Extending Professional and Occupational Regulation

The Report of the Working Group on Extending Professional Regulation


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Prepared by the Extending Professional Regulation Working Group
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Foreword

Professional regulation is largely a hidden part of the systems that underpin health care services across England, Northern Ireland, Scotland, and Wales. While it is a key component of the system to ensure safe, effective, high quality and respectful care for patients and the public, it tends to operate quietly in the background and is generally only noticed by the public when things go wrong. That it is rarely at the forefront of the public mind or a major focus for media scrutiny is a sign that, for the main part, it works well. But as health care changes, new functions evolve, traditional professional practice develops and public expectations of health care increase, it is vital that our systems of professional regulation themselves adapt to provide a flexible and responsive regulatory system that protects public safety in this changing context. It is only by continuing to evolve that individual professionals and health and care workers can sustain public confidence in the health care that they provide to the public - services which the public, ultimately, pay for.

The 2007 White Paper, Trust, Assurance and Safety– The Regulation of Health Professionals in the 21st Century identified the need to continually review the scope of professional regulation to ensure that it secured effective assurance for the public as new forms of health care emerged and as unregulated health workers developed the scale and nature of their interactions with patients. In England, the Next Stage Review, published in 2008, identified the scope of professional regulation as an important issue to ensure that the quality of patient care sat at the heart of NHS policy in England. Similar innovation and policy impulses have been driving an appetite to assure, sustain and develop the safety and quality of care provided by professionals and health and care staff in Scotland, Wales and Northern Ireland’s systems of health care. This has been attested to through the discussions that have taken place within our UK Working Group, and with stakeholders.

So, although not always visible at the frontline of care, the response of each Devolved Administration, and the United Kingdom as a whole, to these policy challenges will be critical to the quality of care that patients and the public receive and experience in the future. For the NHS in England, professional regulation will have an important enabling and assuring role to play in delivering the quality improvement and health improvement agenda set out in the Next Stage Review. Likewise, implementation of quality service delivery strategies in each of the Devolved Administrations rely on a workforce that is well prepared and fit for purpose.

I have been heartened in our discussions that it has been that focus – the safety and experience of the individual patient and member of the public – that has been the guiding principle for the work of the group and its members, whatever their particular background. In
drawing up our recommendations, we have had to weigh and consider a range of other complex issues and variables that impact upon professionals, employers, commissioners, regulators, trades unions, different parts of the United Kingdom and public, private and voluntary providers. These are important interests, as this report potentially impacts upon over a million health care workers and their employers UK wide. The system needs to ensure that the time and money needed to assure the safety and quality of the workforce does not divert resources and staff disproportionately from the core business of improving the health and well-being of the people of the United Kingdom.

So, from the outset, I have been determined to ensure that the work of the group has been informed and developed by those who will have to make its proposals work in practice across the UK. Through the meetings of the group itself and through two inclusive and participative stakeholder events, we have been able to draw on the commitment, expertise and experience of a very wide range of individuals and organisations from across the United Kingdom. In particular, I would like to mention the contribution from Skills for Health that supported our thinking on the decision making framework and the Northern Deanery (in England) research team, who gave their time willingly and freely to ensure we had an extensive review of available research to inform our thinking. All contributions have enriched our thinking immeasurably and helped us to avoid some of the less obvious pitfalls in a complex policy area, where many of the concepts and aspects of policy discussed are devolved from Westminster.

An emerging issue for the Working Group was the often close entwinement of delivery of health and social care services. As a result of this, the terms of reference of the Working Group stated were revised to enable it “…take account of the implications for healthcare workers of developments in the regulation of the social care workforce”. However, as stakeholders have therefore pointed out, the reverse could be equally said to be desirable. We would hope that the content and guiding principles of this report would assist in informing thinking about extending professional and occupational regulation within the social care sector across the UK.

I am very grateful to everyone who gave their time and expertise to support our work and in particular to Professor Norma Brook CBE, who chaired the initial meeting of the group, and who had to resign due to ill-health. Norma sadly passed away while this report was in preparation.

Dr Moira Livingston, FRC Psych
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Executive summary

The Extending Professional Regulation Working Group was established by the Secretary of State for Health in England, in consultation with Ministers in Scotland, Wales and Northern Ireland, to take forward work on the scope of professional regulation that was set out in the White Paper, *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*, published in February 2007.

This report makes recommendations in five key areas: risk, costs and benefits of regulation, new models of assurance, new routes to registration and regulation and involving patients, the public and employers.

1 Introduction

The shape and nature of health care in the United Kingdom has changed almost beyond recognition since the regulation of doctors by statute was introduced just over 150 years ago. As health systems change we need a range of regulatory options to ensure effective and proportionate systems that can develop and support safe and flexible services as the workforce changes. There was large majority agreement within the Working Group that statutory regulation for all is not proportionate, necessary or affordable.

The Working Group agreed that the following principles should guide discussions on extending regulation to professional and occupational groups working in health care:

- The primary purpose of regulation is to secure safe, effective, high quality, and respectful care for the individuals who depend on health care staff for their health and well-being;
- Regulation should be proportionate to the risk to patients and the public;
- Regulatory systems need the confidence of the public and registrants;
- Patients, the public, employers and those responsible for service design should be involved in designing and the effective running of appropriate regulatory systems;
- Regulation should lead to improvements in the quality of care for health care users;
- New regulatory systems need to take account of the wider matrix of regulation and governance systems to minimise duplication and maximise benefit;
- Proportionate regulatory systems need to apply equally well across sectors and employment contexts; and,
- Consistency and coherence of the principles of regulation is desirable, accommodating the different perspectives of England, Scotland, Northern Ireland, and Wales as well as being aligned with the European Union and the requirement of free movement.

The Government has already committed in the White Paper to regulate a range of professional groups. The Working Group did not consider the details of individual professional groups as part of their work. The Working Group recognised that existing work on the regulation of many
professional groups has taken place, or is underway. However, it is hoped that this report, and the menu of regulatory options it presents, will inform discussions on the way in which greater, yet proportionate assurance can be given to the patients and the public for these groups.

This report also recommends that the group developing the proposals for England for regulation of senior NHS managers and leaders consider whether the options set out in this report could provide proportionate solutions for this professional group.

2 Risks of Health Care

In this Chapter the Working Group sets out its approach to defining and quantifying risk. The Working Group considered that there were key factors to identify to assist in these assessments. These included: the type of intervention; where the intervention takes place; the level of supervision for the intervention; how experienced the worker is at the intervention; and, the quality of education, training and appraisal of individuals.

In recommending that regulation should be proportionate to the risk, and that a range of proportionate options are needed, the Working Group recognised the need for a robust evidence-based approach to risk assessment.

As part of the work of the Group, the Department of Health in England commissioned Europe Economics to carry out developmental work on a risk-assessment tool for professional and occupational groups that have been proposed for more formal regulation. The continued refinement of this approach will be an invaluable tool in informing future decisions on the extension of regulation.

3 Costs and Benefits of Professional Regulation

The risk, benefits and costs of professional regulation are complex and multi-dimensional, involving difficult trade-offs and judgements. Where there is uncertainty and complexity, it is important that there is rigorous analysis of available evidence, clear criteria for decision making, and effective governance of the decision making process to avoid conflicts of interests and ensure that patients and the public are at the heart of the system.

When considering all the factors at play that drive professional and occupational groups to seek regulation, or Governments to initiate proposals to regulate, the Working Group recommends that safety of patients and the public, as well as the enhancement of effective, high quality, and respectful care are the legitimate benefits to be considered in assessing whether to extend regulation.

The Working Group agreed that in any regulatory system, patients and the public should be confident in the health professionals who are registered in that regulatory system. It is
therefore important that the expectations of patients and the public, in terms of both the treatment being offered and the evidence-base for that treatment, are well recognised.

4 New Models of Assurance

Having assessed the risks associated with a particular function, professional or occupational group, and judged that further protection and assurance is needed to ensure safe, effective, high quality and respectful care, it is important that the means of providing further assurance is proportionate. In its discussions, the Working Group were clear that while the conventional model of statutory professional regulation may be required for some currently unregulated groups, there were a range of alternative and lighter touch regulatory regimes which could potentially be more appropriate, and merited consideration.

Further work is needed to assess the feasibility, applicability, potential benefits and risks of an extended menu of regulatory options. This assessment needs to include a consideration of the wider regulatory landscape across the UK, including governance and scrutiny arrangements, to ensure that regulatory interventions add value and avoid unnecessary duplication of effort or delays in taking action to protect the public.

Light Touch Regulation: a “Buyer Beware” approach

With this type of regulation the primary burden of responsibility for considering the risks of care are taken by the individual patient or member of the public. This model supports the individual's right to choice and needs to be underpinned by good information that can support informed judgements about care and support.

The Working Group recommends that the Department of Health in England and the Devolved Administrations should jointly commission the Council for Healthcare Regulatory Excellence (CHRE) to develop and publish, in conjunction with stakeholders, a simple guide for the public that describes key considerations in making a decision about approaching a health provider. Work is also needed to consider how existing and potential future regulatory systems can be more widely promoted.

Voluntary Self Regulation

This model is already widely adopted by many unregulated professional and occupational groups within health care as a preparatory stage prior to statutory regulation. The Working Group considered that by providing more robust and consistent approaches to voluntary registration with a stronger degree of assurance and accreditation, the approach of a voluntary registration regime could play a valuable part in the overall system of regulation.

The Working Group recommends that the Department of Health in England and the Devolved Administrations work with CHRE, and other key stakeholders to consider the costs, benefits,
and feasibility of developing a formal voluntary accreditation regime to supplement voluntary registers within the menu of regulatory choices.

**Employer-led regulation**

The Working Group was clear that employers have a vital role to play in ensuring public protection and safety of patients and the public.

A pilot, conducted in Scotland, has tested one potential way of protecting the public through standard setting for Healthcare Support Workers. This pilot tested a set of standards for induction that focus on public protection, a Code of Conduct for employees and a Code of Practice for employers and the potential for a centrally held list of names of those who meet the standards required. At the time of writing the Working Group awaited the formal outcomes of the pilot, in order to assess its merits fully.

The Working Group recommends that the Department of Health in England and the Devolved Administrations should draw on the evidence from the pilot in Scotland to inform the development of the “menu” of regulatory alternatives suggested in this report.

The Working Group were keen to ensure that any employer based model that might be developed for NHS employees should be able to be applied to accommodate workers across health, including those in the independent and voluntary sector.

**A statutory licensing regime**

The Working Group saw this as a potentially more robust alternative to the protection offered by some forms of voluntary self-regulation. For lower risk groups or roles, a licensing regime could focus on ensuring appropriate training or qualifications for the role, securing adherence to a code of conduct and ensuring those whose conduct does not meet the required standard are barred from carrying out these roles in the future.

The Working Group recommends that the Department of Health in England and the Devolved Administrations carry out further work to explore the feasibility, costs, legislative implications and benefits of a statutory licensing regime for health care workers across the four countries.

**A Workforce “Passport”**

The Working Group recommends that, as part of the Department of Health in England’s proposed wider review of professional regulation in 2011, consideration be given to the costs, benefits and practicability of the introduction of a Workforce Passport for all NHS staff in England. This more radical approach to regulation, based on the extension of licensing to the NHS workforce, would enable patients to assure themselves that all the staff they encountered in the service were appropriately qualified and licensed to carry out their roles, by checking
their credentials easily through a smart card, as well as enabling employers to ensure staff were appropriately registered. The Devolved Administrations should consider what, if any, action is needed in this area.

5 Modernising Routes to Regulation and Registration

The recommendations set out in this chapter represent a significant radical change to the way in which decisions about extending professional and occupational regulation should be made and will require further detailed development work. The Working Group recommends the Department of Health in England and the Devolved Administrations should consider the need for a decision making algorithm that would support an evidence-based approach to identifying groups for consideration for regulation, prioritise those groups, assess the risk, and facilitate a decision on the lightest touch approach to regulation that offers assurance. The Working Group also recommends identification of a “gatekeeping” body that should then be asked to lead on this work drawing on the economic and actuarial analysis of risk underway.

Extensive engagement is required with the public, regulators, employers, service commissioners and providers, in the future design and implementation of any new regulatory system.

6 Stakeholder Engagement: Involving Patients, the Public and Employers

Throughout the discussions of the Working Group, there was an ongoing concern about how best to ensure more meaningful and effective engagement of all parties in both the operation and leadership of the existing system of professional regulation and for design and delivery of processes to extend regulation into new professional and occupational groups.

The Working Group recommends that the Department of Health in England and the Devolved Administrations should commission advice from CHRE on more effective mechanisms for engaging patients and the public in the decision making processes on professional regulation, drawing upon the expertise of stakeholders.

The Department of Health in England and the Devolved Administrations should also review the functions, responsibilities and resources available to CHRE to ensure that it has the powers and capabilities needed to lead public discussion about the nature and purpose of regulation.

The Working Group also recommends that the organisation that takes the proposed ‘gatekeeper’ role should have formal and effective mechanisms in place to ensure that it is effectively aligned with other parts of the matrix of assurance across the UK of which professional regulation is only one part.
1 Introduction

The Report

1.1 The report follows the following structure:

- This Chapter provides an overview of the work of the Working Group and the principles it applied in considering its work programme;
- Chapter Two discusses the nature of the risks of health care that regulation seeks to reduce;
- Chapter Three sets out the costs and benefits of regulation;
- Chapter Four considers how alternative systems and approaches might provide proportionate and effective approaches to managing risks, given the risks set out in Chapter Two and the costs and benefits set out in Chapter Three;
- Chapter Five sets out options and proposals for a more transparent and evidence-based process for taking decisions about which groups should be regulated and which approaches to regulation are best suited to those groups;
- Chapter Six discusses the need for greater patient and public involvement in decision making about the extension of professional and occupational regulation, and how employers and commissioners might be more effectively engaged. This chapter makes proposals for how this might be taken forward; and,
- The appendices set out the basis of the Working Group’s deliberations, its interim outputs, research conducted, and a summary of its recommendations.

The Working Group

1.2 The Extending Professional Regulation Working Group was established by the Secretary of State for Health in England, in consultation with Ministers in Scotland, Wales and Northern Ireland, to take forward work on the scope of professional regulation that was set out in the White Paper, Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century (the White Paper), published in February 2007. The terms of reference and membership of the Working Group are set out in Annex A of this report.

1.3 The Working Group first convened on 27th November 2007 and was chaired by Professor Norma Brook CBE who unfortunately then had to step down due to ill-health. Dr Moira Livingston was then appointed to this role in December 2007, and the Working Group has met regularly since that date. The Working Group encompassed a range of interests and expertise, including representatives of the four Health Administrations in the United Kingdom, patient groups, employers, regulatory bodies, trades unions and different parts of the health care workforce.
1.4 The Working Group held two day-long events to enable a much wider range of stakeholders to be drawn into the process of shaping and informing the work of the group, on 7th May 2008 and 18th November 2008. These highly interactive events helped to ensure that as wide a range of interests and perspectives were brought to bear on the key aspects of this report. Importantly, the group also ran a dedicated event in April 2008 for representatives of patient and public interest groups.

1.5 The Working Group published an interim report in June 2008 to set out emerging findings and proposed further work, to enable further stakeholder engagement. This is available at: 

**Interim Report**

**Box A: Health Professionals who are currently regulated by statute**

- Arts therapists,
- Biomedical scientists,
- Chiropodists/podiatrists,
- Chiropractors,
- Clinical scientists,
- Dental hygienists,
- Dental therapists,
- Dentists,
- Dietitians,
- Dispensing opticians,
- Doctors,
- Hearing Aid Dispensers
- Midwives.
- Nurses,
- Occupational therapists,
- Operating department practitioners,
- Optometrists,
- Orthoptists,
- Osteopaths,
- Paramedics,
- Pharmacists,
- Physiotherapists,
- Prosthetists & orthotists,
- Radiographers,
- Speech and language therapists.

**Context**

1.6 As the interim report of the Working Group noted, the shape and nature of health care delivery in the United Kingdom has changed almost beyond recognition since the regulation of doctors by statute was introduced just over 150 years ago. Today, numerous professions are regulated by statute (see Box A).

1.7 In considering what further assurance should be extended to people working in health who are not regulated by statute, our assessment has taken account of the following contextual factors that are likely to be part of the current and future policy environment:

- There is a strong consensus amongst all stakeholders with an interest that the purpose of regulation should be to help secure safe, effective, high quality and respectful care for the individuals who depend on it for their health and well-being;
- That regulation should be proportionate to risk;
- That statutory regulation is not the only option that can provide the necessary protection for the public;
- There is a need for greater recognition that those who employ or contract with health care workers need a regulatory regime that enables, with a minimum of bureaucracy, the introduction of flexibility, responsiveness and innovation in the workforce in a way that sustains and enhances the safety of the people that they serve;
- As currently regulated health professionals develop their roles and acquire specialist expertise, there is a concern to ensure that more advanced and often higher risk
activities are conducted within the right mix of individual, team-based, organisational and statutory regulation;

- As services seek to integrate and coordinate to provide more effective and coherent care to people with mixed health and social care needs, it is important to consider whether there is need for consistency and coherence (where possible) in the regulation of workers who carry out similar roles in both health and social care contexts;

- The professional regulatory system needs to function sympathetically with the spirit and fact of Devolution, enabling the accommodation of the different needs and perspectives of England, Scotland, Wales and Northern Ireland;

- At the same time as it seeks to accommodate Devolution within the United Kingdom, the system also needs to meet European obligations and trends towards more homogeneous international regulatory frameworks that enable the mutual recognition and free movement of health workers across the European Union;

- The system needs to be clear about how, or whether, it should provide assurance to individuals who choose to access complementary and alternative therapies;

- The regulatory system needs to encompass proportionately health workers in whatever employment or contractual setting in which they practise, and cannot simply be tailored to the context of mainstream NHS provision but must also function effectively for the self-employed workforce, small businesses and not-for-profit organisations;

- Decisions about regulation need to be sensitive to the context and environment in which care or treatment is given and how that impacts on the safety of patients and the public, for example, where care is unsupervised or provided in the practitioner’s or patient’s own home; and,

- Professional regulation cannot be seen in isolation from the wider regulatory frameworks for health care, and needs to be designed to ensure it plays a proportionate, effective and coherent role with England’s, Scotland’s, Wales’ and Northern Ireland’s systems for regulation of health care organisations, contractors, agencies and commissioners;

- Outwith the perspective of health policy, there is a wider policy environment in which society, Government, the private sector and the public sector are re-examining for the twenty-first century the costs and benefits of regulation more generally. This is a complex and at times controversial area, in which the level of risk the public can tolerate or accept and the cost of assurance and mitigation that the public and the professions are willing to pay for are ill-defined.

1.8 For patients and the public, or their relatives, who have experienced very poor care, the death or avoidable disability of a friend or a family member, or very rarely malicious behaviour and abuse, there can be a natural and understandable desire to put in place very rigorous controls that minimise risks, whatever the costs. For professionals and other health care workers, the vast majority of whom are motivated by an overriding desire to do the best for those in their care, there is often a frustration, shared by
employers, at the costs and bureaucracy of regulation and an anxiety that well intentioned human error will be used as a pretext for heavy handed or draconian regulation. As a society, we continue to debate how much of the risks inherent in life are something that we should take personal responsibility to guard against on our own behalf, and how much the state should take responsibility to protect us.

1.9 Chapter Three of this report discusses these issues in greater detail, looking at the risks and costs of regulating health care professionals to help inform judgements about the future of professional regulation. In our discussions as a group, we have found it helpful to be guided by the five principles of better regulation (see Box B) set out by the Better Regulation Commission, building on the recommendations in the Hampton Review.

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<th>Box B: Five principles of regulation</th>
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<td>Source: The Better Regulation Commission, Cabinet Office</td>
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<td>• <strong>Proportionality</strong>: Regulators should only intervene when necessary. Remedies should be appropriate to the risk posed and costs identified and minimised.</td>
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<td>• <strong>Accountability</strong>: Regulators must be able to justify decisions and be subject to public scrutiny.</td>
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<td>• <strong>Consistency</strong>: Government rules and standards must be joined up and implemented fairly.</td>
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<td>• <strong>Transparency</strong>: Regulators should be open and keep regulations simple and user-friendly.</td>
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<td>• <strong>Targeting</strong>: Regulation should be focused on the problem and minimise side effects.</td>
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1.10 In considering the groups of workers and professionals who are currently being proposed for a more formal regulatory framework (either by themselves or at the instigation of Government), the Working Group has been conscious that some, but not all, of these groups are different in nature from the professional groups that have been regulated by statute over the years since 1858. A "profession" has conventionally been seen in the past, in the public mind, as a specialised occupation or vocation characterised by intensive training, which leads to an academic award and subsequent professional licensure or authorisation, by a regulatory body – doctors, lawyers, dentists, nurses, teachers and so forth. This essentially nineteenth century framework cannot, two centuries later, encompass the scale, cost, benefit, risk and complexity of those millions of interactions everyday between those employed in health care and those who pay for and use their services.

1.11 Whilst nearly a million unregulated workers in health care bring extraordinary benefit to patients and the public every day, the risks inherent in their work and the training and skills needed for that work are often quite different in impact from the risks brought by professions that require training over many years to enable safe and effective autonomous practice. As such, the Working Group agreed that formal statutory regulation for the majority of such workers might not be appropriate or proportionate. This is not in any way to devalue the important contribution that they make, but rather to
recognise that the level of scrutiny, training and oversight needed for say, a cardiothoracic surgeon specialising in mitral valve repair, is different in kind from that of for example a committed health care worker who plays a vital role by ensuring that frail or elderly people have the basic care, day to day assistance and social interaction, that they need for a better and more independent life.

1.12 Different roles, with different risks, require different levels and intensity of regulation. Whether one role is “professional” or not is largely a matter of status and identity, and irrelevant to the aims of regulation – protecting the public through assuring safe, effective, high quality and respectful care. To date the Health Professions Council (HPC) has made recommendations to the Secretary of State concerning the suitability of new groups for statutory regulation. This power was given to the HPC before the devolution settlement and has remained unchanged. For health care and associated professions introduced to regulation after the Scotland Act 1998, regulation is devolved, in Scotland, to the Scottish Parliament. Scottish Ministers will decide on whether or not a professional or occupational group is to be regulated, and if so how. The groups of health care professionals which the HPC has recommended to the Secretary of State in England should be statutorily regulated (see Box C) are many and diverse, and careful evidence-based policy making is needed to ensure that these proposals are properly considered. In addition, many other groups (some of whom are listed in Box D below) have made representations to the HPC or UK Government that they should be regulated, but whose applications have not been formally made or assessed. Around 1.3 million health care professionals and workers are currently subject to statutory regulation. If all these additional groups were to be regulated through statutory means, then this would mean bringing a further million workers, nearly 4% of the total working population of the UK, into a statutory regime and would mean that a total of around 8% of the UK workforce were in the health care regulatory system. The associated costs to the public purse and bureaucracy of bringing these additional groups within a statutory regime would need to be justified on the grounds of public protection.

1.13 Until now, discussions about these unregulated groups of workers had tended to refer to them as “aspirant” groups. This report avoids the use of this term, originally introduced by the HPC for the purpose of indicating when applications for regulation were made to
it by groups seeking recognition as “professions”, as we felt it has been used by some to place the extension of professional regulation in the context of the needs and aspirations of professional\(^1\) or occupational groups\(^2\), rather than in the perspective of the systems and safeguards needed by patients, the public, employers and commissioners to assure safety and quality of care.

1.14 Government has already committed in the White Paper to regulate practitioner psychologists\(^3\), some healthcare scientists, psychotherapists and counsellors and other psychological therapists. **We believe that, given the risks presented by these groups, they can be relatively easily located within the groups of professionals suited to statutory regulation by the HPC and recommend that the ongoing work to implement statutory regulation should continue whilst the implications of this report for other workers and professionals are considered by the Department of Health in England and the Devolved Administrations\(^4\).**

1.15 Government has also agreed to extend regulation to practitioners of acupuncture, herbal medicine, and traditional Chinese medicine practised in the UK. Much work has taken place concerning regulation of these practitioners over the last decade including a report from the House of Lords’ Committee on Science and technology and three Working Groups and a public consultation. The most recent Steering Group on Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK, who delivered their report to Ministers in the UK in June 2008, strongly recommended regulation of these groups in order to provide the public seeking such treatment with assurance of safe and competent practice. The Working Group understands that a public consultation on the issues raised by the Steering Group is imminent.

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\(^1\)For the purposes of this report the term professional group refers to clinical workers, involved in direct patient care, who use a recognised title following a period of well defined training

\(^2\) The Working Group agreed that rather than discuss individual workers, it was helpful in terms of regulation to group workers into similar roles or functions. The term occupational groups encompasses this attempt to group workers for the purpose of regulation into similar functions and roles

\(^3\) Subject to necessary legislation being approved by Parliament(s) statutory regulation of some practitioner psychologists will commence from July 2009

\(^4\) For instance, statutory regulation for health care science was signalled in the UK wide Modernising Scientific Careers (MSC) proposals, detailed in the Future of the Health care Science Workforce – Modernising Scientific Careers: the Next Steps consultation document published in November 2008
1.16 In addition, whilst the Next Stage Review for the NHS in England considered statutory regulation to be disproportionate for senior NHS managers and leaders, it has committed the Department of Health to consider what further systems might be needed to provide further assurance and safeguards where there appear to be significant individual failings. The Working Group recommends that the group developing these proposals for England consider whether the options set out in this report could provide proportionate solutions for this professional group.

1.17 Considering all of the above, the Working Group recommends that the work it has done in identifying a new landscape of regulatory options to protect the public should inform the way in which greater assurance is given to patients and the public when consideration is given to future regulation of broader professional and occupational groups.

Conclusion

1.18 Having set out the context to this work, the remaining chapters deal with the complex issues of risk, costs and benefits of regulation, the variety of forms of regulation, an approach to modernising routed to regulation and registration, and how stakeholders can be engaged in decision making.
2 The Risks of Health Care

Introduction

2.1 In any discussion of a regulatory system that is focussed on ensuring safe, effective, high quality and respectful care for patients and the public, it is inevitable that discussion focuses on unsafe, ineffective and disrespectful care to identify how best it can be prevented. In doing so it is vitally important to ensure that a discussion of the risks of care does not forget the extraordinary benefits of better health and well-being that health care professionals bring to our society. The health care system, and the people within it, are overwhelmingly beneficial in their impact, but in doing so they may also, inevitably, cause a relatively small amount of harm. Regulation can mitigate some of that risk of that small amount of harm but it has a cost, so decisions to extend regulation need to be informed by a judgement about how much regulation, and what type, is proportionate. It is possible also for systems to be “too safe” to enable services to function effectively.

Box E - Defining Risk: The Ontario Model

"Defining risk is complex. In Ontario, authorities use the concept of the Controlled Act (Government of Ontario 1997) which is defined below:

A “controlled act” is any one of the following done with respect to an individual:

1. Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.
2. Performing a procedure on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, or in or below the surfaces of the teeth, including the scaling of teeth
3. Setting or casting a fracture of a bone or a dislocation of a joint
4. Moving the joints of the spine beyond the individual’s usual physiological range of motion using a fast, low amplitude thrust.
5. Administering a substance by injection or inhalation.
6. Putting an instrument, hand or finger, i. beyond the external ear canal, ii. beyond the point in the nasal passages where they normally narrow, iii. beyond the larynx, iv. beyond the opening of the urethra, v. beyond the labia majora, vi. beyond the anal verge, or vii. into an artificial opening into the body.
7. Applying or ordering the application of a form of energy prescribed by the regulations under this Act.
8. Prescribing, dispensing, selling or compounding a drug as defined in the Drug and Pharmacies Regulation Act, or supervising the part of a pharmacy where such drugs are kept.
9. Prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eye glasses other than simple magnifiers.
11. Fitting or dispensing a dental prosthesis, orthodontic or periodontal appliance or a device used inside the mouth to protect teeth from abnormal functioning.
12. Managing labour or conducting the delivery of a baby.
13. Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.
14. Treating by means of psychotherapy technique, delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception or memory that may seriously impair the individual’s judgement, insight, behaviour, communication or social functioning.
15. Testing, manipulating, storing or handling of human tissue to assist with the diagnosis or treatment of living individuals or the use of tissues from cadavers for similar outcomes”

This seems an appropriate definition of activities in relation to risk. However, in order to cover those who work with human tissue another clause needs to be added to make this fit for purpose within the UK health care context:
Extending Professional and Occupational Regulation

2.2 So, in order to inform judgements about the proportionality and effectiveness of further regulation, it is important to have a clear understanding of the risks which that regulatory system is seeking to reduce. This chapter discusses the nature of those risks.

Controlled Acts: The Risks of Healthcare Interventions

2.3 For health care professionals, the most commonly thought of risks are technical mistakes in the diagnosis or treatment of patients, such as missing an obvious symptom, using the wrong drug or wrong dose of drug, failing to ensure proper hygiene, or performing a surgical procedure incorrectly. The Working Group found the Ontario Model\(^5\), which defines “controlled acts”, as a helpful start in capturing this kind of risk (see Box E above) although felt it was incomplete for the UK health system. The Working Group was conscious that mere performance of the controlled acts themselves would not automatically lead to a requirement for statutory regulation of a professional carrying out such acts. Instead, the Working Group felt that concept could be used as a guide to identifying those acts that may well have the potential to cause more harm.

Quantifying Risk – Relevant Factors

2.4 While the Ontario Model is clear and helpful, it only identifies the existence of risk in a particular act. There are a number of other important dimensions to be considered in relation to the risks of controlled acts. For example, the list does not seek to prioritise the risk of one controlled act against another, informing the degree of risk mitigation that might be needed for professionals carrying out different controlled acts. So, for example, the degree of assurance needed for a controlled act of complex neurosurgery would be higher than that for correctly setting a simple fracture in a cast.

2.5 There are a range of other dimensions of risk which need to be identified and, as far as possible, quantified, in order to inform decisions about how best to manage the risks of particular professional or occupational roles. These include:

- Whether the act is carried out by a professional on their own, or as part of a supervised team who can support, guide and scrutinise practice;
- Whether the act is carried out by a professional who is part of a well managed organisation that has in place managerial assurance systems to protect patients and the public;
- Whether the act is carried out by a professional who has a stable employment pattern, where any problems might be identified over time, or whether it is carried out by a more mobile short tenure practitioner working in a variety of locations, whose practice is less likely to receive consistent oversight;
- The quality of education and training of the practitioner carrying out the act;
- The experience of the practitioner carrying out the act; and,

\(^5\) Definition of Controlled Act - Government of Ontario, Canada, 1997
Whether there are systems in place to ensure that the practitioner is regularly and effectively appraised and developed to ensure that they are up to date with current practice.

2.6 While these factors are relevant to considering individual acts by individual professionals, an assessment of risk also needs to take into account wider factors about the profession or occupational group concerned. For example, while a very small and specialised profession might carry out highly technical and high risk acts, such as operating heart-lung machines during bypass surgery, they may collectively present a lower risk to population health than lower risk activities like hygiene and hand-washing among more than 600,000 nurses. Whilst it can be argued that the opposite is also true: that the more you do an act the more proficient you should be at it, and whilst both groups undoubtedly need risk assurance, ineffective regulation of common lower risk activities may permit greater harm than ineffective regulation of rare high risk activities.

Generic Risks – Inappropriate Behaviour

2.7 In addition to the specific risks attached to specific interventions by health care professionals and workers, there are wider risks that need to be considered when deciding whether to regulate a particular group. Patients and the public place a great deal of trust in professionals and caregivers, often at times when they are ill, dependant, or otherwise vulnerable. The fact that they need help often puts them at a disadvantage and puts the person, from whom they are seeking help, in a position of power, to then provide or deny that care or to exploit the privileged position in which they are placed. A number of rare examples give a flavour of the potential risks involved:

- People with mental health problems have been sexually abused and assaulted by practitioners who have claimed that these assaults are a part of their treatment;
- Vulnerable people have experienced rudeness and emotional abuse from staff;
- Isolated vulnerable adults have experienced fraud, theft and physical assault from staff who were supposed to be caring for them;
- Children and adults with learning disabilities have been physically and sexually assaulted and subjected to emotional abuse by health care staff;
- Health professionals have carried out high risk procedures on desperate patients without properly securing informed consent; and
- Personal and confidential information about patients and the public has been inappropriately shared with others for financial gain or other unethical and unauthorised uses.

2.8 The delivery of care is constantly evolving, with blurring of traditional boundaries between job roles (e.g. in the health care sectors), delivery of care and services (e.g. in supervised and unsupervised environments), and service provider (e.g. public and private sector). The respectful and appropriate behaviour of trusted health practitioners is a legitimate and important focus of the professional regulatory system and decisions about extending professional and occupational regulation need to be informed by...
judgements about the risks of abuse, disrespect and other poor standards of behaviour and the extent to which regulation can reduce these risks. The likelihood of such risks occurring is partly dependent on the relevance of factors set out above and this is discussed in greater depth in Chapter Five. Generally speaking, people’s own moral frameworks and the professional and occupational codes that they adhere to prevent such behaviour, but because of the particular position of trust and authority that they occupy, particular attention is needed to provide safeguards where staff are:

- Practising without the supervision or support of peers, managers and other regulated staff;
- Practising with vulnerable or isolated individuals;
- Highly mobile, locum or short tenure;
- Not guided by a strong professional (or employer) code of conduct; and,
- Carrying out roles where the training and educational requirements are short and there is no extended period through which the ethos and values that underpin safe practice can be imbued.

It should also be remembered that negative outcomes could result from (inadvertent) omissions to act, as well as conscious actions.

Evidence-Based Policy Making

2.9 As part of the work of the Working Group, the Department of Health in England commissioned Europe Economics to carry out developmental work on a risk-assessment tool for professional and occupational groups that have been proposed for more formal regulation. The Working Group welcomed this initiative but, regrettably, a final product was not available for inclusion with this report. The aim of the work is to assess risk on a more scientific, robust and rigorous basis. Those organisations who provide professional indemnity insurance to health professionals have established actuarial systems for assessing the degree of risk and therefore the costs of providing cover and it is important that in weighing up the costs and benefits of extending regulation, policy makers and Ministers have the best information to hand to inform their judgements.

2.10 Such risk assessments may provide the best available information on the costs of litigation and settlement, however, they cannot form the sole basis of such decisions and need to take into account other factors. Such factors to consider include: the importance of public confidence in particular professional and occupational groups; public expectations about professionals; the emotional and social costs of those shortcomings and failings that are relatively low-level (but relatively high volume) and which would never reach the legal, disciplinary or regulatory systems; as well as the financial impact of harm with associated health and legal costs that could result from an ineffective regulatory system. Further, information obtained from the NHS in England’s National Patient Safety Agency, as well as the Health Service Commissioner, could
similarly inform debate. The Working Group recommends that the Department of Health in England continue to refine the risk-based approach in partnership with the Devolved Administrations, the regulators, employers and other key stakeholders. While it is not feasible, given the current state of data and research in this area, to develop an algorithm that removes the need for judgement about priorities and other factors that cannot yet be quantified in the risk model, the continued refinement of the approach will be an invaluable tool in informing future decisions on the extension of regulation.

Conclusions

2.11 Any consideration of regulatory approaches within the health care context must be cognisant of the variable nature of roles, and the risks they entail. This process, combined with an assessment of the relative costs and benefits associated to regulation, provides a robust framework for evidence-based decision making.
3 The Costs and Benefits of Professional Regulation

Introduction

3.1 Whilst Chapter Two set out the key risks which professional and occupational regulation seeks to reduce, any consideration of whether to extend that system needs to take careful consideration of the costs and benefits of extending regulation. This chapter sets out the costs and benefits considered by the Working Group, and the content of the chapter has been derived from the research and modelling work commissioned to support the Working Group, as well as formal submissions from the Working Group members.

3.2 Assessment of the costs and benefits of introducing regulation for a particular profession or occupation will allow the system to apply a decision rule - that when the benefits of regulation exceed the costs, regulation can be considered appropriate. There may be a range of ways in which regulation can be introduced with different levels of cost and effectiveness. The preferred form of regulation would generally be the one whose benefit exceeded costs by the greatest amount. This is discussed in greater depth in Chapters Four and Five.

Costs and Burdens

3.3 The costs of the statutory professional regulatory system in the United Kingdom are significant. In 2007 the combined direct expenditure alone of the professional regulatory bodies, including CHRE, was in excess of £200m. In addition, the costs of regulation include:

- The professional time needed to comply with the requirements of the regulators, including further costs that will be incurred through the introduction of revalidation, which may take professionals away from their primary purpose of providing high quality care to patients and the public;
- The costs to employers of ensuring that professionals have information and systems in place that are necessary for professional regulation (although, ideally, these would be information and system requirements that are necessary locally in any case for effective management, clinical governance, staff development and supervision of health care provision or delivery);
- The costs of professional fees from registrants to their regulators. Ultimately, these are paid for indirectly by the taxpayer or the individual patient or member of the public who pays for private care:
  - Taxpayers fund the wages of NHS staff and increases in professional fees place pressure on the NHS wage bill,
Taxpayers fund the wages of Government officials who put in place statutory frameworks,

All professional fees for regulation attract tax relief, which reduces the funds available for other services, and,

The fees charged to private patients will include an element to cover the professional fees of their practitioner.

- **The transitional costs** of establishing new regulatory regimes for newly regulated bodies, which are normally borne by the taxpayer;
- Statutory professional regulation in the health arena implies a relatively high component of **legal costs**, compared to other forms of assurance, with decisions (especially those concerning a practitioner’s conduct or fitness to practise) being open to challenge in the High Courts, funded from legal indemnity insurance and the regulators’ fees;
- **Unintended constraints on the ability of employers, managers and professionals to adapt to changing patient and public needs**, by putting inflexible constraints on the levels of training, education and regulation needed to change the way that staff work and the tasks that they can carry out to meet the diverse and complex demands of modern health care;
- The regulatory system can be a source of **significant anxiety for professionals** who may fear that they may unjustly be deprived of their livelihood by vexatious complaints or unfair treatment;
- Enshrining professional roles in statute can create “**closed shops**” in which professions unnecessarily protect parts of their own sphere of practice from developing occupational and professional groups;
- The costs of **duplication of effort** between local systems of management and clinical governance on one hand, and regulatory oversight on the other, which carries a concomitant risk of confusion over roles and responsibilities;
- The **potential for gaps** between different systems of oversight due to assuming wrongly that other parts of the system are taking responsibility for detecting and managing risks;
- Putting in place national systems of oversight may result in **weakened local focus** on assurance of staff quality, by creating a perception that this is primarily the responsibility of the statutory regulatory system;
- Slowing the responsiveness of health care services to new challenges and shifting demand, by requiring **longer educational and training programmes** which may not be sufficiently up to date to adapt quickly to current needs;
- The **costs to trainees, employers and taxpayers** of the higher standards of education and of the training infrastructure that statutory regulation may require in order to assure the quality of new entrants to the register;
• The costs to registrants, and opportunity costs to employers and commissioners, of any measures that regulators may take to periodically carry out revalidation to ensure that registrants continue to meet the standards expected of them.

Benefits

3.4 These costs secure significant benefits. It is no accident that the public rightly hold the United Kingdom’s regulated professions, and particularly health professions, in very high regard. The statutory professional regulation system has played an important part in fostering and sustaining this trust and regard, by:

• Controlling entry to the regulated professions;
• Setting standards;
• Ensuring high quality education to assure those standards;
• Removing from practice a proportion of those who fall significantly short of those standards;
• Promoting and enforcing codes of conduct; and,
• Helping to foster, develop and sustain an ethos of professionalism amongst their registrants.

3.5 The benefit of regulation is the reduced risk to patients and the public that they will experience poor treatment or care. The nature of these benefits will depend on the following factors which can be considered for different regulatory options:

• The extent to which poor treatment or care is the result of avoidable adverse events that could have been prevented if regulations were introduced and enforced. Some adverse events are unavoidable due to limitations of current knowledge;
• The numbers of people exposed to the risk of adverse events;
• The number of occasions on which there is an exposure to risk, for example the number of encounters after which there is an experience of misdiagnosis by a particular professional group;
• The seriousness of adverse events (including less than satisfactory outcomes), for example some adverse events could lead to serious injury of a person whilst others might cause some distress or inconvenience; and,
• The change in avoidable adverse incidents that would result if the policy under consideration were perfectly designed and implemented.

3.6 Regulation might be expected to change either the number of occasions that people experience an adverse event or it might reduce the severity of an adverse event, for example, by:

• Ensuring that the professional had the skills to identify and rectify a problem quickly and appropriately;
• Ensuring that registrants have passed through a quality-assured education and training programme before they practise, increasing safety and effectiveness;
Extending Professional and Occupational Regulation

- Ensuring public confidence and trust in health care professionals, so that when people need help they are not worrying about whether or not they are meeting a substandard or poorly behaved professional;
- Removing from practice those who fall short of professional standards, to prevent poor service provision or prevent poor conduct;
- Fostering a sense of belonging and identity amongst registrants which strengthens their attachment to a set of values, or code of conduct, which defines their behaviour and practice; and,
- Enabling the public and employers to distinguish between genuine and bogus practitioners.

3.7 Statutory professional regulation also has a number of other impacts, which are not necessarily related to the issue of safety, effectiveness, quality and respect:

- Professional regulation can increase the status, or perceived worth, of an occupational group by placing it on a par with professions such as medicine and nursing which society tends to hold in high regard;
- Higher status can in turn aid recruitment into particular professional groups. This may stem from perceptions that there are clearer career pathways, or of job satisfaction due to the higher degree or self motivation or autonomy and opportunities likely to accompany professional status;
- Higher status can also be seen as a useful lever by professional groups to improving their pay, terms and conditions;
- Higher status can help to mitigate inter-professional rivalries within multi-professional teams by subverting hierarchies of status based on who is a “proper” profession and who is not; and,
- Statutory regulation can be seen by some groups to give an equivalent clinical legitimacy or perceived evidence base as that of groups currently regulated, so that spheres of practice, where there is controversy about their efficacy, may seek to bolster public confidence through statutory regulation.

3.8 The Working Group was clear that while some or all of these benefits may be legitimate, they were not, given the costs of regulation, primarily relevant to their considerations. When considering all the factors at play that drive professional and occupational groups to seek regulation the Working Group recommends that safety of patients and the public, as well as enhancing effective, high quality, and respectful care, are the legitimate benefits to be considered in assessing whether to extend professional and occupational regulation. The Working Group felt that respect, respectability, status and legitimacy was earned from the public rather than conferred by statutory regulation and that matters of remuneration, inter-professional respect, recruitment and equivalence to conventional biological clinical practice were not the primary function of statutory regulation. However, whilst this is the case, under certain circumstances these issues can serve as intervening variables in driving up quality. Whilst regulation, by assuring educational quality and setting standards, may have the
by-products of increasing public esteem for a particular group, aiding recruitment and improving wages, these by-products were not its primary purpose. Public protection should be the predominant factor when assessing the costs and benefits of extending regulation.

3.9 As some unregulated practitioners, operating on the margins of unconventional treatments, may seek to use regulation as a marketing vehicle for their beliefs or theories (perhaps in order to gain respectability for these), it is important for public protection that the regulatory system continues to enable the public to distinguish between legitimate and unproven treatments when making their choice. As the origins of the United Kingdom’s system of professional regulation lie in a nineteenth century attempt to enable the public to distinguish between qualified and unqualified doctors, it is important that this basic service to the public is continued in the twenty-first century by ensuring transparency and raising public awareness not only about regulation but also about the evidence base of services being offered in order to make well informed choices. The Working Group recommends that, for fields of practice where benefits are unproven or controversial, there may nonetheless be a need for more formal regulation or registration because the treatments used pose a significant risk to patients and the public. The Working Group also agreed that, in any regulatory system, patients and the public should be able to have confidence in the health professionals who are registered within that system. It is therefore important that the expectations of the patients and public in terms of both the treatment being offered, and the evidence-base for that treatment, are well recognised and transparent.

Conclusion

3.10 As Chapters Two and Three have demonstrated, the risk, benefits and costs of professional regulation are complex and multi-dimensional, involving difficult trade-offs and judgements. Where there is uncertainty and complexity it is important that there is rigorous analysis of available evidence, clear criteria for decision making, and effective governance of the decision making process to avoid conflicts of interests and ensure that patients and the public are at the heart of the system. This will ensure that they know what to expect in terms of the standards of care/service provided and how to complain if these are standards are not met.
4 New Models of Assurance

Introduction

4.1 Having assessed the risks of a particular function, professional or occupational group, and judged that further protection and assurance is needed to ensure that patients and the public receive safe, effective, high quality and respectful care, it is important that the means of providing further assurance is proportionate. In its discussions, the Working Group was in large majority agreement that while the conventional model of statutory professional regulation would be required for some unregulated workers, there were a range of alternative and lighter touch regulatory regimes which would be more appropriate and proportionate for others. This chapter outlines some of these alternatives, including:

- A “buyer-beware” approach, supported by improved public information about the risks associated with the practice of particular groups of practitioners or health care workers and through requirements for professional indemnity or insurance;
- Voluntary self regulation of practitioners;
- Employer-led regulation; and;
- A licensing regime, supported in England by the work of the Independent Safeguarding Authority.

Integrated Regulation

4.2 Before discussing each of these alternative approaches in turn it is important to recognise that professional regulation does not exist in a vacuum, but is one component in a system of assurance and governance in which a number of different organisations play a part.

4.3 The General Medical Council (GMC) has for some time promoted the concept of a four-tier model of regulation, each of which contributes to reducing the risk that individual doctors might present. The four tiers are:

- **Personal regulation**, where the innate or acquired professional values of the individual practitioner helps to ensure safe, effective, high quality and respectful practice;
- **Team-based regulation**, where the values, systems, peer and managerial oversight of the team provide protection and assurance against poor practice or unprofessional behaviour;
- **Organisational regulation**, where the systems, values, performance management and governance arrangements of an employer, service provider, contractor or commissioner, helps to assure the safety of both individuals and teams; and,
- The **national professional regulation system**, which seeks to sustain and support these three components and investigate and take necessary action where the three
other components of the system fall short or are unable to deal with concerns themselves.

4.4 When considering the type of professional or occupational regulatory regime appropriate for a particular role or health care worker, the degree of rigour needed has to take into account the robustness of the three other elements. Where there are very strongly embedded personal and professional values, effective teams and robust organisational oversight and assurance in relatively low risk roles and functions, a relatively light touch national professional regulatory regime may be more appropriate.

**Meta-Regulation**

4.5 Meta-regulation is the process by which an independent external agency ensures that regulation is effectively carried out, in effect regulating the regulators. This is done with the aim of bringing about improvement in quality and safety. Meta-regulation offers a higher order regulation, essentially quality assuring the procedures and standards of a regulator. It could apply to all models and offer an independent check on the key features and processes of regulation. Additionally it could, with input from experts, provide oversight on the appropriateness of established standards for certification, procedures for continued professional development, and fitness to practise issues including exclusion from the register. Meta-regulation does not provide direct control of individual workers, but ensures that the practice of workers within a regulatory system is upheld by appropriate and proportionate standards and procedures. It also ensures that workers in different staff groups are regulated by equable procedures.

4.6 Furthermore, for many parts of healthcare, there are further components of regulation which ensure that the premises, technology, drugs and devices used by staff are safe.

**Patient and Public Assurance**

4.7 The final components of assurance are patients and the public themselves. If individual patients and members of the public are well informed about risks, about what constitutes safe and effective care, know how to complain, and, generally speaking, feel that they have a collectively powerful and individually influential role, then this exerts strong protective forces on individual practitioners, staff, teams and organisations. If patients and the public can go elsewhere for their care; are alert to the risks inherent in their care; can complain easily without fear of repercussions; and can easily identify when care is being conducted poorly or inappropriately, then the likelihood of unsafe, ineffective or disrespectful care is dramatically reduced. For example, if a hospital patient feels able to effectively challenge a consultant who does not wash his hands between examinations on a ward-round, the risks of hospital acquired infection are reduced for both the individual patient and for other patients on the ward.
Shared Risk

4.8 So consideration of further regulation for professional or occupational groups needs to be within the context of an overall matrix of assurance through which a proportion of the total risk inherent in particular groups is shared within an integrated system of protection (see Diagram A). In making judgements about which form of regulation might be appropriate for a particular group, or particular function, policy makers must carefully assess the rigour of other parts of that matrix and how much of the total risk it is proportionate to seek to mitigate. Once again, the challenge then lies in finding a model for a given professional or occupational group that is consistent, yet flexibly applied across the UK, to effectively interface with four different healthcare governance systems (for instance, there is no systems regulator in place in Scotland at present).

Diagram A: The Patient/Public Risk Assurance Matrix

4.9 In a system where policy makers and services are seeking increasingly to enable both patients and the public to make their own choices about the nature and provider of their care, these issues about the extent to which risk is assured, and how effectively that overall assurance regime works in practice, will become more and more important.

Light Touch Regulation: “Buyer Beware”

4.10 The lightest touch approach in these considerations would be a “buyer beware” regime, in which the primary burden of responsibility for considering the risks of care are taken by the individual patient or member of the public. In this context, individuals may be
protected to an extent by generic consumer protection legislation and criminal law, but there is no specific regime targeted on practitioners or providers of care. So, for a novel, small scale alternative service provided by an individual working from their own home, members of the public may only have word-of-mouth recommendation, potentially unreliable information from the internet and their own judgement to support them in deciding whether to access such therapy and little means of redress should they encounter difficulties.

4.11 This approach does have the benefits of allowing individuals to make choices about their care, (with or without the support of an advocate for vulnerable adults) without the expense of the regulatory oversight by the state, enabling choice without legal, regulatory or institutional interference. Some individuals who access such therapy may feel that they understand the risks that they are taking and are happy to do so having formed their own judgement. However as there may be no control over the information available to inform this choice there are risks associated with this model if this is all that we support. The more that an individual practitioner carries out care which encompasses the risks set out in chapter three, the more important it is that a “buyer beware” approach is supported by good information for the buyer about those risks. If an individual patient/member of the public’s judgement (supported appropriately by an advocate for vulnerable individuals) is to be the sole safeguard in the matrix of assurance, then it is vital that it is informed by objective information about associated risks, expected standards and guidance on how best to ensure that the person from whom one is seeking care is likely to be safe, effective, of high quality, and respectful.

4.12 In practice, it is generally only for very small, non-invasive, low risk and newly emerging forms of care in some alternative and complementary therapies that a complete absence of regulation is appropriate. New therapies that emerge within conventional medicine tend to do so from within existing regulated professions, and are already encompassed within the existing regulatory regime.

4.13 Although at present individual professional regulatory bodies provide information to the public about the professions that they regulate, there is no single comprehensive source of information about the diverse range of professionals, practitioners, therapists and other people providing health care. For unregulated professionals, where there is either deliberately, or by default, a “buyer beware” regime of assurance, it is not always clear to the public that this is the case.

4.14 The Working Group recommends that the Department of Health in England and the Devolved Administrations should jointly commission CHRE to develop and publish, in conjunction with stakeholders, a simple guide for the public that describes key considerations in making a decision about approaching a health practitioner, which sets out the range of roles, professionals, carers and therapists working in health care, describes the extent to which they are regulated and provides advice on how best to ensure safe, effective, high quality and respectful care from them. This will help to ensure, whatever the balance of
different regulatory mechanisms in place, that the public have access to clear advice about the nature of the risks involved and are able to make an informed judgement about their care. The Department of Health in England and the Devolved Administrations should consider how awareness of information about regulation could be promoted through GP surgeries and other sources of public information in the NHS in England (and its equivalents in Scotland, Northern Ireland, and Wales) and CHRE and the professional regulatory bodies should consider what further action can be taken in this regard.

Voluntary Self Regulation

4.15 Voluntary professional self-regulation is a model through which professionals collaborate and agree a set of standards and practices and codes of conduct, independent of Government or any statutory framework, for the purpose of raising standards and protecting the public. The profession itself takes responsibility for registering its members, setting standards, maintaining a register of practitioners and removing members who are considered to have fallen short of those standards. For example, osteopathy and chiropody both established voluntary registers, as a prelude to statutory regulation. Practitioner psychologists have also established a voluntary register, in advance of their prospective regulation, subject to passing of legislation, in the summer of 2009.

4.16 When the practice of a professional or occupational group gains in popularity and coverage amongst the public, then voluntary self-regulation is usually the next stage of assurance that emerges at the behest of this group and this provides a degree of public protection. However, voluntary self-regulatory groups are unable to take action against those who are not members of their organisation, thus limiting the potential for public protection. Voluntary self-regulation is also a model that is widely adopted by unregulated professions from within conventional healthcare as a preparatory stage prior to statutory regulation. While expressing concerns about the degree of assurance offered by some existing voluntary regulatory approaches, the Working Group considered that with a stronger degree of assurance and accreditation, the approach of a voluntary registration regime could play a valuable part in the overall system of regulation.

4.17 For a number of alternative and complementary therapies the Department of Health in England has decided that due to the nature of these therapies, full blown statutory regulation would be inappropriate, but acknowledged that the public need a greater degree of support in making choices about whether or not to access therapy from these groups. It has therefore supported the start-up costs for the establishment of a voluntary register of these practitioners, the Complementary and Natural Healthcare Council, whose development was facilitated by the Prince’s Foundation for Integrated Health. It opened a voluntary register on 19 January 2009. Individuals who belong to

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6 Appendix D(ii) to this report provides further background on modes and forms of voluntary self regulation.
one of the therapies it covers (Alexander technique, Aromatherapy, Bowen technique, Cranial therapy, Homeopathy, Massage therapy, Naturopathy, Nutritional therapy, Reflexology, Reiki, Shiatsu, Yoga therapy) may choose to register with it but do not have to do so. The register opened initially for massage therapists and nutritional therapists, shortly to be followed by other groups.

4.18 For most voluntary systems of regulation, registration will mean that the practitioner has met certain entry standards (e.g. has an accredited qualification) and that they subscribe to a set of professional standards. Breach of these standards may mean that the practitioner is referred for “fitness to practise” procedures, and could result in their removal from the voluntary register.

4.19 This approach tends to be cost-effective, with arguably no direct burden to the taxpayer, and with voluntary registrants and their “customers” bearing the costs of the system. It enables the profession to determine their own standards of practice and ethics, requirements for entry to the register and allows innovation and good use of the technical expertise of practitioners. The profession itself determines the violations of its own code, sets sanctions and manages its own enforcement regimes.

4.20 While this voluntary regime can provide significant degrees of protection, there are a number of potential weaknesses which means that it is difficult for the public to gauge whether one voluntary register is as effective as another:

- As the register may be effectively owned, financed and controlled by its registrants, it may be insufficiently rigorous in its standards and fitness to practise arrangements because of financial, competition or reputational self-interest;
- There is no legal impediment to a disbarred registrant from continuing to practise without being voluntarily registered; and
- Rival groupings within an individual profession may set up competing registers, with different standards and rules, so it is difficult for the public to distinguish which register is to be preferred.

4.21 The Working Group was concerned that because voluntary regulation was, or could be perceived to be, too often driven by professional concerns and professional initiative, there was a risk that they offered insufficient protection to the public. It recognised that for some professions and occupational groups, however, the UK Government was likely to consider that voluntary regulation regimes would continue to have an important role to play in the overall regulatory matrix of assurance. For professions and occupational groups who were unlikely to meet the requirements and standards necessary for statutory regulation, but who the public continued to access and who presented a significant level of risk, they could provide a valuable ongoing level of protection. For groups that may require more formal and statutory regulation, they were an important transitional vehicle through which the necessary preparation for regulation could be effected, whilst providing a greater degree of protection to the public.
4.22 However, the Working Group was concerned that there was insufficient consistency of standards in voluntary regimes, so that it was difficult for members of the public to assess the degree of assurance that they could expect from different registers. The Working Group recommends that the Department of Health in England and the Devolved Administrations work with CHRE, and other key stakeholders to consider the costs, benefits, and feasibility of developing a formal voluntary accreditation regime to supplement voluntary registers within the menu of regulatory choices. This might, for example:

- Set out minimum standards of governance, to ensure, for example, that only regulators with lay majorities on their governing bodies received accreditation;
- Set minimum standards for timely investigation of complaints by members of the public; and,
- Require adherence to codes of conduct on openness and transparency in the conduct of their affairs.

4.23 In doing so, this may enable fewer professions or groups to be drawn into a full statutory framework, by providing more robust and consistent approaches to voluntary regulation, as the public will know that if they are receiving care from a person who is registered with an accredited voluntary register, then they can expect a reasonable level of objective oversight and assurance. However, careful thought would also have to be given to ensure that maintenance of voluntary regimes considers what should be done to highlight those individuals subject to bars under the Independent Safeguarding Authority (and equivalent) regimes.

Employer-led Regulation and Licensing

4.24 Whilst voluntary registration presents an alternative approach for groups that are not suitable for full blown statutory regulation, or for groups who are unable to meet the requirements of statutory regulation, it was not necessarily felt to be suitable or proportionate for large volume groups of workers, such as health care support workers, where the training requirements can be quite different in nature from the existing groups who are regulated by statute.

4.25 The Working Group recognised that for these groups, full-scale statutory regulation based on the historic model was likely to be disproportionate to the risks involved and risked overly constraining roles and functions that are often designed to meet the needs of patients and the public. The Working Group considered two approaches, each with common aspects, which sought to develop a lighter touch approach to regulation whilst enabling appropriate assurance of skills and conduct in these sections of the health workforce. These were:

- Employer-led regulation; and,
- Licensing.
It is recognised that work is ongoing across the health care arena and in all four countries in relation to these concepts. Therefore, it is hoped that the Working Group’s thinking on them will be useful in informing this work.

Employer-Led Regulation

4.26 The employer-led model of regulation, puts the weight of emphasis on organisations in the regulatory matrix of assurance, recognising the critical role that they play in the day to day management of staff, and their ability, through their proximity to the risk, to manage that risk more effectively. The discussions of the group on employer-led regulation were predominantly informed by the pilot in Scotland for regulation of healthcare support workers, which was conducted in three NHS Boards and one independent hospital. The pilot started in January 2007 and was completed in December 2008. The pilot was managed centrally by NHS Quality Improvement Scotland and is being independently evaluated, with the exception of the independent hospital site, by the Scottish Centre for Social Research on behalf of the Scottish Government.

4.27 The key elements of the model being tested are:

- A set of induction standards that focus on public protection;
- A Code of Conduct for Healthcare Support Workers;
- A Code of Practice for Employers; and,
- A centrally held list of names of those who meet the standards required

4.28 For the purpose of the pilot, ‘Healthcare Support Workers’ were defined as those who provided a direct service to patients and members of the public in the name of NHS Scotland. This included those in support roles to the healthcare professions (such as clinical care assistants) as well as those in other areas (such as porters and domestic staff). For ease of definition, anyone who had an influence on a patient and who was not already statutorily regulated, or due to be, would be included.

4.29 A consultation on the Regulation of Health Care Support Staff and Social Care Support Staff in Scotland, held between May and August 2004, indicated overwhelming support (93%) for the extension of regulatory arrangements to this group, with 90% of responses identifying this as the most appropriate way to ensure public protection. A similar consultation was undertaken in England and Wales. Again, broad support for regulation was expressed, but questions which required further debate were also raised.

4.30 In November 2006, following preparatory work in 2005 – 2006 and a three month period of consultation which suggested overwhelming support for the standards for healthcare support workers and for making them mandatory, Scottish Ministers launched the standards and the Code of Conduct for Healthcare Support Workers and the Code of Practice for Employers. The standards and Codes have been available for voluntary implementation across NHS Scotland since that time. These can be found at Regulation of Healthcare Support Workers:
4.31 Regulation on a Scotland-wide basis would allow Scotland to dovetail arrangements with existing UK-wide frameworks such as the Knowledge and Skills Framework (as part of Agenda for Change for the NHS) and Skills for Health products (for example, National Occupational Standards and National Workforce Competences), where appropriate. This would enable duplication of effort to be kept to a minimum, and existing staff governance arrangements to be used. Implementation of the pilot allowed Scotland to test these arrangements and assess their suitability for wider application and enable the other three UK countries to make a more informed decision on their own ways forward. It should be acknowledged however that the disparate approaches to both staff and organisational governance across the UK will make it difficult simply to extrapolate findings from the Scottish pilot to the rest of the UK.

4.32 The induction standards being used in the pilot are those that were consulted on in 2006. The standards represent the first step towards helping both employers and employees in NHS Scotland fulfil their obligations to patient safety and public protection as part of a potential future regulatory framework for Healthcare Support Workers. The pilot also aimed to establish whether a list of those who have achieved the standards is needed, and, if so, whether such a measure needs to be set in statute.

4.33 It is anticipated that the Protection of Vulnerable Groups (Scotland) Act 2007, once it comes into force, will assist with safe recruitment practice and audit trails around “barred” individuals seeking regulated work. It is anticipated that clinical support workers (as a sub-group of the wider Healthcare Support Worker group), by virtue of their normal duties which include the provision of care, support and assistance, will fall within the definition of working with “protected adults” and will require vetting and barring scheme membership. The vetting and barring scheme should therefore prevent previously registered practitioners who have been de-registered on the grounds of conduct taking employment as a clinical support worker. This will complement any future regulatory measures put in place.

4.34 The outcomes of the pilot will be reported to Scottish Ministers in Spring 2009. As of October 2008, a cohort of just under 500 voluntary participants had been involved in the pilot. This represents one sixth of the eligible number of participants of just fewer than 3,000 across pilot sites. This is the first pilot of its kind and it is hoped that it will contribute to a much needed evidence base for future policy decisions. It has been interesting to observe that the pilot has resulted in fewer than expected support workers taking part. The reasons for this are being considered by the evaluation team and it is hoped that the outputs from the evaluation will throw some light on this.

4.35 The model of employer-led regulation being piloted in Scotland does not have the support of all of the trade unions across the UK who represent healthcare support workers. However, the outcomes of the pilot will throw some light on how healthcare support workers who are involved in the pilot perceive the model of regulation piloted and all of its constituent parts. It is also hoped that the independent evaluation will
provide some information on whether or not this model is effective within the Scottish context and whether it has the potential to enhance public protection.

4.36 The Scottish model has deliberately attempted to reduce duplication of effort through utilising existing frameworks as far as possible. The Knowledge and Skills Framework (KSF) has been key in this. It is acknowledged however that, not only is implementation of the KSF patchy across the UK but, it applies to the NHS sector only. This means that, if the model of regulation was to be adopted by the non-NHS sectors, comparable alternative models for personal development planning and review would have to be used that were fit for purpose for those sectors.

4.37 The Working Group was clear that employers have a vital role to play in ensuring public protection. The pilot in Scotland tests one potential way of protecting the public through standard setting. However, at the time of writing the Group awaited the formal outcomes of the pilot, and its parallel independent evaluation, in order to assess its merits fully. The introduction of any new system of regulation needs to be able to accommodate all employment sectors and all relevant legislation including that relating to the protection of vulnerable groups. Whilst the evaluation of the pilot in Scotland will provide us with an evidence base that can be reviewed it may be some time before informed judgements can be made on the long term implications of this model of regulation should it be applied in one country or across the UK. The Working Group recommends that the Department of Health in England and the Devolved Administrations should draw on the evidence from the pilot in Scotland to inform the development of the “menu” of regulatory alternatives which might be developed for taking forward this report. The Working Group were also keen to ensure that the principles of any employer based model that might be developed for NHS employees should be able to be applied to accommodate workers in independent and voluntary sector settings.

Licensing

4.38 Another alternative to the current model of statutory regulation for health professionals is that of a licensing regime and the Working Group saw this as a potentially more robust alternative to the relatively weak protection offered by some forms of voluntary self-regulation.

4.39 For lower risk groups or roles, a licensing regime would be predominantly focussed on three core aims:

- To ensure appropriate standards based training/qualifications for the role;
- To help secure adherence to a code of conduct; and,
- To ensure those whose conduct does not meet the required standard are barred from carrying out these roles in the future.

4.40 Skills for Health and other stakeholders could agree the qualifications, training and educational standards that the health care worker needs in order to secure a licence to
do their jobs safely, effectively and respectfully. At a basic level, this could be a single uniform standard for the group as a whole, or in a more sophisticated model, could involve a suite of licences reflecting different levels of risk and different occupational roles.

4.41 A licensing body or bodies (yet to be defined), could hold a list of names of licensed workers who had met the necessary requirements for their role and signed up to the relevant code of conduct. Licences could, for example, be removed following complaint and investigation at a tribunal and, if licensees wished to be reinstated, their appeals could be heard in the appropriate Court in England and the corresponding competent Court within the Devolved Administration jurisdictions as appropriate.

4.42 Licensing could be either mandatory, required by statute, or voluntary and dependent upon employers requiring licensure as a condition of employment. The precise form of licensing vehicle would be dependent on the risk posed by the activity and the most proportionate manner required to protect the public from risk. The Security Industry Authority is one example of this regime operating in another sector.

4.43 The HPC have set out more detailed proposals of one possible approach to licensing, and how this might work in practice for health care workers, using an existing Regulator as the potential licensing body (see Box F below).

**Box F - Health Professions Council – licensing proposals for healthcare workers**

Individuals would use a single protected title, Licensed Healthcare Practitioner. Licensing would not be compulsory, but would be voluntary and with the lead of large key employers, become part of the standard conditions of employment. In the medium term the regulator would commence a communications campaign encouraging the public only to be treated by those who are licensed practitioners.

Individuals would join the register after passing a practical test that would normally be achieved after the equivalent of four to six weeks of full time training. Part-time and on-the-job training would be strongly encouraged to minimise costs. The test would be held frequently each year in numerous facilities and the costs of taking the test would be minimal. There would be a single straightforward Standard of Conduct, Performance and Ethics for all licensees. The Standards of Training would focus on issues such as: communication, confidentiality, delegation of tasks, infection control, patient rights, record keeping and team working.

Registrants who fail to maintain standards would have their licence revoked by tribunal, with appeals heard at an appropriate Court. Once the register opened, the regulatory system would be self-funding and would be designed to be affordable to healthcare workers whose salaries can be significantly lower than those of healthcare professionals. The annual £30 registration would be payable in two instalments and would be tax deductible, thus amounting to £2 per month for basic rate taxpayers. Large employers would make the holding of a licence a condition of employment for specific jobs and this would also apply to agency workers.

4.44 The potential HPC model described above suggests a quasi-voluntary regime dependent on market forces making licensed workers a key hallmark of quality, but compulsion could be introduced through statutory licensing regimes. The licensing approach has considerable attractions:
It potentially could operate effectively in public and private sectors (piloting of licensing in these fields would inform this debate further);

- It could be either mandatory or voluntary;
- It can be calibrated according to risk and roles;
- It potentially avoids the costly legalistic approaches of fitness to practise procedures and appeals in the health arena to the High Court (and its equivalents in Scotland), whilst protecting licensees proportionately;
- It is simple in operation and does not depend on large scale information technology across different employment sectors;
- For healthcare it could build on the Knowledge and Skills Framework for NHS staff;
- It sets a quality threshold for entry to the role, with possible thresholds of advancement and career development if a suite of licences is adopted; and,
- It could potentially be operated by a number of the existing regulatory bodies.

The Working Group recommends that the Department of Health in England and the Devolved Administrations carry out further work, in conjunction with stakeholders, on the feasibility, costs, legislative and legal implications and benefits of a licensing regime for health care workers. In addition, the Working Group recommends that this model also be considered for other professional or occupational groups that are judged to need further regulation.

The Workforce Passport

In their discussions, the Working Group considered a more radical approach to regulation, based on the extension of licensing to NHS workforce, which would enable all patients in the NHS in England to assure themselves that all the staff they encountered in the service were appropriately qualified and licensed to carry out their roles. By recording each member of staff’s licence or registration on the Electronic Staff Record and holding this on a smart card, potentially every member of staff in the NHS could carry a “Work Passport”, enabling patients to check their credentials easily, and enabling employers to ensure staff were appropriately registered. Further, any “Work Passport” system would have to be complimentary to the Independent Safeguarding Authority scheme. Whilst the scope of the Electronic Staff Record is not yet sufficiently widely cast into primary care in the NHS at this stage to enable this, and licensing of all staff in the NHS would also need to be in place, there could be significant benefits for patients and employers in this approach. The Working Group recommends that, as part of the Department of Health in England’s proposed wider review of professional regulation in 2011, consideration is given to the costs, benefits and practicability of the introduction of a Workforce Passport in the NHS in England. This might initially be piloted in England for healthcare support workers employed in secondary care settings. The Devolved Administrations should consider what, if any, action is needed in this area.
4.47 In England, further work is needed to ensure that any new model of regulation complements the work of the Independent Safeguarding Authority (ISA), and similar consideration may be needed relating to the implementation of the Protection of Vulnerable Groups (Scotland) Act 2007 (PVG) scheme in Scotland.

4.48 The ISA has been set up under the Safeguarding Vulnerable Groups Act 2006. The ISA will assess every person who wants to work or volunteer with children or vulnerable adults. They will do this by working closely with the Criminal Records Bureau (CRB). The CRB will receive applications to the ISA and will gather and monitor information. It will also use the information previously found in:

- The Protection of Vulnerable Adults (PoVA) list;
- The Protection of Children Act (PoCA) list; and,
- List 99 (a list of people considered unsuitable for work with children, held by the Department for Children, Schools and Families).

4.49 The ISA will then assess this information and decide whether to give the individual concerned ISA registration or put them on one of the ISA Barred Lists. Their records will be constantly updated as fresh information is gathered. If new data indicates that an individual might pose a risk to vulnerable people, they will be put on one of the ISA Barred Lists and their current employer will be informed immediately. It will be a criminal offence to work in a regulated activity if barred by the ISA, and a criminal offence if employers employ somebody in a regulated activity without ensuring that the individual is registered with the ISA. Anybody working with children or vulnerable adults is considered to be working in a regulated activity; in effect, this covers most NHS posts but will also cover non-NHS posts.

4.50 The ISA will be independent. Ministers will no longer be involved in making decisions on individual cases. The ISA will make all the discretionary barring decisions that are currently taken by the Secretary of State based on clear criteria and evidence. Ministers will not be able to intervene in ISA. Whilst the ISA is independent of any government department, it is a Non-Departmental Public Body (NDPB) and as such has statutory responsibilities. Its performance, efficiency and effectiveness will be scrutinised closely by both government and stakeholders.

4.51 The Working Group recommends that in drawing up the menu of alternatives to statutory regulation, the Department of Health in England and the Devolved Administrations ensure that any new approaches function effectively in concert with the work of ISA and PVG scheme, avoiding unnecessary duplication of effort or delays in taking action to protect the public. However, it is important to recognise that ISA and professional/workforce regulation are complimentary and not exclusive of each other. Notably, existing regulators have a wider range of sanctions available to them than barring an individual for a field of work. They can also take action against...
individuals who may have committed lower level actions than those triggering ISA barring decisions (e.g. the breach of relevant code(s) of practice in place). Further, being barred by the ISA is a more severe sanction than being barred, or removed from, the register of existing health care regulators.

**European Regulation**

4.52 In proposing any new method of regulation of healthcare workers it is essential to recognise the position and influence of European Union (EU) law. For the regulation of healthcare professionals, the fundamental principle of the free movement of workers is critical and has been consistently supported in case law and in the development of directives and regulations. There are only very limited circumstances when these principles can be excluded. Any recognised healthcare worker trained and legally established in one member state must be equally recognised and established in another, provided they have met the minimum standards of training and/or practice set out in the relevant European law. Even if the occupation or profession of the immigrant health care worker is not regulated in their home state but is in the host state, provided they can provide suitable evidence that they have been practising their profession in their home state they may have a right to be entered on the register of the host state, subject to making up any shortfalls in training or experience. The Working Group recognised that their proposals would need to be consistent with EU requirements.

**Conclusions**

4.53 While Chapter Two discussed the nature of the risks of health care and Chapter Three set out the costs and benefits of regulatory measures to address those risks, this chapter has mapped out a number of potentially less burdensome approaches that may be more appropriate as decisions are taken to extend regulation further.

4.54 In making those decisions about which groups or roles require further regulation and which model of regulation might be appropriate, it is vital that this assessment is made in the wider context of the matrix of regulatory assurance described above. Should such change be adopted, however, it is vital that the implications of such change are properly assessed for their impact. The following chapter seeks to describe a new process for enabling those complex decisions and judgements to be made in a transparent and evidence-based manner.
5 Modernising Routes to Regulation and Registration

Introduction

5.1 In the past there has been a danger that the extension of professional regulation to new groups has been overly driven by the aspirations of emerging professional groups themselves, as a means to establish themselves as safe and effective players in the health care arena. This has at times led to the use of the terminology of “aspirant” groups. This term was introduced by the HPC for the purpose of indicating when applications for regulation were made to it by groups who were seeking recognition as “professions”. The term has since become associated with those groups seeking regulation through emphasising the risks inherent in their professions in order to secure their positions within health care, for reasons of status and market position as well as for reasons of public protection and patient safety. The Working Group agreed that continuing this approach to statutory regulation would not only have significant costs to the public purse and to the bureaucracy associated with spiralling legislation but would sustain an approach that did not have protection of the public as its primary concern: regulation is there primarily to serve the public, not the professions, and consideration of extension of regulation needs to start from the perspective of risk to the public and consider from that perspective which professional groups should be drawn into the system and how best to do so.

5.2 The Westminster Parliament, the Scottish Parliament and the relevant assemblies of the Devolved Administrations in Wales and Northern Ireland, decide whether statutory regulation is appropriate, and could decide to initiate their own related legislation should they wish to do so. However, there is current commitment on behalf of all four UK countries to UK-wide regulation, sensitive to each country’s needs, and the normal legislative vehicle is an Order under Section 60 of the Health Act 1999 for regulation across the UK. This chapter sets out proposals for a new framework to provide evidence-based advice to Ministers on extending regulation, based on a more robust assessment of risks, costs and benefits, and properly informed by the perspectives of patients, the public, and employers. The Working Group considered the need for a new type of ‘gatekeeper’ role. This new role would provide a single point of access for all decisions on whether regulation is warranted and if so the type of proportionate regulation that will offer the necessary protection for the public.

5.3 This new role would offer a single point of access for assessment of risk and benefits of proportionate regulation from the new menu of choices discussed in Chapter 4. Specifically the ‘gatekeeper’ would:
(i) Identify occupational and professional groups where either the role has changed or risk has been identified and therefore consideration for regulation is needed (with such work instigated upon request of the four countries, or of its own volition following interaction with stakeholders);
(ii) Assess each group for the most appropriate type of regulation based on risk, using a decision making framework to guide the decision;
(iii) Provide timely and effective guidance and prioritisation on type of regulation needed; and,
(iv) Work closely with all the Department of Health in England and the Devolved Administrations, employers, regulators, patients, the public, and other bodies with an interest in patient and public safety, in order that decision making is informed by stakeholder engagement.

5.4 The Working Group recommends that further consideration be given to this new ‘gatekeeper’ role and the most appropriate body to take this on. Going forward this new role would offer a clear entry point for assessment of risk and benefits of regulation.

5.5 The Working Group were keen that whilst further consideration is given to this new single point access ‘gatekeeper’ role, that work is not delayed in taking forward the recommendations in this report. We therefore recommend the approach outlined below is considered as a potentially effective way of making necessary progress in the intervening period.

Identification of Potential Groups for Consideration that require more formal regulation, registration or licensing

5.6 The Working Group recommends that the Department of Health in England and the Devolved Administrations should jointly commission the ‘gatekeeper’, to conduct an overview of unregulated health workers to identify an initial shortlist of groups who need to be considered for more formal regulation, registration or licensing. This would draw on the approaches of other international regulatory regimes, consider the existing groups who have argued that they should be drawn into statutory regulation, but also, importantly consider groups who have not sought regulation, but might nonetheless present significant risk to patients and the public.

Prioritisation of the Shortlist

5.7 As the next stage in the decision making process, the Working Group recommends that the ‘gatekeeper’ should commission expert independent advice, drawing on economic and actuarial analysis of risk, to triage these groups into cohorts of risk. This should be informed by the work under development in the
Department of Health in England to develop tools to guide decision making on risk in professional regulation.

5.8 Having gathered the available evidence, the ‘gatekeeper’ could then establish an Independent Advisory Panel to consider recommendations to Ministers in England, Scotland, Wales and Northern Ireland. In order to reflect the various interests and organisations that compose the matrix of assurance described in Chapter Four, it should include representatives from across the UK who are able to advise on the relative effectiveness of clinical governance, being: employers, professionals themselves, patient/public representatives, regulators and system regulators as advisors in mitigating the risks presented by a particular group. Having considered those risks and the mitigating factors, the Advisory Panel would agree a prioritised list of groups who required further regulation.

Recommendations on Modes of Assurance

5.9 The next stage is to identify the lightest touch mechanism appropriate to provide the assurance required for each group. The ‘gatekeeper’ should work with stakeholders to agree and consult on an algorithm to guide this process, building on the work carried out by Skills for Health to support the deliberations of the Working Group (see Annex C ) on regulation in the health arena. Consideration should start with the lightest touch regimes and work upwards until an appropriate level of assurance is reached. The Working Group agreed that whilst the use of actuarial, economic and other evidence, combined with clear criteria and algorithms for decision making, would be helpful in guiding the formation of advice to Ministers, in the end there would remain a significant element of judgement, given the complexity of factors to be considered. A particularly important trade-off to be made will be the balance between assurance of safety for patients and users of care and the costs and burdens of regulation which will fall to professionals, employers and the taxpayer. It will be particularly important that relevant representatives of employers, or representatives of the independent sector, voluntary, public or commissioning sectors, are consulted on these proposals (and the governance mechanisms of the ‘gatekeeper’ for the provision of advice should ensure this is the case). The governance arrangement should further reflect the need to take account of the prevailing situations in England, Scotland, Wales and Northern Ireland.

Assessing Readiness for Regulation

5.10 If the first “regulation key” is one of risk to patients and the public, held by the future ‘gatekeeper’, and the second “regulation key” is one of proportionate regulation, held by employers, commissioners and contractors, the third key is whether a group of workers has in place the standards, codes of conduct and curricula to enable them to easily move into a more formal regime. Whatever regulatory or assurance regime is
recommended by the ‘gatekeeper’, for most professions the HPC should continue to hold the third key for statutorily regulated professions within the health arena, advising the Secretary of State in England on whether the group has carried out the necessary preparatory work for more formal means of assurance. Ministers in the Devolved Administrations will make any necessary decisions relating to the statutory regulation of future groups within their Administrations.

5.11 The Working Group agreed that whilst the existing criteria for assessing preparedness for conventional modes of statutory regulation were fit for purpose, it recommended that, as and when other modes of assurance such as licensing are developed, there would be a need for similar criteria for entry into these assurance regimes in the health arena. It may be that in carrying out this work it becomes apparent that some lower risk groups are ready for further regulation now, but that some higher risk groups require significant development before they can be effectively regulated. In these circumstances the Working Group agreed that when the need for statutory regulation is identified that support is provided to ensure this is implemented in the most efficient and timely way.

Identifying the Appropriate Body to Carry out Regulation

5.12 The White Paper made clear that the Government would not establish additional new regulators to support the extension of professional regulation, with the general expectation being that the HPC would take on most new professional groups in the health arena, unless there were particularly strong links to existing statutory regulatory bodies professional groups/practice. For example, it made sense to regulate dental technicians through the General Dental Council. No doubt there will be other like examples in the future.

5.13 For a number of workers or groups of workers the case for a natural linkage to an existing professional regulator is less clear cut. It might, for example, be relatively easy to argue that the role of physician assistant should sensibly be regulated under the umbrella of the “medical family” in the General Medical Council. For some roles within more diverse and flexible groupings, such as health care support workers, the case is less obvious. Whilst some have argued that health care support workers are naturally part of the “nursing family” and should therefore be regulated by the Nursing and Midwifery Council, not all support workers’ roles map so easily to nursing roles.

5.14 Whilst it is recognised, as stated in the White Paper, that the HPC would statutorily regulate new health groups, it is recommended that, for those groups where there is a degree of uncertainty about the appropriate regulator, the Department of Health, working with the Devolved Administrations and CHRE, should develop clear criteria for agreeing the most appropriate body to take forward regulation. These might include:
Extending Professional and Occupational Regulation

- The costs associated with different regulators (and therefore economies of scale);
- The capability and capacity of the proposed regulators to absorb new groups into their registration framework;
- The commonality with professional preparation, clinical practice and fitness to practise issues with existing regulated groups; and,
- Ease of public understanding and access to the regulatory system
- The views of staff and employees.

Distributed Regulation

5.15 The White Paper stated that the UK Government would explore the practicality of a system of distributed regulation, including its relationship to revalidation. The terms of reference of the Working Group state that the criteria developed relating to the pathway to statutory regulation should take account of the existence and appropriateness of different types, levels or models of regulation, including the role of distributed regulation.

5.16 Potentially, a system of distributed regulation would operate for those practitioners who are registered with one regulator but later wish to widen their scope of practice to include functions for which standards are not set by their existing regulator but are set by one of the other regulators. In this model, for example, a podiatrist registered with the 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 GMC and accepted by the HPC. What is envisaged in such circumstances is that the HPC would accordingly protect the title or annotate the practitioner’s existing entry on the professional register once the practitioner had met the required standards. The required standards would be clearly defined.

5.17 This model would mean that practitioners would not be required to meet the registration requirements of two different regulators and to pay for costly dual registration. More importantly however, it safeguards patient and public safety through practitioners having to meet the required standards for practice, irrespective of initial registration. It does however require an acceptance that it is the “lead” regulator who sets the standards, in some cases in partnership with another professional or regulatory body, and that all relevant regulatory bodies accept these standards for professional practice in the defined area, even in fitness to practise cases, where due regard would be given to expertise from the field of practice.

5.18 In summary, to use an example for illustrative purposes, the distributed model of regulation would mean that agreed common standards, set by a lead regulator, are used to regulate practice regardless of original professional registration with a regulatory body. With reference to the example in paragraph 5.16 the standards for surgical practice would be defined by the Royal College of Surgeons in partnership with the
Society of Chiropodists and Podiatrists, and endorsed by both the GMC and HPC. While registered with the HPC, in order to practise surgical podiatry the chiropodist/podiatrist would be required to meet the agreed standards for the area of practice. The HPC would accept those standards of practice and regulate accordingly.

5.19 The practicalities of this model of distributed regulation require further consideration. There would be a requirement for discussion on, and resolution of, legal and practical issues before implementation. Whilst theoretically attractive, there are a number of significant disadvantages:

- The system of professional regulation is already complex and this adds a further layer of complexity, requiring a demanding and perhaps unrealistic level of cooperation and communication between regulators who have different rules, different fitness to practise procedures and different sanctions guidelines;
- Such a system would make it confusing for the patients and the public when complaining about registrants;
- The system could appear to be shaped around the convenience of professionals rather than the needs of patients and the public; and,
- It could be argued that an individual who wishes to hold two forms of professional recognition potentially faces incurring additional costs and responsibilities that need to be funded appropriately through the payment of two professional fees.

Legislating for Regulation

5.20 Whatever the outcomes of this revised process for decision making about extending regulation, and given that the agenda is devolved, it is ultimately Ministers, the Westminster and Scottish Parliaments, and the Assemblies of the Devolved Administrations in Wales and Northern Ireland who decide on who should be regulated, how they should be regulated, and by whom. All four countries are currently committed to UK-wide regulation, sensitive to each country’s needs. The innovation of an Order under section 60 of the Health Act 1999 enables this to be put in place, as well as enabling the UK Government to introduce changes and extensions to health regulation in reserved areas (i.e. for professions already regulated pre-devolution), through secondary legislation. This allows the system to be adapted and extended without the Government of the day having to make time in tightly packed programmes of primary legislation.

5.21 At the time, it was hoped that this legislative innovation would also allow legislation to be passed more quickly, but as parliamentary scrutiny has increased, the legislative process has evolved and new requirements have been put in place to ensure appropriate involvement of the Devolved Administrations for changes to the regulation of those professions whose regulation is reserved. Given that the regulation of new professions is a matter devolved to the Scottish Parliament, timescales also have to
accommodate the laying of Section 60 Orders before both the Westminster and the Scottish Parliaments at the same time, often accommodating different Parliamentary recess times. The development and passage of secondary legislation can take as long as two years from start to finish.

5.22 In the past the need for strong Parliamentary oversight of professional regulatory legislation was deemed necessary for a number of reasons. Regulation impacts on the human rights of those regulated, has significant costs, and is an important matter of public safety in which Parliament needed to have a final say. As many of the regulators were overseen by governing councils with a majority of health professionals, it was seen as too risky to leave matters of public protection to the regulators themselves to decide upon.

Conclusion

5.23 The recommendations set out in this Chapter represent a significant radical change to the way in which decisions about extending regulation should be made and will require further detailed development work. In considering their responses, the Department of Health in England and the Devolved Administrations should consider:

- The need for a ‘gatekeeper’ role to lead discussions about an evidence-based approach to extending professional and occupational regulation;
- Commissioning the ‘gatekeeper’ to shortlist currently unregulated groups to assess the need for formal regulation; and,
- Establishing an independent panel to assess the case for regulation and make recommendations to Ministers.
6 Involving Stakeholders: Patients, the Public and Employers

Introduction

6.1 Throughout the discussions of the Working Group, there was an ongoing concern about how best to ensure more meaningful and effective engagement of the public, patients and users of health care in decisions about extending professional regulation.

6.2 In addition, there was a continuing concern to ensure that those who employ or contract with professionals were partners in the design and delivery of new approaches to professional regulation as they are often most significantly affected by both the costs and benefits of national systems.

6.3 We believe that these concerns are entirely consistent with the direction of travel of professional regulatory policy and with the vision set out in the health professional regulation White Paper. Professional regulation has evolved significantly over the past 150 years. Historically, it was predominantly a policy conversation conducted between professionals, their educators, their regulator and the Government. Over the years, all the regulators have made moves to include greater lay involvement in their Councils and to seek to draw in more directly the views of educators and employers. The White Paper, working with the public, the regulators, employers, educators and others, took the next step forward and over the past year, the Health and Social Care Act 2008 and a suite of secondary legislation have resulted in new governance arrangements for the regulators that ensure a minimum of equal lay and professional members on each Council. In addition, the White Paper and its supporting legislation gave CHRE a much stronger and more explicit role as the independent expert voice of the patient and members of the public in the regulatory system. In drawing up the composition of the new health regulator Councils, there has been a much stronger desire to ensure that employers and commissioners have a stronger and more direct role in the oversight and leadership of professional regulation.

6.4 The Working Group agreed that it was highly appropriate to engage patients, the public, employers and service regulators. It agreed that these drives would lead to more effective operation and leadership of the existing system of professional regulation. Active stakeholder involvement was equally appropriate for design and delivery of processes to extend its scope into new professional and occupational groups. In doing so, the group recognised that this is easy to say, but often difficult to put in practice.

Patients and the Public

6.5 There are a number of challenges that need to be addressed to ensure better involvement in decision making:
• There is a need to raise awareness of the regulation systems that are in place to protect the public;
• There is a need for effective branding that becomes the kite mark for safe care for patients and the public;
• There is a need for greater transparency in the way that regulatory systems operate;
• We need better systems that maximise patient, and public involvement. Patients and the public are not a single homogenous group and will have a diverse range of views and expectations, depending on their personal experiences with professionals, their backgrounds and their aspirations. Inclusion of a few patients or public representatives on policy development and implementation groups can never properly capture the complexity of those views and can put those representatives in the impossible position of having to act on behalf of such diversity;
• We need to do more to support lay representatives. Professional regulation is not always easy for the lay newcomer to understand quickly, covering a complex mix of professions and organisations, based on a sometimes apparently labyrinthine legal framework, and with discussion being led by regulators, professionals, civil servants and managers who have become accustomed to using the shorthand of acronyms, jargon and specialist language. In addition, the issues under consideration are rarely “either or” choices, but often involve difficult trade-offs and balances over a number of dimensions. So engaging with professional regulation effectively can be demanding in terms of time, thought and effort to the uninitiated, and we need to recognise that we ask a great deal of lay representatives when we invite them to participate and contribute; and,
• To ensure greater involvement in decision making the public need clear and understandable information concerning regulation, and the issues it raises.

6.6 Given these barriers to participation, it is at times only people who have experienced particularly poor care who have the passion and commitment to give their time. While their perspectives are an absolutely critical part of the debate, it is also important to include other views. For those people who have had broadly satisfactory, good or excellent experiences of health care professionals, there may be less of a sense of urgency and risk and greater concern, as taxpayers, to minimise the costs and burdens of regulation and more of an appetite to trust the professionalism of individual practitioners.

6.7 There is an important and difficult balance in making decisions about regulation. Those who take responsibility for participative policy making in regulation are always conscious that a well-reasoned case for lighter touch regulation, based on analysis of risk, can pose challenges. A light touch approach may enable more good to be done with the resources provided, but it may also mean a rare but individually significant personal tragedy is more likely.

6.8 This is not helped by the fact that public understanding of the nature and purpose of the United Kingdom’s system of professional regulation is not strong and that,
understandably, public and media discussion and analysis of the system generally only takes place in the crucible of manifest failings of professional practice or conduct which shock the public, professionals and politicians alike. In a context where public and media understanding of a complex area is weak, there is danger that employers, regulators and Government will feel obliged to react to respond to a “once in a million” event with measures that unduly or disproportionately constrain the action of health care professionals in the other 999,999 events which go very well. If the action of tighter regulation means that there are fewer events that go well, because more time is spent on preventing harm than doing good, then the trade off between enabling care and preventing harm may be misjudged. A better informed public opinion, based on better engagement of patients and the public, is critical to enable policy makers to work with all stakeholders to ensure that decisions distinguish proportionately between disturbing but rare one-off events that may be near impossible to predict and prevent, and cases where lessons need to be learned and action taken.

6.9 It is also important that a better understanding is fostered about the purpose of regulation. It is not designed as a punitive system for individual professionals. The primary purpose of the system is to protect the public by ensuring that health professionals are fit to do their jobs well and to do so respectfully. On the rare occasions when health care professionals and workers are negligent, dishonest, malicious or abusive, it is for the employers and or the criminal justice system to consider the evidence, pass judgement and pass sentence accordingly.

6.10 Whilst in seeking to protect the public, the regulatory body may suspend health professionals, prevent them from practising ever again, or impose conditions on their continuing rights to practise their profession, it does so solely to protect the public. Whilst such actions may have a punitive effect, by ending the clinical career of the individual concerned, this is a side effect, rather than an intention, of a decision that is solely focussed on ensuring public safety. Equally, if a professional has made a mistake, has insight and regret about that mistake, and the regulator is convinced that it is unlikely to be repeated, then they may reasonably consider that it is safe for that professional to return to full professional practice because the future safety of the public is not threatened by that decision, and, importantly, the benefit that that professional can bring to others in the future is secured. Everyone – professionals, civil servants, journalists, politicians, managers – make mistakes. Sometimes those involved are culpable, but often they are human, and the ability to distinguish coolly between the two is critical. Frequently, the circumstances in which the individual made that mistake may be a significant contributory factor, because the management, resource or organisational systems made the mistake more likely. To someone who has lost a person that they love because of the mistake of an individual it may seem incomprehensible that they are allowed to continue to practise, but it is critical that decisions on regulation are based on evidence about what is likely to bring the greatest benefit to health care in the future.
6.11 This is a critical element of decisions to extend professional regulation. As a Working Group, we are advising Ministers in England, Scotland, Wales and Northern Ireland that for some professional and occupational groups that have been proposed for regulation, that a light touch regime, or even no statutory regime, may be the proportionate response. The further work set out in this report to support evidence-based policy-making will help to give a more rigorous basis for those decisions, and the process described in Chapter Five sets out how Ministers might build greater consensus and shared responsibility across stakeholders and society for these difficult decisions and judgements.

6.12 Whatever regulatory regime is adopted as a result, it is inevitable that, sooner or later, there will be instances in which newly regulated professionals are found wanting, perhaps shockingly so, and the rigour of the regulatory regime is called into question. The more that public and media understanding of the difficulty of these judgements is developed now, and the more that the public and the media are drawn into the complicated and difficult judgements inherent in this area, the more likely it will be that together we can react maturely to events and keep a clear eye on what, ultimately, will ensure the best use of resources to ensure safe, effective, high quality, and respectful care for patients and the public. The easy and safest response is to regulate everything and everyone to the hilt urgently, to guard against future accusations of a lack of vigilance on behalf of the public when things go wrong. The difficult, riskier, but right approach is to engage, explain, discuss and take a shared, well-informed and open judgement about risk, so that we can maximise the benefits that health care professionals bring and, as far as we judge together that it is safe to do so, minimise the regulatory burdens that reduces their potential to do good.

6.13 Within that discussion, it is important that we are clear about where responsibility for management of risk lies. If it is judged, on the available evidence, that a lighter tough regime is appropriate for a particular professional, practitioner or health care worker, then it is important that the public who receive care from professionals within that regime are aware that this is the case and are informed clearly of the risks that they take as a result. If Government, employers or commissioners are not taking part of the responsibility of risk on behalf of the public, then it needs to be explicit that this is the case and that responsibility for that risk lies with the individual who chooses to use that service. Where Government chooses, on the basis of the process proposed in this report, a lighter touch regime, it is important that the Government, employers, and the health care workers themselves, inform the public about the risks, to enable them to make an informed choice about whether to access that care.

6.14 In order to enable an environment for evidence-based policy, the Working Group makes the following recommendations. The Department of Health in England, together with the Devolved Administrations, should review the functions, responsibilities and resources available to CHRE to ensure that it has the powers and capabilities needed to lead, together with regulators, professionals, patients and public discussion about the nature and purpose of regulation, with a view to supporting...
informed media and public discussion about professional regulation. In addition, the Department of Health in England, together with the Devolved Administrations, should commission advice from CHRE on more effective mechanisms for engaging patients and the public in the decision making processes on professional regulation. This should encompass the scope for greater use of direct user-involvement in policy development and implementation; the involvement of representative organisations; the use of public opinion surveys; the use of Citizens’ Juries; public involvement events; proactive engagement with opinion formers, the media and Parliament; and the use of the internet, social networking and other web-based tools for public engagement.

Employers, Contractors and Commissioners

6.15 While patient and public involvement in the policy development and implementation process is a critical part of a modern system to extend professional and occupational regulation, it is also vital that the system engages effectively with employers, commissioners and those who contract with health professionals. As the debate about professional regulation has, in the past, been dominated by a concern to balance patient and public concerns about the safety of health care against professional concerns to avoid unfair, overly burdensome and constraining regulatory approaches, too often the employer voice in the debate has been unheard. As the organisations and individuals who interact on a daily basis with health care professionals, it is they who take the often difficult day-to-day judgements, in partnership with staff, about the dilemmas of balancing the benefits of safety, effectiveness, quality, patient/public experience and efficiency that sit at the heart of modern health care provision.

6.16 As the professional regulation White Paper has resolved many of the tensions around some of the important, but sometimes more symbolic, issues such as the governance of the professional regulators and the standard of proof used in considering concerns about professionals, the policy agenda is not solely about managing understandable tensions between conceptions of professionalism and conceptions of patient and public safety. The focus now must be much more on the design and delivery of effective local systems which enable employers, commissioners and professionals to work together to run systems of regulation, management and clinical governance effectively and proportionately.

6.17 In drawing employers, commissioners and contractors into the co-production of policy design and implementation, it is important also that this is not simply a joint exercise with the NHS. Health care professionals and staff work in a great diversity of settings and employment models, and the decisions taken on their regulation need to encompass the views of private sector healthcare organisations, the third sector and other organisations who employ health care professionals in advisory, research, educational and other capacities.
6.18 The Working Group therefore recommends that in establishing the framework for making decisions on extending regulation, the organisation which takes the ‘gatekeeper’ role for the process should have in place formal and effective arrangements to involve the diverse range of employer, commissioner and contractor interests who will need to make these new arrangements function effectively and proportionately for patients and the public. It should also ensure that it is effectively aligned with other parts of the matrix of assurance of which professional regulation is only one, but important, part.

Conclusion

6.19 For any system of regulation to be fit for purpose it must have the confidence of the public, for whom it is designed to protect. In addition, there is a need to ensure that those impacted by regulatory decisions (be they patients and/or the public, or those operating within the regulatory landscape itself) have up to date and accurate information available to them, so that regulation continues to evolve in a manner appropriate to the risks it is intended to manage.