Council, 22 September 2011

Current approaches to revalidation amongst UK health professional regulators

professions

Executive summary and recommendations

Introduction

The attached report is one of a series of reports as part of the HPC's programme of work exploring revalidation. Its purpose is to describe the work that other UK health professional regulators are carrying out to introduce revalidation for the professions they regulate.

Relevant themes emerging from the attached paper setting out current revalidation proposals and research include the use of feedback from service users, the revalidation of conduct and different approaches to assessing risk.

This report does not draw any conclusions about revalidation. The report will contribute to the Council's discussion about whether revalidation is necessary and, if so, what systems might be appropriate.

Decision

The Council is invited to discuss and agree the attached report.

Background information

This report forms part of a series of projects looking at revalidation. The Council last received an update on these projects at its meeting on 7 July 2011.

http://www.hpc-uk.org/aboutus/committees/archive/index.asp?id=535

Resource implications

There are no resource implications from the Council's decision on this report.

Financial implications

There are no financial implications from the Council's decision on this report.

Appendices

None

Date of paper

12 September 2011



Current approaches to revalidation amongst UK healthcare professional regulators

September 2011

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1. Executive Summary

- 1.1 This report is one of a series of reports on the work that we, the Health Professions Council (HPC), have undertaken on revalidation.¹ Its purpose is to describe the work that other UK health professional regulators are carrying out to introduce revalidation for the professions they regulate.
- 1.2 This report does not draw any conclusions about revalidation. The report will contribute to the Council's discussion about whether revalidation is necessary and, if so, what systems might be appropriate.
- 1.3 Relevant themes emerging from this description of current revalidation proposals and research include the use of feedback from service users, the revalidation of conduct and different approaches to assessing risk.
- 1.4 In making a decision about whether to proceed with a new revalidation system, one of the factors that might be taken into consideration is whether the primary purpose of revalidation is to identify practitioners who do not meet standards (quality control), or to raise the practicing standards of all registrants (quality improvement).
- 1.5 We have based this report on information provided by each of the UK regulators and taken from each of their websites. The information is correct as of 1 August 2011. Where possible, the information presented has been checked with each of the regulators and we are grateful to those who helped us to put the report together. Any errors or omissions remain our responsibility.

¹ References in this report to 'we', 'us' and 'our' are references to the Health Professions Council.

2. Introduction

- 2.1 The purpose of this report is to describe the work that other UK health professional regulators are undertaking to introduce revalidation for the professions they regulate.
- 2.2 We already have a number of systems in place to ensure the continuing fitness to practise of our registrants. These include our registration renewals process, continuing professional development audit process and fitness to practise processes.

Background to our revalidation research programme

Government policy

2.3 In 2007, the previous government published its White paper on reforms to health professional regulation. The paper said that:

"...revalidation is necessary for all health professionals, but its intensity and frequency needs to be proportionate to the risks inherent to the work in which each practitioner is involved..."

- 2.4 In February 2011, the current government published the Command Paper 'Enabling Excellence Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers'. The government said that it remained committed to supporting the introduction of a proportionate and effective system of medical revalidation in England, with the caveat that further piloting would be required before the GMC rolled out revalidation.³
- 2.5 In relation to the other regulated health professions, the government questioned whether a one-size fits all model was appropriate and asked each regulator to continue to develop the evidence base that would inform proposals for revalidation. The government will consider the next steps for implementing revalidation where there is evidence to suggest that revalidation would bring '...significant added value in terms of increased safety or quality of care for users of health care services'.⁴

Non-medical revalidation working group

2.6 The Non-Medical Revalidation Working Group was one of seven groups set up to take forwards the recommendations from the 2007 White Paper 'Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century'. The role of the group was to set out the way forward to implement revalidation for the non-medical professions.

² Department of Health (2007), *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*, paragraphs 2.29 and 2.30.

³ Letter from the Rt Hon Andrew Lansley, Secretary of State for Health to the Chair of the General Medical Council (June 2010).

⁴ Department of Health (2011), *Enabling Excellence: Autonomy and Accountability for Health and Social Care* Staff, paragraph 5.3.

- 2.7 The group published its report in November 2008.⁵ It identified twelve key principles, which were designed to underpin the non-medical regulators' approaches to revalidation. The key principles relevant to this report are summarised below:
 - the regulator should set contemporary professional standards which their registrants must meet to remain registered;
 - where concerns are raised about a registrant there should be the opportunity for remediation, so long as patient safety is not affected;
 - continuing professional development (CPD) should be an integral part of revalidation and a registrant could send evidence of CPD to a regulator as part of the revalidation process;
 - the revalidation process must include quality assurance; and
 - regulators should base their revalidation processes on the risks posed by their registrants and collect information on the basis of risks posed.
- 2.8 The Department of Health asked regulators to submit their proposals for revalidation, in line with these principles, by January 2009.

Quality control and quality improvement

- 2.9 One of the drivers behind the previous government's decision to introduce revalidation was a small number of high profile cases where patient safety was severely compromised. The government directed regulators to introduce revalidation as means of ensuring that all health professionals demonstrate their continuing fitness to practise.⁶ There continues to be debate on where regulators should focus revalidation systems to achieve this.
- 2.10 In the 2008 Continuing Fitness to Practise Report, we explored the potential dichotomy between the different aims of 'quality improvement' and 'quality control'.⁷ Quality improvement is perceived as improving the quality of the service delivered by practitioners at every level; whereas quality control is focussed on the minority of practitioners who fail to meet the threshold standards.
- 2.11 We concluded that our existing processes achieve quality control whilst also acting as a driver for quality improvement but that further research was necessary to identify the risks posed by our registrants to establish whether as well as where additional measures might be required.⁸

⁵ Department of Health (2008), *Principles for Revalidation – Report of the Working Group for non-Medical Revalidation*, page 7

⁶ Department of Health, *Trust, Assurance and Safety*

⁷ Health Professions Council (2008), *Continuing Fitness to Practise: towards an evidence-based approach to revalidation*, page 7

⁸ Health Professions Council, Continuing Fitness to Practise, page 11

3. UK health professional regulators current approaches to revalidation

- 3.1 This section looks at the current status of the UK health professional regulator's different approaches to revalidation. The section concentrates on the non-medical regulators, as their drivers for exploring revalidation are similar to our own. It is important to take account of the following factors when looking at how the other regulators have approached revalidation:
 - The regulators have all started from different positions in developing their revalidation schemes and are at different stages in developing their revalidation programme.
 - There are differences in practice and levels of risk amongst the regulated professions which then affect the regulator's approach to revalidation.
 - There are also differences in the regulatory context. Each of the regulators below is either a uni-professional regulator, or regulates a family of professions.
- 3.2 As a result, it is not possible to provide the same information for all regulators. However, the section provides an overview of the research that each regulator uses to support their approach to revalidation and provides a summary of the regulator's proposed revalidation process to date.

General Chiropractic Council⁹

3.3 The General Chiropractic Council (GCC) regulates over 2,000 chiropractors across the UK.

Research

- 3.4 The GCC commissioned Europe Economics to analyse the risks associated with chiropractic and to investigate the benefits associated with introducing a revalidation process. This included identifying and exploring the adverse events (such as radiation-induced cancer) and sub-optimal outcomes (situations where the outcome of the treatment could have been improved) that could potentially be addressed through revalidation.¹⁰
- 3.5 Europe Economics drew on a combination of a literature review, a survey of the chiropractic profession and a review of the data held by the College of Chiropractors and the professional associations to undertake their research. The literature review involved identifying information on the Quality of Life Years values attached to chiropractic care, best care in general practice the dosage levels involved in exposure to ionising radiation in chiropractic and other topics. The survey asked chiropractors to rank the different causes of sub-optimal outcomes. The researchers also looked at the number of

⁹ It was not possible to check the information presented about the General Chiropractic Council before our Council considered this paper. However, the information has been updated to reflect information in the recent edition of the General Chiropractic Council's newsletter 'News from the GCC'.

¹⁰ Europe Economics (2010), Counterfactual for Revalidation: Report to the General Chiropractic Council,

complaints about poor conduct received by the professional associations to consider how those complaints might lead to sub-optimal outcomes.

- 3.6 Most of the information collected from the research was monetised to allow Europe Economics to calculate the financial impacts of adverse events and sub-optimal outcomes so that Europe Economics could then identify the areas which had the most significant impacts on patient care and needed to be addressed by a revalidation scheme.
- 3.7 The research indicated that sub-optimal outcomes were more costly and more likely to occur within chiropractic practice than adverse events. One of the recommendations drawn from the research was that revalidation should focus on tackling sub-optimal outcomes (in other words, improving health outcomes for patients) rather than being used as a means of addressing patient safety by tackling adverse events.¹¹ The focus on sub-optimal outcomes would help to ensure that the system developed by the GCC was proportionate to the risks posed by chiropractic practice.

Revalidation scheme¹²

3.8 The GCC based their proposals for revalidation on the work undertaken by Europe Economics and their intention to use revalidation to focus on addressing sub-optimal outcomes. As a result, the GCC designed their proposed revalidation scheme to be developmental so that chiropractors would reflect on the proportion of their patients they believe could have had a better outcome if their care had been managed differently and complete an audit to consider how sub-optimal outcomes can be avoided.

Three stage model for revalidation

3.9 Revalidation would run on a five year cycle, with 20 per cent of chiropractors being assessed for revalidation each year. The GCC assumed that the majority of registrants would meet the requirements of the first stage and would not therefore need to move to the next two stages.

Stage one – audit

- 3.10 Stage one begins with the chiropractor reviewing a set of patient records to identify where improvements could be made in the patient outcomes. The chiropractor would then use that review to improve their practice.
- 3.11 The chiropractor then submits the patient records to the GCC for assessment by a Stage one assessor. The assessor's role is to review the records and ensure that the chiropractor has both undertaken the audit in an appropriate manner and developed a plan to improve their practice. The Stage one assessor will not be assessing whether the chiropractor has implemented their plan.

¹¹ General Chiropractic Council (2010, *Consultation on a proposed scheme of revalidation*, page. 10 ¹² We have based this section on the proposed revalidation scheme set out in the GCC consultation document. As set out in paragraphs 3.4 - 3.6, the GCC Council previously agreed not to progress their proposals but are now reviewing how to take their revalidation work forward.

- 3.12 The GCC would expect to see evidence the chiropractor has reflected on themselves and their practice, identified where the assessment and care of patients could be at a higher standard or could be improved and produced a plan to address those areas for improvement.
- 3.13 The Stage one audit process has three outcomes. Registrants can pass, be asked to provide additional information or be deemed unsuccessful.

Stage two - on-site visit

- 3.14 Individuals who are assessed as being 'unsuccessful' at stage one will be passed to the second stage of the audit. This stage involves a documentary review of the audit undertaken in stage one and a visit to the registrant.
- 3.15 The assessor and registrant will work together to formulate a plan to address any requirements to improve practice which were not addressed within the audit submitted in stage one. The chiropractor will then implement the plan and identify improvements to their practice.
- 3.16 The assessor will submit a final report once both the visit and the plan have been implemented and documented. There are three possible outcomes. A registrant can be successful, they can have a three month remediation period followed by a re-visit and decision on their revalidation, or they can be referred to stage three.

Stage three – revalidation test

- 3.17 Individuals who are unsuccessful in stages one and two will be referred for a revalidation test. The revalidation test will consist of a range of assessments designed for the chiropractor to address shortcomings in the audit undertaken by the chiropractor.
- 3.18 If a chiropractor fails to pass the assessment, they can be removed from the Register (subject to a change in the GCC's legislation).

Outcomes of the consultation

- 3.19 The GCC were keen to seek the views of professionals on whether revalidation should focus on sub-optimal care, as proposed within their consultation document. However, many respondents to the consultation did not understand the concept of sub-optimal outcomes whilst others argued that some causes of sub-optimal outcomes are beyond the control of the chiropractor.¹³ In response to these concerns, it was proposed to the GCC's Council that the revalidation scheme should focus on how chiropractors can improve health outcomes for patients rather than reducing sub-optimal outcomes.¹⁴
- 3.20 Many chiropractors responded to the consultation indicating that they supported embedding revalidation within an enhanced CPD process. It was suggested that this approach would be proportionate to the risk of

¹³ General Chiropractic Council (2010), *Outcomes of the consultation on the revalidation process*

¹⁴ General Chiropractic Council, Outcomes of the consultation, pages 12 - 13

chiropractic, would improve patient outcomes and was seen to be consistent with other regulators' proposed revalidation schemes.¹⁵

- 3.21 As a result of the suggestions around CPD and lack of clarity around 'suboptimal care', the recommendations made by the external consultants were that the GCC should develop a revalidation system based on an enhanced CPD process. It was suggested that the enhanced CPD process should include a mandatory audit of clinical practice, sampling 20% of the profession at a time. Auditing chiropractors, rather than developing an enhanced CPD process based solely on self-declaration would allow the GCC to check that chiropractors met the necessary standards in a proportionate way.¹⁶
- 3.22 The GCC's Council considered the outcomes of that consultation at their meeting on 2 March 2011. The GCC considered the consultation report in light of recent government statements about revalidation, in particular that revalidation should demonstrate '...significant added value in terms of increased safety or quality of care for users in healthcare services'.¹⁷
- 3.23 The GCC considered the evidence from the consultation and decided that revalidation for the chiropractic profession did not meet demonstrate 'significant added value'. As a result, the GCC agreed to undertake no further work on revalidation.¹⁸
- 3.24 The GCC told the Department of Health about their decision not to undertake further work. The DH has since stated that it expects regulators to be able to assure themselves that registrants are fit to practise and up to date. As a result, the GCC is now considering the steps it needs to take to introduce a system which meets these requirements.¹⁹

General Dental Council

3.25 The General Dental Council (GDC) regulates over 38,000 dentists and 57,000 dental professionals in the United Kingdom. All dentists, dental nurses, dental technicians, clinical dental technicians, dental hygienists, dental therapists and orthodontic therapists must be registered with the GDC to work in the UK.²⁰ At present, the GDC is currently developing its revalidation proposals in relation to dentists only but will consider how these proposals relate to the rest of the dental care team in the future.

¹⁵ General Chiropractic Council, *Outcomes of the consultation*, pages 102 - 3

¹⁶ General Chiropractic Council, *Outcomes of the consultation*, pages 13 - 14

¹⁷ Letter from the Rt Hon Andrew Lansley, Secretary of State for Health to the Chair of the General Medical Council (June 2010).

¹⁸ Minutes of the General Chiropractic Council meeting, March 2011 http://www.gcc-uk.org/files/link_file/C-020311-Open%20Minutes.pdf

¹⁹ General Chiropractic Council (2011), *News from the GCC – August edition*

²⁰ www.gdc-uk.org/Aboutus/Pages/default.aspx

Research

- 3.26 In 2009, the GDC commissioned Ipsos MORI to carry out research into patients' perspectives of revalidation.²¹ The research involved patient fora, smaller discussion groups and in-depth interviews with a variety of individuals. The researchers found that patients believed that dentists were already subject to periodic checking that they continued to meet the relevant standards and were 'surprised' that this was not the case.
- 3.27 The research focussed on areas of dental practice that patients identified could be improved. They identified several key areas:
 - information on payment and costs;
 - the differences between private and NHS dentistry;
 - respect for patients (including the importance of communication); and
 - managing appointments appropriately.²²
- 3.28 The research also identified four key areas that the GDC would assess in a revalidation system. These are clinical practice, communication, professionalism and management and leadership.²³ The GDC will use these four areas to set out a standards and evidence framework that dentists will have to meet in order to meet the revalidation requirements.
- 3.29 The GDC is currently commissioning an evaluation of risk in dentistry in the UK as part of building the evidence base for revalidation.

Revalidation scheme

- 3.30 The GDC consulted on their current revalidation proposals between October 2010 and January 2011. We have based this on their consultation document but they are currently analysing the responses they received and their final approach to revalidation may change.
- 3.31 The GDC currently proposes a five-year revalidation cycle based on a 3stage model comprising compliance, remediation and assessment.²⁴

Standards and evidence for revalidation

- 3.32 The standards and evidence for revalidation will draw on the four domains set out above in paragraph 3.28. All dentists will need to meet the standards that the GDC sets for revalidation. Most of the standards will be generic, although the GDC will also set frameworks for particular areas of practice accessed through their specialist lists.
- 3.33 The GDC want their standards and evidence for revalidation to develop as the profession changes. All dentists will need to maintain their registration based on current standards, not the standards that applied when they joined the register.

²¹ Ipsos MORI (2009), *Revalidation: the patient perspective*

²² Ipsos MORI, *Revalidation*, page 7

²³ Ipsos MORI, *Revalidation*, pages 53 - 54

²⁴ General Dental Council (2010), *Revalidation for dentists: Our proposals*, pages 6 - 9

Proposed Three stage model of revalidation for dentists

Stage one – compliance check

- 3.34 Dentists will collect evidence throughout the revalidation cycle that shows that they meet the GDC's standards. Dentists can draw evidence from various sources, including CPD, patient feedback, patient record checks and clinical outcome indicators.
- 3.35 An approved external verifier, perhaps through a practice inspection or appraisal, will then assess this evidence. The verifier then provides a certificate that the dentist meets the standards or, where concerns are raised about the dentist's practice, provides feedback or contacts the GDC to raise concerns.²⁵ The GDC hopes that many dentists may be able to use existing organisations which quality assure their practice, such as public bodies, to act as external verifiers.
- 3.36 At the end of their revalidation cycle, all dentists must submit a declaration. The declaration sets out their field of practice during the revalidation cycle and that an approved external verifier has assessed them as meeting the standards set by the GDC.
- 3.37 The GDC will carry out a random audit to check that dentists have had their evidence verified. The GDC will erase from the register dentists who do not respond to the request or do not submit the evidence if selected for audit.

Stage two – remediation phase

- 3.38 The remediation phase is for dentists who cannot demonstrate that they meet all the GDC's standards for revalidation. Dentists will be given six months in which to address any deficiencies in their competency. The GDC have indicated that they do not intend to be responsible for remediating registrants and that the dentist is responsible for the cost of remediation.
- 3.39 The dentist must provide a report from an external verifier that they meet the necessary standards at the end of the period. If they do not, they will be referred to stage three.

Stage three – in-depth assessment against standards

- 3.40 This final stage is for dentists whose non-compliance with the standards is serious. In these cases, the dentist will need to pass an in-depth assessment against the standards to maintain their registration.
- 3.41 As part of their consultation, the GDC sought views on two different stage three assessment models. They proposed either an exam approved by the GDC or a defined period of supervised assessment in practice.²⁶

²⁵ General Dental Council, *Revalidation for dentists*, pages 6 - 7

²⁶ General Dental Council, *Revalidation for dentists*, page 16

- 3.42 The GDC is due to publish a response to the consultation in September 2011. The three-stage model may be adapted and further developed in the light of the consultation findings and further research and development.
- 3.43 The GDC has recently launched a review of their CPD requirements for registrants. The review is considering the role that CPD plays in supporting their registrant's practice and the best ways of monitoring and administering the CPD process. The GDC expects to consult on any changes to their CPD process in 2012, although an initial call for views is currently open along with a short registrant survey. The GDC believes it is important that any future approach to CPD is also fit for the purposes of revalidation.²⁷

General Medical Council

- The General Medical Council (GMC) regulates over 230,000 doctors. The 3.45 GMC holds a list of Registered Medical Practitioners and a list of Registered General Medical Practitioners.
- 3.46 As the context for revalidation for doctors is different from other regulated health professionals, the analysis in this document focuses on the activities of the regulators' of other health professions. However, the evolution of the GMC's approach provides some useful context.

Background

- The concept of revalidation for doctors has been explored over a longer 3.47 period than revalidation of any of the other regulated health professions. As a result, this section does not provide information about all research commissioned, only the research most relevant to this paper.
- 3.48 The GMC first presented their proposals for revalidation in 2000, in the document 'Revalidating doctors. Ensuring standards, securing the future' (although the proposals had been in development for several years prior to this).²⁸ Under the GMC's original proposals, a doctor would be revalidated against defined standards with a local revalidation panel (including lay representation) assessing each doctor. The GMC's revalidation proposals evolved over the years, so that by 2004, revalidation was based on a statement from a doctor's employer to say that the doctor had participated in appraisals and there was no evidence of significant concerns against them. A local revalidation panel would therefore no longer make the decision, nor would the doctor be revalidated against set standards.²⁹
- 3.49 The GMC's proposals were then scrutinised by Dame Janet Smith as part of the Shipman Inquiry and the Chief Medical Officer's in his report 'Good doctors, safer patients'. The GMC's revalidation proposals were challenged in both publications as being 'unfit for purpose as the proposals did not assess whether or not the doctor was 'fit to practise'.³⁰ As a result, the Chief

²⁷ www.gdc-uk.org/GDCcalendar/Consultations/Pages/CPDReview.aspx

²⁸ General Medical Council (2000), *Revalidating doctors. Ensuring standards, securing the future*

²⁹ Department of Health (2006), *Good doctors, safer patients,* pages 66 - 67

³⁰ Shipman Inquiry (2004), Safeguarding patients: lessons from the past – proposals for the future paragraph 205, and Department of Health (2006), Good doctors, safer patients, page 180

Medical Officer subsequently established a working group on medical revalidation and published a report called 'Medical Revalidation – Principles and Next Steps'.³¹ This report made a number of recommendations, including how appraisal could be used to support revalidation and the importance of developing relevant standards to assess doctors against.

3.50 The GMC have revised their revalidation proposals considerably since the publication of the above reports. They have recently consulted on their proposals and we have based the information in this section on those proposals.

Research

- 3.51 A considerable amount of research has been undertaken into medical revalidation. For example, the topic of doctors' fitness to practise is one that regularly features in publications such as the British Medical Journal. Given the breadth of research commissioned on medical revalidation, this section focuses on the research of interest to this paper.
- 3.52 In 2005, the Department of Health published research by Ipsos Mori into public attitudes to medical regulation and revalidation.³² Nearly half of the members of the public interviewed assumed that there were already regular assessments of doctors in place, whilst 90 per cent of the members of the public interviewed thought that a doctor's competence should be assessed 'every few years'.³³ The research also reported that the majority of those interviewed were 'reasonably happy' with the quality of care provided by their GP.³⁴
- 3.53 The GMC also entered into partnership with the Economic and Social Research Council in 2006 to take forward a programme of research into medical revalidation.³⁵ The research covered a number of topics including:
 - identifying risk factors amongst underperforming doctors so that appropriate remediation could be developed;
 - an analysis of registration and fitness to practise data held by the GMC; and
 - investigating how doctors respond to significant change during their practice, including moving to new roles or areas of responsibility.³⁶
- 3.54 Part of the research taken forward by the GMC and ESCR was a project to identify biographical and biopsychosocial risk factors amongst

³¹ Department of Health (2008) *Medical revalidation – principles and next steps: the Report of the Chief Medical Officer for England's Working Group*

³² Ipsos MORI (2005), Attitudes to Medical Regulation and Revalidation of Doctors; Research among Doctors and the General Public

³³ Ipsos MORI, Attitudes to Medical Regulation and Revalidation of Doctors, page 6

³⁴ Ipsos MORI, Attitudes to Medical Regulation and Revalidation of Doctors, page 7

³⁵ General Medical Council, Council paper 2 July 2008, Collaborative Research Programme with the Economic and Social Research Council, http://www.gmc-

uk.org/4___Collaborative_Research_Programme_with_the_Economic_and_Social_Research_Council.pdf_25399861.pdf

³⁶ http://www.gmc-

uk.org/about/research/research_commissioned_in_collaboration_with_the_ESRC.asp Page 14 of 39

underperforming doctors.³⁷ The research found that biospsychosocial factors influenced a doctor's wellbeing and performance at work. Biopsychosocial factors included health factors, personal factors (such as motivation or behavior) and social factors (including isolation and cultural differences). As a result, any remediation process should follow a more holistic or biopsychosocial model rather than a medical model.

3.55 The Academy of Medical Royal Colleges also undertook a number of revalidation projects related to the GMC's work in this area. This included research on the usefulness of multisource feedback and patient surveys and how they can be used to support revalidation.³⁸ The review found that whilst multisource and patient feedback can be useful, it is not the only source of information about the quality of a doctor's practice and must be collected carefully.

Revalidation scheme

Licensing scheme

- 3.56 The GMC introduced licensing for doctors on 16 November 2009. Licensing is the first step towards implementing the GMC's revalidation scheme.³⁹
- 3.57 All doctors who want to practise medicine in the UK must register with the GMC and have a license to practise. Only registered doctors with a licence to practise can carry out a number of functions including working as a doctor in the NHS and prescribing medication.
- 3.58 Doctors who successfully pass the revalidation process will have their licenses renewed. When the GMC introduces licensing, licensed doctors will be required to demonstrate to the GMC that they are practising in accordance with the generic standards of practice set by the GMC (as described in Good Medical Practice).

Standards

- 3.59 Licensed doctors will need to collect evidence showing how they meet the Good Medical Practice Framework for appraisal and revalidation. This framework draws on the GMC's 'Good Medical Practice', which is the core ethical guidance for doctors and is used to inform the education, training and practice of all doctors in the UK.⁴⁰
- 3.60 The Framework is made up of four domains, which are knowledge, skills and performance; safety and quality; communication, partnership and teamwork; and maintaining trust.⁴¹ The evidence collected must come from the following areas:

³⁷ Cohen, D, et al, (2009), *Identifying Biographical and Biopsychosocial Risk Factors amongst Under Performing Doctors*

³⁸ Academy of Medical Royal Colleges (2009), *Multisource feedback, patient surveys and revalidation: report and recommendations*

³⁹ http://www.gmc-uk.org/doctors/licensing.asp

⁴⁰ General Medical Council (2009), *Good Medical Practice*

⁴¹ General Medical Council (2011), *The Good Medical Practice framework for appraisal and revalidation*

- continuing professional development;
- quality improvement activity;
- significant events;
- feedback from colleagues and patients (where applicable); and
- review of complaints and compliments.⁴²

Appraisal model for revalidation

- 3.61 The GMC revalidation scheme is based on a five yearly cycle. Doctors must take part in appraisals as part of the revalidation processes and the framework explored above provides a standard approach for appraisals.
- 3.62 All licensed doctors will need to link to a 'Responsible Officer'. Responsible Officers are appropriately qualified individuals within a healthcare organisation who will make a recommendation about whether an individual doctor should be revalidated.⁴³
- 3.63 Licensed doctors will be expected to participate in annual appraisals where they will discuss the supporting information they have collected. The Responsible Officer will then make a recommendation to the GMC every five years about the licensed doctor's fitness to practise. The recommendation is based on the outcome of a licensed doctor's annual appraisals combined with relevant clinical governance information. The GMC draw on local systems of appraisal to support revalidation but the GMC makes the final decision.
- 3.64 The GMC will develop quality assurance processes to support their proposals.⁴⁴ This may include looking both at the systems in place which support revalidation and the recommendations made by Responsible Officers. For example, the GMC is considering a system that would review the evidence that supports Responsible Officer revalidation recommendations.

Continuing professional development

- 3.65 All doctors are required to keep their knowledge and skills up-to-date under 'Good Medical Practice' but the GMC does not currently operate a CPD scheme. The GMC have proposed that CPD will form part of the portfolio that doctors will submit as part of their revalidation process. Including CPD in the revalidation portfolio is one way of allowing doctors to demonstrate that they remain up-to-date.⁴⁵
- 3.66 The GMC want doctors to undertake CPD that takes account of their learning needs, is relevant to their practice and focuses on outcomes rather than inputs or a time-served approach. They have therefore made a number of proposals around changes to their CPD requirements. The GMC has designed proposals that are flexible enough to accommodate all doctors. Their proposals for CPD are therefore similar to our own in several ways,

⁴² General Medical Council (2011), *Supporting information for appraisal and revalidation*

⁴³ www.gmc-uk.org/doctors/revalidation/9572.asp

⁴⁴ www.gmc-uk.org/doctors/revalidation/9548.asp

⁴⁵ General Medical Council (2010), *Revalidation: The way ahead*, pages 26 - 27

including the emphasis on the individual practitioner choosing their CPD depending on their own learning needs and practice.

General Optical Council⁴⁶

3.67 The General Optical Council (GOC) is the regulator for the optical professions in the UK. They currently register around 24,000 optometrists, dispensing opticians, student opticians and optical businesses.⁴⁷

Research

- 3.68 In line with the principle established by the Non-Medical Revalidation Working Group that regulators should base their revalidation processes on the risks posed by their registrants, the GOC commissioned Europe Economics to undertake research to identify those risks.⁴⁸
- 3.69 The research consisted of a literature review, discussions with the optical community and an analysis of available data. The data drawn upon included Fitness to Practise data, complaints information from the Optical Consumer Complaints Service and information on insurance claims from professional bodies. The researchers also held discussions with stakeholders in the optical community and carried out a literature review to reflect on risk more broadly.⁴⁹
- 3.70 The research did not identify any major risks associated with the optical profession and there was no evidence of high levels of risk due to serious mismanagement or misdiagnosis of eye health conditions. The risks identified were limited to practitioners failing to conduct all appropriate eye health tests or not gathering sufficient information about patient symptoms and issues around communication.
- 3.71 The outcomes of the Europe Economics research are similar to the research on risk commissioned by the GCC (see paragraphs 3.4 3.7). In both cases, the levels of risk related not to serious incidents but to situations where professionals did not provide the optimum care.
- 3.72 The GOC also commissioned research into patient feedback and complaints handling, to explore how patient feedback is handled by optical companies, whether the feedback could be used for revalidation and whether the GOC should accredit patient feedback or complaints systems.⁵⁰
- 3.73 The research found that there is no national survey of patient satisfaction or experience and that most surveys were used for commercial purposes and focussed on overall patient satisfaction, rather than the competence of a particular individual. In addition, anecdotal information suggested that the

⁴⁶ It was not possible to check the information presented about the General Optical Council before this paper was considered by Council.

www.optical.org/en/about_us/intro_to_goc/index.cfm

⁴⁸ Europe Economics (2010), *Risks in the Optical Profession: a report for the General Optical Council*

⁴⁹ Europe Economics (2010), *Risks in the Optical Profession*, pages 8 - 11

⁵⁰ Moore D, (2010) Patient Feedback and Complaints, A GOC Revalidation Project

number of complaints received was small. As a result, the report recommended that neither complaint nor patient feedback mechanisms provided information of sufficient quality and comprehensiveness to be used for revalidating opticians.⁵¹

Revalidation scheme

Continuing education and training (CET)

- 3.74 The GOC sets mandatory requirements for continuing education and training (CET) which all fully qualified optometrists and dispensing opticians must meet.
- 3.75 The CET scheme is a points-based scheme that runs over a three-year cycle. All full registrants must earn a minimum number of CET points by the end of each cycle to stay on the register. Registrants can only gain CET points if the activity if the GOC has assessed and approved the activity.⁵²
- 3.76 Registrants can currently gain their CET points in any competency area and through any form of learning activity, called 'modality'. This means that an optometrist or dispensing optician could meet the GOC's requirements for CET solely in a single competency area and through one method of learning.

CET and revalidation

- 3.77 Revalidation will apply to all GOC registrants, not just those in clinical practice. The GOC proposes that they should revise their CET system so that it can reflect and address key risk areas and deliver the key evidence base for revalidation.⁵³ The GOC will enhance their scheme to ensure that registrants undertake CET that is relevant to their scope of practice, is undertaken regularly and involves peer interaction.
- 3.78 The GOC are proposing a number of changes including encouraging registrants to use interactive CET such as peer review, an optional feature to allow registrants to reflect on their CET and a requirement for registrants to create a personal development plan that links CET to their scope of practice.
- 3.79 For revalidation purposes, registrants will need to meet the CET requirements and show that they have a development plan for their CET activity to ensure that they meet the targets for CET activity and that the CET they undertake is linked to their scope of practice.
- 3.80 The GOC will consult on its proposals to use CET to underpin its revalidation processes and their proposals may change.

⁵¹ Moore D, (2010) Patient Feedback and Complaints, pages 34 - 35

⁵² www.optical.org/en/our_work/Education/CET/index.cfm

⁵³ www.optical.org/en/about_us/revalidation/Current-position.cfm

- 3.81 In addition, optometrists and contact lens opticians who are practicing will also have to demonstrate every six years that they have been subject to a clinical skills assessment in ocular abnormalities and ocular examination.
- 3.82 The GOC's proposals around revised CET are similar to our own CPD requirements. For example, our registrants must undertake CPD, which is relevant to their scope of practice, and the GOC will require registrants to create a plan linking their CPD to their scope of practice.

General Osteopathic Council

3.83 The General Osteopathic Council (GOsC) regulates osteopaths in the UK. There are currently over 4,000 osteopaths on their Register.⁵⁴

Research

- 3.84 The GOsC has commissioned KPMG to undertake a number of projects to support their approach to revalidation.⁵⁵ They are undertaking research on:
 - how osteopaths practise, including the risks of practice;
 - the approaches being taken by other regulators;
 - the costs and benefits of the proposed revalidation scheme;
 - a detailed evaluation of the revalidation pilots; and
 - a final report, evaluating the scheme.
- 3.85 The GOsC anticipate that these reports will, when considered together, explore and outline any business case for revalidation. Alongside the pilot, the GOsC have also published a CPD discussion document, which looks at the ways in which the GOsC can enhance their CPD scheme to help osteopaths to enhance standards continually.
- 3.86 The GOsC have recently published the report into how osteopaths practise.⁵⁶ The research drew upon a study of existing data (such as the GOsC register, report on patient expectations and a draft report on complaints and concerns). The researchers also surveyed a sample of the osteopathic profession and held focus groups to obtain more qualitative data.
- 3.87 The report identifies a number of factors about osteopathic practice that affect both the levels of risk posed and the development of the revalidation scheme:
 - More than half of osteopaths normally practise alone so are frequently alone with patients.
 - Only 15 per cent of osteopaths regularly practise within a managed environment such as an NHS clinic.
 - As many osteopaths practise on their own, formal performance appraisal is rare.

⁵⁴ www.osteopathy.org.uk/about/our-work/

⁵⁵ www.osteopathy.org.uk/practice/standards-of-practice/revalidation/

⁵⁶ KPMG (2011), Report A: How do osteopaths practise?

- Many osteopaths use one or more adjunct therapy (such as acupuncture) and a minority of osteopaths undertake examinations of intimate areas (though most would offer a chaperone when doing so).⁵⁷
- 3.88 As outlined above, the GOsC have commissioned a number of research projects, so the report does not make any detailed conclusions about their eventual revalidation process. However, the report does identify several points that may be relevant to the GOsC's eventual decisions about revalidation. In particular, the fact that many osteopaths practise on their own has implications both for the risks posed by their practice and also may limit the networks of professional support which osteopaths can draw on to support the GOsC's revalidation requirements.⁵⁸
- 3.89 The GOsC have also commissioned research on adverse events and patient expectations, which will contribute to their understanding of the risks posed by osteopaths. The research has not yet been published.

Revalidation scheme

- 3.90 The GOsC originally proposed a four-stage revalidation process, which all osteopaths would have to complete every five years.⁵⁹
- 3.91 The GOsC plan to draw together the findings of their pilot of stage one of the process and the findings from their CPD discussion document into complementary proposals, which they plan to consult on further in 2013-14.
- 3.92 Subject to the consultation findings, they hope to introduce a change in the way that continuing fitness to practise is regulated to support continual enhancement of standards in 2014.
- 3.93 We have based information in the following paragraphs on the GOsC's original revalidation proposals.⁶⁰ The information may be subject to change in light of the pilot and subsequent consultation.

Stage one – self-assessment

- 3.94 All osteopaths complete a self-assessment form, which asks them to assess their practice against the standards set by the GOsC. The standards used as the basis of the assessment are the GOsC's Code of Practice and Osteopathic Practice.⁶¹ The standard the osteopath is required to meet is therefore that of an osteopath on entry to the Register.
- 3.95 The GOsC propose four key areas that the revalidation process will cover. They are professionalism, communication and patient partnership, safety and quality in practice and knowledge, skills and performance. Osteopaths

⁵⁷ KPMG (2011), Report A: How do osteopaths practise?, page 3

⁵⁸ KPMG, *Report A*, page 5

⁵⁹ General Osteopathic Council (2009), *Revalidation for Osteopaths: consultation document*

⁶⁰ General Osteopathic Council, *Revalidation for Osteopaths,* pages 5 - 7

⁶¹ The GOsC has combined these standards into one set of standards called the Osteopathic Practice Standards.

must provide a list of supporting evidence to show that they meet the standards and provide this on request.

- 3.96 If the submission made is unsatisfactory, an osteopath can then be referred to stage two of the process.
- 3.97 The GOsC are currently piloting stage one of the revalidation process but not stages two to four.

Stage two – further information

- 3.98 Under stage two, osteopaths would be asked to provide evidence to support the examples given on the self-assessment form.
- 3.99 In the pilot, the GOsC will refer a random sample of those who submit a selfassessment form to stage two, so that the GOsC can check that osteopaths can provide the evidence they cite.
- 3.100 If an osteopath's submission is unsatisfactory, the GOsC refers them to stage three.

Stage three – peer review

- 3.101 Stage three would involve a peer review of practice to address the concerns raised in stage 2. The GOsC identify a number of different processes that could be followed including a review of written evidence or an interview by a trained assessor.
- 3.102 If peer review is unsatisfactory, the GOsC refers them to stage four.

Stage four – formal assessment

- 3.103 Stage four is a formal assessment of the osteopath's clinical performance. The GOsC suggest that they could use an assessment process similar to that used in education providers to assess final year students.
- 3.104 The GOsC also states that osteopaths could be referred for remediation at any stage in the process in order to be revalidated and readmitted to the Register. The GOsC will not provide remediation itself but will signpost available resources to address particular deficiencies.

General Pharmaceutical Council

3.105 The General Pharmaceutical Council (GPhC) regulates over 45,000 pharmacists, as well as regulating pharmacy technicians and pharmacy premises in Great Britain.

Research

3.106 Along with the other regulators, the Royal Pharmaceutical Society of Great Britain submitted a report to the Department of Health in February 2009 outlining their approach to revalidation.⁶² In their report, they identified a number of areas where they wanted to undertake additional research to inform their decision-making on revalidation. They identified three areas that required further research.

- The risk posed within pharmacy practice (so that the revalidation processes and standards were proportionate to the risks posed).
- An identification and evaluation of potential sources of evidence for revalidation such as CPD records.
- An identification and evaluation of structures within pharmacy, which could help to deliver revalidation.
- 3.107 Research has now been completed in these three areas and was presented to the GPhC Council in January 2011. The Council agreed to set up a 'task and finish group' to take forward GPhC's proposals around revalidation.
- 3.108 As outlined above, GPhC commissioned research into the risks posed within pharmacy practice.⁶³ A number of different research methods were used to gather information on risk. This included a literature review of risk factors, a review of the RPSGB's disciplinary records, interviews with staff and focus groups.⁶⁴
- 3.109 The researchers conceptualised risk as 'the potential for harm to occur in the pharmacy workforce, their organisations or the recipients of their services, as a result of pharmacists' activities'.⁶⁵ The report also identified potential criteria that could be used for identifying high-risk pharmacists.
 - The length of time in practice.
 - The individual's level of English proficiency.
 - Whether individuals trained outside the country of practice.
 - A recent change in sector (e.g. a move from hospital pharmacy to community based pharmacy).
 - Whether the individual had a recent break in practice.
 - Patient contact.
 - Previous sanctions by the Regulator.
 - Sole pharmacist on duty.⁶⁶
- 3.110 The interview data identified that these factors were associated with a perception of higher risk (although this was not borne out in an analysis of factors increasing the likelihood of a pharmacist being referred to a fitness to practise committee and it was recognised that this needed to be evaluated further). In addition, the researchers also identified some criteria which might affect risks (such as workload and staffing, organisational culture and engagement with CPD) but which reflected the context in which pharmacists work, rather than the pharmacists themselves. The report suggests that

⁶² The General Pharmaceutical Society took over the regulation of pharmacists in 2010 from the Royal Pharmaceutical Society of Great Britain after the recommendation was made to separate the professional body functions from those of the regulator.

⁶³ Phipps, D, et al (2010), *Risk assessment in pharmacy practice*

⁶⁴ Phipps, D, *Risk assessment*, pages 2 - 15

⁶⁵ Phipps, D, *Risk assessment,* page 115

⁶⁶ Phipps, D, Risk assessment, pages 79 - 81

those pharmacists identified as posing a 'higher risk' might be subject to more regular revalidation assessment than those who posed a lower risk.⁶⁷

3.111 The GPhC commissioned research seeking pharmacists' views on the standards that the GPhC should use for revalidation.⁶⁸ Many of those who responded to the researchers argued strongly that the standards set for revalidation should not be the same as those for entry into the profession. Respondents argued that pharmacists specialise in their practice as they develop and it would be inappropriate to ask them to meet standards that were no longer relevant to their particular area of practice.⁶⁹ The GPhC have previously argued that revalidation should take place against the standards for entry to the Register, but the research recommended that instead, they should develop a core set of standards for all pharmacists with additional standards for specific areas of practice.

Revalidation scheme

- 3.112 The GPhC have drawn the following preliminary findings from their work on revalidation:
 - CPD is favoured as a source of evidence for revalidation and a revalidation process linked to CPD is likely to be the model developed.
 - A centralised system with some kind of external verification of evidence by trained pharmacy professionals seems to be the preferred option.
 - There is support for the development of a set of generic standards that all registrants would have to meet.
 - Most appraisal systems do not focus on clinical issues and therefore are not currently suitable for use as evidence of fitness to practise.
 - Other sources of evidence, such as inspection visits or PCT monitoring visits largely focus on the pharmacy rather than individuals.⁷⁰
- 3.113 The GPhC have recently agreed to look again at the purpose and principles that underpin its work on revalidation in light of the government's position statement in Enabling Excellence.⁷¹ The GPhC's approach to revalidation may therefore change.

Nursing and Midwifery Council

3.114 The NMC regulates over 606,000 nurses and midwives across the UK.⁷² The NMC have committed to introducing revalidation for nurses and midwives by 2014.⁷³

⁶⁷ Phipps, D, *Risk assessment,* page 116

⁶⁸ Boak, G, et al (2011), An explanation of options for the delivery of revalidation

⁶⁹ Boak, G, An explanation of options, page 82

⁷⁰ www.pharmacyregulation.org/pdfs/council/february2011councilmtgagendaitem90211 05revalidationtaskandfinishgroup.pdf

⁷¹ Minutes of the GPhC Council meeting, 14 April 2011

www.pharmacyregulation.org/pdfs/council/june2011minutesofthelastmeetingapril142011councilmin utes.pdf

⁷² www.nmc-uk.org/About-us/

⁷³ Minutes of the NMC Council meeting, 31 March 2011

Research

- 3.115 In July 2009, the NMC commissioned Matrix Insight Limited to undertake research to support the development of a risk-based approach to revalidation.⁷⁴ The researchers undertook interviews, workshops, surveys and literature reviews to develop the evidence base for their research. They also analysed information form the NHS staff survey and 500 fitness to practise cases.
- 3.116 One of the issues highlighted by the research was the lack of information available about the employment and practice settings within which NMC registrants worked. This meant that it was difficult to develop detailed risk profiles to link to revalidation.
- 3.117 The research looked at two distinct areas of risk. These were the professional duty to manage risk and the need to assess risk so that the revalidation process can be proportionate to the risk posed. Broadly, Matrix identified that higher risk situations were those where either the registrant is practising in a setting of higher risk or the registrant is practising in an environment that does not allow the collection of information about the quality of that individual's practice.75
- 3.118 The research identified a number of factors that could contribute to a higher risk profile:
 - Ione working with limited support:
 - · workers provided through an agency with limited or inconsistent support and changing practice environments;
 - independent contractors with a mix of commercial and professional accountabilities:
 - practitioners employed in organisations whose main business lies outside • healthcare:
 - those who regularly undertake night shifts;
 - practitioners working within weak or failing systems; and
 - practitioners inexperienced in their setting or context e.g. new registrants, • those how have significantly changed their role.⁷⁶
- 3.119 These factors are therefore similar to those identified in the research commissioned by GPhC (see paragraphs 3.106 – 3.111). However, the researchers argued that it was not possible to develop a more detailed risk profile of the nursing and midwifery workforce without collecting more data on that workforce.

www.nmc-uk.org/Documents/CouncilPapersAndDocuments/Council2011/NMCCouncil-openagenda-papers_20110331.PDF

Matrix Insight (2010), Revalidation - demonstrating continuing fitness to practise

⁷⁵ Matrix Insight (2010), *Revalidation – demonstrating continuing fitness to practise*, page 29

⁷⁶ Matrix Insight (2010), Revalidation – demonstrating continuing fitness to practise, page 29

Revalidation scheme

Post-registration education and practice standards

- 3.120 The NMC currently sets post-registration education and practice (Prep) standards. Nurses and midwives must meet these standards to stay registered by demonstrating that they have completed:
 - 450 hours of registered practice in the previous three years; and
 - 35 hours of learning activity (Continuing Professional Development) in the previous three years.⁷⁷
- 3.121 Nurses and midwives can meet the practice standard through administrative, supervisory, teaching, research and managerial roles as well as providing direct patient care.
- 3.122 Nurses and midwives must maintain a personal profile of their learning activity and comply with a request from the NMC to audit those profiles. CPD activities must be relevant to the nurse's or midwife's practice and must help to support improvements in practice.

Prep and revalidation

- 3.123 The NMC want to deliver a system of revalidation that updates and enhances their Prep standards. They want to develop a revalidation system that will address a number of points including that:
 - The Prep standards are no longer fit for purpose and should be revised.
 - There is currently no systematic audit of CPD profiles.
 - The NMC register is essentially a historical record of the qualifications of nurses and midwives and of any fitness to practise history they may have; therefore, it does not provide evidence that nurses and midwives are currently fit to practise.⁷⁸
- 3.124 The NMC's proposed purpose of revalidation is to:
 - enable them to confirm, on a continuous basis that nurses and midwives are fit and safe to practise;
 - enable them to confirm, on a continuous basis, that nurses' and midwives' skills and knowledge are up to date and specific to their current area and scope of practice; and
 - promote a culture of continuous improvement in practice to nurses and midwives.⁷⁹

⁷⁷ Nursing and Midwifery Council (2010), *The Prep Handbook,* page 6

⁷⁸ Nursing and Midwifery Council, Council papers March 2011 www.nmc-

uk.org/Documents/CouncilPapersAndDocuments/Council2011/NMCCouncil-open-agendapapers_20110331.PDF

⁷⁹ Nursing and Midwifery Council, Council papers March 2011 www.nmc-

uk.org/Documents/CouncilPapersAndDocuments/Council2011/NMCCouncil-open-agendapapers 20110331.PDF, page 2

- 3.125 The NMC want to develop a revalidation programme that delivers:
 - a cost-effective, proportionate and evidence-based system built on existing requirements;
 - standards and guidance which builds on Prep and sets out revalidation requirements;
 - improvements to the renewal of registration process;
 - enhancements to the CPD process which will strengthen the links between the learning activities undertaken, the nurse or midwife's scope of practice and the improvements that the learning activities make to practice;
 - a robust audit and assessment process of CPD which is risk based and is linked to renewal of registration.⁸⁰
- 3.126 The NMC is currently working to develop their approach to revalidation. They hope to identify options for consultation and piloting at the beginning of 2012, with the intention that revalidation will be in place by 2014. The aims and objectives outlined above may therefore change as their proposals develop.
- 3.127 As can be seen above, the NMC are proposing changes to their Prep scheme to allow for systematic audit of CPD. In addition, they want registrants to undertake CPD linked to the registrant's scope of practice and which brings improvements to their practice. The NMC's proposals move their CPD requirements away from an inputs base (as they currently require registrants to complete 35 hours of learning activity) towards a focus on outputs in terms of benefits to practice.
- 3.128 The NMC's proposals around CPD are therefore similar to our own requirements. The NMC's proposals rely on a combination of self-declaration and a sampling approach to audit and assessment of CPD. We also use a combination of self-declaration and auditing a sample of registrants. The audit allows us to check that individual registrants meet the standards whilst being proportionate to the risks posed.

Pharmaceutical Society of Northern Ireland

3.129 The Pharmaceutical Society of Northern Ireland (PSNI) currently acts as both the regulator and professional body for pharmacists in Northern Ireland. It registers over 2,000 pharmacists and also registers pharmacy premises.

Research

3.130 PSNI commissioned the University of Manchester to undertake research into the risks posed by pharmacy practice.⁸¹ The University had previously

⁸⁰ I Nursing and Midwifery Council, Council papers March 2011 www.nmcuk.org/Documents/CouncilPapersAndDocuments/Council2011/NMCCouncil-open-agendapapers_20110331.PDF, pages 3-4

⁸¹ Phipps, D et al, (2011), Assessing risk associated with contemporary pharmacy practice in Northern Ireland

undertaken research on behalf of the General Pharmaceutical Council on a similar topic. The researchers surveyed pharmacists in Northern Ireland, held a workshop and had in depth discussions with some individuals who had had career breaks.

- 3.131 The report identifies that pharmacists report similar risk factors to those identified in the report for GPhC. The report breaks risk factors down into three factors. The first are individual factors, such as the registrant's role, their employment history and attitudes. The second are task factors, including those related to the practitioner's technical work. The third are organisational characteristics, including the organisation's sector and safety culture.⁸² These factors influence risk, but also influence how risk is managed. More generally, the report identifies that the risks posed by pharmacists may be increased when the pharmacists are in patient-facing roles, or are returning to practice after a lengthy break (the PSNI does not currently have any returners to practice requirements in place).
- 3.132 The report considers whether it would be appropriate to follow the proposed revalidation scheme set out below, or whether PSNI should draw upon the quality assurance model used in Ontario. Under this model, there would be separate registers of practising and non-practising pharmacists, each register would have its own requirements to maintain registration. Those on the non-practising register would be required to maintain a CPD portfolio and present it upon request. The PSNI would ask practitioners on the practising register to complete a more intensive assessment and submit a CPD portfolio every 5 years.
- 3.133 The report identifies that any risk based revalidation processes must incorporate different types of risk and must take account of existing assessment and development resources.⁸³ The report makes a number of recommendations for PSNI to take forward.
 - Develop explicit standards of safe practice that are used to make revalidation decisions.
 - Consider linking the CPD scheme to the standards for safe practice and provide additional support when creating portfolios.
 - Consider whether a revalidation scheme based only on CPD or a CPD and assessment scheme would be most appropriate.
 - Consider whether PSNI should prioritise within the eventual revalidation scheme pharmacists in patient-facing roles and those returning from a career break.
 - Consider developing guidelines and support for individuals returning to practice.⁸⁴

⁸² Phipps, D, Assessing risk ... in Northern Ireland, pages 78 - 9

⁸³ Phipps, D, Assessing risk ... in Northern Ireland, page 68

⁸⁴ Phipps, D, Assessing risk ... in Northern Ireland, page 82

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Revalidation scheme

- 3.134 We have based the information in this section on the PSNI's response to the Non-Medical Revalidation Working Group.⁸⁵ However, PSNI have indicated that their approach to revalidation may change once they have considered the outcomes of their commissioned research and developments amongst the other regulators.
- 3.135 PSNI proposed a revalidation model based on three different components:
 - continuing professional development;
 - self-certification, whereby a registrant completes a self-assessment form to assess their practice; and
 - a mechanism for review on a targeted or sample basis.

Continuing professional development

- 3.136 CPD has been mandatory for registered pharmacists in Northern Ireland since June 2005. Registrants must keep a portfolio of their CPD activities and must undertake 30 hours of CPD each year.⁸⁶
- 3.137 PSNI defines CPD as a 'systematic, ongoing cyclical process of selfdirected learning'. PSNI conceptualises CPD as a four-stage cycle consisting of identifying learning needs, planning activities to address those needs, and documenting and evaluating what was learnt.
- 3.138 Registrants should keep records based on this cyclical approach in their portfolio. PSNI asks 20 per cent of pharmacists each year to submit their portfolio, which PSNI assesses against evaluation criteria based on these cycles.

Self-certification documentation

- 3.139 In addition to a CPD component, PSNI suggested that their approach to revalidation could also include a self-certification process.
- 3.140 Registrants would be asked to complete an annual self-assessment of their performance against criteria/standards set by the PSNI. The self-assessment would be used to identify areas for development and would be included as part of their CPD portfolio.
- 3.141 PSNI recognise that it would need to identify the risks associated with different areas of practice before setting the standards or criteria used to assess registrants.

Review mechanism

3.142 The third component of the PSNI's proposals is a review mechanism. The suggestion is that PSNI would select a sample of registrants to undertake a review (perhaps involving a peer review), which would contribute to the decision about whether or not to revalidate the registrant.

⁸⁵ www.psni.org.uk/professionals/continuing-professional-development/revalidation.php

⁸⁶ www.psni.org.uk/professionals/continuing-professional-development/cpd-intro-page.php Page 28 of 39

4. Discussion

- 4.1 This report has provided an account of the different approaches to revalidation adopted by the other UK health professional regulators.
- 4.2 This section provides a summary of some key themes drawn from the information provided in the previous section. It covers a number of different areas including:
 - how the other regulators consider revalidation;
 - how the other regulators have conceptualised risk;
 - the intended outcomes of the revalidation schemes, including whether they are focussed on quality improvement or control;
 - the importance of proportionality;
 - the role of continuing professional development in revalidation schemes; and
 - the different processes suggested by each of the regulators.
- 4.3 The purpose of this report is to set out how the other UK health professional regulators have approached revalidation. This report does not draw any conclusions about revalidation or about how each regulator has approached revalidation. It is intended to contribute to the Council's discussion about whether revalidation is necessary and, if so, what systems might be appropriate.

Concept of revalidation

4.4 As outlined above, the concept of 'revalidation' has developed over a number of years. Most of the regulators have developed a definition of revalidation and some examples are given below.

"Revalidation is a mechanism which allows health professionals to demonstrate, at regular intervals, that they remain both up-to-date with regulator's standards, and are fit to practise." (General Optical Council)⁸⁷

"Revalidation is a new process which will require osteopaths to show, at regular intervals, that they remain up to date and fit to practise." (General Osteopathic Council)⁸⁸

"Revalidation is the process by which licensed doctors will, in future, regularly demonstrate to the GMC that they are up to date and fit to practise." (General Medical Council)⁸⁹

4.5 Although the definitions are expressed differently, the core parts of the concept of revalidation are the same. Each definition sets out that revalidation will ensure that professionals are up-to-date and fit to practise. The proposed definitions above are all focussed on quality control as

⁸⁷ www.optical.org/en/about_us/revalidation/index.cfm

⁸⁸ www.osteopathy.org.uk/practice/standards-of-practice/revalidation/

⁸⁹ www.gmc-uk.org/doctors/revalidation.asp

regulators have developed a revalidation system to identify those registrants who are not fit to practise and address and shortfalls.

4.6 We have discussed in this report the differences between quality control and quality improvement. We have yet to make a definitive decision over whether the purpose of revalidation is to identify poorly performing registrants who are not being identified through our fitness process, to improve the standard of practice for all our registrants, or a combination of both.

Research and risk

- 4.7 One of the key recommendations from the Non-Medical Revalidation Working Group was that the revalidation processes developed by regulators should be proportionate to the risks posed by their registrants. This supports statements within Enabling Excellence that for the 'non-medical' professions '...there is a wider spectrum of risk to be addressed by different regulators and a "one size fits all" approach would not be appropriate⁹⁰
- 4.8 In the Continuing Fitness to Practise report, we explored the concept of risk in relation to our registrants.⁹¹ We recognised that risk within a healthcare context arises not only from poor performance but also from human errors and organisational or system failures. Taking a risk-based approach therefore requires clear evidence that we can use to calculate risk. One source of evidence that we could use to consider risk is the data from fitness to practise processes.
- 4.9 We publish an annual fitness to practise report, setting out information about the concerns raised about our registrants. In 2009-2010 0.38% of registrants, had concerns raised against them and only 0.09% of the Register had allegations against them which were considered well founded.⁹² In 2009-2010, 68% of cases that we considered at a final hearing related to issues of misconduct whilst only 14% of cases were purely about a lack of competence.⁹³ These figures are consistent with those from previous years.
- 4.10 These trends support the information provided in the Continuing Fitness to Practise report.⁹⁴ Taken together, it seems likely that conduct more than competence is the overriding risk posed by our registrants in terms of public protection and safety.
- 4.11 All of the regulators have commissioned research into the risks posed by their registrants' practice. The research by NMC, GPhC and PSNI identifies risk factors posed by the individual, such as individuals inexperienced in

 ⁹⁰ Department of Health (2011), Enabling Excellence: Autonomy and Accountability for Health and Social Care Staff, page 19
⁹¹ Health Professions Council (2008), Continuing Fitness to Practise: towards an evidence-based

⁹¹ Health Professions Council (2008), *Continuing Fitness to Practise: towards an evidence-based approach to revalidation*, section 5

⁹² Health Professions Council (2010), *Fitness to Practise annual report*, page 9 and page 36

⁹³ Health Professions Council (2010), *Fitness to Practise annual report*, page 39. The misconduct figure includes 34 cases (13%) which related to convictions or cautions.

⁹⁴ Health Professions Council (2010), *Fitness to Practise annual report*, page 21

their particular area of work, and risks caused by the particular situation in which the registrant is working, such as lone working.

- 4.12 The risks factors identified by the NMC and GPhC are similar to those identified by the Department of Health Extending Professional and Occupational Regulation working group.⁹⁵ The group was set up to make initial decisions about extending professional regulation. They argued that decisions about which groups should be regulated based on the risks posed by practice in a particular area and identified key factors when assessing the risks posed. These included:
 - the type of intervention;
 - where the intervention takes place;
 - the level of supervision;
 - the quality of education, training and appraisal of individuals; and
 - the level of experience of the individual carrying out the intervention.96
- 4.13 The GCC however, took a different approach to risk. The research it commissioned suggested that the risk of harm posed by chiropractic practice was low. As a result, its proposed revalidation scheme focussed on using revalidation to address 'sub-optimal outcomes', in other words, situations where the outcome for the service user is not the best outcome.
- 4.14 The regulators have taken different approaches to quantifying the risks posed by their registrants' practice. The methodologies used have included literature reviews, surveys, interviews, workshops and analysis of data about complaints or concerns. Using these different methodologies allows the researchers to try to establish risk that is not captured through fitness to practise data. However, these approaches are only effective where data exists to support a broader approach to risk. The research commissioned by the NMC for example, makes clear that it is difficult to carry out an in depth analysis of the risks of practice because there is insufficient information about the areas in which nurses practice.
- 4.15 The research commissioned by the GCC adopted an economic model, which outlined in monetary terms the effect that adverse and sub-optimal outcomes might have if revalidation was not introduced for chiropractors. By contrast, the research commissioned by PSNI involved a literature review as well as a survey of registrants to measure risk factors. The different approaches taken to research into risk have resulted in different research outcomes. For example, whilst the GCC research focused on the likelihood of adverse incidents or sub-optimal care and the impact on the patient, the PSNI research has identified factors which could be used to make decisions about the potential risks posed by individual practitioners.
- 4.16 As a result, the regulators have conceptualised risk in different ways. Many of the regulators have focused on the risks posed by the individual or the context in which they are working. The GOsC for example, has identified that many registrants work on their own, sometimes in their or the patient's

⁹⁵ Department of Health (2009), Extending professional and occupational regulation: the report of the Working Group on Extending Professional Regulation

⁹⁶ Department of Health (2009), *Extending professional and occupational regulation: the report of the Working Group on Extending Professional Regulation*, page 8 and chapter 2

own home, which could be considered a more risky environment than a managed one. The GPhC research has identified factors about either the individual or the context in which they are working which may make them more risky. By contrast, the GCC research conceptualised risk as the risk of harm to the individual patient.

4.17 Most of the regulators who have commissioned research into risk have done so based on reasonably homogenous techniques and contexts whilst also being specific about the profession that is the focus of the research. For example, the practice of most chiropractors is fairly homogenous and the majority work in sole or group practice settings in the private sector. However, the researchers commissioned by the NMC made clear that they could not provide a more detailed risk profile of the nursing and midwifery workforce without more data about the workforce and settings within which they worked.

Outcomes of revalidation

- 4.18 Section two above briefly outlines the differences between quality control and quality improvement. Quality improvement is aimed at improving the quality of the service delivered by practitioners at every level; whereas quality control is focussed on the minority of practitioners who fail to meet the threshold standards.
- 4.19 We have not yet decided whether our approach to revalidation should focus on either quality control or quality improvement, or whether it should in fact be a combination of both approaches. 'Trust, Assurance and Safety' stated that the purpose of revalidation was to make professionals demonstrate their continued fitness to practise, in other words, the purpose of revalidation was primarily quality control. However, it is possible that developing a system of quality control can also bring improvements to the practice of registrants by encouraging registrants to reflect on and develop their own practice.
- 4.20 Some of the regulators' proposed revalidation schemes could be described as quality control. For example, the GOsC's revalidation proposals use the standards set for entry to the relevant register. Individuals who do not meet these standards for safe and effective practice could therefore end up being removed from the relevant register and prevented from practising.
- 4.21 By contrast, the scheme proposed by the GCC was focussed more on quality improvement. Based on their research, the GCC prepared a draft revalidation process that designed to support improving health outcomes and reducing sub-optimal outcomes for patients. As sub-optimal outcomes can occur with any professional, not just those who are not meeting the necessary standards, the GCC's proposals would have acted to drive up the quality of the service delivered by all professionals at any level.
- 4.22 However, all of the revalidation schemes are linked to a registration renewal process. A registrant who fails to participate in or pass the revalidation processes will not renew their registration and be removed from the register.

There is therefore an element of quality control about all the proposed revalidation methods.

Proportionality

- 4.23 Most of the regulators, such as the GOsC are developing a phased approach to revalidation. Only those registrants who do not pass a particular phase move on to the next stage and the level of assessment increases with each stage. The first phase is often a paper-based exercise, similar to the process we use to audit CPD. The majority of registrants pass this phase and therefore successfully revalidate. Those who do not 'pass' this phase, usually because of concerns raised about their submission, then move on to further phases which often involve practice based scrutiny.
- 4.24 The phased approach with increased assessment allows the regulator to develop a proportionate and targeted process that addresses the risks posed by each registrant. It also allows the regulator to target its resources in the most effective way, so that it can allocate increased resources to those who do not pass a particular phase and so are deemed to pose a greater risk. It would be disproportionate to ask the majority of registrants to undertake a very detailed assessment of their practice.

Continuing professional development and revalidation

- 4.25 One of the key recommendations from the Non-Medical Revalidation Working Group was that CPD should play an important role in any system of revalidation.
- 4.26 Each of the regulators has different starting points in relation to their own CPD requirements. We already have mandatory CPD requirements, focused on outputs and audit registrants to check that they meet our CPD standards. Some of the other regulators, such as the GCC, the GOC and PSNI have mandatory CPD schemes (albeit with different names). Our CPD requirements focus on outputs in terms of the benefits that CPD can bring to practice, whereas a number of regulators' schemes focus on inputs in terms of hours or points (including the GOC and NMC).
- 4.27 Both the GOC and NMC have indicated that they want to make changes to their existing continuing professional development schemes to incorporate revalidation. For example, the NMC have said that they want to develop a system of revalidation that updates and enhances their existing Prep standards. In addition, the GMC and GDC have both indicated that they are going to review their CPD processes to see how best those processes can support revalidation.
- 4.28 The Council for Healthcare Regulatory Excellence (CHRE) have commented on regulators developing their CPD arrangements to support or replace revalidation in the annual performance review. CHRE argue that it may be a proportionate and cost-effective approach to develop CPD in this

way. However, '...current CPD arrangements are not equivalent to revalidation and do not provide the same level of assurance to the public'.⁹⁷

4.29 However, it is clear that CPD will play a key role in any future revalidation processes for all the regulatory bodies. Both the GOC and the GCC have indicated that a revised/enhanced CPD process will act as their revalidation process.

Existing processes

- 4.30 Alongside developing a revalidation system that is proportionate to the risks posed by registrants, the Command paper made clear that the revalidation process should not impose an unnecessary burden on either the registrant or the regulator. As a result, a number of regulators are developing a revalidation system that draws upon processes that already exist, whether the processes are those of the regulator or an external organisation. For example, the GDC hopes that their registrants will be able to use information gathered from existing processes (such as the processes used to check the quality of services) to show that they meet the standards for revalidation. By contrast, the GOC's proposals around revalidation will enhance the GOC's own continuing education and training requirements.
- 4.31 A number of the regulators have explored whether they can use appraisal systems already in existence to support revalidation. The GMC's revalidation proposals rely on the system of medical appraisals as decisions about whether a doctor are revalidated are made by the Responsible Officer based on information gathered during the appraisal process. The GPhC commissioned research into using appraisals as a source of evidence for revalidation. The report's findings show that whilst many pharmacists may have a regular appraisal, the result of the appraisal was not always a decision about the fitness to practise of a particular pharmacist. As a result, appraisals could only be used as one source of evidence and it would not be possible to base the revalidation system on appraisals alone.
- 4.32 Drawing on existing processes helps to ensure that revalidation proposals are proportionate and can be introduced by the regulators with minimal resource impact. The GMC rely on medical appraisals because they are available to most doctors and resources have been allocated to ensuring that appraisals occur consistently. The GMC anticipates that the Medical Royal Colleges will provide guidance and advice to their members about the revalidation process.⁹⁸ By contrast, the GPhC cannot rely on appraisals alone to make a revalidation decision because the appraisals are not available to all pharmacists (particularly those working in independent pharmacies or acting as locums).
- 4.33 However, it is only possible to use existing processes to support revalidation when the process is widely available and relevant to the decision about whether or not to revalidate an individual. For example, it would be far more difficult to rely on existing processes if a significant minority of professionals

⁹⁷ Council for Healthcare Regulatory Excellence (2010), *Performance review report: Changing regulation in changing times 2010 - 2011,* page 22

⁹⁸ http://www.gmc-uk.org/doctors/revalidation/supporting_information.asp

were sole practitioners and did not therefore have regular appraisals which could support a revalidation decision.

Standards for revalidation

- 4.44 The Non-Medical Revalidation Working Group recommended that each regulator should develop contemporaneous standards against which regulators would revalidate registrants. The group argued that revalidating registrants against contemporary standards allows regulators to check that the individual is up to date and meets the standards required for practice within their particular area of practice. As the practice of a registrant develops over the course of their career, they may find that they no longer need to meet all the entry standards for their profession but may instead need to meet other standards relevant for their particular area of practice.
- 4.45 The GDC have indicated they would revalidate their registrants against 'current' standards, not the standards that registrants had to meet to enter the Register. By contrast, the GOsC has indicated that osteopaths would be revalidated against the standards for entry to the Register.
- 4.46 The GOsC has said that it will use the threshold standards for entry to the Register in order to make a revalidation decision. Their revalidation processes will therefore check whether an osteopath meets the standards necessary for safe and effective practice on entry into the profession. This approach works where the profession is largely homogenous and where individuals may practice at a level above the threshold standards but without specialising into many diverse areas of practice. However, where there is considerable diversity in practice, revalidating registrants against the threshold standards would not assess whether they were fit to practise and up-to-date in their specialised area of practice.

Sources of evidence for revalidation

- 4.47 Alongside setting the standards for revalidation, a number of regulators have also considered the kinds of evidence that can be supplied to support a revalidation decision. One key type of evidence is feedback from 'patients'. The GMC for example, have commissioned research into how patient and multisource feedback can be used to support decisions about whether or not a doctor is fit to practise.
- 4.48 The GDC commissioned research into patient perspectives of revalidation and have drawn on that research to develop their revalidation proposals. In addition, patient feedback is one of the sources of evidence that a dentist can provide to show that they meet the revalidation standards.
- 4.49 Patient or service user feedback can be a useful tool for exploring whether registrants are fit to practise and increases public involvement in regulation. However, many of our registrants do not work in roles with direct contact with 'patients' so any proposals we make around using these sorts of feedback need careful consideration.

4.50 We have commissioned research from Picker Institute Europe into different approaches to service user feedback tools and how they contribute to improved professional practice. The research will identify different tools for obtaining service user feedback and consider the benefits, applicability and utility of those tools. This research will help us to consider whether and how might we incorporate service user feedback tools into our work.

Revalidation of conduct

- 4.51 As identified above in paragraphs 4.8 4.10, the majority of concerns raised about our registrants are about conduct rather than competence. This implies that the majority of the risks posed by our registrants relate to their conduct, rather than their competence.
- 4.52 Several regulators have included conduct elements within their revalidation proposals. The GDC commissioned research into patients' perspectives on revalidation, which highlighted a number of areas of dental practice which could be improved, including respect for patients. As a result, the GDC have included 'professionalism' within the four areas they want to use to set out a 'standards and evidence' framework for revalidation. Professionalism and conduct also feature within the plans developed by the GMC.

Conclusions

- 4.53 This report is not intended to draw definitive conclusions about revalidation. It is intended to feed into the wider discussion about whether revalidation is necessary and, if so, what models might be appropriate.
- 4.54 This study has highlighted the differences and similarities between each regulator's approach to revalidation. Underlying the different approaches to revalidation are the different ways in which regulators have conceptualised revalidation and particularly the link between revalidation and CPD.
- 4.55 We have yet to make a decision about whether the purpose of revalidation should be quality improvement or quality control. However, there are a number of ways in which we could learn from other regulators' approaches. This includes the use of feedback from service users, the revalidation of conduct issues and different approaches to risk.

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