a sense of urgency to proposals, which had made little progress for over a decade, for doctors to have to demonstrate their continuing fitness to practise.

Eventually implemented in 2012 after a protracted period of debate [18], medical revalidation is a system of relicensing whereby all UK doctors are required to demonstrate to the regulator (the GMC) that they are up-to-date and fit to practise, by submitting evidence gathered through annual performance appraisals (see Fig. 2) [19]. Revalidation brought new statutory responsibilities for healthcare organisations. The Health and Social Care Act 2008 and the Medical Professions (Responsible Officer) Regulations 2010 require every doctor to have a “prescribed connection” to a particular healthcare organisation, usually their principal employer, and for every organisation which “employs or contracts with doctors” (termed a “designated body” in the legislation) to appoint a senior doctor as the Responsible Officer (RO) [20,21]. This changed the regulatory landscape in the UK, giving healthcare organisations, and in particular the ROs within each designated body, a direct role in regulating doctors [22,23].

The primary regulatory responsibility of the RO is to make a revalidation recommendation, usually on a five-year cycle, to the

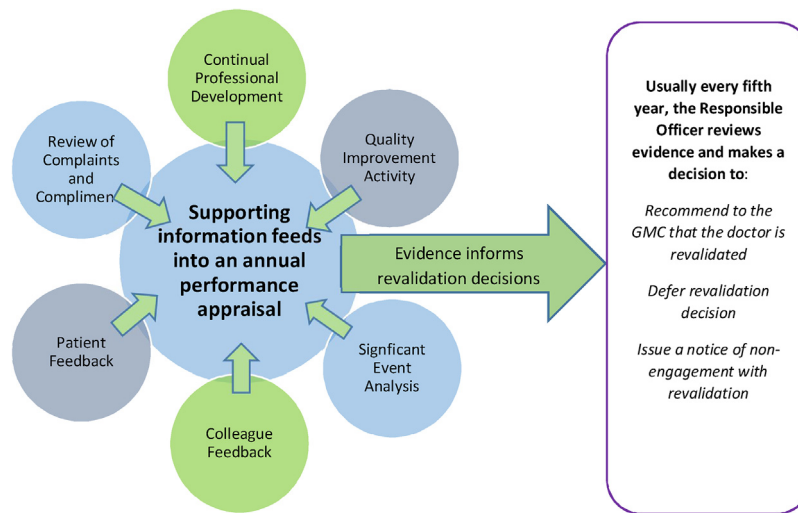


Fig. 2. Supporting information, appraisal and revalidation decisions.

Table 1
Interviews across case studies.

Organisation	Senior doctors	Managers / Directors	Administrators	Total
NHS Foundation Trusts (4)	13	5	4	22
NHS England Area Teams (2)	10	9	2	21
Third Sector / Charities (3)	8	5	1	14
Independent (Private) Hospital (1)	4	1	0	5
Total	35	20	7	62

GMC on each individual doctor within the designated body [24]. The RO also investigates and if necessary refers to the GMC concerns about fitness to practise, and oversees any conditions placed on a medical practitioner’s registration.

In addition, the RO also has an important role in clinical governance. This includes a range of responsibilities related to quality improvement and performance review. The Department of Health’s guidance to ROs states: “The responsible officer has a major role to play in creating and maintaining a culture which not only supports but also encourages good clinical governance” [25].

1.3. Responsible Officers, revalidation and clinical governance

Revalidation has thus created a formal connection between organisational and professional regulation. This is because doctors must evidence, through their appraisal, that they have undertaken clinical governance activities such as clinical audit and significant event analysis [26]. Revalidation is therefore dependent on local clinical governance frameworks and systems [27,28]. Moreover, the remits of the RO role mean that one individual within a designated body now has oversight for both the regulatory process of revalidation and the clinical governance systems that support it.

However, the relationship between revalidation and clinical governance has not been clearly articulated in policy. The GMC’s Chief Executive stated in 2015, that the regulator had neither the capacity nor the statutory remit to “start second guessing and inspecting the clinical governance arrangements” within designated bodies [29, para 95]. Yet it has also been recognised that supporting revalidation is part of clinical governance. Recent guidance issued by the GMC, and co-produced with other regulatory bodies including the CQC, explicitly states that, “deliver[ing]... processes required to support medical revalidation” is one of the “four principles” of “effective clinical governance”. The guidance describes medical revalidation as “a fundamental part of clinical governance for doctors” [30].

2. Methods

This paper draws on semi-structured interviews with medical and non-medical managers, and senior administrators, within designated bodies in England as part of a wider study to examine the organisational impacts of medical revalidation [31]. Using information from a survey of ROs in the UK [32], we purposively sampled 10 case study organisations to give a range of organisational types and sectors (e.g. primary and secondary care), and with different levels of engagement with revalidation, as indicated by the percentage of doctors who had received an appraisal in the previous year.

Sixty-two interviews were conducted with both clinical and non-clinical staff from the case studies (see Table 1). The interviews covered a broad spectrum of roles, including: ROs, deputy ROs, leads for revalidation, appraisal leads, medical directors (if not also the RO), associate medical directors, senior appraisers, heads of clinical governance, appraisal administrators, directors of human resources, and complaints managers amongst others (see Table 2). These roles were chosen for interview as they were directly involved with implementing revalidation and therefore in a position to offer insights into the organisational impacts of this implementation. Of course, these interviewees were not necessarily neutral observers as they were embedded in the organisations we examined. However, we sought to encourage candid reflection through an open approach to interviewing, and interviewed a range of people involved with implementation from each organisation, in order to get a broad perspective and compare different accounts. Semi-structured interviews were undertaken using an interview guide informed by an extensive review of the literature around the determinants of medical performance [33].

Interviews were transcribed and uploaded into qualitative data management software, Dedoose [34]. Data were analysed using a thematic approach; a process of pattern recognition where emerging themes then become categories for analysis [34,35]. Initially, the research team worked together to develop a coding framework

Table 2
Participant roles.

Medical managers / senior doctors
Responsible Officers and former Responsible Officers, Deputy Responsible Officers, Medical directors, Associate medical directors, Appraisers, Clinical lead primary care workforce, development and education
Non-medical managers
Senior HR business partner, Head of medical staffing, Directors of human resources, Senior HR business partners, Head of revalidation, Deputy director of quality and compliance, Heads of clinical governance, Chief nurse and director of operational clinical services, Programme managers, Senior project officers for revalidation, National director of clinical services, Director of professional practice, safety and quality, PAs to senior management, Head of clinical effectiveness, Head of risk, Complaints managers, Consultant liaison and revalidation manager, Local medical committee Chief Executive Officer
Senior administrators
Appraisal administrators, Revalidation administrators, Local Medical Committee secretary

through an analysis of a sample of the data, based on the ways in which revalidation and associated regulatory reforms had been implemented and the subsequent impact on organisational structures and processes. The framework was refined and checked for consistency through a process of blind-coding with five members of the research team, with codes adjusted accordingly [36]. This provided a coding framework that included categories related to the flow of information, decision-making processes involved in revalidation, positive and negative consequences of implementation and organisational contexts. In a further round of coding [37], particular codes that potentially captured data relating to clinical governance were extracted and re-examined for themes specifically related to organisational change as a result of implementing revalidation. The process was both iterative and reflexive, with frequent discussions taking place between members of the research team to interpret the relevance and meaning of the transcribed interview data.

3. Results

Four themes were identified from the process of thematic coding: increased levels of doctor engagement with clinical governance systems; the establishment of systems for easier access to clinical governance data for doctors and leaders within healthcare organisations; more leverage - through the role of the Responsible Officer - to enforce engagement with clinical governance processes, notably in cases where there are issues around clinical performance; and the organisational contexts that determined the extent and nature of the impact of revalidation on clinical governance.

3.1. Increased levels of doctor engagement with clinical governance

ROs, senior managers and administrators reported an increased level of doctor engagement with clinical governance activities as a result of implementing revalidation. In particular, a change in the level of engagement with clinical governance data on serious incidents and complaints was noted. While serious incident and patient complaint reporting were established features of clinical governance systems prior to revalidation, under revalidation doctors have to gain evidence that they have examined and considered any such data relating to their own practice. As a result, interviewees reported that doctors were taking the reporting of incidents and complaints more seriously, and actively seeking out information on incidents and complaints relating to their own practice because of upcoming appraisals, and reflecting on these in their appraisals.

The impact of revalidation in this respect was particularly pronounced for older doctors who had not been as accustomed to being accountable for their practice. Interviewees reported that some of

Table 3
Quotes illustrating increased engagement with clinical governance systems.

"members of staff . . . would come to us and say, can you tell me about this complaint that was raised a couple of months ago, because I've got my appraisal coming up... it's more regular [than pre-2012]." (Interview 51: Complaints manager, NHS mental healthcare foundation trust B)

"doctors' involvement in investigating serious incidents has definitely increased." (Interview 42: Director of HR, NHS mental healthcare foundation trust A)

"And revalidation has identified that actually audit is only one of the tools we can use to show quality improvement." (Interview 68: LMC CEO, NHSE area team B)

"it's actually very difficult for [locum doctors] to do that kind of audit on their work. So, what we've said is, we give a list. . . of what kind of things could be, potentially, quality improvement." (Interview 71: RO, NHS area team A)

"to have evidence of your quality improvement activity and to have evidence of your performance has added a sort of seriousness to the way people think about their professional duties." (Interview 46: RO, NHS acute hospital foundation trust)

"It's [revalidation] made a huge a difference. . . for many of those doctors of our generation, I'm over 60. . . it's taking longer for them to get used to the idea. . . I suppose initially it was around culture, and many senior doctors, I think, had been used to a culture whereby people don't question what they do. . . so I would call it a culture of accountability for outcome, whereas of course revalidation has helped them to understand that what's important is accountability for process, and that actually it's important for you to be able to account for how you do things, as well as for what happens after you've done things to people" (Interview 76: MD, private healthcare provider)

"I think more recently doctor's involvement in investigating serious incidents has definitely increased which means that their contribution to the learning from it and the prevention of recurrence again, it's increased." (NHS mental healthcare foundation trust A, ID: Int 47 - Director of HR)

these doctors were, for the first time, having routinely to engage with these systems and reflect on their practice, particularly in terms of complaints or incidents in which they had been involved. The impact of revalidation was described in terms of changing their attitudes towards a regime of increased accountability.

A further impact of revalidation was to increase the scope for engagement in quality improvement activities. In some cases ROs reported increased levels of doctor engagement in clinical audit as a result of revalidation. However, revalidation had also highlighted the potential for engagement with serious incidents and patient complaints, as alternatives to audit. This impact was most pronounced in primary care and for locum doctors. Engaging with audit can be difficult for these groups, whereas reflecting on complaints and incidents, and conducting case reviews are more accessible and can be useful quality improvement activities. To this extent, the implementation of revalidation had encouraged more doctors to undertake quality improvement practices within their organisations, especially where engagement with clinical audit was a challenge (Table 3).

3.2. Development of information systems

In order to facilitate doctors' access to the requisite information to support their revalidation, interviewees reported the development of systems and processes for collating and transferring clinical governance data, particularly with regards to complaints and serious incidents. While the major driver for these improved systems was to facilitate doctors to access clinical governance information for their appraisal as part of revalidation, it also enabled greater oversight of clinical performance as this data would come to the attention of ROs, deputy ROs and revalidation leads within the organisations.

For example, in the two primary care case studies, systems had been developed to feed information on complaints and serious incidents straight into a doctor's appraisal portfolio, with a clear expectation that the doctor would reflect on this information in their appraisal. The RO would then check for evidence that the doctor had reflected on this information. This effectively increased the

oversight of the doctors, because their engagement with clinical governance activity, particularly around quality improvement, was being more actively monitored.

One limitation to this process was that data on incidents and complaints, and the progress of doctors towards providing the requisite evidence for their revalidation portfolios, would often be held in different electronic systems within an organisation. This meant that in order to make a revalidation decision, someone would have to cross-reference this information. However, across a number of the case studies there were efforts underway to integrate the different reporting systems so that all data could be viewed from a single dashboard, giving ROs a clearer line of sight over performance data.

Revalidation also required ROs to ensure that when doctors moved to new organisations, information could be transferred between organisations. This meant that clinical governance data concerning a doctor's practice could be more readily available and attached to individuals working in different organisations. This was particularly important for private healthcare providers. In the UK, private healthcare providers are often not the employers of the doctors who work in their organisation. Rather, these organisations have a bank of doctors who have "practising privileges" with their organisation. These doctors may conduct some or most of their work in different organisations. Prior to revalidation, there had often been scant information on doctors who worked in private practice as nobody within that practice would automatically have access to information on a particular doctor's performance or engagement with clinical governance activities.

However, under revalidation, all doctors have an RO who has to make revalidation decisions based on the whole scope of their practice. This has meant that the private providers have had to collate clinical governance data on the doctors who have practising privileges with them. Interviewees from a private provider discussed how, in instances where their organisation was responsible for revalidating a doctor, they would have to pull information from other organisations in which the doctor practices in order to get the evidence to make a revalidation recommendation. In cases where one of the doctors practising in their organisation was revalidated by a different organisation, the private provider had to ensure that any data on the doctor related to complaints or incidents, could be moved across to the RO of the doctor's designated body.

In some cases, the implementation of revalidation had also engendered greater communication across teams within organisations. An NHS mental healthcare foundation trust described how those working with incident reporting would, as a result of revalidation, frequently communicate with those administering the revalidation process, to ensure that they had access to the relevant data on an individual doctor. However, not all organisations had implemented effective systems for increasing the flow of information on clinical governance data. Interviewees from one acute trust spoke of the need for improved connection between the revalidation teams and those dealing with incidents and complaints data. This was from an organisation that had been selected because it has low rates of appraisal, suggesting that the extent of the implementation of revalidation varied across organisations (Table 4).

3.3. The leverage of the RO role

ROs reported that their role gave them increased leverage to hold doctors to account for performance issues that are highlighted through clinical governance. The power of the RO in this regard is intrinsically linked to the establishment of enhanced systems for pulling and pushing information, as described above. With revalidation, ROs can more easily link clinical governance data to individual doctors within their organisations.

Two of the ROs we interviewed noted that revalidation had given them the added authority to challenge doctors based on this data.

Table 4
Quotes illustrating development of information systems.

"as part of our development for revalidation... If a complaint comes into NHS England... that then gets taken to the appraisal, the GP will discuss it, and provide evidence for reflection... I check to make sure the information is in there." (Interview 60: Senior project officer for revalidation, NHSE area team B)

"If we get information through from either complaints or the GMC about somebody, what we do is we write to the doctor, and we say, we're aware of this complaint, and what we expect you to do is to write that in your appraisal... Then, we check it." (Interview 70: Deputy MD: NHSE area team A).

"We've made, I think, probably since the revalidation, a great link between the revalidation team, if you like, and the incident team or the safe service team." (Interview 49: RO, NHS mental healthcare foundation trust B)

"We're having a bit of a push at the moment within the team about the MPIT forms [forms to transfer information between organisations], about communication from one RO to the other to try and embed those processes a bit more. And I think that's going on nationally." (Interview 25: RO, mental healthcare charity)

"years ago, in the independent sector, you just used to get an A4 sheet of paper to say, yes they've had appraisal, with no actual information... [now] it's knowing exactly what they're doing in their practice... just pulling it all together" (Interview 78: Clinical governance director, private healthcare provider).

"There's not much of a connection [between revalidation and clinical governance teams]. There should be though... I'd like to have a person that does the 'we've finished, we've boxed off that SI [significant incident], whose portfolio does it go into?'... Complaints likewise." (Interview 36: RO, NHS acute hospital foundation trust).

"And so there'll be a letter that goes to the doctor asking them to reflect on that incident, or complaint, or that sort of thing within the appraisal process and it goes through the same loop that I was talking about earlier. Before we had that process the only other route of referral was into performance and so I think we're certainly resolving things quicker, faster and I think we see less performance concerns arise because certainly the quality of appraisal in this area is really high." (NHSE area team B (primary care), ID: Int 63 – Head of Revalidation).

"So for example, we get information routinely, from complaints departments... But whenever they're mentioned in a complaint, that flags up to the Associate Medical Director of Revalidation... And similarly, with serious incidents, when a doctor is named in a serious incident or involved in a serious incident, named in the root cause analysis perhaps, I should say, then that also feeds in... And part of the judgement we exercise, is to look at those complaints and see whether there is a culpability issue there or whether there is a need to enquire further." (NHS acute hospital and community healthcare, ID: Int 39 – RO & MD)

They suggested that revalidation enabled them to question doctors about data related to their performance, prior to or outside of a more formalised performance management processes. One of the interviewees, from a primary care area team, suggested that this had resulted in fewer issues being escalated to more formalised performance processes, because the RO could address potential concerns at an earlier stage.

The RO therefore, with formalised access to clinical governance data and responsibility for making revalidation recommendations, could use the revalidation process to ensure engagement with clinical governance, such as reflecting on complaints or serious incidents, and this in turn provided leverage in cases where there was an issue of potential underperformance. However, it was suggested by one interviewee that the extent of the RO's leverage may depend on whether the RO role is combined with that of medical director, presumably because the medical director has oversight of and responsibility for clinical governance systems (Table 5).

3.4. Contextual factors that may determine the nature and extent of the impact of revalidation

Interviewees suggested a number of organisational factors that may influence the extent of the impact of revalidation. In primary care, doctors usually work within GP practices. The services of these practices are commissioned by NHS England. Geographically-located area teams within NHS England revalidate up to 3,000 GPs who work within the practices. Thus there is considerable organisational distance between the doctor and the RO. Some interviewees

Table 5
Quotes illustrating the leverage of the RO role.

"I can statutorily say to a doctor: you will discuss this issue at your appraisal. So if I get a complaint and the doctor's response is suboptimal, I will formally write to that doctor and say... I'm instructing you to discuss this complaint at your next appraisal." (Interview 18: Former RO, CIC regional community healthcare provider)

"We have, on occasions, as a result of [revalidation]... I have discussed consultant performance or issues, and invited the consultant in question, to explain why they think they have had three complaints in a month about similar things." (Interview 35: RO, NHS acute hospital and community healthcare)

"I personally think that having the MD and the RO as the same person is important, because obviously they're involved in clinical governance at a high level" (Interview 27: Associate MD, mental healthcare charity)

"And so there'll be a letter that goes to the doctor asking them to reflect on that incident, or complaint, or that sort of thing within the appraisal process and it goes through the same loop that I was talking about earlier. Before we had that process the only other route of referral was into performance and so I think we're certainly resolving things quicker, faster and I think we see less performance concerns arise." (NHSE area team B (primary care), ID: Int 63 – Head of Revalidation).

within our primary care case studies suggested that this organisational distance can make it difficult for clinical governance data such as complaints to feed into revalidation decisions. Indeed, as noted above, interviewees noted that in primary care, if a complaint is made to a doctor's practice and is not escalated, there is no mechanism for ensuring that the complaint would feed up to the revalidation team.

Acute trusts revalidate much smaller numbers of doctors than NHS area teams. However, within our acute trust case studies, interviewees stated that a high number of doctors per RO was a potential barrier to integrating clinical governance data into revalidation decision making.

The extent to which our interviewees perceived revalidation as being embedded to utilise existing clinical governance systems varied across our case studies, even in case studies of a similar size. One RO from a mental healthcare charity described a superficial relationship between the clinical governance and revalidation systems. The clinical governance systems in this case, they argued, were simply being used to provide evidence of having engaged with revalidation, rather to inform a process to enhance practitioner performance. Similarly, another interviewee from an NHS trust discussed a lack of cooperation of clinical governance teams, who were reluctant to engage with the revalidation process at all (Table 6).

4. Discussion

This study sought to explore how the recent implementation of medical revalidation has affected the arrangements for clinical governance in healthcare organisations in England. In our data, we found clear evidence that the implementation of revalidation has: increased doctor engagement with those clinical governance systems, particularly around patient complaints and serious incidents; necessitated the establishment of systems within healthcare organisations to manage clinical governance data so that it is more readily accessible to doctors and leaders; and given more leverage – through the role of the RO – to enforce engagement with clinical governance processes, notably in cases where there are issues around clinical performance.

The way in which revalidation has engendered greater engagement with patient complaints and serious incidents, suggests that revalidation may be playing an important role in increasing the accountability of doctors in the UK. The development of information systems for ensuring that data is available is an important part of this process, as highlighted in the 2018 GMC guidance on clinical governance, which states that organisations should "ensure doc-

Table 6
Quotes illustrating contextual factors that determine the impact of revalidation.

"Well, we can't [ensure complaints come into the appraisal process]... So, what we do is, you know, somebody has to click on a box to declare whether or not they've been involved in a complaint, so there's a probity issue if they don't." (Interview 70: Deputy MD, NHSE area team A)

"Actually it's very difficult to identify those [practice level complaints]. It's only when they get escalated to NHS England that we're able to manage that information." (Interview 60: Senior Project officer for Revalidation, NHSE area team B)

"I get some of the [complaints] and I don't think we're as focused on it as other organisations... because I'm one person with 470 doctors, whereas, I've got colleagues that have got 150 doctors." (Interview 39: Revalidation manager, NHS acute hospital foundation trust)

"[Clinical governance systems are] bypassed by appraisal and revalidation almost entirely... So it seemed to me that the appraisal revalidation system was absolutely sure that individuals are fit to practise, but had no relationship with the concept of fitness for purpose... And indeed it seemed to be believed that the role of clinical governance department, was to fulfil the doctor's revalidation requirements, rather than the other way round... I think they've kind of bypassed a lot of the quality thinking that has been central in the NHS, almost totally, and have re-interpreted it as process, so there has been, it's very much changing, a sort of obsessional concern with regulation, but actually a lot of it internally imposed regulation, and mistaking measuring those sort of outcomes, proxies, for activity, and mistaking those for quality (Interview 43: RO, mental healthcare charity)

"It was that presumed professionalism in a way that was the old way, so what we're now saying is we need a bit of evidence behind that before we can make presumptions. I think that has helped as well, because within the appraisal structure... to be able to have evidence of your quality improvement activity and to have evidence of your performance has added a sort of seriousness to the way people think about their professional duties". (NHS acute hospital foundation trust. (medium), ID: Int 41 – RO)

"We've been trying to engage with those teams... there is a basic report... And just asking them to fill that in, it's just not getting anywhere." (Interview 39: Revalidation manager, NHS acute hospital foundation trust)

tors are supported to collect the required supporting information by being given access to the relevant data and systems" [30]. However, it is important to note that our findings focus on changes to clinical governance processes, and levels of engagement with those processes, from the perspective of the management and leadership within the healthcare organisations. But changes to processes alone may not change outcomes; recent systematic reviews on the impact of patient feedback [38] and reflection on significant events [39] suggest that a number of contextual factors, related to the way in which data is collected and the time and resources afforded reflective activities, may also have a role in determining the effectiveness of these practices. In short, revalidation has changed processes, but we don't yet know if it has changed outcomes for patients.

Part of the increased engagement in clinical governance is due to the leverage of the RO role. Other studies into revalidation have noted the unique power of ROs, derived from their position as both a senior doctor working within their organisations, as well as someone who carries out regulatory responsibilities on behalf of the GMC [22]. This study sheds further light on the way in which ROs are able to exert regulatory power. With oversight of the supporting information that feeds into a revalidation decision, ROs are in a position to challenge doctors about clinical governance data outside of the usual structures for addressing performance issues within the organisation.

This power may be greater where the role of RO is combined with that of medical director as it then brings together formal authority within the organisation, with the statutory responsibilities of making revalidation recommendations. The MD is typically a member of the executive board of the designated body, and thus has substantial influence over the direction of clinical governance policy. It is therefore significant that in around two-thirds of designated bodies, the RO is also the MD, and where the role is split, this is primarily driven by considerations of workload [32]. Further

research could focus on the implications of combining or splitting the RO-MD roles.

It is particularly important to note the role of revalidation in reforming clinical governance in non-NHS organisations. In organisations where doctors are not employees of their designated body, such as private practice, it has been a greater challenge to implement effective clinical governance [40]. In our study, the introduction of revalidation has required private providers to establish systems for collecting and sharing clinical governance data to feed into revalidation decisions. This suggests that revalidation may go some way towards bridging the accountability gap between NHS and private healthcare in the UK.

It has been recognised in the implementation literature that organisations do not only react to changes in the external policy environment, but the impact of these changes is mediated by the organisational context [41]. Here we have found evidence to suggest that the extent and nature of the impact of revalidation may be determined by the size and type of organisation, and that the extent to which revalidation had been embedded within organisations can vary considerably. In addition, this data also suggests that the ratio of doctors to RO, and the organisational distance between doctor and RO, may be an important factor. In primary care, where the organisational distance is greater and where fewer ROs revalidate more doctors, it may be more difficult to ensure that some clinical governance data feeds into the revalidation decision-making process. In some respects this suggests that revalidation is more suited to, or perhaps designed to fit, a secondary care organisational model, where larger organisations have more centralised systems for collecting data. Indeed, revalidation has previously been criticised by some ROs on the grounds that its design only really suits large NHS organisations [32]. This research supports the finding that the structure of revalidation creates specific challenges for different organisations. However, it is also important to note some of the positive responses to revalidation from the primary care case studies, reporting that revalidation had encouraged doctors to engage with quality improvement activities and enhancing the level of oversight over a doctor's engagement with clinical governance. Thus while revalidation's impact has not been uniform across the different organisations, it has increased accountability and oversight in both primary and secondary care, as well as among private providers.

Looking to the wider context, these developments in healthcare organisations in England provide a unique perspective on the nature and development of medical regulation. Medicine has witnessed a regulatory shift, away from autonomy and self-regulation, and towards increased accountability and control from the state [42]. Within the UK, Chamberlain has argued that revalidation represents a way in which medical elites have sought to respond to these pressures for increased oversight, while maintaining a degree of professional self-regulation [43–45]. The introduction of revalidation has positioned Responsible Officers - members of a professional elite - in between the profession and the regulator [22,43]. This has transformed the regulatory relationship between doctors, their employers and the GMC [23].

This research adds a unique perspective on this evolving relationship. While clinical governance had increased the accountability of healthcare organisations since the early 1990s, the medical profession remained largely self-regulating. The way that revalidation works, through drawing on clinical governance systems, and the structural changes related to the establishment of ROs, has therefore created a degree of alignment between organisational and professional regulation that did not exist before. This alignment has facilitated the use of clinical governance systems within organisations to increase the accountability of doctors working in the UK.

5. Conclusion

The implementation of medical revalidation in England shows how a major reform to professional regulation, through a system of relicensing, has developed a higher degree of accountability for clinical performance within healthcare organisations. Our study was limited to the extent that we interviewed only those involved with implementing revalidation, and a wider perspective might have given a clearer picture of how revalidation has impacted on individual doctors working organisations. Future research might focus on whether such changes improve outcomes for patients, and the role of organisational contexts and cultures in determining the nature and extent of such change.

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Authorship

Case study work package led by KW. Research interviews conducted by AT, AB, TP, KW, JF, MB, JTR and KL. Data coding and analysis by TP, JF, AT, JTR, KL. First draft of paper by TP with input from KW, MB, JTR and JA. Subsequent iterations had input from all authors at all stages.

Declaration of Competing Interest

None.

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