hpc health professions council

Communications Committee 5 November 2009

Extending professional and occupational regulation

Executive summary and recommendations

Introduction

The Council on 10 September 2009 discussed a report on extending professional and occupational regulation and alternative models for the future regulation of professions. The Council agreed that the relevant committees would consider the specific issues pertinent to their remit detailed in the report, to feed into the Council's further discussion of the report at its strategy meeting on 11 February 2010.

Decision

The Committee is asked to discuss the communication aspects of the report, including stakeholder engagement.

Background information

Council meeting, 10 September 2009, enclosure 10 (HPC 117/09)

Department of Health Working Group report, available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_102824

Resource implications

None at this time.

Financial implications

None at this time.

Appendices

Copy of Council paper HPC 117/09

Date of paper

29 September 2009.

Council, 10 September 2009

Extending professional and occupational regulation

Executive summary and recommendations

Introduction

In July 2009, the Department of Health published the report of the Extending
Professional Regulation Working Group. The group was tasked with making
recommendations about ongoing policy in the area of extending professional and
occupational regulation, including:
- considering the possible different models of regulation;
- developing criteria for determining whether a group should be regulated;
  and
- providing guidance on how these groups should be prioritised.

The attached paper summarises and discusses the report.

Decision

The Council is invited to discuss the attached paper.

Background information

The Report of the Working Group on Extending Professional Regulation and the
response to the report by Ministers in the administrations can be accessed here:

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndG
uidance/DH_102824

Resource implications

None

Financial implications

None

Appendices

Appendix 1: Summary of Scottish pilot of employer-led regulation
Appendix 2: Skills for Health proposed algorithm

Date of paper

26 August 2009

Extending professional and occupational regulation
Discussion paper on the report of the Working Group on Extending Professional
Regulation

1. Introduction
In February 2007, the White Paper 'Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century' was published and set out the Government's future policy in the area of professional regulation.[1] As part of delivering the agenda set out in the White Paper, the Department of Health set up the Extending Professional Regulation Working Group ('the Group' in this paper) to consider the recommendations in the White Paper relating to extending the scope of statutory, professional regulation. The HPC was represented on the Group by Marc Seale, Chief Executive and Registrar. The Group's report was published in July 2009 alongside a response from the four administrations of England, Northern Ireland, Scotland and Wales.

The report gives a clear indication of the potential future direction of Government policy in the area of professional statutory regulation. This paper discusses and summarises the report's conclusions and recommendations, drawing the Council's attention to those areas of particular relevance to the HPC's role. This paper also provides an opportunity to update the Council as to the ongoing progress on groups due to become HPC registered in the future and to draw links between the findings of the report and the previous discussion and work of the Council.

References to chapters, paragraphs and page numbers are references to pages in the report unless otherwise stated. The cover sheet to this paper provides links to the report. In this paper, Ministers in each of the four countries are referred to collectively as 'the administrations'.

2. Key recommendations
The report makes 26 recommendations, outlined in Appendix E of the report. The key conclusions and recommendations of most relevance to the Council are summarised below.

- **Principles**: The report articulates a number of principles which should guide decisions on extending regulation to professional and occupational groups working in health care. These include that regulation should be proportionate to the risk to patients and the public; command the confidence of the public and registrants; and that regulation should lead to improvements in the quality of care for health care users. (Chapter one, pages 12-18)

- **Risk**: The report discusses approaches to identifying and quantifying risk, identifying key factors which might assist in risk assessment and identifying the need for a robust, evidence-based approach. (Chapter two, pages 19-23)

- **Costs and benefits**: The report discusses the complexity of the risks, benefits and costs of professional regulation, concluding that there needs

---

[1] Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century (February 2007)
www.official-documents.gov.uk/document/cm70/7013/7013.pdf

to be clear criteria for decision making which takes into account patient expectations. (Chapter three, pages 24-28)

- **New models of assurance**: The report concludes that statutory regulation is but one of a number of regulatory options including a light touch 'buyer beware' approach; voluntary self regulation; employer-led regulation; and statutory licensing. (Chapter four, pages 29-42)

- **Modernising routes to regulation and registration**: The report suggests the creation of a new 'gatekeeper' role to make recommendations about the regulatory interventions appropriate to each professional or occupational group. (Chapter five, pages 43-49)

- **Stakeholder engagement**: The report discusses the importance of the involvement of patients, the public and employers in decisions about regulation. (Chapter six, pages 50 to 55)

3. New professions / aspirant groups

The report discusses and makes a number of conclusions and recommendations which are directly relevant to the regulation of new professions by the HPC and potentially, to the HPC's new professions / aspirant groups process.

3.1 Recommendations for regulation

The 2007 White Paper identified a number of groups as the priority for statutory regulation by the HPC. The report concludes with reference to these groups that the process of introducing statutory regulation should continue alongside the consideration of the administrations of the implications of the report for the regulation of other workers and professionals (paragraph 1.14). The administrations agree with this recommendation in their response.

The report notes the statement in the White Paper that '…the Government will not establish any new statutory regulators'. Instead: 'The Government's view is that most new professions should be regulated by the Health Professions Council which was designed for this purpose and has the most expertise in bringing new professions into statutory regulation…' (White Paper, paragraphs 7.16 and 7.17)

The groups identified by the White Paper are listed below with a brief summary indicating progress to date of bringing these groups within statutory regulation.

- **Practitioner psychologists**

Seven types of practitioner psychologist including counselling, health and occupational psychologists became registered by the HPC from 1 July 2009.

- **Some healthcare scientists**

Since 2003, the HPC the following groups of healthcare scientists have been recommended to the Secretary of State for Health following applications via the new professions / aspirant groups process:

- Clinical perfusionists (September 2003)
- Clinical physiologists (October 2003)
- Clinical technologists (May 2004)
- Medical illustrators (May 2004)

- Maxillofacial prosthetists and technicians (September 2005)

The statutory regulation of these groups has been delayed because of an ongoing Department of Health project led by the Chief Scientific Officer, Modernising Scientific Careers, which will reform the structure and education and training of the healthcare science workforce.

The Department of Health consulted on workforce proposals in late 2008 / early 2009 and will consult in the future on its proposals for how these groups and other healthcare scientist groups will become HPC regulated. The HPC attends regular meetings with the modernising scientific careers project board and will keep the Council informed when the future implications for the regulation of these groups are clear.[2]

- **Psychotherapists and counsellors**

In 2008, in light of the conclusion of the White Paper that psychotherapists and counsellors should become regulated by the HPC, the Council established a Professional Liaison Group (PLG) to discuss and make recommendations to the Council about the regulation of psychotherapists and counsellors.

A consultation is currently underway to seek views from stakeholders about the recommendations of the PLG and will close on 16 October 2009. The Council will be asked to consider the outcomes of the consultation and finalise recommendations to the Secretary of State for Health and Ministers in the devolved administrations.

- **Other psychological therapists**

The 'other psychological therapists' group was not defined further in the White Paper and it is currently unclear as to the exact groups that this term includes. However, it has been assumed that this might possibly include occupational groups outside of psychotherapy, counselling and psychology who also deliver psychological therapies to clients. This might potentially include roles created as part of the Improving Access to Psychological Therapies (IAPT) programme, clinical associate psychologists in Scotland and graduate mental health workers.

The Executive has met and continues to meet with interested stakeholders such as the Department of Health, IAPT workforce team and education and training providers to discuss this area. Discussion with stakeholders has identified the need to be aware of the issues around the potential regulation of these groups as part of the separate work on regulating psychotherapists and counsellors, and this is the subject of a question in the current consultation.

The Executive anticipates bringing a paper on this topic to the Council at its March 2010 meeting.

---

[2] HPC response to UK Health Departments consultation: 'The Future of the Healthcare Science Workforce - Modernising Scientific Careers: The Next Steps'. www.hpc-uk.org/aboutus/consultations/external/index.asp?id=79

3.2 HPC's new professions process
The HPC has a new professions (sometimes referred to as 'aspirant groups') process by which it can make recommendations to the Secretary of State for Health about the regulation of new groups.

Normally, a professional body representing a group seeking regulation will make an application to the HPC, demonstrating that the HPC's new professions criteria have been met. If the Council agrees that the criteria have been met and that there is a case on the grounds of public protection to regulate these groups, it will make a recommendation to the Secretary of State. However, the Council can recommend a group in the absence of an application. For example, the Psychotherapists and Counsellors Professional Liaison Group (PLG) was established in the absence of an application, in light of clear government policy in this area (see section 3.1 of this paper).

The report lists the groups recommended by the HPC to the Secretary of State and concludes that '…careful evidence-based policy making is needed to ensure that these proposals are properly considered'. The report also lists a number of other groups who have made representations to the HPC or to Government to be regulated, including nutritionists, play therapists and orthopaedic cast technicians. The report notes that 1.3 million individuals in the healthcare arena or nearly 4% of the total working population of the UK are currently regulated in the health care sector and that this figure would rise to around 8% if all the additional groups were to be statutorily regulated. The report concludes: 'The associated costs to the public purse and bureaucracy of bringing these additional groups within a statutory regime would need to be justified on the grounds of public protection.' (Paragraph 1.12)

A number of the conclusions and recommendations included in the report might potentially, at least in the medium to long term, impact upon the HPC's new professions process and these potential implications are discussed elsewhere in this paper.

4. Risk
The report focuses on the concept of risk and the importance of attempting to quantify that risk in order to make informed decisions about how that risk might best be mitigated.

The report identifies a number of possible factors which might indicate the risk of discrete acts undertaken by health professionals and workers, including, for example, the existence and effectiveness of managerial and professional supervision; whether the act is undertaken in a managed environment with processes for support and quality assurance; the quality of education and training; and the experience of the practitioner carrying out the act. The report also suggests that wider 'health of the population' factors may also be important, concluding that '…ineffective regulation of common lower risk activities may permit greater harm than ineffective regulation of rare high risk activities' (paragraph 2.6).

Interestingly, the report acknowledges that such risks may not always relate to 'technical competence' and recognises the potential impact upon sometimes vulnerable service users of inappropriate behaviour by professionals and caregivers (paragraphs 2.7 and 2.8). This is consistent with the findings of the Continuing Fitness to Practise Professional Liaison Group (PLG) which concluded that there was limited evidence about the risk posed by the professions regulated by the HPC but that, on the basis of the available fitness to practise data, conduct appeared to be a greater risk than technical competence and that it might be appropriate to focus our effort on this aspect of professional practice. The PLG also identified correlations between age and gender and the likelihood of being subject to fitness to practise action.[3]

In line with the PLG's recommendations and as part of building the evidence in this area further, the Executive has recently begun the process of commissioning two pieces of research to look at the link between poor behaviour during education and training and subsequent fitness to practise to action.

The report notes that the Department of Health has commissioned consultants Europe Economics to carry out development work on a risk assessment tool for assessing groups suggested for 'more formal regulation'. Although this work was not available to inform the findings, the report emphasises the importance of making policy decisions though a 'more scientific, robust, and rigorous basis' of assessing risk. It is suggested that evidence drawn from the actuarial risk models used by professional indemnity insurers or from patient safety incidents might inform such assessment and the report recommends that the administrations should continue work to develop a risk based model or tool. The focus in the report on a robust means of assessing risk in this area infers a strong desire to minimise or mitigate the more subjective or 'political' elements of decision making about regulation (paragraphs 2.9 and 2.10).

---

[3] 'Continuing Fitness to Practise – Towards an evidence-based approach to revalidation' – report of the Continuing Fitness to Practise Professional Liaison Group (PLG) www.hpc-uk.org/assets/documents/10002480council_20081001_enclosure06.pdf

In the new professions criteria, Part A of the assessment sets out the eligibility of a profession to apply and to be regulated and is focused, in broad terms, on questions relevant to risk. A group is eligible for application if it can demonstrate at least one of the following activities: invasive procedures; clinical interventions with the potential for harm; exercise of judgement by unsupervised professionals which can substantially impact on patient health or welfare.

The report does acknowledge, however, that decisions cannot be made purely on the basis of an evidence-based risk model. Factors such as the importance of public confidence in particular groups, public expectations about professionals and the potential financial impact of ineffective regulation are also considered salient to the issues of extending professional regulation.

5. Costs and benefits
The report discusses the costs and benefits of professional and occupational regulation, concluding that some of these factors are more legitimately relevant to making decisions about extending regulation than others.

The Council will be familiar with many if not all of the costs and benefits identified in the report as these influence the Council's decision making on a regular basis. The costs and burdens identified include regulatory fees and cost to taxpayers of establishing regulatory systems, as well as the interplay between national regulation and effective local service delivery and decision making. The benefits identified include the ability to remove from practice, where necessary, the small number of practitioners who fall below accepted standards and allowing the public to differentiate between 'bona fide' and 'bogus' practitioners (paragraphs 3.3 to 3.6).

The report recommends that the legitimate benefits to be considered in any decisions about extending regulation are 'safety of patients and the public' and the desire to enhance 'effective, high quality, and respectful care'. The report says that whilst other factors such as legitimacy and status conferred on a profession by regulation may indirectly help to improve quality, public protection should be the primary concern in any decision making (paragraph 3.8).

5.1 The question of efficacy
Perhaps of more interest to the Council given its thinking to date on this topic is the report's recommendation regarding the role that evidence of efficacy of practice should play in decisions about extending regulation. The report notes that statutory regulation can be seen by some 'to give an equivalent clinical legitimacy or perceived evidence base [to] that of groups currently regulated' and acknowledges that there may be some groups for which there is 'controversy' around efficacy (paragraph 3.7). The report's conclusions about this issue appear to try and balance the need to ensure that members of the public can make informed choices against the need to mitigate the risk that may be posed by certain treatments, even if they might be considered by some to lack an appropriate evidence base. The report concludes: '…it is important for public protection [and, it is argued, for public confidence] that the regulatory system continues to enable the public to distinguish between legitimate and unproven treatments when making their choice.' However, it is acknowledged that even where the benefits of treatments in certain fields are 'unproven' or 'controversial'

there may still be a need for formal regulation where the risk posed to patients and the public is 'significant' (paragraph 3.9).

The new professions criteria include the requirement that the applicant group must 'practise based on evidence of efficacy' (criterion 3). In order to meet this criterion applicants are asked to demonstrate the following.

- That their practice is subject to research into its effectiveness (and published in journals accepted as learned by the health sciences and/or social care communities).
- There is an established scientific and measurable basis for measuring outcomes of practice.
- There is subscription to an ethos of evidence-based practice including being open to changing treatment strategies when the evidence is in favour of doing so.

The Council discussed the role of evidence of efficacy in recommending regulation in September 2008 when it considered the report of a Department of Health Steering Group which recommended that acupuncturists, medical herbalists and traditional Chinese medicine practitioners should become statutorily regulated by the HPC.[4] The Council treated the report as if it were an application under the new professions process and recommended these groups for regulation to the Secretary of State for Health.

As part of its discussion, the Council considered the many arguments, (reflected both in the report and in commentary in the broadsheet press following its publication) around the evidence of efficacy of the practice of these groups. The efficacy criterion was scored part met overall, in recognition that although the report acknowledges the limitations of the available evidence base overall, the Steering Group had shown that there is variation in the available evidence base between the groups and that in some areas good quality evidence does exist. The Steering Group had also argued that the practise of these areas does not always readily lend itself to traditional research designs such as randomised control trials (RCTs) and that other forms of research had a role to play in developing the evidence base. The Steering Group concluded that a lack of evidence should not prevent regulation but that the professions should be encouraged and funded to strengthen the evidence base. [5]

This area engages an area of complex ongoing debate. It might be observed that even amongst those professions that have been regulated for a number of years there is a continuing debate about efficacy with professions constantly challenging and evolving their evidence base. There is also an ongoing debate about the rigour of certain types of evidence in helping to contribute towards an assessment of efficacy. For example, in the psychotherapy and counselling field

---

[4] Report of Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the United Kingdom
www.dh.gov.uk/en/Publichealth/Healthimprovement/Complementaryandalternativemedicine/index.htm
[5] Council paper, 'Regulation of Medical Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners', 11 September 2008
www.hpc-uk.org/assets/documents/100023FEcouncil_20080911_enclosure07.pdf

there is an ongoing debate about the value and appropriateness of RCT trials compared to other forms of evidence in providing evidence of the efficacy of different forms of therapy.

It might be appropriate to draw a distinction between the decisions involved in service delivery and those in professional regulation. For a service provider (particularly those using public money) evidence of effectiveness is likely to be important in deciding whether to fund a particular intervention. A King's Fund report recently concluded with reference to complementary practice: 'The public health care system should not sanction an intervention without a demonstrative mechanism for direct health benefit in which there is a degree of common and expert confidence…'[6] However, this may arguably be less relevant to the regulatory goal of mitigating risk of harm – i.e. if patients and clients are already seeking and undergoing treatment that poses a risk of harm, it may be appropriate to regulate even if that treatment might not conform to a traditional scientific assessment of efficacy. Further, whilst the development of an evidence base and ongoing debate of efficacy is important to the professions and to professional bodies in their role as 'learned societies', this may be of less direct concern to professional regulators.

In terms of the HPC's existing processes, a lack of 'accepted' evidence of efficacy is not a barrier to effective regulation. For example, it does not act as a barrier to producing standards of proficiency or making decisions about fitness to practise cases. With reference to the latter, most cases concern conduct or have a conduct element. In cases concerning lack of competence, a panel is deciding whether the registrant's fitness to practise is impaired by looking at whether the standards of proficiency have been met. The majority of such cases are clear cases of lack of competence where there has been a prolonged failure to meet standards of safe and effective practice. In any event, a panel is not arbitrating on efficacy but instead examining whether the actions (or omissions) of a registrant were reasonable in light of the circumstances and the relevant standards.

In its debate, the Council concluded that efficacy should not act as a barrier to regulation because the proper focus should be on public protection, particularly in light of evidence included in the Steering Group's report which indicated the potential for harm to service users. The Department of Health has recently published a consultation on the Steering Group's report in which views on this topic are sought. In particular, the consultation document notes a debate about whether these groups of practitioners should be regulated 'in a way which is different from the regulation of mainstream evidence-based healthcare workers'. A consultation question invites comments on whether these practitioners should be regulated differently from professions 'publicly perceived as having an evidence base of clinical effectiveness'. The Council may wish to consider that, although there may well be arguments to be had about the relative merits of

---

[6] King's Fund, 'Assessing complementary practice – Building consensus on appropriate research methods' (August 2009)
www.kingsfund.org.uk/research/publications/complementary_meds.html

particular regulatory interventions, evidence of efficacy should not be an important factor in the assessment of the appropriate regulatory response.[7]

The Executive will produce a draft response to the consultation for the discussion of the Council at a future meeting. Given the ongoing debate about this subject, if the new professions criteria are reviewed at a future point the Council may wish to discuss whether the criterion relating to efficacy should be removed or amended in some way, to reflect the Council's thinking on this subject.

6. Regulatory options

The report concludes that '…further regulation for professional or occupational groups needs to be within the context of an overall matrix of assurance through which a proportion of the total risk inherent in particular groups is shared within a integrated system of protection' (paragraph 4.8). This is consistent with the findings of the Continuing fitness to Practise PLG which concluded that professional regulation is but one part of a range of systems that ensure quality control and quality improvement including the organisational regulation of service providers and clinical governance systems.

The report concludes that whilst statutory regulation may be appropriate for some unregulated groups, others may be more amenable to one of a range of 'alternative lighter tough regulatory regimes'. Each of these regulatory options is outlined below with discussion of the key points they raise.

6.1 Buyer beware

This option is outlined as one where the consumer bears the burden of the risk, making their own judgements about practitioners and providers on the basis of personal preference, word of mouth and so on. Some protection would be afforded by consumer protection and criminal law but there would be no other specific legal safeguards. The report concludes that this option is only appropriate in limited circumstances such as for 'very small, non-invasive, low risk and newly emerging forms of care in some alternative and complementary therapies' (paragraph 4.12).

However, the report identifies that there is 'no single comprehensive source of information about…professionals, practitioners, therapists and other people providing health care' which might support informed decisions. The report recommends that the CHRE should be commissioned by the administrations to develop and publish a guide for the public that describes the key considerations in making decisions about approaching health practitioners, the different roles, the extent of regulation and 'how best to ensure safe, effective, high quality and respectful care from them'. In addition, the devolved administrations are encouraged to consider how information about regulation might be promoted through GP surgeries and other outlets (paragraph 4.14).

---

[7] Department of Health, 'A joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and other Traditional Medicine systems Practise in the UK' (July 2009) www.dh.gov.uk/en/Consultations/Liveconsultations/DH_103567

The Communications Department has undertaken a number of pieces of work with the aim of increasing public understanding of the role of the HPC and regulation. In particular, the Department distributes public information materials at events, on request, and via direct mail to GP surgeries and other service providers. In addition, in 2006 the health and social care regulators worked together to produce a public leaflet which explains the role of the regulators and gives contact details for the 13 health and social regulators across the UK.[8] The HPC also participates as part of the Joint Regulators' Patient Public Involvement Group.

6.2 Voluntary self regulation
The report suggests that, with a 'stronger degree of assurance', the systems of voluntary self-regulation often run by professional bodies have a potential place within the 'menu' of regulatory options and may be suitable for those groups 'unlikely to meet the requirements and standards necessary for statutory regulation' (paragraph 4.21).

Organisations representing professions who are not currently regulated often operate voluntary registers and have in place systems which are similar to those of a regulator – for example, systems for approving education and training programmes and for considering complaints about members. These registers are sometimes set up to facilitate the easy statutory regulation of practitioners or as an alternative where no statutory assurance exists.

For example, the Association of Operating Department Practitioners (AODP; now the College of Operating Department Practitioners) maintained a register of operating department practitioners. In this particular case, although statutory regulation did not exist become 2004, membership of the AODP register was normally a requirement for posts in the National Health Service (NHS). When operating department practitioners became HPC regulated in October 2004, all those that appeared on the AODP register transferred to the HPC register.

The existence of a voluntary register is included in the new professions criteria. The criteria require the applicant group to demonstrate the existence of a voluntary register that accounts for at least 25% of the group and that associated processes such as clear entry criteria, standards of conduct, and fitness to practise procedures are in place (criterion 5 to 10). These criteria are very much focused on a group's preparedness for regulation and their ease of regulation.

The report sets out some the advantages and disadvantages of voluntary registration. The disadvantages include the potential for professional self-interest; the lack of clarity for members of the public that ensues when multiple, competing registers are established; and the inability to prevent those removed from registers following a complaint from continuing to practise unfettered outside of voluntary registration (paragraph 4.20). The report suggests that to enable better consistency of standards and approach, the administrations should work with the CHRE and other stakeholders to consider the costs, benefits and feasibility of

---

[8] 'Who regulates health and social care professionals?'
www.hpc-
uk.org/assets/documents/1000134FWho_regulates_health_and_social_care_professionals.pdf

developing a formal accreditation regime for voluntary registers. The indicative criteria for such accreditation are broadly consistent with the criteria for voluntary register transfer developed as part of the Psychotherapists and Counsellors Professional Liaison Group (PLG) and currently subject to consultation. Although the recommendation is welcomed in the response from the administrations, it is unclear at this stage who would carry out this accreditation role if this recommendation was adopted (paragraphs 4.21 and 4.22).

6.3 Employer led regulation

The concept of 'employer-led' regulation is suggested as one of the possible regulatory options, particularly in light of the Scottish pilot looking at the regulation of healthcare support workers. Appendix 1 to this paper provides a more detailed summary of the Scottish pilot and the evaluation findings.

In summary, the Scottish pilot tested a model which included induction standards and a code of conduct for healthcare support workers; a code of practice for employers; and a centrally held list of names of those who have met the required standard. The report points to a number of factors to be considered in light of the Scottish pilot including the differences in NHS delivery between Scotland and the rest of the UK; the relatively low participation rate in the pilot; and the level of support of trade unions and other stakeholders (paragraphs 4.26 to 4.36).

The report recommends that the administrations should draw on the evidence from the pilot to 'inform the development of the "menu" of regulatory alternatives which might be developed'. The report also recommends that any development of an employer based model for NHS employees should also be capable of application to workers in the independent and voluntary sectors (paragraph 4.37).

At its February 2009 strategy meeting, the Council discussed employer-led regulation as part of a wider discussion about extending professional regulation. Some of the discussion groups expressed concern about the idea of employer-based regulation. Although it was felt that good employment practices were essential, it was felt that this approach may have a number of potential difficulties. These included the potential for conflict of interest between the imperatives of employers and those of regulation.

6.4 Licensing

At its meetings in December 2008 and February 2009, the Council considered a paper from the Executive about extending professional regulation. The paper outlined progress to date in extending regulation to new groups and put forward the suggestion that some groups including those termed 'healthcare support workers' might potentially be regulated via a licensing model.[9]

The report identifies licensing as a regulatory option which merits further exploration and consideration by the administrations. The report concludes that a licensing regime might be appropriate for 'lower risk groups or roles' and would be focused on dealing with conduct issues (paragraphs 4.38 and 4.39).

The outline of a potential licensing model given in the report is as follows.
- Skills for Health and other stakeholders might agree the qualifications, training and education standards a health care worker needs to do their jobs safely, effectively and respectfully. This might be a uniform standard or standards for different groups.
- A licensing body holds a list of licensees who have met the requirements above and signed up to a code of conduct.

---

[9] 'Discussion paper on extending professional regulation', Council paper, 10 December 2008
http://www.hpc-uk.org/assets/documents/100025D45Extendingprofessionalregulation.pdf

- Complaints could be investigated and, if necessary, a licence removed at tribunal. Licensees could appeal to an appropriate court.
- Licensing could be required by statute or voluntary and dependent on employer requirements. (Paragraphs 4.40 to 4.42)

In the discussion paper previously considered by the Council, a slightly different model was suggested. For those groups where it was possible to identify specific education and training programmes and a discrete title or titles, it was suggested that statutory regulation may be possible. It was suggested that this might particularly be possible where the occupational group has a close relationship with the registered profession – i.e. an assistant physiotherapist or assistant radiographer.

For other groups / occupations the following model was suggested and is summarised in the working group's report:
- There would be single protected title: 'Licensed healthcare practitioner'. Licensing would not be compulsory but would become part of standard conditions of employment. The value of licensing would be communicated to the public by the regulator.
- Entry to the register would be via a practical test achieved after a short period of training. There would be single set of standards of conduct, performance and ethics for all licensees and standards of training would focus on issues such as communication, delegation of tasks and infection control.
- Complaints would be heard by a tribunal and, in cases where standards are acceptable, licenses revoked.
- The licence fee would be around £30 per year, amounting to around £2 per month for basics rate taxpayers.

The report identifies a number of potential advantages of this system and recommends that the administrations consider the feasibility, costs and legal implications of a licensing regime for healthcare workers. The report makes no recommendation about the appropriate body to run the licensing system (paragraph 4.45).

The Executive will keep the Council updated about the work in this area.

7. Decisions about extending regulation

In light of its recommendations about risks, costs and benefits, the Group suggests that a new role is required in order to make future decisions about who should be regulated.

7.1 The gatekeeper

The report recommends the creation of a 'gatekeeper role' to make these recommendations to Ministers and outlines a process by which this might take place (paragraphs 5.2 and 5.3).

The outline process is as follows.

- The gatekeeper undertakes an overview of unregulated health workers to produce an initial shortlist of groups who need to be considered for more formal regulation, registration or licensing.
- The gatekeeper commissions expert independent advice, drawing on economic and actuarial risk, to triage these groups into cohorts of risk.
- The gatekeeper establishes an Independent Advisory Panel (comprised of a variety of stakeholders across the UK) to consider recommendations to Ministers in the administrations. The panel considers the risk and existing mitigating factors and agrees the priorities.
- An algorithm should be developed and consulted on to guide the process. This will aid the decision about which regulatory option provides the necessary assurance, starting with lightest touch upwards. An algorithm put together by Skills for Health is included at Appendix 2.
- The HPC would continue to assess 'readiness for regulation' of those for whom statutory regulation has been recommended. The report concludes that the existing criteria for assessing preparedness for groups for statutory regulation are 'fit for purpose' but that similar criteria may be needed for the other regulatory options. (Paragraphs 5.7 to 5.9)

Although the outline methodology for the gatekeeper proposed by the report is welcomed in the response of the administrations, there appears to be a lack of appetite for establishing a new body or new role to make these recommendations. The administrations note that there was no consensus on the working group as to whether an existing or new body should take on the gatekeeping role. Concern is expressed about the potential for such a role to introduce 'further, unnecessary burdens on individuals, employers, and Government'. The administrations conclude that '…further work is needed before decisions can be taken on whether this series of recommendations could or should be progressed'.[10] A scoping and feasibility assessment is to be undertaken, with the aim of presenting findings by the end of 2009. The Executive will keep the Council updated with any developments in this area.

---

[10] Health administrations of England, Northern Ireland, Scotland and Wales, 'Response to the Report of the Extending Professional Regulation Working Group' (July 2008) www.dh.gov.uk/en/Managingyourorganisation/Humanresourcesandtraining/Modernisingprofessionalregulation/ProfessionalRegulationandPatientSafetyProgramme/ExtendingProfessionalRegulation/index.htm

7.1.1 Implications for the new professions process

In their response to the report, the administrations conclude that the HPC should, until the introduction of a gatekeeper, '…continue its role in advising the Secretary of State for Health in England on whether emerging professions /occupational groups have carried out the necessary preparatory work for more formal means of assurance'. New regulation is a devolved matter; however, the administrations are currently committed to UK-wide regulation. Although the HPC's recommendation is to the Secretary of State for Health and, following recent changes to the Health Professions Order 2001, to Ministers in Scotland, in practice when a recommendation is made all four administrations are advised.

As the administrations have concluded that the HPC's new professions process should continue in the interim period, there does not appear to be any short term implications for the process. However, the report's recommendations do pose some challenges about the continued role of the process. In particular, there continues to be a need to manage the expectations of groups involved in the process. Although the HPC has recommended 12 groups for regulation since 2003, to date, only 2 of those (practitioner psychologists and operating department practitioners) have become regulated (Box C, page 16). There continues to be a need to manage the expectations of groups seeking regulation and applying via the new professions process to ensure that they are aware that any final decision to regulate is one for Government, and that, even if agreed, the timescales for introducing new regulation are lengthy and often frustrating for those involved. However, some groups involved in the process have commented that the work they have undertaken to meet the criteria has been a useful process in the thinking and development of the professional body and the profession it represents.

As noted in the report, the new professions process and criteria are focussed more on 'readiness for regulation', than some of the broader, issues around risk, costs and benefit. For example, one of the criteria is about whether there is a voluntary register to help facilitate easy registration. However, the Council certainly remains focussed on the salient questions around public protection when it deliberates each application.

Although Part A of the assessment does attempt to quantify areas of risk in broad terms in order to determine eligibility for application, the process does not weigh risk and make judgements about priorities in the way suggested for the gatekeeper role in the report. In addition, as to a great extent the process is focussed on the readiness for regulation (i.e. that the professional group and body making the application has in place the necessary processes and systems) there is the potential for the Council to make a recommendation in relation to a group which the Government subsequently assesses as being low risk and meriting a 'lighter touch' regulatory intervention. In addition, there is also the potential that a group that the Government has already decided should not be statutorily regulated might successfully apply. For example, the report notes that for a number of complementary and alternative therapies the Department of Health in England has concluded that 'full blown statutory regulation would be inappropriate'. There would be nothing to preclude any group from making an application to the Council, and potentially a recommendation being made, provided they could demonstrate that the all the criteria had been met.

The Council's independence from Government and from Government policy decisions is of course very important. However, the Council may wish to bear these issues in mind in considering HPC's continued role in this area, in light of the future development of Government policy about extending professional regulation.

The Policy and Standards Department workplan for 2009/2010 includes work to review the new professions process, in light of the outcomes of the working group. This review was not commenced prior to the publication of the report. Given the conclusions of the report and the work being taken forward by the administrations which may develop the approach further in this area, it may not be prudent to review the criteria at this stage.

7.2 Distributed regulation

The report briefly discusses the feasibility of the concept of distributed regulation, a concept suggested in the Review of the regulation of non-medical healthcare professionals.[11]

This concept was developed in recognition that new roles have sometimes meant that professionals performing the same role are regulated by different regulators and to different standards. There is also sometimes the added complication that the role might also be performed by direct entrants who have no 'regulatory home'. For example, the majority of individuals who perform the emergency care practitioner role are HPC registered paramedics, but some are nurses registered with the Nursing and Midwifery Council. Under distributed regulation, one regulator would be appointed as the lead regulator, and would be responsible for establishing the standards for regulation. Individuals who were registered with other regulators would not need to 'move regulatory home' or become dual registered. Their regulator would instead use the lead regulator's standards, for example, to consider a complaint about their practice in that role.

In our response to the Review of the regulation of non-medical professionals, we said that we did not support the proposed model of distributed regulation, chiefly because of concerns about public understanding and consistency in decision making.[12] The report notes that there are a number of 'significant concerns' about such an approach and makes no recommendation that this model should be taken forward (paragraph 5.15 to 5.19).

The report uses the example of podiatric surgery as an example of distributed regulation. Podiatric surgeons are registered podiatrists who have undertaken post-registration training. This area will be considered by the Education and Training Committee as part of its work on post-registration qualifications. The Executive plans to bring a paper to the Education and Training Committee at its December 2009 meeting.

---

[11] Department of Health, The regulation of the non-medical healthcare professionals: a review of the Department of Health (July 2006)
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137239
[12] HPC response to 'The regulation of non-medical healthcare professionals'
www.hpc-uk.org/aboutus/consultations/external/index.asp?id=38

8. Conclusion
The Council is invited to discuss this paper.

Appendix 1
(prepared by Megan Scott, Policy Officer)

Pilot for the regulation of healthcare support workers

Background

There is no statutory provision for the regulation of healthcare support workers in the UK.

The healthcare support worker role has been changing and developing over the last decade. Increasingly, support workers are extending their skills so they can undertake work previously done by registered professionals.

Responses to a Scottish Government consultation on extending the regulation of healthcare professionals indicated strong support for regulation of healthcare support workers. 90% of respondents indicated that statutory regulation was the most appropriate way to ensure public protection.

This pilot tested an employer-led regulation model comprising healthcare support worker standards and a list of healthcare support workers who demonstrated achievement of the standards.

An independent evaluation of the pilot was conducted by the Scottish Centre for Social Research. The evaluation aimed to assess the implementation, operation and potential impact of the pilot.

Participating organisations

Three NHS boards participated in the pilot:
- NHS Ayrshire & Arran
- NHS Lothian
- NSH Lanarkshire

Ross Hall Hospital, Glasgow represented the independent sector. While it was an equal partner to the NHS boards in all aspects of the pilot, the Ross Hall Hospital was not involved in the independent evaluation conducted by the Scottish Centre for Social Research.

Key objectives of the pilot

The overarching aim of the pilot was to explore whether an employer-led regulation model has the potential to enhance public protection.

Key objectives at the outset of the pilot were:

- To create effective systems to demonstrate compliance with the healthcare support worker regulation standards; and to explore how these complement current existing clinical and staff governance arrangements.

Appendix 1
(prepared by Megan Scott, Policy Officer)

- To introduce of an occupational list of healthcare support workers who demonstrate achievement of the standards, for the purpose of public protection.

- To consider how the requirements of the pilot interact with current HR processes and existing governance arrangements, and to identify any gaps that emerge.

Key factors of approach

- Participation in the pilot was voluntary.

- As part of the pilot, healthcare support worker standards were developed. There were three elements to the standards:
    - induction standards for healthcare support workers
    - Code of Conduct for healthcare support workers
    - Code of Practice for NHSScotland Employers

- An assessment toolkit was produced, consisting of an oral and observation assessment process which assessed participants against the induction standards.

- Once a participating healthcare support worker they had passed the assessments they signed a declaration to commit to the code of conduct and were entered onto the occupational list.

- Each participating healthcare support worker was asked to consent to a disclosure Scotland check. Support workers could not be added to the occupational list unless a disclosure check had been completed.

Summary of key learning points and recommendations

The following points are taken from both the final report, published by NHS Quality Improvement Scotland and the independent evaluation report.

General

- There was evidence that the implementation of the standards had the potential to improve patient safety and public protection.

- Participants reported feeling that they knew more about patient safety and felt more able to take actions to keep patients safe.

- Disclosure Scotland checks discovered some minor undisclosed material.

- A clear communications strategy is required to inform and engage healthcare support workers on the way forward.

Appendix 1
(prepared by Megan Scott, Policy Officer)

Participation rates

- 496 individuals participated in the pilot. This equated to 17% of eligible healthcare support workers in participating organisations.

- Organisations fed back several reasons for low participation rates, mostly centred on a lack of understanding about the benefits of regulation.

- The role of the workplace supervisor was a key factor in the success of the pilot. All participating organisations reported that if the workplace supervisor was enthusiastic and motivated to take part, then healthcare workers in their team were enabled to volunteer and supported to work towards achieving the public protection induction standards.

- Some healthcare support workers felt that their workplace supervisor was not sufficiently prepared.

- The evaluation recommended that more consideration needs to be given to the drivers for workplace supervisors, especially for those within non-clinical staff groups who are not themselves subject to regulation.

- If the pilot is extended, the *purpose* of regulation will need to be carefully considered to ensure the model used is accessible to the range of healthcare support workers involved.

Standards, codes and the occupational list

- The induction standards were supported by those involved in the pilot, however they require streamlining and repackaging. The Code of Conduct and Code of Practice were also both supported.

- The standards should be mandatory and separate standards should be developed for clinical and non-clinical healthcare support workers. Other recommendations centred on provide additional clarity to workers.

- There were mixed views about whether a national occupational list is a proportionate response to the perceived level of risk.

- Further work needs to be carried out to map existing and forthcoming education frameworks and educational requirements for healthcare support workers against the public protection induction standards.

- There are close links between the pilot standards and the NHS Knowledge and Skills Framework. The evaluation recommended

reviewing the standards to ensure they do not exceed the skills that are required within a healthcare support workers' KSF foundation post.

Assessment process

- All participants who undertook the oral and observation assessments successfully evidenced that they are meeting the standards. Three participants required reassessment to complete all assessments.

- Workplace supervisors must be provided with more guidance should for assessing the relevance of the different types of evidence of previous achievement.

- Healthcare support workers and workplace supervisors/KSF reviewers could utilise the same skills assessment and evidence collection process to inform achievement of both the public protection induction standards and the KSF foundation gateway review.

Participant views

- Some healthcare support workers, including laboratory staff and domestic assistants, reported that the standards were not applicable for their role.

- The assessment process took longer than expected for some groups of healthcare support workers. This was attributed to the applicability of standards to certain groups and difficulty in understanding the language.

- Some experienced healthcare support workers reported that the process would be more valuable for new workers as they felt that they were already working above the minimum standard. Others experienced workers reported that they did find the process valuable as it made them more aware of what was happening in the workplace.

Resourcing

- Rolling out the pilot to all NHS Boards would potentially carry substantial resource implications, depending on future arrangements.

- Ensuring adequate resource for the successful implementation of an employer-led regulation model is a key consideration.

- In particular, resourcing requirements would differ depending on whether only new starters are registered, or if it applies to all healthcare support workers who are in post.

Appendix 1
(prepared by Megan Scott, Policy Officer)

References

Final Project Report – Pilot for the regulation of healthcare support workers
http://www.nhshealthquality.org/nhsqis/6110.html

Healthcare Support Workers in Scotland: Evaluation of a National Pilot of Standards and Listing in Three NHS Boards
http://www.scotland.gov.uk/Publications/2009/06/01144730/0

Appendix C - Skills for Health Proposed Algorithm on Most Appropriate Regulatory Approaches

Gatekeeper receives occupational role

↓

Work with patients or human tissue —Yes→ **Level 1 or 2 on the Career Framework** —No→ **Level 3 on the Career Framework** —No→ **Level 4 or above on the Career Framework** → **Has current statutory regulation** → **Statutory Regulation will continue**   **Procedures are protocol based** —No→ **Procedures cause significant harm** —Yes→ **Statutory Regulation**

Work with patients or human tissue —No→ **No regulation**

Level 1 or 2 on the Career Framework —Yes→ **Employer Regulation**

Level 3 on the Career Framework —Yes→ **Work directly supervised**

Level 4 or above on the Career Framework ↓ **Not currently regulated** ↓ **Carry out controlled acts**

Procedures are protocol based —Yes→ **Procedures are carried out in an unsupervised environment** —Yes→ **Individual allowed to change plan of care within Agreed protocols but without discussions with Senior staff**

Carry out controlled acts —Yes→ **Procedures are protocol based**

Procedures cause significant harm —No→ **National Licensing**

Procedures cause significant harm —Yes→ **Individual allowed to change plan of care within Agreed protocols but without discussions with Senior staff**

Work directly supervised —No→ **National Licensing**

Work directly supervised —Yes→ **Employer Regulation**

Carry out controlled acts —No→ **National Licensing**

Procedures are carried out in an unsupervised environment —No→ **National Licensing**

Individual allowed to change plan of care within Agreed protocols but without discussions with Senior staff —No→ **National Licensing**