KPMG

Report B – A report on the review of the work undertaken by other regulators to outline, costs, benefits, financial and regulatory risks

November 2010

AUDIT ▪ TAX ▪ ADVISORY

Report B – Work undertaken by other Regulators

Disclaimer

Our report has been prepared for the General Osteopathic Council (GOsC) solely in connection with reporting on their proposed revalidation process. Our report was designed to meet the agreed requirements of the GOsC determined by the GOsC's needs at the time. Our report should not therefore be regarded as suitable to be used or relied on by any party wishing to acquire rights against us other than the GOsC for any purpose or in any context. Any party other than the GOsC who obtains access to our report or a copy and chooses to rely on our report (or any part of it) will do so at its own risk. To the fullest extent permitted by law, KPMG LLP will accept no responsibility or liability in respect of our report to any other party.

Limitations of this report

Regulation is currently being developed by 13 health and social care regulators, 9 of whom are health professional regulatory bodies (overseen by CHRE) . The primary purpose of this report is to inform the GOsC of activities that other healthcare Councils have undertaken, with regards to costs, benefits and risks of revalidation, up to the end of July 2010. This regulators interviewed by KPMG have all reviewed and confirmed the findings related to their organisation, in some instances this has included updating them. This report is therefore current as of end of August 2010.

Acknowledgements

KPMG would like to thank the other Healthcare Regulators who participated in the interviews that provided much of the evidence base for this report.

Contents

Section	Page
Meeting GOsC requirements	3
Executive Summary	4
Purpose and Structure of report	8
Regulatory context	10
Proposed GOsC model	12
Research Findings	14
Analysis	24
Conclusions	30
Appendix 1 – Additional research	31
Appendix 2 – Interview guide	40
Glossary of abbreviations	44

Meeting GOsC requirements

This report has been commissioned as part of a series of reports to meet the GOsC requirements to look at an evaluation and impact assessment of their draft revalidation scheme. This report reviews the work undertaken by other regulators to outline costs, benefits, financial and regulatory risks. The table below gives a high level summary of how these requirements have been met, with an indication of the approach adopted by other medical and non-medical regulators.

	Requirement	How other regulators meet this requirement	Addressed on page
1	**Cost (Planning phase)**	• DH fixed funding is a standard approach for planning costs.	25
2	**Cost (Offset model)**	• Cost saving generated by CPD/CET schemes (reduced complaints, FTP investigations) offsets cost of revalidation. • Affordability argument at GMC where appraisals are part of routine practice, so revalidation is no extra work for NHS professionals	26 26
3	**Benefits (improving internal processes)**	• Revalidation can enhance current services to include and embed new practices, such as appraisals and other quality improvement mechanisms.	27
4	**Benefits (measurement and realisation)**	• There is significant work to be done by regulators to ensure required benefits are identified, measured and realised.	27
5	**Benefits (increased patient safety, quality and performance)**	• Revalidation improves the safety of patients while it also drives up the quality and performance levels within practices.	27
6	**Risk (Conduct)**	• Risk of poor professional conduct (both between professionals and with clients) is managed through the setting of explicit standards in the Code of Conduct that the healthcare professional is expected to abide by as part of their professional registration.	28
7	**Risk (Financial)**	• Many Councils will only commit to a cost model once piloting is complete, which raises concerns given the current economic situation for healthcare.	28
8	**Risk (Proportionality)**	• Proposed non-medical revalidation models should reflect the lower risk of practice and therefore have a sense of proportionality.	28
9	**Risk (Clinical)**	• Risk of poor clinical practice and a lack of appraisals can be minimised by robust CET/CPD schemes.	28
10	**Risk (Outcomes from pilot studies)**	• Risk associated with reaching inadequate or statistically invalid results from pilot studies can be minimised by project rigour and scrutiny as well as audit.	29
11	**Risk (accuracy of self-declarations)**	• Some Councils have adopted a peer review/appraisal-based approach to scrutinising self-declarations.	29

Executive Summary - Key findings and recommendations

This report has been commissioned as part of a series of deliverables to provide the General Osteopathic Council (GOsC) with a full evaluation and impact assessment for the proposed Osteopathic revalidation scheme. This report represents a review of the work undertaken by other regulators to outline costs, benefits, financial and regulatory risks.

It is intended to present an overview of how other similar healthcare regulators are approaching revalidation, with a view to:

- *Providing GOsC with an understanding of alternative methodologies for advancing revalidation, with an overview of associated timescales and progress to date.*
- *Setting out, at a high level,the approach that other regulators are proposing to measure the impact of their schemes .*

This report is intended to support the understanding of the baseline prior to developing our approach to the impact assessment and evaluation which will be set out in Report C. It will also help inform GOsC's development of their revalidation scheme and associated plans for piloting in 2011.

The review of the approach of other health regulators to revalidation has provided many examples of good practice as well as indicating what shortfalls exist. All of these examples will be of benefit to the GOsC as they crystallise their approach to revalidation.

Overall revalidation is perceived as one part of a set of measures available to regulators to improve the practice of healthcare practitioners. The Councils we interviewed have approached revalidation in a very similar vein; and all are testing its feasibility. Currently Councils are ensuring that the core activities needed to deliver revalidation (such as appraisals, self-assessment, CPD and training) are given appropriate attention to raise them to the required standard. Revalidation then becomes the golden thread upon which these core activities hang, delivering revalidation using the simplest mechanism possible.

Whilst progress is varied in terms of implementing revalidation, there is an imperative and will to deliver the regulatory change within the next few years. Most Councils therefore have made similar progress, have adopted similar approaches, are creating and identifying the evidence for their business cases and are assessing costs, benefits and risks. The GCC and GDC are both developing more sophisticated models to try to align risk and cost of their schemes.

It is important to note that GOsC is considering a very similar process to other non-medical Councils and the proposed methodology should be maintained through to implementation. However, there are lessons to be learnt around specific processes within the model. This includes the use of peer review at the General Optical Council to assess geographically remote practitioners and the planned mandatory implementation of appraisals across other professions.

Other Council concerns are centred on Costs, Benefits and Risks. The cost issues show that current funding is finite, so Councils are having to stick to budget or identify further funding themselves. Councils are also using the piloting of revalidation as the conclusive evidence for creating the cost model.

The cost of revalidation is not perceived as prohibitive, although the business case for implementation is not fully understood. All Councils have indicated that the revalidation costs will be borne by registrants post implementation.

It appears that as yet there is no consensus as to what would constitute regulatory risk, and there would appear to be several concepts of what we mean by 'proportionate'. However, the key financial risk around revalidation is the viability of delivering schemes which are sufficiently robust in the current financial climate.

The 'soft' benefits of revalidation have been identified, although regulators have not yet determined how to measure these.

Dual registration does not appear to be a significant issue or concern at other Councils. The most significant overlap lies, unsurprisingly, with the General Chiropractic Council, but they do not believe this to present any additional clinical risk or regulatory issue.

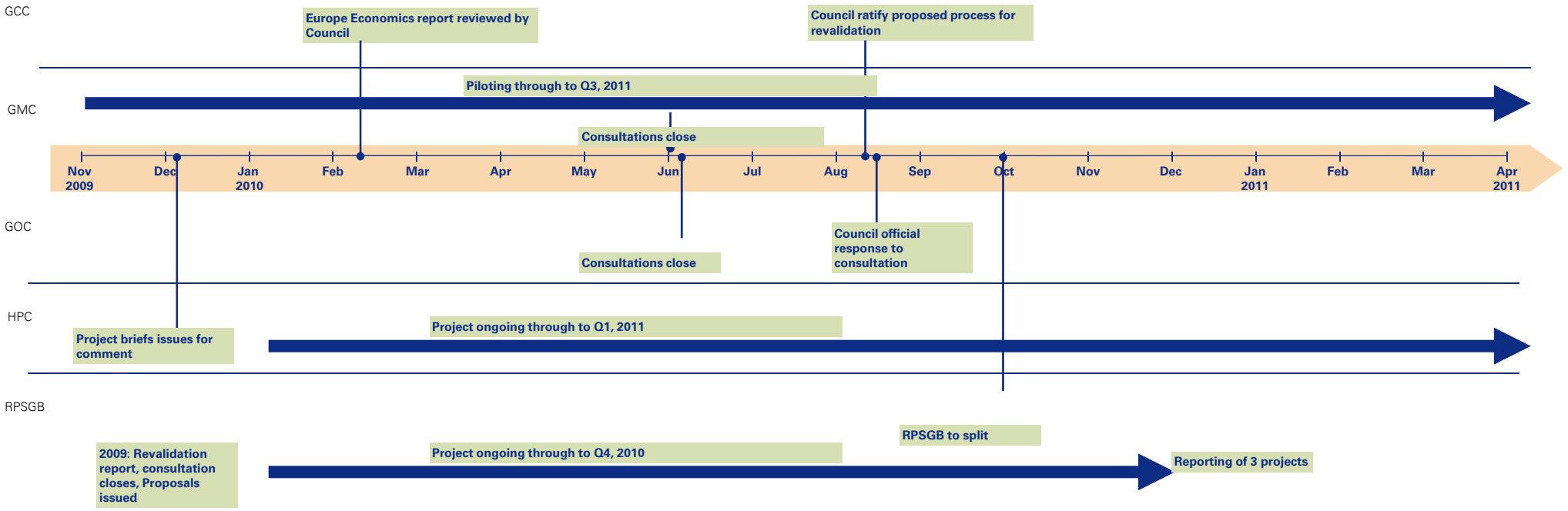
The effect of remediation was discussed with all interviewees. In all cases, there are agreed methods for removal from the register. However, in the context of revalidation, remediation will involve case review and the use of remediation will be signposted throughout the process.

Executive Summary - (cont.) and Progress so far

This is in line with the approach proposed by GOsC. Many Councils believe that remediation in revalidation should be focused on professional development rather than being punitive in nature. In our discussions with BOA, they indicated that they expect to play a significant role in support of their members requiring remediation, although they expect this number to be small.

Piloting, post consultation, is now seen as the core activity in the next financial year to deliver the evidence required to map the process, mitigate risk and assess costs. When GOsC does get to this stage, it is vital that benefits tracking and realisation forms part of the initial planning of pilots, not as a result at the end.

Progress of Other Councils to date (July 2010)



Executive Summary - Impact on the Profession

Research has shown that there are similarities between the conditions treated by GCC and GOsC registrants. Therefore, the approach to creating the Revalidation model at GCC is of particular interest. Given that there is such a significant professional cross-over between chiropractors and osteopaths, the drivers for revalidation should be similar too. For Chiropractors and Osteopaths, the key drivers are:

- Patient safety and experience – even though both professions are deemed to be relatively low risk in terms of their professional practice, there are some risks to safety. There have also been complaints that practises have been deemed inappropriate with patients who were unaware of what to expect.
- Quality of service - delivery of an agreed level of professional service to patients, in a safe environment. The general shortfall in quantity and quality of clinical governance, appraisals and peer review will have a significant impact on professional development. However, both GCC and GOsC support and maintain effective CPD systems. With regards to the safe environment, practice venues are generally considered as high risk because treatments are delivered in unmanaged environments. Therefore, both osteopaths and chiropractors would benefit from revalidation assessments on the safety of their work environment.
- Differential diagnosis – in all non-medical professions, identifying the issue is important to delivering effective treatment. Therefore, revalidation must look to evaluate this skill. This will be pertinent to the GOsC model.
- Appropriate onward referral – a risk for GCC registrants is effective referral. If patients are not referred to the correct specialist, this will cause delays in their treatment and potentially have a detrimental impact on the patient's health. Therefore, the evaluation and assessments carried out as part of revalidation must support the development in referral practices.

Comparator organisations have also demonstrated that there are other facets of revalidation that should be incorporated or considered in the GOsC model:

In all interviews with Councils, revalidation was seen as supporting the professional reputation of registrants. This will be seen as a professional benefit and should be maximised when implementing the proposed revalidation model.

Revalidation should reflect current policy and standards. Should there be changes in professional policy or standards, the revalidation model should be flexible enough to change and adapt to the change.

The level of appraisal, both in terms of quality of process and quantity of appraisals, is perceived as currently being inadequate by all non-medical Councils. This is a serious threat to implementing the revalidation model as appraisal is a core tool to developing the profession. While this is consistently acknowledged as an issues, there are few Councils taking significant steps to ensure appraisals become commonplace and embedded in practice culture. The efforts of the GOC to make appraisals mandatory should provide evidence of good practice that other non-medical Councils can follow.

There is also no agreed view amongst regulators about how they should use tools such as peer review/ appraisal to support an assessment of performance. The key finding we established in this area was that there is a much greater reliance on CPD and completion of mandatory training hours to drive performance than there is in a formal system of appraisal. Interviewees cited this to be largely a symptom of the environment in which non-medical professionals practice, whereby there is a high incidence of solo-practice, as opposed to traditional medical environments where practice often takes place in teams.

Executive Summary - Impact on the Profession and Recommendations

All of this is significant as current trends deviate from best practice as described in *Trust, Assurance and Safety,* which suggested that appraisal should be formative and summative, to ensure objectively that required standards are met' . Whilst CPD and peer-assessment can support a formative assessment of performance (ie. identifying development needs) there is no summative assessment (i.e. no judgement upon assessment of performance against clear standards). With limited appraisal taking place in Osteopathy the GOsC maybe missing an opportunity both for effective performance management and quality improvement and therefore missing an opportunity to enhance the confidence of patients and the public.

This means that Fitness to Practise procedures remain as an important (yet relatively costly) way of identifying poor performance, and regulators are missing an opportunity to avoid such procedures through more proactive assessment of practise. The overall direction of travel around revalidation is likely to involve the practitioner gathering more data to support more objective and impartial appraisal-type discussions. The GOsC should consider how to introduce this in a way which supports the development of the profession.

Most Councils have not considered the form of remediation that will support their revalidation model. While all Councils have processes to remove members from the register, this process will not be engaged until the final stages of revalidation.

Our Recommendations

Our recommendations are directed at the key issues driven out of our analysis:

- The GOsC should focus time and attention in developing those levers which will support the delivery of revalidation – in concert with developing the draft scheme (particularly appraisal/peer review, CPD, development of the Register).
- The GOsC should ensure there is clarity around the timescale for delivering revalidation to ensure momentum towards implementation.
- It is important to design pilots which are representative and scalable.
- They should consider supporting the business case for revalidation with demonstrable or measurable targets (e.g. KPIs, QALYs such as improving health outcomes, health cost avoidance, reducing sub-optimal outcomes).
- Engage the profession and stakeholders as much as possible in each of the phases of implementation (and incentivise involvement this may include reduced subscription fees, reduced revalidation fees, awards for high standards).
- Undertake consideration of how to fund revalidation and structure the costs to registrants in a transparent way.
- Ensure effective audit of all key elements of the revalidation scheme such as the Code of Conduct and analysis of trends in complaints. This will form part of the revalidation model for many Councils, and could form part of the assessment made in the GOsC model.

Purpose and structure of report

1. Background to the Report

This report has been commissioned as part of a series of deliverables to provide the General Osteopathic Council (GOsC) with a full evaluation and impact assessment for the proposed Osteopathic revalidation scheme. This report represents a review of the work undertaken by other regulators to outline costs, benefits, financial and regulatory risks.

2. Objectives

This report is intended to present an overview of how other similar healthcare regulators are approaching revalidation, with a view to:

- Providing GOsC with an understanding of alternative methodologies for advancing revalidation, with an overview of associated timescales and progress to date
- Setting out, at a high level, the approach that other regulators are proposing to measure the impact of their schemes

This report is intended to support our understanding of the baseline prior to developing our approach to the impact assessment and evaluation which will be set out in Report C. It will also help inform GOsC's development of their revalidation scheme and associated plans for piloting in 2011.

3. Process and methodology

This was a 3-month review which has followed the following 3 stages:

- **Desk based research** – to outline work undertaken by other health regulator councils to date (for full list, see Appendix 1).
- **Assessment and scoping alternative methodologies** – to examine alternative revalidation models in more detail and to understand other approaches to revalidation.
- **Developing recommendations** – based on our research and insight from working with other regulators and knowledge of the wider health sector.

4. Project Approach

Our approach was largely qualitative in nature. Once we had undertaken the desk based research we selected 5 regulators which we thought would provide useful comparators for GOsC in the development of their revalidation scheme. These included the Healthcare Professions Council, General Optical Council, General Medical Council, General Pharmaceutical Council and the General Chiropractic Council.

Our rationale for selecting these regulators were as follows:

- Health Professions Council: The body retains oversight of 15 professions and therefore could provide a broad perspective of revalidation across a number of regulators with similarities to Osteopaths such as chiropodists / podiatrists and physiotherapists. It also therefore had the potential to contribute a view of how to treat dual-registrants.
- General Optical Council: The regulator has completed the first stage of consultation on draft proposals for a revalidation scheme for opticians and has developed an interesting approach to CPD which complements the roll out of revalidation. It helps demonstrate the various levers that regulators can use in deploying revalidation.
- General Medical Council: The organisation has the most advanced plans for revalidation compared to other healthcare regulators. The GMC was the forerunner in the design of revalidation and had established detailed draft guidance on a scheme for the licensing and revalidation of doctors in September 2004. The regulator have recently consulted on its approach and is piloting key elements of the scheme such as appraisal.
- Royal Pharmaceutical Society for Great Britain (*shadow General Pharmaceutical Council)* : The regulator has responsibility for a number of locum practitioners which may help inform conclusions about how to mitigate the risks associated with practitioners moving across different practice settings.
- General Chiropractic Council: To be aware of the distinctions between chiropractic and osteopathy and the similarity in terms of conditions treated and environments in which they are practised . They are therefore a useful comparator for GOsC.

Purpose and structure of report

4. Project Approach (continued)

We therefore developed a semi-structured stakeholder interview template, which was approved by the internal Revalidation Project Team (see Appendix 2) to test regulators approaches to revalidation schemes and support development of the key themes emerging from our work. We interviewed:

- Megan Scott, Policy Manager, Health Professions Council
- Grahame Tinsley, Assistant Director of Regulation, General Optical Council
- Richard Marchant, Assistant Director of Regulation, General Medical Council
- Janet Flint, Post Registration Manager and Sadia Khan, Senior Pharmacist, Royal Pharmaceutical Council for Great Britain
- Margaret Coats, CEO and Registrar, General Chiropractic Council
- The BOA executive were also interviewed to provide a view from the profession

5. Structure of this Report

The structure of the remainder of this report is as follows:

Section 1 - Regulatory Context

Section 2 – Research and Interview Findings

Section 3 – Analysis

Appendix – Additional research material

Section 1. Regulatory context

The regulatory reform agenda

- In recent years the work of the Better Regulation Executive (BRE) has set the context to the development of regulatory reform across government. Their role has been one of codifying 'what good looks like' with a view to ensuring that regulatory regimes are meaningful, rather than burdensome and deliver the outcomes they are designed to deliver. BRE set out a number of principles which state that any regulation should be:
  - Transparent;
  - Accountable;
  - Proportionate;
  - Consistent; and
  - Targeted where action is needed.

Regulatory reform in Health

- The Department of Health (DH) has overseen the development of regulation in the health sector, and within this has advanced the regulation of healthcare professionals through revalidation. The DH's White Paper of 2007, 'Trust, Assurance and Safety', described revalidation as 'a mechanism that allows health professionals to demonstrate that they remain up-to-date and fit to practise' and has put the onus on regulators to ensure that it is implemented effectively. Whilst the GMC are the most advanced in terms of this implementation, non-medical regulation has progressed significantly since the publication of the White Paper through the oversight of the Working Group for Non-Medical Revalidation. Their 2008 Report 'Principles for Revalidation: Report of the Working Group' re-iterated the principles set out both in the White paper and from the BRE. Within these principles, non-medical regulators have had the autonomy to design their own models of revalidation. As a result, non-medical regulators reported their plans to the DH in January 2009.
- Ensuring trust in regulation has become an important theme of professional regulation and it is essential that regulators communicate honestly with the profession, public, and other stakeholders when there is a need for regulatory change. This trust is the foundation of revalidation where regulators set the standards, and it is the responsibility of practitioners and employers to meet those requirements. This is especially true in the current economic climate when regulatory activity may be seen as a burden at a time where all spending is under scrutiny. Despite these constraints, patients still expect safe and quality care. It is therefore the duty of regulators to design a system which helps minimise 'sub-optimal outcomes'.
- The recent announcement from the Secretary of State, Andrew Lansley, regarding revalidation and the decision to extend piloting of revalidation in England shows a commitment both to designing the system correctly and evidencing this. "Revalidation is something that the public expect their doctors to undertake... Time is needed to develop a clearer understanding of the costs, benefits and practicalities of implementation."
- There is ever greater pressure upon the regulator to ensure that these systems are sufficiently robust, without being burdensome, or bureaucratic for practitioners or employers. This also puts a responsibility on practitioners and employers to ensure proper arrangements for monitoring and learning are effective. There is likely to be a further announcement in the Autumn 2010 about non medical regulation.
- From our research it has become apparent that non-medical regulators have made significant yet varied progress in advancing plans for revalidation. In many cases they are undertaking consultation, and in some instances undertaking pilots to test their schemes. What is clear is that no single regulator has a definitive answer for how to reduce the risks associated with the provision of healthcare, or indeed to guarantee continuous improvement of standards of care . However, lessons can be learned by looking at other regulators schemes, and how they exercise various levers such as Continuing Professional Development to enhance the safety and effectiveness of practice. This report will therefore look at the key themes that can be drawn around how other regulators have addressed the costs, benefits, and risks of revalidation, the lessons that GOsC can take from this.

Section 1. Regulatory context - CHRE

Council for Healthcare Regulatory Excellence (CHRE)

The Council for Healthcare Regulatory Excellence promotes the health and well-being of patients and the public in the regulation of health professionals. It has an overview role across the healthcare regulators, shares best practice and issues responses to the proposals and consultations put forward for revalidation. They do not issue guidance to regulators on model design. However they have reported and fed back to date on two proposed schemes of the GOC and GMC. They have made clear recommendations that the GOC model should be more patient and outcome focused. The response to the GMC consultation included patient participation in the design phase, the level of proportionality demonstrated and the possible conflicting role of the Responsible officer. All issues raised form part of the consultation evaluation for both Councils, as confirmed in their interviews with us.

The CHRE has also recently published a report, 'Managing extended practice; Is there a place for 'distributed regulation'?' (June 2010). This report makes many relevant recommendations that will support the creation of revalidation models for GOsC and other regulatory Councils. These include:

- Registered health professionals should only practice in areas that they are competent to do so; they are responsible for the care that they provide to patients.
- Employers should have the appropriate support and performance management systems in place if it employs health professionals in extended roles. Whilst many Osteopaths are self employed this may be of relevance where Osteopaths employ associate practitioners.
- Regulators should ensure their codes of conduct adequately reflect the requirement for health professionals to stay up to date and to operate safely within their areas of competence.
- Regulators should only pursue the option of creating a specialist list or annotation on the register when all other approaches have been exhausted.
- All parties should demonstrate an active commitment to cooperating and sharing information to manage risks to patient safety and public protection.

Section 1. GOsC Revalidation proposed model

GOsC believes that the most pragmatic revalidation scheme would be one that is staged, with an initial self-assessment form at Stage 1, which every osteopath would complete and submit to the GOsC once every five years. The self-assessment form would help to identify whether individual osteopaths are meeting the key performance indicators of good osteopathic practise. Additional stages would only apply where Stage 1 had highlighted a concern. The exact nature of the GOsC revalidation scheme to be piloted is still being refined.
The proposed scheme of revalidation is outlined in the diagram (right).

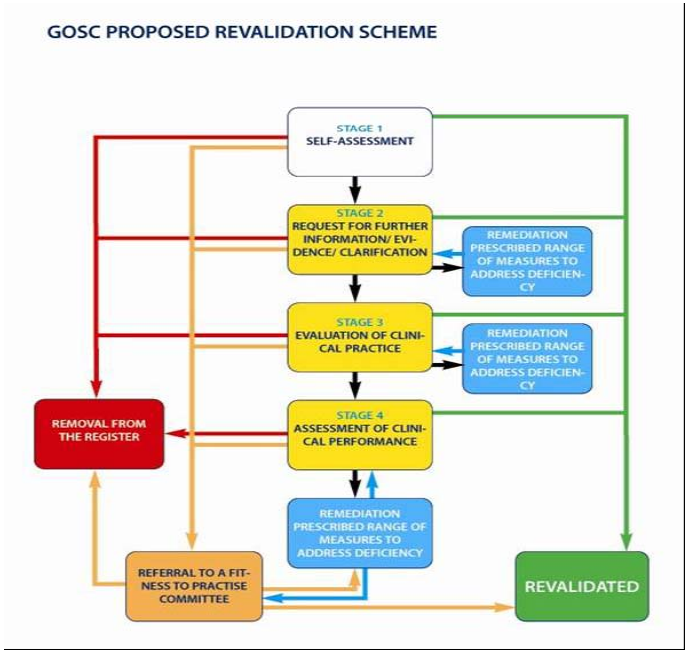
The scheme would consist of four main stages as outlined below.

STAGE 1 – A self-assessment form or the submission of evidence in a portfolio is completed by all osteopaths, which tests the
key performance indicators of safe osteopathic practice contained in the Revalidation Standards and Assessment Framework (which maps to the new Osteopathic Practice Standards document). The Revalidation Standards and Assessment Framework brings together the standards, assessment criteria and examples of evidence in one simple document.
The key areas for revalidation outlined in the Revalidation Standards and Assessment Framework are proposed as follows:

These are:

- Area One – Communication and patient partnership
- Area Two – Knowledge, skills and performance
- Area Three – Safety and quality in practice
- Area Four – Professionalism

Under each Area there will be a number of key performance indicators which the osteopath must demonstrate that they meet. Osteopaths will be required to submit portfolio of evidence to demonstrate that they have met the requirements of each area or to complete a self assessment form listing evidence collected. Currently work is ongoing to develop a variety of methods by which the osteopath can submit evidence including tools or templates such as patient surveys and clinical audit tools.



These will allow the osteopath to easily provide the evidence to demonstrate that they meet the assessment criteria for each of the standards and areas of practice outlined. In order to be clear and transparent the GOsC will also publish the assessment criteria against which an osteopath will be assessed. This work will be published on the GOsC website in Autumn 2010.

An unsatisfactory submission at Stage 1 would lead to Stage 2.

STAGE 2 – This stage is a simple request for further information to clarify the response made at Stage 1 if the information provided is ambiguous or incomplete. The osteopath may be asked to provide further evidence relating to particular standards. In addition, as a quality assurance measure, some osteopaths may be randomly referred through to Stage 2, 3 and 4. If it was still not possible for an osteopath to demonstrate that they had met the standards, a referral to Stage 3 or 4 would take place.

Section 1. GOsC Revalidation proposed model (cont.)

STAGE 3 – A peer review of practice is required as a result of concerns raised at Stage 2.

This could take the form of any of the following:
- A review of written evidence cited
- A review in practice by a trained GOsC assessor – on a general level or focused on a specific area
- An interview with the osteopath by a trained GOsC assessor.
- If it was still not possible for an osteopath to demonstrate that they had met the standards, a referral to Stage 4 would take place.

STAGE 4 – A formal assessment of clinical performance – using a procedure similar to the current assessment for final-year students at osteopathic educational institutions and the test of practical competence employed for some applicants prior to registration.

Section 2. Our Findings - Research and interview approach

The first stage of the research for this report was desk-based. This involved various literature and searches for evidence to show the current level of progress that each healthcare regulator has made against the challenging revalidation agenda. The emphasis was always to identify areas where the experiences or activities of each Council could be directly translated to the issues faced by Osteopaths (as a profession) and GOsC (as a regulator).

What were the main sources of data?

The websites of each regulator provided much of the content for the progress analysis. Typical sources found and used would be:

- Dedicated revalidation areas of each Council's website – most websites offered a Revalidation webpage with links to supporting documents.
- Consultation papers – for those Councils that have already chosen to consult, the relevant documents were made available either through the website or on request.
- Minutes from Board meetings with progress reporting on revalidation – this was an important source as it demonstrates the traction created within each Council in dealing with revalidation.
- Press releases – these provided minimal content but were monitored to ensure no evidence was missed.
- Internal KPMG market knowledge to enhance researched information (both through prior engagements and through market exposure).

Interview methodology and approach

The interview template set up was created in conjunction with Revalidation Project Board at GOsC. This ensured that there was an agreed flow and balance to each interview as well as an applied consistency with regards to the dataset collected. However, it should be noted that the interview template was set as guidance and not an enforced flow. It was agreed that the interviews should collect the majority of the required data that was not collected through the initial research. Interviews were also an opportunity to validate the initial research and build upon that knowledge.

The following slides provide short summaries of the important findings of each regulator researched, including interview summaries.

Section 2. Our Findings - General Chiropractic Council

The General Chiropractic Council (GCC) have commissioned Europe Economics 'to make sure there is a credible business case for a risk-based, proportionate scheme of revalidation'.

Revalidation progress report (February 2010)

Europe Economics has been commissioned by the GCC to make sure there is a credible business case for a risk-based, proportionate scheme of revalidation for the chiropractic profession. This is being developed in consultation with the GCC Revalidation Working Group, which includes representatives from chiropractic professional organisations and patients.

Next steps that need to be completed prior to full consultation with the profession and other stakeholders are as follows

a. Electronic survey of the UK chiropractic profession.

b. Design of contents of revalidation scheme.

c. Piloting to assist in estimating revalidation compliance costs.

d. Assessment of benefits.

Overview of Approach

In its work on revalidation, the GCC and its independent consultants, Europe Economics, are focused on ensuring that any scheme for chiropractors is:

- risk based;
- Proportionate; and
- has a robust business case.

In a progress report presented to Council by Europe Economics on17 February 2010, the potential areas of risk were identified as:

- breaches of ionizing radiation regulations; and
- sub-optimal outcomes for patients.

Electronic survey

Europe Economics will soon distribute a short electronic survey to all chiropractors for whom the GCC has email contact details.

Source: http://www.gcc-uk.org/files/page_file/GCCNews28_WEBversion_March10.pdf

The results of the survey will then be used in a risk-based revalidation model to quantify the magnitude of risks in chiropractic that would occur in the absence of revalidation i.e. the 'counterfactual'. By answering the questions in this survey, chiropractors will make an important contribution to ensuring the proposals, on which they will be consulting later this year, will be proportionate to the identified risk.

Interview summary

- It could be considered that the GCC registrants are professionally the closest to Osteopaths. There are significant overlaps in the professional practices of both Chiropractors and Osteopaths. Both professions work alone or in smaller practices, take a very hands-on approach to therapeutic treatment, are often not employed by NHS but are contracted. Both offer low risk services in a higher risk (unmanaged) environment and there is reported confusion in patients as to which professional to approach given specific symptoms. Both professions also lack infrastructures for systematic and robust performance appraisals. However, there are few dual registrants between GCC and GOsC.
- As a regulator, GCC's statutory duties are to regulate and develop the profession. Their Code of Practice and Standard of Proficiency set out the quality of care that patients are entitled to receive and the CPD system is intended to improve patient services and develop the profession.
- The GCC approach to revalidation appears a factually robust method. Using a Counterfactual report by Europe Economics, GCC has identified that the risk of exposure to ionising radiation and sub-optimal outcomes are the only risks of significance to patients.
- Sub-optimal outcomes will have the greatest justifiable economic impact, through improving performance in correct diagnosis, differential diagnosis and early appropriate referral.
- An interesting example of this economical qualification is the QALYs cost approach. The quality-adjusted life year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived. It is used in assessing the value for money of a medical intervention. The Europe Economics paper assesses the financial risk of not addressing the sub-optimal outcomes (or preventing them occurring). This then gives an opportunity cost for revalidation. Although the calculation to support the minimising of ionising radiation exposure did not show a cost saving, the potential cost saving of reducing the impact of sub-optimal diagnoses is sufficient to justify consultation.

Section 2. Our Findings - General Chiropractic Council (cont.)

- The revalidation model will have three main steps; EVIDENCE, REMEDIATION and a TEST OF COMPETENCE. The Revalidation Working Groups will evaluate the proposals drawn from the Counterfactual paper, with recommendations to be reported to the Council in August 2010.
- The cost model will only be complete after the costs of compliance have been identified by piloting the proposed scheme, with the recognition that the costs will be borne by registrants.

GCC Meeting on Revalidation (18th August 2010)

The August decision of the Council was that the framework of revalidation that will form the basis of the GCC consultation should:

- Focus on chiropractors reflecting on what proportion of their patients they considered could have had a better outcome if their care had been managed and/or implemented differently.
- Include a process audit to be undertaken by chiropractors and assessed against agreed criteria.
- The process audit would be linked to the relevant requirements of the current Code of Practice and Standard of Proficiency, in particular: patient assessment; planning and applying care; communicating with and advising patients; communicating with other healthcare professionals.

Section 2. Our Findings - General Optical Council

Overview of Approach

GOC have completed the first stage of consultation on draft proposals for a revalidation scheme for opticians. The results of this consultation will be used to formulate more detailed proposals which will also be subject to consultation.

Revalidation will apply to all registrants who are active in clinical practice; those on the register but not practising will not be required to be revalidated.

How it will work

They anticipate using an online system, similar to the one used for CET (Continuous Education and Training), to support the revalidation process.

Licence to Practise

They intend to undertake the approach of the General Medical Council (GMC) by seeking the legislation required for registrants, who are practising, to be issued with a Licence to Practise.

Risk profiling

They intend to undertake risk profiling of registrants to inform the revalidation scheme which will be evidence-based wherever possible. Registrants will be asked to provide details of their scope and context of practice.

Competencies

Registrants will be revalidated against entry-level competencies or, where speciality registration is held, the competencies required for entry into a specialty scope and context of practice.

Evidence

The greater the risk to patients of 'competency failure', taking into account the contextual factors of a registrant's practice, the more robust will be the evidence-base required to satisfy the GOC that competency has been maintained.

Intensity and frequency of revalidation and remediation

A Licence to Practise will be issued every six years (matching two three-year CET cycles) following a revalidation review. However, where concerns are identified, a licence may be issued for a shorter period subject to the registrant meeting certain conditions. The cost of undertaking remedial action to meet such conditions will be met by the registrant.

Timescales

A full implementation plan will be published later in the year. GOC plans to start revalidating registrants from the beginning of the 2012-14 CET cycle. One sixth of registrants will undergo revalidation each year (matching two, three-year cycles).

Interview summary

- The majority of optical procedures covered are relatively low risk and most complaints are around CONDUCT rather than CLINICAL deficiency. GOC will make the level of risk assessed in their revalidation model proportionate to the level of risk assessed in their revalidation model to be proportionate to those faced by its registered health professionals.
- GOC are looking at CET as a tool to drive up standards and support a proportionate system of revalidation. However, there are some discrepancies here as optometrists get some protected funding for CET schemes, while dispensing opticians do not get this funding. There was specific reference to glaucoma as a high risk procedure. The CET scheme is seen as core to the solution here.
- Peer review was also seen as a strong option for driving up performance and standards. However, it was recognised that not all practices will be accessible or may be isolated. This solution has not been costed yet. The overall effort is to avoid increases in costs for registrants. The enhanced CET scheme will be IT driven , where the cost will be offset by the potential savings that a strong CET scheme can deliver.
- When asked about the results of the recently closed consultation 'Licence to Practice', GOC indicated that there was a record number of responses and the views were split across 2 options, whether to have a licence to practise or that all should be registered.
- When asked about the outcomes of the Employee Appraisal paper and whether they informed the previously mentioned consultation. GOC stated that most multiples (i.e. SpecSavers, Boots, etc.) would not be willing to adopt their appraisal systems for revalidation purposes. Employer appraisal will not form part of the GOC's scheme for revalidation. GOC are investigating how to make appraisals mandatory.
- When asked about confidence in the data on the register, it became clear that it was an issue of self-declaration, so GOC were bound by the information provided by registrants. There is also scope to bring the management of this system in-house, therefore getting a greater grip on accuracy. This was anticipated for October 2010.

Sources:

- http://www.optical.org/en/about_us/revalidation/gocs-proposals-for-revalidation.cfm

Section 2. Our Findings - Health Professional Council

Background to revalidation

- In October 2008, the Health Professional Council (HPC) approved a report of the Continuing Fitness to Practise Professional Liaison Group (PLG), 'Continuing Fitness to Practise – Towards an evidence based approach to revalidation'. This report concluded that, on the basis of the current evidence, revalidation for the professions regulated by the HPC was not necessary. However, a number of further pieces of work were identified as necessary in order to build the evidence base in this area further.
- In December 2009, the Council approved the 'Revalidation Project Brief' which builds on the PLG's report and outlines the work the HPC will undertake over three phases.

Overview of Approach

They are undertaking work in three phases:

Phase One (current)

- The first phase is focusing on whether additional measures are needed to ensure the continuing fitness to practise of registrants. They are undertaking nine projects in the first phase of revalidation, which will look at:
  - the current level of risk posed to the public by registrants;
  - the systems they already have in place to identify any possible gaps where fitness to practise concerns may not be picked up; and
  - the feasibility and cost of different revalidation approaches that are already in use across the UK and internationally.

Phases Two and Three

- If, after the completion of phase one, they conclude that additional measures are needed for public protection, they would then move on to the second and third phases:
  - Phase Two - develop the standards that registrants would need to meet.
  - Phase Three - develop and pilot the system to be used.

Interview summary

- HPC see their role as giving their registrants the right to practice. It can also recommend new professions that can be regulated in the future.
- The Revalidation approach is based around 9 projects that will form the research to determine whether revalidation is a requirement. The process employed involves gathering evidence, testing feasibility, analysing best practice and reviewing / comparing current processes against the research. Currently, the HPC is not ready to pilot any new system, it is still very much in research stage. They are anticipating a proportionate system, but are unsure of how it will look or what it would be proportionate to.
- They have published information about the revalidation project on their website. The revalidation work is also mentioned at 'listening events' with registrants held throughout the UK on a regular basis. As the projects progress, they plan to consider raising awareness through listening meetings and consultations.
- The projects were selected from a report, written by the Professional Liaison Group, where 9 projects were listed as their priority findings. This report concluded that REVALIDATION was NOT necessary but that further work was necessary in a number of areas. The current strong CPD system would need to be maintained as this would form the core of any future assessments.
- Generally, complaints were not seen as being an issue to the HPC. The perception of them being 'generally very low' was supported by numbers of around 400.
- Dual registrants were not seen to be an issue, even though there is significant diversity within protected job titles at HPC.
- HPC are confident that the projects will be completed within budget but will receive no extra funding. They also do not expect that this will be prioritised over other projects at HPC if funding reduces.

Sources:

- http://www.hpc-uk.org/aboutregistration/revalidation

Section 2. Our Findings - Royal Pharmaceutical Society for Great Britain

Overview of Approach

The RPSGB is in its early stages with developing their revalidation model. They have commissioned research in relation to the development and implementation of a process of periodic revalidation in pharmacy.

The research programme for revalidation in pharmacy consists of three related work streams:

- Work Stream 1: Risk assessment of pharmacy practice

- Work Stream 2: Evidence for revalidation

- Work Stream 3: Structures for delivery of revalidation

Key areas of research:

Workstream 1: Risk assessment of pharmacy practice

Definition and assessment of risk in a regulatory context

Identification of high and low risk practice in pharmacy

Licence-to-practice and registration only

Workstream 2: Evidence for revalidation

Continuing Professional Development (Project 1)

Appraisal and other information (Project 2)

Workstream 3: Structures for delivery of revalidation

Project appraises and compares three different approaches to revalidation:

A decentralised appraisal model

A centralised portfolio model

A model that combines both approaches.

Further detail on the Pharmaceutical Society for Northern Ireland are given in Appendix 1.

Source

- RfP Research programme to support development of revalidation in pharmacy

Interview summary

- The RPSGB set up a Revalidation Advisory Group. This group created a Principles document ('A draft model for revalidation in pharmacy') that recommended 3 workstreams to be set up. Using £260k of Department of Health funding, RPSGB issued 3 tender documents based on the 3 workstreams. These have been allocated now and recommendations are due between now and the end of the year on all three workstreams. However, the RPSGB is splitting into professional and regulatory bodies on 27th September 2010. This means that revalidation has been given a lower immediate priority. The creation of new standards and regulatory criteria has superseded revalidation.
- The RPSGB have implemented a system of CPD based on a Reflective CYCLE OF LEARNING. .. It is based on a cycle of reflection – planning – action – evaluation. While attendance at seminars and courses is a good source of CPD, other forms of learning such as in situ learning are applicable. CPD records have been called in for review since July 2009 at a rate of 400 registrants every 2 weeks with a view to reviewing the CPD records of all registrants within a 5-year cycle. However, due to regulatory issues, CPD is not mandatory. Mandatory CPD will go to consultation later this year, with a view of implementation in early 2011.
- They have the same issue as GOsC, and other non-medical Councils, that practices in the community or as part of multiples, they do not have the robust appraisal processes in place that NHS professionals do. Peer review is not seen as a viable alternative either.
- They do not believe that revalidation is high in pharmacist's current thinking or plans. However, registrants understand that it is coming and the RPSGB have adopted an open policy to the information on their proposals.

RPSGB currently do not have formal plans around the costs or benefits of revalidation. However, they are fully aware of the risks. They have seen an increase in FTP complaints in the last year, even though the level of complaints are perceived as being lower than in the non-medical professions.

Section 2. Our Findings - General Medical Council

Overview of approach and timescales

The GMC has established a UK Revalidation Programme Board to oversee the practical delivery of medical revalidation across all four countries of the UK.

From 1 March - 4 June 2010 GMC consulted on their proposals for the way in which revalidation will be introduced. As part of this they will be seeking feedback on the standards for appraising and revalidating doctors and on the proposals that revalidation should be based on a single set of processes. The GMC is currently evaluating feedback from their consultation and expect the revalidation model to simplify further.

Those organisations involved in early adopter initiatives will be the first to introduce revalidation. The expectation is that this will begin at some point in 2012. Revalidation will be rolled out thereafter over the following five years to all registered doctors holding a licence to practise.

Revalidation projects and pilots

The GMC and others have been engaging in project and pilot work since 2008. This work has the following aims:

- To test the concepts underpinning revalidation
- To evaluate the potential impact
- To describe the components and processes
- To assess the state of readiness of the different sectors and localities.

Project and pilot work broadly falls into three phases:

- Phase 1 - exploratory and scoping work
- Phase 2 - component and system testing and piloting
- Phase 3 - whole process piloting.

Phases 1 and 2 are underway. Phase 3 is likely to begin in post-2011 as systems start to become ready to support revalidation.

While the GMC has led on a number of projects in Phase 1, projects and pilots in phases 2 and 3 are primarily being taken forward by the four Revalidation Delivery Boards as part of their work to prepare local systems for the introduction of revalidation. The UK Revalidation Programme Board will play an important role in ensuring learning from the projects and pilots is shared across the UK.

Further detail on the GMC proposals are given in appendix 1.

Interview summary

- GMC have looked at various tools to support revalidation readiness testing. These include questionnaires, commissioned from Peninsula Medical School, to look at ways to rank doctors performance and flag up the outliers.
- Some organisations have been asked if they can assess their 'system readiness'. There are 10 PATHFINDER sites evaluating readiness for revalidation in England. These are then expected to eventually morph into EARLY ADOPTERS (post-2011). The pathfinder sites are not currently going through revalidation, but just checking that they have the systems in place to rollout the process next year. However, there has been a recent letter from the Secretary of State to say that piloting should be extended by one year to ensure systems are correct, This has therefore impacted on the project timescales for revalidation.
- GMC have drawn up specialty specific frameworks for revalidation for a few specialties. However, due to the many more frameworks that have been requested, GMC do not wish to pursue this path but rather set up a core framework from which all registrants can be validated against
- They do not see remediation as being a fundamental part of revalidation, as it should be happening as part of current normal practice. The GMC does not deliver remediation, employers do.
- COSTS and BENEFITS: the pilots are expected to show the final costs for revalidation. There is an affordability argument that concerns the fact that appraisals should be happening anyway, so the costs of doing revalidation should not be excessively greater than what is currently being faced. However, there are mixed views on this argument, so the pilots will be vital to prove costs. Given the amorphous nature of benefits for revalidation, the process of measuring and tracking them is proving to be very difficult. This is the next piece of work to be done.
- RISK: NON-NHS PROFESSIONALS: there has to be a balance between rolling out straight to NHS professionals and to practitioners outside of managed work environments For these practitioners, the GMC plan to get greater information through their annual subscription process, i.e. sending out questionnaires to get more information on private practice. Locums are also seen as a high-risk group, so escalation of their revalidation process may occur as they may not have the robust appraisal process in place.

Section 2. Our Findings - The Nursing and Midwifery Council

Overview of Approach

Revalidation project: Stage one

In July 2009 NMC appointed researchers Matrix Insight Limited to work with the NMC on this project. Together they will develop a risk-based approach to revalidation by looking at:

- appraisal processes;
- risk management;
- remediation processes, and
- outcome based continuing professional development (CPD).

They will also see if it is a good idea to introduce a period of mandatory preceptorship for nurses and midwives who have already been registered with NMC. NMC thinks that this will help to build nurses and midwives' confidence.

As part of this research, they will look at the preceptorship schemes that employers already use, and how they collect evidence of nurses and midwives' continuing professional development.

Research goals

An important part of this research will be to look at the different areas of nurses and midwives' work (as opposed to job titles), and how this affects NMCs work as the nursing and midwifery regulator. NMC needs this information in order to develop a risk-based approach to revalidation.

NMC will compare and contrast the evidence from Council for Healthcare Regulatory Excellence Advanced Practice: Report to the four UK health departments (June 2009) against the research to see if they need to take any action.

Next steps - phase two

Phase one will finish when the findings and recommendations of the research are published in a report to the Council. The Council will discuss the findings and recommendations before the start of phase two. In phase two of the project NMC will develop a standard through consultation with nurses, midwives and the general public.

Revalidation: Stage one findings - background information

In deciding how to respond to the White Paper, the NMC identified five developmental tools relating to the practice of nurses and midwives to be the pillars for the revalidation process. These are:

- individual professional ownership of safe practice and use of appropriate assessment / profiling techniques (risk);
- processes for supervising and reviewing performance including formal appraisal;
- individual commitment to ongoing learning and continuous professional development (CPD);
- transitional support for new entrants to the profession (preceptorship); and
- targeted support for re-entrants to the profession and those needing to address substandard practice (remediation).

Matrix Insight has been contracted by the NMC to identify how to incorporate these pillars effectively into a suitable model for revalidation. Matrix is employing a range of techniques to explore what evidence should be collected to demonstrate an individual's fitness to practise and developing the process by which it should be collected. These techniques include:

- two stages of large scale survey (what happens in practice and how to ensure that the revalidation process is built on a common understanding and shared interpretation of terminology);
- stakeholder workshop (validating the interpretation of the findings based on the experience of practising in the field of nursing & midwifery);
- consultation with expert advisory group (shaping the project and critically reviewing the approach adopted);
- interviews with stakeholders (targeting the approach of data collection); and
- critical review of published academic research (establishing a clear foundation based on available knowledge).

Source

- http://www.nmc-uk.org/About-us/Policy-and-public-affairs/Politics-and-parliament/Policy-areas/Revalidation/

Section 2. Our Findings - General Dental Council

Overview of Approach

The General Dental Council (GDC) are currently running pilots of a framework for revalidation for all dental professionals. The pilots are focusing on dentists who work in a general practice setting (whether in the NHS, privately, or a mixture of both).

They ran a consultation on revalidation, which was updated on 01 June 2009, the draft standards framework against which dental professionals will revalidate their registration, and diagrams showing how the system might work.

The phase of consultation closed on 9 September 2009.

The Revalidation Working Group

"The Revalidation Working Group is developing a system of revalidation for all registrants. The Group consults widely on its work, and co-opts members from outside the Council to help develop the system. It also sets up sub-groups to consider specific aspects of revalidation development work, so that it has access to expert input."

Proposed Revalidation system

Revalidation will be based on a set of standards, against which the Council will request evidence. The standards will be focused on four headings:

- Professionalism
- Clinical
- Communication
- Management and Leadership

They propose a three-stage process.

- Stage 1 – sifting of all dental professionals
- Stage 2 – assessment of selected dental professionals
- Stage 3 – in-depth assessment

Cost distribution

The Council's Revalidation Working Group has a clear view that at Stage 3 (and possibly also Stage 2), the dental professional should make some contribution (if not the whole contribution), to cost. This would encourage those registrants who meet the standards for continued registration, in that they would not be paying for others who did not meet the required standards. **GDC are working on developing cost models, with a view to commissioning an economic evaluation of revalidation** after completion of the Stage 1 pilots (when it is clearer what the desired shape of the policy will be).

Further detail on GDC's proposed model is shown in appendix 1.

Sources:

- http://www.gdc-uk.org/Our+current+reforms/Revalidation/
- The open consultation

Section 2. Our Findings - BOA

Views from BOA (British Osteopathic Association)

As part of our research, we also met with the British Osteopathic Association Executive team. The leadership provided an insight into the issues raising concern amongst practitioners. These included:

- The impact of models that make osteopaths bear the cost of revalidation. Members would wish to see value for any increment in annual registration fees.
- The model designed has an appropriate workload. The implementation and activities should not be so onerous that they use up excessive time for members to process (thereby introducing an opportunity cost). This may introduce a patient risk due to lost treatment time.
- Once the pilot is complete, BOA see their role as issuing guidance on how to effectively support revalidation and assist remediation. Where BOA believe that skill sets are lacking, they will look to support members through courses and structured learning.
- BOA stated that the process and protocols for the revalidation model must be transparent, as should all assessment criteria. Equally, the criteria to be an assessor should be transparent, as should performance reviews of the assessors.
- The CHRE should also play a part in assessing performance of the revalidation model, from both a leniency and severity perspective.
- Remediation was discussed as part of the model. BOA believe that remediation should focus on evidence. Patient feedback may be useful here.
- Remediation was not seen as an excessive threat, given that there was full transparency in the decision making process and next steps. Actions, such as training courses, must be accessible and timed to coincide with review cycles. There is scope to plan courses in line with the forthcoming core competency CPD scheme that BOA are setting up later in 2010.
- As a potential core benefit to both patients and professionals, developing regular audit tools that support revalidation assessments (where monthly data collection automatically combines to give an annual audit return) were discussed. This would be a significant professional development for osteopaths and would provide outcomes data to the assessment. This would be a real benefit of revalidation.

Section 3. Analysis - Summary of research

Overview

This section will be structured to show:

- the core findings from the research;
- the impact of revalidation and our findings on the osteopathic profession;
- the main issues arising from our research;
- a review of each issue and it s corresponding recommendation, split into three categories (as per GOsC requirements):
  - Costs
  - Benefits
  - Risks (both financial and regulatory); and
- our conclusions drawn from the research and recommendations.

What did the research show?

- Typically, each Council has started the process of designing their revalidation model, although most Councils are currently at different stages of their design pathway.
- In some cases, the models are so progressed, the Council have been able to go to consultation of their registrants.
- However, a few Councils have chosen to use the current and next financial years to evaluate the need for revalidation. This is specifically for non-medical Councils that question the value of revalidation of their members. However, these Councils are looking to implement more rigour into their processes around CPD and appraisals.
- In most cases, Councils were looking to consult membership, but timescales varied significantly.

Funding of the design phase was set to budgets provided by the Department of Health. There was no evidence to suggest that any Council was supplementing this funding

- **The GMC had the most progressed model. However, evidence showed that the GOsC level of progress was similar to that of other non-medical Councils.**
- **The GCC had the greatest professional cross-over with GOsC, in terms of practice, NHS contracting, Code of Conduct and potential for dual registration, and had taken a different approach to setting up revalidation. This would need to be explored further at interview.**

This form of research gave us the bedrock of our analysis. It allowed us compare progress between Councils and GOsC as well as prioritise which Councils would be required for more detailed research through interview. The following slides show the typical information found through this phase of research. Further desk-based research can be found in the appendix.

Section 3. Analysis - Points for consideration from the research

In this section, we set out the broad issues that arose from our research into Revalidation models in other Councils. This section will also address the key areas of progress made by specific Councils that could be seen as good practice for incorporation into the GOsC revalidation model. The specific issues arose in three main categories:

1.COST MODELS FOR REVALIDATION

C1. While it is widely agreed that revalidation will be a necessary regulatory activity, desk based research indicated that the majority of the initial work into revalidation was DH funded. It was also noted, and validated in interviews, that this money was finite and would not be supplemented.

C2. It was acknowledged by all the regulators we spoke to that the affordability of revalidation was significant, either in terms of feasibility of roll-out, or in terms of gaining buy-in from registrants. It was also noted by some regulators that if other regulatory mechanisms were working well (such as appraisals, CPD, and clinical audit/governance), then the costs of introducing revalidation should not be excessive. Demonstrating these costs in a transparent way will be critical going forward and piloting will be a valuable way of developing an accurate forecast.

2. BENEFITS MEASUREMENT AND REALISATION

B1. Revalidation is universally seen as being in the best interest of patients. This is in terms of safety, best practice and quality. Multi Source Feedback can be a useful way of incorporating the patient experience, as can accessing feedback from representative patient groups.

B2. Revalidation processes, such as peer review and appraisal, are seen as a key way to drive up quality and performance.

B3. Most Councils are not in a position or are not far enough into the modelling process to consider benefit realisation or measurement. Many state that the amorphous nature of benefits for revalidation makes the process of measuring and tracking them very difficult.

3. RISKS

R1. For non-medical regulators, the clinical risk is seen as being much lower, so the revalidation model must be proportionate to that risk. A one-size-fits-all approach will not suffice non-medical needs.

R2. Most Councils expect the pilots at pathfinder sites to show the final costs for revalidation. Many Councils are waiting to pilot before determining their final cost model. Most Councils also expect the cost of revalidation to be borne by registrants, with little or no subsidy from the Councils.

R3. Many complaints received by non-medical regulators concerned CONDUCT rather than CLINICAL practice. Therefore, profession-specific Codes of Conduct or Practice are important tools to support the assessment within revalidation.

R4. As there are many professionals working on a contracted basis to the NHS or in private practice, many practitioners are not annually appraised.

R5. Where the revalidation model involves self-declaration, the Council are bound by trust that the content of a practitioner's submission is accurate and correct. For sole practitioners, effective peer review of submissions would be ideal but difficult to implement.

R6. There is a significant reliance on the quality of the outcomes of pilots. For there to be convincing evidence, pilots must be correctly powered to deliver statistically relevant results. Equally, there must be confidence in data collection throughout the process to ensure modelling is based on accurate information.

The following slides will review each of the above issues in further detail. It should also be noted that the list of issues above is not exhaustive, but are the most pertinent to GOsC.

Section 3. Analysis - Cost models for Revalidation

C1. While it is widely agreed that revalidation will be a necessary regulatory activity, desk based research supported by interviews indicated that all initial work into revalidation was DH funded. It was also noted, and validated in interviews, that this money was finite and would not be supplemented.

Ring-fenced funding to kick-off the projects into revalidation was identified and provided from the DH. This allowed Councils to investigate the need and model of delivery for revalidation. However, all interviewees acknowledged that this was a finite provision and the scope of their research into revalidation had to be completed within this budget. It was also understood that many Councils will not be supplementing the cost of this research as there were many competing priorities that superseded revalidation in forthcoming spending plans.

Recommendation: While this is a prudent approach to setting up revalidation, Councils should ensure that there are contingency funds available to support pilots, especially given recent requests from the Secretary of State to GMC to extend piloting arrangements by a further 12 months.

C2. It was acknowledged by all the regulators we spoke to that the affordability of revalidation was important, either in terms of feasibility of roll-out, or in terms of gaining buy-in from registrants. It was also noted by some regulators that if other regulatory mechanisms were working well (such as appraisals, CPD, and clinical audit/governance), then the costs of introducing revalidation should not be excessive. Demonstrating costs in a transparent way will be critical going forward and piloting will be a valuable way of developing an accurate forecast.

The prospective increase in registrant costs to support revalidation will cause concern across professionals. All Councils interviewed made it clear that transparency was core to any consultation and piloting of processes. When dealing with negative perceptions about likely increases to fees, clarity around cost (and any attempts to minimise or avoid costs being passed on to registrants) should be articulated. Interviewees within several Councils stated that revalidation would build-upon activities that already exist within well managed services, and focus on embedding good practise across the profession in areas such as appraisal.

There is a recognition that such systems are more mature in certain professions than others, and there is variability within these groups themselves. In theory, if the practitioner is compliant with good practice, the cost of revalidation should be minimised. This will be more pronounced where systems focused on continuous improvement are more developed.

Recommendation: GOsC must be able to demonstrate a clear and transparent cost model around revalidation which takes into account the maturity of other systems and tools to manage performance.

Section 3. Analysis - Benefits Measurement and Realisation

B1. Revalidation is universally seen as being in the patients' best interest. This is in terms of safety, best practice and quality. Multi Source Feedback can be a useful way of incorporating the patient experience, as can accessing feedback from representative patient groups.

In the case of all interviewees, and in published literature and proposals, Councils agree that the main benefit of revalidation will be to improve patient safety and drive up quality of service. Many non-medical Councils believe that the process is focused on improving Medical standards and performance, especially post-Shipman, so their own revalidation models must be proportionate to the risk posed. This is primarily in terms of clinical risk, although it is recognised that increasing patient expectation will also focus on conduct and quality of care provided.

Recommendation: Improvement in patient safety and quality of care are the core drivers for revalidation and this should be considered by both the regulator and practitioner alike. It is GOsC's role to ensure that standards are set and adhered to and create the right incentives for Osteopaths to reflect on their own practise and consider the patient perspective.

B2. Revalidation processes, such as peer review and appraisal, are seen as a key way to drive up quality and performance.

In many non-medical Councils, practitioners are in sole practices, independent or private practices or in commercial multiples. There are varying levels of appraisals happening for professionals. Given that appraisal and self-assessment will form an important part of many revalidation models, it is important that appraisals become more routine. In cases where practitioners are based in geographically remote locations or operate alone, peer review has been employed by certain Councils to ensure that services are of a specific quality.

The process of revalidation will bring improvements to patient services and drive up quality. For practitioners, the implementing of appraisals and peer review will support their professional development and facilitate the revalidation for them. This would be a significant benefit for Councils as they will have a widespread tool that will support their regulatory role.

Recommendation: The use of appraisals and peer review should be discussed further and their inclusion in the revalidation assessment could also be mandatory. The BOA could discuss practicalities of this with the GOsC.

B3. Most Councils are not in a position or are not far enough into the modelling process to consider benefit realisation or measurement. Many state that the amorphous nature of benefits for revalidation makes the process of measuring and tracking them very difficult.

This is the most important issue to arise on benefits from interviews with Councils. There is a great deal of uncertainty over how to address realisation. While it is agreed that the core desired benefit is patient safety and best practice, each Council is trying to assess what core benefits, specific to their patient and professional groups, can be measured.

In the case of the General Chiropractic Council, an economic evaluation of sub-optimal outcomes has been done. This seems the most progressed approach of the non-medical Councils and the approach is easily transferable to any profession with QALY specific measures.

However, it is important for Councils to have a framework for measuring benefits set up prior to piloting. While quantitative outcomes will be the easiest to analyse, the qualitative measures will supply the greatest insight, such as survey based information on service and professional development. This should be given a high priority in the next phase of work.

Recommendation: Benefits trackers and realisation tools should be devised prior to piloting for the proposed GOsC model.

Section 3. Analysis - Risks

R1. For non-medical regulators, the clinical risk is seen as being much lower, so the revalidation model must be proportionate to that risk. A one-size-fits-all approach will not suffice non-medical needs.

This is the core risk of the revalidation process for many interviewed Councils. The emphasis for non-medical Councils must be that the model employed will demonstrate proportionality. In medical models, the clinical risk to the patient is significantly higher than for most non-medical procedures or services. This must be reflected in the revalidation model.

This is supported by the CHRE in the Managing Extended Practice Report, June 2010, where they recommend that risks to patients can be managed using various tools at regulators disposal. Tools must be selected based on their proportionate risk.

Recommendation: It is advised that all non-medical models follow the same proportionate approach as patients in these professions will not incur the same level of clinical risk as those in traditional NHS settings. However, the risk of patients being seen and treated outside of the NHS by contracted workers must equally be addressed as part of the proportionality of the model.

R2. Most Councils expect the pilots at pathfinder sites to show the final costs for revalidation. Many Councils are waiting to pilot before determining their final cost model. Most Councils also expect the cost of revalidation to be borne by registrants, with little or no subsidy from the Councils.

For all interviewed Councils, the approach to determining the forecast cost model of revalidation has been deferred to piloting stages. In the case of the GMC, pathfinder sites have been identified and are underway. However, the cost model will not be devised until there is confidence that the pilot is working properly. With all non-medical Councils interviewed and researched, the expectation is that successful pilots will be the only logical way to determine cost. There is also an expectation that the majority of the cost of revalidation will be borne by registrants.

Recommendation: While this is again a prudent approach, Councils should be looking to determine where the cost of revalidation can be offset to ensure the profession accepts the increase in annual fees is minimised and justified. The QALYS model used by the General Chiropractic Council is a good example of getting solid economic information to support the adoption of revalidation and shows that the cost could be offset.

R3. Many complaints received by non-medical regulators concerned CONDUCT rather than CLINICAL practice. Therefore, profession-specific Codes of Conduct or Practice are important tools to support the assessment within revalidation and must be in place across all non-medical Councils.

This risk has been addressed by all interviewed and researched Councils and all have stated that there is a Code or Practice or Code of Conduct in place to support their registrants and patients. However when this data is merged with insurer data the balance of complaints seems to be shifted towards clinical issues. Therefore the GOsC should continue to monitor and consider this significance.

Recommendation: Audit against the Code and analysis of trends in complaints will form part of the revalidation model for many Councils, and should form part of the assessment made in the GOsC model.

R4. As there are many professionals working on a contracted basis to the NHS or in private practice, many practitioners are not annually appraised.

Revalidation should be used as a driver to instate appraisal as a core activity for professionals. When this proves difficult for practitioners to achieve, such as sole practitioners or locums, effective peer review or auditable self-assessment could be used to support the professional development of those involved.

Recommendation: Appraisal information should form part of the overall revalidation assessment, so GOsC should explore how practically this could be achieved where many of their registrants are self employed. It may be useful to have discussions with the BOA as to how to encourage registrants to be appraised, with the long term view of making the process mandatory.

** Complaints and claims against osteopaths: a baseline study of the frequency of complaints 2004 – 2008 and a qualitative exploration of patients' complaints (Adverse Events Project 3).* Leach J et al, June 2010 – Draft report submitted to the General Osteopathic Council, p51 which notes that in an analysis of complaints from GOsC and four main professional indemnity insurers, 'The majority of complaints (n=240, 68%) related to Clinical Care, notably including 141 adverse events mainly from the Balens data. The second largest group was Conduct and communications, with 74 (21%) complaints.'

Section 3. Analysis - Risks (cont.)

R5. Where the revalidation model involves self-declaration, the Council are bound by trust that the content of a practitioner's submission is accurate and correct. For sole practitioners, effective peer review of submissions would be ideal but difficult to instate.

The quality of information submitted will be reliant on the accuracy provided by the registrant. The GOsC will then need to find appropriate means to validate this data. One example of this is peer review. However, there is a significant risk here and it also applies directly to the appraisal issue above. If the GOsC cannot effectively instate a level of rigour around the appraisal process, it will be difficult to set up peer review of self-declarations. This will then require the GOsC to review each submission in detail and trust that the registrant has completed their submission fully and correctly.

Recommendation: The GOsC must ensure that their cost models reflect the resourcing required to complete self-declaration reviews. If a peer review model is instated, there must be some benefit that the reviewer received, such a CPD points or reduced revalidation fees.

R6. There is a significant reliance on the quality of the outcomes of pilots. For there to be convincing evidence, pilots must be correctly powered to deliver statistically relevant results. Equally, there must be confidence in data collection throughout the process to ensure modelling is based on accurate information

The pilots appear to be the most crucial part of the revalidation initiation process. These will determine:

- the cost model;
- the most effective delivery route for revalidation;
- the risks and their mitigation;
- the intended benefits of revalidation and how to realise them;
- the enhancements required to maintain the process; and
- and the evidence to support implementation.

Recommendation: To ensure that the pilots have the greatest chance of delivering the above requirements, the GOsC must ensure that each pilot is set up to exact standards and follow set and transferable protocols. While some sites may adopt different processes to test revalidation, the protocols used must be able to transfer to new sites and also have the ability to scale up to whatever size is needed.

Equally, each site must have a suitable sample size of practitioners and activities to ensure that the results of the pilot can provide a convincing argument. Testing a model on a single practitioner will only deliver one result and therefore reduce overall confidence in the pilot.

Section 4. Conclusions

Progress and timescales

This three-month exercise has revealed that most Councils are at the same scoping phase of the revalidation process. The initial research showed that all non-medical Councils, with the exception of the HPC, were either working at proving the need for a revalidation model or consulting with registrants on a proposed model. In either case, Councils were not anticipating implementation within the current financial year. The most progressed model belongs to the GMC, where much of the assessment detail (such as appraisals, assessment of self-declarations) are already in place and pathfinder pilots have begun.

Professional impact

The direct impact for Osteopaths will be similar to that of many other non-medical professionals. Revalidation will have a positive impact on public perception of osteopaths and their reputation. Having their professional status and practice validated will provide patients with a benchmark of quality. Revalidation will also add robust quality assurance of practice to support Osteopaths in their professional development. This is a sentiment echoed by the GCC whose registrants are the most similar to those of GOsC.

Costs and Benefits

With respect to the costs associated with revalidation, all interviewed Councils showed that setup costs were provided by the Department of Health, with no supplementary internal budget. The cost of revalidation is still to be determined; most Councils are waiting for their pilots to complete before making a accurate prediction of costs. While this is a prudent approach, there does seem to be hesitation to offer up the information, especially at interview. However, all interviewees stated that the cost of revalidation will eventually be borne by registrants, with no expectation of subsidy from the Council or Department of Health. Benefits tracking and realisation is an equally unquantified area, with all desk-based research and interviews revealing that Councils plan to wait until launching pilots before designing their trackers. This will be a risk as pilots should only be launched if there are definite and quantifiable outcomes expected. Proving the success of pilots thereafter will become increasingly difficult unless performance metrics and intended outcomes are established now. Reassuringly, all Councils see patient safety and experience as a core benefit to revalidation and are seeking models to develop safety and more effective practices for the patient's benefit.

Risks

There are multiple risks involved with the implementation of revalidation, both from a regulatory and a financial perspective. GOsC has adopted a revalidation approach that will minimise the risk throughout the process, where the proposed interventions through remediation will reduce clinical risk. Codes of Conduct or Practice mitigate against poor conduct, but only if they form part of any self-declaration. The most logical approach to economic risk has come from GCC, where a third party has been contracted to assess the financial impact of failing to perform clinical practice to the highest of standards. GCC were the only interviewed Council to demonstrate this economical approach to prioritising the performance indicators for revalidation. However, HPC are also looking at using a statistical approach determining the priorities that revalidation will assess. Both approaches could be incorporated into the GOsC model.

The approach proposed by GOsC is in line with that of their regulatory fraternity. The possible changes and alterations found at other Councils have been numerated as recommendations.

KPMG

Appendix 1 – Additional research

AUDIT ▪ TAX ▪ ADVISORY

Health Care Regulators

The current 13 UK regulatory bodies

General Chiropractic Council (GCC)
Chiropractors
T: 020 7713 5155
www.gcc-uk.org

General Dental Council (GDC)
Dentists and dental therapists, dental nurses, dental technicians, clinical dental technicians and orthodontic therapists
T: 020 7887 3800
www.gdc-uk.org

General Medical Council (GMC)
Doctors
T: 0845 357 3456
www.gmc-uk.org

Nursing and Midwifery Council (NMC)
Nurses, midwives and specialist community public health nurses
T: 020 7637 7181
www.nmc-uk.org

General Optical Council (GOC)
Opticians
T: 020 7580 3898
www.optical.org

General Osteopathic Council (GOsC)
Osteopaths
T: 020 7357 6655
www.osteopathy.org.uk

Royal Pharmaceutical Society of Great Britain (RPSGB)
Pharmacists, pharmacy technicians and pharmacy premises
T: 020 7572 2510
www.rpsgb.org.uk

Pharmaceutical Society of Northern Ireland
Pharmacists in Northern Ireland
T: 028 9032 6927
www.psni.org.uk

Health Care Regulators (cont.)

General Social Care Council (GSCC)
Social care workers (England)
T: 020 7397 5100
www.gscc.org.uk
This is to be merged into the HPC.

Care Council for Wales
Social care workforce (Wales), qualified social workers, child care managers/workers, adult residential managers/care workers, domiciliary care managers/workers and social work students on approved degree courses in Wales
T: 0845 0700 399
www.ccwales.org.uk

Northern Ireland Social Care Council
Social care workforce (Northern Ireland), qualified social workers, team leaders and all care staff in residential childcare, heads of residential homes, heads of day care facilities and social work students
T: 028 9041 7600
www.niscc.info

Scottish Social Services Council
Social care workforce (Scotland), qualified social workers, care commission officers, residential child care workers and social work students
T: 0845 6030 891
www.sssc.uk.com

Health Professions Council
Arts therapists, biomedical scientists, chiropodists/ podiatrists, clinical scientists, dieticians, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, prosthetists and orthotists, radiographers, speech and language therapists
T: 020 7582 0866
www.hpc-uk.org

Council for Healthcare Regulatory Excellence (CHRE)
The aim of the CHRE is to protect the public, promote best practice and progress excellence in relation to the regulation of healthcare professionals. They oversee nine of the UK healthcare regulators.
www.chre.org.uk
020 7389 8030.

GDC Proposed process

Stage 1: Portfolio of evidence of performance

They anticipate that the majority of dentists will be revalidated at this stage. In order to revalidate, dentists will be required to produce a **portfolio of evidence of performance** for Stage 1. This evidence might come from a variety of sources, but there will be a number of compulsory elements within the portfolio. **The portfolio will be produced over a period of 5 years.**

A principle of revalidation is that it should be flexible enough to be tailored to each individual's practice. GDC will work with other bodies in the profession to ensure that appropriate systems are in place to support dentists as they gather evidence. The GDC would envisage quality assuring existing systems or practice accreditation schemes as satisfying certain components of revalidation so that registrants would not have to duplicate evidence.

Registrants would be expected to submit a **declaration** to the GDC, which would be used to determine whether they had met the requirements for revalidation.

Of those who appear to have met the requirements on the basis of their declaration, the Council would **audit a sample** (for example, around 10 percent) **to check the validity of the Stage 1 process**. GDC will develop a standard assessment tool for this purpose. **Those found not to have actually met the requirements would go into Stages 2 or 3.**

Failure at Stage 1

GDC propose that **non-responders** (i.e. people who do not send in a declaration at all) **should be removed from the register**. Those who respond but fail to meet the requirements at Stage 1 will be granted a further period to remedy their position.

Stages 2 and 3

Dentists who are unable to revalidate at Stage 1 would proceed to stages 2 and/or 3.

The purpose of **Stage 2 would be to provide an opportunity to remedy deficiencies** (perhaps involving peer assessment in the practice or working with a mentor). Those who cannot provide evidence that they meet the standards required would move to Stage 3.

Registrants at Stage 3 would need to be assessed for revalidation either at the end of a defined period or continuously through it. If one form of assessment were a registration exam, **it might also be used for people who have been off the register for a significant time, and who apply to restore. A one-off registration exam might be attractive but additional options should be in place in order to ensure flexibility in the process. GDC shall continue to have discussions with key stakeholders to assist with developing Stages 2 and 3.**

General Medical Council (GMC)

Overview of approach and timescales

The GMC has established a UK Revalidation Programme Board to oversee the practical delivery of medical revalidation across all four countries of the UK.

From 1 March - 4 June 2010 GMC consulted on their proposals for the way in which revalidation will be introduced. As part of this they will be seeking feedback on the standards for appraising and revalidating doctors and on the proposals that revalidation should be based on a single set of processes.

Those organisations involved in early adopter initiatives will be the first to introduce revalidation. The expectation is that this will begin at some point in 2011. Revalidation will be rolled out thereafter over the following five years to all registered doctors holding a licence to practise.

Standards for revalidating doctors

In order to retain their licence to practise, doctors will need to demonstrate to the GMC that they are up to date and fit to practice.

This will involve providing supporting information to show that they are practising in accordance with the generic standards set by the GMC (as described in Good Medical Practice) and any relevant specialty standards set by the medical Royal Colleges and Faculties.

A single process

When the Government published its proposals for revalidation in 2007, it divided revalidation into two elements - relicensing (which would apply to all doctors) and recertification (which would apply additionally to doctors on the GP and Specialist Register).

As a result of the work undertaken to develop the standards and processes, GMC has concluded that revalidation will be simpler, more effective and more efficient if it operates as a single set of processes rather than as the two separate strands of relicensing and recertification that were originally envisaged.

Sources

- http://www.gmc-uk.org/doctors/licensing/revalidation.asp
- Revalidation; The Way Ahead

Appraisal and revalidation

Revalidation will be based on local appraisal systems. The GMC has developed a framework for appraisal and assessment based on Good Medical Practice. In addition specialty-specific standards for appraisal have been developed for GPs and doctors working in a range of specialties.

To support their revalidation, doctors must collect information about their practice to demonstrate that they are up to date and fit to practice. One type of information that doctors will be required to collect is feedback from colleagues and patients (where appropriate - patient feedback will not be required from doctors that do not have direct patient contact).

Revalidation projects and pilots

The GMC and others have been engaging in project and pilot work since 2008. This work has the following aims:

- To test the concepts underpinning revalidation
- To evaluate the potential impact
- To describe the components and processes
- To assess the state of readiness of the different sectors and localities

Project and pilot work broadly falls into three phases:

- Phase 1 - exploratory and scoping work
- Phase 2 - component and system testing and piloting
- Phase 3 - whole process piloting

Phases 1 and 2 are underway. Phase 3 is likely to begin in summer 2011 as systems start to become ready to support revalidation.

While the GMC has led on a number of projects in Phase 1, projects and pilots in phases 2 and 3 are primarily being taken forward by the four Revalidation Delivery Boards as part of their work to prepare local systems for the introduction of revalidation. The UK Revalidation Programme Board will play an important role in ensuring learning from the projects and pilots is shared across the UK.

GMC proposed process

Collection and evaluation of information in the workplace through appraisal

- Revalidation will be based on a **local evaluation of doctors' performance against national generic and specialty standards approved by the GMC**.
- **Doctors will need to maintain a folder or portfolio of information** drawn from their practice to show how they are meeting the required standards. Because each doctor's practice is different, the information collected will vary. The information collected in their portfolio will provide the basis for discussion at their annual appraisal.

The revalidation recommendation and the role of the 'Responsible Officer'

- **The revalidation recommendation will come to the GMC via the local Responsible Officer.**
- The Responsible Officer will be a senior, licensed doctor. In a healthcare organisation, this is likely to be the Medical Director. For GPs, the Responsible Officer is likely to be from the healthcare organisation on whose performers' list they are included.
- Responsible Officer will have statutory responsibility for evaluating the fitness to practise of doctors associated with that organisation. In England, Wales and Northern Ireland they will also be responsible for ensuring that the system of clinical governance (including appraisal) in their healthcare organisation is capable of supporting doctors in meeting the requirements of revalidation. They will not have this additional role in Scotland as this area of responsibility is covered by existing legislation and organisations
- **The Responsible Officer will make a recommendation to the GMC about a doctor's revalidation, normally every five years.**
- To make a revalidation recommendation to the GMC, the Responsible Officer will rely on the outcome of a doctor's annual appraisals over the course of five years, combined with information drawn from the clinical governance systems of the organisation in which the doctor works.
- The Responsible Officer will also be able to draw on advice from others.

Responsible Officers for independent practices

- Some doctors will be in wholly independent practice, or working in organisations which do not provide an appropriate appraisal system or a Responsible Officer. These doctors will need to make alternative arrangements to ensure they undergo an appropriate and regular appraisal and that they link up with a Responsible Officer. This will make their revalidation more straightforward. In particular, it will help to ensure that they are meeting the requirements for revalidation before the time comes for them to revalidate. That way there will be no surprises.
- The Responsible Officer regulations, subject to approval by the UK Parliament and the Northern Ireland Assembly, will designate a small number of organisations whose members are mainly independent practitioners. There are a number of organisations which may be able to help with this. The Independent Doctors Federation and some medical Faculties are considering providing appraisal or Responsible Officer facilities for their members. The Responsible Officers of these organisations will have functions only for their members who are not linked to a Responsible Officer in another way.

The revalidation decision by the GMC

- **Although the Responsible Officer will make the recommendation, it will be for the GMC to decide whether the doctor concerned should be revalidated.**
- GMC also need to be confident that the recommendations they receive are robust, fair and consistently applied. **Both the process leading to the recommendations and the recommendations themselves will therefore be subject to quality assurance.**

GMC proposed process (cont.)

No positive recommendation from the doctor's Responsible Officer

For a small minority of doctors, revalidation may be more difficult and there will be exceptional cases where the **Responsible Officer is not in a position to make a positive recommendation to the GMC**. There are likely to be three main scenarios where this might happen, although the particular circumstances will undoubtedly differ from case to case:

a. There may be exceptional cases in which **a doctor has not been in active practice and has clearly not engaged with any appraisal process or with his or her Responsible Officer.** In these circumstances, there will be little or no evidence on which a Responsible Officer could make a positive recommendation that a doctor is up to date and fit to practise. In these circumstances **the doctor will need to take an alternative route for revalidation or can expect to have his or her licence to practise withdrawn. Any decision to withdraw a licence will be subject to an appeal process.**

b. If there are **gaps in the evidence** provided by the doctor, the GMC, based on the recommendation of the Responsible Officer, may decide to defer revalidation to enable the doctor to collect the necessary information. In the absence of negative information indicating that the doctor's fitness to practise is impaired, there would be insufficient grounds for referring the case to the GMC's fitness to practise procedures, but, equally, it would not be appropriate to renew the doctor's licence where there were significant gaps in the evidence required to show that the doctor was competent and fit to practice.

c. Where there are **concerns about a doctor's practice** these should be identified as early as possible and, where possible, addressed through appraisal and the relevant local clinical governance processes. Action on concerns should not wait until a doctor is due to be revalidated by the GMC. Of course, if there are serious concerns about a doctor's practice, then the Responsible Officer would want to engage with the National Clinical Assessment Service or refer the doctor to the GMC, where there are concerns about patient safety.

It is unlikely that these issues would simply come to light at the point in the process when the Responsible Officer is due to make a recommendation to the GMC. **If any concerns are ongoing at the time of revalidation, the recommendation could be deferred until such time as local, National Clinical Assessment Service or GMC processes have been concluded.**

The role of the medical Royal Colleges and Faculties

The medical Royal Colleges and Faculties have a key role in the revalidation process. Their principal responsibilities can be summarised as follows:

1. Defining the relevant specialty and general practice standards.
2. Validating specialty tools for the evaluation of doctors' practice.
3. Describing the types of supporting information that doctors will need to provide to meet the relevant specialty standards.
4. Providing specialty guidance for appraisees, appraisers and Responsible Officers.

It is clear that the statutory and legal responsibility for making the recommendation to the GMC lies with the Responsible Officer. GMC's preferred model is based on the Colleges' involvement in a quality assurance and advisory role rather than having a direct role in the evaluation of every doctor or input into every recommendation to the GMC by the Responsible Officer. Responsible Officers should seek specialty advice in cases where there are concerns or questions about a doctor's specialist practice from the relevant College or Faculty to help inform their recommendations.

GMC implementation

The UKRPB's terms of reference include overseeing the effective delivery of a revalidation implementation plan. This plan has been compiled from information provided by the four health departments of the UK, the GMC and the Academy of Medical Royal Colleges, and involves an ongoing assessment of when local organisations will be ready to support the introduction of revalidation.

The UKRPB has agreed the basic criteria against which readiness for revalidation would be determined:

1. Responsible Officers appointed.
2. Effective systems of clinical governance established.
3. Effective systems of strengthened appraisal established based on the *Good Medical Practice* Framework for appraisal and assessment .
4. Specialist standards embedded in local appraisal processes
5. Local processes ready to deliver necessary recommendations with appropriate quality assurance.
6. Reliable mechanisms in place to enable doctors to obtain feedback from patients and colleagues.

There is also an expectation that doctors who do need reach the minimum requirements for revalidation would be given time, and retain their license to practice, to collate the necessary evidence that they are fit to practice.

The proposed approach is that, where applicable, those organisations involved in early adopter initiatives will be the first to introduce revalidation. The expectation is that this will begin at some point in 2011 but only once sufficient time has been allowed to enable GMC and others to understand and learn from the outcomes of the earlier pilots. Revalidation will be rolled out thereafter over the following five years to all registered doctors holding a licence to practise.

Pharmaceutical Society of Northern Ireland

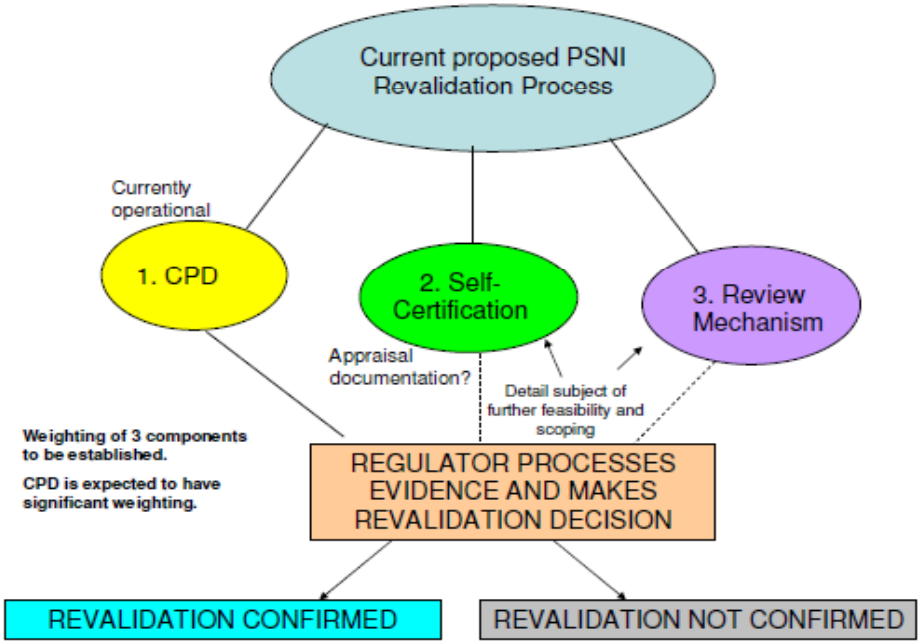


Figure 1: Visual Representation of PSNI proposed revalidation model

The Pharmaceutical Society of Northern Ireland published a draft model in a report for the Department of Health in February 2009.

There are three proposed components of the PSNI's Revalidation Proposals

CPD is likely to have significant weighting within a revalidation exercise, particularly as the Pharmaceutical Society of Northern Ireland's system for sampling, assessing and providing feedback on CPD portfolios is considerably advanced.

Self-Certification could be considered whereby the registrant completes a self-certification document. This would be a personal assessment of their current level of performance against criteria/standards depending on their sphere of practice. Where more than one sphere or practice is involved, the onus would be on the practitioner to complete the necessary self-certification documents. This would build flexibility into the system to deal with the many different practice situations pharmacists might be involved in throughout their careers.

A Review Mechanism could be considered on a targeted and/or sample basis. This could involve a peer review exercise but requires research to enable a decision to be made on its feasibility. It is important to note that the system adopted will require sufficient rigour.

Source

- Revalidation for Pharmacist in Northern Ireland; a draft model.

KPMG

Appendix 2 – Interview Guide

AUDIT ▪ TAX ▪ ADVISORY

Appendix 2 - Interview Guide

Interview Guide 2: How are other regulators approaching revalidation – Report B

This guide is not intended to set out a prescriptive format for conducting interviews with any of the regulators. However, during the course of the interviews, it is essential that information is gathered to address each of the questions listed. Some of the interviewees may be aware of the proposed draft GOsC revalidation scheme and as such they will be familiar with the objectives and issues. However, others are likely to be less familiar and it may be necessary to give them an overview of the principles behind the proposed draft GOsC revalidation scheme (attached at Annex A).

Suggested structure of the interview:

Introduction

Include:

A brief introduction to the report B as set out in the brief attached at Annex B;

If asked:

Any requests for further information about the proposed draft GOsC revalidation scheme should be directed to:

Fiona Browne

Head of Professional Standards

General Osteopathic Council

Osteopathy House

176 Tower Bridge Road

London

SE1 3LU

Tel: 020 7357 6655 x239

Mob: 07826 542435

Web: www.osteopathy.org.uk

Interview Questions

General

Q1. How is your organisation approaching revalidation?

Q2. How are you aligned to existing standards/ agreed principles behind revalidation?

Probes: (e.g. the Foster review, the Better Regulation Executive)

Q3. What is the specialist framework/code of practise that your registrants need to meet the revalidation benchmark?

Q4. What form is this in?

Probes: outcomes, guidance

Q5. What are your timelines for revalidation?

Probes: what has driven these timelines?

Model and process

Q6. What are your processes currently around revalidation?

Probes:

Monitoring – What are you auditing? How do you do this?

Mitigating - What processes are in place if the revalidation is not successful?

Detective – What are the current levels of complaints, referrals and fitness to practise investigations?

Preventative – How do the CPD, Performance Management, Appraisals work? How do they inform revalidation?

Cultural – What is the role of professionals and educators?

Q7. GOsC are proposing a system where remediation is actioned as a consequence of not meeting revalidation criteria. What are your organisations thoughts on remediation: what success criteria would you use and how?

Probes:

How will remediation be used,? Would any further implementation work be required to ensure there is a remediation network available? If so what and when? How would other regulators ensure the 'quality of remediation'.

GOsC idea is to 'signpost', but they need to know what to signpost to. What are the risks in identifying a remediation need, but not being able to address them?

Appendix 2 - Interview Guide

This has frequently come up in the past as a result of FTP outcomes, where a decision is taken by a panel as to what is required and then GOsC has to plug the gap as no development is available, i.e. the provision of mentors. The GOsC does not want to become embroiled in developing a remediation network to address this, so they need information from other regulators about how they deal with this and what they plan to do.

From GOsC perspective remediation could either be developmental or punitive in nature. Developmental could relate to feedback of good practice suggestions as a result of the revalidation exercise – do other regulators plan to take this approach?

How would the outcomes of any remediation requirements be measured if they were punitive in nature? Who would undertake this assessment?

Would someone falling below the standard would always be referred directly to a fitness to practice panel or could any other requirements be imposed directly through revalidation – how would this be balanced?

What other views do they have on referral to fitness to practise?

Proposed Costs

Q8. If applicable: How much will your proposed/ pilot revalidation scheme cost?

Probes: What is the projected future cost for revalidation?

How will this be funded?

How much will you charge registrants?

How will this be determined?

Data

Q9. What is the current level of confidence around data on your register to support revalidation?

Probes: What data sources do you expect to gather? E.g. a portfolio of work, CPD certificates. How do you plan to address any deficiencies in data?

Reputation and Perception

Q10. Have your registrants expressed any view with regards to reputation and perception of their profession/ professional practise with regards to revalidation?

Probes: If so what are they?

Risks

Q11. What do you see as the main risks around revalidation?

Probes: How do you plan to mitigate against the risks?

Are there any particular of groups of professionals who present a higher risk?

Explore whether any further research into risk is being commissioned as part of their revalidation work. Risk might not simply refer to 'groups' but also to treatment approaches, patients, location etc – *need to ensure this is covered.*

How are you treating dual registrants?

Benefits

Q12. What do you see as being the key benefits that revalidation will bring?

Probes: How do you plan to achieve and track these benefits?

Interview close

Thank interviewee for their time and summarise next steps regarding reporting as set out in Annex B. Request permission to contact them/ relevant colleagues in future stages of evaluation and impact assessment.

Annex A. Proposed revalidation scheme

The GOsC believes that the most pragmatic revalidation scheme would be one that is staged, with an initial self-assessment form at Stage 1, which every osteopath would complete and submit to the GOsC once every five years. The self-assessment form would help to identify whether individual osteopaths are meeting the key performance indicators of good osteopathic practice. Additional stages would only apply where Stage 1 had highlighted a concern.

The proposed scheme of revalidation is outlined in the diagram on slide 8.

The scheme would consist of four main stages as outlined in slide 8 .

Appendix 2 - Interview Guide

Remediation

At any stage of the revalidation process an osteopath may be directed to undertake remediation measures in order to be revalidated and re-admitted to the Register. The GOsC will not provide remediation but will aim to 'signpost' the osteopath to sources of training or other measures aimed at addressing the identified deficiency.

Fitness to practise

A referral to the GOsC's fitness to practise procedures could occur at any stage of the revalidation process, in circumstances where a significant level of concern has been identified in relation to the conduct, ethics or performance of an osteopath.

Removal from the Register

If an osteopath fails to submit requested information or to take the required action at Stages 1–4, then he/she will automatically be removed from the Register (subject to the same rights of appeal as other administrative removals). In addition, the osteopath could be removed as a result of a finding by a GOsC fitness to practise panel.

Continuing professional development

The GOsC has considered broadly how its current continuing professional development (CPD) scheme could complement the proposed revalidation scheme. As a result, a section of the self-assessment form has been dedicated to CPD, and osteopaths may use CPD activities as evidence in a number of questions.

Further development

The elements above are to be developed further. The GOsC believes that these proposals meet the principles outlined by the Non-medical Revalidation Working Group.

Annex B – Overview of Report B. Work undertaken by other regulators to outline cost benefits and risks

This report which will be presented to the GOsC in late summer 2010 is intended to present an overview of how other professions are approaching revalidation.

Specifically it will:

- Provide an understanding of how other regulators work – interviews
- Examine alternative revalidation models
- Explore cost benefit and risk of other regulatory approaches (inc. non medical and wider regulatory)

Glossary of abbreviations

CET	Continued Education and Training
CHRE	Council for Healthcare Regulatory Excellence
CPD	Continuing Professional Development
DH	Department of Health
FTP	Fitness to Practice
GCC	General Chiropractic Council
GDC	General Dental Council
GMC	General Medical Council
GOC	General Optical Council
GOsC	General Osteopathic Council
GSCC	General Social Care Council
HPC	Health Professions Council
NMC	Nursing and Midwifery Council
Q&A	Questions and Answers
PLG	Patient Liaison Group