Council, 17 September 2010

CHRE report – Managing extended practice

Executive summary and recommendations

Introduction

In July 2010, the Council for Healthcare Regulatory Excellence (CHRE) published their report 'Managing extended practice – Is there a place for "distributed regulation"?'

The attached paper discusses the conclusions and recommendations made in the report. A copy of the CHRE report is included.

Decision

The Council is invited to discuss the attached paper.

Background information

None.

Resource implications

None.

Financial implications

None.

Appendices

- CHRE report - 'Managing extended practice – Is there a place for "distributed regulation"?'

Date of paper

27 August 2010

Council for Healthcare Regulatory Excellence – Managing extended practice report

1. Introduction

1.1 The Council for Healthcare Regulatory Excellence (CHRE) is sometimes commissioned by the Department of Health to explore a discrete topic and provide advice.

1.2 In January 2010 the CHRE commenced a project to look at how regulators manage situations where health professionals extend their scope of practice to an area where another regulator or professional body may set standards.

1.3 The CHRE were asked to explore whether a model of 'distributed regulation' would be a suitable response to these issues. The distributed regulation model proposes that where professionals extend their practice into another profession's area of practice, they should be required to meet a set of standards agreed by all the relevant regulators.

1.4 In January 2010 the CHRE issued a 'Call for Information' seeking the views of stakeholders on this topic. The Executive responded in February 2010. The final report was published in July 2010.[1]

1.5 This paper summarises and discusses the CHRE report, highlighting key areas for discussion by the Committee. The paper is divided into five sections:

- Section one explains the background to the CHRE report.
- Section two discusses the concept of distributed regulation and looks at how the concept has developed in several policy documents.
- Section three looks at the concept of extended practice and considers how the HPC currently regulates individuals who extend their practice.
- Section four summarises the conclusions and recommendations made within the report.
- Section five identifies points for discussion and consideration.

1.6 References to paragraphs and page numbers shown in brackets are references to the CHRE report.

2. Distributed regulation

2.1 The CHRE report was commissioned to consider the concept of 'distributed regulation' and whether this model of regulation might be suitable for regulating professionals undertaking advanced practice. As the report recognises, the concept of 'distributed regulation' has been

[1] CHRE, Managing extended practice – Is there a place for 'distributed regulation', July 2010 http://www.chre.org.uk/_img/pics/library/100705_Managing_Extended_Practice_Report_FINAL2.pdf

explored in several policy documents and has changed over time (paragraph 4.1, page 7).

2.2 The concept was first discussed in 'The regulation of non-medical professionals: a review by the Department of Health', also known as the 'Foster review', which was published in 2006.[2] The Foster review focussed on the regulation of the non-medical professions, whilst a similar review focussed on the regulation of doctors.[3]

2.3 Distributed regulation was explored in the Foster review as a way of regulating a range of new roles (including surgical care practitioners, anaesthesia practitioners and emergency care practitioners). Often these roles were undertaken by individuals already within statutory regulation, including nurses, operating department practitioners and paramedics.

2.4 Under the proposed model of 'distributed regulation' one regulator would set standards for the whole profession, which all practitioners would have to meet. Individuals who were already regulated would remain with their existing regulator (for example, paramedics would continue to be registered with the HPC) and would demonstrate that they met the additional standards for their new profession.

2.5 The model was proposed to reduce the need for dual registration and also to reduce the costs associated with regulating the profession. It would also ensure appropriate input into the setting of standards.

2.6 The concept of distributed regulation was also considered in the White Paper produced in response to the reviews identified above.[4] The White Paper included a commitment to explore the practicality of a system of distributed regulation, with one 'lead' regulator setting the standards and registering most practitioners, including those who accessed the profession directly.

2.7 Several working groups were established to take forward the recommendations within the White Paper, including the Department of Health Extending Professional and Occupational Regulation working group. This group looked at recommendations on extending the scope of professional and occupational regulation, including distributed regulation.[5]

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[2] 'The regulation of non-medical professionals: a review by the Department of Health' http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137239

[3] 'Good doctors, safer patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients' http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137232

[4] 'Trust, Assurance and Safety: the regulation of health professionals in the 21st century' http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946

[5] Extending professional and occupational regulation report http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_102824, page 47-48

2.8 The group suggested that a system of distributed regulation could be used to regulate individuals who were registered with one regulator but wanted to widen their scope of practice to include standards set by another regulator.

2.9 The report used podiatric surgery as a way of testing this model of distributed regulation. Under this model, a podiatrist who wanted to undertake podiatric surgery would be registered with the HPC. They would also have to meet practice standards agreed by the Royal College of Surgeons and the Society of Chiropodists and Podiatrists. The standards would be endorsed by the General Medical Council and accepted by the HPC.

2.10 The report identified several advantages of this model of distributed regulation, which were similar to those identified in the Foster review above. The report also identified several disadvantages associated with the proposed model around distributed regulation. It acknowledges that distributed regulation might make the system of professional regulation more complex and confusing for patients and the public. As a result, the report recommended that further work be undertaken to explore the practicalities of distributed regulation.

2.11 The CHRE were then commissioned to consider the concept of distributed regulation. In their call for information and in the subsequent report, distributed regulation is proposed as a way of managing situations where health professionals extend their practice into areas where other regulators or professional bodies set standards. They propose that the regulator which regulates the individual would seek input from other bodies to determine the standards which should be set.[6]

2.12 The CHRE propose distributed regulation as a way of allowing regulators to manage issues of dual registration in a more coordinated and cost-effective way. The CHRE also identified a number of advantages and disadvantages associated with distributed regulation, similar to those in the working group report (paragraph 5.1 and table, page 9).

2.13 As can be seen from the summary above, there has been a move in how distributed regulation has been perceived. When the idea was proposed in the Foster review, distributed regulation was seen as a way of regulating new roles which were undertaken partly by individuals who were already regulated and also by those who accessed the profession directly. The model was used to ensure that individuals who were already regulated would not need to be registered again, but also to ensure a direct entry route into a profession for those who were unregulated.

2.14 In the CHRE report, distributed regulation is proposed as a model to manage regulated individuals who have extended their practice into areas where standards are set by a different organisation. This model moves

[6] CHRE Distributed Regulation – A call for information, page 1, Managing extended practice, paragraph 1.3, page 1

away from the regulation of a new profession (albeit a profession which can be entered by already regulated individuals), into consideration of how to regulate extended or advanced practice.

2.15 The focus of the CHRE model of distributed regulation appears to be ensuring that regulators obtain the appropriate input from stakeholders when setting standards. This is particularly relevant where the area of practice for which the standards are being set overlaps with an area of practice which falls within the remit of another organisation (paragraph 1.3, page 1).

3. The HPC and extended practice

3.1 The CHRE report uses the term ‘extended practice’ to mean those circumstances where a registered health professional, as part of their primary role, undertakes clinical tasks or roles associated with another profession. This could be in an area of practice overseen by another regulator, or an unregulated area. Extended practice does not however include the separate practice of two distinct professions (paragraphs 2.1 – 2.2, page 2).

3.2 The report features a number of examples of ‘extended practice’ including podiatric surgeons and emergency care practitioners. Podiatric surgeons are trained podiatrists who undertake surgery on the foot whilst emergency care practitioners are either paramedics or nurses who undertake additional training to provide care to patients in non-elective settings.

3.3 The CHRE report identifies two main areas of risk to patient safety associated with registered professionals extending their scope of practice (paragraph 3.1, page 4). They are:

- Professionals and their supervisors may be unclear about the standards for their extended practice
- Regulators may not have the necessary systems to manage complaints about areas of extended practice

3.4 The CHRE report notes that some regulators, including the General Dental Council, have produced guidance on the activities its registered professionals are trained and competent to undertake. We do not prescribe the areas in which registrants can practice (paragraph 3.3, page 4).

3.5 The practice of our registrants may well move into areas which would fall within the definition of extended practice within the CHRE report. Some registrants may move into areas regulated by other regulators, for example podiatric surgeons. Other registrants may practice in areas which are unregulated, such as physiotherapists who use acupuncture within their practice.

3.6 A registrant must be able to practise safely and effectively. This requirement is written into both the standards of proficiency and standards

of conduct, performance and ethics. The standards of conduct, performance and ethics say:

'You must be capable of meeting the standards of proficiency that apply to your scope of practice. We recognise that your scope of practice may change over time…. You need to make sure that whatever your practice, you are capable of practising safely and effectively.'[7]

3.7 Registrants must sign declarations to say that they have read these standards and also that they continue to meet the standards for their area of practice.

Complaints about registrants with extended practice

3.8 One of the risks identified by the CHRE associated with extended practice is that regulators may not have the necessary systems to enable them to deal with complaints about extended practice.

3.9 We have previously considered complaints about registrants who have extended their scope of practice into specialised or advanced areas where they have undertaken additional post-registration qualifications.

3.10 All registrants must ensure that they have the skills, knowledge and experience necessary to practise safely and effectively in their particular scope of practice. When considering these complaints, panels may seek to understand how the registrant's practice has developed into their current scope of practice. This may include looking at the individual's post-registration training, knowledge and experience.

3.11 Panels have the power to consider expert evidence or standards or guidance produced by other organisations if this is considered relevant to the circumstances of the particular case. However, any final decision made by the panel is based on the standards that we have set as the decision may impact the individual's registration with us.

3.12 The absence of standards published by us that relate to a particular specialist area (whether or not the area is annotated on the Register) does not prevent the investigation of cases involving registrants who have an extended scope of practice and in no way fetters our ability to take appropriate action to protect members of the public.

Annotations of the Register

3.13 The CHRE report recognises that regulators can play a role in managing the risks of extended practice. One way of doing this is through annotations of the register to show where a professional has completed a post-registration qualification or acquired additional skills and competence in a particular field.

[7] HPC, Standards of conduct, performance and ethics, paragraph 5
http://www.hpc-uk.org/publications/standards/index.asp?id=38

3.14 Currently we annotate our Register to indicate where a registrant has undertaken additional training around medicines and has obtained entitlements to supply, administer or prescribe these medicines. We are required to do this by legislation called 'The Prescriptions Only Medicines (Human Use) Order 1997'.

3.15 Annotating post-registration qualifications on the Register allows us to set standards for that annotation and quality assure the education programmes which deliver the qualifications.

4. Conclusions and recommendations from the CHRE report

4.1 The CHRE draw the following conclusions:

- There is no fitness to practise evidence to suggest that there are a disproportionately high number of cases or any particular issues for professionals working in the extended roles identified within the report.
- The areas of risk associated with extended practice are managed by a range of organisations and individuals.
- Good regulation should be shared across a wide range of stakeholders, including individuals, employers and regulators.
- Regulators do not need to set standards for clinical practice for areas they currently regulate or for areas of practice which are unregulated.
- Fitness to practise cases involving extended practice should rely on expert advice where appropriate.
- Extended practice can be managed using the tools that regulators currently have at their disposal.
- There is no need for additional regulation or for the development of a new model of regulation.

4.2 The CHRE report recommends several approaches for different instances of extended practice (paragraphs 7.4 – 7.5, page 12-13):

- Registration should remain with the existing regulator where the employer has identified an extended role which builds on a primary function linked to that registration. In this case, the employer should be confident that the individual has the skills, knowledge and experience to undertake that work.
- Dual registration should continue where practitioners are undertaking two distinctly separate roles which require distinct registration.
- Where a registrant extends their scope of practice into unregulated areas, the standards should make clear that they should only do so in line with agreed good practice.
- The regulator could annotate their register or hold special lists to take account of situations where registrants extend their practice and pose greater risks to the public or require additional standards of proficiency. However, annotations should only happen on an exceptional basis.

4.3 The report recommends several principles which should be adopted by individuals, employers, regulators and governments when managing areas of extended practice. These are discussed below, alongside information about how we meet the principle.

Principle: Employers should have the appropriate support and performance management systems in place where it employs registrants in extended roles.

4.4 This principle relates to the role of employers, who we do not regulate.

Principle: Registered health professionals should only practice in areas that they are competent to do so; they are responsible for the services they provide to service users.

Principle: Regulators should ensure that their codes of conduct adequately reflect the requirement for health professionals to stay up to date and to operate safely within their areas of competence.

4.5 These two principles have been grouped together as the standards that we set help to ensure that registrants only practice in areas they are competent to do so and take responsibility for the services they provide.

4.6 All registrants are required to practice within their scope of practice. Scope of practice is defined as the area in which a registrant has the skills, knowledge and experience to be able to practise legally, safely and effectively. The requirement to practice only within the scope of practice is clearly stated within the standards of conduct, performance and ethics, as outlined in paragraphs 3.6 to 3.7.

4.7 This requirement is also written into the standards of proficiency for each of the professions that we regulate. Each time a registrant renews their registration, they must sign a declaration to say that they continue to meet the standards of proficiency relevant for their scope of practice.

4.8 All registrants are required to undertake continuing professional development (CPD) in order to maintain their registration. CPD can be used by registrants to develop their practice but also as a way of ensuring that they remain up to date.

4.9 These two sets of standards in combination with the CPD requirements reflect the need for registrants to stay up to date and operate safely.

Principle: Regulators should only pursue the option of creating a specialist list or annotation on the register when all other approaches have been exhausted.

4.10 Currently we annotate our Register to indicate where a registrant has undertaken additional training around medicines and has obtained entitlements to supply, administer or prescribe these medicines. We are legally required to do this (see paragraphs 3.13 to 3.15 in this paper).

4.11 We are developing some draft criteria which will enable us to make clear and reasoned decisions about whether a qualification is annotated on our Register. We believe that a qualification should be annotated on our Register only where there is a risk to the public if the Register is not annotated.

Principle: The Secretary of State for Health and Ministers in the Devolved Administrations should assess any application to change legislation in relation to specialist lists or annotations on a register solely against the risks posed to patient safety and public protection.

4.12 This principle relates is not within the HPC's remit.

Principle: All parties should demonstrate an active commitment to cooperating and sharing information to manage risks to patient safety and public protection.

4.13 One of the ways in which we manage risks to patient safety and ensure public protection is by setting standards which registrants must meet to be able to practise safely and effectively. We consult with relevant stakeholders whenever we set standards or produce guidance.

4.14 This consultation process ensures that we cooperate with stakeholders and can take account of their expertise in a particular area where appropriate.

4.15 Our fitness to practise process also helps to ensure public protection, by taking action where registrants do not meet the standards that we set. The final decisions of our fitness to practise panels are published on our website so that they can be accessed by stakeholders.

4.16 We have powers to take action against a registrant following a finding of impairment by another regulator. In addition, where we find impairment and we know that a registrant is also registered with another regulator, we will contact that regulator to give them our decision.

4.17 As the report identifies, employers play an important role in managing the risks associated with extended practice. We do not regulate employers, but have set up a series of regular 'employer' events. The purpose of these meetings is to share information with employers and to give them the opportunity to discuss issues with us. These events are a useful way of explaining how the responsibilities to protect the public differ between regulators and employers.

5. Discussion

5.1 Distributed regulation as currently conceptualised emphasises the importance of engagement, consultation and partnership working when setting standards.

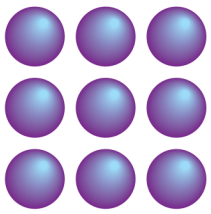
5.2 The Executive concludes that the HPC meets the principles recommended by the CHRE for managing extended practice.

5.3 The Executive concludes that no specific actions are necessary but the Council is invited to discuss the principles outlined in the report and any other relevant areas.

Managing extended practice

Is there a place for 'distributed regulation'?

June 2010



council for healthcare regulatory excellence

About CHRE

The Council for Healthcare Regulatory Excellence promotes the health and well-being of patients and the public in the regulation of health professionals. We scrutinise and oversee the work of the nine regulatory bodies[1] that set standards for training and conduct of health professionals.

We share good practice and knowledge with the regulatory bodies, conduct research and introduce new ideas about regulation to the sector. We monitor policy in the UK and Europe and advise the four UK government health departments on issues relating to the regulation of health professionals. We are an independent body accountable to the UK Parliament.

Our aims

CHRE aims to promote the health, safety and well-being of patients and other members of the public and to be a strong, independent voice for patients in the regulation of health professionals throughout the UK.

Our values and principles

Our values and principles act as a framework for our decision making. They are at the heart of who we are and how we would like to be seen by our stakeholders.

Our values are:

- Patient and public centred
- Independent
- Fair
- Transparent
- Proportionate
- Outcome focused

Our principles are:

- Proportionality
- Accountability
- Consistency
- Targeting
- Transparency
- Agility

Right-touch regulation

Right-touch regulation is based on a careful assessment of risk, which is targeted and proportionate, which provides a framework in which professionalism can flourish and organisational excellence can be achieved. Excellence is the consistent performance of good practice combined with continuous improvement.

1 General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), Royal Pharmaceutical Society of Great Britain (RPSGB)

Contents

1. Introduction

1.1 Health professionals are increasingly extending their practice into areas overseen by other regulators, such as podiatrists undertaking surgery, or into areas that are currently unregulated, such as nurses performing acupuncture. These extended roles can deliver benefits for patients and the public and provide development opportunities to professionals, whilst enabling health services to react flexibly to the increasing pressures being imposed upon them.

1.2 The Secretary of State for Health and Ministers in the Devolved Administrations asked CHRE to provide advice and recommendations on how regulators might respond in these circumstances. This paper outlines how thinking around 'extended practice' has evolved, identifying the risks associated with the extension of practice and assessing how regulators currently deal with these circumstances.

1.3 We were also asked to consider a proposed model of 'distributed regulation' as a response to these issues. Under this approach, professionals who extend their practice into another profession's domain would be subject to a set of standards agreed by all the regulators. Instead of requiring professionals to be dually registered, meeting the standard would be indicated by a marking or 'annotation' on their original register entry.

1.4 This work follows our report on *Advanced Practice*[2] in 2009, which examined whether advanced practice is a regulatory issue. It concluded that much of what is called advanced practice reflects career development and does not warrant additional statutory regulation. However the report went on to say:

'If an area of practice within a profession develops which poses different types of risk to patients and requires new standards of proficiency to be performed safely, which are clearly distinct from the range of those ordinarily associated with the profession, regulatory bodies need to ensure their processes capture this.'

1.5 To inform this report, we issued a *Call for Information*[3] to the regulators, stakeholder organisations, professional bodies, Royal Colleges and our public and professional networks to understand some of the issues associated with professionals who extend their practice and their views on the proposed model of distributed regulation. A list of respondents can be found in Annex 1.

1.6 This report is underpinned by a focus on public protection and patient safety, and is guided by our firm belief in the value of right-touch regulation.[4] It explores the issue from the perspective of identifying the risks and the appropriate response to them. It does not make any judgements on the appropriateness of professionals undertaking certain clinical practices.

2 CHRE. 2009. *Advanced Practice*. London: CHRE.
3 CHRE. 2010. *Distributed regulation – A call for information*. London: CHRE.
4 Right-touch regulation is based on a careful assessment of risk, which is targeted and proportionate, which provides a framework in which professionalism can flourish and organisational excellence can be achieved. Excellence is the consistent performance of good practice combined with continuous improvement.

2. What do we mean by 'extended practice'?

2.1 We use the term extended practice to describe those circumstances when a registered health professional undertakes clinical tasks or roles usually associated with another profession.[5] It may be that an individual is only occasionally required to use a skill associated with extended practice. Throughout this report, however, we use the term when these tasks are performed as part of the health professional's *primary* function. This could be in an area of unregulated practice, or in an area currently overseen by another regulator.

2.2 Extended practice does not refer to the separate practice of two distinct professions – this is explored in Section 5. We focus only on registered professionals, and therefore have not considered the issue of unregulated practitioners working in unregulated areas. Neither have we considered the regulatory issues that would arise when a new healthcare role is carried out by someone who had not previously qualified and registered as a health professional, for example individuals who directly enter roles such as physician assistants.

2.3 Extended practice includes the development of a number of new healthcare roles that have required a registered health professional to extend their practice into areas formerly associated with another profession. This happens frequently within the NHS. We are aware, for instance, that there are approximately 690 emergency care practitioners in England[6] and approximately 160 podiatrists who undertake surgery in the UK.[7] These new roles are not statutorily regulated in their own right. Details about some of their responsibilities and training requirements are provided below.

Emergency care practitioners
Emergency Care Practitioners provide care to patients in non-elective settings using the skills of paramedics and other professionals, such as specialist nurses.[8] They are required to be registered with the NMC or the HPC as nurses or paramedics respectively, and to have undertaken additional training usually with a higher education institution.[9]

Physician assistants (anaesthesia)
Physician assistants (anaesthesia) are qualified to administer anaesthesia under the supervision of an anaesthetist (a medically qualified doctor). Practitioners undertake a 27 month programme of postgraduate training, which leads to a Postgraduate Diploma in Anaesthetic Practice. Their scope of practice is defined by Department of Health guidance,[10] with their competencies developed and assessed by the Royal College of Anaesthetists.

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5 This does not include any managerial or administrative duties that an individual may undertake.
6 The NHS Information Centre
7 The Society of Chiropodists and Podiatrists
8 NHS Careers
9 NHS Jobs
10 Department of Health. 2007. *A toolkit to support the planning and introduction of training for anaesthesia practitioners*. London: DH; Department of Health. 2007. *The Anaesthesia Practitioner Curriculum Framework*. London: DH

Podiatrists who undertake surgery

Podiatrists who undertake surgery are registered with the HPC, have undertaken post-registration training and are able to surgically manage bone, joint and soft tissue disorders within the foot, often under local anaesthetic. After a three year undergraduate degree in podiatric medicine, graduate podiatrists must complete a minimum of one year's post-registration practice before commencing a Masters degree in the Theory of Podiatric Surgery. Completion of the Masters and a further two years of surgery training (minimum) leads to Fellowship of the Society of Chiropodists and Podiatrists' Faculty of Podiatric Surgery.[11]

11 The Society of Chiropodists and Podiatrists and advice from the Scottish Government Health Department.

3. How do the regulators currently manage extended practice?

3.1 There are two main areas of risk to patient safety that might be associated with registered professionals extending their practice:

- Professionals (and their supervisors) might be unclear about the standards for practice that they should be working to in their extended role
- Regulators might not be equipped to manage fitness to practise issues in areas of extended practice.

In this section we discuss how the regulators are currently managing extended practice, illustrating how these new risks are handled with existing regulatory approaches.

3.2 The regulators state in their codes of practice that their registrants must only practice where they are competent to do so. The GCC, for instance, states that 'Chiropractors must recognise and work within the limits of their knowledge, skills and experience'.[12] This places the onus on the health professional to know the limits of their professional practice, and to operate within it. The codes also place the emphasis on the professional to stay up to date in their professional knowledge, skills and practice. See Annex 2 for details of how each regulator addresses these issues. These expectations consequently inform the standards against which concerns about fitness to practise can be assessed.

3.3 Some of the regulators, such as the GDC, have produced guidance on the activities its registered professions are trained and competent to undertake. The HPC has taken a different approach. They do not collect information on scope of practice, nor do they prescribe the areas in which their registrants work, 'Instead, registrants must ensure that they practice safely and effectively within their chosen scope of practice'.[13] The GOsC is currently developing its scope of practice for osteopaths, but reaffirmed that 'regulators should regulate the whole practice of those they register'.

3.4 Some regulators told us that registered professionals who use unregulated (e.g. complementary) therapies in their practice are still subject to the regulator's standards of ethics and behaviour. The GDC told us that these standards still apply even if these therapies are used outside of dental treatment. The NMC Code states that 'You must ensure that the use of complementary or alternative therapies is safe and in the best interests of those in your care'.[14] Codes also make provision for ensuring that patient and public trust in the profession is not undermined by a registrant's practice. We note that there may be additional risks associated with registered professionals undertaking unregulated practices; that a patient may make an assumption about the evidence base of certain treatments.

3.5 Responses to our call for information highlighted a number of examples of regulators working together to manage regulatory issues when professionals' practice is extended.

12 GCC. 2005. *Code of Practice and Standard of Proficiency December 2005 to June 2010*. London: GCC.
13 HPC response to our Call for Information.
14 NMC. 2008. *The code*. London: NMC.

3.6 *Example 1: Oral and maxillofacial surgeons*
It used to be the case that oral and maxillofacial surgeons had to be dually registered with the GDC and the GMC. The legal requirement to hold dual registration was removed as both regulators saw it as unnecessary and over-burdensome. Oral and maxillofacial surgery[15] is a medical specialty and in order to be included in the GMC's specialist register, these practitioners are now only required to be registered with the GMC. The legal requirement to be dually *qualified* remains. The GMC told us:

'…it was felt to add no regulatory value in terms of public protection, but did impose a financial and regulatory burden on the practitioners concerned...A small number of doctors have chosen to retain their dual registration, but the public does not receive an additional layer of protection where this is the case.'

3.7 *Example 2: Doctors and sight tests*
The GOC told us that 'the Opticians Act 1989 enables both a registered optometrist (registered with the GOC) and a registered medical practitioner (registered with the GMC) to test the sight of another person and fit and supply optical appliances.' On the 'rare occasions' that a complaint has been made to the GOC involving a doctor performing a sight test, it has been referred to the GMC.

3.8 *Example 3: Dentists* and *radiography*
The GDC told us that dentists often have to carry out additional practices for which they are not separately registered. This includes taking and interpreting radiographs.[16] This is allowed through their GDC registration and as such, they are not required to be registered as radiographers (through the HPC). The GDC requires dentists who undertake this practice to follow the relevant current standards, and would seek appropriate expert advice as part of any investigation of concerns about a professional's fitness to practise.

3.9 *Example 4: Maxillofacial prosthetists and technologists*
The GDC told us that maxillofacial prosthetists and technologists (MPTs)[17] were intended to be a distinct dental care group, to be registered with the HPC. However, this transition has not taken place, and the group remains registered as dental technicians in the knowledge that 'their scope of practice goes far beyond that of other registered dental technicians'. In the event of a fitness to practise case, the GDC told us that suitable expert advice would be sought.

3.10 *Example 5: Bassilious v GMC (2008)*
This case concerned an anaesthetist who carried out, on a part-time basis, conscious sedation in a dental surgery. He was still functioning as a medical practitioner, but guidelines on the use of conscious sedation had been produced by the Department of Health in relation to primary dental care. The GMC's case made extensive use of the guidelines. The Panel treated the guidelines as 'not totally

15 Oral and maxillofacial surgery is the surgical specialty concerned with the diagnosis and treatment of diseases affecting the mouth, jaws, face and neck.
16 Similarly chiropractors, in their pre-registration training, have to demonstrate that they are competent to take and interpret x-rays. When they perform these functions they are required to comply with the relevant legislation (GCC response to our Call for Information).
17 MPTs are responsible for restoring function and appearance to patients following surgery, trauma or an abnormality.

binding' but 'one of a number of sources to which he was properly required to have regard in order to determine how to practice safely.'[18]

3.11 *Example 6: Sharing information*
The HPC, NMC[19] and GOC told us that they have the power to take action against a registrant following a finding of impairment by another regulator. We understand that the other regulators have a similar ability to take action in these circumstances.[20]

3.12 These examples illustrate to us how regulators are taking a pragmatic and proportionate approach to regulating practice that transcends traditional professional boundaries. These examples have not involved the introduction of additional or complex systems of regulation but require regulators to share information with each other where care crosses traditional boundaries. We support this approach. Interrogation of CHRE's fitness to practise data has not revealed any specific issues, or a disproportionately high number of cases, for professionals in the extended roles identified in Section 2.

18 Legal advice received by CHRE. *Bassilious v General Medical Council* [2008] EWHC 2857
19 The Nursing and Midwifery Order 2001 (Article 11 (1)(a)(v)) gives the NMC the power to take action following a finding from another body
20 PSNI raised a concern that misconduct issues for dual registrants could come to the attention of one regulator but not the other. This can be an issue for individuals practising in more than one profession, or in the same profession in different countries. In response, PSNI has developed an information sharing protocol with the Pharmaceutical Society of Ireland in relation to fitness to practice cases involving registrants in both countries.

4. Development of 'distributed regulation'

4.1 The concept of 'distributed regulation' has evolved through a number of policy documents since 2006, as outlined below in Table 1. It was developed as a possible way to ensure that new and extended roles would be regulated, but as an alternative to full statutory regulation.

Table 1: List of policy documents that discuss 'distributed regulation'

Date	Report
July 2006	*The regulation of non-medical healthcare professionals: A review by the Department of Health*
February 2007	*Trust, Assurance and Safety – The regulation of health professionals in the 21st century*
May 2008	*Distributed regulation model – Discussion paper*, Scottish Government Health Directorates Extending Professional Regulation Implementation Group
July 2009	*Extending professional and occupational regulation - The Report of the Working Group on Extending Professional Regulation*

4.2 The early focus of the concept was on a number of new roles that had emerged within the NHS. In 2006 *The regulation of non-medical healthcare professionals*[21] recommended the urgent statutory regulation of the following roles:

- Surgical care practitioners
- Anaesthesia practitioners
- Medical care practitioners
- Emergency care practitioners
- Endoscopy practitioners.

4.3 The 2006 report proposed a system of 'distributed regulation' to enable an individual in one of these groups to remain registered with their existing regulator. In order to do so, the individual would have to meet the standards set by a 'lead regulator'. This, it was argued, would avoid costly and bureaucratic dual regulation, whilst recognising the degree of loyalty that professionals can feel 'to the specific group in which they were first registered'.[22] This idea was based on the assumption that these new roles would soon be regulated in their own right as a way of managing any direct entrants into these roles.[23] A commitment to explore the

21 Department of Health. 2006. *The regulation of non-medical healthcare professionals: A review of the Department of Health*. London: The Stationery Office.
22 Ibid.
23 By definition, direct entrants to these new roles cannot extend their practice, and discussion of the appropriate regulatory response in these circumstances falls outside the scope of this report.

practicality of a system of 'distributed regulation' was then outlined in *Trust, Assurance and Safety.*[24]

4.4 The concept developed further to encompass roles with an 'extended' scope of practice. An example used in the *Distributed regulation model – Discussion paper* (2008) describes podiatrists who undertake surgery as a possible candidate for the distributed model:

'…a podiatrist registered with the Health Professions Council (HPC) may wish, or be required, to undertake podiatric surgery, for which standards relating to practice would be agreed, in partnership, between the Royal College of Surgeons and the Society of Chiropodists and Podiatrists and would be endorsed by the General Medical Council (GMC) and accepted by the HPC.'

4.5 It has since been proposed to us that the distributed model could be used to develop standards in areas of practice that are currently unregulated, such as acupuncture. In theory, these standards would be developed by a 'lead regulator', and would then be endorsed by all of the other regulators. This would mean that any registered health professional who extends their practice into one of these areas would have to adhere to these agreed standards. This would have the advantage of ensuring professionals work to the same standards, irrespective of their initial registration.

24 Department of Health. 2007. *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*. London: The Stationery Office.

5. Is there a place for distributed regulation?

5.1 Table 2 below summarises the potential advantages and disadvantages associated with the proposed model of distributed regulation. This draws on arguments made in policy papers, responses to our call for information and existing research.

Table 2: Advantages and disadvantages of the model of 'distributed regulation'

Advantages

- It could provide safeguards by ensuring that practitioners have to meet agreed standards in areas of extended practice, irrespective of their initial registration
- It would address concerns about a gap between the requirements of basic registration and the extended practice that some professionals are undertaking
- It would be an alternative to a full statutory model of regulation for areas of extended practice
- It would prevent the need for costly dual registration in areas of extended practice
- If two regulators come to different conclusions about a fitness to practise case, it could undermine public confidence in regulation.

Disadvantages

- It is not a proportionate response to a problem which is difficult to identify or quantify
- Professional regulation is already complex and this could add a further layer of complexity
- Persuading regulators to lead on developing standards, and getting remaining regulators to endorse them, could be difficult
- It could be confusing for patients and the public when complaining about certain professionals
- The system could appear to be shaped around the convenience of professionals rather than the needs of patients and the public
- It could inhibit innovation and the development of practice if a professional's scope of practice is defined too rigidly
- Criteria and processes would need to be identified to decide which areas of practice warrant the additional standards
- Displaying information on standards on a register entry that relate to other fields could be confusing.

5.2 One of the advantages of the distributed model is avoiding the need for registered professionals who extend their practice having to register with two different statutory regulators, also known as 'dual registration'. When professionals practice

in two distinct regulated areas of practice they are required to do this. Examples might include doctors who also practise as dentists, or physiotherapists who are also osteopaths. We believe it is entirely right that a registrant's conduct should be subject to the scrutiny of different regulators if they hold dual registration. This was supported by the majority of responses to our *Call for Information*.

5.3 When an area of practice develops as a natural extension to their primary function, as illustrated in the examples provided in Section 2, we do not believe that dual registration would be a proportionate response to this issue. The example of oral and maxillofacial surgeons (see Section 3) shows that dual registration can be an unnecessary regulatory burden.

5.4 Another advantage suggested is that distributed regulation would mean that it was clear which standards registrants should follow. However, it is important to acknowledge that while regulators set the standards for conduct and competence, they do not set standards for clinical practice. Therefore to expect the regulators to do so in evolving areas of healthcare practice would be to present them with new challenges. They generally refer to guidance produced by Royal Colleges and other professional bodies to describe what is expected of registrants' clinical practice. For example:

'Clinical standards in dentistry are constantly developing. We do not issue clinical guidelines or statements on clinical standards.'[25]

- General Dental Council

'The GOC does not issue any professional guidance apart from the codes of conduct. Instead, we review the guidance that is issued by other professional and representative optical bodies, such as the College of Optometrists and the Association of British Dispensing Opticians. We often refer to their guidance and advice in aspects of our work.'[26]

- General Optical Council

In our view this would represent a considerable change in practice and a challenge to the introduction of any formal model of distributed regulation across the statutory regulators.

5.5 Given the mix of advantages and disadvantages the model poses, it is possible that introducing a new model may not enhance patient safety and public protection in a proportionate fashion. The GMC told us that distributed regulation could represent a shift away from a model of regulating title to regulating function, which 'carries significant risks associated with added complexity and inflexibility, without necessarily enhancing public protection,' and we find this a persuasive argument.

25 GDC. 2005. *Standards for Dental Professionals.* London: GDC.
26 The GOC website

6. Sharing responsibility for extended practice

6.1 We understand that new risks may emerge as registered professionals extend their practice. However, it is evident that there are a range of organisations and individuals who already have a responsibility or the opportunity to contribute to the management of these risks.

6.2 In our *Policy Framework*,[27] we state that 'it is the professionalism of health professionals which prevents them from attempting procedures which are beyond their competence, and ensures that they will involve colleagues with appropriate competence where necessary.' We believe that there is an onus on health professionals to only practice in areas they are trained and competent to do so (see Annex 2). As such, we reiterate the finding we made in *Advanced Practice*:

'Professionals are accountable to their regulatory body for all of their professional activities, whatever the level and context of their practice, the title they use or the type of activities they undertake.'[28]

6.3 In addition to individual responsibility, it is also the responsibility of the employer to ensure that the creation of any new or extended role comes with appropriate support and performance management mechanisms. It is important for the health system to have flexibility over how it utilises its resources to respond to service requirements, and to therefore deploy its staff appropriately. The employer must ensure that any professional working in these roles is qualified and trained to do so, and that its clinical governance and administrative systems can support the maintenance and development of individual professional competence.

6.4 The regulators are able to play a role in managing risks from emerging areas of extended practice. They can, if necessary, make annotations on the register to indicate where a professional has undertaken a post-registration qualification and/or acquired additional skills and competence in a particular field. This information can be presented in specialist lists, as held by the GMC and GDC, or as annotations to the register, as in the case of PSNI and RPSGB, for example. The GDC keeps specialist lists for dentists in 13 areas. They told us:

'…inclusion on a specialist list demonstrates to patients that a dentist is able to work at a level significantly beyond that of basic registration in a particular area of practice...'

6.5 We believe that only in exceptional circumstances should a regulator pursue the creation of a specialist list or annotation on its register. Any marking should reflect the extra risk posed to the public. This echoes our conclusions in our report on advanced practice:

'Primary responsibility for the governance of new roles designed to meet the needs of the service provision environment should rest with employers and commissioners. … Additional intervention by regulatory bodies would only contribute to public protection were the arrangements in place inadequately controlling the types of practice professionals were undertaking.'

27 CHRE. 2009. *Policy Framework.* London: CHRE.
28 CHRE. 2009. *Advanced Practice.* London: CHRE.

7. Conclusions and recommendations

7.1 In assessing whether regulators have the tools to manage extended practice, we have considered our test for right-touch regulation. This requires us to identify the problem before the solution, and then to quantify the risks associated with it. They also direct us to focus on outcomes not inputs. We state in our *Policy Framework*[29] that 'making changes to regulatory functions can be a solution, but we do not assume it is always the most appropriate or proportionate response to a problem'.

7.2 We believe that the broad areas of risk to patients associated with extended practice, identified in Section 3, can be managed by the tools that the regulators currently have at their disposal. Therefore we have not identified a need to establish a new model of regulation in these circumstances. In our view, regulators are already using proportionate and targeted approaches to regulating professionals as and when these new risks emerge. The example of oral and maxillofacial surgeons, for instance, illustrates how two regulators have worked together to reduce the burden of regulation whilst ensuring adequate protection of the public.

7.3 Good regulation should be shared across a wide range of stakeholders. Regulators should demonstrate agility in regulating professionals who extend their practice, in collaboration with the individual, their employer, professional bodies and other regulators. Regulators should continue to work with these stakeholders in order to protect the public and maintain standards of care. We do not, however, believe it is the place for regulators to set standards of clinical practice, in areas they currently oversee, or in unregulated areas or in areas covered elsewhere by other organisations. Investigation of fitness to practise cases that relate to areas of extended or specialist practice should call upon expert advice, mirroring the expectation on registrants to work to existing best practice within their areas of competence.

7.4 Assessing the mix of individual, employer and regulatory oversight of the roles fulfilled by registered health professionals may help to guide policymakers in identifying the appropriate course of action in different circumstances. Keeping a simple system of oversight and assurance is an important guiding principle, avoiding unnecessary blurring of boundaries and the introduction of complex models to regulate practice. With this in mind we suggest the following approaches for different instances of extended practice:

- Where an extended role is identified by an employer (and that extended role builds on the primary function associated with their current registration, for example a nurse), the proportionate response is for their registration to remain with their existing regulator and for employers to assure themselves that the individual is capable of safe and effective care. This may be through the identification of necessary competencies and skills for the role, training and development needs in collaboration with professional bodies
- In situations where professionals are fulfilling two distinctly separate roles that require separate registration it is appropriate that they are dually registered

29 CHRE. 2009. *Policy Framework*. London: CHRE.

- When a registrant extends their practice to unregulated areas, the codes and standards underpinning their existing professional registration make it clear that this should only be done in line with agreed good practice. Furthermore, they should guard against inadvertently providing false reassurance, by virtue of their registered status, about the quality and efficacy of treatments where it has been questioned.

7.5 A fourth example of managing risks of extended practice arises when risks to patient safety and public protection are managed through the regulator. Annotations to the register or specialist lists are an appropriate mechanism for regulators to accommodate their registrants when they extend their professional practice, pose a greater risk to patients, and require different levels of proficiency, to those traditionally associated with the profession. However, we believe this approach should only be used in exceptional circumstances, in order to protect the public, and in practical terms it may be determined by a critical mass of registrants extending their practice for this to represent a proportionate regulatory reaction. Establishing a specialist list or annotation should not be used as a symbol of professional status.

7.6 We therefore recommend that the following principles are adhered to at the individual, employer, regulator and Government level when managing areas of extended practice:

- Registered health professionals should only practice in areas that they are competent to do so; they are responsible for the care that they provide to patients
- Employers should have the appropriate support and performance management systems in place if it employs health professionals in extended roles
- Regulators should ensure their codes of conduct adequately reflect the requirement for health professionals to stay up to date and to operate safely within their areas of competence
- Regulators should only pursue the option of creating a specialist list or annotation on the register when all other approaches have been exhausted
- The Secretary of State for Health and Ministers in the Devolved Administrations should assess any application to change legislation in relation to specialist lists or annotations on a register solely against the risks posed to patient safety and public protection
- All parties should demonstrate an active commitment to cooperating and sharing information to manage risks to patient safety and public protection.

Annex 1: List of organisations who responded to our Call for Information

The health professional regulators
Individual members of our public and professional stakeholder networks
Association of Cardiothoracic Surgical Care Practitioners
British Dental Association
Complementary and Natural Healthcare Council
The National Association of Assistants in Surgical Practice
The National Clinical Assessment Service
Royal College of Nursing
Royal College of Physicians and Surgeons of Glasgow
The Society of Chiropodists and Podiatrists

Annex 2: Regulators' approach to professionals acting within their competence and staying up to date

Regulator	Approach
GCC	The GCC's *Code of Practice* states that, 'Chiropractors must recognise and work within the limits of their knowledge, skills and experience' and that 'Chiropractors must maintain and improve their professional knowledge, skills and performance'[30]
GDC	The GDC informs its registrants that they are still subject to their standards of ethics and behaviour when using complementary (i.e. unregulated) therapies, 'including when using these therapies within and outside of dental treatment'.[31] *Standards for Dental Professionals* states that 'As a dental professional, you are responsible for making sure you do the following: 'Be familiar with and understand • Current standards which affect your work; and • Relevant guidelines issued by organisations other than us; and • Available sources of evidence that support current standards' It goes on to state that dental professionals should: • 'Recognise that your qualification for registration was the first stage in your professional education. Develop and update your knowledge and skills throughout your working life. • 'Continuously review your performance, skills and professional performance. Reflect on them, and identify and understand your limits as well as your strengths • 'Find out about current best practice in the fields in which you work. • Provide a good standard of care based on available up-to-date evidence and reliable guidance'[32]

30 GCC. 2005. *Code of Practice and Standard of Proficiency*. London: GCC. Note: The 2010 code will state, 'Knowing your own limits: You must recognise and work within the limits of your own knowledge, skills and competence.'
31 GDC response to our Call for Information.
32 GDC. 2005. *Standards for dental professionals*. London: GDC.

GMC	*Good Medical Practice* states that registrants must, 'recognise and work within the limits of your competence'.[33] It also states that 'you 'must keep your knowledge and skills up to date throughout your working life. You should be familiar with relevant guidelines and developments that affect your work. You should regularly take part in educational activities that maintain and further develop your competence and performance' and that 'You must keep up to date with, and adhere to, the laws and codes of practice relevant to your work'.
GOC	The GOC *Code of Conduct* states its registrants must, 'Recognise, and act within, the limits of your professional competence' and 'Keep professional knowledge and skills up to date'.[34]
GOsC	The GOsC is currently developing its scope of practice for osteopaths, but reaffirmed that 'regulators should regulate the whole practice of those they register…The public could be at risk if regulation is too rigidly defined.'[35] The GOsC's *Code of Practice* states that osteopaths are expected to recognise and work within the limits of their competence and should maintain and develop their knowledge and skills.[36]
HPC	The HPC does not prescribe the areas in which their registrants work.[37] Their *Standards of conduct, performance and ethics* states, 'You must act within the limits of your knowledge, skills and experience and, if necessary, refer the matter to another practitioner.' It also states that 'You must keep your professional knowledge and skills up to date. You must make sure that your knowledge, skills and performance are of a good quality, up to date, and relevant to your scope of practice'.[38]

33 GMC. 2006. *Good Medical Practice*. London: GMC.
34 GOC. 2010. *Code of Conduct for Individual Registrants.* London: GOC.
35 GOsC response to our *Call for Information.*
36 GOsC. 2005. *Code of Practice*. London: GOsC
37 HPC response to our *Call for Information.*
38 HPC. 2008. *Standards of conduct, performance and ethics*. London: HPC.

NMC	*The Code* states: 'Keep your skills and knowledge up to date • You must have the knowledge and skills for safe and effective practice when working without direct supervision • You must keep your knowledge and skills up to date throughout your working life Use the best available evidence • You must deliver care based on the best available evidence or best practice • You must ensure any advice you give is evidence based if you are suggesting healthcare products or services' It also states that 'You must ensure that the use of complementary or alternative therapies is safe and in the best interests of those in your care.'[39]
PSNI	PSNI's *Code of Ethics* states that registrants must, 'Only practise within your realm of competency and refer to others where necessary' and they must 'Keep your knowledge and skills up to date, evidence-based and relevant to your role and responsibilities.' [40]
RPSGB	The RPSGB's *Code* states registrants must 'Recognise the limits of your professional competence; practise only in those areas in which you are competent to do so and refer to others where necessary' and must 'Maintain and improve the quality of your work by keeping your knowledge and skills up to date, evidence-based and relevant to your role and responsibilities'.[41]

39 NMC. 2008. *The Code*. London: NMC.
40 PSNI. 2009. *Code of ethics for pharmacists.* Belfast: PSNI.
41 RPSGB. 2009. Code of Ethics. London: RPSGB

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