18 July 2012

Council

To consider

Revalidation: Licence to Practise and Revalidation Regulations, Consultation Report and Guide for Doctors

Issue

1. Between October 2011 and January 2012 we undertook a public consultation on the draft General Medical Council (Licence to Practise and Revalidation) Regulations 2012 (‘the Regulations’). The Regulations are required for the implementation of revalidation. We have prepared a report on the results of the consultation and amended the draft Regulations in the light of the feedback we received. We have also developed a draft guide for doctors to accompany the Regulations.

Recommendations

2. 
   a. To endorse the report of the consultation on the Licence to Practise and Revalidation Regulations at Annex A (paragraphs 8 -11).
   b. To approve the General Medical Council (Licence to Practise and Revalidation) Regulations 2012 at Annex B (paragraphs 12 - 18).
   c. To agree that the Chair be authorised to make the Regulations on behalf of Council following the autumn assessment of readiness for revalidation to begin (paragraphs 12 - 18).
   d. To approve the guide for doctors at Annex C (paragraphs 20 - 21).

Further information

3. If you require further information about this paper, please contact us by email: gmc@gmc-uk.org or tel. 0161 923 6602.
Background

3. Strategic aim 2 of the 2012 Business Plan is to give all our key interest groups confidence that doctors are fit to practise. To this end, in 2012 we will start to introduce revalidation across the UK.

4. Before revalidation can begin the necessary legislation must be in place. Amendments to the Medical Act 1983 (the Act) have already been made but have not yet been commenced. Once they are in force, the Act will provide the broad framework for how revalidation will operate. However, the detail will be set out in regulations, accompanied by guidance and operational processes.

5. In September 2011 Council approved the draft General Medical Council (Licence to Practise and Revalidation) Regulations as a basis for public consultation. These Regulations revoke the existing Licence to Practise Regulations and put in place a new set of regulations covering both licensing and revalidation. They cover our existing powers in relation to the licence to practise, plus the additional powers we will need to maintain, withdraw, restore or refuse to restore licences in the context of revalidation. They also describe the arrangements for the GMC to receive revalidation recommendations.

6. This paper considers the report on the consultation, the Regulations and the accompanying guide for doctors.

Discussion

Report on the consultation

7. The public consultation ran from 17 October 2011 to 27 January 2012. The report of the consultation is at Annex A.

8. We received 174 responses to the consultation. Two Council members, Iqbal Singh and Stephen Whittle, were asked to scrutinise the consultation responses and the draft consultation report to ensure that we had fully and accurately reflected the feedback we received. They confirmed that overall our report is an accurate account of the consultation responses. They did, however, suggest some relatively minor amendments and we have adjusted our report to take account of their comments.

9. The majority of respondents supported the arrangements set out in the draft Regulations. Our consultation nevertheless elicited a large number of questions and comments about how revalidation would work in practice for different groups of doctors in different circumstances. These are detailed in our consultation report at Annex A, where we also set out our proposed responses to the particular issues raised.

10. For the most part, the consultation feedback does not point to a need to amend the draft Regulations, but rather to a need for further information about the practicalities of revalidation and how it will affect individual doctors.
**Recommendation:** To endorse the report of the consultation on the Licence to Practise and Revalidation Regulations at Annex A.

*The General Medical Council (Licence to Practise and Revalidation) Regulations 2012*

11. The draft Regulations are at Annex B. As our consultation report indicates, in most areas the Regulations provide the balance of flexibility and specificity necessary to accommodate the different circumstances in which doctors practice, while at the same time ensuring that the public interest is protected. In one key area, however, the feedback we received confirmed a need to amend the draft Regulations.

12. Regulation 5(6) of the consultation draft had contained a specific provision covering the revalidation of GMC licensed doctors working in the Channel Islands and the Isle of Man. The Responsible Officer Regulations \(^1\) which apply to doctors practising in the UK do not apply in the Channel Islands and the Isle of Man. Unlike most UK based doctors, therefore, licensed doctors working in these jurisdictions cannot link with a Responsible Officer for the purposes of their revalidation. To address this problem the draft Licence to Practise and Revalidation Regulations made provision for revalidation recommendations for Channel Islands and Isle of Man doctors to be made by a ‘suitable person’ performing functions equivalent to those of a UK based statutory Responsible Officer. The Channel Islands is currently putting in place legislation which will require the establishment of an equivalent to the UK system of Responsible Officers.

13. In our consultation we asked whether we should explore the possibility of developing the ‘suitable person’ concept for the small number of UK licensed doctors who do not have a statutory link to a Responsible Officer. The very clear message from the consultation is that we should do so.

14. Accordingly, Regulations 5(6) - (7) of the draft Licence to Practise and Revalidation Regulations now provide for revalidation recommendations to be made by a ‘suitable person’ where a doctor has no statutory connection with a Responsible Officer under the Responsible Officer Regulations. It is important to stress, however, that this provision does not in any way undermine the effect of the Responsible Officer Regulations or allow a doctor who has a statutory connection to a Responsible Officer under those Regulations to pick and choose an alternative ‘suitable person’. Furthermore, any arrangement to provide a revalidation recommendation via a ‘suitable person’ can only be made by a registered medical practitioner who has been ‘approved’ by the Registrar to perform this function in respect of a particular doctor. We are currently developing criteria which will set out the conditions to be met before such permission would be granted. In this way we will facilitate the revalidation of the small number of doctors who do not have a connection to a statutory Responsible Officer, while at the same time ensuring that an equivalent rigour is applied.

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\(^1\) Responsible officer regulations and guidance were developed by the [Department of Health (England)](https://www.gov.uk) for England, Scotland and Wales and by the [Department of Health, Social Services and Public Safety](https://www.gov.uk) for Northern Ireland.
Making the Licence to Practise and Revalidation Regulations

15. The Secretary of State for Health is expected to complete his assessment of the health care services’ readiness for the introduction of revalidation in autumn 2012. We do not want Council formally to make the Licence to Practise and Revalidation Regulations until that has been done.

16. However, we would like to make sure that all the elements necessary to begin revalidation are in place as early as possible. We are therefore inviting Council to approve the content of the draft Regulations now, subject to the outcome of the readiness assessment, and authorise the Chair to make the Regulations once that assessment is complete.

17. We would also like Council to agree that, following its July meeting, should the need for minor drafting changes to the Regulations be identified, the Chair be authorised to approve such changes on behalf of Council before making the Regulations, provided that any such changes do not affect the agreed policy intentions behind the Regulations.

Recommendation: To approve the General Medical Council (Licence to Practise and Revalidation) Regulations 2012 at Annex B.

Recommendation: To agree that the Chair be authorised to make the Regulations on behalf of Council following the autumn assessment of readiness for revalidation to begin.

18. The Regulations would come into force in December 2012.

Guide for doctors to accompany the Regulations

19. The responses we received to our consultation have highlighted the need for further guidance about how revalidation will work in practice. The guide we have drafted is at Annex C. It aims to explain the content of the Regulations (which are necessarily couched in legalistic terms) in user-friendly language and set out the practical effect for doctors. In particular, we have tried to provide further detail and clarification on the points raised by respondents to our consultation.

20. The guide has been shared with members of the Continued Practice, Registration and Revalidation Board and our revalidation implementation partners.

Recommendation: To approve the guide for doctors at Annex C.

Resource implications

21. There are no resource implications arising from this paper.
Equality

22. One purpose of the consultation was to ensure fairness and transparency in the application of the Regulations. We specifically asked respondents whether there were particular groups of doctors for whom the Regulations would have an unfair or disproportionate impact. The main groups of doctors identified by respondents were doctors with no Responsible Officer, doctors working in roles outside the medical mainstream and doctors taking a break from practice. The key themes are discussed in detail in the consultation report at Annex A.

23. Our guidance highlights the flexibility built into the Regulations for doctors who take a break from practice and doctors who do not have a Responsible Officer. We have also amended the draft Regulations to facilitate the revalidation of the small number of doctors without a Responsible Officer.

24. The responses to the consultation have been considered in our Equality Analysis for revalidation as a whole.
1. The ‘Report of the GMC Consultation on the Draft General Medical Council (Licence to Practise and Revalidation) Regulations’ is attached.
Report of the GMC Consultation on the Draft General Medical Council (Licence to Practise and Revalidation) Regulations

Introduction

Background

1. All licensed doctors will need to demonstrate to the GMC, on a regular basis, that they remain up to date and fit to practise. This process is called revalidation, and all licensed doctors will need to participate as a condition of keeping their licence to practise. The purpose of revalidation is to assure patients and the public that licensed doctors are up to date and practising in accordance with the values and principles set out in our core guidance, Good Medical Practice.

2. In 2010 we consulted on proposals for how revalidation would work. Following that consultation, the overarching policy and process for revalidation were agreed.

3. In October 2011 we began a consultation on the draft regulations required for us to implement the policy. The draft regulations set out the legal powers, rights and responsibilities of those involved in revalidation. They apply both to the GMC and to the doctors we regulate. The regulations do not, however, describe the detailed operational policies and processes that show how the regulations will be implemented. These are set out in separate guidance for doctors.

4. Revalidation is a legal requirement. The consultation was therefore not about whether we should introduce it, but how.

The Licence to Practice and Revalidation Regulations

5. The General Medical Council (Licence to Practise) Regulations came into force in October 2009. They set out the GMC’s powers to grant, withdraw, restore or refuse to restore licences in a range of circumstances.

6. We will replace these regulations with the General Medical Council (Licence to Practise and Revalidation) Regulations. These regulations cover our existing powers plus the additional powers we need to maintain, withdraw, restore or refuse to restore licences in the context of revalidation.

7. On publication, the Regulations will be accompanied by detailed guidance setting out operational policies and processes through which the regulations will be implemented.
The consultation

8. The public consultation on the draft Licence to Practice and Revalidation Regulations ran from 17 October 2011 to 27 January 2012. The ten questions on which we consulted are at annex A.

Methodology

9. For each of the consultation questions, respondents could answer ‘Yes’, ‘No’ or ‘Not Sure’. We encouraged those who did not agree with our proposals, or who were not sure, to provide further comments in the free text space provided.

10. Respondents were able to reply to the consultation online via the GMC website using our e-consultation tool, by email or in writing.

11. We used a range of methods to publicise the consultation. It was prominent on our website and highlighted in our email newsletter to all doctors.

12. At the start of the consultation we notified 161 stakeholders of its launch and invited responses. We also contacted individuals and organisations who had responded to our previous revalidation consultation and those who had signed up to receive our revalidation e-bulletin. During the course of the consultation we used presentations and our exhibition stands at a range of events to publicise the consultation. In the final weeks we made follow-up calls to a number of key organisations to encourage them to respond.

13. Several organisations (including the Revalidation Support Team and some of the medical Royal Colleges) helped us disseminate information about the consultation by advertising it on their websites and notifying their members and stakeholders.

14. We received 174 consultation responses. Of these, 13 respondents did not reply to individual questions but provided broader comment on the consultation. These comments were included in the free-text analysis, but not in the statistical analysis, as we could not clearly attribute a ‘Yes’, ‘No’ or ‘Not Sure’ response. One respondent supported the proposals but the answers given did not correspond to the questions posed, and therefore we did not include this response in the statistical analysis.

15. During the consultation we held two events with groups of general practitioners. Feedback from these events has been included in relevant parts of this report.
Breakdown of responses

16. We received 109 responses from individuals. The overwhelming majority of those responses were from individual doctors. Other key individuals who responded included medical managers, medical educators and one member of the public.

17. 65 responses were received on behalf of organisations. Of these, the largest groups were bodies representing doctors, NHS/HSC organisations and postgraduate medical institutions. 12 organisations identified themselves as ‘other’. These were mainly healthcare-related organisations, as well as one charity and one consumer group.

18. We included all medical Royal Colleges and Faculties in the category ‘postgraduate medical institution’ irrespective of their self-selection. Most colleges and faculties had identified themselves as ‘other’ or ‘postgraduate medical institution’ and one had identified itself as ‘bodies representing doctors’.

<table>
<thead>
<tr>
<th>Organisations</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Body representing doctors</td>
<td>14</td>
</tr>
<tr>
<td>Body representing patients or public</td>
<td>3</td>
</tr>
<tr>
<td>Government department</td>
<td>2</td>
</tr>
<tr>
<td>Independent healthcare provider</td>
<td>3</td>
</tr>
<tr>
<td>Medical School (undergraduate)</td>
<td>1</td>
</tr>
<tr>
<td>Postgraduate medical institution</td>
<td>17</td>
</tr>
<tr>
<td>NHS/HSC organisation</td>
<td>12</td>
</tr>
<tr>
<td>Regulatory body</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>12</td>
</tr>
<tr>
<td><strong>Total organisations</strong></td>
<td><strong>65</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Individuals</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>94</td>
</tr>
<tr>
<td>Medical educator (teaching, delivering or administrating)</td>
<td>3</td>
</tr>
<tr>
<td>Medical manager</td>
<td>8</td>
</tr>
<tr>
<td>Member of the public</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total individuals</strong></td>
<td><strong>109</strong></td>
</tr>
<tr>
<td><strong>Overall total</strong></td>
<td><strong>174</strong></td>
</tr>
</tbody>
</table>
Summary of findings

19. The majority of respondents supported the arrangements set out in the draft regulations. However, many issues were raised that were not in response to individual questions in the consultation and did not relate to the Revalidation Regulations themselves, but to the revalidation process more generally. This highlighted the fact that the Regulations must be accompanied by detailed guidance to address these issues and we have discussed this throughout the report.

20. A number of themes emerged.

The need for further detail and guidance

21. A key theme across all questions was the need for more detail about how the regulations would be implemented in practice. This included, among other things, guidance about non-participation in revalidation, our ability to vary a doctor's revalidation date and the deferral of recommendations to revalidate.

22. A range of guidance and information for doctors, employers, Responsible Officers and the public has been prepared to help meet this need. We have, therefore, not attempted in this consultation report to answer the many and varied questions asked by our respondents except where this has a direct bearing on the content of the regulations or the need to amend them in the light of respondents’ comments.

Flexibility in the revalidation process

23. Many respondents raised questions about how the regulations would apply to doctors working part-time or in different professional roles, and the need for flexibility to accommodate those who are, for example, ill, on maternity leave or taking career breaks, or continue to hold a licence to practise while working overseas.

24. We recognise that revalidation must work for doctors in a wide range of different circumstances. We asked two specific questions in the consultation about whether the regulations will ensure flexibility, fairness and transparency for doctors. In addition to this, some of the feedback provided in other areas of the consultation also relate to the fairness and transparency of the proposed regulations.

25. We consider the regulations provide us with the ability to put in place flexible process to take into account the wide range of circumstances highlighted in the responses. How that flexibility will operate in practice is set out in the guidance and further information we have prepared.
Doctors without a Responsible Officer

26. Respondents raised questions about the position of doctors who do not have a Responsible Officer and how they would revalidate. In particular, questions were raised about doctors who continue to hold a licence to practise while they work overseas.

27. The regulations are designed to enable doctors to revalidate regardless of whether they have a Responsible Officer. Paragraphs 113 - 129 of this report dealing with consultation question 6 show how they will do this. Further detail is provided in separate guidance for doctors.

Guiding principles for revalidation

Question 1 - Guiding principles for the Regulations

28. In preparing the Regulations, we were guided by the following principles: certainty, fairness, flexibility, minimalism and transparency. We asked whether these principles were the right principles upon which to build the regulations.

Summary statistics

Table 1: Responses to Question 1 Part A by number and percentage of respondents

<table>
<thead>
<tr>
<th>Question: 1A</th>
<th>Are the principles upon which we have built the regulations, the right ones?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Answer Option</td>
<td>Response #</td>
</tr>
<tr>
<td>Yes</td>
<td>122</td>
</tr>
<tr>
<td>No</td>
<td>13</td>
</tr>
<tr>
<td>Not sure</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>157</td>
</tr>
</tbody>
</table>

29. Of the doctors who responded, 69 (76%) answered ‘Yes’, 10 (11%) answered ‘No’ and 11 (12%) were ‘Not sure’. Of the eight medical managers who responded, seven answered ‘Yes’ and one answered ‘Not sure’. Seven bodies representing doctors responded to this question and all agreed the principles. 12 of the 16 postgraduate medical institutions responded ‘Yes’, with the remaining four responding ‘Not sure’.
Discussion

30. 48 respondents provided further comments to support their answers. Of these, five agreed with our principles. The BMA stated:

*The fact that 'flexibility' has been defined as one of the guiding principles is useful, given the wide-ranging nature of medical practice, workplace settings and contracts.*

31. 12 respondents wanted more information about what the principles meant in practice. Some were concerned about how consistency would be achieved across all doctors and specialties, as the principles could be interpreted, applied and balanced in different ways. A number of respondents raised concerns about how the principles would apply to different groups of doctors, particularly doctors in non-clinical roles and European Economic Area (EEA) doctors. Several respondents questioned how the tensions between principles such as flexibility and certainty, minimalism and transparency, could be reconciled.

32. One postgraduate medical institution stated

*The principles upon which the regulations are founded are the right ones. However, the GMC must achieve an appropriate balance between minimalism and transparency. There is still a considerable amount of information and communication due from the GMC regarding the implementation of revalidation.*

33. Several commentators proposed additional principles, including: minimising the burden on doctors, protection of patients and the public, functionality, and proportionality in place of minimalism.

Other comments relevant to revalidation

34. A number of respondents took the opportunity to comment on, or ask questions about, revalidation in general. While their comments are not directly related to this question, or indeed to the regulations, they are summarised below for the sake of completeness:

- Concern that revalidation would be a bureaucratic burden, expensive, and unnecessary.
- The need for consistency and standardisation in revalidation.
- The need for education and training and good practice in assessment to be a principle underlying the regulations.
- How doctors in non-clinical or non-mainstream clinical practice would revalidate.
• Issues relating to the use of appraisal in revalidation.
• The need for knowledge tests as part of revalidation.
• Revalidation for EEA doctors.
• The risk of bias in Responsible Officer recommendations to the GMC.

Response

35. A clear majority of respondents support the principles which have shaped our approach to preparing the regulations.

36. The additional principles suggested by respondents are applicable not just to the regulations but to revalidation as a whole. We consider, however, that they are reflected in the approach we have taken to the regulations. For example, public protection considerations are evident in the ability to vary a doctor’s revalidation date in response to risk.

37. We agree that the revalidation process needs to follow the principle of proportionality in the duties it imposes and in its effects, but the regulations need to contain the minimum level of detail necessary to achieve this outcome. The more detailed the regulations the more difficult it will be to adjust our operational processes in the light of experience so as to maintain proportionality. The principles of proportionality and minimalism are complementary, not alternatives.

38. Our approach has therefore been to use the guidance we have developed for doctors to address many of the questions asked by our respondents while the regulations provide the legislative underpinning to that guidance.

Draft General Medical Council (Licence to Practise and Revalidation) Regulations

Question 2 - Regulation 3: Withdrawal of a licence

39. The current Licence to Practise Regulations already permit the GMC to remove a doctor’s licence in certain circumstances. These are where the licence has been fraudulently gained, granted in error or where a doctor has failed to comply with any requirement in the Regulations.

40. The new Regulations will require the Registrar to withdraw a doctor’s licence where a doctor fails to participate in revalidation.
The Registrar will also have discretion to withdraw a licence where a doctor has failed to provide information requested about their scope of practice, failed to provide details of the organisation where they work and the name of their Responsible Officer (if they have one), or failed to provide any other information relevant to their revalidation. A licence may also be withdrawn where the doctor provides information which is inaccurate or unverifiable. In short, the Registrar may remove a licence where a doctor fails to co-operate with the revalidation process.

The new Regulations also allow a licence to be withdrawn where the doctor fails to pay any fee associated with revalidation. The power to charge a fee would rarely be used. That is because for the vast majority of doctors the revalidation evaluation will be carried out locally through appraisal and the recommendation made to the GMC by the Responsible Officer. However, this regulation allows for the possibility that there will be a small number of doctors who have no Responsible Officer and no medical practice and that the burden of evaluating their fitness to practise will fall on the GMC. That evaluation might, for example, include a formal assessment where a doctor has no evidence of medical practice to draw upon for their revalidation. The cost of that assessment would be borne by the doctor.

It is important to stress that the fact that a doctor has no Responsible Officer would not, in itself, be a reason for us to impose a fee. Under question 6 of this consultation report, and in our accompanying guidance for doctors, we describe our proposals for facilitating the revalidation of doctors with no Responsible Officer.

We will not need to demonstrate that a doctor’s fitness to practise is impaired in order to withdraw a licence under this regulation. However, the Registrar must notify the doctor that he is minded to withdraw the licence and provide reasons. The doctor then has 28 days to make representations. The Registrar must take any representations into account before making a decision.

Where the Registrar decides to withdraw a doctor’s licence under this regulation, the doctor has statutory right of appeal. The licence cannot be withdrawn until the doctor has had the opportunity to exercise that right of appeal.

We asked whether the arrangements set out in regulation 3 for withdrawing a licence to practise where a doctor has failed to cooperate with the revalidation process are reasonable.
Summary statistics

Table 2: Responses to Question 2 Part A by number and percentage of respondents

<table>
<thead>
<tr>
<th>Question: 2A</th>
<th>Response #</th>
<th>Response %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the arrangements set out in regulation 3 for withdrawing a licence to practise where a doctor has failed to co-operate with the revalidation process reasonable?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>87</td>
<td>58</td>
</tr>
<tr>
<td>No</td>
<td>27</td>
<td>18</td>
</tr>
<tr>
<td>Not sure</td>
<td>36</td>
<td>24</td>
</tr>
<tr>
<td>Total</td>
<td>150</td>
<td>100</td>
</tr>
</tbody>
</table>

47. Of the doctors who responded, 46 (51%) answered ‘Yes’, 21 (23%) answered ‘No’ and 17 (19%) answered ‘Not sure’. 50 organisations responded to this question; 31 (62%) answered Yes, four (8%) answered No and 15 (30%) answered Not sure. Of the three bodies representing patients and the public, two answered ‘Yes’ and one said ‘Not sure’.

Discussion

48. 71 respondents provided further comments to support their answer.

Provision of information and non-compliance

49. A number of respondents were concerned that a licence might be withdrawn under regulation 3. They argued that removal of a licence for non-participation in revalidation or failure to comply with a request for information was heavy handed. Four respondents said that a licence should not be removed unless it could be demonstrated that a doctor’s fitness to practice is impaired.

50. One postgraduate medical institution stated:

   We are concerned that the Registrar may withdraw a licence to practise simply because a practitioner has failed to co-operate with some part of the revalidation process. This might be a trivial issue and could be seen as a sledgehammer to crack a nut. We would prefer items which might fall within this category to be described.

51. Two respondents felt that these provisions would be unfair for doctors who did not have a Responsible Officer as it would be more difficult for them to participate in revalidation.
52. Some respondents were concerned that the licence could be withdrawn because information that had been provided was not verifiable. They stated that not all information can be verified, and where there are no means to verify the information it should be assumed that the information is correct. Some thought that doctors overseas may find it particularly difficult to provide verifiable information. A medical manager commented:

> Whilst broadly agreeing with the whole of Regulation 3, in para 25, the ability for the Registrar to revoke a licence because information is unverifiable would seem to me to be a hostage to fortune. There will be significant information provided by doctors in their appraisal, which will be difficult or impossible to verify.

53. Seven respondents expressed concern that doctors could be penalised if they were unable to provide information because their employer was not adequately prepared for the revalidation of its doctors. Others suggested that appraisers or Responsible Officers might exploit the existence of this regulation to bully doctors or make unreasonable demands for information. The Academy of Medical Royal Colleges (AoMRC) stated:

> However there are cases where doctors may have had difficulties either gathering the relevant supporting information due to organisational problems, or due to their own ill health. In this case appropriate support needs to be offered, and deferral should be considered. Indeed we understand that in many cases this may lead to deferral rather than trying to get the doctor through revalidation.

Notice period and notification

54. Eleven respondents thought that where the Registrar is minded to withdraw the licence a doctor should have more than 28 days in which to make representations or provide any requested information. It was suggested that the permitted period should be between three and six months. Those arguing for a longer period were concerned that a doctor might be unable to respond in time owing to ill health, being overseas, or the notice not being received in time.

55. One respondent requested that all notifications be made in writing and posted to the doctor’s most recent registered address. Another proposed a requirement for the Registrar to consult with the Responsible Officer who may have information relevant to the decision.

Requests for more detailed information or guidance

56. Respondents wanted more information on how regulation 3 would work in practice, including examples of the circumstances where it might apply. They wanted to know what would constitute non-participation in revalidation. They also wanted to know what information the GMC would require from them.
Fees for revalidation

57. Fifteen respondents commented on the GMC’s ability to charge fees for revalidation. Three thought this was unreasonable and argued that the cost should be covered by the GMC. Five respondents argued that this would impact unfairly on doctors without a Responsible Officer.

58. Other commentators said that any fee must be small, capped at a maximum amount and published.

Appeal procedure

59. Four respondents commented on the appeals procedure. One said that the right of appeal should be explicit in the regulations. Another referred to a doctor’s right to be represented at an appeal hearing.

Response

60. Participation in revalidation will be mandatory for all licensed doctors. It is therefore essential that the GMC has a means of enforcing this regulatory requirement. The majority of respondents acknowledged this and agreed that, where a doctor has failed to participate in revalidation, we should have the power to withdraw that doctor’s licence.

61. However, we understand the concerns that have been raised about how this power would be used in practice. We would use this provision as a last resort and would not expect it to be invoked to address ‘trivial issue[s]’. We are developing further information, criteria and case studies for when and how this power will be used. This will also describe what constitutes non-participation in revalidation and set out criteria that a Responsible Officer must be able to satisfy before they can inform the GMC that a doctor is not participating in local systems and processes that support revalidation.

62. Doctors will not be penalised for failures on the part of employers or Responsible Officers in preparing for revalidation or putting in place effective systems of appraisal. Nor will this power be used where ill-health has hampered doctors’ attempts to engage fully with the revalidation process.
63. Some respondents were concerned that the proposed 28 days’ notice of the Registrar’s intention to withdraw a licence was insufficient. However, it is important to remember that this would not be the first notification the doctor would receive, but the final statutory notification before action was taken. In practice, the doctor would have five years’ notice of their revalidation due date, followed by a reminder six months before the due date and then a further formal notice three months from the submission date. Where, during the course of the five year cycle, it becomes apparent that the doctor is not engaging in the process (whether because of failure to provide information about where they work or because we have been advised by a Responsible Officer of non-participation in appraisal) there will be further opportunities for us to try and engage with the doctor and encourage their participation. In that context, a final 28 day notification of our intention to take action would seem proportionate. The further six months suggested by some respondents seems merely to encourage and extend the period of non-engagement.

64. Concern was raised that a licence could be withdrawn if a doctor provided unverifiable information. In the vast majority of cases we would not expect to seek such verification. Revalidation recommendations will be received from the doctor’s Responsible Officer and we will not need to scrutinise the supporting information upon which the recommendation is based. However, regulation 3(2)(c) gives us a discretionary power which will help us to obtain clarification where we have grounds for believing that the information provided is inaccurate or misleading.

65. As explained in paragraphs 39 - 40 above, we envisage that a doctor would only incur a fee connected with revalidation in those cases where the doctor had no professional practice of any kind and wished to demonstrate his or her continuing fitness to practise by undergoing a formal assessment. In effect, any fee would be for the cost of the assessment. Were the GMC to bear the cost of such an assessment it would, in effect, be borne by other registered doctors through the annual retention fee. The level of any fees charged for an assessment carried out by the GMC would be published as part of our Fees Regulations.

66. It is neither possible nor necessary to provide in the revalidation regulations the details of the appeal process against withdrawal of a licence. This is because the process is already set out in the Medical Act 1983 and in the Registration Appeals Panels Rules. Its absence from the revalidation regulations does not affect doctors’ rights and we will have a duty to ensure that doctors are informed of their rights.

**Question 3 – Regulation 4: Restoration of a licence**

67. Doctors can already relinquish their licence if they stop practising, and apply to have it restored when they wish to resume practice. In future, once the licence is restored, the doctor will re-enter the revalidation cycle and be revalidated in due course.
68. Regulation 4 sets out the rare and limited circumstances in which the Registrar has the discretion to require a doctor to revalidate before restoring their licence.

69. These circumstances are where the doctor has been out of practice for five or more years (and during those five years has not participated in revalidation or appraisal), or where the Registrar has reason to believe that the doctor has engaged in ‘gaming’. Gaming is when a doctor repeatedly relinquishes their licence to avoid revalidation on the set date, and then seeks to restore the licence immediately afterwards.

70. Doctors who have been out of practice for five or more years may need to demonstrate their fitness to practise by undergoing an objective assessment, as they will not have any other information to draw on.

71. We asked if the circumstances in which a doctor may be required to revalidate as a prerequisite to restoring a licence to practise were appropriate.

Statistical analysis

Table 3: Responses to Question 3 Part A by number and percentage of respondents

<table>
<thead>
<tr>
<th>Question: 3A</th>
<th>Answer Option</th>
<th>Response #</th>
<th>Response %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the circumstances in which a doctor may be required to revalidate as a pre-requisite to restoring a licence to practise appropriate?</td>
<td>Yes</td>
<td>94</td>
<td>64</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>16</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Not sure</td>
<td>37</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>147</td>
<td>100</td>
</tr>
</tbody>
</table>

72. Of the doctors who responded, 52 (57%) answered ‘Yes’, nine (10%) answered ‘No’ and 22 (24%) answered ‘Not sure’. Of the three bodies representing patients or public, one answered ‘Yes’ and two answered ‘No’. Of the nine bodies representing doctors, eight said ‘Yes’. Out of 15, six postgraduate institutions said ‘Yes’, two said ‘No’ and seven said ‘Not sure’.

Discussion

73. 59 respondents provided further comments to support their answer.
The length of time a doctor has been ‘out of practice’

74. 13 respondents commented on the five-year time period. Three felt that the five-year threshold was too long. One suggested that the threshold should be set at three years. Two respondents said that a five-year threshold was arbitrary and decisions should be based on individual circumstances. Several respondents sought clarification of what constituted being out of practice.

75. One body representing patients and the public felt that any doctor whose registration had been suspended or withdrawn as a result of fitness to practise action should revalidate at the point of restoration. In fact, any doctor whose registration has been suspended or withdrawn in such circumstances is required to satisfy the GMC of their fitness to practise before their registration is restored.

The objective assessment

76. In total, 31 respondents provided comments on the objective assessment itself, most of whom wanted more information about the assessments that would be used.

77. Several commentators were opposed to the use of objective assessments, arguing that this was incompatible with the principle that revalidation was an ongoing assessment of practice through appraisal.

Return to practice processes

78. Some respondents highlighted the importance of local employment and royal college processes for supporting doctors returning to medical practice. We agree about the importance of such support systems. However, these are separate from the regulator’s need to be satisfied of an individual’s fitness to have their licence restored where there has been a prolonged absence from medical practice.

Response

79. It is important to note that the use of this regulation is at the discretion of the Registrar. It will be applied on a case by case basis in very rare and limited circumstances. The majority of our respondents supported this.

80. We acknowledge that setting a time limit after which a doctor may be required to undergo revalidation as a condition of restoration of a licence is, to some degree, arbitrary. However, we suggest that setting a period of not less than 5 years is consistent with the normal revalidation cycle and strikes the right balance between patient protection and the need to allow most doctors to relinquish or restore their licences easily.
81. We also acknowledge that requiring a doctor to undergo a formal assessment at the point of restoration is very different from the sort of ongoing evaluation of performance in practice which will normally provide the basis for revalidation. It is for this reason that we regard the use of such assessments as an exception rather than the norm. However, it is important that the regulations provide us with the flexibility and tools to manage such exceptions when they arise. This is in the interests of both patients and doctors.

Regulation 5: Revalidation

Question 4 – Varying a doctor’s revalidation date

82. Doctors will revalidate every five years. However, the new regulations allow the Registrar to extend or reduce this timeframe. This can be done in relation to individual doctors or groups of doctors. The Registrar must always provide reasons for varying the time frame.

83. Regulation 5 provides operational flexibility. It will enable the Registrar to bring forward the revalidation date for a doctor who, for example, wanted to revalidate early before taking a break from practice. It also allows for early revalidation of doctors returning from a lengthy break from practise, or where a risk to patients has been indentified.

84. We asked if the powers to vary a doctor’s revalidation date provide the right balance between flexibility to respond to doctors’ individual circumstances and the ability to respond to protect the public interest.

Statistical analysis

Table 4: Responses to Question 4 Part A by number and percentage of respondents

<table>
<thead>
<tr>
<th>Question: 4A</th>
<th>Response #</th>
<th>Response %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you think that the powers in regulation 5(2) for the Registrar to vary a doctor’s revalidation date provide the right balance between flexibility to respond to doctors’ individual circumstances and the ability to respond to protect the public interest?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>105</td>
<td>72</td>
</tr>
<tr>
<td>No</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Not sure</td>
<td>26</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>146</td>
<td>100</td>
</tr>
</tbody>
</table>
Of the doctors who responded, 61 (67%) answered ‘Yes’, eight (9%) answered ‘No’ and 12 (13%) answered ‘Not sure’. Of the 50 organisations that responded, 32 (64%) said ‘Yes’, six (12%) said ‘No’ and 12 (24%) said ‘Not Sure’. Of the ten bodies representing doctors, 50% said ‘Yes’.

Discussion

51 respondents provided further comments to support their answer. One body which endorsed the proposal, noted:

Flexibility is very important particularly for women doctors many of whom at some point in their careers are likely to take maternity leave. It is therefore very important that there is flexibility within the date for revalidation.

Nine respondents supported the principle but emphasised that the Registrar must give full and clear reasons for varying any revalidation dates. The regulation requires this.

One respondent noted that the ability to provide flexibility about revalidation dates must not be at the expense of certainty for Responsible Officers about when doctors would be required to revalidate. We agree. The ability to vary revalidation dates will not remove the Registrar’s obligation to adhere to the statutory notice periods specified in the regulations.

Extension of the Registrar’s powers

A number of respondents were concerned at the extent of the Registrar’s discretion to vary a revalidation date where he ‘thinks fit to do so’. There were concerns that the power could be misused in response to political, public or media pressure. For this reason some respondents sought safeguards to prevent the Registrar varying a doctor’s revalidation date without first involving the doctor concerned or the Responsible Officer. Another felt that the doctor should be able to appeal the change of the revalidation date.

Concerns were raised that doctors on career breaks, maternity or sick leave and those who have some gaps in practice should not be penalised or disadvantaged.

Requests for more detail

A significant number of respondents requested more information about the process for changing a doctor’s revalidation date. They wanted to know the criteria that the Registrar would apply when making his decision and examples of the sort of cases where a change to a doctor’s revalidation date would be appropriate. More detail was requested about scrutiny of the Registrar’s decision and quality assurance processes.
Length of the revalidation cycle

92. Three respondents suggested that five years should be the maximum time between revalidations. One body representing patients and the public stated:

...five years as the absolute upper limit for the revalidation cycle and would strongly oppose any moves to extend it for any individual doctors or for any groups of doctors. In our view, the regulations should permit the Registrar to reduce the length of the cycle but not to extend it other than in the most exceptional circumstances.

Identifying risks to patients

93. Nine comments were made specifically in relation to allowing early revalidation where a risk to patients has been identified. Respondents queried how the GMC would identify any risks to patient safety, not being a systems regulator, and whether we would use fitness to practise information. One respondent stated that the GMC would have to work alongside systems regulators to identify these risks to patients.

94. Some respondents raised concerns about this regulation being used to target doctors of a particular specialty, or to target certain individuals. One respondent stated that it would be unfair to require doctors in some specialties to revalidate more regularly than doctors in other specialties because their field was considered to be a higher risk to patient safety.

95. Two respondents commented that any systematic or proven risks to patient safety should not be addressed by revalidation, and were matters for fitness to practise procedures.

96. There were also some suggestions that local systems of performance management are used to manage risks to patient safety where identified, rather than relying on revalidation to address these risks. One respondent emphasised that any changes made to the revalidation date due to deferral need be distinct from any fitness to practise issue.

Response

97. The power to require a doctor’s revalidation whenever the Registrar ‘sees fit to do so’ is derived from section 29A(4) of the Medical Act 1983. Since the Act makes this a matter for the Registrar’s discretion, it would not be appropriate for the regulations to fetter that discretion by fixing maximum or minimum time limits within which revalidation dates may be varied. It is, however, reasonable for us to set out in guidance examples of where we might need to vary a doctor’s revalidation date. Further protection is provided by the fact that the Registrar must give reasons for his decision in every case.
The Act provides no right of appeal against a decision to vary a doctor’s revalidation date. A right of appeal cannot, therefore, be incorporated into the regulations. In any event, we do not think such a right of appeal would be appropriate. That is because the doctor’s licence would be unaffected. It is important to remember that requests to vary a revalidation date may, in fact, come from the doctor concerned.

We agree that we will need to work closely with the systems regulators to identify any risks which might warrant action on revalidation dates.

This regulation will not adversely impact on doctors taking a career break or other absence from practice. Where these doctors require more time to prepare for revalidation, a deferral of the revalidation may be appropriate.

Question 5 – Minimum notice period for revalidation

Regulation 5(3) requires the Registrar to give a doctor at least three months’ notice of their revalidation ‘submission date’. This is the date by which we expect the doctor’s Responsible Officer to submit a recommendation to the GMC about the doctor’s suitability to be revalidated. We will notify the Responsible Officer at the same time as the doctor.

Although the proposed statutory minimum notice period is three months, in practice our operational processes will mean that each doctor will usually know their submission date nine months before their revalidation is due. It should also be remembered that at each revalidation a doctor will be given a provisional date for their next revalidation. Therefore, the three month notice of the submission date constitutes the final formal notification the doctor will receive, not the first.

We asked if a statutory notice period of three months given to the doctor before a revalidation submission is due is sufficient.

Summary statistics

Table 5: Responses to Question 5 Part A by number and percentage of respondents

<table>
<thead>
<tr>
<th>Question: 5A</th>
<th>Response #</th>
<th>Response %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the statutory minimum notice period of three months given to the doctor before a revalidation submission is due sufficient?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>83</td>
<td>58</td>
</tr>
<tr>
<td>No</td>
<td>25</td>
<td>17</td>
</tr>
<tr>
<td>Not sure</td>
<td>36</td>
<td>25</td>
</tr>
<tr>
<td>Total</td>
<td>144</td>
<td>100</td>
</tr>
</tbody>
</table>
104. Of the doctors who responded, 41 (45%) answered ‘Yes’, 19 (21%) answered ‘No’ and 21 (23%) answered ‘Not sure’. Of the seven medical managers who responded to this question, five answered ‘Yes’, one answered ‘No’ and one answered ‘Not sure’. Of the 48 organisations that responded, 33 (69%) said ‘Yes’, three (6%) said ‘No’ and 12 (25%) said ‘Not sure’.

Discussion

105. 73 respondents provided further comments to support their answer.

Three months notice is not sufficient

106. 31 respondents provided additional comments explaining why they did not think that a minimum three month notice period was sufficient. Many of these were concerned that this was insufficient time to organise their appraisal and supporting information. One individual doctor stated

"It has taken me four months just to get an appointment for annual appraisal from my current NHS employer. In previous employments it has taken even longer. So completing the necessary paperwork for revalidation is going to need more than three months notice."

107. Others cited difficulties associated with on holidays, maternity or sickness leave, sitting career examinations, working overseas and problems for locums in assembling the required information. In some of these instances, a request for a deferral of the revalidation date may be appropriate.

108. Three respondents commented that a three month notice period was not sufficient for the first cycle of revalidation, but it was sufficient for the following cycles.

109. Three respondents questioned why the time period had to be so short, because if a doctor was posing a risk to patients, the GMC still had the power to suspend their licence.

110. 24 respondents suggested longer notice periods ranging from six to twelve months.

Response

111. The responses have highlighted some confusion about the revalidation process and what needs to happen in the three months after the notice of the submission date has been received. Our guidance to doctors will need to address this.

112. It is important to remember that revalidation is a five year process, not a fifth year event. Participation in annual appraisal and the reflection and discussion of supporting information at those appraisals is an ongoing process throughout a doctor’s career. They should not take place only after the three month notice has been received.
113. Once the notice has been issued very little will be required of the doctor. Rather, the Responsible Officer will need to confirm to the GMC that the doctor has participated in an annual appraisal and the collection of supporting information, and that there are no unaddressed concerns. This will be the basis for the doctor’s revalidation.

114. We have noted the concerns about the effect of the notice period on doctors who are absent due to maternity, sickness or holiday leave, or on a career break. We have also considered the concerns expressed about the position of locums. The Responsible Officer will be able to make a recommendation about these doctors where they have participated in revalidation over the course of the five year cycle and there are no unaddressed concerns. Alternatively, if the Responsible Officer needs further information, they can request a deferral of the recommendation submission date under regulation 5(17). In the small number of cases where a doctor has no Responsible Officer, the doctor will be able to make a deferral request direct to the GMC. The deferral would allow the doctor more time to assemble information, participate in appraisal and demonstrate that they are up to date and fit to practise for the purposes of revalidation. We do not consider, therefore, that there is any disadvantage for doctors in what is proposed.

115. We have considered whether the notice period should be longer than three months. However, we remain of the view that this is appropriate given that it will constitute the final, not the first, notice and there are opportunities to defer the submission date. A longer statutory notice period could even act to doctors’ disadvantage for doctors seeking an earlier revalidation to fit with changing career plans.

**Question 6 – Revalidating doctors with no Responsible Officer**

116. The vast majority of licensed doctors in the UK have a connection to a Responsible Officer, who will make a recommendation to the GMC regarding their revalidation. For most doctors, this connection will be through the organisation in which they work or which contracts their services. The types of organisations required to appoint a Responsible Officer, and the connections between those organisation and individual doctors, are prescribed in legislation and further details are available on the [Department of Health (England)](http://www.dh.gov.uk) and the [Department of Health, Social Services and Public Safety (Northern Ireland)](http://www.dhni.gov.uk) website.

117. A minority of doctors will not have a Responsible Officer. We asked whether we should explore the possibility of allowing additional UK bodies to perform the functions of the Responsible Officer in evaluating doctors’ fitness to practise and making recommendations to the GMC regarding doctors’ revalidation. For ease of reference, this document will refer to these other bodies as ‘suitable bodies’ or ‘suitable persons’ (the term us in the regulations).
Summary statistics

Table 6: Responses to Question 6 Part A by number and percentage of respondents

<table>
<thead>
<tr>
<th>Question: 6A</th>
<th>Do you think we should explore the possibility of allowing additional UK organisations to perform the functions a Responsible Officer in evaluating doctors’ fitness to practise and making recommendations to the GMC regarding doctors’ revalidation?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Answer Option</strong></td>
<td><strong>Response #</strong></td>
</tr>
<tr>
<td>Yes</td>
<td>89</td>
</tr>
<tr>
<td>No</td>
<td>12</td>
</tr>
<tr>
<td>Not sure</td>
<td>45</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>146</strong></td>
</tr>
</tbody>
</table>

118. Of the doctors who responded, 56 (62%) answered ‘Yes’, seven (8%) answered ‘No’ and 19 (21%) answered ‘Not sure’. Of the 49 organisations that responded, 23 (47%) said ‘Yes’, three (6%) said ‘No’ and 23 (47%) said ‘Not sure’.

Discussion

119. 26 respondents provided further comments in support of our proposal. One medical education provider stated

Yes the GMC should explore this as a matter of urgency. Although only a minority of doctors will not be linked to a responsible officer, this will be a significant minority.

120. One postgraduate medical institution stated

We think it is important that the GMC explores and puts in place systems for doctors who fall outside the ‘norm’ and do not obviously link with a Responsible Officer. Although this category of doctor will be a minority, we feel the numbers could still be substantial.

121. 11 respondents agreed with the proposal because it provided flexibility for the wide variety of doctors with no Responsible Officer. One respondent commented that it was in the interests of public safety as all doctors would then be linked to a Responsible Officer or a suitable person performing a function equivalent to that of a Responsible Officer.

122. Six respondents said that this option should be extended to overseas organisations to cater for licensed doctors working abroad.
Criteria to determine who can undertake this function

123. 32 responses identified the need for strict criteria covering the sort of organisations that could undertake this function. These emphasised the importance of the suitable person function being robust and genuinely equivalent to that of the Responsible Officer, and not a diluted version of the role which would provide an easier or less credible route to revalidation. One NHC/SHC organisation stated:

> Exploring the options would be advantageous, however it is also important that the revalidation process is fair and consistent as much as possible across all ROs.

124. A doctor stated:

> In principle yes as it will enable more Doctors to have a link to an RO, easier transfer of information and increased public safety and confidence. However there must be sufficient quality control that all other processes are in place e.g clinical governance, appraisal.

Concerns about the suitable person role

125. Four respondents felt that the list of designated bodies was already exhaustive and, in the interests of simplification, did not need to be added to. Some respondents were concerned that more people performing Responsible Officer functions would make it difficult to achieve consistency in recommendations and standards, and may dilute the quality of those recommendations.

126. A small number of respondents were concerned about the fees that those performing suitable person functions might charge, and the potential conflict of interest where these suitable persons are making revalidation recommendations to the GMC. It should be noted, however, that the Responsible Officer Regulations already provide for fees to be charged in some circumstances in relation to the Responsible Officer function.¹

127. Two respondents thought that the need for suitable bodies was not yet clear, and we should await the learning from the first few years of revalidation before making further changes.

128. One respondent highlighted the fact that assessing the suitability of the organisation to carry out the function will have to be done by the GMC and this would be an additional burden for the regulator.

¹ The Medical Profession (Responsible Officer) Regulations 2010, regulation 19(3) and The Medical Profession (Responsible Officer) Regulations (Northern Ireland) 2010 regulation 17(3)
Other options suggested

129. A number of respondents had suggestions for how the proposed system might work for doctors with no prescribed connection to a Responsible Officer. These included using only organisations designated by the Responsible Officer Regulations on the grounds that they already have systems of appraisal and clinical governance in place, and their recommendations would be consistent.

Response

130. We are committed to finding a pathway to revalidation for all doctors who require a licence to practise. The consultation responses show a clear appetite for us to explore further the option of accepting revalidation recommendations from suitable persons who are performing functions equivalent to those of a Responsible Officer. We do not think we can, as some respondents suggested, await the learning from the first few years of revalidation before making a decision, as this risks disadvantaging some doctors who we know will not have a prescribed connection with a Responsible Officer.

131. The draft regulations upon which we consulted made provision for the suitable person role, but it was limited to doctors working in the Channel Islands and Isle of Man. We accept that provisions are needed which can be used more widely for doctors who do not have a link to a Responsible Officer under the Responsible Officer Regulations. The draft Licence to Practise and Revalidation Regulations have been amended accordingly.

132. We are clear that any suitable person making recommendations to the GMC about a doctor’s fitness to practise will need to have the same functions and duties as statutory Responsible Officers. We are developing supporting criteria for determining who can undertake this function so that we can be assured that any recommendations received are robust and consistent. All recommendations will be subject to the same quality assurance as recommendations from statutory Responsible Officers.

Question 7 – Factors the Registrar can take into account in making a revalidation decision

133. The new regulations set out the factors that the Registrar can take into account in making their decision about each doctor’s revalidation. Those factors are:

- Any information provided by the doctor’s Responsible Officer
- Any information provided by the doctor
- The results of any objective assessment undertaken by the doctor
- Whether the doctor has participated in a process of annual appraisal
- Any other relevant information in the Registrar’s possession
134. We asked whether there are other factors that the Registrar should take into account when deciding whether a doctor should be revalidated.

Statistical analysis

Table 7: Responses to Question 7 Part A by number and percentage of respondents

<table>
<thead>
<tr>
<th>Question: 7A</th>
<th>Answer Option</th>
<th>Response #</th>
<th>Response %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there other factors, besides those listed in regulation 5(15) which the Registrar should take into account when deciding whether a doctor should be revalidated?</td>
<td>Yes</td>
<td>34</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>86</td>
<td>61</td>
</tr>
<tr>
<td></td>
<td>Not sure</td>
<td>21</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>141</td>
<td>100</td>
</tr>
</tbody>
</table>

135. Of the doctors who responded, 17 (19%) answered ‘Yes’, 47 (52%) answered ‘No’ and 15 (16%) answered ‘Not sure’.

Discussion

136. 51 respondents provided further comments to support their answer.

137. Responses to this question highlighted some confusion about what information doctors were required to provide at a local level during their appraisal, and the statements that a Responsible Officer would make to the GMC.

138. Among the items that respondents thought the Registrar should take into account were complaints, colleague and patient feedback, significant events and appraisal documentation. Other information suggested included the results of fitness to practise investigations, information held by employers, criminal records, evidence of the doctor’s good standing with overseas regulators, information about overseas practice and the doctor’s record of participation in mandatory training.

139. One postgraduate institution stated

The Registrar should be able to take into account any information provided by any other body whether or not requested by the GMC.
Requesting further information from doctors

140. Comments were also received about the GMC’s powers under regulation 5 to require doctors to provide additional information about their past, current or proposed employment, and information about their participation in appraisal which might be relevant to their revalidation. A number of respondents requested more detail of the information the GMC might seek.

141. Respondents also noted that under regulation 5 doctors would have 28 days in which to comply with a request for information. Failure to comply, or to explain why the request could not be complied with, could result in withdrawal of the doctor’s licence. There was some concern that 28 days would not always be enough time to comply with such a request if, for example, the doctor was on holiday, ill or overseas. One respondent suggested 50 to 60 days would be more appropriate.

Response

142. Most respondents thought that the factors listed in the regulations which the Registrar can take into account for the purposes of revalidating a doctor were the correct ones.

143. We would not expect the Registrar to review appraisal documentation or individual pieces of supporting information collected by doctors for their appraisal. Instead, Responsible Officers will need to assure themselves that they have systems in place to ensure that doctors are participating in annual appraisal and collecting and discussing the required supporting information at appraisal. The Responsible Officer will then make a statement to the GMC to confirm that each doctor is participating in revalidation and there are no unaddressed concerns. This statement is one of the key factors that the Registrar will take into account in making the revalidation decision.

144. The fact that the regulations allow the Registrar to take into account any information relevant to his decision which he may receive ensures that he can, for example, take account of information received from other regulatory jurisdictions and the outcome of Fitness to Practice investigations.

145. The power to remove the licence of a doctor who fails to provide within 28 days information requested by the Registrar is discretionary, not mandatory or automatic. The doctor also has the opportunity to explain why he or she cannot comply and any decision to remove a licence in these circumstances would be subject to appeal. The licence cannot be removed until the appeal process has run its course. There are, therefore, safeguards to ensure the power is exercised in a fair and reasonable manner.
146. Some respondents felt that 28 days was insufficient time for a doctor to respond to a request for information. However, the 28 day notice would be issued only after earlier attempts to engage with the doctor have failed. In these circumstances it would be inappropriate to build in longer statutory delays.

**Question 8 – deferring revalidation**

147. There will be occasions when doctors are unable to collect the supporting information needed for their appraisal and revalidation and therefore the Responsible Officer will be unable to make a recommendation to the GMC. This might happen where, for example, a doctor has been on a lengthy period of sick leave or a career break during the revalidation cycle.

148. The new regulations allow the Registrar to defer the revalidation submission date to provide more time for information to be collected so that a recommendation can be made. No negative inferences should be drawn from the decision to defer revalidation. The doctor’s licence will not be affected.

149. The deferral may be on the Registrar’s own initiative, at the request of the doctor’s Responsible Officer or, where the doctor has no Responsible Officer, at the doctor’s own request. Where the submission date is deferred, the Registrar must provide reasons for the deferral.

150. We asked whether there might be adverse consequences for a doctor in deferring the submission date.

**Statistical analysis**

**Table 8: Responses to Question 8 Part A by number and percentage of respondents**

<table>
<thead>
<tr>
<th>Question: 8A</th>
<th>Response #</th>
<th>Response %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can you think of any reason why there might be adverse consequences for a doctor in deferring their revalidation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>25</td>
<td>18</td>
</tr>
<tr>
<td>No</td>
<td>91</td>
<td>65</td>
</tr>
<tr>
<td>Not sure</td>
<td>25</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>141</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

151. Of the doctors who responded, 12 (13%) answered ‘Yes’, 56 (62%) answered ‘No’ and 12 (13%) answered ‘Not sure’.
**Discussion**

152. 54 respondents provided further comments to support their answer, 23 of whom identified potential adverse consequences from deferral. These included the possibility that negative connotations would be associated with deferral which could damage a doctor’s credibility. Some thought that deferral could lead to people mistakenly thinking there were concerns about a doctor. Some felt it might have an impact on a doctor’s insurance cover. One respondent thought that doctors may be disadvantaged during litigation if lawyers use the fact of the deferral to undermine them.

153. Ten respondents identified a potential impact for doctors applying for new jobs or negotiating contract renewals. They felt that employers might prefer individuals whose revalidation had not been deferred. One body representing doctors stated:

> It all depends how this is interpreted by their employer or contract holder. It could be misinterpreted and the GMC would need to make it very clear that this is not a penalty.

154. Some respondents therefore highlighted the need for clear reasons for the deferral to be given to the doctor and the Responsible Officer. The GMC needed to make it clear that there were no negative connotations associated with deferral.

**Patient safety and protection of the public**

155. Issues relating to patient safety and protection of the public were raised by seven respondents. They stressed that deferral must not be used if there is a risk of harm to patients from a doctor continuing to practise. One body representing patients and the public stated:

> The priority, in our view, is to ensure that Registrars are not allowed to defer decisions about revalidation unless they can demonstrate that there are no additional risks to patients and the public in allowing the doctor to continue to practise beyond their original revalidation date.

We agree. Patient safety risks should be dealt with through the normal local or GMC processes, rather than through deferral of revalidation.

**Requests for more information**

156. A number of respondents requested further information about the circumstances in which deferral would be used and the length of the deferrals. One respondent asked how multiple or regular requests for deferral would be handled. Another respondent asked whether there was an appeal mechanism if the Responsible Officer requested a deferral and the doctor did not agree.
Publication of the deferral

157. Seven respondents raised concerns about the possible stigma associated with the publication of information about a deferral although another felt that publication would provide transparency and therefore reduce the risk of stigma.

Response

158. The ability to defer the date of a recommendation is important in providing doctors with a flexible framework for revalidation. There are many reasons why a doctor may require more time to collect supporting information for revalidation. Removal of this flexibility would have adverse consequences for doctors taking a career break or other absence.

159. It is, of course, impossible to prevent others mistakenly drawing negative inferences from a deferral. However, since deferral does not in any way constitute a regulatory sanction there would be no reason for the GMC to publish information about an individual case and the doctor’s licence to practise would be unaffected.

160. We will develop clear guidance specifically for responsible officers explaining how the powers of deferral will be used and how they should be understood.

161. We will also monitor the use of deferrals to ensure that the flexibility is not abused or being used to delay revalidation unnecessarily.

Ensuring fairness and transparency

Question 9 – Flexibility in the revalidation process

162. Subject to the exceptions set out in regulation 5(1), all doctors registered with a licence to practise will be required to participate in revalidation. However, we recognise that doctors’ practice varies widely and have tried to provide sufficient flexibility in the regulations to reflect this. One example of the flexibility afforded in the regulations is the Registrar’s discretion to vary a doctor’s revalidation date in response to individual circumstances. Another example is the proposed ‘suitable person’ provisions aimed at facilitating the revalidation of doctors with no Responsible Officer.

163. We asked whether the regulations provide enough flexibility.
Statistical analysis

Table 9: Responses to Question 9 Part A by number and percentage of respondents

<table>
<thead>
<tr>
<th>Question: 9A</th>
<th>Answer Option</th>
<th>Response #</th>
<th>Response %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do the regulations provide sufficient flexibility in the revalidation process to make it possible for all licensed doctors to demonstrate their continuing fitness to practise?</td>
<td>Yes</td>
<td>80</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>19</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Not sure</td>
<td>43</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>142</td>
<td>100</td>
</tr>
</tbody>
</table>

164. Of the doctors who responded, 42 (46%) answered ‘Yes’, 14 (15%) responded No and 25 (27%) answered Not sure. Of the six medical managers who responded to this question, five answered Yes and one answered Not sure. Of the 47 organisation that responded to this question, 31 (66%) answered Yes, three (6%) answered No and 13 (28%) answered Not sure.

Discussion

165. 71 respondents provided further comments to support their answer. Most of these commented on, or raised concerns about, how different groups of doctors would revalidate. These included, among others, locums, tribunal doctors, researchers, doctors in pharmaceutical medicine, doctors working overseas, retired doctors, doctors in part-time practice, doctors working outside recognised specialties and staff grade doctors. One individual doctor stated

They are a good attempt - but are still primarily focussed on doctors in "regular" patterns of practice. They need to be more creative to allow for those who do not have a responsible officer, who may be perfectly competent but struggle to build up the trail of paperwork that is required for revalidation.

166. A small number of respondents referred to challenges in accessing information and the burdens of collecting the information, pointing out that not all employers have electronic records. One respondent asked how revalidation would apply to a doctor moving from a clinical to a non-clinical role.

Allowing additional UK bodies to perform Responsible Officer functions
167. 14 respondents reiterated the comments discussed earlier in this report about the desirability of allowing additional UK bodies to perform Responsible Officer functions.

Varying revalidation dates

168. This question also provoked further comments about varying revalidation dates. One respondent suggested the need for additional flexibility by giving individual doctors the right to request deferral.

Questions about GMC Fitness to Practice procedures

169. Two respondents commented that the interface between revalidation and the GMC’s fitness to practise procedures was not clear in the regulations and sought further information about how this would work in different circumstances. Further detail of this kind will be provided in our guidance.

Further comments on revalidation

170. A number of individual respondents provided additional comments on the flexibility in revalidation. One respondent raised the risk of doctors abusing the flexibility provided. Two respondents were concerned that the timeframes set out in the regulations might limit flexibility.

171. Three respondents commented on an objective assessment or evaluation of information by the GMC for those doctors with no Responsible Officer, recognising the flexibility this would provide, but also perceiving a conflict of interest for the GMC in overseeing the assessment and making the revalidation decision.

Response

172. We have included a range of measures in the regulations to ensure that revalidation is sufficiently flexible to reflect the variety of roles that doctors undertake. The consultation feedback highlights the importance of the guidance which will accompany the regulations to explain how revalidation will work in practice for all groups of doctors.

Question 10 – mitigating unfair or disproportionate impacts on particular groups of doctors

173. We asked if there were particular groups of doctors for whom the Regulations would have an unfair or disproportionate impact.
**Statistical analysis**

**Table 10: Responses to Question 10 Part A by number and percentage of respondents**

<table>
<thead>
<tr>
<th>Question: 10A</th>
<th>Answer Option</th>
<th>Response #</th>
<th>Response %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there particular groups of doctors for whom the Regulations would have an unfair or disproportionate impact?</td>
<td>Yes</td>
<td>69</td>
<td>49</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>38</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Not sure</td>
<td>35</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>141</td>
<td>100</td>
</tr>
</tbody>
</table>

174. Of the doctors who responded, 43 (47%) answered ‘Yes’, 19 (21%) answered ‘No’ and 18 (20%) answered ‘Not sure’. Of the 48 organisations that responded to this question, 19 (40%) answered ‘Yes’, 16 (33%) answered ‘No’ and 13 (27%) answered ‘Not sure’.

**Discussion**

175. 94 respondents provided further comments to support their answer.

176. Respondents identified a wide range of groups who might be disadvantaged. Almost all of those cited were doctors who were not in full-time mainstream NHS practice, such as doctors in independent practice, doctors in staff grade posts, those in non-clinical work, doctors working overseas, doctors involved in medical education, medico-legal services, tribunal services, medical researchers and doctors in medical management. A number of responses mentioned doctors in atypical posts, such as medical acupuncture.

177. Many of these groups were felt to be at a disadvantage because of perceived problems collecting the supporting information for revalidation and the lack of connection with a Responsible Officer. Doctors in the independent sector were also felt by some to be disadvantaged because, unlike their NHS colleagues, they might have to pay for appraisal and for the services of a Responsible Officer. One individual doctor stated

> Independent ‘portfolio’ doctors are likely to find revalidation more of a challenge than those of us that have more ‘standard’ working practices, and they may need to be imaginative to ensure they can provide adequate revalidation evidence that is relevant to their work.
178. Locum doctors and doctors in staff grade posts were identified as more likely to experience difficulties collecting the information necessary to support their revalidation and in accessing appraisal and responses highlighted the importance of ensuring these doctors were supported.

179. Doctors on career breaks, or absent from work due to maternity leave or long-term sick leave, were identified by 13 respondents as potentially being unfairly or disproportionately affected. Again, the main concern for these doctors was that they would not be able to collect supporting information or undertake appraisals.

180. Concerns were also raised about the position of doctors in organisations which lacked adequate information and appraisal systems

Response

181. The striking feature of most of the concerns raised in relation to this question and, indeed, in response to the consultation overall, is that they relate less to the Revalidation Regulations themselves than to concerns about the revalidation process more generally. We are confident that the Regulations will not impact unfairly. The flexibility they incorporate is designed to accommodate the wide range of circumstances in which doctors practice. It is clear, however, that the Regulations must be accompanied by detailed guidance which addresses these concerns by explaining clearly the operational policies and processes through which the Regulations will be implemented.
Annex A

**Question 1:** Are the principles upon which we have built the regulations, the right ones?

**Question 2:** Are the arrangements set out in regulation 3 for withdrawing a licence to practise where a doctor has failed to co-operate with the revalidation process reasonable?

**Question 3:** Are the circumstances in which a doctor may be required to revalidate as a pre-requisite to restoring a licence to practise appropriate?

**Question 4:** Do you think that the powers in regulation 5(2) for the Registrar to vary a doctor’s revalidation date provide the right balance between flexibility to respond to doctors’ individual circumstances and the ability to respond to protect the public interest?

**Question 5:** Is the statutory minimum notice period of three months given to the doctor before a revalidation submission is due sufficient?

**Question 6:** Do you think we should explore the possibility of allowing additional UK organisations to perform the functions a Responsible Officer in evaluating doctors’ fitness to practise and making recommendations to the GMC regarding doctors’ revalidation?

**Question 7:** Are there other factors, besides those listed in regulation 5(15) which the Registrar should take into account when deciding whether a doctor should be revalidated?

**Question 8:** Can you think of any reason why there might be adverse consequences for a doctor in deferring their revalidation?

**Question 9:** Do the regulations provide sufficient flexibility in the revalidation process to make it possible for all licensed doctors to demonstrate their continuing fitness to practise?

**Question 10:** Are there particular groups of doctors for whom the Regulations would have an unfair or disproportionate impact?