Health Professions Council
6th December 2005

FOSTER REVIEW

Executive Summary and Recommendations

Introduction

The Department of Health's review of non-medical regulation, the "Foster" review, is scheduled to conclude its work by the end of the year when recommendations will made to the Secretary of State for Health. The recommendations will probably be published in January 2006, as will those of the review of medical regulation, the "Donaldson" review.

The Foster Advisory Group drafted and made available six Key Theme papers. In addition, two presentations were made to the Advisory Group conference on 8th November, on "Emerging preliminary views" and "Conference feedback". Copies of the Theme papers and the two presentations are attached for reference.

The two reviews may make significant changes to the statutory regulation of healthcare professionals and others. The changes may include:

- Changing Council membership and the election process
- Harmonisation of legalisation
- Establishing a new organisation to investigate and hear fitness to practise cases
- Expanding regulation to non-professional healthcare workers
- Regulation of new roles
- Revalidation
- Reducing the number of statutory regulators of healthcare professionals
- Extending the role of CHRE.

However, it should be noted that the recommendations may require the 1999 Health Act to be amended and therefore they would not be implemented before 2008 at the earliest.

Decision

The Council is asked to agree that the Executive should:

- Distribute the recommendations to Council and Committee members as soon as published;
- Prepare a briefing paper for the March Council meeting.

Background information

None

Resource implications

None

Financial implications

None

Appendices
None

Date of paper
25th November 2005

1.

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Members of the Reference Group
Non-Medical Review of Professional Regulation.

1st November, 2005

Dear Delegate,

Reference Group Conference: 8 November, 2005, New Connaught Rooms, Covent Garden.

Most of you will have attended the earlier Conference in July and I am pleased to report that, since then, a considerable amount of progress has been made. The attached papers now present a summary of the discussions with the Advisory Group and identifies the areas where there is common ground and also areas where options about the way forward remain. Over the next two months, we will be focusing discussions on the latter and for this reason will be devoting much of the discussion at the Conference on these issues.

Discussions with the Advisory Group were, of course helpfully informed by the earlier Reference Group Conference and responses to the 'Call for Ideas'. I hope therefore that this Conference presents a further opportunity for the Reference Group to put their views forward.

As I have already indicated, the key theme papers still represent work in progress. Following this Conference and further discussions with the Advisory Group in December, I will be reporting my findings to Ministers with a view to reporting the outcomes early next year. As before, we will continue to update you following meetings of the Advisory Group.

Many thanks for your continued support to this important review and I look forward to meeting you at the Conference.

Yours sincerely,

Andrew Foster
Director of Workforce
Department of Health

REVIEW OF NON-MEDICAL PROFESSIONAL REGULATION

DEMONSTRATING INITIAL AND CONTINUING FITNESS TO PRACTISE

Introduction

1. The Review's terms of reference include a requirement to "consider and advise about the measures needed to ensure the operation of effective systems of CPD and appraisal for non medical health care staff and make progress towards revalidation where appropriate." At the meeting in May, the Group decided that they would pursue six key themes, the first of which was **demonstrating initial and continuing fitness to practise**. This note reflects our initial analysis and ideas as discussed and amended by the Group and has also been amended to reflect comments and the outcome of discussions elsewhere.

2. Some definitions may be helpful and Annex 1 contains working definitions of key terms. *Revalidation* is the process by which a regulated professional periodically has to demonstrate that he or she remains fit to practise. It differs from compulsory CPD in attempting to evaluate fitness to practise (FtP). In addition to up-to-date relevant professional knowledge, competence or even performance, it therefore demands some level of evidence that none of the factors said in legislation to impair FtP are present. The full list of factors is:

- performance
- conduct
- criminal convictions, in the UK or elsewhere
- adverse physical or mental health
- determinations by other health or social care profession regulators (in the UK or elsewhere) that the person's FtP is impaired.

3. Revalidation therefore has a clear safety benefit over and above that which flows from the requirement to demonstrate that CPD is up to date - and an extra cost, particularly if it does take on the challenge of measuring performance rather than competence. This would have to use a combination of techniques including perhaps the observation of clinical practice. A midwife suggested to us at the July conference that the statutory supervision of midwives, which includes such an element, provided a good model.

4. This paper discusses how professionals should demonstrate they are fit to practise:

(a) at first registration, and
(b) through the rest of their careers.

Fitness to practise, ie to be on the register at all, differs from fitness for purpose, ie fitness to do the tasks currently expected of the person, although some of the Group had reservations about "currently expected" as a possibly confusing term to introduce at this point in relation to revalidation. All registered professionals, whatever their working environment, are under an ethical obligation to self-limit according to their training and competence, and GDC have stated that in developing revalidation registrants' competence in current performance will be assessed in the field(s) of practice in which they perform. Having said that, revalidation needs to capture evidence of fitness for purpose if it is to protect patients adequately.

5. Ideas for change have been considered in the light of the Group's view that any recommendations need to be proportionate to the risks faced, to avoid undue burdens of extra bureaucracy or cost and to aim for the simplest approach which would promote patient safety.

Current position

6. The current position is best described in two parts – what employers do, and expect of their staff, and what regulators require. Of course the foundation of initial fitness to practise is successful completion of a training process (usually lasting three years or more) and it is largely from this training that members of professions derive the professional standards, attitudes and behaviours which normally protect patients effectively. Education includes the standards set by the regulator. An applicant without a qualification recognised by the regulator does not get to the starting line.

7. Employers: this section considers only the NHS. However, in some professions such as pharmacy or dentistry the majority are employed by other organisations or are self-employed. The NHS employer's main check when a professional starts their career is that they are registered with the relevant regulatory body. However to this can be added occupational health checks, checks with the Criminal Records Bureau (CRB) (or equivalent in each of the four UK countries) and the lists either held or planned to be held across the UK under the Protection of Children Act (POCA) and Protection of Vulnerable Adults (POVA). Existing arrangements may need to be modified in the light of the Bichard recommendations, and government should satisfy itself that all these different systems work in a joined-up way. Special rules apply for primary care practitioners (including dentists, pharmacists and opticians as well as GPs), who need (or will do under present plans) to fulfil conditions to be placed on a PCT performers list. These checks can only provide security at a fixed point in time; RPSGB has recently added a declaration to its retention fee process but notes that these systems need to be joined up to be used effectively.

8. The NHS Reform (Scotland) Act 2004 makes NHS employers legally accountable for staff governance, in the same way that they are already responsible under law for the quality of clinical care and for appropriate financial management. The Staff Governance Standard is the key policy document which defines five elements that make up the standards of employment practice that are expected form NHS employers. Employers need to demonstrate how they ensure that staff are well informed, appropriately trained, involved in decisions that affect them, treated fairly and consistently and provided with an improved and safe working environment. The Standard also shows how staff governance fits into a broader strategic framework, as well as describing the roles and responsibilities of different groups in relation to the Standard.

9. The Standard features a range of targets and standards that is subject to self assessment as well as internal and external audit. This is supplemented by a biennial staff survey where every member of NHS Scotland's 150,000 staff has the opportunity to feedback on their perception of working in the NHS. One of the key features of the Standard is that policy frameworks are determined nationally in partnership between the Department, employers and trades unions known as Partnership Information

Network (PIN) policies. These help to strike the right balance between developing consistency for all staff and local determination to reflect local circumstances.

10. The different regulatory bodies have similar, though not identical, requirements of people seeking new registration. Their requirements thereafter also vary. The three tables in the Annex illustrate this. To sum up, regulators require evidence that a new registrant is fit to practise, mostly in terms of health, character and training[1], and all regulators (except the GMC, which has a different system) require, or will shortly require, mandatory CPD for a person to remain on the register. Insurance is also becoming a requirement over time. However, admission to a regulatory body's register is not automatic for newly qualified individuals. The GCC and GOsC can refuse addition to their registers based on a persons 'portfolio.' The NMC requests declarations of good character whilst also amending their register if something warrants that action. The GOC has recently introduced student registrations that require individuals to be registered even before they begin an optometry degree course. Some regulators, but not all, are considering moving beyond CPD to a requirement for revalidation, but only the GMC has legal provisions already enacted (and these are not in force).

11. In an attempt to simplify the recording of evidence about the suitability of new staff, some NHS Trusts in England are piloting a credentialing system for junior doctors using smart cards. In this trial, credentialing means that the card contains essential data about eg occupational health and GMC registration, which allows the hospital to let the doctor start work. If this proved positive, it might be rolled out to non-medical staff and could be integrated with the developing Electronic Staff Record (ESR). The ESR is part of the NHS National Programme for IT in England. It will replace dozens of separate current HR and payroll IT systems. ESR is now being piloted and is due for complete rollout in the NHS in England by 2008.

12. The Scottish Workforce Information Strategic System (SWISS) will implement a national workforce information database with a common set of data. Over the next 3 – 5 years, an integrated / interfaced HR / payroll system for NHS Scotland will be procured.

13. Individual professionals and their employers invest very substantially in CPD. In the NHS there has been a trend to require (and fund) CPD which is relevant to the employer's needs. Regulators have begun to require CPD as a condition of continuing registration (some, but not all, see this as only the first step towards full revalidation.)

14. Arrangements for appraisal for NHS staff covered by Agenda for Change have been developed (but not yet rolled out) as part of the NHS Knowledge and Skills Framework's (KSF) Development Review. Although appraisal for doctors is further

[1] *Ensuring that only properly qualified people are registered involves a wide range of regulatory activity, including quality assurance of education, training and experience through for example: accreditation of programmes and providers; setting indicative (and formal exam) syllabus; running national registration exams; accrediting tutors, mentors etc. and appointing external examiners, Setting standards of competence (knowledge and skills) and performance in core areas of professional and clinical practice and setting assessment standards for initial registration (and advanced registration eg supplementary prescribing or extended scope of practice*

advanced (introduced in a phased way from 2001, it is now in place for all NHS doctors) as Dame Janet has made clear, it is not necessarily more effective. It is designed to give NHS doctors the opportunity to discuss their practice with a trained appraiser and identify areas for development. The main purpose of the KSF is to provide an NHS-wide framework that can be used consistently across the service to support:

- Personal development in post
- Career development
- Service development.

15. The development of appraisal for Agenda for Change staff will bring in the discussion of objectives linked to service and organisational needs, and development required for recertification/revalidation where appropriate. Further work will depend on the findings of this review.

16. The NHS KSF is designed to identify the knowledge and skills that people need to apply:

- In their post
- To help guide development
- To provide a fair and objective framework on which to base review
- To provide the basics of pay progression in the service.

The KSF is a broad generic framework that focuses on the application of knowledge and skills – it does not describe the exact knowledge and skills that people need to develop. The regulatory activities about setting educational standards described in the footnote to paragraph 10 need to sit alongside the KSF. Linked to the KSF, the National Occupational Standards produced by Skills for Health have been praised for producing a consistent basis across the UK for describing particular competences.

17. All staff will have annual development reviews, which will include appraisal, assessment against the KSF and the production of a Personal Development Plan using the KSF as a development tool. All four Government Health Departments are developing appraisal systems integral to the KSF Development Review based on a wide range of good appraisal practice which currently exists in NHS organisations such as PCTs and Trusts in England. The KSF began to roll out in October 2004 for NHS staff in England and will be fully implemented for all 1.2 million staff by October 2006. Note that the KSF does not assume everyone has all the skills needed for their post on day one, but instead has a "First Gateway" for pay purposes which people should pass after about a year in post.

18. Some members have observed that the KSF has been designed to be used formatively and suggest that it would be hard for it to be adapted, even if values and attitudes were added, for use as a summative tool for either initial or continuing fitness to practise. Certainly the Personal Development Planning & Review (PDPR) process of the KSF is about personal development and should be viewed as standing separate from the need to demonstrate continued fitness to practice.

<u>Problems with the current position and opportunities for improvement</u>

19. One area to address will be the lack of co-ordination between NHS and regulators' demands for information and evidence from a newly-qualified profession starting their first job. While there is a for more work to understand how the range of different requirements has grown up, it ought in principle to be possible to arrive at a package of information and evidence which a person can provide just once to a single organisation, whether employer or regulator, who then assures others who need it that the information has been received and validated as necessary. We should not underestimate the practical and political complexity of achieving that, however. Regulators are legally required to collect information at present and if some of this is delegated, it should be clear who is accountable for the quality of the information. Such evidence is of course time-limited, and satisfying the requirements for initial registration would need to be followed up by appropriate and timely checks. The Group was receptive to the idea of a single set of shared information but needed reassurance that the legal issues would be dealt with.

20. If it could be done this could reduce the amount of paperwork needed, for example, to get onto a PCT performers list. Any data held about a practitioner would, of course, need to be immediately updated should important information come to light (e.g.in England by way of any Bichard notification scheme). Mechanisms would need to be put in place so that this information was flagged up proactively, without the regulator or employer needing to go and look for it.

21. Linked to this, we might want to seek more consistency about the evidence needed at first registration – more consistency between employers and regulators, and between different regulators. Within this, it would probably be advantageous to come to a single view about what is meant by "good character"; one of the regulators' requirements. This expression began life as a fairly subjective assessment and has gradually acquired some more objective tests such as the absence of criminal convictions, adverse regulatory decisions and so on. Clearly, this is an area which could usefully be codified. There is work at European level to promote information sharing on 'good character', and this impetus should continue. Additionally, to the extent that good character requires a new graduate to be 'signed' off by his or her Dean/Head of School, thought needs to be given as to whether all regulators should have similar schemes for determining student (mis)conduct. We understand that CHRE is developing work on the definition of good character.

22. Most regulators currently have no powers for dealing with fitness to practise concerns about students or trainees before the point of application for registration. The Council of Heads of Medical Schools has recently issued revised principles for the selection and admission of students to medical schools which make clear that when medical schools select students they must choose people on the basis that they will actually go on to become doctors rather than relying entirely on their academic capabilities. The revised principles include the statement that "fitness to practise issues must therefore be considered when selecting students".

23. The first contact several regulatory bodies have with students is the point of application, raising calls for earlier contact by the regulators to address fitness to practise concerns. This is true for the GCC, HPC, GOsC and GMC, but views differ as to the extent of the problem. How a regulatory body perceives the problem is influenced by the content of the training courses, specifically the amount of patient

contact required. As mentioned, the GOC introduced student registrations because of student-patient contact during their degree course and previous incidents with students that would have warranted a FTP investigation. The GCC and HPC have no plans to involve themselves further with student registrations, preferring to guide institutions about student conduct rather than actively engage with the student. The GOsC and GMC are debating the issue due to concerns about identity fraud and student FTP. The RPSGB and PSNI benefit from the existence of the pre-registration year, in which they are closely involved. Most regulators would like to work with HEIs on health and conduct requirements and how they need to be monitored, throughout the course and at entry to the course, if this will lead to registration.

24. Scotland currently continues to index pre-registration nursing and midwifery students following the repeal of the Nurses, Midwives and Health Visitors Act and the replacement of UKCC and the three National Boards with the NMC. The NMC itself has also questioned whether a newly-registered nurse has enough clinical skills, raising the question of whether an approach like preceptorship or provisional registration might be needed. The NMC has consulted on this and also has plans to reintroduce student indexing.

25. Moving on to the area of revalidation, the problem we need to solve here is to design something which:

> (a) is consistent with the outcome of CMO's review, following Dame Janet Smith's concern that NHS appraisal does not deliver the policy and legislative commitment to an "evaluation of …fitness to practise", and yet at the same time
> (b) is proportionate to the actual risks posed by different health professionals.

Whilst (a) is likely to pull doctors, and after them the other health professions, in the direction of something more resource-intensive than current systems, (b) challenges us to justify this.

26. One approach, suggested by the HPC, was for fairly simple self-certification whenever a registrant renews his registration, for example that his CPD is up to date, he has had no criminal convictions since his last declaration etc. This would be policed by taking a sample of the declarations and checking their veracity. Those found wanting would be denied renewal of registration until the deficits (in eg CPD) had been put right. This approach has attractions because it gives the individual the lead responsibility for their registration. The individual and his employer, if any, would have a shared interest in resolving any problem with registration renewal as quickly as possible since he could not practise until this had been done. The HPC suggested to us that this "renewal-based" regime avoided much of the possibility of litigation which was implied in a revalidation regime where the regulator exercised judgements, against which there was an appeal. There was some doubt about whether the law allowed appeal to be excluded so easily and others pointed out that assessment of CPD often had to be somewhat subjective. The GOC has just introduced an approach which resembles this in several respects. It is clear that some of the unvalidated declarations could be fraudulent. We are told that the UKCC found in the 1990s how fake CPD portfolios could be bought, and came to the conclusion that it would have needed to visit some applicants to be sure they were genuine.

27. Another possible approach, which is being developed by the GMC, could be to vary the "intensity" of revalidation depending on a risk assessment. The more impact on patient safety a person's conduct or practice would be likely to have and the more likely that there would be such an impact, the more effort and expense can be justified in testing their competence and attitude by means of regular revalidation, which could for example be more frequent and intrusive.

28. Note that this is different from the test of whose impact would be greater if their CPD is not up to date. An example of the CPD test is that a neurosurgeon with out of date clinical skills would probably have more impact on patient safety than an out of date dental hygienist. An example of the revalidation test is that a single-handed dentist who whose job solely involves carrying out domiciliary visits in a nursing home setting, and who has no stable clinical environment, and who failed to report an alcohol problem, would be more likely to harm a patient than such a dentist working in a group practice.

29. To assign professions or individuals within professions to higher and lower risk groups in this way (i.e. in relation to their potential impact on patient safety) would involve some difficulties, both technical and political. Groups assigned to lower risk status might feel this reflected on their relative status, though perhaps they would also be relieved to be spared the more rigorous forms of revalidation and the higher registration fees needed to pay for them. The question of cost should not however determine which groups should be subject to more rigorous tests. And if some revalidations cost more than others, there was a question about how much cross-subsidy if any would be justified.

30. Further consideration of this is needed. A definition of what the risk is, is needed, eg at risk at the hands of incompetent practitioners; at risk of abuse or another criminal act? The following table relates to a number of factors considered to be relevant to risk, eg competence, currency of practice, conduct, level of interventions, level of responsibility, leadership status, service standards and audit, levels supervision, etc. However, it is sensible to assume that professionals with an adverse conduct record require a different level of monitoring. It was suggested that a possible model was the Canadian sift-based system. This model also enables targeting based on risk scores, and factors such as age and working environment are taken into account. Defining a risk model does potentially raise questions in relation to sanction. Since fitness to practise encompasses knowledge, health, competence, performance and conduct, any risk model should try to reflect this, rather than be based on safety alone.

31. A possible hierarchy of risk might look something like the following table:

HIGHER	LOWER
High level of responsibility for patient safety inherent in scope of practice	Low level of responsibility for patient safety inherent in scope of practice
Leaders of clinical teams	Team members
People who practise outside managed environments such as a hospital or clinic	People who practise within such environments
People whose working environment is	People whose working environment is

not subject to NHS standards of clinical governance	subject to NHS standards of clinical governance
Practitioners who are frequently alone with patients/clients (including in their homes)	Practitioners who always work in a team / do not work face to face with patients/clients
Unsupervised practitioners/posts	Supervised practitioners/posts
People in their first few years of registration (and possibly also their last few, according to some evidence)	Registrants in mid (or late?) career
Recent adverse finding by a regulator	Clean regulatory record
Recent appraisals show concern about performance	Good performance record
People who are in current practise	People who are not practising (some regulators have proposed a scheme where non-practising registrants need not revalidate at all) Those who are not practising should not be required to revalidate as there is no risk to the public. This does however have implications for re-entry to the register.
People using invasive, high-risk interventions	People using lower-risk interventions

32. The table boils down to a distinction between inherent nature of the practice (high or low risk) and the context. For example, single-handed practitioners and locums should be monitored more closely, partly because problems will be slower to emerge than in a managed environment, but also because rogue practitioners are not evenly distributed between environments: those who set out to steal, abuse or exploit will seek out situations where they have more opportunity to do so.

33. If a few hard and fast categories could be established, even with a certain amount of rough justice (provided there was an evidence base for the broad principles), then different levels of revalidation could be assigned to risk categories. These could be identified both in terms of frequency/intensity of checks required (eg (a) full check every 2 years, (b) requiring recent CRB check/ self-declaration every 5 years, and so on) and also how such checks might be carried out (e.g. self-certification at the lowest level, through certification by the employer, to independent certification for those with the highest responsibility for patient safety). Furthermore, if someone fell into several of the higher risk boxes in the table they might be assigned to more intensive revalidation than if they only appeared in one.

34 If employers' assessments were to be used, they would have to be capable of producing assessments of competence or performance that would lead to nationally consistent decisions relating to continuing fitness to practice. One suggestion was that practitioners working for employers accredited by the Healthcare Commission could be subject to lighter-touch regulation; e.g. NHS Trusts. In the community pharmacy context this is much less feasible because of the very large number of employers and the absence of Healthcare Commission accreditation.

35. A related area is the need for the register to provide more information about post-registration qualifications. As professions specialise, information about a person's

post-registration qualifications becomes more important to his continuing fitness to practise. Some regulators make marks in their Registers to record these. The main issues here are:

- what level of post-registration qualifications is it useful/necessary to record for patient protection purposes? Eg those relevant to someone at level 6 of the Career Framework for the NHS like a community psychiatric nurse, level 7 (eg specialist midwife) or level 8 (eg nurse consultant). We think that level 7 ought to be the threshold. This is a 'fitness for purpose' issue rather than a 'fitness to practise' one.
- once such a qualification or specialisation is recorded, do we need to apply any rules about compulsory CPD or revalidation to the specialty as well as to the basic registration? Presumably patient protection does require us to know that a person is competent to carry out his current tasks, and this includes remaining up to date in any relevant specialism such as being a prescribing optometrist. The NMC is currently consulting on specialisation and the responses they receive could be informative.

Constraints

36. Apart from passing our tests of proportionality and simplicity, any proposed changes would have to deal with other constraints. Far-reaching change would need careful management, and take a long time (for example, changes to the rules for primary care performers lists, even if likely to be welcomed by the professions, need to be negotiated with them; effective systems of appraisal take some years to implement).

37. If we moved to a much greater sharing of information between employers and regulators, this would have to be done within an ethical and legal framework which took account of data protection legislation to balance rights to privacy with the public interest in patient protection.

38. The delegation of functions to employers has attractions but also raises problems, as the regulator's legal functions simply cannot be delegated. (This is undoubtedly the present state of the law, though it could in principle be amended.) The multiplicity of employers could tend to intensify problems of consistency and fairness. Not all employers are equally trustworthy and indeed the regulators who regulate companies sometimes have to take FtP action against them. On the other hand, it might be possible to have a regime in which some functions were delegated to employers who gained accreditation, perhaps from the Healthcare Commission. Where a registrant

did not have an accredited employer, he would be regulated directly by the regulator as now in respect of all the regulatory functions.

39. The regulators' position is that their sole driver is public protection. Employers and service providers, including the government, have other concerns, and there are situations in which there will be tension between public protection and the effective functioning of services. It would be unacceptable for the latter to compromise the former. This may make employers inherently unsuitable to carry out core regulatory functions. Fragmentation of responsibility, with involvement of a number of different employers, could also lead to inconsistency and a reduction in quality, thereby increasing risk to patients. However increased participation by employers leading to a more effective partnership would be welcomed by the regulators.

40. There also is a lack of evidence that employers actually wish to get involved in this process rather than simply being able to obtain assurances from regulatory bodies that their staff have the necessary competences and appropriate attitudes. They could well raise funding questions. However, as part of their existing clinical governance responsibilities (and the common-law duty of care to patients) they already have obligations to ensure that their staff are fit to practise and fit for purpose.

41. Using the KSF to support revalidation may be attractive to employers but it sits alongside and does not replace the base learning of professionals. For revalidation to be meaningful it has to be about more than just knowledge and skills. Attitudes and behaviours need to be considered, and perhaps these could find a place in the KSF at some stage too. Annual performance assessment against the KSF appears a very attractive basis for revalidation if the challenges could be overcome. These might include the need to negotiate such a use of the KSF with the various trades unions.

Recommendations

42. There is scope to protect patients better by implementing more streamlined systems for initial and subsequent checks of a professional's fitness to practise. It is not justified to confine revalidation to doctors, but at the same time a model for revalidation needs to be selected which is proportionate to the risks posed by different staff. The following should be explored further:

- More co-ordinated handling of information between employers and regulators so that a new professional provides evidence once, which is then shared possibly via an articulated electronic record system.
- Demands for information need to be rationalised so that one agreed data set is used.
- Qualifications beyond those needed for initial registration should be validated and shown on the Register and a suitable system developed. The Controlled Acts concept is a potential approach. Presumably, only those needed for public protection (eg prescribing) should be recorded.
- The definition of all the various elements (appraisal, revalidation, "good character", and so on needs to be harmonised, taking account only of genuine, practice-based variations. It ought to be possible to arrive at some key definitions in relation to appraisal and revalidation and possibly also high level frameworks for them, and for the regulators then to apply their expertise to defining the detail of revalidation schemes for the professions they regulate, which would take into account working practices, employment status and environment.

Consideration needs to be given to whether re-validation can be introduced for all, using a risk-based approach (using fairly broad and crude risk categories) to reduce unnecessary cost and impact on individual practitioners whilst maximising patient safety.

Annex 1: Definitions

Regulation

Regulation is the set of systems and activities intended to ensure that healthcare staff have the necessary knowledge, skills, attitudes and behaviours to provide healthcare safely.

This encompasses activity undertaken by individual professionals, teams, employers, regulatory bodies and other organisations such as Higher Education Institutions.

The core activities of regulation are therefore listed in the Health Act (1999) as:

(a) keeping the register of members admitted to practice,

(b) determining standards of education and training for admission to practice,

(c) giving advice about standards of conduct and performance,

(d) administering procedures (including making rules) relating to misconduct, unfitness to practise and similar matters.

Revalidation

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

– in terms of competence, or perhaps better, performance (see below), health, and conduct/character.

Appraisal

Appraisal is the process by which others (whether peers, superiors or others) assist a person to review their performance and draw lessons from it.

Competence

An example of an individual competence would be history taking and consultation skills. In a wider sense, "competence" to carry out an entire role consists of having all the individual competences required, plus the ability to use judgement at a higher level (for example by knowing when to use which competence and when it is clinically right to depart from a standard clinical approach).

The agreed working definition from the (Scottish) OPRS Committee is the "consistent integration of skills, knowledge, attitudes, values and abilities that underpin safe and effective performance in a professional or occupational role."

Competence is a practitioner's current ability to practise *an entire role*, combining individual competences and the use of wider judgement.

Performance

There is an important difference between knowing what to do (competence)and actually doing it (performance). A competent radiographer knows how to use X-rays safely, but might sometimes fail to do so: one who performs adequately is a radiographer who always works in a safe way. Revalidation would be much more relevant to patient safety if it can test performance rather than competence.

Performance is the manner in which a practitioner has carried out a particular task or function. This is the observable part of competence.

Character and Conduct

Character is the combination of personal qualities which are relevant to a person's fitness to practise.

Conduct is that part of a person's behaviour which is relevant to his fitness to practise.

It has been suggested that "character" is not a desirable concept since attributing professionalism to personal qualities, such as integrity, altruism, autonomy, is not only unsatisfactory as a means of defining professional behaviour but can be dangerous: *"I am a doctor therefore I am good"*. Presumed goodness leads to arrogance and worse. Instead it might be better to define professionals by what they do, not by what they are - skills and competencies. A professional is someone who behaves correctly not someone who has a particular set of character attributes (though of course someone who behaves well may also have those attributes).

We need to separate out presumptions made from desirable qualities. The 'moral strength' to know what is right should be emphasised.

Having said that, we do in fact want to exclude thieves and murderers, but that is not about a skill or competency. These two viewpoints may be reconcilable: perhaps what we need is no longer a "character" test but some "competence" and "conduct" ones. The 'moral strength' to know what is right is what is important and is a feature of self-regulation. Irrespective of professional status this 'quality' should be expected / articulated.

Annex 2: Regulators' requirements for initial registration, CPD and revalidation
(source: CHRE Performance Review 2005)
Initial registration

	Requirements for UK Applicants	**Requirements for International Applicants**	**Types of Registration available**
GCC	Qualification Good Health Good Character Evidence of Identity	Qualification Good Health Good Character Evidence of Identity	Conditional Provisional Full
GDC	Qualification Good Health Good Character Identity	Qualification Good Health Good Character English language skills* Identity	Temporary Full
GMC	Qualification (full registration – experience) Identity (from 2004)	EEA - qualification and good standing in other member state(s) Identity Other overseas – Qualification Identity Good Character Knowledge and Skills Experience English language skills* Selection for Employment	Provisional Limited Full Temporary Full Specialist
GOC	Qualification Experience	Qualification Good Character	
GOsC	Qualification Good Health Good Character incl CRB check	Qualification Good Health Good Character incl CRB check Assessment of Clinical Competence (for non-EU applicants)	Provisional Full
HPC	Qualification Good Health Good Character	Qualification English language skills *	
NMC	Qualification Good Health (2004) Good Character	Qualification English language skills *	
PSNI	Qualification	(parity agreement with RPSGB)	
RPSGB	Qualification Good Health Good Character Experience	Qualification Good Health Good Character English language skills* Experience	

* At the time of writing, English language requirements are not permitted under EU law in respect of members of EEA States.

CPD:
(source: CHRE Performance Review 2005, HPC)

GCC	The General Chiropractic Council (Continuing Professional Development) Rules 2004 came into force on 1 September 2004. Participation is mandatory for all registrants and failure to comply will lead to removal from the register. Provisions are being made for the first year of CPD to be directed.
GDC	CPD is a requirement for continuing registration for dentists, and will be for PCDs. The details of the CPD scheme are on the website – use the following link: http://www.gdc-uk.org/lifelong/LifelongNew
GMC	All practising doctors must keep up to date. We provide guidance on CPD. The medical Royal Colleges log the CPD activities of their members. No statutory requirements, but would be required when revalidation comes into force.
GOC	The GOC has just acquired the powers to introduce a mandatory scheme for continuing education and training (CET) and launches this on 1 July 2005. Further details of the guidelines and principles for the GOC's CET Scheme are available on the CET website at www.cetoptics.com
GOsC	In May 2004, GOsC launched Forming Knowledge, its mandatory Continuing Professional Development (CPD) scheme. This drew on broad research into best practice elsewhere. Osteopaths are required to complete 30 hours CPD per annum, a minimum of 15 of these hours must be 'learning with others'.
HPC	The HPC introduced a compulsory CPD scheme on 9th July 2005. All 168,000 registrants from the 13 professions that are currently regulated will be required to keep a CPD portfolio. Sampling will commence in July 2008 and registrants not undertaking CPD will not be allowed to renew their registration
NMC	The NMC's predecessor set minimum requirements for its 656,000 registrants in 1995. These apply for each registration that the person holds and consist of 35 hours continuing professional development in the three years preceding re-registration (implemented from 1998) and 750 hours of practice in the five years preceding re-registration (implemented from 2000). Participation is mandatory. This standard is currently being reviewed having been fully implemented for 5 years and also to reflect contemporary changes in practice and education.
PSNI	Not yet. NICPPET has piloted CPD in preparation for mandatory introduction in June 2005. Every member will be required to record 30 hours of CPD and the assessment of that will be by an educational panel.
RPSGB	The Society completed the roll out of its scheme for CPD in October 2004. The CPD scheme requires pharmacists to keep records of their CPD either on paper or electronically and to submit these to the Society on request. Every pharmacist will have their records reviewed by the Society against a set of good CPD practice criteria at least every five years. Participation in CPD is currently a professional obligation. Pharmacists can choose to register with the Society as practising or non-practising. Non-practising members will not be required to do CPD but they will also not be allowed to practise or give professional advice. When the Section 60 Order takes effect, CPD will become mandatory for all pharmacists on the practising register.

Revalidation:
(source: CHRE Performance Review 2005)

GCC	No, but 'The GCC is following with close interest the current debate about the work of the GMC in this regard'.
GDC	Not yet, but plans 'The details of our work on revalidation are on the website – use the following link: http://www.gdc-uk.org/wayforward/revalidation.html
GMC	'Yes, we are working towards a system of revalidation'
GOC	Not yet, but plans 'The GOC has been working, with the other optical bodies, for some two years on the introduction of a revalidation system for optometrists and dispensing opticians. Given the long delay on the present Section 60 Order it was not seen that there was a need to finalise proposals for legislation until the outcome of Shipman etc was known. An overall system, which is sensitive to the different issue of optometrists and dispensing opticians, is being proposed. This will be reviewed in the light of considered best practise. Consultation is proposed for late in 2005 when the government's response to Shipman has been considered.'
GOsC	Not yet 'The CPD scheme was designed with the future development of revalidation mechanisms in mind. GOsC is working towards this and monitoring the implementation of other schemes.'
HPC	No 'The Health Professions Order 2001 does not give the Council the power to establish a system of revalidation. If it becomes Government policy that all health professions and other liberal professions for example solicitors must undertake revalidation, then it should be noted HPC's registration fees would have to rise significantly.'
NMC	No 'The timescale for practice will alter in 2006 in accordance with new registration rules to synchronise CPD and Practice requirements over a three year period (the registration period).'
PSNI	No 'Council has not addresses the revalidation issue formally but is looking at options it may consider in the future. The Shipman Report may influence Council's thinking on this.'
RPSGB	Not yet, but plans 'The Society's CPD scheme will form part of a system for revalidation that is currently planned to be developed through to 2006. Development of a revalidation scheme will reflect development of post registration/ specialisation training. It is recognised that the current DH review of medical revalidation may necessitate a review of the current timetable for the development and implementation of proposals for a revalidation system in pharmacy.'

FITNESS TO PRACTISE INVESTIGATIONS

Introduction

1. The Review's terms of reference include a requirement to "consider and advise about the measures needed to strengthen procedures for ensuring that the performance or conduct of non-medical healthcare professionals and other healthcare staff does not pose a threat to patient safety or the effective functioning of services, particularly focusing on the effective and fair operation of fitness to practise procedures." At the meeting in May, the Group decided that they would pursue six key themes, the second of which was **fitness to practise investigations**. This note reflects our initial analysis and ideas as discussed and amended by the Group and has also been amended to reflect comments and the outcome of discussions elsewhere.

2. The previous section discusses how a registrant should have to demonstrate that they meet the standards required to be on the register and to stay on the register. The processes discussed there would apply to all registrants. In addition, there must be processes to test a specific doubt that a registrant remains fit to be on the register – that is, fit to practise. For example the registrant might have been convicted, or accused, of a serious crime, or the regulator might have received an allegation. For convenience, these processes are called the "fitness to practise system."

3. This paper considers what changes to the fitness to practise (FtP) system might be necessary or desirable. These should be considered in the light of the Group's decision that its recommendations would need to be proportionate to the risks faced, to avoid undue burdens of extra bureaucracy or cost and to aim for the simplest approach which would promote patient safety.

Current position

4. A FtP system is one of the four core activities of a regulatory body in current law, and is enshrined in the legislation setting up each regulator. Thus there are nine separate FtP systems, though they have many similarities.

5. The table below gives an indication of the number of cases which take place in a year. The low conversion rate from complaints to cases put to a committee is largely an indication that many complaints are about something which the FtP system is not designed to address. For some regulators, the number of complaints also reflects the circumstances of practice: the RPSGB, for example, regularly receives complaints relating to the consumer environment in pharmacy. RPSGB also reported that they are in the process of introducing a monitoring system for the source of complaints.

6. The key components of all the FtP systems are more or less the following (some of the regulators, such as the RPSGB, have older systems which are in the course of being updated in section 60 Orders):

(i) definition of the scope of the system: "impaired fitness to practise" (this can cover conduct, performance, health, conviction for an offence or adverse finding by another regulator)
(ii) two-stage investigation system in which the regulator first decides if there is a case to answer, and if so, proceeds to a hearing (the threshold or criteria for moving from one stage to the next varying from regulator to regulator)

Council	No of complaints & No per 100 registrants	Received from:			Referred to a "Disciplinary" Committee*	Percentage of complaints referred to a committee
		Public (%)	Profession (%)	Public authority (%)		
PSNI	4 (0.2)	50	0	50	2	50
GCC	20 (0.9)	70	30	0	3	15
10. HPC**	172 (0.001)	17	5	17	81	47
GOsC***	121 (1.9)	84	14	2	15	12
GOC	220 (1.5)	92	4	3	11	5
RPSGB	596 (1.3)	N/a	N/a	N/a	57	10
GDC	911 (0.2)	59	4.5	18.5	44	5
NMC****	1304 (0.2)	32	0******	62	316	24
GMC	3943 (1.9)	75	6.5	14	385	10

Source: CHRE, HPC

* Councils used different terms for this committee ***Figures for Two Years **** Figures from 2001-2002. ***** The NMC does receive complaints from professionals, included in the 'public authority figures'. Since August 04 NMC can deal with a wider range of charges and have a broader range of sanctions
Note – sources of complaints may not sum to 100% as some cases are started at the regulator's initiative.

(iii) hearing by a mixture of lay people and professionals, now not usually members of the regulatory Council (although the GCC, GOC, GOsC and NMC have at least one Council member on each panel)

(iv) findings of fact and a finding whether or not FtP is impaired

(v) if it is, a power to give an order for:
a. – erasure/removal from the register/striking off
b. – suspension from the register (with or without an automatic review hearing)
c. – imposing conditions on the person's registration (with or without an automatic review hearing)
d. – imposing a caution on the person's registration
e. – imposing an informal warning/admonishment
f. – accepting formal undertakings limiting a registrant's practice

(vi) a power to make an interim suspension order where necessary for the immediate protection of the public, pending hearing or appeal

(vii) a right of appeal for the registrant to the High Court

(viii) a right (since 2002) for CHRE to refer a decision which appears unduly lenient to the High Court, where this appears to be in the public interest.

7. To summarise, the present legal framework is designed to produce a fair decision about whether or not a registrant's fitness to practise is impaired, and if so to provide an appropriate and proportionate remedy for the protection of the public and maintenance of confidence in the profession. It is not a complaint resolution system, though some complainants mistake it for one. Fitness to practise systems have become complex and highly legalistic, in order to comply with Human Rights considerations for the person accused, and to guard against successful legal challenge (including judicial review). There has been increased media/public interest in the FtP process (investigations & adjudications) as a result of the high profile cases such as Bristol, Alder Hey, Shipman and Allitt. The link between local complaints, employment disciplinary, criminal prosecutions, civil litigation and professional FtP cases has been under the spotlight more recently, as complainants try to decide which is the most appropriate route for resolution of their complaint.

Problems with the current position and opportunities for improvement

8. While much criticised the current system has some strengths. There are occasional high profile cases where the public has clearly been left at risk from an unsafe registrant who continues to practise. In absolute terms however the numbers of these are very low. In the last year, the CHRE has used its powers to refer questionable decisions to the High Court in only eight cases. Nor does the system appear to be unduly hard on registrants who are accused: we are not aware of successful judicial reviews on this basis, and successful appeals are also relatively rare. We are aware, however, that the length of time taken for a case to be resolved (which varies from regulator to regulator) may be unsatisfactory to both complainant and registrant. Some delays are caused by unavoidable external factors like criminal cases which need resolution first.

9. FtP systems are sometimes perceived as intimidating or unresponsive to members of the public who make a complaint. Some regulators have adopted good practices such as:

- witness care schemes,
- a helpline where staff can take details on the telephone and turn it into a statement for the complainant to sign, and
- better information for complainants.

RPSGB has reported on their unique Inspectorate[2] role and the recent development of a more customer friendly approach in relation to pharmacists which may be relevant

[2] the inspectorate was set up to fulfil the Society's statutory enforcement functions under the Poisons Act 1972 and the Pharmacy Act. The Society was given additional duties by the Secretary of State for the enforcement of many provisions of the Medicines Act 1968 relating to the retail sale and supply of medicines. The inspectors also investigate complaints against pharmacists and pharmacy owners and fulfil a wide range of other roles detailed in papers the RPSGB has supplied to the review. In Northern Ireland the role rests with the relevant

to improving relationships with complaints. More could be done and other regulators could learn from best practice where identified, although the successful separation of these roles in N. Ireland also needs to be taken into account.

10. At the highest level, complainants would benefit from having a single source of advice (perhaps a portal on a website and/or telephone service) which would help them decide whether they wanted to make an NHS complaint, a complaint to a private resolution procedure such as the GDC and GOC are setting up, take civil legal action, institute criminal proceedings, or refer a professional to a regulator. This would help members of the public identify the true role of the regulator as having the right people on, and off, the register, rather than being an alternative investigatory route or source of any kind of redress. A portal of this kind was a Shipman recommendation; one which the Group would support.

11. There is a debate about whether a single portal should be a source of advice (possibly provided by NHS Direct or the Healthcare Commission) or a redirection service, where all complaints are made and then sent to the most appropriate place to handle them. In an ideal system a patient ought to be able to enter at any point, knowing that even a misdirected complaint is in the system and confident that it will be correctly redirected. Recipients would have responsibility not just for redirection but also for notifying the complainant that this redirection has taken place (perhaps even following up to ensure the redirected complaint has been received). The benefits from any of these changes might well be more in the area of service to the public than patient protection, although arguably, if regulators were able to spend less time weeding out cases which were not appropriate to their remit, this would free up resources to deal more speedily with cases where the public could be at risk from a person's unrestricted registration. And the complexity of the current system, and the likelihood of wrongly directed complaints, may lead to patients not following up legitimate concerns.

12. The different FtP systems can be criticised for being inconsistent with each other. A doctor and a nurse involved in the same incident may find their cases being handled in different ways, which is confusing to the patient who has referred the matter to the regulator. A major legislative effort to bring the different pieces of law into line will be completed in the next 12 months. This will go a long way to ensure greater consistency (giving regulators, for example, access to the widest range of possible sanctions), but it will not eradicate inconsistency entirely. CHRE has started some work on convergence in FtP and indicative sanctions guidance which will address some of these issues.

13. It can also be reasonably claimed that there is too much law in this field. When eight regulators have separate FtP systems which each require Rules made under different Acts of Parliament, and these need amendment from time to time to close loopholes or reflect new policy, the result is a small cottage industry which is inefficient at producing good quality, consistent law. This increases costs, as solicitors

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Government Department and was the subject of favourable comment by the Shipman Inquiry. This inspection role is wider than that of the RPSGB and extends across the use of medicines by any professional within or outside the HPSS sector and demonstrates that successful separation of these roles is possible.

and barristers who work for a number of regulators (as prosecutors, defenders, or legal assessors) in FtP cases have to be familiar with a range of different FtP law. This all adds to overall FtP costs. Problems have arisen in developing the law because of changing goalposts and there is a need to ensure consistency in drafting.

14. There is a degree of duplication with employers' disciplinary and complaints procedures. If a professional is investigated by their employer for misconduct, there may well be a parallel investigation by the regulator, albeit asking different questions and perhaps using different evidential standards. The same problem can arise in a performance or health case. One possible way forward could be towards a single investigation at local level that can provide a report and evidence for these different purposes. An investigation needs to determine what actually happened. In this respect, we need to distinguish between ascertaining the facts and determining how then to proceed. Were this to happen, complainants would be able to receive explanations and apologies (without prejudice) soon after a complaint is lodged. This demonstrates action and taking the complaint seriously, and is likely to act to lessen the frustration of the complainant. DH is giving some thought to this in preparing its Shipman response. Expertise would be needed at local level which may not always be there at present.

15. Concern has been expressed about the risk to the public if issues are dealt with by employers without information going to regulators, when it is they who should more appropriately be taking action. RPSGB relies heavily on its inspectors, who follow due process in complaints handling and who have extensive powers of entry, search and seizure, and would accordingly have concerns about the effectiveness of local investigation using a different evidential standard. Due process is important to withstand legal challenge, and the initial investigation needs to be done to the right standard.

16. However, consideration of possible convergence would encourage us to give some thought to the standards used in different processes. At present, for example, it is possible for a complaint to be upheld, the complainant notified that the case will be referred to the regulator, and the regulator refuse to take the case because it is 'insufficiently serious'. In a healthcare system focussed on patients and patients' experiences, this needs to be addressed. At minimum, we do need to be able to explain why for example the complaints system and the regulation system apply a different standard (because they serve different purposes).

17. It might also be possible to introduce a threshold of seriousness below which all cases had to be resolved locally, somewhat in the way that the NMC tries to deal with professional performance cases now. The GMC has recently announced that it will refer certain complaints back to the NHS employer for local resolution. If this pattern was generally adopted, we should need to find a way to identify worrying patterns of low-level problems and pick them up, also bearing in mind that using low-level cases to inform learning, policy and research is also valuable.

18. Discussion elsewhere has suggested that complaints data could be a fruitful source of information to improve patient services – emphasising the need for effective data sharing between regulators and employers. We would endorse this suggestion too.

19. The recommendations which Dame Janet Smith made for GMC procedures in her Fifth Report have some implications for other regulators, given the similarities between these. The recommendations are summarised below.

(a) *adjudication must be undertaken by a body independent of the GMC*

(b) *consider sharing full-time FtP panellists between all regulators* - having "professional panellists" might however make it difficult for panellists to stay in touch with circumstances within each profession and lead to a loss of confidence in the system among registrants at the loss of the professional "peer" element.

(c) *develop consistent criteria, standards and thresholds* - should this be consistency within, or across professions? There is a need for consistency across professions where different groups are undertaking new roles, for example prescribing, but Dame Janet was arguing for consistency of decision-making based on, for example, standards of proof, the use of referral criteria and indicative sanctions, and process audit, as well as a "principles plus standards" approach to codes of conduct.

(d) *CHRE should play a role in developing such criteria/standards/thresholds*

(e) *performance standards in a FtP case should be the same as at initial entry.* One regulator suggests that the performance standards in a fitness to practise case should be **no lower** than at initial entry, but that there is a balance between professionalism and regulation that, proportionately, must place some reliance on professionals undertaking to work only within their own areas of competence.

(f) *experiment with legally qualified chairs* – the RPSGB has used this system since 1954 and found it beneficial

(g) *all panels should set out reasons for their findings of fact*

(h) *an assessment should normally be needed before a suspension is lifted*

(i) *those who fail an assessment should normally be erased, not retake it*

(j) *the GMC should set out all the details of the process in Rules*.

Not all regulators are convinced that there is evidence that these changes would increase patient safety.

20. The recommended approach of putting every detail into statutory Rules is probably not appealing. Ministers want to move away from the need for so many Rules, and the requirement to legislate for all the details slows down the regulators' ability to update their systems in response to emerging problems. The remaining recommendations repay close consideration. Taken together, they seem to combine greater protection for patients (and the visible delivery of greater protection) with some extra safeguards for those who are investigated.

21. The concept of an independent adjudicator mentioned by Dame Janet Smith (see 19(a) leads naturally to that of a single adjudicator, for example as operated in New Zealand since 2003 (however, the separation of investigation and adjudication in the medical profession there dates back to 1995). In New Zealand different committees for individual professions have the responsibility to investigate allegations, but adjudications in serious cases are made by a single tribunal. It is of course rather early to be able to tell whether these changes have improved regulation in New Zealand, and what works in a relatively small country might not readily translate to one where over a million people are registered with regulators.

22. The Group has considered further papers relating to the concept of a single independent adjudicator and recognises there is support amongst some but not all of the regulators for such a radical change.

Constraints

23. Apart from passing our tests of proportionality and simplicity, any proposed changes would have to deal with some other constraints. In legal terms, any type of proceeding which could deprive a person of their livelihood needs to meet the tests in the Human Rights Act if it is to avoid successful challenge in the courts. Another issue is that the current involvement of professionals in hearing a case is said to give the wider profession a sense of ownership of the system and consequently some allegiance to it. It is unclear whether this applies to FtP systems as much as some claim (but it is certainly a powerful factor in e.g. the setting of standards). Finally, far-reaching change would need careful management, and take a long time (for example to transfer FtP functions to a single adjudicator would require primary legislation rather than a Section 60 Order).

Recommendations

24. This section concludes that the current FtP systems have real strengths which should not lightly be discarded. It would be possible to strengthen patient protection however by building on these strengths via the following recommendations

- All or most of the improvements suggested by Dame Janet Smith should be explored further, but clear evidence is needed before changes are made.
- More and better advice should be provided to complainants about the differences between different complaints avenues, so that they direct their complaints where they are most likely to bring the desired outcome.
- A single set of legal provisions for FtP should be devised across all professions based on current identified best practice

- There should be consideration of introducing either a single adjudicator, or alternatively, a series of steps should be taken in that direction, including: a common pool of adjudicators, lay and professional; a common pool of legal assessors; and a common set of indicative sanctions guidance.
- There should be an enhanced role for the employer in investigation, with a reduction in the duplication between different investigations for different purposes.

REVIEW OF NON-MEDICAL PROFESSIONAL REGULATION

REGULATION OF HEALTHCARE SUPPORT WORKERS

Introduction

1. The Review's terms of reference include a requirement to "ensure the effective regulation of health care staff working in new roles within the healthcare sector and of other staff in regular contact with patients." At the meeting in May, the Group decided that they would pursue six key themes, the third of which was **support workers and regulation**. This note reflects our initial analysis and ideas as discussed and amended by the Group and has also been amended to reflect comments and the outcome of discussions elsewhere.

Background

2. In England, there have been calls for consideration of regulation of support workers since 1999, on the basis that as roles develop much of the work formerly done by registered professionals is now done by healthcare assistants and other support staff. Assistant practitioners (as described in the draft Career Framework for the NHS in England) in particular are being developed to free up more professional staff to take on more advanced roles. A review of whether professional registration is set at the right level to ensure public protection was heralded by the commitment in the English NHS Plan 2000 to consider proposals for the effective regulation of support workers. Similar considerations apply to Wales and Scotland. In N Ireland, in contrast to the remainder of the UK, healthcare and social care operational responsibilities are carried out by unitary organisations. This has led to a blurring of boundaries for support staff and the present position is that persons engaged in the provision of personal care for any person" are eligible to be registered with the Northern Ireland Social Care Council as social care workers. The Department in N Ireland has the power under Section 8 of the HPSS Act (NI) 2001, to "by regulations make provision for prohibiting persons from working in such positions as may be prescribed unless they are registered in, or in a particular part of, a relevant register" i.e. in Northern Ireland the NISCC Register.

Consultation on extending regulation to the wider healthcare team

3. The Department of Health carried out a public consultation on behalf of England, Wales and Northern Ireland, with a parallel consultation by the Scottish Executive Health Department in 2004. The questions in the DH consultation are at Annex A. The responses to the DH led consultation have been analysed and a draft summary prepared, which has not yet been formally published. The summary indicates that

- There was a general feeling that there is a need for more debate: a fuller consideration of the implications and options.
- The majority of respondents were in favour of statutory regulation for some, but not necessarily all, support staff, but a minority felt this was unnecessary.
- There was roughly a 70%/30% split in favour of HPC regulating support workers (70%), with many nurses and professional bodies preferring NMC to regulate HCAs/nursing assistants; also professional bodies wanting to regulate those who support their own professions.
- There was thought to be a need for more work on collaborative regulation. Professional bodies and staff wish to share development of standards for their

support staff with input from the staff involved. There was no clear consensus on who should be involved in setting standards and who should own them.

- Suggestions for regulating new groups included a wide range of support workers at different levels on the career framework and very different stages of readiness in terms of nationally-recognised competences and training:
    - assistant practitioners;
    - HCAs/care assistants;
    - therapy assistants;
    - scientific support staff;
    - ambulance technicians;

  Some suggested that porters, administrative and clerical staff and educational assistants should also be regulated.

- Others suggested that statutory regulation was not the answer for support staff since it could be burdensome and reduce recruitment if registration dependent on qualification was a pre-requisite for employment.

4. Responses to the parallel consultation in Scotland similarly supported the introduction of statutory regulation. Respondents also felt that, to avoid multiple registration and to facilitate transferability of staff between the 4 UK countries, it would make sense for existing regulators to work together to develop core/common standards, with some discipline specific standards. 64% of respondents felt that Scotland should follow any decision that might be taken in England.

Main Issues for discussion

5. Level of registration. Should this take place either

- As for professionals, at point of competence at exit from training including basic preparation, or, where appropriate, when qualification has been achieved?

- Or, for support staff working under delegation, at point of entry to training to acquire competences, following basic induction and employment checks?

It is suggested that this issue be addressed in the context of the Career Framework for the NHS (currently England's framework is being considered for its applicability to Scotland) in which levels 1 – 4 encompass support worker roles. Different approaches are possible - for example, registration could begin at either levels 1/2 **or** at 3/4. Or different arrangements might apply to different levels; eg 'registration' of staff at levels 1 and 2 could possibly be managed through employer-led regulation (with a centralised 'occupational register' for level 1 as is planned in Scotland) and levels 3 and 4 through alignment with and augmentation of professional regulators' systems.

6. Benefits of statutory regulation of support workers. Guaranteed nationally-recognised standards of competence backed up by fitness to practise procedures and protected titles would provide:

- Public protection through restricted entry to the register and conduct work
- Consistency of application of standards
- Transferability across geographical boundaries
- Transferability of nationally recognised qualifications
- Career pathway opportunities
- Enhanced employee status and recognition
- Increased professional staffs' confidence to delegate more interesting and responsible work to support staff
- Increased employers' confidence that risks of such delegation were being managed properly.

7. Disadvantages of statutory regulation. These might include

- Timescales and costs associated with legislation vis a vis proportionality
- Possible barrier to recruitment if registration based on qualification is seen as an obstacle, although this might be offset if regulation were perceived as facilitating progression upwards through a defined career framework.
- Training and assessment of qualifications could be expensive to provide universally
- Registration fees could be disproportionately burdensome for this section of the workforce
- Need to identify suitable regulator(s) for roles across a very diverse section of the workforce with movement across work settings and sectors
- Jobs at these level may reflect local needs to so great an extent that agreeing common generic standards could be difficult, meaningless, or unnecessarily restrictive.

8. Alternatives to statutory regulation if legal restraint from practice is not necessary. These are mainly focused around employer-based schemes, in which the employer would be responsible for local implementation within an overall national framework to which the regulators would have contributed, and might include

- Employer-based code of conduct and basic induction and training embedded in employment contract as part of staff governance arrangements
- Voluntary regulation system operated by professional bodies and/or staff organisations or a central registration body.
- Mandatory (non-statutory) 'occupational registration' based on achievement of fundamental standards for induction, conduct, competence and scope of practice.
- Accreditation of training, where quality and standardised training is prime need. Employers could then decide to employ only people with training accredited by a professional or occupational body. This would ensure competence but not necessarily conduct.
- National or UK wide negative register of individuals found to be unfit for employment in these roles, in line with measures for the protection of vulnerable adults and children. This will be put in place through post-Bichard protection measures.
- Monitoring of employers' operation of the scheme, either via CHRE or as part of an existing monitoring/audit regime eg Healthcare Commission or NAO.

9. In Scotland, it has been agreed to establish a pilot scheme to test the validity of an employer-led approach, backed by a non-statutory register, as a model for the way forward across the UK. More work is needed on:-

- Standard setting for admission to the register
- Consideration of using National Occupational Standards to provide descriptors for induction and competence requirements
- Whether different approaches might be appropriate for different groups
- Use of risk assessment to identify those groups to be given priority for inclusion
- Use of Agenda for Change levels (e.g. 3 and 4) as criteria for point of entry
- The balance between individual and employer responsibilities in relation to keeping track of training and similar updating requirements
- Providing for effective audit and monitoring of the employer-led activity
- Logistic issues such as which independent body should keep the register, keeping the register up-to-date, funding and involvement of informal employers

All these issues are currently under consideration in the context of work in Scotland, which is being taken forward under the aegis of a 4-country Steering Group which met for the first time in Edinburgh on 19 October 2005.

Recommendation

10. The most suitable way forward would be to establish a framework within which employers could register and regulate support workers, with a non-statutory register established across the UK to provide the essential information base. Such an approach should be trialled and evaluated in Scotland. Such regulation should

- Be confined to those in formal employment (i.e. employed by organisations rather than by individual patients and/or carers) although those employing care staff informally should have access to the register if they wished to employ "registered" staff
- Apply to those at levels 3 and 4 of Agenda for Change, or the equivalent in organisations outside AfC
- Offer opportunities for considering integration with the future regulation of social care support staff
- Build on the essential principle that all employees should bear a degree of responsibility for their own practice but that this should be supported and reinforced by a two-tier employer-led system designed
    i. To ensure that all the negative checks on suitability (CRB, PoVA/PoCA, Bichard) were properly applied and updated and that employees have appropriate basic skills training; and
    ii. Where there is a higher level of risk to patients (which would need to be defined) that some form of revalidation ensures that staff continue to be fit to practice (or perhaps tests fitness to

continue to be registered – as fitness to practice is a concept more in keeping with professional status or with higher level support workers where they work under a clause of delegation from a professional).

and that such a framework should be approved by the external regulatory framework, both in terms of the overall national scheme and of its detailed working within employers at ground level.

Secretariat

ANNEX A

Questions asked in the 2004 Department of Health consultation on extending regulation to the wider healthcare team

Q1 How far should assistants and support staff be accountable for their own practice?

Q2 Should assistants and support staff set their own standards OR should those with overall responsibility for the work of these staff share in, or take, the lead in setting these standards?

Q3 Should regulatory arrangements be extended to healthcare assistants, therapy assistants, assistant practitioners, and others performing similar roles in routine care? If not, which staff should be included and on what criteria?

Q4 Is statutory regulation appropriate or should other approaches be taken?

Q5 Should the Health Professions Council (HPC) regulate those groups of assistants and support staff identified for statutory regulation? Are other options preferable?

Q6 If the HPC is the most appropriate body, should regulation be by way of a statutory Health Occupations Committee or would other options be preferable?

Q7 Would regulation of assistants and support staff by the bodies responsible for regulating those whom they support lead to other problems such as 'second class' workers?

Q8 Are there other options for the structure of statutory self-regulation we should consider?

Q9 How can multi-disciplinary issues best be addressed? Should the regulators set common standards and/or recognise each other's so that workers can move between different health and social care settings without the need for multiple registration?

OR Could all assistants and support staff be regulated as a single group within a single framework including some shared standards and some discipline-specific standards?

REGULATION OF NEW ADVANCED PRACTITIONER ROLES

Introduction

1. The Review's terms of reference include a requirement to "ensure the effective regulation of health care staff working in new roles within the healthcare sector". At the meeting in May, the Group decided that they would pursue six key themes, the fourth of which was **how should new and extended professional roles be regulated?** This note reflects our initial analysis and ideas as discussed and amended by the Group and has also been amended to reflect comments and the outcome of discussions elsewhere.

Scope and purpose of the paper

2. This paper aims to identify where new roles are developed beyond the extension of scope of practice within an existing regulated profession. It then explores, in the light of agreements reached at the meeting on 13 June covering the position in England, how these new roles may be statutorily regulated. The aim is to ensure public protection by applying common standards to all practitioners regardless of original background, while minimising the regulatory burden on those already registered in another profession. This is designed to meet employers' needs for risk management in the clinical governance context, while avoiding too restrictive an approach to workforce development and diversification. The position in Scotland is also set out, including discussion of current differences of principle and detail.

Extended scope of practice

3. Many healthcare professionals expand their practice to take on duties previously done by others, or to extend their breadth of skills and knowledge within traditional roles. This extended scope of practice does not necessarily require further regulation in its own right since it may be recognised through revalidation or CPD requirements for renewal of registration in an existing professional register. Some regulators also record post-registration specialist qualifications on their register. Medical regulation includes a system of specialist registration operated by bodies other than the initial regulator to denote qualifications and competence at a higher level than initial registration. It may be worth considering whether it is appropriate that 'extended' scopes of practice should be recognised as 'specialist' or 'advanced' levels of practice, or whether this focuses on issues of 'fitness for purpose' and professional enhancement rather than on 'fitness to practise'. There is a need for further work on the circumstances in which extended practice ought to be regulated and recorded on the register. For example, there is wide agreement that being allowed to prescribe was an extension of practise which required special training and annotation on the register. This has implications for CPD and revalidation.

4. Since professional development is a continuing process, it is not always possible to define scope of practice in detail since the need to update the related standards of proficiency could be continuous. Most regulators keep these standards under review over time and update them when necessary.

The position in England and Wales in relation to new advanced practitioner roles

5. The New Ways of Working programme has been taking role development beyond extended scope of practice by designing new roles which are significantly different and which cut across into the medical domain much more than others. These include:

- **Surgical Care Practitioners (SCPs)**, who assess and treat patients not only pre and post operatively but also perform elements of or the complete surgical procedure. Most current trainees are former ODPs and nurses.
- **Anaesthesia Practitioners (APs)**, whose role includes maintaining anaesthesia as well as other duties previously performed by medically qualified anaesthetic staff. Most current trainees are former ODPs and nurses. This role is currently being piloted in N Ireland.
- **Medical Care Practitioners (MCPs)**, who assess, make high-level differential diagnosis, treat and provide follow up care holistically across the patient's overall physical and psychological condition, in primary care or acute medical settings. Current trainees are from a wide variety of backgrounds: medically-trained people from overseas (including refugee doctors unable to register with the GMC), graduates in science or psychology, nurses, physiotherapists and other AHPs.
- **Emergency Care Practitioners (ECPs)**, who undertake independent see, treat, discharge or referral practices. Most ECPs come from practice as paramedics or nurses.
- **Endoscopy Practitioners (EPs)**, who perform complex endoscopy procedures. Most EPs come from a nursing background and there are nurse endoscopists in N Ireland.

6. Although trainees in the roles as they are being developed are building on their original professional backgrounds, the intention for most of these roles is that once their competences and training have been established it will be possible to add further training to allow people from other backgrounds to reach the same standard if they have the potential to practise at this level. For example, these roles may be attractive to medical orderlies from the armed services, who have some relevant knowledge and skills on which to build.

7. These roles are under development and there may be some scope for overlap or merging between them. However, at a meeting on 13 June 2005 of all the national (English) stakeholders, including the regulatory bodies, the Department of Health, professional bodies and interested medical Royal Colleges and educationalists involved in developing the new roles, it was agreed that they share characteristics which indicate that there is a case for separate statutory regulation for these new roles in their own right. At the meeting it was agreed that the reasons for regulating a new role are primarily:

- when a new role is developed with sufficient impact on patient care that patient safety and quality of care need to be addressed by setting standards of practice and training in law; this may be clarified by

reference to the concept of **controlled** or **regulated acts** (in contrast to regulation by **protection of title**) and

- when the new role is so significantly different from the original registered qualification that members of the profession and the public need to be able to identify the new practitioner and understand the education, training and assessment associated with the new role.

8. In addition, statutory regulation is the gateway to accessing statutory responsibilities such as prescribing (possibly an example of a controlled act). If such responsibilities are part of the competences needed for the new role, statutory regulation must be in place before they can be permitted. Finally, separate regulation provides a mechanism for recruiting entrants from non-healthcare professions, or new entrants to the healthcare workforce following completion of training/qualification, directly to the new roles, to allow the widest possible access by anyone with the necessary potential to fill them.

9. As roles are extended and new roles established we will increasingly have similar roles undertaken by individuals coming from different professional backgrounds. Prescribing is a case in point. What is at stake is the competency to undertake the role and relative to say, prescribing, the fundamental science to underpin the practice. If we are to provide for public confidence we need a more foundational approach to competency ensuring that the fundamental underpinning knowledge is in place and not just some superficial accredited training. To that end we need to ensure that individuals doing the same job are all equally capable of doing it.

Position in Scotland

10. For Scotland, by contrast, SEHD believes that there is a continuum between roles that are clearly expanded practice roles and those that are completely new and that require new arrangement for **professional** regulation. The following are considered to be essential in the identification of roles requiring new regulatory arrangements:

- Where a need for a new professional group has been identified as being required by the service.
- Where there is a unique and discrete body of knowledge and scope of practice: (although it is recognised that there is some overlap in the knowledge and scope of practice of many existing regulated professions, the uniqueness of a new role comes from the combination of areas of knowledge and practice within that role). Scottish colleagues are unclear whether it is appropriate to assume that the uniqueness of a new role comes from the combination of areas of knowledge and scope of practice of existing professions and considers it important to have clear criteria for the recognition of a new professional group. They suggest that CHRE could have a role to play here. Scottish colleagues also suggest that the activities of a group that performs as support workers to a profession could be 'governed' through the controlled acts concept and /or through a clause of delegation in line with existing regulatory arrangements for healthcare professions.

- Where the practitioner occupying the new role is not already working, or it is clear that they need not or do not work, under delegation from or supervision of a regulated healthcare professional.

SEHD would prefer to find a UK solution to moving forward on the regulation of new roles and seeks further discussion on decisions made in England to date.

Transition from extended scope of practice to new role

11. Many – but not all – of those practitioners developing the new roles have come from existing professions. This has led some to see their new practice as an extension of their previous professional role. The development has taken place in a number of pilot sites in England and has focussed as much on the specialism and preference of the role developer and supervising consultant as on the higher-level practice of the advanced practitioner. This has led to confusion about:

- What it is that characterises the new role: the general higher level knowledge, skill and aptitude, rather than the specialist knowledge and skill needed in that particular specialism
- Whether those initially coming into the new roles themselves need to undertake the further training over and above that which they receive while developing the role, once that training is developed based on the competences needed for the developed role
- Whether those initially coming into the new roles need to be assessed against the standards of proficiency which will eventually be drawn up based on the roles they have developed, since if they are performing the roles already they are already doing so safely.

Once these issues have been properly resolved, 'grand-parenting' arrangements and verification of competence through portfolios of practice could be applied.

12. From a patient safety point of view there is nothing to be gained by requiring initial entrants to the roles from existing healthcare backgrounds to undertake formal training, once it exists, if it replicates training they have already received while developing the role. But there is a need for individual practitioners to demonstrate their fitness to practise against the standards of proficiency based on the competences developed once the role itself has been established and the decision taken to regulate it in its own right. So if the advanced practitioner roles become statutorily regulated, all those who wish to practise in those roles will need to demonstrate that they are fit to practise as such to achieve registration in the new role.

13. Although they agree with this observation, Scottish colleagues consider that the issue here is more about the roles that require statutory regulation, ie, is the individual working under delegation / supervision as a 'support' worker or do they have a new body of knowledge that is applied in practice? This will be necessary even though the competences may overlap with extended scope of practice in other traditional professions, especially if there are no specific standards set for extended scope of practice.

When to regulate

14. Criteria which need to be met before statutory regulation can be introduced have been developed by those regulators who have experience of admitting new groups into regulation. The Health Professions Council's criteria are:

- Discrete area of activity
- Defined body of knowledge
- Evidence based practice
- One professional body representing most practitioners
- Voluntary register
- Defined entry routes to training
- Independently assessed qualifications
- Code of conduct applied to voluntary registrants
- Disciplinary processes applied to voluntary registrants
- Commitment to Continuing Professional Development.

15. It should be noted that these are not criteria for recognition as a separate professional group per se, which might be developed further by CHRE. In the case of advanced practitioner roles, the area of activity and body of knowledge are likely to overlap with elements of those of existing professions. But what is unique to the new roles will be the combination of activities and knowledge which make up the scope of practice for the new role. A toolkit (one that includes criteria to be met) might be a good idea for the instigation of regulatory processes for new roles. Such a toolkit would lead to a decision about whether a new role was sufficiently new and unique to warrant regulation, and on who the correct regulator should be.

11. What to regulate

16. The roles to be regulated should be those that meet the criteria in paragraph 7. More work is to be done to consider if there is scope to merge some of the roles listed in paragraph 5. The practice of all the roles involves sufficient **risk** to patients to be worth considering them for statutory regulation, which will be necessary for any of the roles for which prescribing responsibilities would be an essential part of the role to give maximum value for service delivery.

17. The roles regulated should also be broadly and generically based to meet maximum **demand**. Since roles have been developed across the country in a number of pilot sites, each role will have been developed slightly differently to meet local needs, just as local roles within existing professions differ to meet local operational practice. The work of the National Ways of Working programme has been to draw together common practice and develop common competences which may translate into nationally-useful and transferable qualifications. The competences are being developed with input from Skills for Health, which is UK-wide in its remit, and links are being forged with similar developmental work in Wales, Scotland (on new mental health roles in psychology) and Northern Ireland so there may eventually be the possibility of regulating these roles on a UK wide basis.

(a) Who should regulate

18. The 13 June meeting agreed that, for England, the same standards should be applied to all practitioners within a new role, regardless of their original professional background. The preferred way of doing this was to have one regulator, not necessarily the same for each role, but whichever was the most relevant, setting the standards and approving qualifications and in doing so drawing on the expertise of those involved in developing the competences and curriculum for the role, such as relevant medical Royal Colleges for instance. Registrants with other regulators who wished to practise in the role could meet the same competences by gaining the same approved qualification and having that recognised as part of their existing registration, by an annotation mandatory for practice in the new role.: For Scotland, SEHD wishes this decision to be considered within a UK context to ensure that decisions made are appropriate and applicable to the UK as a whole.

19. More work will in any case need to be done on how this will work legally, but one possible way would be to legislate for one regulator to be given statutory responsibility to regulate each role, set standards of proficiency, approve education and training and operate fitness to practise procedures. The first entrants to the register would be grandparented role developers who could show they met the standards of proficiency; and people with the approved qualification. These would be either registrants on the main regulator's register (this would include anyone from a non-healthcare background originally who had accessed the training directly) or registrants on another register whose regulator recognised their additional qualification.

20. Statutory provision would need to be made for the main regulator to be required to collaborate with others with an interest in standard-setting, and also for other regulators to adopt the main regulator's standards and qualifications without alteration.

21. Further issues for consideration include the fact that registrants in both roles would need to meet CPD requirements for both roles in order to keep both initial registration and the recognised annotation. Also it would be necessary for fitness to practise cases relating to the new/annotated role to be dealt with by the body regulating the new role. The other regulator would then need to consider whether the outcome also affected the individual's eligibility to remain registered in their original role.

(i) Further consideration

22. Some issues require further work: in particular the reservations identified in respect of Scotland will need to be addressed as the Group agrees that a UK-wide solution must be developed. These reservations are set out in more detail in the Annex to this section.

Recommendation

20. It is recognised that a distinction needs to be drawn between roles which can legitimately be regulated as "extended scope of practice" and those for which new

arrangements are needed. We recommend that the criteria for determining the basis for separate regulation of new and emerging groups of staff be based on those agreed at the June meeting, adjusted to ensure that they can be applied appropriately throughout the UK. In particular, the concerns and reservation expressed by SEHD need careful consideration. The model of distributed regulation should be developed and introduced in appropriate circumstances, bearing in mind that such a model cannot operate if the core competencies of the new role are outside those of the parent regulator of existing professionals (as opposed to the core regulator for the new role, with input from relevant partners).

ANNEX – SEHD RESERVATIONS

1. While SEHD acknowledges that England is pursuing an English solution to workforce design, decisions regarding regulation impact on the rest of the UK. SEHD would prefer to find a UK solution to moving forward on the regulation of new roles and seeks further discussion on decisions made in England to date.

2. SEHD believes that statutory professional regulation should be reserved for those groups that have a unique and discreet body of knowledge and scope of practice. Where such a practitioner is not already regulated or is not working under delegation from or the supervision of a regulated healthcare professional then this would be an appropriate criterion for regulation.

3. SEHD believes that there needs to be a line drawn between those already regulated who will expand their scope of practice to meet the needs of the service and those who will follow a 'direct entry' model. SEHD are committed to maintaining the titles we already have in order to ensure clarity for patients and the public, rather than inventing new 'practitioner' titles. In both cases however there will be a requirement for a common set of competencies to be met where the roles and functions are similar.

4. SEHD would agree that it is sensible for other regulators to recognise the standards of competence, qualifications and registration decisions by another regulator and apply them to some of their registrants. Any conduct issues could give due regard to 'expert witnesses' in the field of practice.

5. SEHD would not support dual registration solely on the grounds of expanded practice. Where a healthcare professional is being investigated as a result of a fitness to practise issue, concerning what would be recognised as 'expanded practice', then the following should apply:

    - If the professional concerned is on a professional regulatory body's register then that regulator should conduct any fitness to practise investigations. Where this investigation concerns expanded scope of practice, then due regard should be paid to 'expert witnesses' within the relevant clinical field of practice. For example, a surgeon should assist judgements on the competence of a registered nurse to carry out surgery where the registered nurse's competence to carry out surgery is in question. Any such fitness to practise investigation should be on the grounds of concerns over conduct or practice in relation to recognised professional regulatory standards (ie public protection standards) and not on the grounds of concerns that should be resolved at employer level.
    - Should it be considered by the professional regulatory body that the registered nurse is not competent to carry out surgery but is competent to remain on the professional nursing register then a condition of practice order may be appropriate. If however, the

conduct or practice issues were such that the professional regulatory body is concerned for patient safety then the registered nurse should be removed from the professional register. Systems exists for communicating this in order to protect the public.

- Employers are responsible for assuring themselves that employees are competent to fill roles. Employers, and professionals themselves, are responsible for ensuring that the level of competence necessary to carry out a role (ie roles required by employers) is facilitated and achieved. It is also the employer's responsibility to ensure that practitioners lacking competence for an expanded role are not requested to undertake that role, likewise it is the responsibility of the employee to refuse to undertake a role that he / she is not competent to undertake. Where the role is part of a job description however, and the post-holder is not functioning at the level required, then issues of capability apply and should be managed through existing staff governance arrangements. In Scotland, the PIN publication on Management of Employee Capability applies here.

HOW DOES REGULATION FIT INTO THE WIDER CONTEXT OF ISSUES CURRENTLY FACING HEALTH SERVICES?

Introduction

1. To fulfil the Review's terms of reference the Group agreed, at its meeting in May, that one of the six key themes to consider was the context within which the Review of non-medical professional regulation was taking place. This note reflects our initial analysis and ideas as discussed and amended by the Group and has also been amended to reflect comments and the outcome of discussions elsewhere.

2. In particular, there is clearly a need to identify recent workforce and related initiatives and the extent these need to be taken into account in formulating the recommendations from this Review. Also critical to the Review will be the need to ensure that all potential solutions are suitable in each of the four constituent countries, where different service issues exist and where regulatory systems and developments may differ, and across the full spectrum of healthcare sectors, including the private sector.

3. In considering the context of this Review, it is helpful to consider the professional groups in two, distinct, though related, categories:

- those who work within a managed environment such as in the NHS or in privately run hospitals or similar locations, and,

- those who work in a commercial practice environment and/or as single handed practitioners with no direct management (including GPs, GDPs and other principals in primary care).

The former has established systems and processes for the management of staff including fitness to practice issues, whilst the latter relies more heavily on national regulatory systems in assuring continued fitness to practise. This review clearly needs to deal fairly and equitably with each of these groups, taking account of these different environments and recent developments in both.

4. This paper explores these issues in the context of these two groups, focusing on:

(i) patient safety and quality of services;

(ii) recent related workforce initiatives and the pace and direction of change;

(iii) the development of systems and related IT developments on which recommendations from this review might build.

Patient Safety and quality of service initiatives

5. In taking forward the review of regulation, the emphasis placed on patient safety and current approaches to quality assurance by other organisations bearing on the healthcare sector is an important piece of context. Over recent years, a growing number of initiatives have resulted in various quality assurance systems being put in place, including:

- systems to monitor the performance of NHS and private providers of healthcare. This is undertaken in England and Wales by the Healthcare Commission and in Scotland by the NHS QIS and Scottish Care Commission. In N Ireland the Health and Social Services Regional Improvement Authority has been established with independent powers to inspect and report on performance across the health and personal social service sector.

- Systems to ensure that patients, health professionals and the public have authoritative and robust advice on "best practice" covering individual health technologies and the clinical management of specific conditions. In England and Wales this is undertaken by the National Institute for Clinical Excellence (NICE); and in Scotland by the NHS QIS and SIGN (Scottish Intercollegiate Guidelines Network).

- the Medicines and Healthcare Products Regulatory Authority (MHRA) ensures that all medicines and equipment on the market in England and Wales meet appropriate standards of safety, quality and performance. In Scotland this function is undertaken by the Scottish Medicines Consortium.

Also worthy of note is that since 1999, NHS Chief Executives have been held responsible for quality of services in their particular Trusts across the UK.

6. Although much has been achieved in modernising regulatory practices, most recently through Section 60 Orders, consideration needs to be given as to whether a more radical approach is needed in line with the current pace and direction of travel. The recent Review of the Section 60 process carried out by the Department of Health identified a number of improvements designed to improve and accelerate the process of reform. These are being introduced, including the possible development of "portmanteau" Orders to facilitate harmonisation.

7. Patient safety is also one of the key themes of the UK Presidency of the European Union, illustrating the importance which the Government places on this issue. Specifically relating to the review of regulation, a project dealing with the free movement of health professionals across EU borders will demonstrate how information exchange about fitness to practise can reduce risks to patients.

8. Initiatives to assure the quality and safety of services to patients bite on directly managed/employed health professionals and those working in non-directly managed environments, with procedures to assure quality tailored to those differing sets of circumstances. For example, for those professions contracted to the NHS, provisions are in pace which to some degree mirror those in the NHS by placing a responsibility for initial and continuing fitness to practise issues in the

hands of the PCT. Through the Health and Social Care Act 2001, pharmacists now also have to apply to be included in an NHS list before they are able to provide NHS services, as is the case already with doctors, dentists and optometrists. This approach, where mirroring or similar systems are put in place in the different environments will need to be adopted in carrying forward any changes to the regulatory system designed to better assure patient safety. While improved local clinical governance systems would have a clear role in contributing to the effectiveness of a revalidation system, the private sector also needs addressing. It is not sufficient to think only in the direction of the NHS by – for example – considering enhancing PCT responsibilities or NHS clinical governance requirements to fill 'regulatory gaps'. There is an absence of checks and balances in the private sector at local level and this should be a priority for reform.

9. From the perspective of health service users, the increasing number and visibility of systems to assure quality of healthcare services is likely to lead to a greater public awareness of quality and safety issues. Work on patient empowerment and systems designed to inform the public about services to enable choices between providers, will also lead to greater demands for information about services and the professionals providing them. Taken together, this will undoubtedly give further impetus to the development of systems that allow the public and particularly patients, to be clear that the professional treating them is sufficiently competent to do so, whatever environment they are practising in.

The Healthcare Workforce and the pace of change

10. The increasing demand for more staff in the healthcare sector has led to unprecedented growth, particularly in the established professions. For example in the NHS in England during 2004 an extra 8,000 more doctors, 11,200 more nurses and 3,000 more allied professionals were recruited (source NHS workforce census for England as at 30 September 2004). The NHS now employs more than 1.33 million people of which 84% of those staff are directly involved in patient care. There has also been substantial growth in the number of GPs.

11. It will be important to take account of this fast growing and changing workforce. Regulatory systems need to be able to keep pace with recruitment including from overseas, ensuring that systems are sufficiently robust to check fitness to practise whilst at the same time trying to avoid substantial delays. Some changes have been made by regulators to facilitate a smooth flow of overseas recruits into the service. For example, the GDC has recently increased opportunities for overseas applicants to take its International Qualifying Exam on a greater range of dates in order to reduce registration delays. The pace of recruitment to the NHS, both to existing roles and in new or extended roles, is likely to continue. Regulatory systems and processes need to develop in a way that is consistent with this level of growth. Systems to assure fitness for practice for professionals working in non-directly managed environments similarly will need to be able to cope with rapid change. This suggests that regulatory bodies need to be aware of recruitment policies and the development of new roles at an early stage and to ensure that information systems are sufficiently robust to allow for rapid exchanges with other regulatory bodies, employers and others in

assessing fitness for practice. The implications of the expansion of the EU remain a source of concern for some regulators.

12. In the NHS in England, this rapid rate of growth has led to the development and implementation of a comprehensive workforce strategy. This includes education and training opportunities tied into the skills escalator, underpinned by a new modernised pay system. Opportunities exist to build further on these initiatives; for example, the introduction of Agenda for Change (discussed further below) could provide the means for better defining the responsibilities of the employer and the regulatory bodies on fitness to practise issues particularly in new or extended roles.

13. The needs of employers and staff are also changing. The desire to improve working lives, fuelled by EC Directives and associated national and local initiatives, has served to increase the pressure on employers to introduce different and more flexible working patterns and redesign or introduce new roles. Initiatives to improve access and choice also affect staffing requirements, for example, by providing services locally through smaller multi-disciplinary teams, rather than in more traditional settings. Staff increasingly also demand new challenges and development and are perhaps less content to stay in the same role for a long period than hitherto. This in turn continues to place new pressures on regulators, as illustrated by the work going forward on advanced practitioners and other aspirant groups. This is not simply a workforce pressure – it arises as the complexity of modern healthcare increases, and increased specialisation may be the only answer to the escalating knowledge base.

14. As already mentioned, in the NHS one of the most significant changes which are pertinent to this Review is the introduction of Agenda for Change (AfC), covering the majority of non-medical directly employed staff in the NHS. Roll out in England commenced on 1 December 2004, with an effective date of 1 October 2004 for most terms and conditions, and full implementation is expected soon. Specifically AfC provides opportunities for staff by creating a clearer career pathway and methodology for measuring posts using the NHS Job Evaluation Scheme. Traditional entry points, such as pre-registration programmes, for established professions can be complemented by other entry routes, such as cadet schemes and role conversion, opening up job opportunities to a wider range of people and professions. These developments also help employers: given the structured programme of skills development, they can help to recruit and retain staff in sometimes hard to fill posts.

15. The NHS Knowledge and Skills Framework (KSF) is particularly relevant in the context of professional regulation. The KSF is designed to:

- Support the development of individuals in their post and in their careers;
- Provide an equitable framework for staff
- Be feasible and simple to implement, and
- Be capable of linking with current and emerging competency frameworks.

This process takes place through annual development reviews, included as part of the normal appraisal and PDP process. This review needs to build on these

developments, in terms of complementing the role and responsibility of employers in the NHS and more practically exploring what this means for the future.

16. For those professions working in non-directly managed environments a similar approach could be taken, for example in better defining the role of the regulatory bodies and the contractor in determining fitness to practice at the point of entry to the list and ongoing fitness to practise issues. This also raises some unique but not insurmountable issues of its own. Special approaches to revalidation may be needed, for professionals working in a contracted capacity and for those who work in the private sector outside a managed, quality assured HR framework.

Development of employer responsibilities and related systems.

17. The development of employer based HR systems have led to some specific developments in the NHS of particular interest to this Review. These include the development of Occupational Health Smart Cards, Electronic Staff Records and related IT developments. Developments are moving at different speeds in different parts of the UK.

18. In England, the Occupational Health Smart Card (OHSC) for doctors provides a secure, streamlined and reliable system of recording health clearance for trusts and the doctors themselves, as envisaged in Supporting Doctors, Protecting Patients (1999). The scheme currently covers secondary care medical training grades, but will ultimately be extended to medical school students, locum doctors and consultant and non-consultant career grades (NCCG). A crucial aspect of the card is the live link to the GMC registration database, providing current registration status, and the digital photograph after proof of identity. Discussions are underway to ensure this project will be within the overall umbrella of the Connecting for Health IT programme (formerly NPfIT).

19. The Electronic Staff Record (ESR) continues to be developed and rolled out in the NHS in England. The ESR will ultimately replace 29 payroll systems and 38 HR systems with a single, national, integrated solution providing information at all levels; rollout is expected to be completed by 2008 in the NHS secondary care sector but is limited to PCT administration staff in primary care. Specifically pertinent to this review, the ESR will be tied into pay modernisation and contain an employee's training record; competencies and qualifications alongside other key personal data. Given that the ESR provides for exchanges of information between NHS organisations, this provides opportunities to further dovetail employer and regulatory body information systems. However there may be legal limitations and there are still questions about who first verifies these details **and** if and when they should be rechecked and/or updated.

20. The Scottish Workforce Information Strategic System (SWISS) will implement a national workforce information database with a common set of data. Over the next 3 – 5 years, an integrated / interfaced HR / payroll system for NHS Scotland will be procured.

21. Central to the Connecting for Health IT Programme (CfH) is the sharing of

patient records through the NHS Care Record Service. Access by healthcare professionals will be restricted by the issue of a 'key card', which will also require a system of approval and authenticity. In addition the CfH infrastructure holds the potential to provide easier transmission of information between employers, should this be required.

22. These IT developments provide an opportunity to develop a wider system of credentialing. 'Supporting Doctors, Protecting Patients' identified three key questions. **Has the doctor**

- ***been subject to any action by an appropriate licensing or regulatory body in the UK or another country?***
- ***been involved in a high number of complaints by patients or litigation cases?***
- ***obtained the qualifications and experience listed in their curriculum vitae?***

23. Further consideration of credentialing has been based on the information required by an employer to make an informed offer of employment. This includes:

- **Registration/licence status direct from regulatory body** (registered/not registered/suspended/erased/active case/interim suspension/referred to panel hearing)
- **Identity checks** (birth certificate/passport/driving licence seen and verified/not verified)
- **Pre and post employment checks** (guidance by NHS Employers on Safer Recruitment)
- **Work permits** (if required/date & continued validity)

24. There has been some limited scoping work as part of the post-Shipman agenda as to how the OHSC system could be extended to deliver this and the associated legal and technical questions arising. This initiative would also cover the non-medical professions. Although this initiative is directly relevant to employed staff, this could be extended to contractor professions with the PCT mirroring the role of the employer (subject to the outcome of the current NHS structural review). This system could equally be used in a private care setting.

25. Given these developments, it will be important to ensure that systems used by regulatory bodies for registration and determining continuing fitness to practise fit, as far as is possible, fit and build further with these developments. For example, how can regulatory bodies build on the introduction of KSF in the context of assessment of competence and fitness to practise? In the context of ESR development and roll out and wider IT initiatives, what work might need to be done to ensure IT systems are compatible and information exchange and interrogation of systems is possible to avoid duplicated effort? At the same time, it must be recognised that this is a two-way process; regulators deal with professionals in all working environments and across the UK, and not just those employed by the NHS in England. A significant number of healthcare professionals are not employed within the NHS infrastructure and the new

workforce systems etc. do not apply to them- and many healthcare professionals working within or for the NHS also practise in the independent sector.

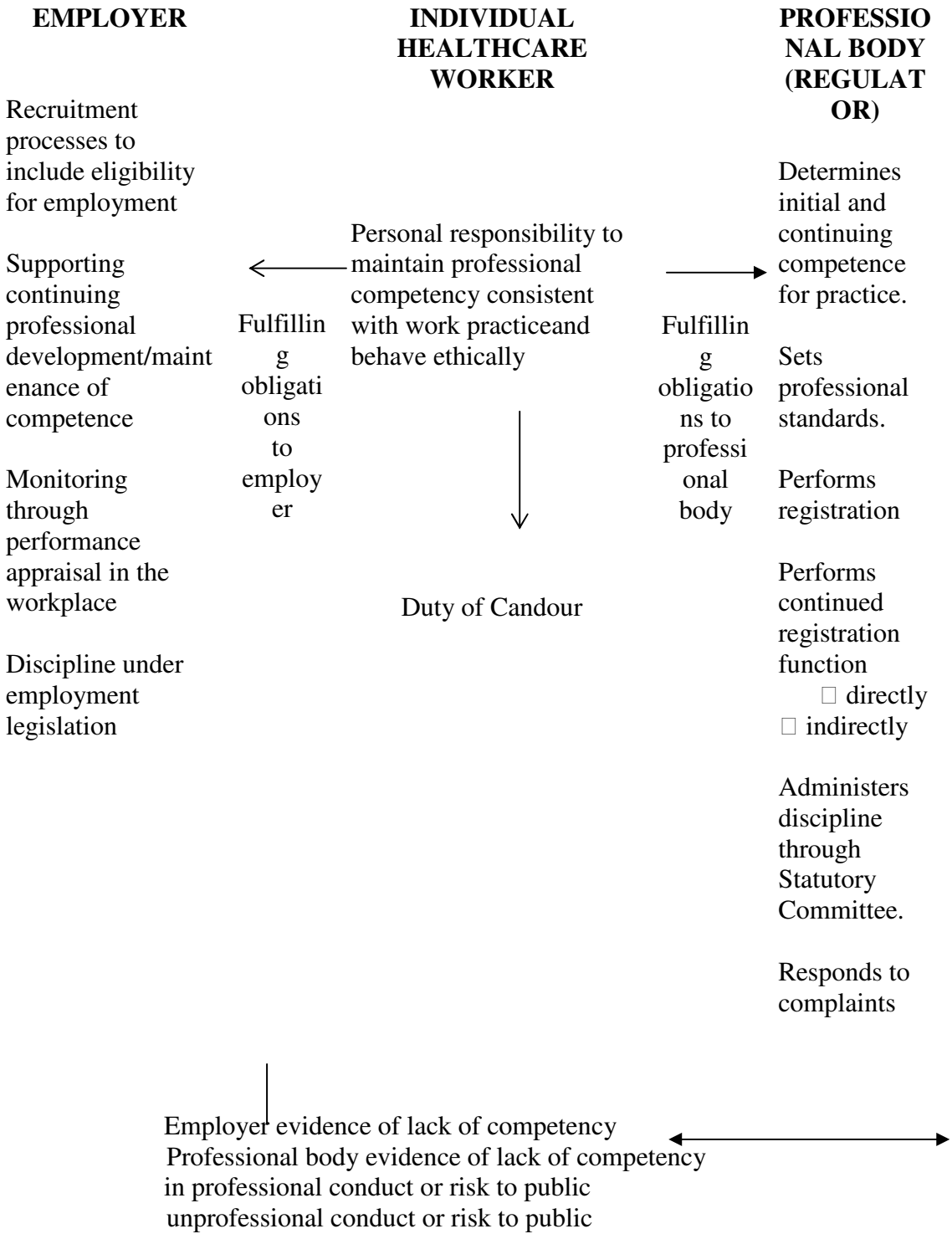
26. Finally, discussions have exposed a potential tension between regulator(professional body) led regulation and employer-led regulation and it may be helpful to examine the various roles via the diagram annexed to this section which seeks to ascribe roles and establish appropriate linkages. This is set in the context of 'employers' with the ability to fulfil the roles attributed to them. It does not adequately deal with the contracted/private sector where the same organisational structure does not exist and where there are owner practitioners.

Recommendations/further questions

27. In the context of the above issues, the Advisory Group has given consideration to the following questions:

a. To what extent do the current system of regulation and the quality assurance processes intended to assure patient safety both within and outside the NHS fit well together? Is there scope to achieve more integration and be more effective?
b. In the context of workforce growth and changes, is the system of regulation sufficiently dynamic and responsive to change? Does it sufficiently focus efforts on public protection? Is the pace of required change sufficiently well facilitated by the available tools (S60 Orders)?
c. How might regulatory bodies build on the developments taken forward under pay modernisation and specifically AfC and the NHS Knowledge and Skills Framework. Specifically, could job evaluation help assess risks to patients and inform proportionality issues.? At the same time, how can regulatory processes reinforce the KSF, which focuses on knowledge and skills with concepts such as conduct and character omitted, to facilitate public protection and management of risk? And how can this be extended beyond the NHS?
d. What implications are there from the increased focus on fitness to practice at local level, particularly in relation to those professionals working in non-directly managed environments? Given the significant variations across the professions in the degree to which focus on ongoing fitness to practise at local level takes place, how can practice be made more consistent? Should there be consistency in how fitness to practise is judged / managed and by whom locally?
e. How do we ensure that systems for all professionals, working in different environments, join up and offer equal amounts of protection for patients? Is there a role for individual self-regulation?

In raising these questions the Group is not suggesting specific answers but instead recommending further work in these areas to facilitate the overall aims of the review.



THE EMPLOYER, INDIVIDUAL AND PROFESSIONAL BODY RESPONSIBILITY INTERFACE

REVIEW OF NON-MEDICAL PROFESSIONAL REGULATION

THE ROLE, FUNCTIONS, GOVERNANCE, STRUCTURE AND NUMBERS OF REGULATORS

Introduction

1. This sixth and final section differs from the previous five. The earlier sections dealt with the main body of the Review's terms of reference and examined patient safety issues relating to:

- How to demonstrate initial and continuing fitness to practice
- Fitness to practise investigations
- Support workers and regulation
- New and extended professional roles, and
- How regulation supports its wider context.

2. The terms of reference then charge us, "in the light of these [deliberations,] to consider and recommend any changes needed to the role, structure, functions and number of regulators of non-medical healthcare professional staff." The task in this section is to set out the issues, arguments and broad agreements around this complex set of issues.

3. To the four topics of role, structure, functions and number of regulators, the Advisory Group decided in April to add the topic of governance. The Group's view then was that this should be one of the cross-cutting themes, and that it should encompass both the balance between public safety and professional buy-in and the issue of the separation of roles between that of regulator and that of professional bodies.

4. In looking, as the terms of reference require, at any changes needed in this area, the Advisory Group has focused attention on any good features of the existing arrangements which must be retained, and particularly any which might be at risk from proposed changes and so need to be actively protected during any change process.

5. The paper takes the five topics in a slightly different order to those in the terms of reference. It reviews what we have learnt about regulators' roles, functions and governance, and then asks what lessons this should teach us about their optimum structure, including the number of different organisations which is desirable. This note reflects our initial analysis and ideas as discussed and amended by the Group and has also been amended to reflect comments and the outcome of discussions elsewhere.

Role

6. The role of the regulators is the logical starting point. The key point here is an uncontroversial one. The Review has been clear from the start that the role of the regulatory system, and of regulatory bodies within it, is to ensure patient safety,

although there are subsidiary objectives eg to maintain public confidence and trust. The definitions annex to Section 1 defines regulation as the set of systems and activities intended to ensure that healthcare staff have the necessary knowledge, skills attitudes and behaviours to provide healthcare safely. Within this broad statement about the role of the overall system, individual functions for regulators are picked out in the next section of this paper. As discussed in section 5, some regulatory body roles could be shared - or form a continuum - with employers to a greater extent than today, but none can be abandoned. (This view of the role of regulation is also consistent with existing and planned statements in legislation about the roles of individual regulatory bodies.)

7. There is however one area in which more clarity could be sought about regulators' role. Four regulators currently have a function outside the scope of regulation. The RPSGB, the PSNI, the General Chiropractic Council and the General Osteopathic Council are each charged in law or in a Charter with promoting their profession, in subtly different ways. There is no suggestion that they are expected to put the good of the profession before that of the public – the reverse, in fact – but this departure from the general regulatory model has caused uncertainty and dispute at times. The Review might identify options for change which focussed the role of each body more narrowly on regulation. The RPSGB has commented that its roles of professional leadership and promoting the profession, which under its Charter have to be exercised for the public benefit, do indeed benefit the public and has provided a detailed paper setting out why it considers that its tasks are not significantly different from many other regulators, and how combining them serves the public good.

8. One comment made was that the role of regulating premises, partnerships and companies is not appropriate and should be removed from the regulators' functions with the responsibility for undertaking these tasks handed over to other organisations. At least one of the regulators with this role disagrees and emphasises the influence of large companies and the need for corporate regulation.

Functions

9. A regulator's functions amount to a more detailed exposition of its role. The definitions annex notes the existing legal position, which identifies four core functions. However, this 1999 definition may underestimate the importance of revalidation or compulsory CPD, and so this paper now proposes that regulators' existing and future functions are better thought of in a threefold division:

1. setting and promoting standards for admission to the register and retention on the register (this was the first of our key themes for the review) Standards have to be kept up to date. This includes oversight of the educational standards which underpin initial registration.
2. keeping a register of those who meet those standards, and
3. administering procedures (including making rules) for dealing with cases where a registrant's right to remain on the register is called into question (this was the second of our key themes for the review).

10. To begin with standard-setting, it is essential for professionals to feel personal ownership of the standards to which they work. Regulators have stressed this in their comments. Standard-setting, or some part of it, is central to an individual profession's identity (and power). This does not mean, however, that standards are the sole property of the profession (they need to be developed in discussion with health care commissioners, providers and service users if they are to support the best possible current service delivery rather than aspirational professional agendas) and a modern regulator should be promoting best practice. Nor does it mean that each profession's standards have to be set by one regulator which regulates one profession. The HPC regulates thirteen different professional groups and so its experience (for example in its recent work to agree a standard of proficiency for the newly-regulated Operating Department Practitioners) is highly relevant. The HPC is a relatively new organisation and there may be benefit in its role being independently evaluated before this model is recommended for wider adoption. One regulator commented that while not disagreeing that one regulator could set standards for more than one group, success was more likely when the regulated groups were similar. Tensions could otherwise develop, including with professional representative bodies.

11. Standards for admission to and retention on the register can be divided into two parts. There is a competence-based part and one which includes conduct (or character) and health. While the former contains elements which are unique to, say, chiropody or dentistry, it also contains substantial elements not only of science but also of effective therapeutic relationships with patients which are common to large groups of professions. When we turn to the second group of standards, we find that some regulatory bodies have already been able to agree one common statement of these. The point has also been well made that the GMC's Duties of a Doctor would still make sense if the word "doctor" were replaced with the name of any of the other professions.

12. Standard-setting, then, provides mixed evidence of a need for change. It is clear, for example, that some very effective educational (and other) standards have been produced by single profession regulators. The HPC has a single standard of Education and Training for all 13 professions it currently regulates. In addition, as the number of professions it regulates increases the single standard will continue to be used. At times, the setting of educational standards has been a less happy experience (as the story of regulating nursing education has suggested to some observers). It is also clear that existing professions aspire to control their own standards, and that patients benefit from the self-policing of individual professionals who adhere voluntarily to a standard because they feel a sense of ownership of it. To sum up, standard setting can be done better in some areas but this is best addressed by spreading best practice and where necessary tackling entrenched interests piecemeal: structural change would risk alienating wider groups of professionals with harmful results.

13. Moving on to the keeping of the register, this core activity of regulators is often little understood by the outside world. This complex task requires good management skills and much wariness about challenges such as fraud and identity theft. Adequate resources and skills are needed to keep the entries accurate and up to date, and this involves links with the regulator's other activities (especially education, CPD and FtP.) When regulators have from time to time failed to meet the high standards they

set themselves in this area, they have hindered timely recruitment in the health services, denied fair treatment to applicants and attracted unwelcome publicity. There is now a substantial body of expertise in the largest regulators about how to do this task well, and it is unsurprising that one smaller regulator wants to contract with one of the largest to keep its Registers.

14. The one issue of principle about the registers is probably that the right people (from public to employers) should be able to see the right information on each register, implying a need for common standards about what is published in relation to each registrant.

15. The Review has accepted the principle that regulation should be harmonised between professions where this improves patient safety. The complexity of registration work, and the ability to gain economies of scale, make a case for concentrating administrative registration work into a smaller number of organisations in this way. This case is based on effectiveness (patient protection and customer service to registrants and employers) as well as efficiency. A single register (or alternatively a website presenting the contents of different registers as a virtual single register) would assist the public, employers and regulators themselves in identifying an individual professional. It is less clear whether the benefits of that would outweigh the considerable set-up costs and risks to service continuity. There is support also for making it easier to check someone's registration history and even for a virtual single register, which presented the contents of a set of organisationally separate ones for this purpose.

16. The appearance on the scene of revalidation or compulsory CPD means that maintaining a register is no longer only an administrative task. However the new tasks can still be understood within the threefold division of functions set out paragraph 9: standards (for retention on the register) are set, administrative tasks are undertaken to record compliance or otherwise, and in cases of dispute an adjudication can be made. (In passing, the same division also makes sense for other forms of registration casework such as making decisions on the acceptability of overseas qualifications.)

17. This discussion of functions concludes by considering fitness to practise procedures. These can be broken down into:

1. **making Rules**: The Government wants all regulators' Rules in this area to be the same, at least in their effects, and section 60 Orders already made or nearly completed have taken us a long way towards this. A single piece of legislation governing this field is a recommendation from paper FR 3-3. This would remove the need for each regulator to make separate Rules and secure Parliamentary approval for them.
2. **receiving and sifting complaints**: Not all cases begin with a complaint, but for those which do we have already accepted the case for a common portal to assist members of the public. This would only be a front-end, however, and if regulators retain separate Rules and separate processes, each will continue to need to sift their own complaints against their own criteria
3. **investigating** the arguments in favour of taking action on someone's registration, where this is judged necessary at step 2, and presenting these to

the adjudicator: we have made the case for convergence but also noted voluntary work in this direction already under way among the regulators, led by CHRE.

4. **adjudicating** on allegations made by the regulator's fitness to practise staff in step 3: we have elsewhere recommended a single adjudicator, or that a series of steps be taken in that direction (including a common pool of adjudicators, lay and professional; a common pool of legal assessors; and a common set of indicative sanctions guidance)

(For completeness we may note that steps 3 and 4 also take place in restoration cases following erasure, and step 3 or a process like it is required if a case goes to court on appeal.)

18. One regulator added that much work can be done through effective collaboration, which would potentially obviate the need for legislation or restructuring (and the further delays to public protection that these options would engender). The regulators are already working together, with CHRE, on a number of these issues.

19. If we were starting with a clean sheet of paper, we might well set up a single fitness to practise system for all the regulated health professions, although some did not accept that the evidence clearly supported this. The issues for the review are about what moves in that direction would be practical, and proportionate, in the much more complex situation from which we actually begin. Funding flows will be an important element to get right.

20. This decision also involves addressing the question of whether the sense of professional ownership (discussed in relation to standards in paragraph 12) is also important here. Part of that is the value attached to "being tried by a jury of one's peers", though the objectively valuable goal of having adjudicators who understand the clinical circumstances of a case - something quite different - could be achieved in a variety of different ways. The HPC, for instance, already runs a FtP system for 13 professional groups in which the panel sitting in judgement on a physiotherapist will always include at least one other physiotherapist.

21. Consideration about fitness to practise functions also needs to include the issue of the 3 regulators who (in any sense of the word) "register" either premises or businesses and have procedures to remove unsatisfactory ones. The importance of "corporate regulation" could grow as more NHS and private healthcare services are delivered by corporate bodies.

22. One member commented that their own careful review of all the functions of the nine existing UK regulators of health professions has identified no functions that cannot be shared.

<u>Governance</u>

23. The subject of governance was added to our tasks (paragraph 3) because the Advisory Group wanted to look at the balance between public safety and professional ownership. We should avoid the false assumption that professional members of

Councils and committees see themselves as there to serve "selfish" interests of their profession. There is much evidence to the contrary. There are two valid considerations however. Firstly, some elected professional members do at times behave in ways calculated to promote their own profiles within their profession (including, unsurprisingly, their own re-election) and this has caused wider difficulties in the governance of at least one regulator. Secondly, the public perceives regulators as dominated by members of the profession they regulate, and the fact of election plus the type of member it can produce strengthen this unhelpful perception.

24. We should consider governance in relation to three areas: the main Council of the regulator, its fitness to practise machinery and other areas. Council is the most critical. Dame Janet Smith's Fifth Report from the Shipman Inquiry said on this subject:

> "the GMC's constitution should be reconsidered, with a view to changing its balance, so that elected medical members do not have an overall majority. Medical and lay members who are to be appointed (by the Privy Council) should be selected for nomination to the Privy Council by the Public Appointments Commission following open competition" (recommendation 106).

25. Our Review and CMO's should seek a common way forward on this point since the issues are the same for each regulator. Professions and regulators rightly fear a move to take away the professional majority on regulators' Councils, but if the analysis here is correct, then changing the number of professionals on Council is not the point. It is the preponderance of elected members which has at times had harmful effects. A replacement of some of the elected members by appointed professional ones, selected on the lines Dame Janet Smith recommended, may be the way forward. A clear person specification would be required, identifying desirable qualities and possibly also excluding individuals with a perceived conflict of interests (such as, arguably, those holding national office in representative bodies for the profession, or professional defence organisations). Needless to say, such a change could be seen by professional bodies as an attack on democracy, but such views would probably not command public support. Training would also be required and some could be developed jointly. Much good quality training for members is already delivered.

26. Commentators sometimes criticise the effectiveness of measures to use lay members to add a citizen and patient perspective, though the standard of individual lay members is widely thought to be high. Without going into the detailed literature, there would definitely be value in bringing together a representative group of lay members and public interest groups, perhaps under the auspices of CHRE, to look into issues such as:

- role definition
- support for lay members to give them more legitimacy and power/information – or better support for all members
- selection, including person specification
- personal development and possibly career progression (from smaller to larger participative roles in regulation)

- wider ways of capturing the citizen's perspective in addition to lay membership, such as better consultation, standing patients' forums or other means.

It is possible that several of these areas for development also apply to professional members. RPSGB comments suggested that role definitions should set out common duties and responsibilities for all council members.

27. In making any changes to governance it will be important to hold onto some key strengths of the existing arrangements. Regulators are independent of government and employers, and unafraid to lobby, resist and criticise when they think this is necessary for patient protection (for example over the language issue for European registrants), and have emphasised the value of this to us. The position on the accountability of regulatory bodies, involving responsibilities to Parliament and a relationship with CHRE, was settled in 2002 and seems to work well at present.

28. Turning from Councils themselves to the governance of the fitness to practise machinery, we again have a Shipman recommendation which should provide the basis for a common line with CMO's Review. Dame Janet Smith called for:

> "The adjudication stage of the FtP procedures [to] be undertaken by a body independent of the GMC…. [Recommendation 51] Consideration should be given to appointing a body of full-time, or nearly full-time, panellists who could sit on the FtP panels of all the healthcare regulatory bodies." (Recommendation 52)

29. If we were to adopt this recommendation literally, we would have to create nine independent adjudication bodies, one for each regulator. This would run into the problem of critical mass. Elsewhere we recommend a single, unified, independent adjudication service or at least that steps be taken towards this.

30. If a single adjudicator is not preferred, lesser steps towards more sharing of the burdens would still be attractive, including Dame Janet's shared body of panellists. It could be best if they are not full-time, since the professionals among the panellists gain in usefulness and credibility by keeping up professional practice (and the lay ones may bring similar extra value to their panel work from their other activities). Other steps on similar lines would include common pools of legal assessors and expert (eg occupational health) witnesses; shared training for chairs, panellists, "prosecutors" and investigators, and a common set of indicative sanctions guidance. CHRE is already promoting the last of these. These suggestions won support from many of the regulators

31. Issues about other areas of governance can be dealt with much more briefly. In addition to fitness to practise panels, regulators have other important committees including those which prepare standards and oversee pre-registration education. Much of what has been said about lay and professional members already applies to the members of these committees. Regulators make good use of co-option of non-Council members onto these committees.

32. When thinking about governance issues it may be worthwhile to apply lessons from other fields, for example recommendations in the reports of the Better Regulation Task Force and in the Clementi Report on the regulation of the legal professions (though the Law Society and Bar Council have responsibilities relating to members' employment terms and conditions which health regulators do not.)

33. Finally, it may be worth mentioning some issues linked to the role of the Privy Council. This has traditionally been valued as a way to add some weight to the processes by which, for example, the Government recommends regulators' Rules to Parliament for approval. At the same time however, approval procedures can be time-consuming and lack transparency. We have already made a lot of progress in for example removing the need for Privy Council approval of lay member appointments and changes to retention fees. This direction of travel should continue, with a Privy Council role retained for the key issues only.

Structure and Numbers

35. What, then, are the criteria for making the recommendation to Ministers in December about any changes to structure and numbers? The decision should rest on evidence about what structures and numbers best deliver the desired **regulation outcomes discussed in this set of papers**, and the improvements in governance which we seek.

36. To summarise the discussion in paragraphs 6-33:

1. Role:
    - no major change required beyond a common definition (some roles can be shared with employers to a greater extent than now but none can be abandoned)
    - examine possible role conflict in their organisations with RPSGB, PSNI, GCC and GOsC.

2. Functions:

    - standard-setting - can be done better at times, but best addressed by spreading best practice and where necessary tackling entrenched interests piecemeal: structural change would risk alienating wider groups of professionals with harmful results
    - keeping the register – concentrate the administrative tasks in one place or a smaller number of places: if well implemented, would bring significant gains in effectiveness as well as efficiency. Some regulators disagreed pointing to a previous unsuccessful attempt to outsource some of these functions, from which lessons should be learned.
    - fitness to practise procedures - if starting with a clean sheet of paper, we would set up a single fitness to practise system. Starting from where we are, aim for:
        - a common portal for complaints for signposting/referral (centralised complaint handling was not supported),

- common standards for decision-making within the regulator at each stage, and either
- a single adjudicator, or
- a series of steps in that direction such as a common pool of adjudicators, lay and professional; a common pool of legal assessors; a common set of indicative sanctions guidance,
- subject to further discussion about benefits, costs and risks, a single body of law.

3. Governance: on the basis of a common way forward with CMO's Review, possibly covering:

    - Keep a professional Council majority but change some or most of the professionals from elected to appointed (under a transparent and independent system)
    - Review the effectiveness of lay membership, working with existing lay members, CHRE and others
    - Fitness to practise governance changes described in 29(2).

37. This summary points us in the direction of some changes in structure, with more functions being shared between regulators. Depending on the judgement made about how much should be shared, this could lead us to conclude that some professions would be more effectively regulated than today as a result of full-scale mergers. The question of critical mass is important here. Do we know that a regulator with less than a certain number of registrants cannot carry out all the functions now needed of it, or do so cost-effectively? (And if we do, what is this number?)

38. A purely illustrative annex sets out a range of possible options for more or less radical changes to the overall structure of regulation, including some analysis of the risks involved. This was the single major issue on which the Group has so far failed to reach conclusions, as most (but not all) of the regulators have so far rejected options including radical structural change in favour of continued progress towards harmonisation and common procedures via S60 Order.

ANNEX 1– For illustration only

A possible approach to option appraisal might look like this:

Options:

1: single regulator for all - The farthest-reaching change in structure. Could also adopt new governance arrangements proposed here or for any of the other options.

2: single non-medical regulator.

3: two non-medical regulatory bodies (NMC plus extended HPC) – the HPC absorbing the professional groups covered by the five smaller regulators.

4: three non-medical regulatory bodies (NMC, extended HPC and body for dentistry, opticians and pharmacy) - setting up a new regulator for the professions where independent contractors are predominant, to be a centre of expertise in dealing with "commercial" style issues like private sector complaints and conflicts of interest between professional values and commercial goals.

5: five non-medical regulatory bodies (NMC, extended HPC, RPSGB, GDC, GOC) – similar to (3) but with the HPC absorbing only the two smallest groups, chiropractors and osteopaths.

6: no change to numbers – Some changes, perhaps, to functions and governance, but not so radical as to require significant changes in structure and therefore numbers.

7: no change to numbers but some changes to structure - A range of possibilities including single portal for complaints and single adjudicator, but none calls the viability of any of the regulators into question.

These options are of course broad brush. The many details lacking include decisions on where new groups like acupuncture and herbalism should go, and consideration of pharmacy in Northern Ireland.

Criteria

- Patient protection
- Economic these are not straightforward and largest may not be best
- Public acceptance
- Professional acceptance
- Speed of change
- Risk

Using the criteria to compare these options might lead to a table like that overleaf.

	Patient protection	Economic	Public acceptance	Professional acceptance	Speed of change	Risk
1. Single body	High (if successful)	Possible Economies of scale after large initial investment	Moderate to high	Probably low, except among some scientist groups	Slow: needs primary legislation	High, especially professional acceptance, loss of expertise and change management capacity
2. Single non-medical body	High (if successful)	Possible Economies of scale after large initial investment – less than 1	Moderate to high – lower than 1?	Low among non-medical professions	Slow: needs primary legislation	High, especially professional acceptance, loss of expertise and change management capacity
3. two non-medical bodies	High (if successful)	Smaller economies of scale possible than 2	?	Probably low, at least among those losing existing regulator	Slow: needs primary legislation	High, especially professional acceptance, loss of expertise and change management capacity
4. three non-medical bodies	High (if successful)	Smaller economies of scale possible than 3. significant investment	?	Probably low, at least among those losing existing regulator	Slow: needs primary legislation	High, especially professional acceptance, loss of expertise and change management capacity
5. five non-medical bodies	High (if successful)	Smaller economies of scale possible than 4 and lower costs	?	Probably low, at least among those losing existing regulator	Slow: needs primary legislation	High, especially professional acceptance, loss of expertise and change management capacity

	Patient protection	Economic	Public acceptance	Professional acceptance	Speed of change	Risk
6. No change	moderate to high	costs continue to increase; revalidation would add new expense (under all options)	moderate	moderate	High (already in place)	moderate: Current problems attract growing criticism
7. No change, but more common structures	High (if successful)	Nearly as many possible economies as 1, for less investment	Moderate to high	Moderate, if well managed	Moderate to slow, depending on type of legislation	Moderate (or slightly higher) – much depends on pace

More analysis is needed of the impacts if the changes were not successful, including political and reputational risks.

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