
Council, 10 September 2009

Revalidation project update

Executive summary and recommendations

Introduction

The brief attached paper updates the Council about ongoing work in the area of revalidation, building upon the Council's previous discussion on this topic.

Decision

The Council is invited to discuss the outline project described in this paper.

The Executive will bring back a further paper to the October 2009 Council meeting in order to further define the scope of this project and to outline the project milestones.

Background information

None

Resource implications

Outlined in attached paper.

Financial implications

Outlined in attached paper.

Appendices

- Continuing Fitness to Practise – Towards an evidence based approach to revalidation' – Report of the Continuing Fitness to Practise Professional Liaison Group (PLG)
- Health Professions Council response to 'Principles for Revalidation – Report of the Working Group for Non-Medical Revalidation'

Date of paper

26 August 2009

Revalidation project update

1. Introduction

Revalidation is the idea that registered health professionals should be subject to some kind of periodic check to ensure that they continue to remain fit to practise beyond the point of initial registration.

The Department of Health has considered submissions from the non-medical regulators about the revalidation of non-medical healthcare professionals and has recently met with each regulator to discuss how the development of revalidation might be progressed for the professional groups reach regulates. As part of this, the Department of Health has made funds available to the regulators to aid in the development of revalidation / further exploration of the feasibility of models of revalidation.

The HPC has recently been successful in being awarded a grant of £360,000 for the 2009/2010 financial year, with more potentially available for year two.

This paper briefly summarises the Council's previous discussion and position on this topic and then outlines in broad terms the Executive's planned further work in this area. The Council is invited to discuss the proposed further work in this area which will inform a further paper on this topic.

Two documents are appended which clearly articulate the Council's view to date on this topic. These are the report of the Continuing Fitness to Practise PLG and the HPC's response to the Department of Health's Principles for Non-Medical Revalidation.

2. Revalidation

The 2007 White Paper, 'Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century' concluded that revalidation was necessary for all health professionals but that the approach taken should be guided by the risk profile for each practitioner.

In response to the White Paper's conclusions, the Council established the Continuing Fitness to Practise Professional Liaison Group (PLG) to explore and made recommendations in this area. This work considered revalidation within the wider context of 'continuing fitness to practise' which we broadly defined as 'all those steps taken by regulators, employers, health professionals and others which support the maintenance of fitness to practise beyond the point of initial registration'. The PLG made a number of conclusions and recommendations about this topic. In particular, the PLG concluded that, 'existing regulatory processes are currently appropriate and sufficient when considered in the context of the wider environment in which they operate and the risk of harm posed by the professions regulated by the HPC'. However, the PLG also identified a number of areas where further work would be necessary, including work to explore the link between conduct during pre-registration education and training and subsequent fitness to practise action.

In November 2008, the report of the Department of Health Working Group for Non-Medical Revalidation was published. The report sets out broad principles for the revalidation of the non-medical healthcare professions. In February 2009, we responded to the principles document, outlining how we believed our existing processes and planned future work would meet the principles outlined.

3. Department of Health grant

The Department of Health has met with the Executive and the HPC Chair to discuss the development of revalidation for the professions regulated by the HPC, in light of the HPC's response to the Principles for Non-Medical Revalidation.

The Department of Health has acknowledged the arguments put forward by the HPC, and the 'significant challenge' of developing a model of regulation for the 14 professions regulated by the HPC. In implementing the policy direction outlined in the White Paper, the Department of Health has said that it would want to be assured that the processes HPC has or will put in place:

- represent a positive affirmation of fitness to practise, supported by appropriate external verification;
- command public confidence and demonstrate benefit to members of the public; and
- are proportionate to the available evidence of risk.

The Department of Health has awarded the HPC a grant of £360,000 for the 2009/2010 financial year with a further grant possible in the following year. The Department has given this grant to enable the HPC to undertake further work both to explore the evidence which will inform any revalidation system and to explore the potential feasibility of possible models of revalidation. The HPC is, however, not funded to pilot, introduce or maintain a revalidation process; only to undertake the work necessary to develop and test potential models. The project will build upon and 'test' the findings and conclusions of the PLG.

The Department of Health has indicated that the progress of the revalidation project would be monitored via regular meetings between the HPC's revalidation lead (the Director of Policy and Standards) and the Head of Non-Medical revalidation. The Department of Health has also asked to receive any papers or reports considered by the Council on this topic.

4. Proposed project

The broad areas of work agreed by the Department of Health in their confirmation of the grant funds are as follows:

- Commissioning of the required literature reviews to ensure that best practise elsewhere is taken account of in development of the model.
- Commissioning statistical research relating to analysis of Fitness to Practise cases and CPD audits.
- Development of revalidation tools required – they should include areas such as competence, conduct, communications and ethics.
- Development of a risk-based model / profile to inform development of the revalidation model and which meets the HPC's diverse needs across professional groups.
- An exploration of the links between revalidation and initial education.

- Scoping of the implications of revalidation on current IT systems and their fitness for the purpose of revalidation.

However, there is some flexibility as to the specific pieces of work to be undertaken, so that the course of the project can be informed by the emerging conclusions / findings of any research.

4.1 Project 'streams'

The project will consist of two distinct 'streams' which will run side by side:

4.1.1 Research

The Executive will undertake research; both internally conducted and externally commissioned, to better establish the potential evidence base for revalidation. This will include the areas for further research identified in the PLG's recommendations.

For example:

- The PLG recommended that research should be undertaken to explore the links between poor conduct during education and training and subsequent fitness to practise action. The Executive has begun the process of commissioning this research and has invited researchers to submit proposals for two research studies in this area.
- The PLG recommend that further research might be undertaken to further explore the trends in fitness to practise data and the outcomes of the recent CPD audits. This might be helpful in contributing to further thinking / research into the area of risk. The PLG concluded that the evidence of risk for the professions regulated by the HPC was limited and work in this area would help to better establish that risk profile.

The above provides a broad indication of the possible areas of enquiry in this area, which would assist in exploring revalidation for the professions regulated by the HPC. However, this is not exhaustive and the Executive plans to further develop the possible areas of research and provide further information to the Council at a future meeting. This will be informed by the Council's discussion about this area of work.

4.1.2 Feasibility

In parallel to the research looking at the issues salient to revalidation, the project will also explore the feasibility of a number of different potential models which will then be tested in light of the research findings.

This will include considering models in existence elsewhere in the world, such as those in existence in North America. For example, in some areas online systems have been developed which test registrants' knowledge and skills in a number of discrete areas, providing an external assessment which then helps to inform that individual's learning needs. As part of this project 'stream', the Executive plans to undertake a 'fact finding' visit to a number of regulators in the USA and Canada in order to benefit from their experiences and to ascertain the feasibility of such processes for the HPC.

Dependent on the initial assessment of feasibility, further work might include beginning to develop and further test a series of 'revalidation tools' which might include question banks and other interactive media.

4.2 Outcomes

The purpose of the project is to both explore the evidence salient to revalidation for the professions regulated by the HPC and, in parallel, to explore the potential feasibility of a number of revalidation models and tools.

The final outcome of this work might include, for example, proceeding to a further stage, if shown to be necessary and feasible, in order to develop, 'operationalise' and introduce an additional process or system. Alternatively, one conclusion might be that only minor changes are necessary to existing processes or, potentially, that no changes are necessary – the HPC's findings would then form the basis of further discussion with the Department of Health.

The progress and outcomes of this project will be subject to the scrutiny of the Council.

5. Resources

A Policy Manager position is currently being advertised to work on this project. The position is being advertised on a two year fixed term contract.

It is also planned to recruit an additional project manager to manage the project.

6. More information

The Executive will prepare a further paper on this topic for consideration at the October 2009 Council meeting, which will build on the overview provided by this paper and which will be informed by the discussion of the Council at this meeting.

Continuing Fitness to Practise – Towards an evidence-based approach to revalidation

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1. Executive summary

1. The HPC regards revalidation as one part of the process of assuring continuing fitness to practise. Continuing fitness to practise encompasses all those steps taken by regulators, employers, health professionals and others which support the maintenance of fitness to practise beyond the point of initial registration.
2. The current evidence suggests that the risk posed by the professions regulated by the HPC overall is low. However, this is an area which merits further exploration. For example, our findings suggest that professional conduct represents a higher 'risk' area than competence and research on the potential link between fitness to practise outcomes and performance and conduct during pre-registration education and training is needed before implementation of any further periodic checks on registrants.
3. Public trust in the health professionals regulated by the HPC is high. However, further work on ways to increase public involvement in regulation is merited. Service user feedback might be one way of achieving external input into the HPC's existing processes.
4. The potential costs of additional regulatory processes are likely to be significant and as such must be clearly justified, balancing the costs against demonstrable benefits.
5. In the light of these findings, existing regulatory processes are currently appropriate and sufficient when considered in the context of the wider environment in which they operate and the risk of harm posed by the professions regulated by the HPC.

2. Introduction

1. This is a report to the HPC Council ('the Council') of the Continuing Fitness to Practise Professional Liaison Group (PLG). The PLG consisted of members with a broad range of backgrounds and expertise, including lay and registrant members of the HPC Council and representatives from professional bodies, unions, regulatory bodies, the Scottish Government and employer organisations. Please see Appendix 1 for a full list of group members.

2. The group met five times between November 2007 and September 2008. At its first meeting, the group benefited from the input of representatives from professional bodies.

3. The group was tasked with:

- defining continuing fitness to practise;
- identifying good practice in this area;
- reviewing the evidence base / literature on continuing fitness to practise in a number of key areas;
- exploring the issues raised by the White Paper; and
- making recommendations to the Council for next steps.

4. This report incorporates the group's discussion, research undertaken for and after PLG meetings and draws conclusions and recommendations for next steps.

5. The group's work was complementary to that of the Department of Health Non-Medical Revalidation working group, established to take forward the proposals outlined in the White Paper for the revalidation of non-medical healthcare professionals.

3. Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century

1. The background to this work is the recommendations contained within the White Paper – Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century published in February 2007.

2. The recommendations in the White Paper are detailed below.

‘Revalidation is necessary for all health professionals, but its intensity and frequency needs to be proportionate to the risks inherent in the work in which each practitioner is involved.’ (paragraph 2.29)

‘...the regulatory body for each non-medical profession should be in charge of approving standards which registrants will need to meet to maintain their registration on a regular basis.’ (paragraph 2.30)

There will be three groups for revalidation:

- Employees of an approved body – employers make recommendations to the professional regulators.
- Self-employed contractors and others performing commissioned activities - commissioning organisations or regulators make recommendations.
- Others – regulator develops direct revalidation requirements. (paragraph 2.32)

‘Information gathered under the Knowledge and Skills Framework should be used as far as possible as the basis of revalidation, with any additional requirements justified by risk analysis.’ (paragraph 2.34)

‘The Government will discuss with the Devolved Administrations and with public private and voluntary sector employers the development of an affordable and manageable timetable for the effective implementation of revalidation.’(paragraph 2.38)¹

¹ Department of Health, Trust, Assurance and Safety – The Regulation of Health Professions in the 21st Century (2007).

4. Definitions, purpose and process

1. A number of important preliminary issues were identified at an early stage of the PLG's work. These included the need for clarity around the definition of revalidation and its purpose. There are also considerable challenges in finding a meaningful process for a revalidation system which could be applicable to the thirteen professions regulated by the HPC. Some of the issues identified are briefly described below.

Definitions

2. The following definitions have been put forward for revalidation:

'The regular demonstration by registered doctors that they remain fit to practise in their chosen field(s).'

Ensuring standards, securing the future – consultation document
(General Medical Council, 2000)

'Revalidation is the process by which a regulated professional periodically has to demonstrate that he or she remains fit to practise.'

The regulation of the non-medical healthcare professionals
(Department of Health, 2006)

'Revalidation is a mechanism that allows health professionals to demonstrate that they are up-to-date and fit to practise.'

(Trust, Assurance and Safety – The regulation of health professionals in the 21st century, 2007)

3. There is a continued lack of clarity around the term 'revalidation'. Although there are common features in the definitions put forward about revalidation above, there are also notable differences. In particular, the White Paper seems to place Continuing Professional Development (CPD) within revalidation with reference to practitioners remaining 'up to date'. In contrast CPD has often been viewed as a separate process from revalidation, but one which might generate some of the evidence upon which a revalidation decision is made.

4. Continuing fitness to practise is broadly defined as encompassing all those steps taken by regulators, employers, health professionals and others which support the maintenance of fitness to practise beyond the point of initial registration. This includes, but is not limited to, measures for 'revalidation'.

Purpose

5. The purpose of revalidation is often unclear. Is revalidation aimed at identifying poorly performing registrants who are not being identified as part of the fitness to practise process? Or is it aimed at improving the standard of practice for all practitioners?

6. There is a potential dichotomy in the aims of revalidation between 'quality improvement' and 'quality control' mechanisms. Quality control is aimed at ensuring compliance through threshold standards; the focus is on the minority of practitioners who fail to meet the necessary standards.

7. Quality improvement is aimed at improving the quality of the service delivered by practitioners at every level.

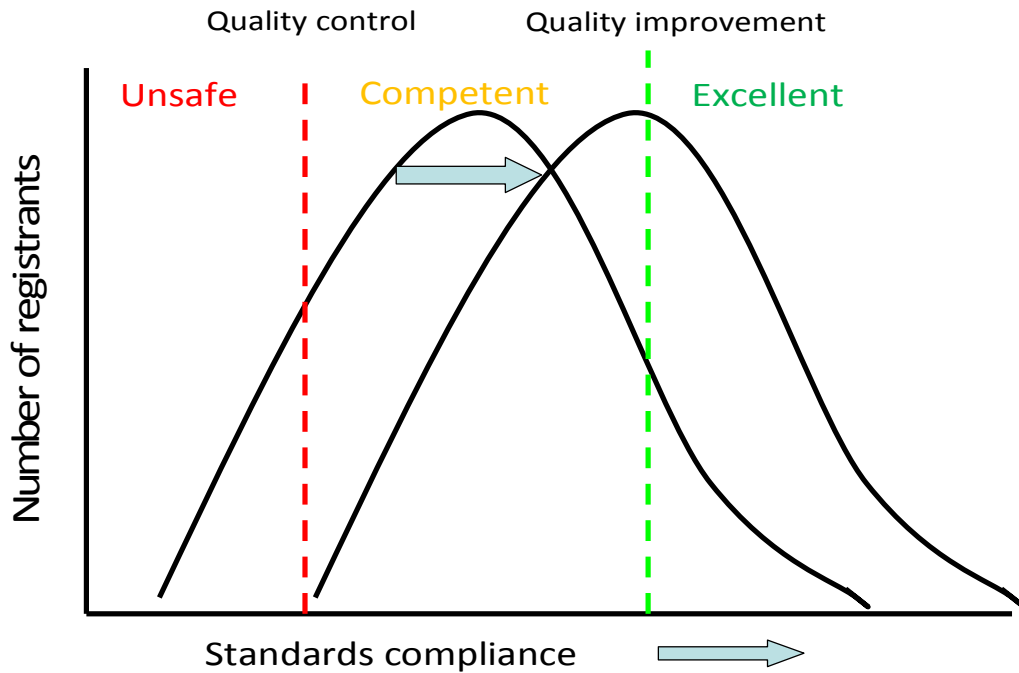
8. Such approaches are not necessarily mutually exclusive and both might be achieved simultaneously. The HPC's existing processes achieve quality control whilst also acting as a driver for quality improvement. Figure 1 overleaf illustrates the comparison between quality control (ensuring safe, threshold practice) and quality improvement (practitioners at each level have increased competence).

9. This conclusion supports the perspective expressed in the Foster review of non-medical regulation:

'For regulation to motivate and engage with the majority who always aim to Practise safely, it must aim for improvement, not mere compliance.'²

² Department of Health, The Regulation of the Non-medical Healthcare Professionals (2006), p. 11.

Figure 1 – Quality control and quality improvement



Process

10. A number of process related issues have also been identified, many of which are about the practicalities of additional periodic assessment.

11. These include:

- **Standards and assessment**

Against which standards should any revalidation assessment take place?

Is it possible to assess all aspects of fitness to practise (i.e. competence, character, health)?

How frequently should any assessment be carried out?

- **Context**

Should or can registrants who do not work in a clinical or patient / client facing environment be revalidated?

- **Risk**

Is it possible to identify those groups of registrants who pose the greatest 'risk' of future harm to the public?

5. Existing mechanisms for assuring continuing fitness to practise

1. A number of different mechanisms used in assuring or promoting continuing fitness to practise in the UK and worldwide have been considered. This consideration focused on how effective these mechanisms were, how they worked and why they worked. The mechanisms were also judged against the recommendations of the White Paper to ask whether they could form a sufficient basis for revalidation.

2. The assessment of the effectiveness of mechanisms which exist within and outside the professional regulatory environment is important in order to help assess whether an additional layer of regulation is necessary at the professional regulatory level.

3. The existing mechanisms examined and discussed in this section are divided into:

- HPC mechanisms (paragraphs 4 to 28)
- National and local mechanisms (paragraphs 29 to 62)
- International mechanisms (paragraphs 63 to 75)
- UK revalidation (paragraphs 76 to 82)

5.1 HPC mechanisms

4. The HPC sets standards, approves education and training programmes that meet those standards, holds a register of individuals who pass those programmes and holds its registrants to its standards. Four processes are described below which have a role in continuing registration and continuing fitness to practise.

Pre-registration mechanisms

5. Although in this report the focus is on continuing fitness to practise (i.e. fitness to practise beyond the point of initial registration), the role that regulators play at the pre-registration stage is also important in helping to assure and enable continuing fitness to practise once an individual is registered.

6. Such 'pre-registration mechanisms' include:

- Approval and monitoring of pre-registration education and training programmes against standards of education and training and standards of proficiency. This ensures that only those who have met the threshold standards for safe and effective practice are eligible for entry to the Register.
- Health and character checks on admission to pre-registration education and training programmes and on admission to the Register. For more information about health and character checks on admission and renewal, please see paragraphs 9 and 10.

Self-certification

7. Applicants for admission and readmission to the Register make a declaration that they have read and will comply with the standards of proficiency, conduct, performance and ethics and that they have read and will comply with the standards for CPD. Applicants are also required to declare any convictions or cautions or determinations of other regulators responsible for licensing a health or social care profession as part of the application process.

8. Every two years when they renew their registration, registrants are required to sign a declaration to confirm that they continue to meet the standards of proficiency which apply to their practice; that there have been no changes to their health or relating to their good character which they not advised the HPC about and which would affect the safe and effective practice of their profession; and that they continue to meet the standards for CPD.

9. The self-certification process is supported by the health and character process. If a registrant declares an issue relevant to their good character on application or renewal (e.g. a caution or conviction), a health reference raises

possible concern, or a registrant makes a self-referral during their registration cycle, this will be considered by a registration panel. The panel determines whether the applicant should be admitted to the Register or permitted to renew their registration. Or, in the case of a self-referral, the panel decides whether the matter should be referred into the fitness to practise process.

10. Between June 2005 and December 2007, 560 declarations on admission or renewal to the Register were considered by the HPC and concluded. In this same period, 239 self referrals were concluded. In 97% of declaration cases, admission or renewal to the Register was allowed; in 75% of self-referral cases the matters were considered not to impact upon the registrant's fitness to practise.³

11. Self-certification and self-referral of important information demonstrates the registrant's commitment to maintain their fitness to practise. It also demonstrates behaviours commensurate with professionalism.

12. It is acknowledged that as this is self-certification, there is a lack of external verification as to the declaration made by the registrant or applicant, unless a subsequent matter is brought to the Council's attention (or the registrant is audited to demonstrate compliance with the CPD standards).

CPD standards and audit

13. The Council sets standards for CPD that are outcomes-based. Registrants are required to undertake CPD, record their CPD, ensure that their CPD contributes to the quality of their practice and service delivery, and ensure that it will benefit service users.

14. CPD audits check registrant compliance with the CPD standards. Random audits to check compliance with the CPD standards began in May 2008 and are linked with renewal. The sample size for the first two professions, chiropodists and podiatrists and operating department practitioners, is 5%.

15. The CPD standards and audit are seen as both quality control and quality improvement mechanisms. The audit is a quality control mechanism in that registrants are sampled to check compliance with the standards. The standards are based on outcomes with a focus on benefits to service users and therefore are a mechanism for quality improvement.

16. The outcome of a failure to meet the standards is administrative removal from the Register.

17. Future analysis of the outcomes of the CPD audits will help in the development of risk indicators for the regulated professions.

³ HPC Education and Training Committee, 26 March 2008
www.hpc-
uk.org/assets/documents/10002168education_and_training_committee_20080326_enclosure
09.pdf

Returns to practice

18. Health professionals seeking readmission to the Register who have been out of practice must undertake an updating period of 30 days for between two and five years out of practice and 60 days for five or more years out of practice.

19. The updating period can consist of private study, formal study and supervised practice and has to be countersigned by a registrant from the same part of the Register who has been in registered practice for three years or more.

20. The returns to practice requirements are primarily a quality control mechanism aimed at mitigating the potential risks involved in returning to practise after a break, demonstrating that the returner is up to date and supporting fitness to practise. The returns to practice requirements are threshold requirements which may be exceeded by the requirements of others, such as employers.

Fitness to practise

21. The fitness to practise process is the way in which the HPC can consider complaints against registrants. (Complaints via our fitness to practise process are referred to in our legislation as 'allegations'.)

22. If a panel finds that a registrant's fitness to practise is impaired, they have a range of sanctions available in order to protect members of the public including cautioning a registrant, making their registration subject to conditions, suspending their registration or striking them off the Register.

23. The fitness to practise process is a quality control mechanism and relies on a system of exception reporting. In 2007/08, 0.24% of registrants were subject to a complaint (please see section 6.1).

Conclusions

24. The processes described above and on the previous page should not be considered in isolation, and should be seen instead within the context of other activities undertaken by the HPC which help to contribute towards continuing fitness to practise.

25. For example, the HPC's role in approving education and training programmes is focused on ensuring that appropriate standards are met, which will equip future registrants for lifelong continuing fitness to practise. In addition, the work of regulators (and other organisations) in providing guidance to registrants can be seen as making a positive contribution towards

continuing fitness to practise and might be linked to improved outcomes. Philip Hampton concluded that 'better advice leads to better regulatory outcomes'.⁴

26. There is no evidence to suggest that the processes outlined above are ineffective in achieving quality control and promoting quality improvement amongst registrants.

27. Considering each of these processes in isolation, we could conclude that whilst they do contribute towards continuing fitness to practise, they do not represent a positive affirmation of fitness to practise in the sense of a regular or periodic, external assessment of each registrant against standards of conduct and competence at a given point in time. For example, the CPD and returners to practice processes have no direct or explicit link to standards of conduct or competence.

28. However, considering these processes together, in light of the wider environment in which these processes operate and our assessment of the risk profile for the professions regulated by the HPC, we conclude that these processes are appropriate and sufficient.

⁴ HM Treasury, Reducing Administrative Burdens: Effective inspection and enforcement, (2005), p.9.

5.2 National and local mechanisms

29. A number of different mechanisms outside of the regulation of healthcare professionals that may be relevant to the continuing fitness to practise of registrants have been considered.

30. In this section, a small number of those mechanisms are described in more detail. This is not intended as an exhaustive list or as a comprehensive exploration of the different mechanisms considered by the group but is intended to summarise and illustrate the interplay between such national and local mechanisms and regulation.

31. Where relevant, specific examples are given which are relevant to the professions regulated by the HPC. However, it is acknowledged that many of these mechanisms also exist for other professions. Equally, some of the mechanisms described may not be applicable to some professions or indeed to all registrants.

32. Table 1 lists and compares some of the models examined. This is not intended as an exhaustive list, but it does illustrate the wide range of mechanisms which contribute to practitioners continuing fitness to practise.

Table 1 – National and local mechanisms

Individual	Employer	Professional body	Institutional	Regulatory
Clinical supervision and peer review	Annual appraisal/KSF	Accreditation schemes	Professional indemnity insurance	Ombudsman's offices
Re-certification	Clinical governance	CPD support	National Patient Safety Agency (NPSA)	Service regulation
CPD activity	Risk management	Mentoring schemes		Quality Assurance Agency (QAA)
Further training & research	Mentoring schemes	Specific Interest Groups / professional networking schemes		
	Support for CPD activities			

33. Six models are described in more detail overleaf.

Recertification

34. Recertification is one mechanism used to assess continuing fitness to practise on an individual level. The only profession regulated by the HPC currently using recertification is the paramedic profession. Some National Health Service (NHS) Ambulance Trusts require paramedics to undertake training and assessment in order to demonstrate their continuing competence. This model is employer led without the involvement of the statutory regulator.

35. The exact format of recertification varies between NHS Trusts, however, it can include:

- a period of observed practice to identify personal development needs;
- a short period of CPD courses (around 5 days) including training in areas and competencies key to paramedic practice; and
- assessment of those areas against relevant standards.

36. If recertification is failed, the practitioner may be required to spend time in supervised practice, sometimes at a lower grade, and remedial training is offered.

37. This model is noteworthy because it involves periodic assessment, usually against threshold standards. It is also the model amongst the HPC regulated professions which most closely approximates revalidation as defined in the White Paper, albeit employer-led. The outcome is a pass or fail with remediation for those who fail.

38. In practice, this form of 'revalidation' has a number of difficulties. First, it is not always delivered because of financial constraints; second, the standard varies between employers; and third, the focus on previously learnt information may mean that there is not a direct relationship with fitness to practise. Despite having this system in place, HPC fitness to practise data indicates that paramedics account for the largest proportion of complaints and that conduct is more frequently a problem than competence (please see section 6.1).

Annual Development Review

39. There are many well established annual review processes used by professionals working in the NHS and the independent sector. In the NHS, annual development review is conducted using the Knowledge and Skills Framework (KSF). The KSF is a tool which is focused on defining and describing the knowledge and skills that NHS staff need to apply to deliver quality services within a defined role.

40. The KSF consists of 30 dimensions that identify the functions required by the NHS to provide a good quality service. Six of the dimensions are core dimensions describing core areas such as communication with the remainder covering knowledge and skills which are specific to some (though not all) jobs in the NHS. These core dimensions have been mapped by the KSF Group of the NHS Staff Council against the HPC standards of proficiency and standards of conduct, performance and ethics.

41. The KSF is used to develop an outline for each post (so that the skills and knowledge required are clear) and is used as the basis of reviewing the performance of staff. It is concerned with developing staff within their role, and incorporates CPD.

42. The White Paper recommended that, for those registrants working within the NHS, information gained during the KSF performance review process should form the basis of revalidation, with employers providing evidence to regulators.

43. The following observations about the KSF can be made:

- The KSF was developed in partnership with staff as a developmental tool and was not intended as a tool for revalidation.
- The KSF would apply to a significant number of registrants working within the NHS but not those who worked in other managed environments or who are in private practice.
- The KSF might potentially contribute evidence for revalidation.
- The KSF was still being implemented by some organisations within the NHS and as such is not yet ready to contribute towards revalidation in some areas.

44. Appendix 2 gives an example of good practice in the implementation of the KSF.

45. The KSF Group of the NHS Staff Council has been commissioned to undertake work with regulators, employers (both within and outside the NHS) and others to explore the potential for the use of the KSF in a revalidation process. This work is due to conclude in December 2008.

Peer review and clinical supervision

46. 'Peer review' is an activity that supports the continuing fitness to practise of registrants by providing an opportunity for the discussion and review of practice by peers.

47. Arrangements for peer review, including models and approaches to this activity, may vary between professions. How such activity is funded, resourced or supported by employers may additionally vary.

48. For many of the professions registered by the HPC supervision (sometimes referred to as clinical supervision) is seen as an important part of practice. Supervision, including peer supervision, mentoring, reflection-on-practice and case review offers many opportunities for assessment of practice, learning and development by the practitioner or by colleagues and managers. The process results in improved learning, practice delivery and communication and produces evidence to support the HPC's CPD standards and audit.

48. In the arts therapy professions (art, music and drama therapy), as in the other therapy and psychotherapy professions, clinical supervision is embedded in the profession ethos of good practice.

49. Such supervision provides a forum in which the therapeutic relationship between client and practitioner can be monitored, via discussion with another colleague. Supervision in the arts therapies is profession led and supported by employers but is not a specific regulatory requirement for ongoing registration.

50. In midwifery, there is a system of statutory supervision which is similarly a peer-oriented, supportive process which is aimed at identifying any problems and acting quickly to remedy them in a supportive manner.

Clinical governance

51. Like annual development review, clinical governance is a well established local mechanism for assuring quality amongst teams of professionals. The principles of multi-disciplinary clinical audit have been developed into a general framework for clinical governance and accountability of NHS trusts and strategic health authorities.⁵

52. The framework encompasses a range of quality improvement initiatives, such as clinical audit, improving clinical effectiveness, supporting the implementation of evidence based practice and improving record keeping. The focus is on locally driven initiatives with local ownership by individual practitioners, teams and managers.

53. In England such local arrangements are supported by clinical governance teams. The 'Standards for Better Health' by which the Healthcare Commission in England assesses both public and private sector facilities, require that 'health care organisations work together to ensure that... the principles of clinical governance are underpinning the work of every clinical team and every clinical service'.⁶

⁵ Scally G, and Donaldson LJ, 'Clinical governance and the drive for quality improvement in the new NHS in England, *British Medical Journal*, 317, (1998) 61-65.

Department of Health. Clinical governance reporting processes (November 2002).

⁶ Department of Health, National Standards, Local Action - Health and Social Care Standards and Planning Framework 2005/06—2007/08 (2004), Annex 1.

54. Although the application of clinical governance may vary across the UK, there is widespread commitment across the four NHS systems to the principle of quality improvement and the need for all staff to take responsibility for their part in its implementation at local level.

Public Services Ombudsman

55. Another example of an external control on quality is the Public services Ombudsman. In each of the four UK countries, a Ombudsman has a role in reviewing complaints about public bodies including the NHS.

56. A complainant who is dissatisfied with the response of a public body to a complaint can ask the Ombudsman to review their complaint. If the Ombudsman upholds a complaint, it can order the public body to resolve the situation.

57. The Ombudsman therefore has a proactive role in quality improvement. The Ombudsman encourages public bodies to review procedures regularly to ensure they are effective, ask for feedback to improve services and learn lessons from complaints.⁷ The Ombudsman often makes recommendations which lead to direct changes in the policies or procedures of public bodies.

Institutional inspection

58. Inspection and assessment of organisations which deliver health or social care can be seen as both a quality control and quality improvement mechanism. A number of organisations undertake this function including the Healthcare Commission in England, Healthcare Inspectorate Wales, NHS Quality Improvement Scotland and the Regulation and Quality Improvement Authority in Northern Ireland. A number of similar organisations also carry out an inspection role in the social services sector.

59. The role of these organisations is focused on the quality of service delivery at an organisational level. These organisations are involved in assessing the performance of healthcare providers against clear standards and disseminating good practice to assure patient safety.

⁷ Parliamentary and Health Service Ombudsman, Annual Report 2006/2007 - Putting principles into practice (July 2007).

Parliamentary and Health Service Ombudsman, Principles for Remedy (2007).

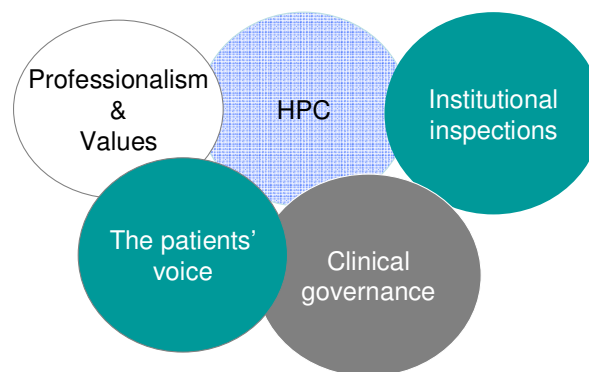
Conclusions

60. The mechanisms outlined vary as to their focus and aims, but have overlapping purposes. In many cases HPC registrants will participate in, have contact with or will be influenced in some way by the mechanisms described. However, it is acknowledged that some of these models may not apply to registrants who do not work within managed environments.

61. In the existing professions regulated by the HPC, a number of the models outlined are voluntary and dependent upon professional buy-in, or are required by an employer. The model is led by the profession and / or employer and not by a professional regulator.

62. However, they collectively contribute to the continuing fitness to practise of registrants. Professional regulation is therefore but one part of the whole; quality improvement and quality control are subject to a number of interlocking checks and balances. Figure 2 below illustrates this point.

Figure 2 – Professional regulation as part of the quality and safety agenda



5.3. International mechanisms for assuring continuing fitness to practise

63. Regulatory mechanisms in place in Canada, the United States of America, Australia and Europe that are focused on continued registration were also considered as part of this work.

64. Table 2 below provides a comparative summary of the different models. Three models considered are described below.

Table 2 – Summary of features of different systems used worldwide

	Self-certification	CPD	Portfolio / tools	Periodic Assessment	Remediation
Physiotherapists (Ontario, CA)	✓	✓	✓	✓	✓
Occupational Therapists (Ontario, CA)	✓	✓	✓	✓	✓
Physical therapists (Alberta, CA)	✓	✓	✓	X	X
Physicians and Surgeons (Ontario, CA)	✓	✓	✓	✓	✓
Doctors (Ohio, US)	✓	✓	X	✓	X
Physician Assistants (Certification, US)	X	✓	X	X	X
Emergency Medical Technicians (Certification, US)	✓	✓	X	X	X
Occupational Therapists (NZ)	✓	✓	✓	✓	✓
Nurses (Tasmania, AUS)	✓	✓	✓	X	X
RIBIZ (Netherlands)	X	X	X	✓	✓

College of Physiotherapists of Ontario

65. The College of Physiotherapists of Ontario (Canada), runs a 'Quality Management Program' (QMP) which consists of three stages:

- Competency reflection and integration

Registrants create and maintain a professional portfolio which contains information about their practice, CPD, and may include feedback from patients or colleagues. Compliance with this is not routinely checked; registrants have to sign a declaration to confirm that they meet the requirements when they renew their registration.

- Competency assessment

Each registrant is subject to an onsite assessment by a peer assessor every five to ten years. Registrants are expected to demonstrate competency within the role that they perform.

If the College feels that there are concerns about the registrant's practice, they may set conditions for the registrant to bring their knowledge, skills and judgement up to the required level.

- Competency improvement

This is a remediation stage to assist registrants with competency problems to meet the required standards. Registrants may participate as a result of competency assessment or as a result of a separate disciplinary investigation. Between 1997 and 2001, 1% of registrants who participated in the program were required to complete a period of remediation.

66. The QMP is ring-fenced from the College's fitness to practise process.

National Commission on Certification of Physician Assistants

67. The National Commission on Certification of Physician Assistants (NCCPA) runs a system of certification in the United States. Certification with NCCPA is one of the criteria to become a licensed physician assistant in each of the states. Graduates from accredited courses undertake an exam, and, if successful, achieve certification.

68. Recertification happens in six yearly cycles. Every two years, 100 hours of continuing medical education must be undertaken, logged and a renewal fee paid. By the end of the sixth year, a recertification exam must also be passed which covers general medical surgical knowledge. However, not all state boards require recertification for licence renewal.

Healthcare Providers Registration and Information

69. In the Netherlands, 'Healthcare Providers Registration and Information' or 'RIBIZ' holds a register of over 350,000 health professionals.

70. In 2009, RIBIZ plans to introduce re-registration requirements for nurses, midwives and physiotherapists. At present, a registrant can remain on the Dutch Register indefinitely.

71. Registrants in these professions will have to demonstrate that they have practised the equivalent of one working day a week during the last four to five year period, or else undergo additional training which RIBIZ will prescribe. RIBIZ believes that these changes will ensure that their Register is a measure of the competence of healthcare professionals in the Netherlands but this has yet to be piloted and evaluated.

Conclusions

72. There are a number of features common between some, if not all, of the different international models studied. These include self-certification against standards, compulsory CPD, the structured identification of learning needs, periodic assessment of competency and remediation.

73. The approach in Ontario around periodic assessment of practitioners is noteworthy in terms of its approach to risk. The Ontario model is characterised by a 'funnel', in that the proportion of registrants involved decreases greatly at each stage, as the thoroughness of the check increases. This approach targets most resources (i.e. in the remediation stage) at those registrants where performance difficulties have been identified, and is in line with the approach taken by the National Clinical Assessment Service (NCAS) in the UK, and other medical programmes for poorly performing doctors worldwide.⁸

74. Many of the models studied use a 'structured' or 'enhanced' CPD approach. Compulsory CPD requirements are supported by tools registrants can use to identify and reflect on their learning needs and structure CPD to meet those needs.

⁸ Knight JR., Sanchez, LT., Sherritt L., Bresnahan LR., Fromson JA., 'Outcomes of a Monitoring Program for Physicians with Mental and Behavioral Health Problems', *Journal of Psychiatric Practice*, 13(1), (2007) 25-32.

Cohen D., Rhydderch M., 'Measuring a doctor's performance: personality, health and well-being', *Occupational Medicine* (London) 56(7), (2006) 438-40.

75. The costs and resources involved in developing and administering many of the models are likely to be substantial. Many of these models exist in a uni-professional environment and there are differences between the physical and financial environment in which the professions involved practise compared with the UK. Those regulators who use a regular performance assessment approach are also far smaller in terms of registrant numbers compared to the HPC.

5.4. UK revalidation

76. The revalidation systems currently in development by the General Dental Council (GDC) and General Medical Council (GMC) are briefly summarised below.

General Dental Council

77. The GDC has concluded that there is insufficient evidence at this time in order to establish groups of registrants for revalidation who carry more risk than others – ‘static group risks’. Instead, the GDC propose to approach revalidation in terms of ‘static individual risk’ – i.e. the risk the individual registrant may pose owing to previous fitness to practise action or future non-compliance with revalidation.

78. The GDC have developed a three step model. Step one is an all registrant sift where all registrants submit information. Step two is peer assessment in practice of those about whom potential problems have been identified. Step three is an in depth assessment of those registrants about whom concern still remains. The assessment would take place against standards and information drawn from appraisal might form one of the pieces of evidence submitted by a registrant. The fine detail of each stage is currently under development. It is intended that the outcome for those who fail to participate in or who fail the stages of the revalidation process will be administrative erasure.

General Medical Council

79. The GMC’s proposals are currently undergoing further development and piloting. They consist of two stages.

- Relicensing of basic medical registration

This would require a portfolio of evidence (e.g. clinical audit, prescribing data, multi-source feedback and appraisal) collected against standards from the GMC’s Good Medical Practice. Responsible officers in the local area would be asked to review the portfolio and affirm the Doctor’s fitness to practise.

- Recertification of specialism

Standards would be set by the relevant Royal Colleges and specialist associations and approved by the GMC. Evidence for recertification would include appraisal, audit and patient feedback.

Conclusions

80. The proposed General Dental Council model applies the principle of risk and proportionality to the process itself – the thoroughness of the check increases as registrants progress through the stages (please see section 6).

81. The proposed General Medical Council model is noteworthy in incorporating multi-source feedback into the process and it is useful to consider whether such an approach would be meaningful and add benefit in the context of the professions regulated by the HPC (please see section 9).

82. The costs of these proposed models have not yet been fully assessed but have the potential to be significant. Any HPC approach to revalidation would need to be based on a thorough cost analysis, compared to an analysis of the demonstrable benefits of additional regulation (please see section 7).

6. Risk

1. The White Paper states that: 'Revalidation is necessary for all health professionals, but its intensity and frequency needs to be proportionate to the risks inherent in the work in which each practitioner is involved.' (paragraph 2.29)

2. We have considered whether there is evidence of risks of harm to public safety amongst the professions regulated by the HPC that are not sufficiently mitigated by existing mechanisms and which therefore might indicate that some kind of additional regulation is necessary.

3. The White Paper included a table which highlighted some areas which might indicate whether a registrant was higher or lower risk (Appendix 3). The following observations can be made:

- The areas have some intuitive basis but such assumptions would need to be supported by clear evidence related to the professions regulated by the HPC.
- The table suggests homogeneity of practice environment which may not always exist within some settings.
- The table is not exhaustive – other factors such as age and gender are also known to be important.
- There are potentially a number of logistical obstacles to any risk based approach – particularly around the logistical difficulty of capturing reliable information about the practice of registrants and the possible impact upon areas of practice considered 'high risk'.

4. Furthermore, risk in the context of health care arises not only from risks associated with poor performance (i.e. harm resulting from shortcomings in competence). It also arises from human errors (i.e. wrong diagnosis of serious diseases) and organisational dysfunction or error to leading system failures in care (i.e. deaths due to infection in hospital).⁹

5. Taking a risk based approach is both complex and challenging without evidence to guide the parameters that might be used to calculate risk of harm to service users.

6. This section is sub-divided into three areas:

- Fitness to practise (paragraphs 7 to 43)
- System risks (paragraphs 44 to 47)
- Professionalism (paragraphs 48 to 57)

⁹ Department of Health, Good Doctors, Safer Patients (2006).

6.1. Fitness to practise

7. The group considered data from the fitness to practise process as evidence of risk indicators amongst the professions regulated by the HPC (as well as evidence which might support a rationale for revalidation).

8. This section compares the proportion of complaints received in particular areas, against other information available from the Register. As the number of complaints is statistically small relative to the HPC Register as a whole, the numbers involved in the proportions described is correspondingly small. In 2007/2008, 422 complaints were received about registrants.

Data on overall trends

9. In 2007/2008, 0.24% of registrants were subject to a complaint via our fitness to practise. This figure was 0.18% in 2006/2007.¹⁰

10. In 2006/2007, 10% of complaints considered were purely about lack of competence, compared with 88% which had a conduct element. (Of these, 13% were about convictions and cautions.)

11. In 2007/2008 misconduct cases considered including making false statements on a CV; drug misuse; inappropriate relationships with patients; and fraudulent use of employer property.

12. Lack of competence cases often concerned a prolonged failure to meet the required standards of proficiency. Issues considered included failures in assessment, treatment and follow up care.

13. In 2007/2008, less than 1% of complaints were about the physical or mental health of the registrant.

14. Taken together, these trends indicate that conduct more than competence is the predominant 'risk' in terms of public protection and safety for the professions regulated by the HPC.

15. The number of complaints as a proportion of registrants considered by the HPC seems lower compared to those of other regulators. In 2006/2007, the HPC received 1.8 complaints per 1000 registrants, the lowest of the nine regulators of healthcare professionals.¹¹ Whilst these figures could partly be accounted for by differences in the processes of the regulators, and in public awareness of their role and the professions they regulate, they potentially suggest that the professions regulated by the HPC are 'lower risk' than others.

¹⁰ Fitness to practise data is taken from the Health Professions Council Fitness to Practise Annual reports, 2006/2007 and 2007/2008.

¹¹ Council for Healthcare Regulatory Excellence (CHRE), Annual Report 2006/2007.

16. This is supported by other evidence. A recent report from the Information Centre for Health and Social Care (2007) revealed that 60% of complaints in the National Health Service (NHS) related to nursing and medical staff, compared to 5% for 'professions allied to medicine'.¹²

17. The HPC's fitness to practise process does not exist in isolation but exists in an environment which includes complaints mechanisms operated by employers and other organisations. These mechanisms often have a different purpose, focusing on matters more related to service delivery, for example, or handling complaints at a local level which would not normally justify regulatory action.

18. We are unable to quantify the extent to which, if at all, matters that should be dealt with at a professional regulatory level fail to be brought to the attention of the regulator. However, this is a common potential issue across all the regulators of health professionals and the available data does still indicate that the professions regulated by the HPC are overall 'lower risk' compared to others.

Complaints by profession

19. Analysis of fitness to practise data by profession reveals that there is some variation in the proportion of complaints received by profession (please see figure three overleaf).

20. In 2007/2008, the rate of complaints was higher for arts therapists, chiropodists / podiatrists, operating department practitioners, paramedics and prosthetists and orthotists than would be expected by the proportion of these professions on the Register. In 2006/2007, this trend was the same for chiropodists / podiatrists, operating department practitioners and paramedics.

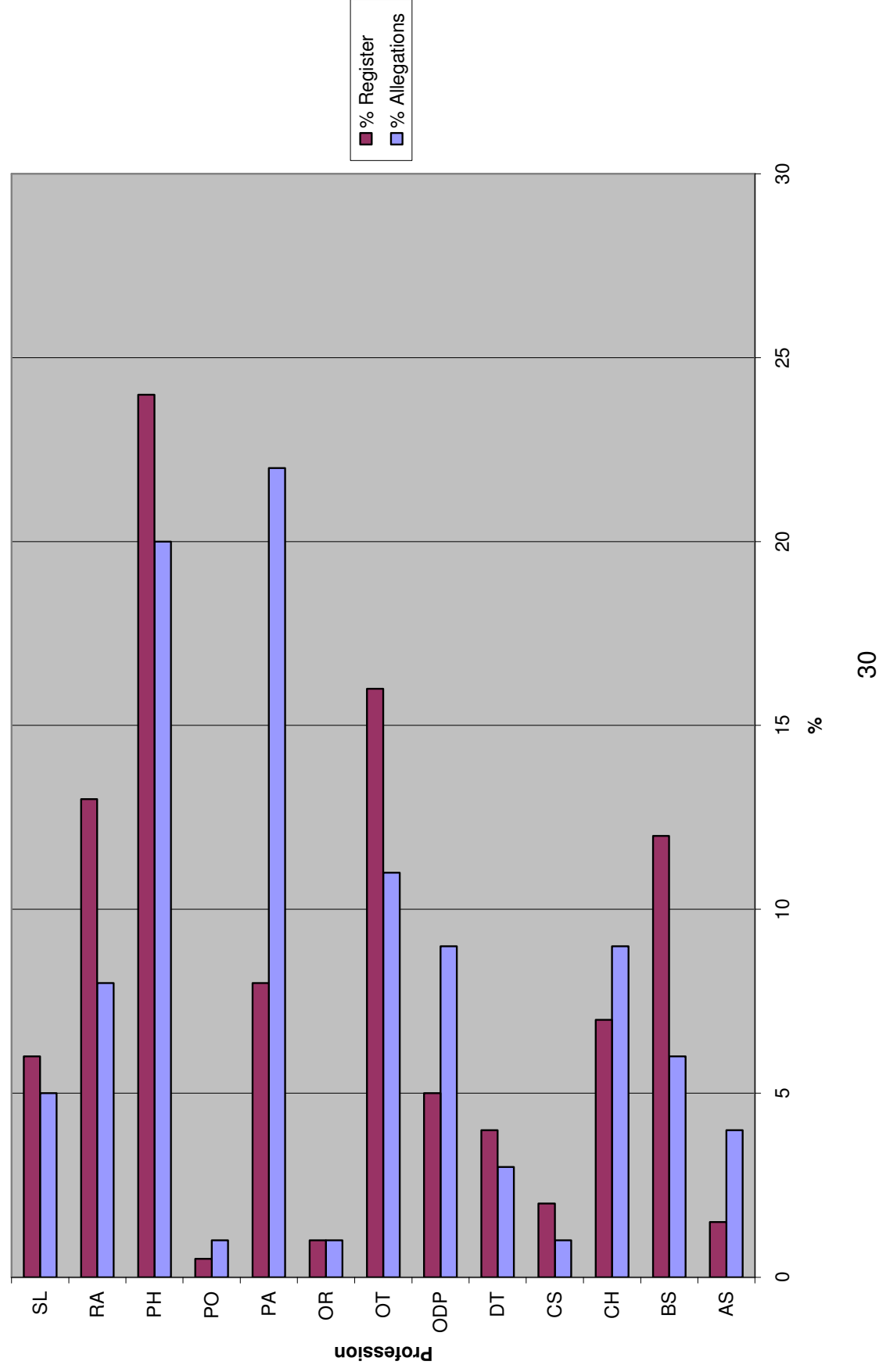
21. In 2006/2007 and 2007/2008, paramedics accounted for the largest proportion of complaints. In 2007/2008, paramedics accounted for 22% of complaints but made up 8% of the total number of registrants. This was consistent with trends in previous years.

22. This trend may be due to a number of factors. It may reflect the nature of paramedic practice in that paramedics have direct contact with members of the public and are therefore more likely to be subject to complaint, compared to some of the other professions, such as biomedical scientists, who typically have little or no direct contact. It might also be linked to the invasive nature of some procedures undertaken by paramedics and a practice environment which typically includes working outside of the hospital environment, dealing with situations which may be unpredictable and may involve some lone working.

¹² Information Centre for Health and Social Care, Data on written complaints in the NHS 2006/07 (2007).

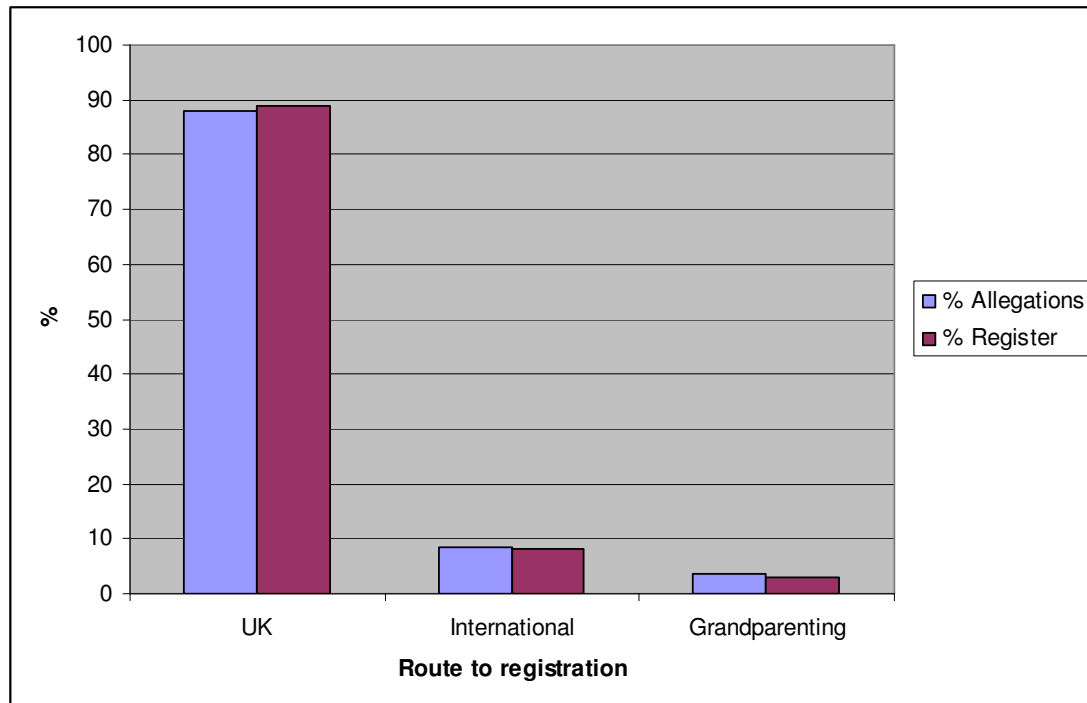
23. As with all cases overall, most cases about paramedics concerned conduct rather than competence issues.

Figure 3: Allegations by profession, compared to the proportion of registrants on the Register



Complaints by route to registration

Figure 4 - Allegations by route to registration, compared to the proportion of registrants on the Register



24. An analysis of complaints by route to registration indicates that there is a correlation between the percentage of registrants who entered the Register via a particular route and the route to registration of those subject to a complaint.

25. There are three ways of gaining registration, which we refer to as 'routes to registration':

- UK approved course

This refers to individuals who register having successfully completed a programme delivered in the UK that we approve.

- International

This refers to individuals who have completed education and training outside of the UK who apply for registration via the international route to registration.

- Grandparenting

Normally, when the HPC regulates a new profession there will be a time-limited 'grandparenting' period.

The grandparenting period allows people who have previously been practising the profession, but who could not become voluntarily registered, to apply for registration, provided that they can meet certain criteria.

26. There is no significant difference between complaints compared to the way in which those complained about registered. For example, 89% of our Register is made up of individuals who registered having completed an approved course, and 88% of complaints received in 2007/2008 were about registrants from this route to registration.

27. We can conclude therefore that there is no significant difference in risk between registrants on the basis of their registration background.

Complaints by gender

28. In contrast, the data suggests that gender is a factor in any assessment of the risk of registrants. Male registrants are more likely than their female counterparts to be subject to a complaint (please see figures 5 and 6 overleaf).

29. In 2007/2008, women accounted for 76% of the total number of registrants and men 24%. However, 57% of complaints were about men and in every profession the proportion of complaints about men was higher than the proportion of males in that profession.

30. This trend is particularly marked amongst operating department practitioners, where 79% of complaints were about male registrants, compared to 38% of male registrants in this profession.

31. Evidence from the medical profession has also indicated that gender might be an important factor in fitness to practise. One US study found that male doctors were three times more likely to be subject to malpractice claims than their female counterparts.¹³

32. In the UK, Firth-Cozens observed that conduct and drug dependency concerns about doctors are also predominantly about male doctors. She suggests that women's communication skills and emotional intelligence 'may make them forge better relationships with patients and make them less likely to be the subject of complaints'.¹⁴

¹³ Taragin, M., Wilczek, A., Karns, M., Trout, R., Carson, J., 'Physician demographics and the risk of medical malpractice', *American Medical Journal*, 93, (1992) 535-42.

¹⁴ Firth-Cozens, Jenny, 'Effects of gender on performance in medicines', *British Medical Journal*, 336, (2008) 731-2.

Figure 5 – Proportion of allegations against female registrants, compared to the proportion of females on the Register

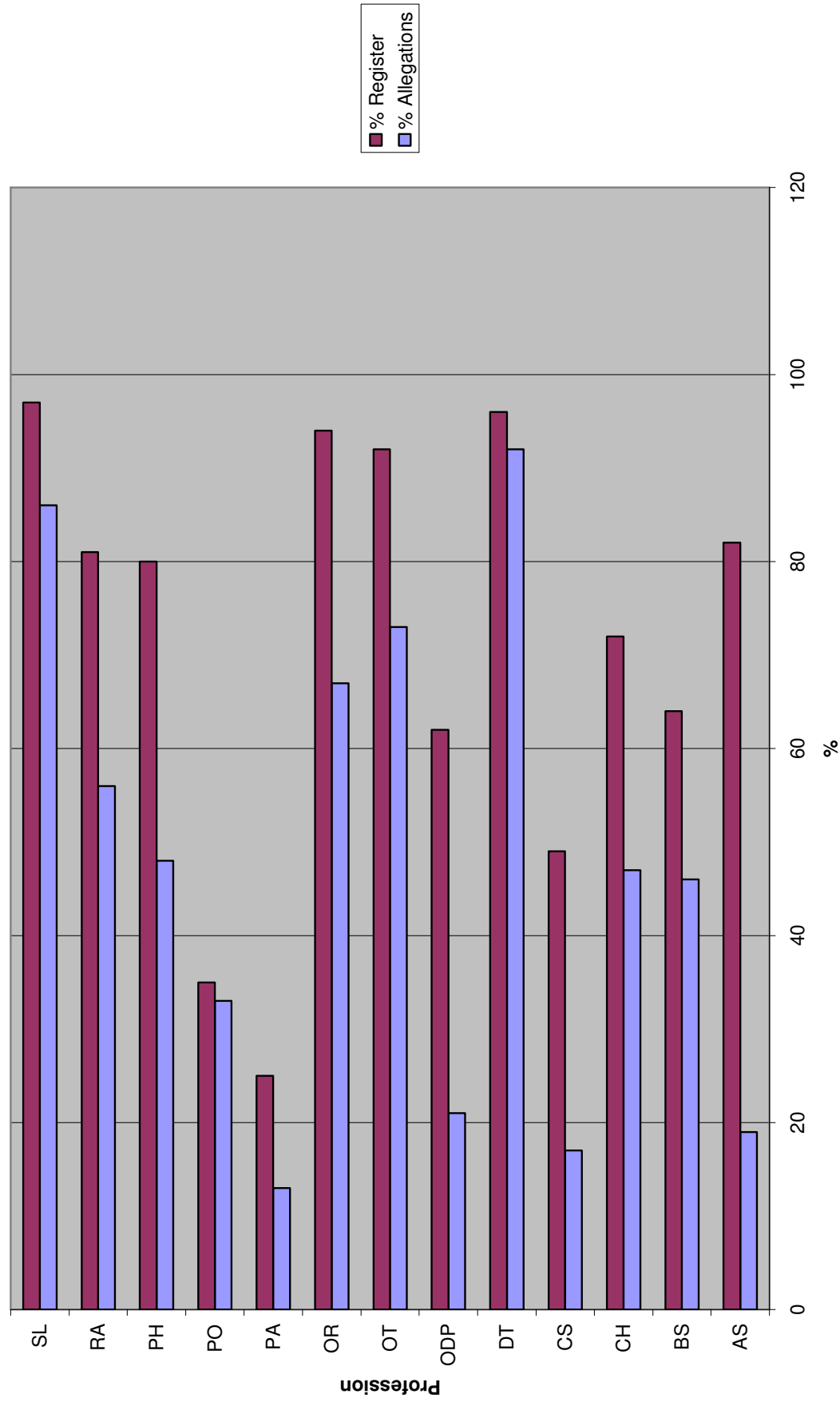
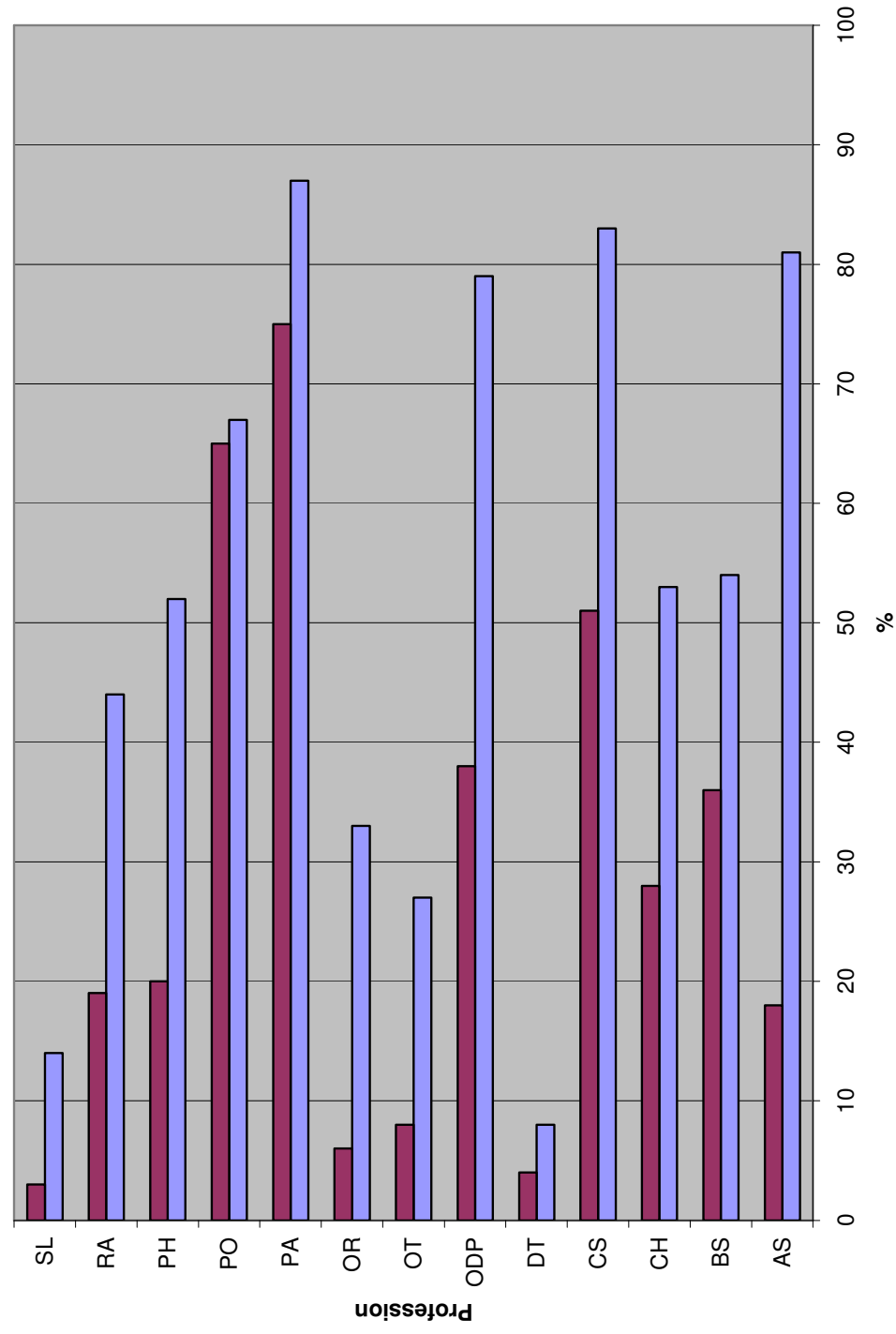


Figure 6 – Proportion of allegations against male registrants, compared to the proportion of males on the Register



Complaints by age

33. An analysis of data against age range reveals that certain age groups are more likely to be subject to a complaint than might be expected by the proportion of registrants in that age group (Please see Figure 7 overleaf).

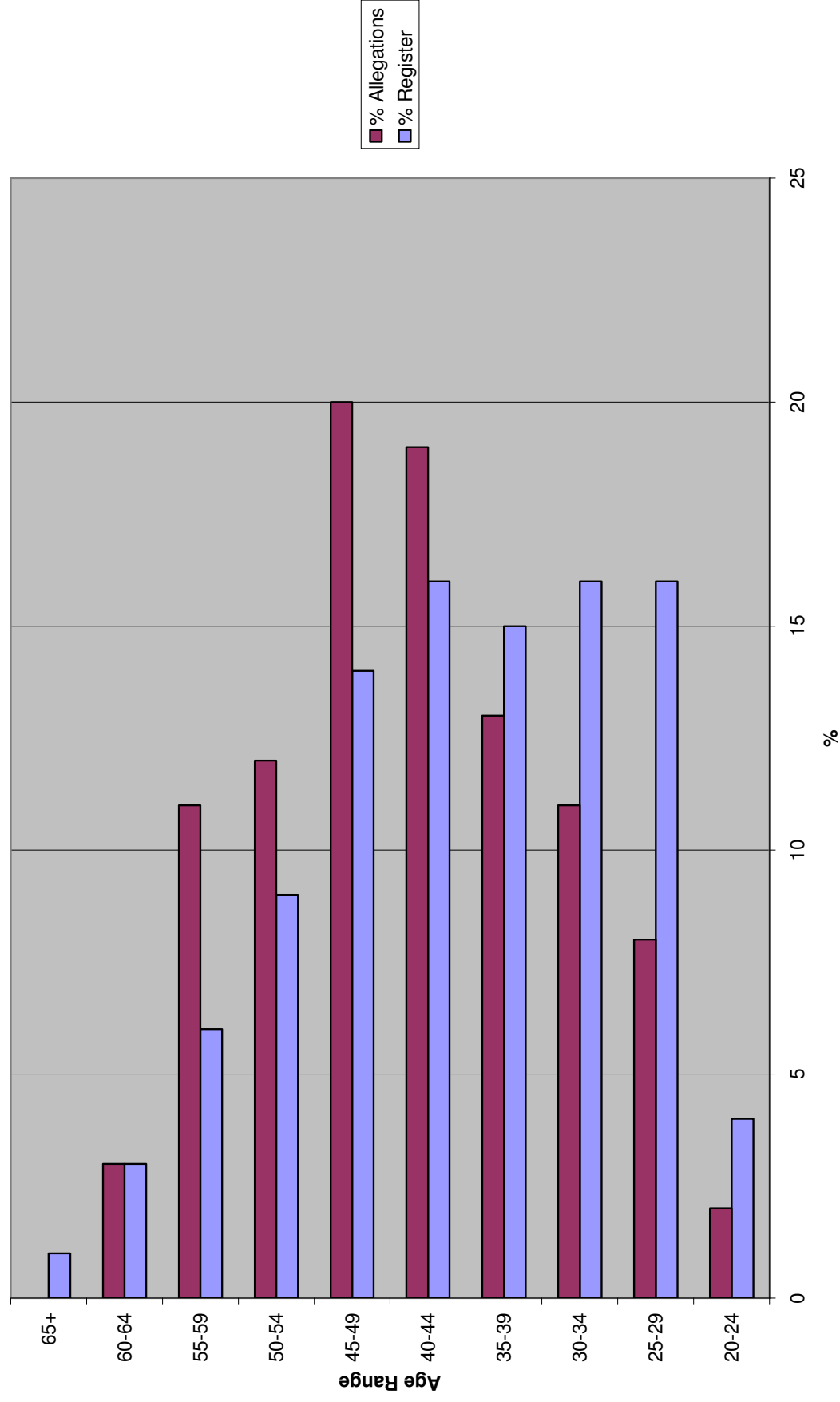
34. In 2007/2008, registrants between the ages of 40 and 59 were disproportionately subject to more complaints. This trend was most marked in the 45-49 age group, which accounted for 20% of complaints but only 14% of the whole Register.

35. Registrants between 20 and 39 were proportionately subject to fewer complaints and no complaints were received about registrants aged 65 or over.

36. This data seems to suggest that there may be some correlation between the age of a registrant and risk. This is supported by evidence in the medical profession. For example, an analysis of data from referrals to the National Clinical Assessment Service (NCAS) revealed that the rate of referral to NCAS increases with age.¹⁵

¹⁵ National Clinical Assessment Service, Analysis of the first four years referral data (July 2006).

Figure 7 – Proportion of allegations by age group, compared to the proportion of each age group on the Register



Complaints by practice environment

37. Collection of data relating to the practice environment of registrants subject to a complaint has recently begun. The HPC Fitness to Practise Department now classifies complaints by where the matters alleged occurred, under the following headings:

- NHS Hospital
- Other public sector place of employment
- Patient home
- Private clinic
- Private hospital
- Not during work
- Other

38. Therefore, at this time, there is a lack of available quantitative evidence in order to assess whether different environments (i.e. independent practice compared to managed environments) pose more risk than others. It is worth noting here that the biggest complainant group remains employers, accounting for 50% of complaints in 2006/2007 and 40% of complaints in 2007/2008.

Conclusions

39. The vast majority of registrants never have any contact with the fitness to practise process and hence the numbers involved are small relative to numbers on the Register. However, analysis of the data does identify some interesting trends.

40. The majority of cases concern conduct or have a conduct element to them, suggesting that conduct is a higher area of risk or more frequently a 'problem' than competence. Conduct is associated with the attitudes and values which influence future behaviour – intangible aspects of practice which are difficult to identify and measure. Therefore, it may be difficult to revalidate conduct in any meaningful way and it is unlikely that a revalidation process would prevent poor conduct occurring.

41. This poses the question whether additional regulation focused on competence (which is far easier to identify and measure in concrete terms) would be properly focused on the area of greatest risk.

42. Given the limited information available, it is not possible at this time to revalidate on the basis of risk – in the sense of treating registrants differently dependent upon using a pre-determined assessment of the risk that their practice attracts.

43. The data indicates that the professions regulated by the HPC overall are lower risk compared to other regulators. However, the data did reveal that

some professions may be 'higher risk' than others, and further work in this area is warranted.

6.2 Systemic risks

44. The group also explored the risks arising from mechanisms and environments which have an impact upon patient safety.

45. The National Patient Safety Agency (NPSA) has examined studies into patient safety incidents and concluded that: '...the best way of reducing error rates is to target the underlying mechanisms failures, rather than take action against individual members of staff.' The NPSA's seven steps to patient safety reveal risks which occur at an organisational or system level and which can be tackled and mitigated at that level.¹⁶ These risks are often cultural in nature and concern communication, leadership and the empowerment of staff to identify, report and tackle safety problems.

46. The work of the organisations involved in institutional inspection are similarly focused on service / mechanisms and quality improvement. The clinical governance agenda within the NHS is also about mitigating risk and ensuring patient safety (please see section 5.2, paragraphs 58 and 59).

47. The risks associated with individual practitioners are only one part of a picture which includes risks associated with mechanisms and organisational culture. This raises the question of whether revalidating the individual practitioner is properly focused on the area of greatest risk.

¹⁶ National Patient Safety Agency, Seven steps to patient safety (2004).

6.3 Professionalism

48. The HPC's own fitness to practise data indicates that conduct or professional behaviour is more frequently a problem than competence. This raises questions about the nature of any proposed new system for revalidation.

49. The definitions of revalidation put forward so far often refer to 'fitness to practise'. Fitness to practise is more than just technical ability and is defined as the combination of conduct, competence, health and character necessary to practise safely and effectively.¹⁷ This raises the question of the ability of any revalidation process to positively revalidate 'conduct', 'character' or 'professionalism', despite our assessment of risk.

50. Work undertaken in the medical profession on the issue of professionalism may provide us with a way forward. The Royal College of Physicians and the King's Fund have defined this more intangible aspect of practice as 'a set of values, behaviours, and relationships that underpins the trust the public has in doctors.'¹⁸ Such a definition might be extended to other health professionals. Professionalism is clearly linked to public trust, and this is consistent with research undertaken into the views and expectations of members of the public (please see section eight).

51. Research undertaken in the United States has revealed that doctors who had identified concerns about their professionalism whilst students were more likely to be subsequently disciplined by their state medical board once qualified than those without any such concerns.

52. One study considered whether disciplinary action taken against licensees by the State Medical Board could be predicted in the behaviour of these doctors whilst medical students. A professionalism measure identified that poor reliability and responsibility, lack of self improvement and adaptability and poor initiative and motivation were the domains which predicted future disciplinary action. 95% of the disciplinary actions subsequently taken by the State Medical Board were for deficiencies in professionalism.¹⁹

53. Another study found that admissions material did not predict professional behaviour in later years, only academic achievement. Instead, this study suggested that it was possible to identify 'context bound' and 'concrete' areas which could predict future behaviour, and which were more helpful than more generic expressions of what is meant by professionalism and professional behaviour. For example, the study found that medical students' failures to complete evaluations and failures to comply with immunisation requirements

¹⁷ Health Professions Council, *Managing Fitness to Practise: a guide for registrants and employers* (2008), p.2.

¹⁸ King's Fund and Royal College of Physicians, *Understanding Doctors – Harnessing Professionalism* (2008), p.x.

¹⁹ Papadakis, M., Hodgson C., Teherani, A., Kohatsu N., 'Unprofessional behaviour in medical school is associated with subsequent disciplinary action by a state medical board', *Academic Medicine*, 79(3) (2004) 244-249.

were specific predictors of later poor performance.²⁰ In the UK, there is a broad consensus that attention needs to be given to both selecting applicants who demonstrate professional behaviours and teaching and assessing professionalism during medical training.

54. In some US medical schools, these measures of professionalism are now used as part of the overall monitoring of student development.

55. The findings from these studies are helpful in that they suggest that it might be possible to specifically identify the areas which predict future professional behaviour. We have previously identified the difficulty of 'revalidating' conduct; instead such an approach would seek to measure aspects of professional behaviour and ongoing conduct from an early stage.

56. If such findings were extended to the professions regulated by the HPC, they might suggest that more regulatory effort should be focused on promoting understanding of professionalism in pre-registration education and training, as this is the area which is most likely to predict future professional behaviour.

57. However, no such research exists in the professions regulated by the HPC. We found no comparable studies of our professions and a recent independent literature review found a lack of evidence generally about complaints against non-medical healthcare professionals.²¹ This is an area where further investigation would be beneficial.

²⁰ Stern, David, 'The Prediction of Professional Behaviour', *Medical Education*, 39(1), (2005) 75-82.

²¹ Gulland, Jackie, Scoping report on existing research on complaints mechanisms, (January 2008).

<http://www.hpc-uk.org/assets/documents/100021EB230408-enclosure4-Complaintsreview.pdf>

7. Costs and resources

1. An analysis of the likely cost and resource implications of any form of additional regulation is important in our discussion of revalidation.
2. The assessment of the likely costs of revalidation is hampered by limited information around the costs of existing models.
3. However, the limited available information does help us develop a picture of the likely costs involved.

Costs of other HPC assessment processes

4. The group considered the costs of two existing HPC processes.

- International registration assessment

Applicants for registration who qualified outside of the United Kingdom are assessed via a paper based process by two registration assessors.

In 2006, an external auditing exercise put the costs of international application process, including assessment, administration costs and overheads at £354 per applicant.

- Continuing Professional Development

Registrants' CPD profiles are assessed by two CPD assessors and a decision reached. The current audit is of 5% of the Register but it is anticipated that this will drop to 2.5%. The estimated cost of assessing CPD profiles is £77.27 per profile – this figure includes fees, administrative costs and overheads but does not include development costs (i.e. standards development, literature, assessor training).

UK regulators

5. There was a lack of information about the costing of revalidation undertaken by other UK regulators of healthcare professionals. The costing of the models developed by the General Medical Council and General Dental Council is ongoing or is to be commenced shortly.
6. For reference, in 2001 the General Medical Council estimated the cost of their revalidation proposals (which have subsequently changed and are currently under development) as £7.85m per annum.²²

²² General Medical Council: www.gmc-uk.org/about/council/papers/2001_05.asp

College of Physiotherapists of Ontario

7. The College of Physiotherapists of Ontario provided a breakdown of the costs involved in their 'Quality Management Program' which included marketing, development and legal expenses as well as the direct costs of assessment (please section 5.3, paragraphs 65 and 66).

8. The direct costs of individual registrant assessment in the competency assessment stage, including assessor travel costs were around CA\$400 per assessment (around £200).

Hypothetical costs

9. Any costing of a revalidation process inevitably relies on key assumptions about the number of registrants, the frequency of revalidation and the mechanism of the revalidation process.

10. We considered whether a costing model could be developed to produce an indication of the hypothetical costs of various forms of revalidation. However, there are potentially a huge number of possible options for how revalidation might be delivered – ranging from making small changes to existing processes up to comprehensive individual assessment. The non-assessment related costs involved are also likely to be extensive including communications activity, standards development and evaluation. As such, it would be difficult to produce an estimate of hypothetical costs which would be meaningful and account for all these possibilities.

Wider costs

11. The White Paper indicated that the government would consider the impact revalidation would have on 'diverting frontline staff from direct patient care' and the 'capacity of regulators and employers for each group' (paragraph 2.38).

12. This highlights the wider costs in implementing any revalidation system. These wider costs include the question about whether regulatory time, finances and resources might be better focused on other areas, such as bringing new professions into statutory regulation, where this is warranted.

Conclusions

13. The costs of revalidation are potentially significant and would increase pressure on the level of the registration fee. However, there is a lack of information on which to quantify this conclusion in absolute terms.

14. However, any assessment of whether additional regulation was necessary would need to include a cost-benefit analysis and the outcome of this may vary enormously with the nature of any approach taken. For example, a

tokenistic approach to revalidation may well carry with it little cost but may achieve few demonstrable benefits and would do little to obviate risk.

15. The evaluation of any future piloting of a revalidation approach would need to include a comprehensive impact assessment including a thorough understanding of cost.

8. The public

1. The role that patients and members of the public play in the revalidation debate was also considered.

2. Potential issues include differences in public awareness, public expectations and public involvement. These are explored below.

Public awareness

3. Research was undertaken as part of the review of the regulation of non-medical health professionals to gauge attitudes of members of the public to the regulation of professionals other than doctors.²³ The research concluded that there was very little public understanding of the existing system of health regulation.

4. MORI research commissioned by the HPC found that around one in seven UK residents had heard of the HPC. Awareness of the functions and purpose of professional regulation was also low, with 32% of the general public unable to identify what the role of a regulator of health professionals might be at all.²⁴

Public expectations

5. The work on public expectations is less clear cut. On the one hand, the Department of Health commissioned research concluded that there was 'strong public support for regular checks being carried out on the non-medical healthcare professionals'.

6. In contrast, the Department of Health research also concluded that there was a high level of satisfaction with non-medical healthcare professionals – 88% of research participants reported that they were satisfied with their last contact with a non-medical healthcare professional. Recent surveys of patient satisfaction by the Picker Institute and by the Healthcare Commission show that levels of satisfaction are rising, with a higher proportion of patients expressing satisfaction with their care than in previous years. One recent report revealed that non-medical primary care staff have consistently had the highest levels of trust and confidence amongst patients surveyed.²⁵

7. There is also a body of work exploring in more depth what the public expect from health professionals. Technical competence is certainly one expectation,

²³ Mori (Commissioned by the Department of Health), Attitudes to Regulation of Non-medical Healthcare Professionals (2005).

²⁴ Mori (Commissioned by the Health Professions Council), Health Professions Council – Public, Registrant and Stakeholder Views, (2007).

²⁵ Healthcare commission, National survey of local health services (2008). Richards, N and Coulter, A, Is the NHS becoming more patient centred? Trends from the national surveys of NHS Patients in England 2002-2007 (2007), p.10.

but patients also say they want to be treated with respect, to be listened to and to have a clear explanation of their diagnosis and treatment options.²⁶

8. The characteristics highlighted as important for trust and confidence in non-medical healthcare professions in the Department of Health research were listening skills; giving the impression of caring / showing concern; taking the time to speak to patients; and giving personal treatment / treating patients as 'humans'.

Public involvement

9. Public involvement in developing and monitoring healthcare professional practice is also a key influence on the current regulatory process, although public awareness of this is also likely to be limited.

10. At the HPC, lay council and committee members, lay panel members and patient groups as well as voluntary sector organisations are involved not only in the governance of the regulatory body itself, but also in the development and revision of standards, fitness to practise panels and in specific projects. The HPC also participates in the work of the Joint Regulators' Patient Public Involvement (PPI) Group, which aims to promote patient involvement in the regulatory process. In some areas in education there has been a move toward service user involvement in the development and delivery of pre-registration education. These are all examples of public involvement which are less well known but are nevertheless a crucial aspect of quality control and quality improvement in regulation.

Conclusions

11. Research has shown that public awareness of the function of regulators is low and public expectations of the existing system differ from the reality. This, however, needs to be seen in the overall context of high levels of trust of health professionals and low levels of complaint against the professionals regulated by the HPC.

12. Any additional regulation must be meaningful and easy to communicate with members of the public. An approach which was tokenistic might have the

²⁶ Elwyn, G., Edwards, A., Kinnersley, P, 'Shared decision making in primary care: the neglected second half of the consultation' British Journal of General Practice, 49 (1999) 477-482.

Donaldson, L, 'Expert patients usher in a new era of opportunity in the NHS' British Medical Journal, 329 (2003) 1279-1280.

Coulter, A, 'Paternalism or Partnership?', British Medical Journal, 319 (1999) 719-720.

Gott, M., Stevens, T., Small, A., Ahmedzai, S, 'Involving users, improving services; the example of cancer', British Journal of Clinical Governance, 7;(2), (2002) 81-85.

effect of providing false reassurance to the public which would be counter-productive in terms of public safety and maintaining public trust and confidence.

13. It could further be argued that the current mechanisms are appropriate given the low risk profile of the professions regulated by the HPC (in light of the available information) and, if the public had more knowledge of the existing system and the rationale behind it, they would be reassured by it. The areas identified by the Department of Health are around so called 'soft skills' – the more intangible aspects of practice that are inevitably more difficult to assess and which would be much more challenging to revalidate.

14. This certainly accords with evidence from the National Clinical Assessment Service which seems to indicate that the areas of concern and, we might conclude, risk, are around issues with communication, patient involvement and information exchange. Information about complaints made about the NHS also show that these are the prevalent areas of patient complaint.²⁷ These 'soft skills' are, however, also some of the skills associated with 'professionalism' (please see section 6.2).

15. The CPD standards and audit process is partly focused on the benefits of registrants' learning to those who use or are affected by their practice. However, service user feedback, which might be helpful in terms of providing feedback on 'soft skills', is not specifically integrated within the CPD standards or CPD process. Such tools are also a potential, structured way of achieving further public involvement in the regulatory processes.

16. This is an area where further investigation is indicated.

²⁷ Scottish Public Services Ombudsman Annual Report 2006/07
Public Services Ombudsman for Wales Annual Report 2007/08

9. Options for further work

1. In this section, possible options for further work or enhancements to the HPC's processes are discussed in the light of analysis included in this report.

Structured patient feedback

2. A feedback tool or feedback tools could be useful in promoting the integration of feedback from service users and colleagues into the work of registrants and in achieving higher levels of public involvement in regulation.

3. This section refers to 'structured patient feedback' as a potential starting point for our exploration of the usefulness of such tools. However, it is acknowledged that many registrants do not work in roles with direct contact with patients and that accordingly further ongoing work would be necessary.

4. Multi-source feedback from patients and colleagues is part of the General Medical Council's revalidation proposals, and research and piloting has been undertaken to test the reliability and validity of assessment tools.

5. In 2006, a Picker Institute study concluded that patient questionnaires could be an effective way of testing the core qualities of a doctor's performance, but that the quality of questionnaires could be variable and that further research was necessary.²⁸

6. Research commissioned by the General Medical Council to validate a patient and colleague assessment concluded that the proposed patient and colleague questionnaires do offer a 'reliable basis for the assessment of professionalism'. The research further concluded: 'If used in the revalidation of doctors' registration, they would be capable of discriminating a range of professional performance among doctors, and potentially identifying a minority whose practice should be subjected to further scrutiny.'²⁹

7. The self-certification and CPD processes largely rely on the trust placed in health professionals in assessing their own compliance with standards. A patient feedback measure could have the potential to provide structured, regular, external input and verification, which is currently missing from the existing HPC processes.

8. Research would be needed to validate the reliability of any tool in the context of the practice of the professions regulated by the HPC and the variety

²⁸ Chisholm, A and Askham, J, A review of questionnaires for gathering patients' feedback on their doctor (Picker Europe, 2006).

²⁹ Campbell, J., Richard, S., Dickens, A., Greco, M., Narayanan, A., Brearley, S., 'Assessing the professional performance of UK doctors: an evaluation of the utility of the General Medical Council patient and colleague questionnaires', *Quality and Safety in Health Care*, 17, (2008) 187-193.

of different working contexts of registrants. Depending on the outcome of this research, further work would be necessary to consider how such a tool might be integrated within the HPC's processes. For example, whether such a tool might provide a helpful way for registrants to reflect on their practice and identify their CPD needs as a result.

Understanding poor conduct and professionalism

9. The evidence of the models examined suggests that competence or performance is tackled directly by other mechanisms (e.g. clinical governance, supervision, accreditation) in a way that aspects of conduct may not be.

10. Our analysis has highlighted that conduct represents the main risk amongst the professions regulated by the HPC. As such, we need to explore this further and look at ways in which we can measure and monitor it more effectively.

11. In particular, a clearer understanding of the potential link between poor conduct during pre-registration education and training and subsequent fitness to practise action would be helpful here in directing our efforts to the area of greatest risk.

12. A greater understanding of this area may also be useful when considering future work around the standards of conduct, performance and ethics (and any future guidance) and their role in the continued professionalism of registrants.

Data analysis

13. Analysis of fitness to practise data has been helpful in developing an assessment of the risk posed by the professions regulated by the HPC, and further analysis of data, particularly relating to practice environment, would be helpful.

14. Ongoing analysis of data will be helpful in terms of identifying trends, assessing the ongoing effectiveness of HPC's processes and further developing our assessment of risk. In particular, analysis of the outcomes of the ongoing CPD audits is likely to be helpful in this regard.

15. Further consideration of data available elsewhere may also be helpful.

10. Summary and overall conclusions

1. In line with the White Paper proposal that revalidation must be risk based and proportionate, the HPC has taken an evidence-based approach to exploring what revalidation might mean for the professions it regulates.
2. Based on the evidence considered, we conclude that revalidation as described in the White Paper is not necessary at this time for the professions regulated by the HPC.
3. The existing system operated by the HPC is a successful one and overall there is a lack of evidence to suggest that the existing system is not working. The HPC system does not exist in a vacuum but is one part of an interlocking process of checks and balances which help to assure continuing fitness to practise. This system is not limited to service regulation but includes many other initiatives which are employer, profession or individual led and which exist without compulsion. This interlocking process involves the individual registrant, peers, employers, regulators, professional bodies, service users and others as a collective driver for continued fitness to practise.
4. All of these contribute to promoting a culture of accountability – where accountability to the regulator is just one aspect of good professional practice.
5. Any additional regulation must be clearly justified, balancing the costs of regulation against clear benefits. The costs of revalidation have the potential to be significant. The need for additional regulation and the benefits to public protection and public confidence are unclear at this time and it is important that we avoid an approach which is tokenistic in nature and fails to add value to the HPC's existing processes.
6. Public awareness and understanding of the role of regulation is low, but trust in the non-medical healthcare professions is high. The research indicates that the areas of practice linked to trust and confidence are those that are linked to professionalism and which may be more difficult to directly and meaningfully revalidate. Any additional regulation must be meaningful and focused in the areas of greatest risk if it is to maintain already high levels of public trust and confidence.
7. The models of revalidation examined, in the UK and elsewhere, are not appropriate for use by the HPC at this time as they could not be justified by the available evidence. They could also not be easily applied across the professions regulated by the HPC and the diverse settings in which registrants work. However, the integration of patient feedback suggested in one of the developing models is identified as an area which merits further exploration and has the potential to achieve meaningful external input.
8. Analysis of fitness to practise data indicates a low overall risk profile for the professions regulated by the HPC and that conduct is much more frequently a concern than competence. We should therefore focus our efforts on

professionalism and its constituents rather than on competence which is already being monitored through other means.

9. The HPC remains committed to an ongoing process of review in order to adapt to meet changing needs and challenges and to constantly improve the efficiency of its performance. A number of avenues for further work have been identified.

10. In the light of the evidence presented, we recommend that further work should be undertaken before any additional layer of regulation is introduced for the professions regulated by the HPC.

11. A number of pieces of further work are indicated, to further develop our understanding of risk (please see section 11).

11. Recommendations

1. At this stage we have concluded that further regulation in this area is not necessary for the professions regulated by the HPC. However, a number of areas for further exploration have been identified.

2. We recommend further investigation via a series of pilot projects:

- Analysis of fitness to practise data to explore correlations between age, location of practice and fitness to practise.
- Analysis of the outcomes of the CPD audits currently being conducted.
- A retrospective study to explore whether registrants from a particular profession who have undergone fitness to practise action are more likely to have been involved in disciplinary procedures or to demonstrate a poor record in professional behaviour during training.
- A prospective study piloting the use of a professionalism tool with education and training providers for two different professions and track progress of students over 5 years.
- Depending upon the outcome from these studies, wider use of this tool in education and training programmes for other professions may be recommended.
- In parallel, explore further the teaching of 'professionalism' on pre-registration programmes across the 13 professions and look at ways of promoting this further, for example, via the standards of education and training.
- A prospective study looking at the application of a patient feedback tool with a random sample of registrants and students.

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Profession

AS – Arts therapists
BS – Biomedical scientists
CS – Clinical scientists
CH – Chiropodists /Podiatrists
DT - Dietitians
ODP – Operating Department Practitioners
OR - Orthoptists
OT – Occupational Therapists
PA - Paramedics
PH - Physiotherapists
PO – Prosthetists and Orthotists
RA - Radiographers
SL – Speech and Language Therapists

6 February 2009

Health Professions Council (HPC) response to ‘Principles for Revalidation – Report of the Working Group for Non-Medical Revalidation’

1. Introduction

1.1 The nine UK-Health regulators have been asked by the Department of Health to respond to the report of the Working Group for Non-Medical Revalidation, outlining their current work and proposals around revalidation, and setting out how they meet the principles for revalidation.

1.2 In this document, a summary is provided of the HPC’s work on this subject to date. The document then outlines how the HPC’s planned approach is consistent with the twelve principles outlined in the Report.

2. The HPC’s approach to revalidation

2.1 The Health Professions Council’s thinking on revalidation has been informed by the work of the Professional Liaison Group (PLG) on Continuing Fitness to Practise. This group met five times between November 2007 and September 2008 and also benefited from a meeting with a wider group of representatives of organisations representing the professionals we regulate.

2.2 The Group made its report and recommendations to the HPC Council in October 2008. A copy of the report is appended and cross references are given in this document.

2.3 The Group considered revalidation in the wider context of ‘continuing fitness to practise’ which we broadly defined as ‘all those steps taken by regulators, employers, health professionals and others which support the maintenance of fitness to practise beyond the point of initial registration’. In its work the Group considered, amongst other topics:

- the existing mechanisms for assuring continuing fitness to practise (including existing regulatory systems and those in place outside of professional regulation);
- the evidence of the risk posed by the professions regulated by the HPC;
- the likely costs and resources of any additional layer of inspection; and
- the opinions and expectations of members of the public.

2.4 The Group concluded (sections 1 and 10 of the report):

- Revalidation is but one part of the process of assuring continuing fitness to practise.
- The current evidence suggests that the risk posed by the professions regulated by the HPC overall is low. However, this area merits further exploration, in particular, conduct was identified as an area of greater risk than competence.
- Public trust in the health professions regulated by the HPC is high. However, further work on ways to increase public involvement in regulation is merited.
- The potential costs of additional regulatory systems are likely to be significant and as such must be clearly justified, balancing the costs against demonstrable benefits.
- In the light of these findings, existing regulatory systems are currently appropriate and sufficient when considered in the context of the wider environment in which they operate and the risk of harm posed by the professions regulated by the HPC.

2.5 The Group made the following recommendations for further work (section 10):

- Analysis of fitness to practise data to explore correlations between age, location of practice and fitness to practise (section 6).
- Analysis of the outcomes of the CPD audits currently being conducted (section 5.1, paragraphs 13-17).
- A retrospective study to explore whether registrants from a particular profession who have undergone fitness to practise action are more likely to have been involved in disciplinary procedures or to demonstrate a poor record in professional behaviour during training (section 6.3).
- A prospective study piloting the use of a professionalism tool with education and training providers for two different professions and track progress of students over five years (section 6.3).
- Depending upon the outcome from these studies, wider use of this tool in education and training programmes for other professions may be recommended (section 6.3).
- In parallel, explore further the teaching of 'professionalism' on pre-registration programmes across the 13 professions and look at ways of promoting this further, for example, via the standards of education and training (section 6.3).

- A prospective study looking at the application of a patient feedback tool with a random sample of registrants and students (section 8).

2.6 In summary, we intend to take a systematic, evidence based approach to revalidation, in light of our assessment of the risk profile of the professions we regulate.

The Europe Economics research commissioned by the Department of Health concluded that any assessment of revalidation would need to recognise existing regulatory systems and how they identify registrants performing at a below-standard level, and take these into account in forming a view of the incremental costs and benefits a new policy would bring (A1.12). We have considered our existing systems in our work on this topic and conclude that the totality of these existing systems (including self-certification, CPD standards and audit and returners to practice requirements), when seen in the broader context in which they operate, are currently sufficient in assuring continuing fitness to practise. Put another way, revalidation for our purposes consists of the combination of these systems (see section 5.1).

We believe that further work is merited in the areas outlined in paragraph 2.5. In particular, we will focus our efforts in the area of conduct, identified as the area of greatest risk for the professionals we register. To that end, we are preparing to commission research on the links between poor conduct during education and training and subsequent fitness to practise action.

3. Principles for Revalidation

In this section, we have outlined how our approach to revalidation meets the non-medical revalidation principles.

3.1 Transparency

Principle 1 (Consistency) *Models should be consistent with the Better Regulation Executive's five principles of good regulation.*

Our approach to revalidation outlined in section two of this document is consistent with the Better Regulation Executive's principles of good regulation. In particular, our approach is proportionate and targeted in that it is based on our assessment of the overall risk profile of the professions regulated by the HPC, and targeted in the areas we consider merit further attention. In particular, our proposed work on the link between pre-registration education and training and subsequent fitness to practise action is based on the assessment that, for our professions, conduct is more frequently an issue post-registration than competence and therefore requires further scrutiny.

Please also see our response to principle 5 on our proportionate approach to auditing compliance with our standards for continuing professional development.

Principle 2 (Professional standards) *The regulatory body for each profession should at all times set out the contemporary professional standards which registrants will have to meet in order to maintain registration.*

Registrants are required to renew their registration every two years, and sign a declaration to confirm that they continue to meet the standards of proficiency; that there have been no changes to their health or relating to their good character which they have not advised the HPC about and which would affect the safe and effective practice of their profession; and that they continue to meet standards for CPD. We are clear that registrants need to continue to meet those standards of proficiency that are relevant to their scope of practice.

Principle 3 (Remediation) *Where revalidation systems highlight performance concerns there should be scope for remediation of the professional but measures to secure public safety must remain paramount.*

The professions we regulate do not have the infrastructure necessary to support a robust system package of remediation. In the medical profession, this infrastructure is available in the form of the work of organisations such as the National Clinical Assessment Service and the Postgraduate Medical Deanaries. This is an area that we would wish to explore further in the future.

Our CPD audit process demonstrates an approach consistent with the principle of remediation (please see principle 5). The audit process has been designed to provide registrants who struggle to meet the standards with support to do so. If from a CPD profile it is unclear that the required standards have been met, we can ask a registrant for further information, highlighting the areas in which the standards have not been met. If a registrant has not met the standards fully but there is a demonstrable commitment to CPD, they can be given an extra three months to go away, with the benefit of clear guidance, and undertake more CPD

and/or rewrite their CPD profile. In summary, we have designed a process that provides registrants with the support necessary to meet the standards and maintain their registration. Analysis of the outcomes of the CPD audits will help us to assess the effectiveness of this approach and how that might be extended to other systems that we develop.

3.2 Accountable

Principle 4 (Patient and Public Involvement) *A successful revalidation process must have the confidence of the public that it is appropriate, relevant and fit for purpose.*

The principle says that the public and service users must be involved in and seen to be involved in the design and delivery of the revalidation systems.

The expectations of patients and public are central to our approach to revalidation. Research has shown that public awareness of the HPC (and the other regulators overall) is low. However, we believe that this needs to be seen in the overall context of high levels of trust in health professionals and low levels of complaint against the professions regulated by the HPC. Research has also identified that the main areas of patients' concern about the practice of health professionals are most frequently 'soft skills' around communication, respect and involvement – all of which are aspects of practice that may be far harder to revalidate or assess in a meaningful way.

Further, we believe that any additional regulation must be meaningful, easy to communicate with members of the public and avoid tokenism which might have the effect of providing false reassurance to the public, and would be counter-productive in terms of public safety and maintaining public trust and confidence.

The CPD standards and audit process is deliberately focused on the benefits of registrants' learning to 'service users' - i.e. those who use or are affected by their practice. However, service user feedback, which might be helpful in terms of providing feedback on 'soft skills' is not currently integrated within the CPD standards or CPD process, although many practitioners are choosing to submit this feedback as evidence. In the light of the conclusions from a similar ongoing study in the field of medical revalidation, we intend to undertake a prospective study looking at the application of a patient feedback tool with a random sample of registrants and students. A patient feedback measure could have the potential to provide structured, regular, external input and verification, which is currently missing from the existing HPC systems. The outcomes of this study might lead to changes to the HPC's existing systems. For example, we might consider whether such a tool would provide a helpful way for registrants to reflect on their practice and identify their CPD needs as a result (section 9, paragraphs 2 to 8).

Principle 5 (Continuing Professional Development) (CPD) *This is the process by which individual registrants keep themselves up to date with healthcare developments in order to maintain the highest standards of professional practice.*

The principles set out that CPD may provide a source of evidence for revalidation; must be relevant to the practitioner's scope of practice; and should be based on outcomes.

The CPD standards and audits are one part of the systems that we believe collectively assure the fitness to practise of registrants.

We set standards for CPD that are outcomes based and relevant to the practitioner's scope of practice. Registrants are required to:

- maintain a continuous, up-to-date and accurate record of their CPD activities;
- demonstrate that their CPD activities are a mixture of learning activities relevant to current or future practice;
- seek to ensure that their CPD has contributed to the quality of their practice and service delivery;
- seek to ensure that their CPD benefits the service user; and
- present a written profile containing evidence of their CPD upon request.'

CPD audits to check registrant compliance with the standards started in May 2008 with a 5% sample of registrants from the first two professions being audited. We are reviewing the sample size in light of the outcomes of the first two audits.

The outcome of a failure to meet the standards is administrative removal from the Register.

The outcomes of the CPD audits are likely to help further in the development of risk indicators for the regulated professions and we will undertake further analysis as the audits progress.

Principle 6 (Quality Assurance) *Quality assurance mechanisms must be built into revalidation systems.*

Robust quality assurance mechanisms are built in to our existing systems. We will ensure robust quality assurance systems in any amendments to our existing systems or additional systems which are indicated as a result of our planned research programme.

In the area of CPD, registrant profile submissions are considered at meetings of CPD assessors, professionals from each of the professions on our register who assess profiles on our behalf. Profiles are assessed against clear criteria and using clear documentation.

Such meetings allow assessors to share their views of profiles, ensuring greater consistency in decision making. The quality of decisions and reasoning for these decisions is also checked administratively to ensure consistency of approach and so that any potential problems are identified. Profiles can also be moderated by a third assessor, if necessary, in borderline cases or where there is disagreement amongst assessors. Decisions are also subject to a clear appeals process.

The CPD process and our other systems are also subject to regular internal audit, and external audit as part of our registration with the BSI to ISO9001 standards.

3.3 Consistent

Principle 7 (Equality) *Equality and diversity considerations must be evident in the development of all systems and systems.*

The HPC publishes an equality and diversity scheme which explains how it takes account of equality and diversity considerations in all aspects of its work. Reporting on the implications for equality and diversity will form part of our commissions for research and thorough equality and diversity impact assessment will form part of any subsequent proposals.

Principle 8 (Integration) *The implementation of clinical governance frameworks yields information on professionals' performance and practice. Where appropriate, effective connections need to be made between them and the system of revalidation.*

We agree that the role that clinical governance frameworks and other local appraisal systems play in assuring the continuing fitness to practise of registrants, and in generating information that might demonstrate that fitness to practise, should be taken into account in any revalidation proposals.

Within our existing systems, we also seek to ensure that there is integration with other systems where possible in order to avoid duplication of effort. For example, information gained from participation in the National Health Service (NHS) Knowledge and Skills Framework (KSF) could be used by a registrant to demonstrate that they have met our standards for continuing professional development. Further, many of the CPD schemes set up by professional bodies to support their members in undertaking CPD make explicit links between these local appraisal systems and HPC's CPD standards, helping to minimise duplication.

Principle 9 (UK-wide) *Revalidation arrangements should be consistent in outcome across the United Kingdom.*

We agree that any systems should be UK-wide and we will take into account differences between the four countries in the research we intend to undertake.

We already have well established mechanisms for dialogue with stakeholders across the four home countries, including regular meetings with the devolved administrations.

3.4 Proportionate and Targeted

Principle 10 (Demonstrating Benefits – effective in confirming fitness to practise) *The structures and systems of revalidation should be effective in confirming fitness to practise.*

The principle says that the structures and systems of revalidation should ‘knit together in a coherent, unbureaucratic and proportionate manner to ensure that the resources invested yield valid and reliable outcomes, together with the anticipated benefits to service users and health professionals’.

In paragraphs 2.4, 2.5 and 2.6 we outline our approach to revalidation and how we intend to take a systematic, evidence-based approach, informed by our evolving assessment of the risk profile of the professions we regulate. We believe that the totality of our existing systems, when seen in the wider environment in which they operate, are effective in confirming fitness to practise. However, we have identified a number of pieces of further work, to further develop our understanding of risk, which can be used in considering whether we should introduce any additional structures or systems.

Our approach to revalidation closely mirrors the requirements of this principle; our focus is on ensuring that revalidation is meaningful for practitioners and members of the public; is targeted in the area or areas of greatest risk; avoids tokenism; and is clearly beneficial in addition to existing systems.

In addition to our responses to principles 5, 8 and 11 (which provide more information about our standards for continuing professional development, our approach to risk and our desire to ensure integration of systems), we have outlined our existing systems below in order to demonstrate how we are meeting this principle. We have also outlined how our proposed research is focused on the salient issues around fitness to practise for our registrants.

Existing systems for assuring continuing fitness to practise

Our proposals outlined in paragraph 2.5 are made in light of our existing systems and the wider environment in which they operate. We believe that the assessment of the effectiveness of systems which exist within and outside the professional regulatory environment is important in order to help assess the extent to which an additional layer of regulation is necessary at the professional regulatory level.

Our existing systems include:

- Self certification (section 5.1, paragraphs 7 to 12)

Applicants for admission and readmission to the Register make a declaration that they have read and will comply with the standards of proficiency, conduct, performance and ethics and that they have read and will comply with the standards for CPD. Applicants are also required to declare any convictions or cautions or determinations of other regulators responsible for licensing a health or social care profession, as part of the application process.

Every two years when they renew their registration, registrants are required to sign a declaration to confirm that they continue to meet the standards of proficiency which apply to their practice; that there have been no changes to their health or relating to their good character which they not advised the HPC about and which would affect the safe and effective practice of their profession; and that they continue to meet the standards for CPD.

The self-certification process is supported by the health and character process. If a registrant declares an issue relevant to their good character on application or renewal (e.g. a caution or conviction), a health reference raises possible concern, or a registrant makes a self-referral during their registration cycle, this will be considered by a registration panel. The panel determines whether the applicant should be admitted to the Register or permitted to renew their registration. Or, in the case of a self-referral, the panel decides whether the matter should be referred into the fitness to practise process.

Self-certification and self-referral of important information demonstrates the registrant's commitment to maintain their fitness to practise. It also demonstrates behaviours commensurate with professionalism.

- CPD standards and audit

We set standards for CPD that are outcomes based. Registrants are required to undertake CPD, record their CPD, ensure that their CPD contributes to the quality of their practice and service delivery, and ensure that it will benefit service users. We also audit to check compliance with the CPD standards and a failure to meet the standards is administrative removal from the Register (please see our response to principle five).

- Returners to practice

Health professionals seeking readmission to the Register who have been out of practice must undertake an updating period of 30 days for between two and five years out of practice and 60 days for five or more years out of practice.

The updating period can consist of private study, formal study and supervised practice and has to be countersigned by a registrant from the same part of the Register who has been in regulated practice for three years or more.

The returners to practice requirements are primarily a quality control mechanism aimed at mitigating the potential risks involved in returning to practise after a break, demonstrating that the returner is up to date and supporting fitness to practise. The returners to practice requirements are threshold requirements which may be exceeded by the requirements of others, such as employers.

These systems sit alongside other systems such as the fitness to practise process and the role of regulators in assuring standards in pre-registration education and training.

They also exist in an environment that includes other systems and structures that exist outside of professional regulation but which nonetheless are an important part of the picture of ensuring continuing fitness to practise.

We believe that the consideration of any additional system of regulation needs to consider this wider environment and how systems, both within and outside of regulation, collectively serve to ensure the continuing fitness to practise of registrants.

Research

The benefits of any additional inspection must be clear in order to justify the likely costs. We conclude that at present, in light of our assessment, the benefits to public protection and public confidence are unclear.

The Europe Economics research said of the existing evidence base: 'The pre-existing data sources focused upon the issue of revalidation are limited, and uniformly silent with regards to quantifying the benefits of the policy.' (A1.27) In this document (and in the appended report) we have outlined an approach to build the evidence base in this area, in order to make informed, evidence based decisions that would ensure that any refinements to our existing systems or additional systems are coherent, proportionate and clearly beneficial to service users and health professionals. In particular:

- Our proposed research into the links between pre-registration education and training and fitness to practise will help to further identify the area of greatest risk, the nature of that risk and the best way of mitigating that risk.
- Further analysis of the outcomes of the CPD audits and fitness to practise data will help to build our assessment of risk.
- A study looking at the application of a patient feedback tool might identify where service user feedback might be better incorporated into existing systems, for the benefit of both members of the public and health professionals.

We appended an outline timetable for the delivery of this work.

Principle 11 (Information) *The nature of the information required by each regulatory body will be based on their risk profiling of their registrant groups.*

The principle says that: '...the nature of the information required will be based on the regulator's risk profiling of their registrant groups. The frequency and breadth/depth of evidence each regulator requires information on and the evaluation / assessment methods will be based on the assessed potential risk posed by practitioners to patients and the public.'

We believe that any revalidation system must be proportionate to the assessment of the risk posed in order for it to be meaningful.

We have considered data from our fitness to practise cases (section 6.1) and, in summary, have made the following findings and conclusions:

- The numbers of registrants involved in the fitness to practise process are small relative to the numbers on the Register and compared to other

regulators. In 2007/2008, 0.24% of registrants were subject to a complaint via our fitness to practise process.

- The majority of complaints considered were about misconduct / convictions and cautions; only 10% of cases in 2006/2007 were purely about competence matters.
- The available data is limited and as such it is not possible at this time to revalidate on the basis of risk – in the sense of treating registrants differently dependent upon a pre-determined assessment of the risk that their practice attracts.
- The data suggests that, for the professions we regulate, conduct is a higher area of risk or more frequently an issue than competence. As conduct is associated with the attitudes and values which influence behaviour (intangible aspects of practice that are difficult to identify and measure) it is better to focus regulatory effort in this area.
- Further analysis of the outcomes of fitness to practise cases may be helpful in developing our assessment of risk.

We are proposing further research in order to further develop our risk profile, in particular, to focus on the area of conduct.

Principle 12 (Introduction) *The introduction of revalidation should be incremental.*

We agree that the introduction of any additional systems should be incremental. We are proposing an evidence-based approach as we believe this is necessary to ensure that any additional system is robust and meaningful.

We believe that such an approach is necessary in order to command the confidence of stakeholders including registrants and members of the public.