# Extending Professional Regulation Working Group

*Interim Report: Protecting the public by ensuring that workforce standards are met*

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## *Interim Report: Protecting the public by ensuring that workforce standards are met*

**Dr Moira Livingston, Chair of the Working Group on Extending Professional Regulation**

| DH Information Reader Box | | | |
|---|---|---|---|
| HR/Workforce | | | |
| **Document purpose:** | For Information | | |
| **ROCR ref:** | | **Gateway ref:** | 10028 |
| **Title:** | Extending Professional Regulation Working Group Interim Report | | |
| **Author:** | Dr Moira Livingston (North East SHA) | | |
| **Publication date:** | 6.6.08 | | |
| **Target audience:** | PCT CEs, NHS Trust CEs. SHA CEs, Foundation Trust CEs, Medical Directors, Directors of Public Health, Directors of Nursing, Directors of Adult SSs, PCT PEC Chairs, NHS Trust Board Chairs, Special HA CEs, Directors of HR, Allied Health Professionals, GPs, Emergency Care Leads, Regulatory Bodies, Professional bodies and unions, Patient groups, Charities | | |
| **Circulation list:** | | | |
| **Description:** | An interim report outlining progress of the Extending Professional Regulation Working Group. The Working Group are one of the workstreams taking forward recommendations proposed in the White paper "Trust, Assurance, Safety". | | |
| **Cross ref:** | White Paper "Trust, Assurance, Safety – The regulation of health professionals in the 21st century." | | |
| **Superseded docs:** | | | |
| **Action required:** | None | | |
| **Timing:** | NA | | |
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| **For recipient's use:** | | | |

First published 5 June 2008

Published to DH website, in electronic PDF format only.
http://www.dh.gov.uk/extendingprofessionalregulation
http://www.dh.gov.uk/publications

# Executive summary

In February 2007 the Government White Paper "Trust, Assurance, Safety – The regulation of health professionals in the 21st Century" set out Government proposals for improving public safety by strengthening the system of professional regulation for health care professionals. The paper also considered plans for extending statutory regulation to more healthcare professions / occupational groups. A Working Group of representatives from across the UK, including from health and social care sectors, academia, regulatory bodies, and government have been tasked with taking forward this complex area of health policy.

This interim report sets out our thinking so far, and makes recommendations about the work that is required before a final report can be submitted on this subject.

The Working Group have worked with key stakeholders to understand the issues and challenges surrounding the decision to extend statutory regulation to further health care professions / occupational groups. It has become clear that the regulatory systems of the healthcare workforce need to adapt to the environment in which the service is to be delivered. There are a number of healthcare professions / occupational groups that are not statutorily regulated, but perhaps should be. The decision to extend statutory regulation to a profession / occupational group has implications for the public, professionals, and employers, and therefore cannot be taken lightly. The Working Group has commissioned research and further work to identify the range of potential methods for safeguarding the public, and will also explore how we might use tools already available to identify the risk posed by un-regulated healthcare professionals / occupational groups to public safety.

The Working Group shall take forward this work and make final recommendations in December 2008.

# Contents

# 1. Introduction

1.1. In the UK, statutory regulation[1] is generally perceived to be the best method of maintaining public safety and ensuring professional standards. However, with regulation by statute (by law) come restrictions on scope of practice, and consequently this can restrict the development of regulated roles to meet changing healthcare requirements. There are also usually administrative requirements for the healthcare professional / occupational group[2], which can take some time to finalise, as well as financial costs for the healthcare professional / occupational group, the employer, and the government. Therefore, the decision to extend statutory regulation to a new group is not always clear-cut, and requires the input of a large number of stakeholders and consideration of many – often conflicting – factors.

1.2. In 1858, statutory regulation was introduced for the medical profession. 150 years on, 24 other professions have also become regulated by statute, with the intention of ensuring that agreed standards for education, practice and conduct are met. In the delivery of modern healthcare[3], there are many other healthcare professional and occupational groups who are not currently statutorily regulated.

1.3. Chapter seven of the White Paper "Trust, Assurance, Safety"[4] sets out Government proposals for extending statutory regulation to more healthcare professions / occupational groups. This Working Group of representatives from across the UK, including from health and social care sectors, academia, regulatory bodies, and government have been tasked with taking forward this complex area of health policy. Six White Paper tasks were set for the group and are outlined in annex A, along with the Working Groups' Terms of Reference that developed out of these. Progress against each task is addressed as we move through this interim report.

1.4. England, Scotland, Northern Ireland and Wales are committed to effective UK-wide regulation of health professionals. However, it is essential within this context to take account of the different systems for, and approaches to, delivering health services across the four UK countries. To this end, the Working Group includes representatives from the devolved administrations to ensure that any recommendations made are suited, as far as possible, to the operational systems of all four countries.

1.5. The Working Group's main intention is to create a common approach across the UK for determining which healthcare professional and occupational groups should be subject to regulation now and in the future, and the most appropriate type of regulation for these professional and occupational groups. In addition to taking forward the policy intentions laid out in the White Paper, the Working Group has agreed it will respond

[1] Statutory regulation is the process whereby the state legislates to ensure that there are quality controls on entry to and practice of a profession. This involves defined standards of education, competence and conduct, which practitioners are required to meet by law in order to take on a particular title or role. In UK practice, statutory regulation involves the establishment of a register held by an independent regulatory body which a practitioner is required to remain on in order to practice said profession within the jurisdiction of that regulatory body.

[2] An occupational group is one which is recognised as providing a specific function within the health workforce; all members of the group are recognised as such, eg. theatre technicians, phlebotomists. Not all occupational groups will be recognised as professions; therefore a distinction has to be made.

[3] "healthcare", in this document, refers to healthcare in the broadest sense both in and outside of the NHS

[4] "Trust, Assurance, Safety – The Regulation of Health Professionals in the 21st Century", The Stationery Office. 2007.

positively to requests to take on a supportive role for emerging government policies that impact on regulation across all four countries of the UK[5].

1.6. The Working Group has met three times under the current chair, since January 2008 and we are now in a position to set out our proposed way forward. We intend to submit our final report in December 2008. (See annex B for membership)

[5] This includes, for England, Lord Darzi's Next Stage Review of the NHS, which has substantial policy overlaps with the White Paper.

# 2. Background

2.1. Currently 25 health professions come under statutory regulation. Several groups, including: the public, the NHS, and professional and occupational groups, wish statutory regulation to be introduced for additional healthcare professional / occupational groups, often without consistency of approach or clarity of purpose. These groups vary in type, and range from psychotherapists to orthopaedic cast technicians.

2.2. Some of these professions have long-running voluntary registration schemes in place, have common standards of training and accredited qualifications, and some also have disciplinary procedures run by their main professional body. However, others have no form of register in place, no common standards of training and practise, and no disciplinary monitoring or enforcement. Some professions work mainly within employment in the health services of the UK, some in independent health services, others work solely as self-employed in private practice, and some straddle all three.

2.3. The list of professions currently seeking, or being considered by the UK Government and regulatory bodies for professional regulation is long, and is constantly growing as new health professions and roles emerge in the healthcare workforce. The driver for statutory regulation is often complicated by the desire to raise the professional standing of a group and not always driven by the need to ensure public safety.

# 3. Emerging Issues

3.1. We need a system of regulation that can appropriately deal with the regulatory implications of current and future healthcare delivery on the workforce, including that in the private and voluntary sectors, ensuring that the workforce is fit for purpose and that the system is meets the principles of "Better Regulation".[6]

3.2. Healthcare is changing; employers tell us they need a more flexible workforce to ensure effective delivery of safe services, and that this has implications for workforce development, taking it beyond the traditional roles we are familiar with. For example, in England, world class commissioning[7] will encourage new providers to deliver care on behalf of the NHS and this will inevitably result in considerations around the shape and development of the workforce to ensure efficiencies.

3.3. Employers are already taking action to change their workforce to meet patients' needs, and this illustrates the changing world in which regulation needs to be set. New roles have been developed with new responsibilities. **Healthcare Support Workers,** such as **"Assistant Practitioners"**, now carry out many tasks within the health service, and are often responsible for "delivering protocol-based clinical care that was previously under the remit of registered professionals, under the direction and supervision of a registered practitioner"[8]. There are also an increasing number of individuals at this level delivering healthcare in a *social care* setting. The roles undertaken by Healthcare Support Workers vary greatly, as do the training and qualification requirements and supervision arrangements placed on them by their employer. Some job descriptions state that the role will involve "often working alone and without direct supervision in the community"[9] and while it is acknowledged that this could present a high risk to patients, the closer the role is designed to meet local needs, the greater the challenge is in finding a UK wide regulatory solution.

3.4. Healthcare professional groups who are already statutorily regulated can expand and advance their practice according to service need. This is exemplified through the **advanced nurse practitioner** role. However, such developments in practice can become complicated by a lack of consistency over titles used by employers and individuals. The professions are keen to have these advanced roles statutorily recognised - in part for credibility, but more appropriately for public protection. What is vitally important is that common standards are recognised and achieved for the purpose of public protection, and ways of achieving this are important.

3.5. There are an increasing number of alternative healthcare providers; and new providers outside the NHS can employ a range of workers to carry out specific roles, out with Agenda for Change.

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[6] www.berr.gov.uk/bre

[7] http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Worldclasscommissioning/index.htm

[8] Skills for Health – NHS Career Framework 2005

[9] Assistant practitioner vacancy job description – NHS Jobs, May 2008

3.6. There is an increasing interest in complementary and non-western medical healthcare.

3.7. The European and international dimension will play an increasing role in influencing our workforce.

3.8. The regulatory system will increasingly need to effectively address public safety in a range of new environments such as the self employed workforce, small businesses and not-for-profit organisations.

3.9. Of the current complaints dealt with by regulators, issues of competence represent a small proportion. The majority relate to conduct and ethical issues where employers also have a role. As we progress this work we recognise the potential for closer working and clarification of responsibilities between employers, the commissioners of services, the self employed, and the regulators. This can be facilitated by the Council for Healthcare Regulatory Excellence (CHRE) and is acknowledged in the White Paper.

# 4. Progress So Far

## 4.1. Stakeholder engagement and communications

4.1.1. The Working Group has been keen to ensure that those who will be affected by this work have been able to inform our thinking and are kept up to date on progress.

4.1.2. The Department of Health website (www.dh.gov.uk) has been regularly updated with information on Working Group progress, and has received over 2700 hits on Extending Regulation pages (www.dh.gov.uk/extendingprofessionalregulation) since December 2007.

4.1.3. Over 200 stakeholders from patient and public involvement groups, the health services of the UK, professional bodies, and academia have fed into the Working Group's thinking.

4.1.4. A stakeholders' conference was held on 5 June 2007 to discuss the implementation plan for the whole of the White Paper. At this event 218 stakeholders commented on the White Paper, and gave feedback on extending professional regulation (see annex C for a summary of Extending Professional Regulation discussion at that event). As a follow-up to this event, and as recommended in the White Paper, a similar event (entitled the "National Advisory Group") is planned for late summer 2008, to which the Department of Health intend to invite 500 stakeholders.

4.1.5. The Department of Health held a specialist engagement event on 24 April 2008 for representatives of patient and public interest groups (PPI). This event covered all the White Paper workstreams, providing this specialist group of stakeholders with an opportunity to learn more about how the programme of regulatory reform will have an impact on the user groups they represent. A breakout session was held at this event on the work of the Extending Regulation Working Group and the Scottish pilot for the regulation of healthcare support workers. This was well-received by the PPI representatives, who felt the model being tested held public safety as paramount.

4.1.6. The conference "Extending Professional Regulation: A Vision for the Future" was held on 7 May 2008 in Newcastle, where 68 key stakeholders attended from across the UK and engaged in a comprehensive dialogue on this subject. The key messages from this event were that future decisions to extend regulation should be based on perceived risk to public safety, that other methods of regulation need to be considered and that the role of the employer and the self employed also needs clarifying. Positive feedback was received, supporting the development of a framework to guide future decision making around regulation.

4.1.7. Additionally, a number of key stakeholders have met with Working Group members, and the group has received submissions from key constituents outlining their concerns / issues / areas of expertise to inform the groups thinking. This,

importantly, has included read-across to the Scottish implementation group for Extending Professional Regulation.

## 4.2. Future communications

4.2.1. The extending regulation pages of the web site will be regularly updated.

4.2.2. The attendees from the 7 May "Vision for the Future" event have agreed to act as an electronic reference group.

4.2.3. A follow-up to "Vision for the Future" is planned on 24 September, where the Working Group will present the latest draft report, providing a further opportunity for comment on the Working Groups' proposals.

## 4.3 Progress against each task

### 4.3.1. *Task 1: develop criteria to determine which roles should be statutorily regulated*

The Working Group has considered the Health Professions Council (HPC) criteria for extending regulation, and agrees that when considering whether to extend statutory regulation to a group / role there are four main assessments required of that role or group:

- Will statutory regulation of this role improve public safety and will it add benefits that are not achievable by non-statutory means?
- Is the risk associated with practice proportionate to the resulting restrictions and cost associated with introducing statutory regulation?
- How does the proposed regulation of this role fit with other performance standards' mechanisms, including revalidation and appraisal, or individual and system governance approaches?
- Is there an alternative model of regulation that would bring the same benefits?

In answering these questions, the Working Group agrees that extending regulation to a new role or profession should be proportionate and judged on the grounds of **risk,** ie based on the potential threat to public safety that the unregulated profession / group could pose. *There is currently, however, no clear way to judge the risk associated with roles.*

Action: The Working Group intends to commission a piece of research which will consider how risk can be measured and judged within the healthcare professions (see annex D for research proposal).

### 4.3.2. *Task 2: discuss with the Devolved Administrations and key stakeholders whether a formal mechanism should be devised to consider the national need for new roles and the regulation of new roles;*

Through the Working Group's stakeholder communications and engagement, we have identified a consensus from Patient and Public Interest groups, professional bodies, and employer organisations that we need a common nationwide approach to extending regulation. This is important to promote safe workforce mobility throughout the UK; setting common standards of training, competence, and codes of conduct for all roles irrespective of sector or context, at the same time ensuring that decisions to regulate are based on the principle of proportionality.

There has also been call for consideration of the European dimension to professional mobility. The UK health service has benefitted from free movement of health professionals within the European Economic Area (EEA), but with free movement and EU laws requiring mutual recognition of professional qualifications for some health professions, may come potential threats to public safety where there are not common approaches to regulation across the EEA.

Action: The group will review different regulatory mechanisms in Europe and internationally as part of the proposed research.

Action: The group will consider the potential for a framework to define proportionate risk-based regulation for employers and the professions based on the task being carried out, the context it is in, where it is carried out and the level of supervision. Skills for Health will support this work.

4.3.3. *Task 3*: *assess the professional / occupational group's state of readiness for regulation*

The Health Professions Council (HPC) has a set of criteria to assess a profession's suitability for regulation. The Working Group has considered those criteria, and agree that with some changes they are useful for assessing if a profession is *ready* for statutory regulation (see annex E for amended list of criteria for readiness).

4.3.4. *Task 4*: *explore the practicality of a system of distributed regulation, including its relationship to revalidation, in which a lead regulator will set the standards against which a practitioner will be recognised and judged. This would apply to already statutorily regulated professions and ensures that all professional groups – irrespective of parent regulator - meets, and is judged against, the same set of standards for an area of practise, irrespective of professional title or regulatory body with which registered;*

Action: This group aims to consider the appropriateness and practical / legal implications of that method along with other models of ensuring public safety, including proposals emerging from other UK Working Groups.

4.3.5. *Task 5*: *evaluate the results of the Scottish pilot study [into regulation of healthcare support workers] and consider the way forward with stakeholders;*

The report from the Scottish independent evaluation team is expected by January 2009, with early policy proposals formulated by the Scottish Executive at a national stakeholder event in October 2008. These, and the evaluation report, will be considered by Scottish Ministers in 2009.

Action: The Working Group is working closely with Scottish officials to monitor progress of the pilot, and is considering the applicability of it for similar health groups in England, Wales and Northern Ireland. The proposed Scottish policy intentions will be used to inform our final report in December 2008.

4.3.6. *Task 6*: *consider whether there is sufficient demand for the introduction of statutory regulation for any assistant practitioner roles at levels 3 and 4 on the Skills for Health Career Framework*

The group considers there is a case for some form of regulation of these roles, particularly those that involve carrying out procedures previously performed by registered professionals, when working with little or no supervision. However, decisions on a way forward need to be future-proofed to accommodate the different requirements across the UK. We understand that the Scottish Extending Professional Regulation Implementation Group has not yet fully considered this issue, although it is clear that, in Scotland, the standards being tested through the healthcare support worker pilot would apply to all support workers – irrespective of placement on Career Framework.

Action: The Working Group will consider if and how these roles should be regulated once we have a concrete understanding of the levels of risk associated with them, and of other regulation opportunities that may be appropriate.

## 4.4. Alternatives to Statutory Regulation

The Working Group recognises that statutory regulation is not the only method of ensuring that standards are agreed and met, nor the only way of protecting the public from poor professional standards.

As we progress this work, the Working Group will review alternative models of standard setting aimed at protecting the public, including the role of the employer in ensuring that workforce standards are met and maintained.

Action: The group proposes to extend the piece of commissioned research on “risk” to include a literature review of examples of regulatory best practice from an international and multi-professional perspective (see annex D). This will potentially allow the Working Group to make recommendations for ways of ensuring workforce standards are met and safeguarding patients for those occupational/ professional groups which we feel are not suited to statutory regulation.

# 5. Conclusion

5.1. In conclusion further work is needed to:

- Understand other methods of regulation of the workforce and what support they might offer UK healthcare delivery
- Identify other methods of protecting the public by ensuring that workforce standards are met
- Understand risk in relation to roles, using competence-based approaches, eg. building on the Knowledge and Skills Framework (KSF) and Job Evaluation Criteria currently used by the NHS and other similar frameworks.

5.2. Key Output

The key output will be an evidence–based report that will be accessible to patients, the public and key stakeholders.

Within this report we aim to present an easy to understand proportionate risk-based framework that will guide the system to identify when different types of regulation can be used to offer the best option for particular occupational and professional groups. The underpinning ethos of the working group's work is to ensure that, by whatever means, the interests of patients and the public are secured through achieving practical ways of ensuring that workforce standards are met.

We shall submit our final report in December 2008.

Dr Moira Livingston (FRCPsych)

Chair Extending Professional Regulation Working Group

5 June 2008

# ANNEX A: Tasks & Terms of Reference

## Summary of White paper tasks for the Working Group

1. "**develop criteria to determine which roles should be statutorily regulated;**

2. **discuss with the Devolved Administrations and key stakeholders whether a formal mechanism should be devised to consider the national need for new roles and the regulation of new roles;**

3. **assess that role's state of readiness for regulation against agreed criteria, such as those used by the Health Professions Council;**

4. **explore the practicality of a system of distributed regulation, including its relationship to revalidation;**

5. **evaluate the results of the Scottish pilot study [into regulation of healthcare support workers] and consider the way forward with stakeholders;**

6. **consider whether there is sufficient demand for the introduction of statutory regulation for any assistant practitioner roles at levels 3 and 4 on the Skills for Health Career Framework."**[10]

## Terms of Reference

To consider the recommendations in *Trust, Assurance and Safety* relating to extending the scope of statutory professional regulation to appropriate professional healthcare groups, and create a Framework for Extending Professional Regulation, which:

1. Sets out what models of regulation for healthcare professional and occupational groups are available across the four nations.

2. Sets out criteria, against which, all healthcare professional and occupational groups and roles seeking or requiring statutory regulation in the UK will be judged to determine whether statutory regulation, or another model of regulation, is appropriate. The criteria should take account of :
   2.1. the wide variety of existing and emerging professions that are either seeking statutory regulation or, on the basis of risk, may require regulation;
   2.2. the work carried out by the UK New Ways of Working Group that seeks to provide strategic direction on the development of new roles;

[10] Trust, Assurance and Safety – The regulation of health professionals in the 21st century; Department of Health

2.3. existing evidence that supports the demand for regulation of emerging professional and occupational groups within healthcare services across the UK;

2.4. the existence and appropriateness of different types, levels or models of regulation.

3. Tests groups known to be seeking statutory regulation against the criteria and identifies where there may be a need for an alternative solution or different model of regulation.

4. Undertake research into internationally used alternatives to statutory regulation.

5. Sets out guidance on how to prioritise the professional and occupational healthcare groups seeking or requiring statutory regulation.

6. Work closely with the Non-Medical Revalidation and Health for Health Professionals Working Groups, developing and using shared products and outputs as necessary.

7. Take account of the implications for healthcare workers of developments in the regulation of the social care workforce.

8. To act on recommendations from UK health policy.

# Annex B: Membership of the Extending Professional Regulation Working Group

| | |
|---|---|
| Dr Moira Livingston | Strategic Head of Workforce, and Deputy Medical Director at North East Strategic Health Authority |
| Alastair Henderson (deputy Sean King) | NHS Employers |
| Audrey Cowie | Scottish Executive Health Department |
| Barbara Bale | National Assembly for Wales, Health Department |
| Chris Mullen | NHS Northwest |
| Dr Ron Walton | Vale of Glamorgan Community Health Council |
| Heather Wing | General Social Care Council (GSCC) |
| Helen Issit | Derby City PCT |
| Ieuan Ellis | Associate Dean of Leeds Metropolitan University and member of the Executive Team, Council of Deans of Health |
| Jackie Landman | Nutrition Society & Patient representative |
| Joyce Cairns | Department of Health, Social Services and Public Safety for Northern Ireland (DHSSPSNI) |
| Kate Horsfield | DH Secretariat |
| Kathryn Halford | National Governance Group / Skills for Health |
| Marc Seale | Health Professions Council (HPC) |
| Martha McLean | DH Secretariat |
| Mike Pittilo | Chair of Complementary and Alternative Medicine (CAMS) Regulation Working Party |
| Nick Grimshaw | Blackpool, Fylde and Wyre Hospital Foundation Trust |
| Rosemary Macalister-Smith (deputy Douglas Bilton) | Council for Healthcare Regulatory Excellence (CHRE) |
| Sandra Verkuyten | Hearing Aid Council |
| Sarah Goodson | Basingstoke and North Hampshire NHS Foundation Trust |
| Stewart Rouse (deputy Gail Adams) | UNISON |

# Annex C: Summary from the Stakeholders' Conference 5 June 2007

The following comments were generated across the two sessions on Extending Professional Regulation, held at the 5 June event:

**Terms of Reference**

- Need to define and agree terms, such as post-registration specialist, within the same profession, across many professions, and those that in undertaking this may move into a new profession;
- Part of this must be to articulate the difference between registration threshold and post registration specialisms;
- The way in which some practitioners combine the specialist practice within existing role and others shift entirely to the specialist practice and develop further into new role. How then is this element both recognised as higher level practice and the new role recognised for the purpose of patient safety;
- Consider the scope of regulation, particularly in relation to function rather than title;
- There needs to be acknowledgement of where roles/standards overlap between health & social care and children's services;
- 'Distributed' regulation needs to avoid dual regulation but look across common standards;
- The potential for problems and cost implication of common standards across professions/regulators without stifling movement/development. Link to CHRE's work on common standards where functions/competencies are shared by regulators;
- In terms of timing, the process needed speeded up so that further delays were avoided where professions had already been waiting a long time for statutory regulation. This was for two reasons: firstly so momentum was not lost on roles that were being supported and developed and secondly for patient and professional safety;
- The issue of UK wide transferability was mentioned, plus the need to agree standards, roles, titles across the board as well as develop employer and service provider guidance. The European context must also be taken account of;
- Over-regulating needed to be avoided. It should not be specialisms that are individually regulated, but generic professions, especially to ensure flexibility of the workforce;

- The consequences of introducing regulation if those unhappy with the agreed way forward avoided the system by just renaming themselves;

- This links to the fact that as healthcare generally advances traditional skills or practices done by one profession may shift to another as it becomes more routine, or there are simply more tasks for the profession to do;

- The development of the multi-disciplinary approach as well as the context of care has affected the scope of roles indirectly. It will continue to do so in the foreseeable future;

- Group must consider if dispersing responsibility from existing regulated profession to new regulated group is the right way forward – may be against public safety;

- Regulation of roles at different levels needs also to be considered. It may be on a spectrum that covers both assistants as well as professional;

- The issue of which regulator might regulate was also raised;

- There should be some consideration of Fitness to Practise and Fitness for Purpose.

**Criteria**

- Work needs to be done to define the level of risk posed by different aspirant groups in order to generate a priority to regulate across a spectrum of risk, taking into account things such as the volume of practitioners and the opportunity for such things as abuse. It must also acknowledged that that risk is not necessarily just about the most dangerous procedures;

- The criteria must be the key to decisions by working group, including elements such as is it in interest of patients, the potential for regulation to reduce availability of workforce, that regulation can drive up standards not just tackle bad apples. It should also reflect on how it works for existing regulatory professions, to see if lessons can be learnt;

- The different entry routes and arrangements for CPD need to take account of different employment settings, and must also link with the non-medical revalidation working group;

- The aspiration of the profession to be regulated, and their understanding of this must also be considered. Tension can develop between the academic and regulatory aspirations of professions and the actual service providers' and users' needs;

- Protect public against own lifestyle choice (tattooists, cosmetic contact lenses), some of which is done by local authorities already in England and in Scotland covers acupuncture as well;

- Efficacy should not be over – emphasised (important to decide funding, but not at the risk of public safety);

- The issue of voluntary registers needs looking at further as not all groups understand why this is important.

**Membership**

- There is a need for a wide input of stakeholders into the working group, from comments, feedback as well as input into its work;

- Members of the group need to be able to contribute to the wider debate, not just represent interests of groups wanting to be regulated or the service or the regulators;

- However, it would be useful to receive evidence from newly regulated or to be regulated professions, to hear their experiences. Or perhaps some individual practitioners that work in these new roles that need to be considered. They would be able to give unique voice to the impact of regulation and the problems they are currently experiencing without it or with only existing professional regulation behind them;

- Members also need to cover the independent sector and other employers than just the NHS;

- It needs to be inclusive before decisions are made, including strong patient and user representation. If there is to be a wider reference group then there must be balance as to where representatives go. For example, education and training commissioning play a crucial role in supporting development, but often unaware of regulatory aspects. There needs to be real engagement with such a reference group so that it can really contribute to the process and not just rubber stamp the decisions at the end.

# Annex D: Proposal for Research

## Professional Regulation: Risk & Regulation

### 1. Background

1.1 The Government is committed to improving public safety, and is currently reviewing professional regulation across the UK, as set out in the White Paper "Trust, Assurance, Safety – The Regulation of Health Professionals in the 21st Century". The review concluded that the approach to extending regulation in the UK does not necessarily target the most important groups and roles, in order to provide the best protection of public safety.

1.2 Additionally, the Better Regulation Executive (BRE) which is part of the Department for Business, Enterprise, and Regulatory Reform (BERR) recommends that regulation should be risk-based, proportionate, consistent, and targeted only at cases where regulation is needed.

1.3 Therefore, the White Paper tasked a Working Group of experts with the following:

*Task 1.* "**develop criteria to determine which roles should be statutorily regulated;**

*Task 2.* **discuss with the Devolved Administrations and key stakeholders whether a formal mechanism should be devised to consider the national need for new roles and the regulation of new roles;**

*Task 3.* **assess that role's state of readiness for regulation against agreed criteria, such as those used by the Health Professions Council;**

*Task 4.* **explore the practicality of a system of distributed regulation, including its relationship to revalidation, in which a lead regulator will set the standards against which a practitioner will be recognised and judged. This would apply to already statutorily regulated professions and ensures that all professional groups – irrespective of parent regulator - meets, and is judged against, the same set of standards for an area of practise, irrespective of professional title or regulatory body with which registered;**

*Task 5.* **evaluate the results of the Scottish pilot study [into regulation of healthcare support workers] and consider the way forward with stakeholders;**

*Task 6.* **consider whether there is sufficient demand for the introduction of statutory regulation for any assistant practitioner roles at levels 3 and 4 on the Skills for Health Career Framework."**[11]

1.4 The group has agreed that in order to deliver these tasks further research is required.

### 2. Business Need

[11] Trust, Assurance and Safety – The regulation of health professionals in the 21st century; Department of Health

2.1 The Working Group considers that in order to protect public safety and meet the recommendations of the BRE, the main driver for considering extending statutory regulation to an occupational group or profession should be the **risk** associated with that occupational group or profession; based on what they do, where they do it and the supervision arrangements in place. This risk can then be compared to the costs and benefits of regulating that role, to ensure it is proportionate.

2.2 There is no clear method of assessing risk associated with healthcare roles in the UK. Yet there are standardised approaches to categorising roles and responsibilities – particularly within the NHS

1. The Skills for Health Career Framework[12]
2. The Knowledge and Skills Framework (KSF)[13]
3. The NHS job evaluation tool[14]

The Working Group considers that an analysis of the risk associated with different bands or levels, using tools currently available and in use, would be beneficial to the work of the group.

2.3 In order to inform future decisions on extending professional regulation, the Government requires an analysis tool for assessing the risk associated with individual healthcare roles.

2.4 The Government acknowledges that statutory regulation is not the only solution to improving public safety, and that it may not be the most effective method for all healthcare roles. There may be lessons to be learnt from European and international models of regulation.

## 3. Objectives

3.1 Undertake an assessment of the risk to public associated with different roles in the NHS and outside the NHS, using the Skills for Health framework as a basis;

3.2 Provide a risk-analysis tool that can be applied by the Government and Regulatory Bodies when considering the impact on public safety of extending statutory regulation;

3.3 Evaluate alternative models to statutory regulation, including methods used internationally, voluntary registers, and employer-led models. Make recommendations about when these models would be most appropriate.

## 4. Timing

The Working Group requires this piece of work to be undertaken as soon as possible. The group is due to produce their first draft of the final report on Extending Regulation by September, so this research is required to be concluded by then.

## 5. Resources

In order to achieve the objectives of this piece of work, we require academic experts who have a background in undertaking research into healthcare workforce issues, including professional regulation.

## 6. Interdependencies

The Non-Medical Revalidation Working Group is also looking at the risk associated with various healthcare roles and is interested in the outcomes from this work.

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[12] http://www.skillsforhealth.org.uk/page/career-frameworks

[13] The NHS Knowledge and Skills Framework (NHS KSF) and the Development Review Process Department of Health, October 2004

[14] NHS Job Evaluation Handbook 2nd Edition; Department of Health, October 2004

# Annex E: Proposed criteria for assessment of state of readiness for statutory regulation (amended from the Health Professions Council criteria)[15]

i) The scope of practice of the profession, or occupation must have been agreed and defined. If not, it will not be possible to pursue statutory regulation further, until such time as agreement about the function and scope of practice exists.

ii) The defined scope of practice must be clearly separate from the scope of practice of existing statutorily regulated professional and occupational groups. If it is, then the role may be considered appropriate for statutory regulation. If the scope of practice is similar to that of an existing statutorily regulated professional group, then the role may be more appropriately regulated through voluntary means by one of the existing professional bodies linked to the statutorily regulated group.

iii) In the case of existing statutorily regulated professional groups, if the scope of practice differs significantly from that required for initial entry to the register, such as in the case of certain advanced or "expanded scope" practitioners, then an annotation to the existing register where the practitioner's name appears may be more appropriate than additional registration. In many cases this annotation will be statutorily necessary and the additional standards achieved and educational and competency requirements must be clearly defined. This might be appropriate for those practising in areas where there is a statutory requirement to meet standards and qualifications, such as prescribing roles or roles in another profession eligible for distributed regulation.

iv) Is there evidence of entry points from different professional or occupational backgrounds? If so, this may be an appropriate scenario for the model of distributed regulation which consists of a lead regulator setting and applying standards for the profession, which the original regulator may then annotate on its register in respect of practitioners already registered in another profession.

v) There must be a clear demand for the profession or occupation from employers or service users. However, demand should be measured not only in terms of numbers of posts, but there should also be evidence that the role creates a benefit for people using healthcare services. If a role is only deployed locally, then it may be for the employer to control/regulate practice.

[15] http://www.hpc-uk.org/aboutregistration/newprofessions/criteria/
"Trust, Assurance, Safety – The Regulation of Health Professionals in the 21st Century", para 7.11 page 83. TSO 2007.

vi) There must be defined minimum standards for practice which are independently assessed. If these do not exist, then they should be developed before statutory regulation can be considered.

vii) Agreed and accredited training designed to meet the required standards must exist, if it does not already then it needs to be established before statutory regulation can be considered.

viii) A voluntary register should normally be established prior to statutory regulation being taken forward, as it is necessary for transition onto the statutory professional register. The statutory register must contain only registrants who are deemed fit to practise on the day it is opened.

ix) Agreed standards in relation to conduct, performance and ethics must be developed prior to consideration for statutory regulation.

x) Fitness to Practise procedures for conduct and capability must have been developed to enforce those standards. If not, these should be progressed prior to consideration for statutory regulation.

xi) A system should be in place to ensure that practitioners remain competent to practise after registration, or there should be plans in place to implement such a system.

xii) There should be standards around continuing professional development and a demonstrable commitment on the part of any representative bodies to this.

xiii) Assuming all other criteria have been met, the suitability of non-statutory forms of regulation should have been considered and there should be a compelling argument for transferring any existing system of non-statutory regulation to a statutory system.