

Council, 10 September 2009

CHRE reports

Executive summary and recommendations

### **Introduction**

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

In doing this, the CHRE normally meets with or asks for the written comments and views of the regulatory bodies.

The CHRE has recently published reports in relation to a number of Department of Health commissions. The brief attached paper indicates, where applicable, further work the Executive plans to undertake in relation these reports and indicates where CHRE work is ongoing. The reports are appended.

The reports are:

- Regulatory bodies' health requirements for registration (June 2009)
- Advanced practice (July 2009)
- How regulatory bodies approach the problem of data misuse (July 09)
- Scope for sharing functions between regulators (June 09)
- How regulators quality assure undergraduate education (June 09)

### **Decision**

This paper is to note. No decision is required.

### **Background information**

Information about CHRE reports can be found here:  
[www.chre.org.uk/research/](http://www.chre.org.uk/research/)

### **Resource implications**

None

### **Financial implications**

None

## **Appendices**

- Regulatory bodies' health requirements for registration (June 2009)
- Advanced practice (July 2009)
- How regulatory bodies approach the problem of data misuse (July 09)
- Scope for sharing functions between regulators (June 09)
- How regulators quality assure undergraduate education (June 09)

## **Date of paper**

26 August 2009

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## **CHRE reports**

- **Regulatory bodies' health requirements for registration**

The Education and Training Committee previously discussed the topic of health and registration, in particular, the continued role of health references as a requirement for admission or readmission to the Register.

The Executive will invite the Education and Training Committee to discuss the recommendations of the report at its meeting in September 2009, and will ask the Committee to consider whether the existing health reference requirement might be replaced with a self declaration. Subject to the outcomes of this discussion, a paper will be brought to the Council at its December 2009 meeting.

- **Advanced practice**

The Education and Training Committee has previously discussed the topic of advanced practice as part of its discussion on the question of annotating the Register to indicate where post-registration qualifications are held. At its meeting in December 2008, the Committee agreed that any policy on post-registration qualifications should apply to all the HPC regulated professions and that the Register should only be annotated in exceptional circumstances where an annotation would improve protection of the public and where the annotation permitted an extension of practice.

The final development of the Committee's policy and progress in this area was delayed in anticipation of the report of the Department of Health Extending Professional Regulation Working Group. Now that this report has been published, the Executive will bring a further paper to the Committee at its meeting in December 2009, suggesting the Committee's possible next steps.

- **How regulators quality assurance undergraduate education (June 09)**

After the publication of this report, the CHRE has indicated that it will work in consultation with the regulatory bodies to consider whether its standards for good regulation (used as part of the performance review process) should be amended in line with good practice.

## **Health Conditions: Report to the four UK Health Departments**

**Unique ID 11/2008**

**June 2009**

### **Executive summary**

All the health professional regulatory bodies have means to take an applicant's health into account when making a decision on whether to register them. For some regulatory bodies this is phrased in terms of the 'good health' of the applicant; others require that an applicant's fitness to practise is not impaired, although 'adverse physical or mental health' is one ground on which fitness to practise may be found impaired.

The regulatory bodies state that the only judgement they make about an applicant is whether the person would practise in accordance with the competence and conduct standards they set for the profession's safe and effective practice. The regulatory bodies do not set or apply standards for health that posit a general state of health required as a condition of registration; rather they consider a person's health only in relation to the effect it has on their practice, in order to determine whether their practice will meet the standards of competence and conduct. In making this assessment, they discuss with the individual their approach to their practice and seek evidence about their individual circumstances from suitably qualified professionals with expertise in the specific area. The purpose is to determine whether the person would practise with any necessary adjustments in ways that meet the required standards in one of the range of roles within the profession. We have seen no evidence that they do not follow this process.

Regulatory bodies have varying provisions for how they consider issues around a registrant's health in fitness to practise procedures. In considering whether a professional is fit to practise, the regulatory body is assessing whether their practice meets the necessary competence and conduct standards. Some regulatory bodies have separate committees for cases in which issues around a registrant's health are the underlying reason for their failure to practise in line with standards; others have a single committee for all types of case where a registrant's fitness to practise is in question.

We believe that there is an important distinction between formal health requirements and fitness to practise requirements. Regulatory bodies do not need health requirements that go beyond determining whether someone is fit to practise, either at registration or during fitness to practise procedures. Health issues may be material in determining whether a person meets the competence and conduct standards, but should not sit outwith this as a separate requirement. However, health needs to be one of the grounds on which a regulatory body can find a person's fitness to practise to be impaired. This is because if issues around the person's health are an underlying reason for their practice not meeting the competence and conduct standards, it is the health issues that are a ground for

establishing this and then finding fitness to practise to be impaired – failure to meet standards does not itself ground a finding.

We recommend that the language regarding the health of registrants is significantly modified. For both registration and fitness to practise procedures the concern of the regulatory body is whether the person is fit to practise – whether their practice meets the necessary competence and conduct standards. However, in some cases the particular circumstances of an individual's health and their approach to their practice may be of material relevance to the question of whether their practice meets these standards, and regulatory bodies need the ability to access and consider such information. We believe that there should be single requirement of fitness to practise for registration and that consideration be given to reordering regulatory bodies' fitness to practise procedures so that there is a single committee with responsibility for all fitness to practise hearings. The purpose of these changes would be to make clear that health is not considered in isolation, but only insofar as it relates whether a person's practice meets the necessary competence and conduct standards.

Engagement between regulatory bodies and registrants and prospective registrants is important to reassure them that disclosing information to regulatory bodies does not put their career at risk; rather their registration is only at risk if their practice is not in line with the profession's standards of competence and conduct. There is also clear evidence that interpretations of regulatory bodies' requirements by other parties has led to disabled people being discriminated against. There is a clear role for further guidance to these parties to help prevent this discrimination taking place and to ensure that disabled people are not impeded or discouraged from participation in the health professions.

## 1 Introduction

- 1.1 The core purpose of health professional regulatory bodies' registration requirements is to seek to assure the fitness to practise of those on the register and thereby entitled to practise as a member of the profession.<sup>1</sup> A person's fitness to practise as a member of a given profession is a question of whether they practise the profession safely and effectively – in line with the standards of competence and conduct set by the profession's regulatory body. The regulatory bodies all currently ask questions regarding an applicant's health on initial entry to the register. These vary in type across the regulatory bodies, from requiring full references from a medical practitioner to a self-declaration that nothing about the applicant's health calls into question their fitness to practise as a member of the profession. The regulatory bodies also have means by which they can consider the health of a registrant in their fitness to practise procedures, although the formal provisions for doing so vary.
- 1.2 In 2007 the Disability Rights Commission<sup>2</sup> published *Maintaining Standards: Promoting Equality*.<sup>3</sup> This report concluded that regulatory bodies having health requirements for those on, or seeking admittance to, their register leads to discrimination and has a negative effect on disabled people's access to the health professions.
- 1.3 The Department of Health commissioned the Council for Healthcare Regulatory Excellence to provide advice on the use and purpose of the health professional regulatory bodies' requirements regarding registrants' health. In particular, the Department sought to ascertain:
- Whether or not the registration procedures of any of the regulatory bodies includes a requirement on the registrant to be in good health at initial registration.
  - Where regulatory bodies, as part of their registration process and/or revalidation process, ask questions about the health and/or disability of applicants or registrant, what the purpose is this serves.
  - Whether there are any rules or other provisions that require the regulatory bodies to take account of health and/or disability as part of their fitness to practise procedures.
  - The volumes of complaints regulatory bodies receive regarding discrimination against disabled people.

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<sup>1</sup> The nine health professional regulatory bodies are the General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI) and Royal Pharmaceutical Society of Great Britain (RPSGB).

<sup>2</sup> In October 2007, the Equality and Human Rights Commission took over the role and functions of the Disability Rights Commission along with those of the Commission for Racial Equality and the Equal Opportunities Commission.

<sup>3</sup> Disability Rights Commission (2007) *Maintaining Standards: Promoting Equality – Professional regulation within nursing teaching and social work and disabled people's access to these professions*. Available at: <http://www.maintainingstandards.org> (accessed 22 May 2009).

- Whether or not there would be any detriment to individual registrants or public protection if the health standards were to be removed from the legislative frameworks for the regulatory bodies.
- Whether the same requirements should apply to all regulatory bodies or whether it would be appropriate for different approaches to be taken for different professions.

1.4 The statutory main objective of CHRE when exercising our functions is to promote the health, safety and well-being of patients and other members of the public. The safety of patients and other members of the public is the underpinning principle throughout this report.

## **2 Registration**

2.1 The core purpose of regulatory bodies' registration requirements is to seek to assure the fitness to practise of those on the register and thereby entitled to practise as a member of the profession. A person's fitness to practise as a member of a given profession is a question of whether they practise the profession safely and effectively, in line with the standards of competence and conduct set by the profession's regulatory body. It is important that these standards are expressed in terms of the competences necessary for practising as a member of the profession. Regulatory bodies' competence standards should not be expressed in terms that require the use of a particular method unless competence in that method is itself an essential part of a profession's safe and effective practice. The regulatory bodies have all stressed to us their commitment in seeking to ensure their standards are fair and are under an obligation to do so in order to meet their legal duties under the Disability Discrimination Act. Throughout this document when we talk about standards for competence and conduct, we are meaning legitimate competence standards in accordance with the DDA. By this we are not intending to pass judgement on the nature of regulatory bodies' existing standards with regard to the DDA; rather we are referring to the role competence and conduct standards have in the regulation of health professionals.

2.2 The regulation of professionals operates on a principle of taking action to protect the public before they are put at unwarranted risk of harm, not just reacting to adverse events. As a result, the regulatory bodies all require evidence about applicants for the purpose of ensuring there is no reason to believe the person will not practise in accordance with the expected standards should they be registered. To this end, they currently require evidence of applicants that: they have an appropriate professional qualification for entering the register which signals that they have the requisite professional knowledge and skills to practise in line with the profession's standards; their past actions do not give reason to believe they will behave in ways that are not in line the profession's standards; and factors to do with the personal circumstances of their health and management of their practice do not call into question their capability to practise in line with standards.

2.3 Across the regulatory bodies there are differences in the specific type of evidence required about an applicant's health. There are also differences in the legislative frameworks that underpin their registration requirements. These are summarised in an annex to this document.

- 2.4 The GCC, GDC, GOsC, HPC, and PSNI all require applicants to provide a formal health reference from a medical practitioner. Most of the regulatory bodies provide some guidance to the applicant and the medical practitioner on the purpose of the health reference and the sort of information they require. However, there is wide variation in the detail of the guidance. Robust guidance on the nature of a profession's practice and the necessary competencies is highly important because the purpose of requiring disclosure is to determine whether there may be any effects on the safety or effectiveness of their practice as a member of that profession, which require further consideration with the applicant. Regulatory bodies do not need access to unnecessary information or wrongful questioning of an applicant's fitness to practise from a medical practitioner making assumptions about how a profession is, and can be, practised. Although regulatory bodies would not take any action in relation to information unrelated to the safety and effectiveness of a person's practice, these unnecessary disclosures may serve to complicate the registration process and potentially cause confusion and distress to an applicant about their professional future.
- 2.5 The GMC, GOC, NMC and RPSGB require applicants to make a self-declaration on their registration forms to the effect that the applicant is not aware of anything about their physical and/or mental health that might raise a question about their fitness to practise as a member of the profession. The NMC and RPSGB also require that an application is signed off by either the applicant's education institution (NMC) or their supervisor in their pre-registration year in practice (RPSGB). The NMC and RPSGB both expect the person making this declaration to highlight any issues which might undermine the applicant's ability to practise in accordance with the necessary standards.
- 2.6 None of the regulatory bodies referred to in paragraph 2.4 above which require a full reference on initial registration have the same requirement for continuing registration. Most use a self-declaration on renewal of registration forms and place registrants under a general duty to inform their regulatory body if changes in their health affect their ability to practise in line with their regulatory body's standards. We have heard no convincing argument as to why practitioners might pose additional risks to public protection at initial registration justifying the requirement of a full reference, compared with accepting a self-declaration for renewing registration. There is no evidence that regulatory bodies with self-declarations have increased rates of fitness to practise cases within a couple of years of registration in which health is an underlying reason for a practitioner failing to meet their professional standards.
- 2.7 Most regulatory bodies have 'good health' as a formal requirement of registration, which emerges from its use in their respective legislative frameworks (see annex 1). The use of terms such as 'good health' does not add value to public protection and can obscure the issue regulatory bodies are seeking to address: will the person practise in accordance with the competence and conduct standards it sets for the profession's safe and effective practice. The phrase suggests there is some general state of health that is required for registration and implies there are standards set for health in and of itself, rather than health only being of relevance in relation to competence and conduct. The concern of regulatory bodies is not the state of a person's health in itself. The concern of regulatory bodies is whether a person is capable of practising in accordance with the standards of competence and conduct it sets for the profession. In itself, a health condition says nothing informative about this from which conclusions can be drawn to answer this question. The diagnosis of a

health condition does not provide reasons to conclude that in practice a person would pose a risk to the safety of patients or other members of the public. A risk would only arise if a person does not manage their practice to meet the necessary standards for safe and effective practice. In this sense, any person who does not practise in line with the necessary standards may be putting the safety of patients or colleagues at risk, regardless of whether their health is an underlying reason for this.

- 2.8 All the regulatory bodies are emphatic that they do not set specific standards for health on the basis of which diagnosis driven judgements are made; rather they judge each person's case on an individual basis. The regulatory bodies discuss with the individual their approach to their practice and seek evidence on their individual circumstances from suitably qualified professionals with expertise in the specific area. The purpose is to determine whether the person has the capability to practise with any necessary adjustments in ways that meet the required standards in one of the range of roles within the profession. The regulatory bodies see the function of their powers regarding health being to enable them to consider any impact of the wider issues around an applicant's health on their capability to practise safely and effectively in line with the standards of the profession. The function is not to set any additional standards outwith those set for professional competence and conduct, but to seek evidence there is no reason to believe an applicant would fail to comply with their obligations under these. All the regulatory bodies strongly believe that their processes are free from discrimination, involve no unjustified assumptions and are based solely on assessments of an individual case using detailed information from those with expertise on the risks involved. In no case would diagnosis itself be used as a predictor of professional performance such that the diagnosis alone is used as grounds for an absolute bar to registration. We have seen no evidence that leads us to doubt that the regulatory bodies apply their processes in this way.
- 2.9 Across the health professional regulatory bodies, there have been very few cases in recent years in which applicants have been refused registration on the basis of information regarding their health. We have learned of no cases in recent years in which health has been a sole basis for refusing registration, although we have been informed of a small number of cases in which information regarding an applicant's health has been considered material in the context of other issues raised with respect to their knowledge, skills and behaviours. There have also been a number of cases in which the registration process has taken longer for applicants with an impairment or health condition if a regulatory body has sought further information, such as expert opinions and discussions with the applicant about their strategies for managing their practice, before making a final decision to register them.
- 2.10 However, the semantics of 'good health' also raises problems beyond being an inaccurate descriptor for the regulatory bodies' purpose. Although many of the regulatory bodies provide advice to applicants, registrants and medical practitioners filling in health references about the requirement, with varying degrees of detail, the term can still create problems. Applicants, registrants and medical practitioners are formally being asked to attest to 'good health' and this has the potential to cause confusion to the parties involved when they may consider that their health is not 'good', but does not affect the safety or effectiveness of their practice. Similarly, a medical practitioner filling in a health reference might not fully understand the nature of a different profession's practice and how the expected standards can be met and so erroneously consider a person's health or impairment as an impediment to safe and effective practice.

- 2.11 We have seen evidence of instances in which having ‘good health’ as a formal requirement to be entitled to practise a profession creates the opportunity for bullying and discrimination of those with impairments or health conditions by other parties, even where regulatory bodies’ own processes are applied so as to be free from discrimination. *Maintaining Standards* highlighted a number of cases in which employers had bullied employees on the basis that they are required to be of ‘good health’ to be registered and allowed to practise their profession.<sup>4</sup> It is unfortunate that regulatory bodies’ requirements are misrepresented in this way. Wider issues around this and the role of guidance are discussed further in section six. The report also highlighted cases in which higher education institutions had sought to interpret regulatory bodies’ requirements regarding whether a person would ultimately be registered and made unwarranted assumptions about disabled people leading to outcomes which discriminated against people who had a disability or health condition.<sup>5</sup>
- 2.12 The Scottish Social Services Council (SSSC), which regulates social workers and certain other social services workers, provides an instructive comparison to the health professional regulatory bodies because it does not have formal requirements regarding health. However, the SSSC has other means by which it receives and assesses information where an applicant for registration who has a health condition may not be meeting its standards due to not managing their practice appropriately. (It should be noted that the UK’s professional regulatory bodies for social workers only enforce codes of practice regarding conduct but not competence in the same way the health professional regulatory bodies do, which limits the ways in which professionals might not practise in line with standards.)
- 2.13 The SSSC requires applicants to have their suitability to practise endorsed by their employer, in which the employer is required to raise any issues which might affect their suitability – including any issues about their management of their health/practice. There is a code of practice for employers which includes responsibilities on endorsing applications and is enforced by the systems regulatory body, the Scottish Commission for the Regulation of Care. If issues are raised in the endorsement the SSSC will discuss management strategies with the person to explain how they manage their condition and practice to be in line with the SSSC’s standards. If the person fails to co-operate with the SSSC, it will deem them to be unsuitable and not register them. The SSSC may also ask for access to medical records and for the person to have a medical assessment, failure to co-operate will lead to the SSSC determine that the person is not suitable to be registered. Therefore, although the SSSC does not have any formal rules for considering an applicant’s health at initial registration, it has other means to find out if an applicant’s management of a health condition and their practice calls into question their ability to practise social work. The SSSC considers having available these means which allow it to consider implications in practice of a person’s health where they emerge as being important in ensuring public protection. It is important that regulatory bodies have means to find out if there are issues surrounding a person’s management of

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<sup>4</sup> See Disability Rights Commission (2007) *Maintaining Standards: Promoting Equality – Professional regulation within nursing teaching and social work and disabled people’s access to these professions*, p173-4.

<sup>5</sup> See Disability Rights Commission (2007) *Maintaining Standards: Promoting Equality – Professional regulation within nursing teaching and social work and disabled people’s access to these professions*, p160-5.

their practice for which health is an underlying reason that mean they are unable to meet the necessary competence or conduct standards.

- 2.14 There are features of the employment arrangements that the SSSC regulates that sharply contrast with those of the health professional regulatory bodies. These mean that the health professional regulatory bodies would not have access to the information which the SSSC can get through references from employers. The SSSC has taken on the role of regulating an existing workforce of whom more than 99% are in established employment. The formal employment relationship provides a source of information from employers provided according to a code enforced by the systems regulatory body for which the health professional regulatory bodies have no equivalent. The SSSC also operates student registration meaning all students are registered and regulated against its code of practice for registrants before going into practice-based learning, providing another avenue for questions of suitability to be brought to its attention before a person is granted full registration.
- 2.15 We recommend that the language of 'good health' should be removed from the legislative frameworks governing the regulatory bodies' registration procedures. The only legitimate consideration for the regulatory body is whether a person is fit to practise. This is a question of whether the person will practise in accordance with the regulatory bodies' competence and conduct standards, although in some cases a person's health in relation to the way they practise may be relevant in making this determination. Regulatory bodies need access to this information and the ability to consider it where it is relevant to the question of whether a person will practise in accordance with competence and conduct standards.

### **3 Fitness to practise**

- 3.1 The term 'fitness to practise' relates to whether someone meets the standards a regulatory body sets for competence or conduct; it is used as a term for a particular legal purpose. The use of the word 'fitness' is not intended to relate to any general state of health. In using the term it is not the purpose of the regulatory bodies to be making any abstract statements about an individual's fitness as regards their physical or mental health. Similarly, the use of the term 'impairment' when a person's fitness to practise is found to be impaired, is used in a legal sense and is not intended to relate to any disability, other physical impairment or health condition a person may have. If someone needs to limit their practice in certain ways for it to be safe and effective, and they do so, they are following their professional obligations – there is no sense in which as a result of this they are impaired in terms of fitness to practise.
- 3.2 Regulatory bodies' fitness to practise procedures should have the same focus as registration procedures: is the person's practice safe and effective and in accordance with the profession's standards for competence and conduct set by the regulatory body? This is the core of judging whether a person is fit to practise or whether their fitness to practise is impaired and action on their registration required. As with registration procedures, the regulatory bodies assure us that they do not set specific standards regarding registrants' health. The regulatory bodies use their powers regarding health to enable consideration of how the particular circumstances around a registrant's health do or do not affect their capability for safe and effective practice in line with the regulatory body's competence and conduct standards. Consideration of their particular circumstances will include factors such as management strategies and adjustments in their practice, information on their personal circumstances from

appropriately qualified practitioners and any wider evidence that may be relevant in their individual case.

- 3.3 Regulatory bodies have the role of setting standards for competence and conduct and need the ability to consider the health of applicants and registrants insofar as it is a factor relating to the person's capability of meeting these. This should not be framed in terms of standards or specific regulations regarding health. It should be framed in terms of fitness to practise, with health a factor that can be considered where it may affect the person's practice such that it calls into question whether they can practise in line with the regulatory bodies' standards. In a policy statement on the meaning of fitness to practise, the GMC illustrates how it considers health can be a factor in terms of fitness to practise:

The GMC does not need to be involved merely because a doctor is unwell, even if the illness is serious. However, a doctor's fitness to practise is brought into question if it appears that the doctor has a serious medical condition (including an addiction to drugs or alcohol); AND the doctor does not appear to be following the appropriate medical advice about modifying his or her practice as necessary in order to minimise the risks to patients.<sup>6</sup>

- 3.4 This represents a situation in which the professional is failing to practise in accordance with the regulatory body's standards because their practice is putting patients at unwarranted risk of harm. We believe this is the appropriate way for regulatory bodies to consider the impact of a person's health on their fitness to practise. It demonstrates that it is not a health condition in itself that is the basis of the determination, but rather a professional's practice. The facts regarding a person's health and management of a condition may be relevant in determining whether and, if so, how they are able or unable to meet the regulatory body's standards. A diagnosis is no basis for concluding whether a person's fitness to practise is or is not impaired. As the DRC noted in *Maintaining Standards*:

Health might be material to compliance with competence or conduct standards, or may not be, but diagnosis is irrelevant in determining competence or conduct.<sup>7</sup>

- 3.5 We agree with the DRC's statement. Regulatory bodies should not have any requirements for the state of a person's health as a condition of registration that go beyond the question of whether they can practise in line with the profession's competence and conduct standards. Regulatory bodies need the power to consider the effects health may have on a professional's practice to carry out their role of protecting the public. A diagnosis may mean a professional needs to modify the way they practise to ensure it is safe and effective, but the diagnosis itself does not mean the professional is not capable of practicing in line with their standards. It is only where the professional is unwilling to, has failed to, or for any reason cannot take appropriate steps to modify the way they practise in light of their health that their fitness to practise is in question. However, non-compliance with competence and

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<sup>6</sup> General Medical Council (2007) *The Meaning of Fitness to Practise*. Available at: [http://www.gmc-uk.org/concerns/the\\_investigation\\_process/the\\_meaning\\_of\\_fitness\\_to\\_practise.pdf](http://www.gmc-uk.org/concerns/the_investigation_process/the_meaning_of_fitness_to_practise.pdf) (accessed 22 May 2009).

<sup>7</sup> Disability Rights Commission (2007) *Maintaining Standards: Promoting Equality – Professional regulation within nursing teaching and social work and disabled people's access to these professions*, p113.

conduct standards is not itself the legal grounds for finding a professional's fitness to practise to be impaired. A finding of impairment requires an incident or other fact regarding the professional to be found proved which is determined to represent a significant or persistent departure from the regulatory body's standards, as the grounds for finding the professional's fitness to practise to be impaired. If a health condition is an underlying reason why a professional is departing from standards, regulatory bodies need to be able to establish this fact and consider whether the person's actions with respect to their health and practice represent a significant or persistent departure from their professional obligations, in order to make a determination on their fitness to practise.

- 3.6 Regulatory bodies suggested to us that not to be able to fully consider health or deem it an underlying reason for fitness to practise being impaired would prevent a complete assessment being made on the specific risks involved in a given case. Testing a professional's competence only provides a snapshot at one moment in time and may not provide a full picture if a person has a fluctuating condition that they inadequately manage in relation to their practice. Such particularities need to be grounds a panel can consider if it is to make a comprehensive determination of the risks a person's practice poses to patients, the public or colleagues and then decide on any appropriate sanction.
- 3.7 In a similar vein, we were told that if health could not form grounds for panels in determining whether fitness to practise is impaired, at times this may impede the regulatory body's ability to build a comprehensive case. It may take the regulatory body more time to build a case in which appropriate action could be taken based solely on grounds of deficient professional performance or misconduct if wider information on their health and management of their practice could not be fully taken into account in the grounds for a decision. This would require more evidence of deficient professional performance or misconduct to ground a finding and may mean the regulatory body would be unable to take appropriate action until after more significant instances of deficient professional performance or misconduct had occurred. We were informed that the Council for the Professions Supplementary to Medicine had experienced problems in this specific regard prior to its supersession by the HPC with the power to consider health in its procedures. The GOC and RPSGB also noted that they had felt unable to take action when they believed a registrant's practice failed to meet standards prior to legislative changes that gave them the power to consider health as grounds in fitness to practise cases. However, like the other regulatory bodies, they only use health as grounds in determining whether a person's practice does not fall short of the
- 3.8 The largest number of fitness to practise cases in which health is an underlying reason for a person's failure to practise in line with their regulatory body's standards involve alcohol or drug dependency, which is not covered by the DDA. However, a significant proportion of cases involve a professional with a mental health condition that underlies effects in practice such that they are failing to practise in line with the regulatory body's standards. There are also a handful of cases involving other impairments or health conditions. Examples the regulatory bodies gave us of what these cases might involve include: epilepsy if the person is having regular and unpredictable episodes and practises in ways that may put patients at risk; early onset dementia if a professional is unable to recall relevant information in ways that may jeopardise the safety of those in their care; and some degenerative conditions if

a professional does not make needed adjustments in their practice to maintain its safety if the condition is having an effect on their physical capabilities.

- 3.9 We recommend that consideration is given to reordering regulatory bodies' fitness to practise procedures so that there is a single committee with responsibility for all fitness to practise hearings. This would help to make clear that the issue at hand in proceedings is a person's compliance with the regulatory bodies' competence and conduct standards in their professional practice, and that a person's health and surrounding issues are only considered where they are of material relevance to this. The GMC recently moved to having a single committee for fitness to practise hearings and believes that this far better facilitates consideration of different factors which may underlie a person's failure to practise in line with their standards. In such a system there can still be provisions to enable adjustments to be made for hearings to ensure the confidentiality of sensitive personal information or if other requirements are involved in a given case.

#### **4 Public protection**

- 4.1 We have sought to highlight how the regulatory bodies' procedures regarding professionals' health relates to public protection throughout this report. Similar principles apply regarding risks to the safety of colleagues if a professional is not practising in line with competence and conduct standards. Our core findings are presented in the paragraphs below.
- 4.2 The obscure language around 'good health' should be removed from the legislative frameworks of those regulatory bodies in which it is present. The concern of regulatory bodies should be whether a person is fit to practise, which is a question of whether they would meet the standards of competence and conduct. Issues around a person's health are of relevance only in relation to these standards, not in themselves. There need be no provisions for health to be assessed outwith its impact on the competence and conduct of the person and their capability for practising in line with these standards. A single requirement that a person's fitness to practise is not impaired to be eligible for registration is used by the GMC, GOC and RPSGB and has had no negative impact on public protection.
- 4.3 Regulatory bodies need to be able to find out if there is any reason a person's management of a health condition in relation to their practice might lead to them to be unable to practise in accordance with the regulatory bodies' standards of competence and conduct, and to prevent a person being registered if necessary. Although there are few cases in which a health professional regulatory body has turned applicants down on the grounds of health, we have heard of a number of cases in which a regulatory body has considered a person's management of their practice with regard to health to be material to their potential compliance with standards and the threat of not being registered has contributed to public protection. In such cases, people have taken further steps to ensure their practice meets the necessary standards, for example discussing with suitably qualified professionals or the regulatory body how best they can adapt their practice or making voluntary undertakings on this prior to registration. The SSSC, which lacks any formal legal powers regarding applicants' health, has established mechanisms to ascertain where health issues impact on a person's practice and may undermine their suitability. It considers these to be important to its role of protecting the public. All regulatory bodies are under a legal duty to ensure that their means for finding out this information are proportionate and

do not lead to any unjustified discrimination or disadvantage against disabled people, this is defined in the DDA. The regulatory bodies are also under a duty to make individualised assessments in relation to their competence and conduct standards, and taking into account the full circumstances of a person's particular case and considering evidence from those with appropriate expertise.

- 4.4 In fitness to practise procedures, like registration, the question is whether the person's practice is in line with the profession's competence and conduct standards. Health issues are relevant only in relation to making a determination on this. The GMC's view on the meaning of fitness to practise demonstrates how health issues should be considered by regulatory bodies in making decisions about a person's fitness to practise. We believe that it is important for public protection that regulatory bodies are able to consider issues around a professional's health in this way. The regulatory bodies assure us that they do not make decisions based on solely a diagnosis, which would be discriminatory to a professional and could not be justified on the basis of public protection. However, if issues around health are a major underlying reason why someone does not meet the standards of proficiency, they are grounds on which the person's fitness to practise is impaired. Consequently, we believe that there still needs to be appropriate provision in the regulatory bodies' legislative frameworks for them to be able to make this finding.
- 4.5 We believe that the same framework of assessing fitness to practise on registration and having single fitness to practise committees can apply equally across all the regulatory bodies. However, the way they operate within this must vary according to the context of different professions. There are different competence standards for different professions and so regulatory bodies' handling of issues regarding how an individual's circumstances might affect their ability to meet standards must be made according to their specific standards for the profession and context of its practice. In this respect, regulatory bodies' processes and requirements need to be specific to the profession. The nature of a profession's safe and effective practice is the grounds for regulatory bodies' competence and conduct standards, from which the type of evidence that is relevant on the question of whether someone meets these and is fit to practise can be determined. There is an onus on regulatory bodies to ensure all its standards are evidence-based and proportionate and to be transparent about how it processes operate and the ways it will consider people's information. Clarity in procedures could help reassure professionals that disclosing information to their regulatory body does not itself put their career at risk; rather their registration will only be at risk if their practice is not in line with the profession's standards of competence and conduct.<sup>8</sup>
- 4.6 We have also commissioned a piece of qualitative research into the opinions of patients, carers and other members of the public into how regulatory bodies should act with regard to the health of professionals. The conclusions were that the professional has the primary responsibility to recognise any impacts their health has on their practice and, along with an employer if relevant, manage their situation and make any necessary adjustments in order to meet the standards set out by their regulatory body. Regulatory bodies were expected to intervene when an issue was

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<sup>8</sup> This fear was highlighted in Stanley N, Ridley J, Manthorpe J, Harris J and Hurst A (2007) *Disclosing Disability: Disabled students and practitioners in social work, teaching and nursing*. This was a research study to inform the DRC's investigation and is available at <http://www.maintainingstandards.org> (accessed 22 May).

not being satisfactorily managed, but did not need to be involved if a professional has a health issue which does not affect their practice.

## **5 Complaints to regulatory bodies about disability discrimination**

- 5.1 Although in many cases the health professional regulatory bodies do not specifically code complaints regarding discrimination against those with disabilities, they have told us that to the best of their knowledge they receive few complaints in this regard. Some told us that they have never received any such complaint. They suggest that most of the complaints received are identify others as the discriminating party, particularly education and training institutions, rather than being directed against the regulatory body's own procedures or actions. We were told that complaints often regarded failures to make reasonable adjustments, particularly for examinations.

## **6 Guidance**

- 6.1 There is wide variation in the level of guidance provided by regulatory bodies provide to potential applicants, registrants, education and training providers and others. We believe there are a number of reasons why it is important that high-quality guidance on health issues is provided to registrants, applicants and others who may be considering a particular health profession as a career. Guidance on how health issues are relevant in fitness to practise would promote transparency and help reassure people that no general assumptions will be made about them on the basis of any health condition they may have. It should stress that information with regard to health is assessed with regard to competence and conduct standards, and health in itself never forms the basis of decisions. The guidance should also made strong references to the rights that people have, particularly under the DDA, so that people do not feel as disempowered in the process and know that regulatory bodies are legally accountable for the information they request and the decisions they make.
- 6.2 Guidance to professionals would also be useful in empowering them where employers might use their health condition to bully them and threaten them with referral to their regulatory body, numerous cases of which were found by the DRC.<sup>9</sup> If professionals know that as long as they are practising safely and effectively in line with their regulatory body's standards of competence and conduct, their health provides no grounds on which action will be taken against them, this could help remove the fear which enables such bullying to take place. Professionals, and prospective professionals, should be made aware that a health condition or impairment limiting the extent of their practice has no direct bearing on their fitness to practise; rather of relevance is that the person acts appropriately in their individual circumstances by managing their practice to meet their professional obligations to practise safely. Fitness to practise is only in question if a professional fails to do this and places the safety of patients or colleagues at risk as a result. Last year concerns and misapprehensions regarding this difference emerged to GMC as a significant issue during its series of events for students on fitness to practise. Engagement with registrants and prospective registrants over this issue has potential to reassure people with impairments or health conditions that they are not at risk of losing their career if they are open about their condition and enhance their confidence in participating fully in public life.

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<sup>9</sup> See Disability Rights Commission (2007) *Maintaining Standards: Promoting Equality – Professional regulation within nursing teaching and social work and disabled people's access to these professions*, p173-4.

6.3 Guidance to education and training institutions is important because they make decisions with regard to the relevant regulatory body's policies. As responsibility for interpreting regulatory bodies' policies rests solely with individual institutions they may apply different criteria in practice – the greater the range of interpretations open to institutions, the greater the likelihood of such differences occurring. Roberts et al (2005) found that in the medical profession the consequence of this was that 'students with the same disability may be admitted to one medical school whilst being denied entry to another'<sup>10</sup> (this study was before the GMC launched its range of guidance documents). Where institutions are making decisions on students' fitness to practise and making judgements using regulatory bodies' standards, formal structures in institutions and guidance from regulatory bodies would increase the transparency of decision-making and could help to ensure that students do not receive unfair discriminatory or differential treatment. The DRC noted in *Maintaining Standards* that:

...in relation to nursing the DRC did not find, during its investigation, any evidence of complaints of disability discrimination against the NMC in the use of its powers to remove people from the register (or to refuse re-registration). However we came across cases and complaints where the "good health and good character" requirements were used as justification for discrimination against disabled people being refused entry onto higher education courses.<sup>11</sup>

6.4 Although a regulatory body might not itself be discriminating against disabled people, education and training institutions look to the regulatory bodies' policies in making their own assessments.<sup>12</sup> If other parties are using a regulatory body's policies as a basis for discriminatory decisions, it should seek to take action within their powers to prevent this by bringing maximum clarity to how their requirements should be interpreted. Institutions have their own legal obligations to make reasonable adjustments under the DDA and should have established procedures for so doing. However, as with admissions decisions there is significant potential for different institutions to make different decisions on whether making certain adjustments means the student may no longer be achieving a competence standard the regulatory body requires as an outcome of students. In both these cases, there is a role for regulatory bodies to work with institutions to ensure fair and consistent decisions are made and students not discriminated against or otherwise unjustly disadvantaged. This might help more people get on to and make it through courses and help promote the participation of disabled people in public life, which is something all public authorities must have due regard to under the DDA. There is also an onus on education and training institutions to provide effective counselling to disabled students about their future career options. We have heard of many cases in which institutions can make significant reasonable adjustments which enable students to pass through the course, but the students then face difficulties in finding employment where the types

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<sup>10</sup> Roberts TE, Butler A and Boursicot KAM (2005) *Disabled students, disabled doctors – time for a change? A study of different societal views of disabled people's inclusion to the study and practice of medicine*. The Higher Education Academy Subject Centre for Medicine, Dentistry and Veterinary Medicine: Special Report 4.

<sup>11</sup> See Disability Rights Commission (2007) *Maintaining Standards: Promoting Equality – Professional regulation within nursing teaching and social work and disabled people's access to these professions*, p130.

<sup>12</sup> See Wray J, Gibson H and Aspland J (2007) *Research into decisions relating to 'fitness' in training, qualifying and working within Teaching, Nursing and Social Work*. This was research funded by the DRC as part of its investigation and is available at <http://www.maintainingstandards.org> (accessed 22 May).

of adjustments that were reasonable in the context of a university may not be in the context of smaller employers with fewer resources.

- 6.5 Some of the smaller regulatory bodies have told us the cost of producing guidance would be very high relative to the number of registrants or potential registrants with impairments or health conditions, but that they would welcome discussing any issues with registrants on an individual basis. However, there is a difficulty here in that if professionals are fearful that mentioning an impairment or health condition to their regulatory body may lead to action being taken against them, they may be unwilling to approach the regulatory body for advice in the first place.
- 6.6 This is an area in which collaboration involving a number of regulatory bodies may be useful to share good practice and lower each body's respective costs and facilitate greater involvement from groups with expertise who may otherwise struggle to engage with many different regulatory bodies due to lack of time or resources. There are many similar themes and standards across different professions which could facilitate joint working on guidance. Many individuals in education institutions and occupational health services will serve professionals from a number of different regulatory bodies meaning that shared guidance could ensure greater clarity and more consistent application in practice.
- 6.7 The NMC has recently conducted a major literature review to identify good practice in guidance around making reasonable adjustments in nursing and midwifery, which also explored adjustments in other health professions. It has disseminated the final document widely to interested parties. It provides a basis for regulatory bodies taking forward their own initiatives, as do documents already produced by some of the regulatory bodies<sup>13</sup>. The regulatory bodies have an established joint forum on equality and diversity that provides a vehicle for collaborating and taking forward work on good practice across a range of equality and diversity issues, of which the regulatory bodies have identified ensuring their processes are free from any form of discrimination against disabled people to be a key one.

## **7 Recommendations**

- 7.1 There are a range of provisions in the regulatory bodies' respective legislative frameworks regarding the health of registrants with regard to initial registration and staying on the register. The regulatory bodies are clear that the only judgement they make about an applicant at registration or a registrant during fitness to practise procedures is whether the person would practise safely and effectively in accordance with the competence and conduct standards it sets for the profession. We have seen no evidence that leads us to doubt this.
- 7.2 There is a crucial distinction between formal health requirements and fitness to practise requirements. Regulatory bodies do not need health requirements that sit outside determining whether someone is fit to practise, either at registration or during fitness to practise procedures. Health issues may be material in determining whether a person meets the competence and conduct standards, but should not sit outwith

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<sup>13</sup> See for example the GMC (2008) *Gateways to the Professions – Advising medical schools: encouraging disabled students*, available at [http://www.gmc-uk.org/education/undergraduate/undergraduate\\_policy/gateways\\_guidance/index.asp](http://www.gmc-uk.org/education/undergraduate/undergraduate_policy/gateways_guidance/index.asp) (accessed 22 May 2009) and HPC (2006) *A disabled person's guide to becoming a health professional*, available at <http://www.hpc-uk.org/publications/brochures/> (accessed 22 May 2009)

this as a separate requirement. However, health needs to be one of the grounds on which a regulatory body can find a person's fitness to practise to be impaired. This is because if issues around the person's health are an underlying reason for their practice not being in line with the competence and conduct standards, the health issues are a ground for establishing this and then finding fitness to practise to be impaired – failure to meet standards does not itself ground a finding.

7.3 We have five core recommendations to the Department of Health and the regulatory bodies on the role of regulatory bodies in relation to the health of their registrants and prospective registrants:

- (1) We recommend that the language of health should be overhauled. In the regulatory bodies' respective legislative frameworks, we recommend removing all references to 'good health' as a requirement for registration and that there be a single requirement that an applicant's fitness to practise is not impaired for them to be eligible for registration. The language of 'good health' is archaic and implies that there is some general state of health that is required for registration and implies there are standards for a state of health considered in abstraction; rather than health only being of relevance in relation to practising safely and effectively in line with competence and conduct standards.
- (2) We recommend consideration is given to making changes to the regulatory bodies' respective legislative frameworks to move them to operating with a single fitness to practise committee. This would help to make clear that the issue at hand in proceedings is the safety and effectiveness person's practice and whether they can and do meet their professional obligations set out in their regulatory body's competence and conduct; health is only considered when it is relevant in this context and is not otherwise be grounds for finding impairment in fitness to practise proceedings. It may also be the case that moving to a single committee facilitates better consideration of the relation the different factors involved in a person's failure to meet standards in order to make a comprehensive assessment, as has been found by the GMC.
- (3) We recommend that regulatory bodies examine how best they can ascertain the information they need to determine whether an applicant is capable of meeting their standards. We have heard no convincing argument as to why a full health reference from a medical practitioner is proportionate for initial registration, but a self-declaration proportionate for ongoing registration. There is no evidence that regulatory bodies with a self-declaration at initial entry have more fitness to practise cases which relate to a registrants health during the first couple of years of a professional's practice following registration. However, we have heard of a number of cases in which the information from self-declarations or health references has led regulatory bodies to discuss an applicant's particular circumstances with them, which in turn has led the applicant to seek further advice from suitably qualified professionals or undertake to manage their practice in particular ways so that it is in line with the regulatory body's competence and conduct standards. We believe that it is appropriate for regulatory bodies to seek particular kinds of information on applicants' health for use in assessing an applicant's fitness to

practise, but regulatory bodies should ensure their methods for so doing are proportionate to the information required. They should also ensure that they have clear guidance to those filling in any declaration about the kind of evidence they seek, why it is relevant to assessing an applicant's fitness to practise the profession, and that the assessment is only made in relation to an applicant's practice and is not in any way about their health in general.

- (4) We recommend that regulatory bodies examine how they can best provide information to and engage with registrants, applicants, students and others considering a career in the profession over the role of health in regulatory processes. The aim is to assure people that the only concern of the regulatory body is the person's capability to practise in line with competence and conduct standards, not the state of their health or any impairment they might have, and explain that there are ways they can manage their practice to meet the regulatory body's standards. The purpose of this engagement is to promote the full participation of disabled people in the health professions by removing common fears about regulatory processes, helping them understand better how they can manage their practice to meet standards and seeking to undermine one of the grounds on which disabled professionals are victimised.
- (5) We recommend that regulatory bodies issue further guidance to education and training institutions and occupational health services, which explains their requirements for fitness to practise for those on or entering the register. This is important to end the different interpretations of regulatory bodies' requirements, which has led to discrimination against disabled people and made the profession less accessible to them. It should cover how and why knowledge, skills and behaviours are required for a profession's safe and effective practice. Guidance should also make clear to institutions that students need to have certain competences as course outcomes, but that reasonable adjustments can be made in the methods by which these are reached. It may be worth the regulatory bodies consider the potential of collaboration to help ensure clarity and consistency for education institutions and occupational health services serving different health professions, to improve the cost-efficiency of comprehensive guidance, and to facilitate the greatest involvement from those external parties which have expertise in this area.

## **Annex 1: Legislative requirements of regulatory bodies regarding applicants' health at initial registration**

- The GCC, GDC, GOsC have the requirement a person 'satisfies' the Registrar 'that he is in good health, both physically and mentally' in order to be entitled to be registered. This is laid down in legislation in the Chiropractors Act 1994, the Dentists Act 1984 and the Osteopaths Act 1993 respectively.
- The GMC and RPSGB have the requirement, from the Medical Act 1983 and the Pharmacy and Pharmacy Technicians Order 2007 respectively, that a person's 'fitness to practise is not impaired' for them to be entitled to be registered. Both pieces of legislation specify that 'a person's fitness to practise shall be regarded as "impaired" for the purposes of this [Act/Order] by reason ... of ... adverse physical or mental health'.
- The GOC has the requirement from the Opticians Act 1989 that a person must be a 'fit person to practise as an optometrist or dispensing optician' in order to be entitled to be registered. The GOC defines a fit person as someone whose fitness to practise is not impaired under the terms of the Act, one ground on which this can be found is 'adverse physical or mental health'.
- The HPC and NMC, under the Health Professions Order 2001 and the Nursing and Midwifery Order 2001 respectively, have the power to 'prescribe the requirements to be met as to the evidence of good health ... in order to satisfy the Education and Training Committee that an applicant is capable of safe and effective practice under that part of the register' (HPC) for them to be entitled to be registered. For the NMC the latter part of the extract reads '...in order to satisfy the Registrar that an applicant is capable of safe and effective practice as a nurse or midwife'.
- The PSNI, under the Pharmacy (Northern Ireland) Order 1976 may 'make regulations with respect to ... the conditions as to character, physical and mental health and other matters to be satisfied by persons desirous of being registered as pharmaceutical chemists under this Order'.

## **Annex 2: Disability Equality Impact Assessment**

There is no evidence that the health professional regulatory bodies discriminate against disabled people in the application of their current registration or fitness to practise requirements. We have been informed by all nine regulatory bodies that they always judge a person's application for registration on its own merits without making any assumptions about a person's capability for practise on the basis of any impairment or health condition the person may have. This judgement is based on whether the person would practice in line with the regulatory body's competence and conduct standards, and will take the person's full individual circumstances into account and seeking expertise from suitably qualified professionals. We have seen no evidence that leads us to doubt this.

If regulatory bodies are making assessments in this way, unjustified discrimination against disabled people should not arise (providing the competence and conduct standards do not unnecessarily prescribe particular methods of a competence being achieved which disadvantage disabled people who could reach them in different ways). Therefore any changes to the legislation governing regulatory bodies' registration procedures is unlikely to have any direct impact on unjustified discrimination against disabled people when they are applying for registration.

It is important that these competence and conduct standards that professionals are judged against are expressed in terms of the competences necessary for practising as a member of the profession. Regulatory bodies' competence standards should not be expressed in terms that require the use of a particular method unless competence in that method is itself an essential part of a profession's safe and effective practice. The regulatory bodies have all stressed to us their commitment in seeking to ensure their standards are fair and are under an obligation to do so in order to meet their legal duties under the DDA. When reviewing standards ensuring they are expressed in terms of essential competencies, rather than any inessential methods, is necessary to prevent disabled people being judged against these standards suffering unjustified discrimination. Assessing whether a person is fit to practise, where the effect of their health may be an underlying reason for this being in question, is about whether their practice meets competence and conduct standards. Therefore it will only be free from discrimination if the content of these standards do not put disabled people at an unfair disadvantage in meeting them.

The regulatory bodies have told us that complete removal of powers with regard to health may hinder their ability to refuse registration to a person if health issues are an underlying reason why they believe the person may not be able to practise in line with their competence and conduct standards. Therefore there may be circumstances in which disabled people would be able to register if there were no powers available to regulatory bodies, but would be unable to if the regulatory body is allowed to consider health issues in relation to a person's practice as a reason they were not capable of practising safely and effectively. It is difficult to predict the size of any impact as there are so few cases where regulatory bodies have refused registration on these grounds from which to draw conclusions. If regulatory bodies are making assessments in the way they assure us they are – and we have seen no evidence that leads us to doubt this – there should not be any unjustified discrimination. The only cases that should be able to arise currently are where someone is turned down for registration because the effects of their health in relation to their practice prevent them from practising safely and effectively in line with the regulatory body's competence and conduct standards.

Complete removal of any powers for regulatory bodies to consider applicants' health as part of registration would prevent delays to disabled people being registered that currently occur if regulatory bodies decide they need further information before making a final decision. Whilst regulatory bodies will pay for the costs of assessments from suitably qualified practitioners, there is potential for a financial cost to the applicant if they are unable to start work in their profession because they are not yet on the register.

There is no evidence of different rates of participation in the social care professions by disabled people between Scotland and England, where the GSCC unlike its Scottish counterpart does assess health on application for registration. However, there could be other factors involved that have not been controlled for and make this an inadequate basis on which to draw conclusions about the effect of this assessment on disabled people's participation.

Changing the language around requirements to remove references to 'good health' and similar terms and replacing it with a single fitness to practise requirement may help limit the opportunities for disabled people to be victimised where threats to report their health to the regulatory body is the basis for the victimisation. Making it more clear that regulatory bodies will not take action on the basis of health alone, but only where a person is failing to practise in line with competence and conduct standards, may help limit the disempowerment disabled people feel vis-à-vis regulatory processes. Complete removal of health as a grounds on which fitness to practise can be found to be impaired might have an even greater reassuring impact, although for reasons outlined in the report we do not recommend this option.

Guidance and engagement with professionals to communicate this message and which highlights the rights disabled people have under the DDA and the ways regulatory bodies are legally accountable for their actions would be essential in efforts to empower disabled people in relation to victimisation and fear of negative impacts on them from regulatory processes.<sup>14</sup> This could help to limit one aspect of the workplace discrimination disabled people are exposed to encourage the fuller participation of disabled people in public life without fear of negative consequences.

Guidance to students, potential students and registrants on managing fitness to practise could have positive impacts for disabled people regarding suspicions of regulatory processes, and may help prevent adverse events by helping people feel more at ease about being open about seeking advice and making adjustments to their practice. For example, stressing a health condition or impairment limiting the extent of their practice has no direct relation to their fitness to practise; rather of relevance is that the person acts appropriately in their individual circumstances by taking any necessary advice and managing their practice to meet their professional obligations to practise safely.<sup>15</sup>

Guidance to education and training institutions on regulatory bodies' requirements could prevent the differential interpretation of these on the basis of which disabled people have received discriminatory treatment and been refused entry to some courses.<sup>16</sup> This

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<sup>14</sup> Both these fears are highlighted in Disability Rights Commission (2007) *Maintaining Standards: Promoting Equality – Professional regulation within nursing teaching and social work and disabled people's access to these professions*

<sup>15</sup> Misapprehensions on the difference between these amongst students were highlighted by the GMC as a key issue emerging from its information sessions for students on fitness to practise.

<sup>16</sup> See Roberts TE, Butler A and Boursicot KAM (2005) *Disabled students, disabled doctors – time for a change? A study of different societal views of disabled people's inclusion to the study and practice of medicine*. The Higher Education Academy. Special Report 4. See also Wray J, Gibson H and Aspland J

discrimination based on wrong interpretations of regulatory bodies' requirements has prevented disabled people becoming health professionals and serves as a barrier to disabled people's participation in public life. Engagement between regulatory bodies and education and training institutions could help limit this discrimination and increase the accessibility of the professions to disabled people. Similarly, guidance on how reasonable adjustments can be made without this meaning a student is no longer reaching a defined necessary course outcome could help disabled students progress through courses and become health professionals.

**Advanced Practice: Report to the four UK Health Departments**  
**Unique ID 17/2008**  
**July 2009**

**Executive Summary**

The underlying purpose of this work has been to examine whether 'advanced practice' is a regulatory issue. We believe that much of what is often called 'advanced practice' across many of the health professions does not make additional statutory regulation necessary. Often what is termed advanced practice reflects career development within a profession and is appropriately governed by mechanisms other than additional statutory regulation. The existing provisions of the regulatory framework mean that, whatever the level or context of a professional's practice, they are always accountable to their regulatory body for their practice. All health professionals have duties from the core Code/Standards documents of their respective regulatory body only to practise where they are capable of doing so safely and effectively. The activities professionals are undertaking do not lie beyond the scope of existing regulation.

The core focus of regulatory bodies is professionals' fitness to practise. Where the nature of a profession's practice changes for some professionals to such a significant extent that their scope of practice is fundamentally different from that at initial registration – rather than more subtly evolving over time – regulatory bodies may need to consider whether action is necessary to assure the professional's fitness to practise in the context of a very different nature of practice where risk to the public is evident. Such cases would be where the standards for practising proficiently in these roles are significantly different to those assessed against at initial registration, going far beyond ordinary progression within a given scope of practice, and where the risks to patients from these roles are of a qualitatively different nature from those ordinarily associated with the practice of the profession. However, much of what is often called advanced practice appears to represent career development within a profession over time and not a fundamental break with a profession's practice such that the risks to patient safety are not adequately captured by the existing standards of proficiency and ethical duties – which set a framework in which a professional can develop and extend their practice within a profession's scope of practice.

Primary responsibility for the governance of new roles designed to meet the needs of the service provision environment should rest with employers and commissioners. Employers and commissioners should ensure there are robust organisational governance arrangements surrounding all types of practice that those they employ undertake. This provides the most effective means of controlling for risks to patient safety from an individual professional's practice and provides a proportionate local response. Additional intervention by regulatory bodies would only contribute to public protection were the arrangements in place inadequately controlling the types of practice professionals were undertaking.

## 1 Introduction

1.1 The Council for Healthcare Regulatory Excellence was commissioned by the Department of Health, on behalf of all four UK Health Departments, to provide advice on regulatory bodies' handling of developments in professionals' practice after initial registration. The Departments sought to ascertain:

- How individual regulatory bodies define terms such as 'advanced', 'specialist' and 'expanded' practice and whether the use and application of the different terms create opportunities for professionals to undertake activities beyond the range of practices regulated by their regulatory body.
- How the regulatory bodies use post-registration qualification standards, as well as extended scope of practice to protect the public and what commonalities there are across the regulatory bodies.
- Whether there are any additional risks to the safety of patients and other members of the public from health professionals practising in these roles.
- The role of the regulatory body in identifying and controlling risks arising from advanced practice; in particular, regarding the fitness to practise of professionals in these roles, as distinct from the role of the employer in determining a professional's fitness for employment in a particular role.
- Whether there are wider regulatory implications from professionals taking on these roles, such as register annotations or with regard to distributed models of regulation.

1.2 The statutory main objective of CHRE when exercising our functions is to promote the health, safety and well-being of patients and other members of the public. The safety of patients and other members of the public is the underpinning principle throughout this report. To inform our analysis we have met with and brought together information from regulatory bodies, professional bodies, professional officers, employers, patients and the public, and other sources from across the UK. These include the emerging outputs from the Extending Professional Regulation working group set up following the publication of the UK White Paper *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*.

## 2 Current use of terms across the health professions

2.1 Across the health professions there are significant differences in the ways in which the terms 'advanced practice' and 'specialist practice' are used. The term 'expanded practice' is rarely used for any of the health professions, although the job title 'extended scope practitioner' is sometimes used in allied health professions where a professional is in a job involving the application of additional knowledge or skills not generally associated with their primary practice linked to particular job roles.

2.2 There is general consensus that advanced practice is a level of practice along a continuum in which practitioners develop their professional, knowledge, skills and behaviours to a high level, at which they are capable of safe and effective practice in more complex situations and with greater autonomy, responsibility and clinical accountability. It can take place across different domains of practice – in specialist

fields, generalist practice and at varying degrees of specialisation. As a level of practice, what constitutes an advanced level of practice can only be understood in the context of a particular profession at a particular time. The professional roles and responsibilities that are of an advanced level are relative to the ordinary scopes of practice of members of a profession. As the ordinary scopes of practice are themselves dynamic as professions evolve over time, what constitutes an advanced level of practice in comparison to them is also subject to change.

- 2.3 The use of the term 'advanced practice' is often intertwined with Agenda for Change banding in the NHS. It is clear to us that there are different professionally-led discussions taking place amongst professional groups in different professions regarding how far beyond the ordinary scope, practice should be in order to be considered advanced for the purpose of considering whether a need for any additional regulation exists.
- 2.4 This may pose more of a question for leaders of the professions seeking consistency in policies across different professions than for regulatory bodies. Action by regulatory bodies should not be instigated on the basis of job titles being taken on in the professions they regulate or by calls for professional parity or recognition of status. Actions should be based on a thorough assessment of any risks to patient safety from a profession's practice that are otherwise inadequately controlled for. In making this assessment the key concerns for the regulatory body are the roles and responsibilities being taken on by professionals in practice, in the context of other governance arrangements, not the pressure to react to changes in professionals' job titles.
- 2.5 The use of the term 'specialist practice' also varies across different professions. In some professions 'specialist' job titles are used where a professional is specialising in a particular area of practice and develops and applies their professional knowledge and skills in this area, without necessarily denoting that they are practising at any specific level. In other professions the use of the title specialist is directly related to having gained very high level skills in a particular area of practice which go well beyond those associated with the practice of the profession in general.
- 2.6 As with the use of the term advanced practice, regulatory bodies should be more concerned with the risks to patient safety from roles and responsibilities associated with specialist practice rather than with job titles. However, the differences around nomenclature do raise issues for regulatory bodies in terms of the vocabulary they use to describe any regulatory action they might take. In some professions the term specialist is used to denote both level and focus of practice considered together; in other professions the term specialist is used to denote focus and is often considered separately from level. For example, the General Dental Council has 13 specialist lists in different branches of dentistry which control the use of particular specialist titles to those who have gained very high-level specialist knowledge and skills in one focussed area of practice. In other professions, such as nursing, there is established use of the term specialist to describe roles at all levels in which professionals have chosen to specialise in one contextual area of practice which do not relate to the level at which they practice.
- 2.7 We commissioned a piece of qualitative research into the interpretation of the terms 'specialist' and 'advanced' by patients, carers and other members of the public. The term specialist was interpreted as a focus on one area of practice, and was

associated with concentrated training in this area and a better quality of care. The status of being a specialist inspired trust and confidence, because it was viewed as implying the professional had invested time in specialising in one focussed area in which they were expected to have more skill than other professionals. The term advanced was perceived as more vague. It was assumed that it meant more qualified or experienced in some way, but people were unsure in what way and what being 'advanced' actually said about the professional. However, some people found it inspired confidence where they had personal experience of advanced staff. The term was also judged to relate significantly to career stage and progression, rather than being directly tied to progression in clinical skills in the way the term specialist was believed to do.

### **3 Are professionals practising outwith the range of practices regulated by their regulatory body?**

- 3.1 Professionals are accountable to their regulatory body for all of their professional activities, whatever the level and context of their practice, the title they use or the type of activities they undertake. In this sense, they are not practising beyond the scope of regulation, although their regulatory body may not have any specific regulations requiring a professional demonstrate to it their competence in a particular type of practice before undertaking it. The respective core Code/Standards documents of all the regulatory bodies are unambiguous in their requirements to the effect that registrants have a duty only to practise where they are competent to do so and not engage in any activities that may put patients or other members of the public at unwarranted risk of harm. Failure to abide by these requirements may call into question a professional's fitness to practise and lead to action being taken against their registration. Similarly, if asked by their employer to deliver care which they feel could be unsafe, registrants are required to consider their actions carefully and raise concerns – regulatory bodies require that the best interests and safety of those in their care should always be the guiding principle for a professional's action.
- 3.2 In terms of protecting the public through fitness to practise proceedings, regulatory bodies which currently have annotations or entries on specialist registers lack the power to take specific action to remove these separately from a professional's ordinary registration. However, with the exception of the Pharmaceutical Society of Northern Ireland which currently lacks the necessary statutory powers, panels can impose formal conditions to limit the way professionals are allowed to practise. This means that the regulatory bodies are able to limit a professional's practice in any specialty or limit their activities so as to limit the level at which they can practise. Suspension or erasure from the main register will automatically remove any other entries a professional may have.
- 3.3 Many professionals will develop the level of their professional knowledge, skills and behaviours beyond that which they were assessed against for the purpose of initial entry to the register. This is part of professional development and career progression which does not, in itself, necessitate regulatory action. Robust and well-enforced continuing professional development requirements that are targeted so to relate to a professional's current scope of practice provides a further mechanism for regulatory control. An exception to this is the PSNI, which has continuing professional development requirements for registrants, but currently lacks statutory powers regarding the enforcement of these.

## 4 Current approaches of the regulatory bodies to post-registration qualifications

4.1 The current approaches of the regulatory bodies to professionals' post-registration development can be brought under three broad categories:

(1) *Controlling the use of particular specialist titles*

The General Dental Council's specialist lists include those who have gained very high-level specialist knowledge and skills in one focussed area of practice. This requires a Certificate of Completion of Specialist Training issued by the GDC following successful completion of a Royal College specialist training programme and passing of the exit examination. No functions are restricted solely to dentists on these lists. The Nursing and Midwifery Council uses part of its register to denote those who have met its standards to be called a Specialist Community Public Health Nurse (SCPHN). Although again there is no protection of function, the NMC determined that the nature of SCPHN practice was different from other nursing practice and so needed to be considered separately for regulatory purposes.

(2) *Controlling entry to particular types of practice*

The General Optical Council, the Health Professions Council, the Nursing and Midwifery Council, the Pharmaceutical Society of Northern Ireland and the Royal Pharmaceutical Society of Great Britain all annotate their registers to denote practitioners who have the qualifications entitling them to prescribe medicines. It is a legislative requirement that entry to this type of practice is limited to those with the appropriate qualification on the register. The GOC uses this method to protect entry to contact lens fitting by dispensing opticians. This method is facilitated where there is a discrete extension of practice requiring competences going beyond those required for initial registration that are tied to a particular qualification and a perceived risk.

(3) *Providing information*

The NMC also annotates its register with Specialist Practitioner Qualifications (SPQs) which serve to denote additional learning within one context of a particular field of practice. Whilst the qualification is acknowledged on the register, it does not necessarily signify that a practitioner has a higher level of competence than other nurses in the field as a result of that qualification; rather that they have completed that particular course of preparation, and there are other means by which a nurse can develop their competencies within their field of practice. There is no restriction of practice associated with SPQs or prevention of other nurses using specialist job titles in their area of practice.

4.2 The General Medical Council's specialist and GP registers have a slightly different basis to those detailed above and are tied to the entitlement for appointment to (specialist) or working in (GP) the NHS, rather than being entitlements across the profession as a whole.

4.3 In all the above approaches to post-registration qualifications the respective regulatory bodies have mechanisms in place regarding the quality assurance of the

qualification. This is crucial to the integrity of the register as an authoritative source of the information it provides on a professional, for the public, employers and others, which is an essential part of effective regulation.

## **5 Are there additional risks to the safety of patients and the public?**

5.1 The main sources of risks to the safety of patients and other members of the public from professionals taking on new or higher level practices are the same as the sources of risks from other types of practice. These are that professionals may take on roles and responsibilities which they lack the capability to perform safely and effectively or if professionals/employers do not ensure there are appropriate safeguards in place in their practice.

5.2 The source of the risk may be the same, but because the roles and responsibilities being taken on are different – in terms of activities being undertaken and clinical accountability for them – the nature of the risk to patients and the public may vary accordingly. The crucial challenge in protecting the public is ensuring that there are adequate governance arrangements to mitigate the risks to patients associated with individual professionals practising outside their scope of competence or practising without appropriate safeguards in place.

## **6 Roles of regulatory bodies and employer in identifying and controlling for risks to patient safety**

6.1 Ensuring that there is adequate governance around professionals' practice is a task which requires an active focus on the actual types of roles and responsibilities that professionals are taking on in practice, rather than reacting to job titles or additional qualifications obtained. Professional regulatory bodies, systems regulatory bodies, employers and professionals themselves all have crucial roles in ensuring patient safety through governing practice of the health professions.

6.2 It is the core role of the regulatory body to assure a professional's fitness to practise the profession, through setting and enforcing standards of proficiency and conduct. It is the core role of the employer to ensure that a professional has the specific set of competencies – within the range of those associated with the profession – to be suitable for a particular job. Once employed in a particular job, the employer must ensure that the employee is assigned tasks appropriate to their skills, manage the complexity of their workload and provide appropriate support for them to keep their skills up-to-date. Systems regulation assists through monitoring compliance with the necessary standards of employers in this regard. Overlapping with all this, is the responsibility of the registrant to practise in line with the requirements of the Code/Standards of their regulatory body by ensuring they do not practice where they cannot do so safely and effectively or where a lack of appropriate safeguards may put their patients at unwarranted risk of harm and by keeping their skills up-to-date relevant to their scope of practice.

6.3 The General Medical Council has modelled four tiers on which actions regulating professionals take place, which is useful in considering the governance of professional practice:

- (1) Self-regulation: in which a professional acts in accordance with their sense of professionalism and their wider ethical duties.

- (2) Team regulation: in which a team provides an environment in which members mutually oversee the performance of their fellow professionals and are in a position to identify problems that may be arising.
  - (3) Employment: in which employers – who have their own legal responsibilities for the safety of the care they provide – have controls to identify the initial and ongoing fitness for purpose of employees, and have clinical governance arrangements to oversee employees' performance.
  - (4) Statutory regulation: which can fill gaps in governance arrangements that the other tiers are not in a position to, by setting core standards of ethics and proficiency at a national level and using fitness to practise procedures where these are not met to make sure the public are appropriately protected.
- 6.4 Statutory regulation being furthest away from an individual professional's practice is a far more generic instrument than the other tiers, but by virtue of being at such a level has the capacity to protect patient safety by taking action others are not in a position to take. With regard to any higher level roles and responsibilities professionals may be taking on, employers, teams and professionals themselves are best placed to identify and control for risks emerging from an individual professional's practice. Regulatory bodies are only best placed to act if there is a need for clear national standards for proficient practice to be identified and enforced in order to uphold the safety of patients and to ensure registrants are fit to practise.
- 6.5 On initial employment, employers are in a position to use job descriptions that are tailored to a specific post to ensure that the professional they appoint has the necessary knowledge, skills and other attributes to be fit for the particular purpose. Once employed, clinical governance and administrative controls provide a key mechanism to ensure members of a particular workforce are employed in appropriate roles and their performance properly managed. This is the best way to identify and control risks that might emerge from a professional practising where they lack the necessary competence. It is crucial for patient safety that robust clinical governance and administrative systems are in place and employers should ensure professionals are effectively appraised and receive appropriate support to maintain and develop their professional competence.
- 6.6 Where a professional's primary relationship is with a commissioning organisation, rather than an employer, it is important that the commissioner takes responsibility for ensuring those it contracts to deliver a service are appropriately qualified to do so and will have adequate systems in place to uphold the safety of patients. This may prove particularly challenging in the case of locum practitioners and agencies as proxy employers, but it is an important component in upholding patient safety. Self-employed professionals are under the general requirements of their regulatory body and must only practice where they are capable of doing so safely and effectively, and at all times the best interests and safety of those in their care must guide their actions. Similarly, self-employed professionals have the responsibility to ensure that they practise with appropriate safeguards in place so as not to put their patients at unwarranted risk of harm and must keep their skills up-to-date relative to their scope of practice.

- 6.7 Regulatory bodies, whilst their policies should facilitate professionals developing their practice, should not be providing the materials by which professionals advance their careers. Professional bodies, however, have a different role to play, including a role in governance arrangements. Many professional bodies run schemes to support the professional development of their members which can serve to signal to employers the levels or skills a member has attained. Professional bodies have an important role in issuing additional guidance to their members to assist them with ethical and practice issues which might arise, which is benchmarked against the relevant regulatory body's Code/Standards. This becomes particularly important if professionals are applying their knowledge and skills in new settings and contexts quite different from those they have been used to previously.
- 6.8 Statutory regulation is not as close to a professional as their employer and so is not best placed to identify and control for the specific risks arising from an individual professional's practice. Statutory regulation is better placed to control for generic risks relating to a profession's practice or general types of a profession's practice being undertaken. However, robust and well-enforced requirements for continuing professional development provide a contribution regulatory bodies can make to the governance arrangements over professionals' practice.
- 6.9 As part of the pending introduction of revalidation across the health professions it is expected that regulatory bodies will risk profile both types of registrants' practice and types of practice settings. This will enable them to determine the types of practice being taken on by their registrants that are of highest risk to patients and the types of setting where other institutional controls are weakest. Following this, regulatory bodies should ultimately be in a position to target the breadth and depth of evidence they require for revalidation, and their assessment methods, according to the risks which emerge from different types of practice and setting. Such an approach would enhance the governance of professionals where the existing arrangements are weakest or where practitioners are engaged in the highest risk activities.
- 6.10 In terms of controlling for the general types of risk to patient safety, regulatory bodies can place general requirements on professionals to practise only where competent, to always prioritise patient safety and to keep skills up-to-date relative to their scope of practice. Regulatory bodies can additionally control for risks posed by an individual professional by reacting after an event through their fitness to practise procedures, and can set threshold standards for those entitled to practice in particular ways or use specific titles. There is currently no systematic evidence, from fitness to practise cases or other sources, regarding whether professionals are taking on new roles and responsibilities where they are not competent to do so and thereby putting the safety of patients at risk. Before a regulatory body takes further intervention it should establish that its current regulatory controls, and other existing mechanisms, are not adequately protecting the safety of patients and the public, and determine how best it can work to overcome any such deficiencies within the wider framework of arrangements that govern professionals' practice.
- 6.11 As professionals develop their careers and practice from initial registration it is unfeasible for regulatory bodies to require specific credentials for every area of practice a professional might be working in. Aside from the effect this could have of rigidifying practice and making it less amenable to innovation and developments that could benefit patients, it is not possible for a regulatory body to have sufficient knowledge about a professional for it to be the grounds on which their suitability for a

particular role is determined. Regulatory bodies cannot systematically assume that, unless proven otherwise, their registrants will break their Code/Standards and practice where not competent to do so safely. Where this does occur regulatory bodies can already take action through fitness to practise proceedings. Where registrants knowingly practice beyond their competence or employers are willing to employ them without the person being appropriately qualified, it is unclear whether further regulation protecting a title or function would have the effect of making them unwilling to do so. Additionally, the low levels of public recognition of 'advanced' job title means that alternative titles could be used by those in such roles. There could be an effect where a professional falsely believes they are competent to practice in a particular way. These cases should be picked up by employers, commissioners or colleagues closer to the professional's practice or as part of screening for initial employment or during a contracting process, where a professional has such relationships. There is no systematic evidence from fitness to practise proceedings on the frequency of cases being brought to the regulatory body where a professional has unwittingly practised where they lack the necessary competence to indicate whether this is a significant problem.

## **7 Wider regulatory implications of professionals in advanced practice roles**

- 7.1 Regulatory bodies should only use their power to statutorily restrict a title or function to those with approved credentials where the safety of patients and the public is not adequately upheld by other systems of governance. The analysis of where it may be appropriate for the regulatory body to intervene will need to focus on: the risks to the safety of patients and the public from the roles and responsibilities being taken on by a member of that particular profession; the adequacy with which other mechanisms control for these; and, how these risks would be mitigated effectively by intervening.
- 7.2 We are unconvinced that much of what is often called 'advanced practice' in many professions represents such a significant shift in the nature of practice that it is inadequately controlled for through current arrangements. In many cases the use of the term appears to represent progression in experience and skills that could be expected to take place as professionals develop their practice over the course of their careers or reflects changes in career structures within a profession. It more often represents career progression and developments within a profession over time, than a major shift in the nature of a profession's practice. Risks to patient safety that may not be adequately captured in existing regulation are more likely to occur if the roles and responsibilities a professional is taking on represent a significant shift in the nature of a profession's practice. This is not just a question of the roles and responsibilities that are being taken on, but also the fact that they are being taken on by a member of a particular profession developing from an initial point. This is why the significance of any new risks to patient safety that might arise is likely to be tied to the qualitative shift in the nature of the scopes of practice within a group of regulated professionals.
- 7.3 As the main control available to regulatory bodies is setting and enforcing national standards of proficiency for the practice, they would need to identify clear risks to patient safety and associated standards of proficiency that go far beyond those of the ordinary scope of a profession's practice. This would require there to be credentials clearly necessary to demonstrate competence and which could form a coherent basis for annotating a register to denote the new standards of proficient practice governing the professional. The significance of the shift in the qualitative nature of both the

practice and the risks to patients, in the context of other controls in place, is important in making such judgements. It is only where a practice is so significantly outwith the ordinary scope of profession's practice, such that the level of public protection from its associated standards become inadequate taking into account other controls, that further standards – clearly different from the ordinary ones – would be a coherent basis for controlling professional practice. Where a professional is taking on more activities or responsibilities of a similar nature or using appropriate learning opportunities to make more subtle developments to their practice, there are unlikely to be such qualitatively different risks to patients making the existing regulatory structure inadequate. In the context of the dental professions, the GDC has sought to address this issue by defining professional group's scope of practice to define where the point is where roles and responsibilities are of such a different nature that the risks to patient safety make necessary different types of registration based on distinct standards of proficiency and qualifications.

- 7.4 Regulatory bodies must be forward-looking and have good links with employers and professional bodies to identify where any challenges to public protection may lie and ensuring that any regulatory action is targeted and proportionate so that developments in practice are not unduly stifled. Any regulatory intervention should be where there are clear gaps in the existing mechanisms governing the risks to patient safety which only the regulatory body is appropriately positioned to close. If a regulatory body does intervene it must ensure that it has a satisfactory mechanism for assuring the quality of the qualifications required to demonstrate competence, in order that the integrity of the register is not compromised. If additional standards of proficiency are deemed necessary for the purpose of public protection they should be tied to some form of protection of title or function. Annotations without protection of title or function, and so which serve not to protect the public directly but to denote professional status, add little to the ordinary human resources checks by employers to ensure applicants have the credentials necessary for a particular job or to existing regulatory requirements that professionals only practise where they are competent to do so.
- 7.5 Regulatory bodies cannot provide all the information from which an applicant's fitness for a specific job can be determined. Regulatory bodies would never have sufficient assured information on all the qualifications, courses, continuing professional development and other learning opportunities a registrant had undertaken and the experience they have, which is the basis for making such a decision. Consequently, employers will always have to do their own checks of an applicant's experience and qualifications specific to a given job. Any additional regulation must not be seen by employers or professionals as defining fitness for employment in a specific job. Regulatory bodies do not have the competence to make this determination; it is one an employer must make with the potential employee. It is important that any additional steps taken by regulatory bodies, such as annotating registers, are not seen by employers as providing all the necessary information on a professional's practice. If it were, and employers abdicated their responsibility in determining an applicant's fitness for a particular job, either wholly or in part, statutory regulation would do more to jeopardise than uphold patient safety.
- 7.6 It is important to acknowledge that there would be major difficulties to regulating a level of practice effectively, compared with discrete extensions to practice such as prescribing, even if the practices are of a significantly different nature from those in which members of the profession are ordinarily engaged. Where the competences

required for extensions of practice are associated with particular qualifications, such as with prescribing, and the risks merit regulatory action, it is simpler for the regulatory body to act by linking protection of title or function directly to the qualification and annotating a register entry. It is far more difficult for this to be done effectively where professionals are not making discrete extensions of their practice into new areas, but changing the overall nature of their practice and the responsibilities it encompasses. Across a profession, professionals are likely to have very diverse roles and responsibilities that would make it extremely difficult to draw together a set of standards of proficiency that could form a coherent basis for an annotation across the profession.

- 7.7 Any enabling standards that regulatory bodies were to introduce would need to be generic enough so not to serve to confuse information on the register or divide up practice into discrete areas preventing competent professionals making full use of their abilities at the borders of the different areas. Such standards would also have to be designed so they are relevant to the actual roles and responsibilities being taken on, otherwise the purpose of regulatory action would be fundamentally undermined. However, any bar set too low in order to provide generic standards that would apply in many different situations may not serve to protect patients or the public, but simply unnecessarily stifle those practising at its margins. It would also be a significant challenge to regulatory bodies to ensure that their definitions remain up-to-date as the scope of practice in a profession is dynamic and progresses, often significantly, over time. It would be important that standards set at one moment in time do not curb professionals practising where competent to do so as the profession evolves.
- 7.8 Protection of title may be of limited use in protecting the public because terms such as 'advanced' have little purchase amongst members of the public. Consequently, similar alternative terms could easily be used in job titles by professionals and employers, without the public having any real understanding of the differences between those with the protected title and those using an alternative, but similar sounding, title. Protection of function also has significant potential drawbacks, as outlined above, in terms of fettering professional practice and of being relevant to the diverse roles and responsibilities characterising practice across a profession. In this context, the credentialing of professional practice through robust organisational governance provides a mechanism for targeting the risks to patient safety most specifically to the actual types of practice professionals undertaking without some of the wider effects that may come from a regulatory body intervening to protect title or function.

## 8 Conclusions

- 8.1 Risks to patient safety come from professionals taking on roles and responsibilities which they lack the competence to carry out safely and effectively or where they practise with inadequate safeguards and thereby put patients at unwarranted risk of harm. Therefore **regulatory bodies should be concerned with the risks to patients and other members of the public from the roles and responsibilities that professionals are taking on in the context of other established governance arrangements involving existing regulation, employers' procedures and any contributions from other parties.** The concern should not be with professionals developing the level or extensions of their practice by its own virtue.

- 8.2 Whatever the nature of practice professionals are to undertake, employers have the most important responsibility for ensuring patient safety. Employers must always assess the fitness for purpose of employees and job applicants with regard to the specific competences required for the given job. Employers – not regulatory bodies – are in a position to determine this by considering the specific roles and responsibilities the professional would be taking on. The importance of employers having appropriate policies in place cannot be stressed highly enough. Regulatory body intervention would only contribute to public protection where employers' arrangements fail to ensure that only those suitable for types of roles practise in them. **Robust organisational governance arrangements provide the most effective means of controlling for risks to patient safety from an individual professional's practice.** Significant measures in this area include moves strengthening the governance arrangements of professionals close to the delivery of care and ensuring that there are robust procedures for assessing the need for different types of role and the necessary credentials for professionals to undertake them. Systems regulation also has an important role in monitoring service providers' compliance with the duties placed upon them in relation to their workforces.
- 8.3 Where a professional's primary relationship is with a commissioning organisation, **it is crucial commissioners ensure that they take appropriate steps in their contracting procedures to be satisfied those carrying out the specified activities are competent to do so and that necessary safeguards will not be lacking.** Self-employed professionals are under duties not to practise in ways they lack the competence to do safely and to ensure that in the service they provide the necessary steps will be taken to ensure patients are not put at unwarranted risk of harm.
- 8.4 Whatever context a professional is practising in, they are accountable to their regulatory body for their practice under the current regulatory framework. **As a registrant, a professional must abide by duties laid out in their regulatory body's core Code/Standards documents which make clear that they must only practise where they are capable of doing so safely and effectively,** and should raise concerns and always act in the best interest of their patients if they feel they are being asked to work without appropriate safeguards. Self-employed professionals must ensure that they do not work without any safeguards necessary to protect the safety of their patients. As registrants all professionals are also under a duty to keep their skills up-to-date relevant to their scope of practice. Regulatory bodies are empowered to act through their fitness to practise proceedings if professionals fail to comply with these requirements, whatever roles and responsibilities characterise their practice.
- 8.5 Where professionals are taking on roles and responsibilities that are associated with another profession of a different regulatory body, it is important that professionals from both groups are regulated to appropriately similar standards. It may be appropriate for a piece of work to be undertaken considering how consistency can best be ensured. This work could examine the current approaches of different regulatory bodies to determine what, if any, issues arise; and explore ways in which the regulatory framework could overcome these, looking at the contribution ideas such as the distributed model of regulation could make.
- 8.6 **Revalidation provides an opportunity for regulatory bodies to enhance governance of professional practice.** By risk profiling the types of practice of their

registrants and targeting checks and assessment requirements to the risks to patient safety from professionals' type of practice and types of settings where other controls are weakest, revalidation would enhance governance of these practices without additional statutory regulation of practice or title.

- 8.7 The power of regulatory bodies to set national standards for practice is a generic, but powerful instrument in upholding public protection. With regard to roles and responsibilities professionals may be taking on, it is only where a practice is so significantly outwith the ordinary scope of profession's practice, such that the level of public protection from its associated standards become inadequate taking into account other controls, that further standards – clearly different from the ordinary ones – would be a coherent basis for controlling professional practice. **Where a professional is taking on more activities or responsibilities of a similar nature or using appropriate learning opportunities to make more subtle developments to their practice over time, there are unlikely to be such qualitatively different risks to patients making the existing regulatory structure inadequate.**
- 8.8 We believe that much of what is often called 'advanced practice' across many of the health professions does not represent a shift in a profession's practice that renders the existing regulatory framework inadequate. **If an area of practice within a profession develops which poses different types of risk to patients and requires new standards of proficiency to be performed safely, which are clearly distinct from the range of those ordinarily associated with the profession, regulatory bodies need to ensure their processes capture this.** Only the relevant regulatory body, in consultation with professionals, employers and other interested parties, has the competence to determine whether action is needed regarding these specific practitioners, but action should not be taken which serves to denote their career progress or professional status. The primary responsibility must be taken by employers to ensure they have robust organisational governance of all types of practice their employees undertake. **Action by regulatory bodies should be based on evidence of gaps in public protection that the types of practice expose the public to, which require additional action at the level of statutory regulation to be mitigated effectively.**

## **Data misuse and the health professional regulators**

(ID 21/2008)

July 2009

### **Executive summary**

1. CHRE have been asked by the Secretary of State to provide advice about the current codes of conduct for the regulated healthcare professions around data misuse.
2. Patients' personal data is at the heart of healthcare. Patients consent to share their personal medical data with professionals. In turn this drives diagnosis and treatment, plays a key role in aiding the delivery of care, allows a record of an individual's medical history to be built up, and supports patient safety. The sensitive nature of personal information places obligations and duties on health professionals to ensure that when data are recorded, stored, shared and accessed this is done in accordance with legal and ethical standards and requirements.
3. The confidentiality and security of patients' data is a core value for all health professionals and this is reflected in all regulators' core codes and standards. Some regulators also issue supplementary guidance to help registrants manage patients' information in particular situations they may encounter in the course of their practice. Standards and codes of conduct are generally reviewed and updated on a five yearly basis. However, immediate updates are made if changes are made to wider legislation.
4. Other legal duties govern health professionals' use of patients' data. These include obligations such as those laid down by the Data Protection Act 1998, the Human Rights Act 1998, and the common law of confidentiality. This is as well as guidance provided by professional bodies and employing organisations such as the NHS. These sources are cross-referenced in regulators' standards and codes.
5. The advent of new forms of data storage and management present different risks around data misuse. The regulators shared a view that different methods of storing or handling personal data in healthcare settings did not require different approaches to standards or fitness to practise.
6. It is difficult to identify trends in complaints to regulators about this issue. The number of cases involving data misuse is often small and some regulators do not record this level of detail of subject of complaints for further analysis. Furthermore, charges relating to the misuse of patients' data may be considered alongside other unrelated charges. Each series of charges is therefore unique and the circumstances and evidence equally individual. Even when misconduct may be found, the sanction that may be applied can be influenced by a registrant demonstrating insight and awareness of their actions.
7. However, we have to accept and anticipate changing views and expectations among the public about the confidentiality and security of their data, both in healthcare and more widely. When regulators provide guidance to registrants it is essential that changes in the public's expectations around these issues are noted and reflected, as well as new legal requirements or challenges that emerge from innovative use of

information technology. The principles embedded in regulators' codes and standards about confidentiality and security are neutral in terms of practice settings. However, their interpretation by health professionals has to be contemporary and respond to new risks and expectations, as well as established threats. Additional guidance from regulators is welcome to support professionals' practice, especially when these circumstances change. Assessments of complaints about fitness to practise should reflect the circumstances of the alleged misconduct, and we believe this should include consideration of the public's current expectations of professionals' handling of their personal data.

## Introduction

1. The Council for Healthcare Regulatory Excellence (CHRE) is an independent body accountable to Parliament. Our primary purpose is to promote the health, safety and well-being of patients and other members of the public. We scrutinise and oversee the health professional regulatory bodies<sup>1</sup>, work with them to identify and promote good practice in regulation, carry out research, develop policy and give advice.
2. Under section 26A of the National Health Service and Health Profession Reform Act 2002, we have been asked by the Secretary of State to provide advice about the current codes of conduct for the regulated healthcare professions around data misuse. In particular we have been asked to:

*‘work with Professional Regulation bodies to provide clarification about personal misconduct in relation to data misuses and transparency in relation to how these issues are reported in particular, by providing advice on the following:*

- *The extent to which they reflect the information governance requirements that now prevail within the NHS;*
- *Suggestions to whether these codes of conduct might need reviewing so that they more adequately (if required) reflect the information governance requirements in relation to electronic information relating to patients and staff; and any role the Department might play in such reviews; and*
- *If it would be feasible or desirable to incorporate into definitions of misconduct the responsibilities of all parties in relation to electronic person identifiable data.’*

3. This report provides our response to this request. In preparing our response we have considered the standards registrants are expected to demonstrate and the regulators’ management of fitness to practise issues that can arise when registrants fail to meet these standards. First we describe the current approaches taken in regulators’ codes of conduct around data misuse. We then consider these approaches in relation to other information governance requirements that prevail in healthcare. Finally we consider misconduct around data handling, how it is managed by the regulators, and discuss whether changes are necessary. Appendix 1 outlines current standards and guidance from regulators relating to data misuse.
4. In considering the Secretary of State’s questions, we asked the health professional regulatory bodies the following questions.
  - In your view, do different methods of storing and handling personal data in healthcare settings demand different approaches to standards and fitness to practise?
  - Are you aware of any trends in your fitness to practise cases involving data security issues?
  - What guidance and training do you provide to fitness to practise (FTP) panellists on the issues of data misuse and data security?
  - How often do you update your guidance to a) registrants and b) FTP panellists in this area?

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<sup>1</sup> The regulatory bodies we oversee are: General Chiropractic Council, General Dental Council, General Medical Council, General Optical Council, General Osteopathic Council, Health Professions Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland, Royal Pharmaceutical Society of Great Britain

## Personal data in healthcare

5. Patients' personal data is at the heart of healthcare. Patients consent to share their personal medical data with professionals. In turn this drives diagnosis and treatment, plays a key role in aiding the delivery of care, allows a record of an individual's medical history to be built up, and supports patient safety. The sensitive nature of personal information places obligations and duties on health professionals to ensure that when data are recorded, stored, shared and accessed this is done in accordance with legal and ethical standards and requirements.
6. The confidentiality of patients' data is a core value for all health professionals. This is reflected in the prominence given to this issue in the Chief Executives' statement on common values for health professionals: 'Keep information about patients and clients confidential'.<sup>2</sup>
7. Through their core standards and codes of conduct and practice, each regulator describes the expectations of registrants when they handle personal data. The topics covered are recording information, maintaining confidentiality and security, and how and when information may be released, with and without consent. These standards apply wherever a health professional is practising. Some regulators also issue supplementary guidance to help registrants manage patients' information in line with current legal and ethical requirements. The following is a list of relevant current standards and guidance documents for registrants provided by the health professional regulators:

General Chiropractic Council (GCC)	<i>Code of practice and standard of proficiency</i> (2005; revised version in 2010)
General Dental Council (GDC)	<i>Standards for dental professionals</i> (2005) <i>Principles of patient confidentiality</i> (2007)
General Medical Council (GMC)	<i>Good medical practice</i> (2006) <i>Confidentiality: protecting and providing information</i> (2004; revised version due late 2009)
General Optical Council (GOC)	<i>Code of conduct for individual registrants</i> (2005) <i>Code of conduct for business registrants</i> (2005)
General Osteopathic Council (GOsC)	<i>Code of practice</i> (2004)
Health Professions Council (HPC)	<i>Standards of conduct, performance and ethics</i> (2008) <i>Guidance on confidentiality</i> (2008)
Nursing and Midwifery Council (NMC)	<i>The Code: Standards of conduct, performance and ethics for nurses and midwives</i> (2008) <i>Confidentiality advice sheet</i> (2009) <i>Record keeping: guidance for nurses and midwives</i> (2009)
Pharmaceutical Society of Northern Ireland (PSNI)	<i>Code of ethics</i> (2009) <i>Professional standards and guidance for patient confidentiality</i> (2009)

<sup>2</sup> Common Values Statement by the Chief Executives Group of the Health Care Regulators on professional values. 2006. Available at: [http://www.chre.org.uk/img/pics/library/Common\\_values\\_statement.pdf](http://www.chre.org.uk/img/pics/library/Common_values_statement.pdf) [accessed 3 July 2009]

Royal Pharmaceutical Society of Great Britain (RPSGB)	<i>Code of Ethics (2007) Professional standards and guidance for patient confidentiality (2007)</i>
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8. Standards and codes of conduct are generally reviewed and updated on a five yearly basis. However, when regulators' guidance in this area reflects and incorporates wider legal duties, more immediate updates are made when legislation changes.
9. We recognise that health professionals will also handle personal data as they fulfil other roles such as managers, employers, or business registrants. Some regulators have provided guidance to their registrants about the management of non-clinical, personal data about staff or clients that is not specifically about clinical or medical needs. For example:

*'You must, as appropriate to your particular management responsibilities, ensure that: ...procedures respect and protect confidential information about patients and employees in accordance with current legislation, relevant codes of practice and professional guidelines.'* (RPSGB) <sup>3</sup>

*'... chiropractors should make sure that if they employ a bookkeeper or an accountant then financial information on payments can be looked at separately from clinical records. Secondly, if a chiropractor wishes to pursue a patient for overdue payments, then only the minimum information for the situation in hand should be supplied to outside bodies (eg for legal proceedings or for debt collection). Thirdly, for chiropractors thinking of selling their business there is a need to gain the patients' specific consent to the transfer of their records as otherwise their confidentiality could be compromised.'* (GCC) <sup>4</sup>

*'If you have wider responsibilities for consent and confidentiality issues within your organisation you should keep up to date with and observe the legal and ethical guidelines on handling confidential information, with particular reference to the Data Protection and Freedom of Information Acts.'* (GMC) <sup>5</sup>

10. While not directly relevant to the commission's interest in the codes of conduct issued by regulators' to registrants, it is important to acknowledge that sensitive personal data from patients can form part of evidence in regulators' fitness to practise cases and it is essential that it is handled appropriately. The guidance and training provided to panellists focuses on their duties as panellists to ensure data are protected while panellists discharge their duties. The NMC told us that 'Confidentiality is a key theme in FTP panellist training' and the PSNI ensured specialists training by an external consultant 'which includes elements related to data misuse and security'. The RPSGB provided panellists with data protection guidance in November 2008.
11. In preparing this advice we have focused on patients' clinical records and misuses that can arise from this in the course of providing healthcare. We have not considered potential secondary uses of patients' data, for example in research, although misuse

<sup>3</sup> RPSGB, 2007. Professional Standards for Pharmacists and Pharmacy Technicians in Positions of Authority. Available at: <http://www.rpsgb.org/pdfs/coepsposauth.pdf> [accessed 3 July 2009]

<sup>4</sup> GCC, 2005. Code of practice and standard of proficiency. Available at: [http://www.gcc-uk.org/files/link\\_file/COPSOP\\_Dec05\\_WEB\(with\\_glossary\)07Jan09.pdf](http://www.gcc-uk.org/files/link_file/COPSOP_Dec05_WEB(with_glossary)07Jan09.pdf) [accessed 3 July 2009]

<sup>5</sup> GMC, 2006. Management for Doctors. Available at: [http://www.gmc-uk.org/guidance/current/library/management\\_for\\_doctors.asp](http://www.gmc-uk.org/guidance/current/library/management_for_doctors.asp) [accessed 3 July 2009]

and misconduct may occur in these situations. Our emphasis on use of data in delivery of healthcare does not deny the important issues around management of non-clinical, personal data such as payroll, references and financial arrangements with clients and business partners. This focus allows us to concentrate on the particular specifics of managing the security and confidentiality of personal medical information that is distinctive to the working circumstances of health professionals.

### **Other standards, codes and guidance**

12. Alongside the standards set by regulators, other legal duties govern health professionals' use of patients' data. These include obligations such as those laid down by the Data Protection Act 1998, the Human Rights Act 1998, and the common law of confidentiality. This is as well as guidance provided by professional bodies and employing organisations such as the NHS. These sources are cross-referenced in regulators' standards and codes. For example, the RPSGB state:

*'This document does not detail specific legal requirements, but you must ensure you comply with relevant legislative requirements set out in the Data Protection Act and associated legislation, as well complying with common law principles and with any NHS or employment policies that may apply to your work.'*<sup>6</sup>

In England, further details of the full range of requirements covering this area can be found in the Department of Health publication *NHS information governance – guidance on legal and professional obligations*.<sup>7</sup>

13. Professional organisations also provide guidance in various aspects of these matters. These are explicitly referenced in the GOC codes of conduct, as individual and business registrants are expected to refer to guidance published by professional bodies such as the College of Optometrists and the Association of British Dispensing Opticians.<sup>8</sup>
14. Regulators of health and social care services place obligations on service providers around the management of records. For example, the Care Quality Commission, the service regulator in England, is working with the following draft regulations for registration:

#### *Regulation 18 – Records*

*18.—(1) The registered person must ensure that service users are protected against the risks of unsafe or inappropriate care and treatment arising from a lack of proper information about them by means of the maintenance of—*

*(a) an accurate record in respect of each service user which shall include appropriate information and documents in relation to the care and treatment provided to each service user; and*

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<sup>6</sup> RPSGB, 2007. Professional Standards and Guidance for Patient Confidentiality. Available at: <http://www.rpsgb.org/pdfs/coepsgpatconf.pdf> [accessed 3 July 2009]

<sup>7</sup> Department of Health, 2007. NHS information governance – guidance on legal and professional obligations. Available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_079616](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079616) [accessed 26 June 2009]

<sup>8</sup> GOC Code of conduct for individual registrants. [http://www.optical.org/goc/filemanager/root/site\\_assets/codes\\_of\\_conduct/code\\_registrants.pdf](http://www.optical.org/goc/filemanager/root/site_assets/codes_of_conduct/code_registrants.pdf) [accessed 30 June 2009]

*(b) such other records as are appropriate in relation to the carrying on of the regulated activity.*

*(2) The registered person must ensure that the records referred to in paragraph (1) (which may be in paper or electronic form) are—*

*(a) kept securely and can be located promptly when required;*

*(b) retained for an appropriate period of time; and*

*(c) subject to sub-paragraph (b), securely destroyed when it is appropriate to do so.*

*(3) In deciding what records are appropriate for the purposes of paragraph (1)(b), and for how long such records should be retained for the purposes of paragraph (2)(b), the registered person must have regard to guidance issued by the Commission.<sup>9</sup>*

15. Across the UK, NHS organisations are expected to follow national codes of practice as part of wider information governance frameworks. For example in England, the NHS Information Governance Standard provides a framework under four headings – management and accountability, process, people, assessment and audit. Within ‘Process’, reference is made to guidance in the form of three existing NHS Codes of practice – Confidentiality, Information Governance, and Records Management – and the NHS Care Record Guarantee.<sup>10</sup> The administrations in Northern Ireland, Scotland and Wales also have codes of practice around confidentiality as part of national information governance policies.<sup>11</sup> These are similar in form and content to the codes and standards outlined by the health professional regulators.
16. Together these codes, standards, policies and governance frameworks provide a matrix of assurance for the management of patients’ information. They share principles, policies and good practice around records management, information security, and confidentiality in healthcare settings. Given the considerable overlapping interests in this area there could be a threat of guidance overload, so joint ventures are welcome. The GMC described work they have undertaken with the Information Commissioner and the DH in England on the use of IT equipment and access to patient data.<sup>12</sup>

### **Taking action against incidents of data misuse**

17. Misuse of patients’ information can take many forms. For example, discussing confidential information in earshot of third parties, deletion of records, not locking filing cabinets, or the unsecure disposal of records. Media reports of breaches of security and confidentiality include the following:

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<sup>9</sup> Care Quality Commission, 2009. Consultation on new registration standards. Available at: <http://www.cqc.org.uk/getinvolved/consultations/consultationonnewregistrationstandards.cfm> [accessed 29 June 2009]

<sup>10</sup> Draft IG standard published in IGAP closure document Appendix 2 <http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/igap/igapclosure.pdf> [accessed 29 June 2009]

<sup>11</sup> Department of Health, Social Services and Public Safety, Northern Ireland, 2009. Code of practice on protecting the confidentiality of service user information Available at: <http://www.dhsspsni.gov.uk/confidentiality-code-of-practice0109.pdf> [accessed 3 July 2009]; NHS Scotland Code of Practice on Protecting Patient Confidentiality, 2004; NHS Wales, 2005. Confidentiality Code of Practice for Health and Social Care in Wales. Available at: <http://wales.gov.uk/docrepos/40382/4038212/403821/4038211/4038211/CodeofPractice?lang=en> [accessed 3 July 2009]

<sup>12</sup> GMC, DH, ICO. Joint guidance on use of it equipment and access to patient data. Available at: [http://www.gmc-uk.org/guidance/news\\_consultation/Joint\\_guidance\\_on\\_use\\_of\\_IT\\_equipment.pdf](http://www.gmc-uk.org/guidance/news_consultation/Joint_guidance_on_use_of_IT_equipment.pdf) [accessed 30 June 2009]

- Theft of records from a maternity hospital, containing mothers' names, date of caesarean section, time of birth<sup>13</sup>
- Theft of a laptop carrying unencrypted data of around 5000 patients and loss of a memory stick containing unencrypted data about patients and staff<sup>14</sup>
- A survey of a London teaching hospital found that among 105 doctors, 92 carried memory sticks, 79 held confidential patient data on memory sticks, only five were password protected. The researchers found that the memory sticks were, 'usually attached to keys or ID badges carried inside and outside hospitals. They could be easily mislaid.'<sup>15</sup>

18. The advent of new forms of data storage and management may present different risks around data misuse. The regulators shared a view that different methods of storing or handling personal data in healthcare settings did not require different approaches to standards or fitness to practise:

*'... fitness to practise procedures are based on the principles set out in the guidelines. The individual circumstances of a case may need to be considered, but standards should remain consistent.'* (GMC)

*'The existing guidelines for record keeping for nurses and midwives assert that the principles of good record keeping apply to all types of records.'* (NMC)

*'The minimum standards of data protection should remain the same regardless of how the data is stored or handled.'* (RPSGB)

*'The obligations of protecting data are the same regardless of data format, and different methods are not necessary.'* (GDC)

A similar sentiment is reflected in the guidance on confidentiality for health and social care staff working in Northern Ireland:

*'Service users' right to privacy and the staff's duty to confidentiality apply regardless of the form in which information is held or communicated, for example electronic, paper, photographic or biological.'*<sup>16</sup>

19. Fitness to practise proceedings arise from complaints raised with regulators when conduct has fallen below the standards expected and sufficient evidence being available for the regulator to take a case to a hearing before an independent panel. When this does occur, charges relating to the misuse of patients' data may be considered alongside others. Each series of charges is therefore unique and the circumstances and evidence equally individual. Even when misconduct may be found, the sanction that may be applied can be influenced by a registrant demonstrating insight and awareness of their actions.

<sup>13</sup> 2009. Baby records theft sparks inquiry. *BBC News*, 11 May 2009. Available at: [http://news.bbc.co.uk/1/hi/scotland/north\\_east/8043566.stm](http://news.bbc.co.uk/1/hi/scotland/north_east/8043566.stm) [accessed 29 June 2009]

<sup>14</sup> West, D, 2009. Trusts breached patient data protection rules. *Health Service Journal*, 29 Jan 09 <http://www.hsj.co.uk/trusts-breached-patient-data-protection-rules/1973988.article> [accessed 29 June 2009]

<sup>15</sup> Putnis, S, Bircher A, 2008. Data protection in the NHS - a ticking time bomb? *Health Service Journal* 4 September 2008. Available at: <http://www.hsj.co.uk/data-protection-in-the-nhs-a-ticking-time-bomb/1832759.article> [accessed 29 June 2009]

<sup>16</sup> Department of Health, Social Services and Public Safety, Northern Ireland, 2009. Code of practice on protecting the confidentiality of service user information Available at: <http://www.dhsspsni.gov.uk/confidentiality-code-of-practice0109.pdf> [accessed 3 July 2009];

20. It is difficult to identify trends in complaints to regulators about this issue. The number of cases involving data misuse is often small and some regulators do not record this level of detail of subject of complaints for further analysis.
- The HPC reported a small number of cases each year
  - The NMC told us they are not aware of any trends with cases relating to data security issues, though some cases may have data misuse encompassed as part of the wider charges in a case
  - The RPSGB reported that ‘from general experience the most visible trend involving data security issues related to the management of patient medication records in community pharmacy’
  - The PSNI reported a case where patient’s information was misused by a professional to obtain controlled drugs by deception
  - The GCC described cases where registrants were reported to be discussing patient information in inappropriate circumstances, or not locking filing cabinets that contained sensitive information.
21. From our database of fitness to practise determinations, there have been few cases involving data misuse (approximately 20 out of a total of around 3000 since 2006). Drawing robust conclusions from this small number is not possible as the circumstances of each instance were different.

## Discussion

22. Data misuse is clearly a live issue for the healthcare sector and concerns have been expressed by some about how well personal data is protected. For example, in April 2009 the Information Commissioner called on the NHS to handle sensitive patient information with the right level of security:

*‘It is a matter of significant concern to us that in the last six months it has been necessary to take regulatory action against 14 NHS organisations for data breaches. In these latest cases staff members have accessed patient records without authorisation and on occasions, have failed to adhere to policies to protect such information in transit. There is little point in encrypting a portable media device and then attaching the password to it.’<sup>17</sup>*

23. New and different challenges to data handling arise from innovations in communication technology through access-based controls to electronic records, greater use of email, and the opportunity to store large amounts of data in relatively small devices. Furthermore, the cultural and behavioural aspects of the management of patients’ information should not be overlooked. The recent review of data sharing undertaken by Richard Thomas and Mark Walport recommended ‘a significant improvement in the personal and organisational culture of those who collect, manage and share personal data’.<sup>18</sup>

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<sup>17</sup> Information Commissioner, 2009. ICO issues stark reminder to NHS bodies on patient records, 30 April 2009. Available at:

[http://www.ico.gov.uk/upload/documents/pressreleases/2009/nhs\\_trusts\\_undertakings\\_280409.pdf](http://www.ico.gov.uk/upload/documents/pressreleases/2009/nhs_trusts_undertakings_280409.pdf) [accessed 3 July 2009]

<sup>18</sup> Thomas R, Walport M. 2009 Data Sharing Review Report. Available at: <http://www.justice.gov.uk/reviews/datasharing-intro.htm> [accessed 3 July 2009]

24. We have to remain alert to other challenges to the confidentiality and security of patients' information that may arise from beyond the healthcare sector. Emphasis in public policy for more widespread proactive sharing of personal data between different public services may lead to confusion among health professionals and others in healthcare about their obligations. It may also undermine the public's trust that their medical data is being held securely and confidentially for the purpose it was collected, and for which they gave their consent.
25. The GMC told us about research commissioned to examine public and professional attitudes to the privacy of healthcare data as part of their recent review of guidance on confidentiality. This report found that:
- The public appears to be becoming more comfortable with computer technology, which may reduce fears over privacy, but with increasing expectations over security and choice about access to their records
  - Doctors seem poorly briefed on privacy issues
  - Not much research has been done with other professions despite their use of records in patient care
  - Professionals' concerns are centred on legal or regulatory uncertainties, gauging risks of internal and external threats to privacy, and assuring patients of their confidentiality.
- This review reflected on the changing context of healthcare records. Whereas historically their role was in ensuring treatment, continuity of care and providing some legal defence, the authors remarked that changing legislation and the introduction of new technologies marked a change that enabled and demanded greater sharing of information and wider thoughts about ownership of records.<sup>19</sup>
26. We should not expect every instance of professional practice to be covered in detail by the regulators' standards. This would be disproportionate. Regulators' standards and codes of conduct emphasise the responsibilities of professionals that should be adhered to in the course of practice. Employers' and organisations' policies echo these principles in guidance on their implementation in the context of practice.
27. However, we have to accept and anticipate changing views and expectations among the public about the confidentiality and security of their data, both in healthcare and more widely. The public profile of threats to personal data demands that regulators act promptly and take this issue seriously.
28. When regulators provide guidance to registrants it is essential that changes in the public's expectations around these issues are noted and reflected, as well as new legal requirements or challenges that emerge from innovative use of information technology. We were interested to learn that the GMC plan further work with doctors to promote their revised guidance on confidentiality. They will be exploring the possibility of developing practical tools such as screensavers for doctors to download that highlight the importance of locking computers and not sharing passwords.
29. In considering whether further action around codes of conduct is necessary, it would be helpful to be able to assess the current threats and risks to the security of personal medical data. These may arise from technical, systemic or behavioural issues.

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<sup>19</sup> GMC, 2007. Public and Professional attitudes to privacy of healthcare data: a survey of the literature. Available at: [http://www.gmc-uk.org/guidance/news\\_consultation/GMC\\_Privacy\\_Attitudes\\_Final\\_Report\\_with\\_Addendum.pdf](http://www.gmc-uk.org/guidance/news_consultation/GMC_Privacy_Attitudes_Final_Report_with_Addendum.pdf) [accessed 29 June 2009]

However, it is hard to draw conclusions based on regulators' experience; the number of cases considered by FTP panels is relatively small and cases represent a particular set of circumstances. Furthermore, regulators can only take action when in receipt of a complaint and data misuse issues may be dealt with locally by employers.

30. The commission asks whether the definition of misconduct should be changed to incorporate the responsibilities of different parties with respect to electronic data. We use 'misconduct' as a general reference to indicate impaired fitness to practise as it is not a term consistently defined in all regulatory bodies' legislation. That being so, and given the principle-based, context-neutral nature of regulators' standards, redefining the term 'misconduct' would not, in our view, be an appropriate or necessary course of action.
31. None the less, electronic data can introduce new threats in practice which may be involved in complaints about fitness to practise. Thinking about individual cases, a challenge may arise in ensuring that changing social expectations and awareness of emerging threats from technical innovation are appreciated by FTP panellists. Through our reviews of the outcomes of FTP cases CHRE offers feedback and learning points to regulators to help promote excellence in regulation and we have expressed concern when issues around personal data appear to have been taken lightly.

## **Conclusion**

32. Data misuse in healthcare is a challenge, not least because of changing individual and social expectations around personal data generally and in healthcare. New methods of storing and accessing data present novel threats both in terms of the scale of potential losses and in the opportunity for misuse. We would expect regulators and other agencies to take the rapid developments in this area seriously and respond in a timely way. At the same time, the risks to patient confidentiality posed by the design of healthcare settings, permitting confidential discussions to be overheard, for example on hospital wards, in reception areas and in lifts, cannot be overlooked.
33. The principles embedded in regulators' codes and standards about confidentiality and security of patients' information are timeless and neutral in terms of practice settings. The standards themselves are satisfactory in their current form. However, their application by health professionals and regulators is contemporary and has to respond to changes in the wider environment to ensure data is not misused. We welcome additional guidance from regulators to support professionals' practice. This should be available in a timely fashion to enable registrants to meet patients' needs and expectations, especially when circumstances change. Where misconduct may arise, assessments of complaints about fitness to practise should reflect the wider circumstances of the allegations, and we believe this should include consideration of the public's current expectations of professionals' handling of their personal data and a clear appreciation of the new threats that emerge from developments in technology.
34. The health professional regulators are one part of the framework guiding professionals' use of patients' data. The regulators' role and responsibility in influencing the conduct of health professionals is complemented by the work of other agencies, notably employers, commissioners, other regulators and governments. Ultimately the prevention of data misuse is a joint effort across these organisations.

The actions that regulators can take to prevent data misuse or to apply sanctions in cases of misconduct are one element of this endeavour.

## Appendix 1: Data misuse

### Relevant extracts from regulators' core standards and codes of conduct

#### General Chiropractic Council - Code of Practice and Standard of Proficiency

A2. Chiropractors must keep information about patients confidential.<sup>20</sup>

Specifically chiropractors:

A2.1. must take the appropriate precautions when communicating confidential or sensitive information electronically, in writing or orally. Such precautions should take account of: who might overhear or oversee the information; who might access the information; the information that might be communicated by the practitioner's actions.

A2.2. must not disclose information about a patient, including the identity of the patient, either during or after the lifetime of the patient without the consent of the patient or the patient's legal representative.<sup>21</sup>

A2.3. must store information in, and retrieve it from, recording systems consistent with the requirements of legislation relating to information and its use. Specifically chiropractors should ensure that when they use electronic recording systems, the records are safe from access outside the practice, the security and integrity of data is maintained and the system is safely backed-up at regular intervals.

A2.4. must maintain patient confidentiality during the handling, storage and disposal of records.

A2.5. must obtain consent from patients before responding to any requests for information about them. The chiropractor must also explain to the patient the chiropractor's own responsibilities in the process.

A2.6. must take all reasonable steps to ensure that others who work for or with them also maintain confidentiality.

A2.7. may make exceptions to the general rule of confidentiality and disclose information to a third party if:

- the chiropractor believes it to be in the patient's best interest to disclose information to another health professional or relevant agency
- the chiropractor believes that disclosure to someone other than another health professional is essential for the sake of the patient's health<sup>22</sup>
- disclosure is required by statute
- the chiropractor is directed to disclose the information by any official having a legal power to order disclosure, or
- having sought appropriate advice, the chiropractor is advised that disclosure should be made in the public interest.<sup>23</sup>

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<sup>20</sup> Legislation relating to information and its use includes: the Data Protection Act 1998. "This Act provides a framework that governs the processing of information that identifies living individuals – personal data. Processing includes holding, obtaining, recording, using and disclosing of information and the Act applies to all forms of media, including paper and images. It applies to confidential patient information but is far wider in its scope eg it also covers personnel records". Department of Health, July 2003, *Confidentiality: NHS Code of Practice*, DH, London. This document contains other information likely to be of interest to chiropractors.

<sup>21</sup> This requirement has specific implications in a number of ways for chiropractors. Firstly, chiropractors should make sure that if they employ a bookkeeper or an accountant then financial information on payments can be looked at separately from clinical records. Secondly, if a chiropractor wishes to pursue a patient for overdue payments, then only the minimum information for the situation in hand should be supplied to outside bodies (eg for legal proceedings or for debt collection). Thirdly, for chiropractors thinking of selling their business there is a need to gain the patients'

<sup>22</sup> See section **E2.7** for further guidance on child protection.

<sup>23</sup> Public interest means those "exceptional circumstances that justify overruling the right of an individual to confidentiality in order to serve a broader societal interest. Decisions about the public interest are complex and must take account of both the potential harm that disclosure may cause and the interest of society in the continued provision of confidential health services." (Department of Health, 1993, *Confidentiality: NHS Code of Practice*, DH, London).

In each case where disclosure is made by a chiropractor in accordance with an exception to the general rules of confidentiality a chiropractor must:

- as far as reasonably practicable, inform the patient before the disclosure takes place<sup>24</sup>
- as far as reasonably practicable, make clear to the patient the extent of the information to be disclosed, the reason for the disclosure and the likely consequence of the disclosure, where it is appropriate to do this
- record in writing the reasons for the disclosure and to whom it was made
- record in writing the information disclosed and the justification for such disclosure
- where the patient is not informed before the disclosure takes place, record in writing the reasons why it was not reasonably practicable to do so
- disclose only such information as is relevant ensuring that the person to whom the disclosure is made undertakes to hold the information on the same terms as those to which the chiropractor is subject.

### **General Dental Council - *Standards for Dental Professionals***

#### **3. Protect the confidentiality of patients' information**

3.1. Treat information about patients as confidential and only use it for the purposes for which it is given.

3.2. Prevent information from being accidentally revealed and prevent unauthorised access by keeping information secure at all times.

3.3. In exceptional circumstances, it may be justified to make confidential patient information known without consent if it is in the public interest or the patient's interest. You should get appropriate advice before revealing information on this basis. Follow our guidance 'Principles of patient confidentiality'.

### **General Medical Council - *Good Medical Practice***

37. Patients have a right to expect that information about them will be held in confidence by their doctors. You must treat information about patients as confidential, including after a patient has died. If you are considering disclosing confidential information without a patient's consent, you must follow the guidance in with *Confidentiality: Protecting and providing information*.

#### *Confidentiality: protecting and providing information*

1. Patients have a right to expect that information about them will be held in confidence by their doctors. Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care. If you are asked to provide information about patients you must:

- inform patients about the disclosure, or check that they have already received information about it;
- anonymise data where unidentifiable data will serve the purpose;

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<sup>24</sup> "This will not be possible in certain circumstances, eg where the likelihood of a violent response is significant or where informing a potential suspect in a criminal investigation might allow them to evade custody, destroy evidence or disrupt an investigation." (Department of Health, 1993, *Confidentiality: NHS Code of Practice*, DH, London).

- be satisfied that patients know about disclosures necessary to provide their care, or for local clinical audit of that care, that they can object to these disclosures but have not done so;
- seek patients' express consent to disclosure of information, where identifiable data is needed for any purpose other than the provision of care or for clinical audit – save in the exceptional circumstances described in this booklet;
- keep disclosures to the minimum necessary; and
- keep up to date with and observe the requirements of statute and common law, including data protection legislation.

...

4. When you are responsible for personal information about patients you must make sure that it is effectively protected against improper disclosure at all times.

5. Many improper disclosures are unintentional. You should not discuss patients where you can be overheard or leave patients' records, either on paper or on screen, where they can be seen by other patients, unauthorised health care staff or the public. You should take all reasonable steps to ensure that your consultations with patients are private.

### **General Optical Council - Code of conduct for individual registrants**

A registered optometrist or dispensing optician must:

3. respect patients' dignity and privacy;

...

6. maintain adequate patients' records;

...

12. respect and protect confidential information;

### **General Osteopathic Council - Code of Practice**

As an osteopath, you must:

Maintain, respect and protect patient information, by

- taking full and accurate case histories
- maintaining full and accurate clinical records
- keeping patient information confidential
- keeping all patient records secure.

...

104. Patients have a right to expect that you will observe the rules of confidentiality. Unless you do so, patients will be reluctant to give you the information you need to provide good care.

105. In normal circumstances, you should keep confidential your patients' identities and other personal information you learn and record, along with the opinions you form in the course of your professional work. This duty extends to your staff and survives the death of any patient.

106. Similarly, you should not release or discuss the personal information, medical details or care of a patient with their partner or family members unless you have the patient's consent to do so.

107. You must ensure that the confidential information for which you are responsible is at all times secure against loss, theft and improper disclosure.

108. You may release confidential information if a patient, or someone appointed on their behalf, gives you specific permission to disclose it. It may not always be necessary to disclose all the information you hold on a patient. When seeking a patient's consent to disclose information about them, you must make sure they understand the extent of what you will be disclosing, the reasons for doing so and the likely consequences.

109. You must explain to patients the circumstances in which information about them is likely to be disclosed to others in your workplace and involved in their healthcare. Allow them to withhold permission for this if they wish. You must advise healthcare workers to whom you disclose information that they must also respect the patient's confidentiality.

...

120. Any patient records that you keep are subject to the provisions of the Data Protection Act 1998. If you retain personal information on individuals, you must register with the Information Commissioner.

### **Health Professions Council - *The standards of conduct, performance and ethics***

2. You must respect the confidentiality of service users.

You must treat information about service users as confidential and use it only for the purposes they have provided it for. You must not knowingly release any personal or confidential information to anyone who is not entitled to it, and you should check that people who ask for information are entitled to it.

You must only use information about a service user:

- to continue to care for that person; or
- for purposes where that person has given you specific permission to use the information.

You must also keep to the conditions of any relevant data protection laws and always follow best practice for handling confidential information. Best practice is likely to change over time, and you must stay up to date.

...

10. You must keep accurate records.

Making and keeping records is an essential part of care and you must keep records for everyone you treat or who asks for your advice or services. You must complete all records promptly. If you are using paper-based records, they must be clearly written and easy to read, and you should write, sign and date all entries.

You have a duty to make sure, as far as possible, that records completed by students under your supervision are clearly written, accurate and appropriate.

Whenever you review records, you should update them and include a record of any arrangements you have made for the continuing care of the service user.

You must protect information in records from being lost, damaged, accessed by someone without appropriate authority, or tampered with. If you update a record, you must not delete information that was previously there, or make that information difficult to read. Instead, you must mark it in some way (for example, by drawing a line through the old information).

**Nursing and Midwifery Council - *The Code: Standards of conduct, performance and ethics for nurses and midwives***

Respect people's confidentiality

- You must respect people's right to confidentiality
- You must ensure people are informed about how and why information is shared by those who will be providing their care
- You must disclose information if you believe someone may be at risk of harm, in line with the law of the country in which you are practicing

Keep clear and accurate records

- You must keep clear and accurate records of the discussions you have, the assessments you make, the treatment and medicines you give and how effective these have been
- You must complete records as soon as possible after an event has occurred
- You must not tamper with original records in any way
- You must ensure any entries you make in someone's paper records are clearly and legibly signed, dated and timed
- You must ensure any entries you make in someone's electronic records are clearly attributable to you
- You must ensure all records are kept confidentially and securely

**Pharmaceutical Society of Northern Ireland - *Code of Ethics***

Principle 2:

Respect and protect confidential information

Obligations:

2.1 Respect the confidentiality of information, professional or otherwise, acquired in the course of professional practice and only use it for the purposes for which it is given and in compliance with current legislation.

2.2 Maintain systems which ensure security of information and prevent unauthorised access to it.

2.3 Ensure that all who have access to patient/client information know and respect its confidential nature.

2.4 Ensure that confidential information is not disclosed without consent, except where legally permitted or in exceptional circumstances.

**Royal Pharmaceutical Society of Great Britain – *Code of Ethics***

The Code of Ethics sets out seven principles of ethical practice that you must follow as a pharmacist or pharmacy technician. It is your responsibility to apply the principles to your daily work, using your professional judgement in light of the principles.

3.5 Respect and protect the dignity and privacy of others. Take all reasonable steps to prevent accidental disclosure or unauthorised access to confidential information and ensure that you do not disclose confidential information without consent, apart from where permitted to do so by the law or in exceptional circumstances.

3.6 Obtain consent for the professional services, treatment or care you provide and the patient information you use.

3.7 Use information obtained in the course of professional practice only for the purposes for which it was given or where otherwise lawful.

6.6 Comply with legal requirements, mandatory professional standards and accepted best practice guidance.

**Shared Functions  
(Unique ID: 01/2009)  
July 2009**

**Executive Summary**

CHRE explored shared functions with the nine health professional regulatory bodies of the United Kingdom. We note the original commission did not define the functions to be shared, so we have, in this response, taken 'functions' to mean any part of a regulatory body's activities which we divide into business functions, policy functions and regulatory functions.

We posed five questions to the regulators to understand their appetite and vision for sharing functions. All nine regulatory bodies responded. We found within those responses that there were three streams of functions with the potential for sharing: business and support, policy, and regulatory activities. However, it is important to note that there was no complete agreement on exactly what shared functions means, and what constitutes a function.

We have found that with such broadly expressed questions it is not possible to provide a conclusive answer. With a defined set of terms, it would be possible to engage in a more decisive study of shared functions. CHRE does not include business functions within its oversight of the health professional regulators. CHRE is concerned with the outcomes of regulation and considers the way in which regulators manage themselves is for them to decide. There is of course a general public interest in the efficiency of regulators and sharing functions may or may not contribute this.

**1. Introduction**

1.1 The Council for Healthcare Regulatory Excellence is an independent body accountable to Parliament. Our primary purpose is to promote the health, safety and well-being of patients and other members of the public. We scrutinise and oversee the health professions regulators, working with them in identifying and promoting good practice in regulation, carrying out research, developing policy and giving advice.

1.2 On 20 March 2009, we received a commission from the Department of Health to explore the topic of shared functions with the nine health professional regulatory bodies in the United Kingdom.

1.3 According to the commission received by CHRE:

‘The Secretary of State would welcome advice about any steps that DH could take, including legislative change, to enable regulatory bodies to share functions in the interest of improved efficiency and cost to the registrant, whilst maintaining public protection.’

1.4 We were asked to explore two areas. Firstly, we were asked to explore the desire of the regulators for ‘the Department to legislate to enable the sharing of functions,’ and whether ‘there any additional risks to the safety of members of the public from this.’ Second, ‘the role of the regulatory body in identifying and controlling risks arising from use of shared functions.’

1.5 In response to the request of the Secretary of State, we posed five questions to the nine health professional regulatory bodies:

- 1) Is there any interest on your part to pursue shared functions? If so, how might shared functions impact on the rest of your business?
- 2) Which specific functions would you be interested in sharing with other regulatory bodies? Why these specific functions?
- 3) What potential difficulties do you anticipate could prove obstructive to sharing functions amongst regulatory bodies?
- 4) Would sharing functions provide a cost effective avenue for regulatory practice?
- 5) What are the potential threats to public protection through sharing functions amongst regulators? How could the risks be managed?

1.6 The GCC responded on the assumption that shared functions were those deemed as ‘back room’ in business terms and did not respond further as these matters are outside of the regulatory remit. This is a view with which CHRE sympathises.

1.7 We did not provide any definition or guidance to the regulators further than assuming shared functions included any or all functions of the regulators’ activities, in the hope that this would lead to an open discussion.

## **2. Business and Support Functions**

2.1 CHRE is concerned with the outcomes of regulation and considers the way in which regulators manage themselves is for them to decide. However, in the responses we received, many regulators discussed business functions. We therefore report on the regulators views about the sharing of business and support functions.

2.2 Business functions are understood as those functions which are part of the day-to-day affairs of the regulatory bodies, but not necessarily part of the regulatory process, or ‘core’ functions. Included in business functions are activities such as procurement, IT, finance, accounting, facilities management, support staff, and other general administration facets. They could also be called support functions. CHRE has no opinion on the business functions of the regulators where there is no direct effect on the regulatory outcomes.

2.3 Amongst some the regulators there is a sense that sharing business functions would prove cost effective. However, there are notable differences of opinion on the matter. The GCC interprets shared functions to mean the business functions; viewing these matters as a matter of operational management, they did not pursue a discussion on the possibility of sharing them. The GOsC noted that sharing business functions was a possibility previously explored to a limited extent, and did not present notable cost savings.

- Human Resources

2.4 One area that could be shared is human resources. Here the regulators could move in a centralized system for recruitment, training, performance evaluation, payroll, employee relations, and development, among other things. This could streamline the individual process across regulators providing one framework for employees and potential employees to access.

2.5 Some regulators suggested that support staff, such as those working in IT, could be shared amongst the regulators. These are areas where there could be both cost benefits and improved service delivery, presumably this would require shared buildings in some cases.

- Financial Management

2.6 Regulators suggested that sharing the financial management processes could be beneficial. Matters such as accounting, could be managed by one regulator for all regulators, by which there might be cost savings.

2.7 The difficulties faced in sharing the business functions come in normalising the processes across the regulators. The process of harmonising support functions would pose the risk of a loss of information and requires a period of adaptation. The GDC stated that financial accountability must be present in any sharing of the business functions, and any arrangement would require appropriate management and governance.

2.8 Some regulators expressed the belief that sharing their business functions could prove cost effective. The NMC suggested that procurement, finance, and facilities management offered the most scope for sharing. As they put it, 'The volume-based services offered by the regulatory bodies – those transactional, processing, and administrative services – and services delivered to most employees, or to external customers could well be maximised by aligning the economies of scale.'

- Location and Facilities

2.9 Some regulators discussed the possibility of sharing locations and facilities. There are two areas in which this could be done: facility management and security, and shared use of existing facilities.

2.10 Regulators identified that facility management and security were areas that could potentially be shared. The types of activities involved in facility management would include front-desk reception, cleaning services, and related work. The GDC, NMC, and GMC noted the possibility of sharing facilities management.

2.11 Security is large in scope in terms of service delivery, as it would require regulators to share permanent location to have the same security personnel. However, security could include shared contracts with security service providers and shared security policy.

2.12 One area proposed was the shared use of existing facilities, particularly those outside of London and in the devolved countries. PSNI suggested in its response that it, 'sees potential in other regulatory bodies making use of our Northern Ireland based Fitness to Practise structures and premises as a means of both reducing their costs when undertaking activity in Northern Ireland, as well as providing a means for raising their profile regionally.' Additionally, RPSGB suggested that the GPhC could potentially share premises with other regulators in Scotland and Wales.

2.13 It is important to note, that within business and support functions, there is not a consistent definition, amongst the regulators, as to the composition of these functions. In CHRE's view the risk and benefits of sharing functions is a matter for regulators to decide. Our concern would be if sharing these functions impacted upon regulation.

### **3. Sharing Good Practice**

3.1 It was a common theme that the sharing of good practice could be improved amongst the regulators. The GOsC asserted that within the existing structure of regulation there is already a considerable amount sharing of know-how. CHRE is always actively supporting the sharing of good practice across the regulators. We are currently in the process of establishing the CHRE International Regulatory Observatory, which will look at good practice, among other aspects of regulation.

3.2 In terms of information sharing, there is the possibility of creating 'common portals' among the regulators. This would be a place where information from all the regulatory bodies could be made available to the public in a streamlined fashion. The format remains to be defined, but a joint website with relevant information leading to the correct channels is one option. An example of this, given by the GOC, is the possibility of normalizing similar data releases, for example annual reports, across the regulators.

3.3 It has been suggested, by the GOC for example, that joint campaigning and raising awareness, could be an area where regulators collaborate. The terms, target audiences and other details would have to be discussed and developed for these kinds of activities.

3.4 The regulators discussed the possibility of sharing models of service delivery. As opposed to sharing a function, the regulators could simply perform their functions identically. Essentially what is being discussed are 'templates of expertise,' which could be shared. Models that work within one regulator could be applied to the same function by another.

3.5 Innovation by one regulator could influence change in other regulatory bodies. In practice, the regulators would be sharing functions in an indirect manner, by performing functions in similar, if not identical, ways.

3.6 CHRE is committed to promoting good practice across the regulators, and undertakes work to deliver this. We promote good practice through our performance reviews, in sharing learning points arising from fitness to practise cases we review, and through hosting good practice seminars with the regulators. We also promote good practice across the regulators through our policy work, for example, we have developed proposals for greater consistency in sanctions availability and terminology.<sup>1</sup>

#### **4. Regulatory Functions**

4.1 Regulatory functions are those which are integral to the regulatory business of regulators. These functions are: standards and guidance, registration, fitness to practise, and education.

4.2 Any move to sharing regulatory functions amongst the regulators would require considerable study, as is noted by the GMC:

'A strategic review and impact assessment would need to be carried out with a view to determining potential costs and benefits and the likely achievement of the desired effects. This would include consideration of the likely impact on our charitable status, legislative framework, statutory purpose, fees and funding structure. It would also need to address critical infrastructure and human resources issues.'

4.3 Further, the caution needed in sharing regulatory functions was noted by the GDC: '... any pooling of resources and effort would need to be underpinned by appropriate new governance arrangements.' This underlines the type of shift necessary to share regulatory functions. However, this does not preclude regulatory functions being shared.

4.4 For example, registration is a function that could potentially be shared. The process of registering all professionals could be processed at one location. However, there are some concerns about specialized needs not being addressed within a single registration mechanism. For example, the GOsC noted, 'the risk is that questions from potential registrants that were not of the most straightforward, top line kind, would not be handled effectively from a call centre staffed with basic skills.' Also, there could be systemic differences, such as different renewal periods.

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<sup>1</sup> CHRE, 2008. Harmonising Sanctions. Available at: <http://www.chre.org.uk/satellite/124/>

4.5 In terms of fitness to practise, the Office of the Health Professions Adjudicator will be a shared function. Though not all regulators are participating initially, OHPA for those who are participating is a shared fitness to practise mechanism. However, OHPA is a new independent organisation and as therefore increases rather than reducing the number of bodies involved in regulation.

4.6 If shared functions is taken to include core regulatory activities, it is clear that intensive study would have to be undertaken. This would be necessary to both gauge healthcare professional regulatory body reaction and assess the potential benefits. There would be legislative requirements, as well as pragmatic concerns to consider. This would have to be clearly articulated, that shared functions includes core regulatory activities, such that regulators could assess the potential.

## **5. Obstacles**

5.1 Regardless of a regulator's appetite, or lack thereof, to share functions, there will be obstacles that will complicate the process. Though not insurmountable, there are certain elements in the current regulatory regime that will have to be overcome to make any fundamental changes. Of all the obstacles, it is perhaps most important to consider the possibility that each regulator's culture and system is not necessarily transferable.

5.2 The nine regulatory bodies have gone through individual processes of development and maturation. With this, each has developed its own way of working, and essentially, its own culture. This may cause compatibility issues in establishing function sharing between two or more regulators.

## **6. Cost Effectiveness**

6.1 The Department of Health question, in part, deals with cost effectiveness. Any function to be shared must present itself as something that not only works as effectively for registrants, patients, and the public, it must prove to be a cost-saving measure.

6.2 It is not possible to reach a conclusive finding that shared functions would prove cost effective, except on a case by case basis. According to some of the regulators, that there is a possibility of cost savings through sharing functions. For example, if support functions were shared amongst all nine regulators, then there could potentially be savings based on economies of scale.

6.3 There may cost savings to the registrants, for example, the HPC asserted that costs to the registrant are significantly lower with more professions in the same registration scheme. In fact, the real point is that size generates economies of scale and the larger regulators have lower charges to their registrants. Refer to Annex A of this document for a breakdown of the number of registrants and registrations costs for each regulatory body.

6.4 However, it would be imperative to undertake a cost/benefit analysis to prove that cost savings would result from sharing functions. Particularly, this would have to be demonstrated for the long term, as some regulators pointed to the front end costs of setting up the new structures or merging old ones.

## **7. Risks**

7.1 Risks may outweigh cost effectiveness and the appetite of regulators to share functions. Thus, risks must be considered, and properly planned for, to make sharing functions viable. From the submissions and discussions, the regulatory bodies noted some areas of concern.

7.2 Concerns have been raised about pragmatic issues with sharing functions. In aggregating functions there would be a transfer of a considerable amount of sensitive data. Thus, there is a potential for private data to be lost, or be acquired for unscrupulous uses. Data security measures would have to be taken for the transfer or sharing of any data.

7.3 However, experience suggests the transfer of functions seems to be fairly straightforward, given the right precautions are taken. If one takes the example of the current Hearing Aid Council into the HPC process. The HPC, in relation to this process, noted, 'the risk of transfer is small.'

7.4 Some of the major risks noted seem to be less about infrastructure and more about intangibles key to the regulatory process. There is a sense amongst the regulators that the profession-specific knowledge that is provided by the current regulatory regime could be lost, and that the expertise provided to registrants and the public would not necessarily find its way into a shared scheme between regulators.

7.5 There is a sense that if regulators were to undertake functions together, the lack of individuality would negate the possibility for change, and growth, as a profession develops. Sharing functions may temper regulators ability to adapt to a new dynamic in the profession it is regulating. As the GMC puts it, 'uniformity may sometimes inhibit innovation.' CHRE believes it crucial that regulation and regulatory bodies are agile and adaptable to changes in its environment.

## **8. Summary**

8.1 For CHRE the topic of shared functions has value in improving regulation if it is defined as something directly related to the outcomes of regulation, and grounded in benefits to patient safety and public protection. The way in which regulators manage themselves is for them to decide, and only become a matter of CHRE's concern if it affects regulation.

8.2 There would be an appetite for sharing functions, as generally expressed by most regulators and there are potential benefits to such measures. However, to ascertain a more definitive answer to questions about sharing

functions, it is necessary to provide a concrete framework. Proper assessment would require defined terms for adequate exploration.

8.3 With defined terms, a cost and service delivery analysis could provide a better indication of what shared functions would entail for the regulators. More importantly, it would allow for a more concrete analysis of the risks involved and how those risks measure up to the potential benefits. With that noted, shared functions could be an avenue for change in service delivery, given the suggestions presented by the regulatory bodies. However, this would require that the concept of shared functions is clearly defined, in order to ascertain a credible evidence base.

## Annex A

Regulator	No. of Registrants	Cost of Registration per year
GCC	2,483	£1,000
GDC	92,150	Dental care professionals – up to £96 Dentists – up to £438
GMC	248,287	£410
GOC	19,156	£219
GOsC	4,088	£375 (Year 1) £500 (Year 2) £750 (Year 3 onwards)
HPC	183,615	£76
NMC	686,886	£76
PSNI	2,025	£372
RPSGB	56,676	£413

Note: Number of registrants as at the end of 2008. Registration fees checked on regulators website as at June 2009.

## **Quality assurance of undergraduate education by the healthcare professional regulators**

**Unique ID: 16/2008**

**June 2009**

### **1. Executive summary**

- 1.1 We were asked by the Secretary of State for Health to provide advice on the approaches to quality assurance of undergraduate health programmes taken by the healthcare professional regulators.
- 1.2 Quality assurance of undergraduate education is not targeted at individual students aspiring to become healthcare professionals, but focused on education programmes and education providers. Successful completion of approved programmes by individuals, together with registration requirements allows individuals to apply to join a profession. Preserving the integrity of the register, and the fundamental role this plays in ensuring that regulators fulfil their duty to protect the public lies at the heart of quality assurance activities.
- 1.3 There are both similarities and differences in regulators' approaches. The broad structure is the same, following a pattern of programme approval, monitoring and reapproval, but differences become clear both in the methods and frequency regulators adopt in employing these aspects of quality assurance. The rationale for different approaches in part can be explained by the different role played by undergraduate education in meeting pre-registration requirements, but also reflects differences between the professions and the regulators themselves.
- 1.4 Regulators have demonstrated methods and approaches to manage the impact of changes in practice on education and their quality assurance processes, through planned reviews of standards, strategic reviews of approaches to education and focusing on high-level outcomes and criteria that allow education providers to keep curricula current. Furthermore, if practice is changing, quality assurance by the regulators is a means by which we can be confident that educational programmes ensure that new professionals are fit to practise.
- 1.5 Patient safety and public protection are at the heart of healthcare professional regulation and consequently underlie all work in quality assurance. The weakest student who passes a programme has to be fit to enter the register and fit to practise. The regulators work through a range of practical steps including methods and approaches in education programmes, involving patients and the public in quality assurance processes, integrating the principles of patient-centred care in the standards underpinning quality assurance, and through strong links to other areas of regulatory activity, including standards, registration and fitness to practise.

- 1.6 Relationships between regulators and professional bodies in this area depend greatly on the nature of the individual profession. For some they are the only profession-focused organisation involved in quality assurance. The HPC work with the greatest number of professional bodies and told us they work to ensure that they coordinate quality assurance activities wherever possible.
- 1.7 The regulators' activities should be considered in the context of other QA exercises that education providers are engaged with. At institutional level in England, Wales and Northern Ireland, the Quality Assurance Agency (QAA) carry out six-yearly institutional audits, focusing on the ability of the higher education institution to manage the quality of its educational provision. In Scotland a similar function, enhancement-led institutional reviews, are carried out on a four-yearly cycle. These external quality assurance activities are in addition to higher education institutions' own internal quality assurance processes.
- 1.8 For certain health programmes, other bodies take an active interest. In England strategic health authorities as the commissioners of nursing, midwifery and allied health education monitor value for money of the contracts they award to education providers. Lord Darzi's 2008 report, *A High Quality Workforce*,<sup>1</sup> placed further emphasis on this and work is ongoing to deliver an 'education commissioning for quality' programme through SHAs. We understand that similar processes are in preparation in Wales, where the National Leadership and Innovation Agency for Healthcare (NLIAH) are responsible for annual contract reviews with education providers. In Scotland, NHS Education for Scotland has recently taken on the role of contract monitoring on behalf of the Scottish Government Health Directorates.
- 1.9 Some professional bodies also have interests in the quality of undergraduate education, adopting similar approval and monitoring approaches in their rolling accreditation of programmes.
- 1.10 Views from higher education suggest to us that the legitimacy of the regulators' involvement in quality assurance is not questioned and indeed it is valued for the confidence and subject-specific insight that it can provide. But there is concern about the total impact and possible overlap of different quality assurance type processes on higher education, and that healthcare professional regulators are part of that impact.
- 1.11 This is a constantly changing field with many legitimate players who nevertheless cumulatively have disproportionate impact. We believe it would be impractical to try and seek a definitive solution. Instead it may be more productive to focus on establishing ways to live with change and manage tensions, and in that spirit we make the following observations and recommendations:
  - Different approaches are inevitable given the current legislative framework for healthcare professional regulation.
  - As programmes are subject to scrutiny by the different agencies, including the NHS, greater clarity and understanding is needed about their respective roles, including regulatory bodies.

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<sup>1</sup> Department of Health, 2008. *A high quality workforce: NHS Next Stage Review*. London: DH. Available at: [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_085840](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085840) [Accessed 20 May 2009]

- All regulators must be willing and able to demonstrate how their processes link proportionately to patient safety and public protection, maintaining the focus on the issue of being fit to join the register, or making further progress towards this point, is essential. Demonstrating the contribution of quality assurance to the main duty to protect the public would be valuable, both in improving education and in assuring the public of the competency of newly qualified healthcare professionals.
- Finally, CHRE will work with the regulators and other stakeholders to review our standard of good regulation around quality assurance of education for the 2009/2010 performance review, taking into account current perspectives on good practice. Given the regulators' willingness to review and refine their approaches in the light of developments in practice, feedback and evaluation, there is potential to make changes that demonstrate good practice, proportionality and transparency in quality assurance.

## 2. Introduction

- 2.1 In October 2008 CHRE were commissioned by the Secretary of State for Health to provide advice on the process for quality assurance of undergraduate health programmes by the nine healthcare professional regulators:

*The Secretary of State requests advice about the quality assurance regimes applied by the health professions regulatory bodies on Higher Education Institutions. The Secretary of State wishes to ascertain:*

- (i) the similarities and differences in approach that are taken by different bodies in the quality assurance of undergraduate healthcare programmes across the UK;*
- (ii) how the health professions regulators keep pace with changes in professional practice that may influence the structure or content of professional education;*
- (iii) whether the approaches of health professions regulatory bodies ensure they meet their statutory duties to ensure that future healthcare professionals are trained to sufficient competence to ensure high levels of patient safety in their everyday practice (taking account of the relative risk to patient safety of different areas of healthcare professionals' practice);*
- (iv) how the health professions regulators manage their relationships with the professional bodies; and*
- (v) whether there is potentially scope (should it be desirable to do so) to alter processes without adversely affecting public protection.*

*It would also be helpful if the Council could identify examples of good practice in the approach to quality assurance.*

*Public protection and patient safety must be the guiding principles throughout this analysis.*

- 2.2 In February 2009 we provided an interim report on our work. This is reproduced in Annex 1, with slight revisions.

- 2.3 Our interim report discussed the current approaches taken by the regulatory bodies<sup>2</sup> we oversee, under powers given to us in the NHS Reform and Health Care Professions Act 2002. We identified the broad similarities and differences, discussed the means by which these regulators keep pace with changes in practice, how quality assurance contributes to patient safety and public protection, and the way they work with other organisations in this field. In brief we found that:

- There are similarities and differences in the approaches taken by the regulatory bodies to quality assuring undergraduate education. The broad structure of the approaches is the same, following a pattern of programme approval, monitoring and reapproval, but differences become clear both in the methods and frequency regulators adopt in employing these aspects of

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<sup>2</sup> General Chiropractic Council, General Dental Council, General Medical Council, General Optical Council, General Osteopathic Council, Health Professions Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland, Royal Pharmaceutical Society of Great Britain

quality assurance. The rationale for different approaches in part can be explained by the different role played by undergraduate education in meeting pre-registration requirements, but also reflects differences between the professions and the regulators themselves.

- Regulators have demonstrated methods and approaches to manage the impact of changes in practice on education and their quality assurance processes, through planned reviews of standards, strategic reviews of approaches to education and focusing on high-level outcomes and criteria that allow education providers to keep curricula current. Furthermore, if practice is changing, quality assurance by the regulators is a means by which we can be confident that educational programmes ensure that new professionals are fit to practise.
  - Patient safety and public protection are at the heart of healthcare professional regulation and consequently underlie all work in quality assurance. The weakest student who passes a programme has to be fit to enter the register and fit to practise. The regulators work through a range of practical steps including methods and approaches in education programmes, involving patients and the public in quality assurance processes, integrating the principles of patient-centred care in the standards underpinning quality assurance, and through strong links to other areas of regulatory activity, including standards, registration and fitness to practise.
  - Relationships between regulators and professional bodies in this area depend greatly on the nature of the individual profession. For some they are the only profession-focused organisation involved in quality assurance. The HPC work with the greatest number of professional bodies and told us they work to ensure that they coordinate quality assurance activities wherever possible.
- 2.4 This final report complements the interim report. Here we briefly describe the wider context of quality assurance of undergraduate education, before considering whether there is scope to change current approaches by regulators and identifying good practice.
- 2.5 We would like to acknowledge the help, advice and time given by colleagues across a range of organisations in completing this work. We have benefitted tremendously from the useful and wide-ranging discussions.

### **3. The regulators' role**

- 3.1 Quality assurance of *pre-registration* education by healthcare professional regulators is driven by a need to ensure the fitness of new entrants to practice the profession, confirming that they may join the register. An absence of quality assurance of programmes at this point before registration, without the use of alternative means of assurance, would pose a serious challenge to the integrity of registers.
- 3.2 This commission is focused on undergraduate education. Completing undergraduate education does not mean the same thing or have the same value for all healthcare professions. For some, the next step is registration. For others, graduation enables progress to another period of pre-registration training or study, before eventually joining the register. This variation may help explain some of the differences in the approaches currently taken by the healthcare professional regulators.

- 3.3 Quality assurance of undergraduate education is not targeted at individual students aspiring to become healthcare professionals, but focused on education programmes and education providers. Successful completion of approved programmes by individuals, together with registration requirements allows individuals to apply to join a profession. Preserving the integrity of the register, and the fundamental role this plays in ensuring that regulators fulfil their duty to protect the public lies at the heart of quality assurance activities.

#### 4. The wider context of quality assurance

- 4.1 The regulators' activities should be considered in the context of other QA exercises that education providers are engaged with.<sup>3</sup> At institutional level in England, Wales and Northern Ireland, the Quality Assurance Agency (QAA) carry out six-yearly institutional audits, focusing on the ability of the higher education institution to manage the quality of its educational provision. In Scotland a similar function, enhancement-led institutional reviews, are carried out on a four-yearly cycle.
- 4.2 These external quality assurance activities are in addition to higher education institutions' own internal quality assurance processes, including external examiners, described by QAA as 'the keystone of supporting academic quality in the UK'.
- 4.3 For certain health programmes, other bodies take an active interest. For example, in England strategic health authorities as the commissioners of nursing, midwifery and some allied health education monitor value for money of the contracts they award to education providers.
- 4.4 Lord Darzi's 2008 report, *A High Quality Workforce*<sup>4</sup>, placed further emphasis on this and work is ongoing to deliver an 'education commissioning for quality' programme through SHAs. We understand that similar processes are in preparation in Wales, where the National Leadership and Innovation Agency for Healthcare (NLIH) are responsible for annual contract reviews with education providers. In Scotland, NHS Education for Scotland has recently taken on the role of contract monitoring on behalf of the Scottish Government Health Directorates.
- 4.5 Alongside the funders (commissioners) of education programmes, some professional bodies also have interests in the quality of undergraduate education, adopting similar approval and monitoring approaches in their rolling accreditation of programmes.<sup>5</sup>
- 4.6 The tension is sometimes described as the need for successful students on these programmes to achieve three qualitatively different outcomes at the same time. They are fit to practise in the eyes of their regulator, fit for purpose in the eyes of the employer/commissioner, and fit for award of a degree in the eyes of the education provider.

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<sup>3</sup> Universities UK. *Quality and standards in UK universities: a guide to how the system works*. London: Universities UK. Available at [www.universitiesuk.ac.uk/Publications/Pages/Quality-and-standards-in-UK-universities-A-guide-to-how-the-system-works.aspx](http://www.universitiesuk.ac.uk/Publications/Pages/Quality-and-standards-in-UK-universities-A-guide-to-how-the-system-works.aspx) [Accessed 20 May 2009]

<sup>4</sup> Department of Health, 2008. *A high quality workforce: NHS Next Stage Review*. London: DH. Available at: [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_085840](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085840) [Accessed 20 May 2009]

<sup>5</sup> Elsewhere professional and statutory regulatory bodies are often grouped as one sector – PSRBs – but for the purposes of our work here, it is important that a distinction is retained.

- 4.7 These overlapping but fundamentally distinct interests in the quality of education are not peculiar to health. Statutory regulators of other professions are active in quality assurance relevant programmes, in broadly similar ways to those adopted by the regulators we oversee, with expected similarities and differences reflecting of the nature of the programme, the nature of the profession, and the route to registration.
- 4.8 For example, the General Social Care Council's oversight of institutions providing social work training in England is a two stage process. The institution is approved every five years in a joint event alongside internal quality assurance, followed by paper-based annual monitoring exercises. Reapproval of a course can be based on a site visit if risk suggests this is appropriate, alternatively this may be solely paper-based. The Architects Registration Board does not carry out approval visits except in exceptional circumstances, relying on a paper-based approval of a programme following the submission of evidence by the education provider. Recognition of the course in this case last for up to four years and the annual monitoring process within this includes checks on any conditions that may have been imposed when the course was approved. The Royal College of Veterinary Surgeons requires a site visit every ten years, assuming approval is unconditional and paper reviews carried out after five years do not suggest any major concerns are need for a new visit.

## 5. Views on quality assurance of health programmes

- 5.1 A study of international best practice by Skills for Health in 2005 found that the UK is seen as a front runner in the quality assurance of healthcare education, and commented that this area had become more complicated since devolution. Reflecting on the question of similarities and differences, this review also concluded that a single model or 'one size fits all' is not appropriate.<sup>6</sup>
- 5.2 A quality assurance review of all NHS funded healthcare education in England, 'Major Review', carried out in 2003-2006, drew together regulators, professional bodies, workforce planners and education providers in a coordinated effort. There were 90 reviews across 15 healthcare disciplines. Reviewers had confidence in the academic and practitioner standards across all 90 reviews and the project concluded that 'healthcare programmes ensured that students who successfully completed their programmes were fit for practice, purpose and award.'<sup>7</sup> However, subsequent reviews of quality assurance have questioned the proportionality of Major Review.<sup>8</sup>
- 5.3 Institutions themselves have, over time, expressed views about the approach and collective impact of quality assurance. Universities UK has described PSRB

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<sup>6</sup> Skills for Health, 2005. *QA international best practice report. Executive summary*. Available at [www.skillsforhealth.org.uk/js/uploaded/Quality%20Assurance/QA%20International%20Best%20Practice%20Report%20Summary%20-%20Dec%202005.doc](http://www.skillsforhealth.org.uk/js/uploaded/Quality%20Assurance/QA%20International%20Best%20Practice%20Report%20Summary%20-%20Dec%202005.doc) [Accessed 20 May 2009]

<sup>7</sup> Quality Assurance Agency, 2007. *Major review of NHS-funded healthcare programmes in England. Final review trends report 2003-06*. Gloucester: QAA. Available at [www.qaa.ac.uk/health/majorreview/reviewTrends0306/ReviewTrends0307.pdf](http://www.qaa.ac.uk/health/majorreview/reviewTrends0306/ReviewTrends0307.pdf) [Accessed 20 May 2009]

<sup>8</sup> Quality Assurance Framework Review Group, 2008. *Review of the Quality Assurance Framework. Phase three outcomes: Assessment of the impacts of reviews of collaborative provision*. HEFCE: 2008. Available at: [www.hefce.ac.uk/pubs/hefce/2008/08\\_21/](http://www.hefce.ac.uk/pubs/hefce/2008/08_21/) [Accessed 20 May 2009]

oversight as helping to provide independence, objectivity and additional confidence that standards and quality of the degree are appropriate.<sup>9</sup>

- 5.4 However, concerns have also been raised. The final report of the Higher Education Regulation Review Group (HERRG) in July 2008 commented on the 'large number of bodies' involved in the regulation of healthcare programmes and they expressed concern that in their view they sensed a 'lack of commitment to better regulation'.<sup>10</sup>
- 5.5 Through the course of this project we have received feedback and views from some working in higher education about the impact of regulators' quality assurance:
- *We have struggled on occasions to match the narrative with the grade provided*
  - *It is proportionate, targeted and transparent*
  - *We have been made to validate the same course three times in one year. No problems were ever discovered.*
  - *The reporting was helpful to the quality enhancement of an emerging source and institution as well as providing assurance of the quality of provision*
  - *Overall the QA is targeted and transparent however aspects of the process do not seem proportionate*
  - *What upsets people the most is when they cannot identify where you have 'gone wrong'*
  - *I think current arrangements have been very effective*
  - *Harmonisation of the regulatory and professional bodies would be welcomed by Higher Educational Institutions*
  - *It was mostly useful and positive*
  - *Overall the process is a comprehensive and searching review (if slightly too protracted) which has a very high degree of legitimacy*
- 5.6 These comments should not be considered a representative view, but they help to provide a flavour of the some perspectives on regulators' quality assurance. Time constraints prevented us establishing a more comprehensive view of the higher education sector.
- 5.7 Taken together these perspectives suggest to us that the legitimacy of the regulators' involvement in quality assurance is not questioned and indeed it is valued for the confidence and subject-specific insight that it can provide. But there is concern about the total impact and possible overlap of different quality assurance type processes on higher education, and healthcare professional regulators are part of that impact.

## 6. Is there scope for change?

- 6.1 We were impressed by regulators' plans for regular evaluation, feedback and review of their quality assurance processes. Several outlined their mechanisms for feedback and evaluation that are built into annual monitoring and approval

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<sup>9</sup> Universities UK. *Quality and standards in UK universities: a guide to how the system works*. London: Universities UK. Available at [www.universitiesuk.ac.uk/Publications/Pages/Quality-and-standards-in-UK-universities-A-guide-to-how-the-system-works.aspx](http://www.universitiesuk.ac.uk/Publications/Pages/Quality-and-standards-in-UK-universities-A-guide-to-how-the-system-works.aspx) [Accessed 20 May 2009]

<sup>10</sup> Bundred, S, 2008. *The better regulation of higher education and the work of HERRG in 2007/08*. Available at: [www.dfes.gov.uk/hegateway/uploads/HERRG%20Annual%20Report%20V5%20-%20FINAL.doc](http://www.dfes.gov.uk/hegateway/uploads/HERRG%20Annual%20Report%20V5%20-%20FINAL.doc) [Accessed 20 May 2009]

- events. We are aware that some – the GDC, GMC, GOC and RPSGB – are currently in the midst of larger strategic reviews of education and alterations to quality assurance processes may well result from these activities. Other regulators have highlighted their desire for change, for example establishing complaints processes, increasing involvement by lay people and students, or having the power to approve their own programmes rather than the Privy Council, which does seem to suggest an unnecessary level of involvement.
- 6.2 The CHRE performance review standards offer an opportunity to identify where changes in individual approaches could be introduced. Our standards, against which the regulators' performance is reviewed on an annual basis, describe what the public should expect from regulators and identify some principles of good practice. For quality assurance of education we ask that:
- 'The regulator has a transparent and proportionate system of quality assurance for education and training providers.'
- 6.3 This standard covers the regulators' quality assurance activities across all education and training, not only those focused on undergraduate education, and as with all our standards we set out minimum requirements. They are not exhaustive, but they must be met in order to meet the standard. For quality assurance these are:
- i. The regulator assesses education and training providers, including arrangements for placements, at appropriate intervals which may vary between establishments proportionally to risk.
  - ii. Educational providers that meet the required standards are approved, and appropriate and targeted steps are taken where a provider falls short of the standards.
  - iii. Students' and patients' perspectives are taken into account as part of the evaluation.
  - iv. Information on the assessment process and final results of assessments are accessible to all stakeholders.
- 6.4 In terms of undergraduate education, while we can see that all regulators through their different ways are working to achieve these minimum requirements, it is evident from views expressed above that there are concerns about some current approaches. This highlights to us a constant need for regulators to be able to demonstrate the evidence that provides support for their style and approach. Where activities may be felt to be disproportionate, we would expect that regulators can demonstrate the need for such action in terms of the value to patient safety and public protection, or to make changes as necessary.
- 6.5 The importance of securing patients' perspectives is something that some regulators have indicated is a current challenge in certain programmes, so we are encouraged that the NMC are leading a project on behalf of other regulators that aims to deliver greater direct involvement of patients and the public in future quality assurance activities. We look forward to seeing how this initiative develops over time. It may also be possible for regulators to increase the involvement of the public and students as part of teams on approval visits, and we note that QAA are presently recruiting student members of institutional audit teams, echoing an aspect of the GMC's methodology.
- 6.6 The fourth minimum requirement focuses on the accessibility of information. This involves the publication of assessment reports, a requirement fulfilled by

some but not all regulators and we expect to see action in this area shortly by those who do not presently publish this information.

- 6.7 There are inherent tensions in any system of quality assurance that seeks to be proportionate and targeted. We believe there is scope to go beyond these current requirements, and a broader discussion about the characteristics of such a system of quality assurance would be valuable.
- 6.8 We asked the regulators what they considered to be good practice in quality assurance and their responses included the following:
- Clear focus on the aims and objectives
  - Linking quality assurance work into the wider work of the regulator
  - Encouraging education providers to work together
  - Avoiding duplication
  - Being robust without being burdensome
  - Multiprofessional standards
  - Balancing minimum burden against role in public protection
  - Consistency, transparency, clear communications, evidence based, timeliness
  - Following principles of good regulation – proportionality, transparency, accountability, consistency, targeted
  - Identifying and sharing good practice in education
  - Promoting equality and diversity
  - Being transparent and publicly accountable
  - Evaluation and reflection on the process
  - Complementing other quality assurance processes
  - Using experts and peers
  - Seeing quality assurance as a developmental process offering opportunity for reflection and improvement
- 6.9 The question of good practice in quality assurance has been considered by other organisations. The European Association for Quality Assurance in Higher Education has published standards and guidelines for both external quality assurance and external quality assurance agencies (see Annex 2)<sup>11</sup> and the World Federation for Medical Education has published 'elements of proper accreditation', with the aim of supporting international mobility of medical students and professionals (see Annex 3).<sup>12</sup>
- 6.10 Taken together these have led us to identify the following characteristics of good practice in quality assurance of undergraduate education by the healthcare professional regulatory bodies:
- Builds on other quality assurance activities, including the processes adopted internally by the education provider and other external interests to minimise impact, and works to coordinate visits with other bodies with an interest wherever possible
  - Actively involves and seeks perspectives of students, patients and other members of the public

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<sup>11</sup> European Association for Quality Assurance in Higher Education, 2009. *Standards and guidelines for quality assurance in the European higher education area*, 3rd edition. Available at: [http://www.enqa.eu/files/ESG\\_3edition%20\(2\).pdf](http://www.enqa.eu/files/ESG_3edition%20(2).pdf) [Accessed 20 May 2009]

<sup>12</sup> Karle, H, 2008. *World Federation for Medical Education Policy on International Recognition of Medical Schools' Programme*. *Ann Acad Med Sing* 37:1041–1043

- Builds from duty to protect the public that underpins all regulatory activity and this objective drive the process
  - All processes, criteria and procedures are predetermined and publicly available, and decision-making is based on criteria that are consistently applied
  - All elements within quality assurance are fit for purpose and subject to review, including visitor/reviewer recruitment, training and appraisal
  - Reports are publicly available and narratives clearly support decisions taken and subsequent actions
  - Summary reports providing analysis of trends and general findings produced on periodic basis demonstrating the value of quality assurance and facilitating the sharing of good practice in education and training
- 6.11 We propose these for the basis for further discussion with the regulators, and other stakeholders, ahead of our performance review of regulators in 2009-2010. Once agreed, if it is not possible to account for activities as proportionate and transparent, seeking alterations to specific elements of individual regulators' approaches may be necessary. An approach may appear disproportionate, as some of the reports from higher education have indicated, but we would expect regulators to be able to point to evidence that supports their style and approach in terms of a proportionate response to their duties in protecting the public.
- 6.12 Going beyond this, as we have already described, undergraduate education is not a common point in pre-registration across all regulators. Across nine organisations and more than twenty five professions, working in a variety of contexts and routes to entry, each regulator is operating in a qualitatively different environments and similarities and differences are to be expected.

## 7. Conclusion

- 7.1 Patient safety and public protection drive the work of CHRE and the regulators we oversee and both are supported by quality assurance of undergraduate education. In our view quality assuring education programmes represents a proportionate approach to the task of maintaining the integrity of the register at this point in an individual's career. Equally it is reasonable to expect that quality assurance will be carried out in a proportionate and transparent manner. In theory too much or too little quality assurance, or poorly focussed quality assurance could all threaten fitness to practise. To maximise the benefit from the costs of this aspect of regulatory activity we need a balanced, proportionate approach, focused on fitness to join the register.
- 7.2 We can anticipate current and future policy developments around innovation and quality in healthcare, and the prospect of greater international mobility of healthcare students and the workforce. Throughout this the duty of regulators to protect the public should not be hampered.
- 7.3 During our work a wider question was raised about the readiness of new entrants to professions to practise. One indirect assessment of the effectiveness of quality assurance of undergraduate education is the performance of newly registered professionals in practice. A recent GMC-commissioned study on the preparedness of medical graduates identified that undergraduate placements should have greater consistency and structure, that medical students should have a role in teams, and there should be more prescriptive guidelines on shadowing F1 roles. This research is feeding into the current review of

Tomorrow's Doctors.<sup>13</sup> In contrast, recent work commissioned by the Scottish Government has found that new entrants to nursing in Scotland were fit to practice and cautioned that lack of confidence at the start of a career should not be confused with a lack of competency.<sup>14</sup> The respective roles and responsibilities of regulators and employers in ensuring safe practice at this point in a registrant's career may be worth further examination, taking into account the variety of routes to registration. Analysis of such data may also help in targeting future quality assurance and in informing strategic reviews of regulators' approach to education.

- 7.4 We are aware from work predating this project that the issue of quality assurance of health programmes in higher education is one that appears difficult to resolve. Many different agencies and organisations can take an interest in undergraduate health programmes, and it is apparent that tensions arise. The anecdotal feedback we have received shows some feel that more could be done to demonstrate the proportionality and transparency of current approaches.
- 7.5 However, in as fluid a field, it would be impractical to try and seek a definitive solution. Instead it may be more productive to focus on establishing ways to live with change and manage tensions. In that spirit we make the following observations and recommendations:
- Different approaches are inevitable given the current legislative framework for healthcare professional regulation.
  - As programmes are subject to scrutiny by the different agencies, including the NHS, greater clarity and understanding is needed about their respective roles, including regulatory bodies.
  - All regulators must be willing and able to demonstrate how their processes link proportionately to patient safety and public protection, maintaining the focus on the issue of being fit to join the register. Demonstrating the contribution of quality assurance to the main duty to protect the public would be valuable, both in continuing improvements in education and in assuring the public of the competency of newly qualified healthcare professionals.
  - Finally, CHRE will work with the regulators and other stakeholders to review our standard of good regulation around quality assurance of education for the 2009/2010 performance review, taking into account current perspectives on good practice. Given the regulators' willingness to review and refine their approaches in the light of developments in practice, feedback and evaluation, there is potential to make changes that demonstrate good practice, proportionality and transparency in quality assurance.

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<sup>13</sup> Illing, J, et al, 2008. *How prepared are medical graduates to begin practice? A comparison of three diverse UK medical schools*. London: GMC. Available at: [www.gmc-uk.org/about/research/REPORT%20-preparedness%20of%20medical%20grads.pdf](http://www.gmc-uk.org/about/research/REPORT%20-preparedness%20of%20medical%20grads.pdf) [Accessed 20 May 2009]

<sup>14</sup> Lauder, W, et al, 2008. *Nursing and midwifery in Scotland: being fit for practice*. Available at: [www.nes.scot.nhs.uk/practice\\_education/work/evaluation/](http://www.nes.scot.nhs.uk/practice_education/work/evaluation/) [Accessed 20 May 2009]

## **Annex 1 Interim report**

### **The quality assurance regimes applied by the health professions regulatory bodies on higher education institutions**

Unique ID: 16/2008

Interim report, February 2009<sup>1</sup>

#### **INTRODUCTION**

The Council for Healthcare Regulatory Excellence is an independent body accountable to Parliament. Our primary purpose is to promote the health, safety and well-being of patients and other members of the public. We scrutinise and oversee the health professions regulators<sup>2</sup>, work with them to identify and promote good practice in regulation, carry out research, develop policy and give advice.

#### **The request for advice**

On 24 October 2008, in accordance with section 26(7) of the NHS Reform and Health Care Professions Act 2002, the Secretary of State for Health asked CHRE for advice on the matter of the quality assurance regimes applied by the health professions regulatory bodies on higher education institutions.

In particular, the Secretary of State wished to ascertain:

- (i) the similarities and differences in approach that are taken by different bodies in the quality assurance of undergraduate healthcare programmes across the UK;
- (ii) how the health professions regulators keep pace with changes in professional practice that may influence the structure or content of professional education;
- (iii) whether the approaches of health professions regulatory bodies ensure they meet their statutory duties to ensure that future healthcare professionals are trained to sufficient competence to ensure high levels of patient safety in their everyday practice (taking account of the relative risk to patient safety of different areas of healthcare professionals' practice);
- (iv) how the health professions regulators manage their relationships with the professional bodies; and
- (v) whether there is potentially scope (should it be desirable to do so) to alter processes without adversely affecting public protection.

Taking public protection and patient safety as guiding principles in the analysis, CHRE was also asked to identify examples of good practice in this area.

This report provides an interim update on early findings. The final report will be submitted by end of March 2009.

#### **Scope of the study**

Ahead of a discussion of our early findings, it is worth describing the scope of our work. We have taken a broad definition of 'healthcare' and below consider the approaches by all health professions regulators overseen by CHRE.

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<sup>1</sup> Revised May 2009

<sup>2</sup> General Chiropractic Council, General Dental Council, General Medical Council, General Optical Council, General Osteopathic Council, Health Professions Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland, Royal Pharmaceutical Society of Great Britain

We were asked to focus on undergraduate programmes. Not all healthcare professionals join the register following a period of prescribed undergraduate study – some do more, some do less. While for some regulators and some professions undergraduate education corresponds exactly to pre-registration requirements, it should not be assumed to be the case for all. We have not considered regulators' approaches to quality assurance of other education and training, for example, post-registration training, continuing professional development and return to practise courses.

### **Acknowledgements**

We wish to formally acknowledge the considerable help, support and cooperation in the nine health professions regulators in this project so far. Annex A summarises the QA approaches taken by the nine regulators.

## **QUALITY ASSURANCE OF UNDERGRADUATE EDUCATION BY REGULATORY BODIES**

An essential element of the legislation establishing health professions regulators is their role in quality assuring education of aspiring professionals. As guardians of the register and through their duty to protect the public, it is essential that regulators are able to judge whether a healthcare student is fit to join the register once they have completed their pre-registration education and training.

However, the challenge for regulators in delivering against this duty is by no means uniform. While GMC, GCC, PSNI, and GOsC all regulate a single profession, GDC regulates the dental team, GOC regulates both optometrists and dispensing opticians, NMC regulates nurses and midwives, and HPC regulates a total of 13 allied healthcare professions in areas as otherwise unrelated as radiography and art therapy. There are advanced plans to regulate pharmacy technicians alongside pharmacists in the RPSGB.<sup>3</sup>

As well as the differences between the ranges of professions administered by each regulator, the complexity of each profession's educational demands also varies greatly, from five years of undergraduate study for dentists or doctors to mostly on the job training for dental nurses. The risks associated with poor performance vary greatly between the professions too.

Considerable variation exists in the nature of courses, numbers of programmes and institutions requiring approval, before considering the relative risk of the different professions and the rate at which professional practice evolves. The workloads associated with QA processes for undergraduate education can vary too; while there are currently three institutions offering chiropractic qualifications, there are 84 institutions offering over 1100 nursing and midwifery programmes.

So while primary legislation governing regulators may appear broadly identical in many cases, the interpretation of this statutory duty may look and feel quite different in practice.

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<sup>3</sup> The register of Pharmacy Technicians opens on 1 July 2009.

Alongside this inherent variation, this is also a dynamic area of regulatory practice. We asked regulators how their quality assurance processes have changed over recent years, and received a wide range of responses highlighting:

- periodic reviews of standards
- introduction of lay visitors and student visitors
- open recruitment, appraisal and training for visitors
- visit evaluations
- greater involvement of patients and the public
- wholesale strategic review of education
- online case management systems
- outsourcing supply of QA
- increased transparency
- increased emphasis on patient protection
- focus on outcomes of education
- shorter reports
- streamlined visits
- greater engagement with stakeholders.

Given the plans regulators have for future revisions in QA approaches, this report should be seen as a snapshot in time.

### **1. Similarities and differences in the approach to quality assurance**

In broad terms regulators quality assure education against outcomes and processes. Learning outcomes are usually high level principles describing the level and breadth of knowledge, skill and practical experience an aspiring health professional must have at the point they join the register. These outcomes are explicitly linked to the standards of proficiency and codes of conduct that regulators expect of their registrants.

To guide the achievement of these outcomes regulators provide guidance on the processes to be undertaken by institutions. This may include what is expected to be included in the curriculum of a course of study for the given profession. The degree of specificity for this varies between regulators, but none are so prescriptive as to remove course curricula decisions from the institution. Other areas covered by standards include admissions, assessment, recruitment, student health and welfare and staffing.

One example of the distinction between outcomes and processes can be found in the approach of HPC in their Standards of Proficiency (SOPs) for graduates in each profession it regulates and generic Standards of Education and Training (SETs) that institutions must meet in order to ensure they can deliver suitably proficient graduates.

GDC, meanwhile, makes a point of emphasising an outcomes focus and a desire to leave institutions relatively free to develop their programmes as they wish, so long as they result in dental and dental-health graduates of an acceptable standard for registration.

The GMC's standards for undergraduate medicine, which provide the framework for quality assurance, are published in the document *Tomorrow's Doctors* (currently under review). This sets high level outcomes and principles so that medical schools are able to devise and quality manage evolving curricula that are responsive to emerging practice and changing healthcare environments.

The NMC takes a different approach. Alongside their standards for pre-registration education, their QA approach focuses on risks to be controlled in the delivery of programmes, including:

- resource inadequacy
- inadequate safeguards for monitoring student conduct
- inadequate governance of practice learning
- failure to provide learning opportunities of a suitable quality
- unreliable conformation of achievement
- failure to incorporate essential skill clusters or address required learning outcomes
- failure of internal QA systems to provides assurance against NMC standards.

### **The approach to quality assurance**

There are four main areas of QA activity:

- New programme approval
- Ongoing monitoring of approved programmes
- Approving major changes to programmes
- Programme re-approval

#### *a. New programme approval*

All the regulators have specific processes for the initial approval of professional courses offered in their field of healthcare. The GMC, GOC and RPSGB take a cohort approach to the approval of new courses, visiting each year to assess the development and delivery of the course. The GDC adopt the same approach with new BDS (dentistry) programmes.

Other regulators approve the course on a single visit. For the HPC, this programme approval is open-ended, with any subsequent visit prompted only by major change or a concern raised during in annual monitoring processes. The GDC visit dental care professional training programmes towards the end of the first cohort. For GCC initial approval is usually offered for five years, as does the NMC, who approve new programmes jointly with education providers and their placement provider partners. For new osteopathic courses, it is unlikely that they will be granted a 5 year RQ as the GOsC will want to visit shortly after to ensure that the establishment of the course has gone to plan. This would usually be in the space of 1-2 years.

#### *b. Ongoing monitoring of approved programmes*

Once approved, a programme is subject to ongoing monitoring and re-approval (where carried out). Monitoring is usually undertaken at yearly intervals when programme re-approval is not scheduled. The majority of regulators adopt a purely paper-based approach to ongoing monitoring. In doing so, they allow institutions to provide material already compiled and supplied for other purposes, for example QAA monitoring or internal QA processes. The intention is to establish what progress has been made against particular conditions of approval, identify any significant changes in programmes, and to ensure that standards are being maintained. Should annual monitoring throw up significant concerns, regulators may opt to revisit.

Exceptions to this are the GOsC and the NMC. The GOsC also include site visits as part of their monitoring reviews. The NMC through their QA suppliers carry out annual monitoring visits to the majority of institutions as well as annual reporting. In 2008-2009, around a third of providers have 'earned autonomy' status from the NMC exempting

them from a visit, and allowing additional visits to be carried out at those institutions who, based on monitoring reports, have been judged to have 'weak control of risk'.

*c. Approval of major changes to programmes*

Changes made to programmes can vary in their impact on outcomes. Generally, regulators' requirements are broad and flexible enough that education providers are free to make necessary changes to their curriculum and administration processes with minimal involvement from their respective regulators beyond annual monitoring, providing there is no impact on learning outcomes. However, there are situations in which major changes to programmes may demand more intensive scrutiny, including a visit.

*d. Programme re-approval*

As described above, HPC's 'open-ended' approval is the notable exception to the formal re-approval process. The other regulators re-approve programmes approximately every 5 years. There can be some flexibility in this timescale if conditions are placed on programme approval. Institutional visits form the foundation of programme re-approval by regulators. Alongside re-approval visits, the NMC and the GOsC also use visits in the ongoing annual monitoring of approved programmes (see above).

For the majority, this is a process carried out and managed in-house drawing on the expertise of external visitors (reviewers). Two regulators contract out the visit process to external suppliers: GOsC use QAA and NMC use HLSP in England, Northern Ireland and Scotland and HIW in Wales.

In the broadest terms, the visit process for each regulator can be broken down into three basic phases:

- pre-visit planning and information gathering
- the visit itself (one to three days)
- report preparation (including providing/receiving feedback from the education provider).

However, the execution of each of these phases differs from regulator to regulator, as does the time-frame for the process from start to finish. The GMC visit and reporting process takes 18 months from initial notification of a visit through to final endorsement of the visiting team's report, whereas the NMC process sees annual monitoring visits completed within 10-11 weeks of process initiation.

The number and range of visitors varies between regulators from two (HPC) up to ten (GMC). In part this arises from the different types of visitor engaged. Across the regulators, visitors are drawn from:

- the regulator (staff and/or council)
- lay people (patients and the public)
- educationalists
- members of the profession
- students
- QA consultants.

No regulator uses all these groups.

While on the visit, feedback is sought from a range of sources: university administrators, academic and clinical staff, and students. Beyond this, some regulators seek input from prospective employers, NHS and patients.

While the terminology may vary, in each case regulator's visit processes result in one several possible judgments on an institution/course:

- Approved
- Approved with conditions
- Approved with conditions and recommendations
- Approved with recommendations
- Not approved.

The result of a conditional approval is generally the provision of assurances and evidence (action plans) by the institution that any issues identified will be addressed. Providers may not be required to meet recommendations but they are likely to be considered subsequently.

Finally, while for the most part regulators are assessing similar things with broadly similar processes, the level of detail provided in their final accreditation reports varies between them and not all approval reports are available online.

## **2. Keeping pace with change**

Innovation and evolution of professional practice provides considerable benefits for patient care. This is sustained, in part, through changes in structure and content of education. We asked the regulators how they ensured flexibility and agility in their QA processes to 'keep pace with changes in practice'.

In their work to manage the impact of change in practices on their approach to QA, the regulators highlighted number of strategies:

- Periodic review of standards – for example the GMC are currently reviewing *Tomorrow's Doctors*. Also GCC, GOC, GOsC, HPC, NMC, RPSGB
- Indicative standards – broadly describing the outcome needed rather than prescriptively identifying the inputs required (GDC, GMC, HPC, NMC, RPSGB)
- Focus on high level outcomes and principles to allow education providers to devise curricula in variety of ways and phrasing criteria to demand that programmes remain current (GMC, NMC, RPSGB)
- Specific criteria to ensure syllabus remains up to date and responds to evolving legislation (RPSGB)
- Swift decisions on programme changes where appropriate (HPC, RPSGB)
- Peer reviewers introduce contemporary practice perspective, from across employment sectors (GMC, NMC, PSNI, RPSGB)
- Targeted visits to ensure areas of greatest interest are focused on (NMC)
- Risk-based approach to monitoring helps to target on areas of greatest impact on patients and the public (NMC)
- Issuing supplementary guidance as necessary, for example around student fitness to practise, disability and health (GDC, GMC, GOC, HPC, NMC, RPSGB)
- Devising urgent revisions to standards if circumstances demand (GOsC, HPC)
- Annual monitoring tailored to institutions, focused on conditions specific to each provider, encouraging continuous development and corrective action (GDC, GMC, GOC, NMC)
- Asking for feedback from education providers and visitors to highlight areas for improvement (GMC, GOC, HPC, RPSGB).

## **3. Ensuring patient safety and public protection**

We asked regulators how they thought their quality assurance processes contributed to patient safety and public protection. The role of QA and approval of education programmes means that successful students will obtain the skills and competencies needed to join the register. This was described by the GOC: 'Patient safety and public protection are at the heart of the GOC's quality assurance role. When setting the standard required by developing and reviewing the core competencies and the requirements for approving optics training programmes, the GOC has to assure itself that even the weakest student who passes the programme meets the standard required to ensure that they are fit to practise.'

Broadly, there are three main approaches to ensuring patient safety and public protection:

- a. Practical steps
  - Ensuring student fitness to practise processes are in place
  - Strong internal quality assurance processes and robust assessment systems to ensure that students meet learning outcomes
  - Explicit emphasis on patient safety and public protection in the course
  - Supplementary guidance, for example on student fitness to practise, where needed
  - Encouraging the sharing of good practice in education between providers
  - Patient and public involvement in education, through visitor teams, provision of feedback, involvement in design and delivery of education.
- b. Principles of patient-centred care
  - Learning outcomes are derived from standards of practice
  - Principles of good health and good character are emphasised in courses and at admissions
  - Emphasising the patient – in standards and in education programmes derived from them.
  - Focusing on outcomes rather than inputs.
- c. Integration of quality assurance with other regulatory activity
  - Within the regulatory body, through strong links with standards, fitness to practise, and registration.
  - With other regulators – for example, GMC and NMC have memoranda of understanding with the Healthcare Commission to enable them to share information when education has wider implications for patient safety.

#### **4. Managing relationships with other organisations**

We asked the regulatory bodies whether other bodies in their sector were involved in QA and if they were, how, when and where the regulators worked with them.

This prompted a mixed response. For some regulators, they are the only profession-specific organisation with a formal role in quality assurance. However, this does not preclude good working relationships with professional bodies, for example around regular reviews of standards of proficiency and codes of practice.

The widest experience, unsurprising given their breadth of register, came from the HPC. Many professional bodies are involved, but there is no consistency to the extent and level of involvement. Some develop detailed curriculum guidance (referred to in 4.2 of

HPC's standards of education and training). Some have their own accreditation processes, such as the Chartered Society of Physiotherapy. In these situations, the HPC told us they would aim to run visits alongside other bodies if that was what the education provider wanted. However, all decision-making remained independent.

The GMC reported a close informal working relationship with the QAA. In their current review of *Tomorrow's Doctors* the GMC have undertaken standards mapping exercises and are proposing that QAA standards be referred to where they are relevant and sufficient rather than creating medicine-specific standards. The Postgraduate Medical Education and Training Board is due to be merged with the GMC in 2010, placing responsibility for all medical education in the GMC.

Beyond the professional bodies, there are other organisations with an interest in QA that regulators work with – QAA, Skills for Health, Ofsted, QCA, SQA. Regulators also told us of close working relationships with representatives of higher education and deans of schools. For example, the RPSGB referred to the value of a single forum in which they can speak to all heads of pharmacy in the Council of University Heads of Pharmacy.

## **5. Summary and next steps**

Our work so far has revealed some of the similarities and differences in approaches taken by regulatory bodies to quality assuring undergraduate (pre-registration) education, outlined how patient safety and public protection are ensured in education, the flexibility in current approaches and the nature of relationships with some other bodies in the sector.

A key question is whether the nature of these similarities and differences is a cause for concern, and for whom, and what the impact (direct or indirect) may be on patient safety and public protection. The assurance of clinical practice placements, and relationships between employer and education providers on this issue is worthy of further investigation. We intend to gather views from across the sector, and beyond, and from this we will seek to identify areas of good practice and whether there is scope for alteration in current approaches.

## **Annex A – brief overview of regulators’ quality assurance processes**

### **General Chiropractic Council**

The GCC publish *Criteria for Recognition of Degrees in Chiropractic*, focusing on programme outcomes. These outcomes are linked directly to the GCC standards for the ethical, competent and safe practice of chiropractors and must be met for a degree programme to gain approval. Currently three institutions provide chiropractic degree programmes in the UK. Between them they generate around 270 graduates per year.

GCC operates a recognition system whereby every five years the course offered will be ‘re-recognised’ under the same process as initial recognition. Following submission of business plans and other documentation to the Education Committee, and the Committee is satisfied about the financial position for delivering the degree programme, full recognition process begins.

At least two months after the submission of the document a visit will take place involving a panel of 5-6 visitors, chaired by a lay member of the Council, and including two chiropractic members, one or two educationalist members and a QA consultant. During this time, a detailed analysis of the documentation will have been undertaken and considered by the Education Committee, so that it can identify any particular areas of concern to be pursued by the visiting panel. A report and recommendations are sent to the Education Committee normally within six weeks.

The Committee considers the report and invites the Institution to comment before final recommendations are made by the Education Committee to the General Council. From here, the GCC then seeks the approval of the Privy Council. It can take some months for the Privy Council to respond, so to avoid undue delay the GCC asks the Privy Council Office to agree that the Institution can advertise the qualification as being ‘subject to the approval of the Privy Council’ (much as some degrees are advertised as ‘subject to validation’).

Recognition, with or without conditions, is always given for a specified period of time so Institutions will need to build this into their ongoing planning and development. Conditions will identify whether additional visits are required during the period of recognition. All institutions are required to submit an Annual Report to the GCC’s Education Committee.

### **General Dental Council**

In the UK there are 16 university dental schools, 19 institutions (mostly universities) producing about 200 dental hygienists and dental therapists per year; 11 institutions producing about 150 dental technicians per year; seven institutions producing 20-30 orthodontic therapists per year; and two institutions training clinical dental technicians in small numbers.

The GDC are midway through implementing the findings of an extensive strategic review of their work in education. As a consequence, QA processes are being radically revised to focus on learning outcomes (i.e. what a new graduate is competent and safe to do) and away from prescriptive guidance on what should be contained in a training programme (inputs). Thorough review of all curriculum guidance and QA processes is ongoing, complemented by new student fitness to practise guidance.

Previously, each dental school was visited in every six years, in the same two year period, based on the standards document *The first five years*. Traditionally very thorough, the last round of visits took place in 2003-2005. For new schools, visits happened annually to follow the progress of the first cohort.

For those providing education for dental care professionals, a more flexible approach to QA has been adopted over the last two years with a smaller panel of visitors, appropriate to the course, looking at thresholds and sufficiency.

Paper-based annual monitoring has been introduced for all dental education providers. While the strategic review is being fully implemented, annual monitoring will stay in place for 2009, and the new process will be introduced in October 2010.

### **General Medical Council**

There are 29 universities offering undergraduate medical degrees in the UK.

The GMC's standards for undergraduate medicine, which provide the framework for quality assurance, are published in the document *Tomorrow's Doctors* (currently under review). The GMC's role is to define the outcomes graduates are expected to reach and sets standards for the delivery of the programme. These outcomes and principles are set at a high level so that medical schools are able to devise and quality manage evolving curricula that are responsive to emerging practice and changing healthcare environments. *Tomorrow's Doctors* is a flexible framework that allows the provision of supplementary guidance in response to needs identified through quality assurance processes or other stakeholder engagement.

The GMC's quality assurance programme is known as QABME (Quality Assurance of Basic Medical Education). QABME has two key elements: an annual return provided by all medical schools and a visit process that is adapted for new medical schools and medical schools undergoing significant change.

The annual returns process facilitates monitoring of corrective action, innovation and other changes without the constraint of a bureaucratic approvals process. It encourages continuous development of curricula while allowing the GMC to keep abreast of development and target further investigation and quality assurance activities where there are concerns.

The GMC will visit each medical school at least twice within every 10 years. Visits are undertaken on behalf of the GMC by a team of approximately 8-10 medical and educational professionals, medical students and lay members. The visiting teams are assigned to a school and are responsible for all stages of the visit process for their school. Visitors undergo mandatory annual training.

The main stages of the visit process are:

1. Collecting information (June to December)
2. Confirming information (January to July)
3. Integrating information and making judgements (June to August)

These time frames may vary slightly to respond to individual school timetables. The visit process for an established school is generally 18 months from notification of selection to the GMC's endorsement of the visiting team's report.

The visit process may vary for established schools proposing major changes to curriculum, facilities or supervisory structures. For example, if changes are limited to one or two years of the school's curriculum the visit process may be completed in the standard 18 month timeframe. Alternatively, if extensive changes are planned across the curriculum the visit process may be repeated over a number of years as the changes are rolled out. Similarly, the visit process will vary for established medical schools wishing to change their degree awarding arrangements.

Four new medical schools have been established in recent years. The process for monitoring the progress of these schools involves the same systematic three-stage process applied to established schools. However, quality assurance activities are carried out for each year for the duration of the first medical student intake's degree course, assessing the development and delivery. This process results in annual reports that enable the Education Committee to gauge the progress of each school and compare progress across schools.

Final reports provide summary of key findings including any requirements, identification of areas for quality enhancement and identification of areas of innovation and good practise. The main body of the report then provides a detailed analysis of curricular outcomes, curricular content, student performance and competence and student health and conduct. Reports also include a response by the medical school.

Through the Annual Return process every year, each medical school must provide a return to the GMC that:

- Identifies significant changes to curricula, assessments or staffing.
- Highlights risks or issues of concern, proposed solutions and corrective actions taken.
- Identifies examples of innovation and good practice.
- Responds to issues of interest and debate in medical education, including promoting equality and valuing diversity.
- Identifies progress on any requirements or recommendations arising from the QABME visit process.

If there is need to investigate an issue, for example the introduction of a new curriculum or significant changes to the curriculum or facilities, the school may be requested to submit detailed information for analysis or may be selected for the QABME visit process.

### **General Optical Council**

GOC approves eight training institutions to provide optometry degree programmes and five institutions to provide ophthalmic dispensing training programmes in the UK. GOC requirements for both optometry and dispensing optician courses address course construction, teaching learning and assessment, student progression and achievement, staffing and resources and facilities.

In 2008, the GOC concluded that the curriculum for UK undergraduate training in optometry should be redefined as competency statements to be:

- compatible with the GOC's strategy of a competency based registration process;
- to allow for easier comparison with European curricula; and
- to be compatible with the principles of the Bologna Agreement.

The GOC operates a visit process to quality assure optics training in the UK. Currently, visits are annual for the first cohort of students taking the course, and every three to five years thereafter. Each Visitor Panel consists of six members, supported by a GOC Officer, who are on site for no more than three days. The GOC maintains a list of 18 fully trained Visitors, made up of dispensing opticians, optometrists, ophthalmologists and educationalists. Panel members undergo comprehensive training throughout their tenure, including annual refresher sessions, self assessments and appraisals.

A letter to be sent to existing providers one year before the process is due to commence, and with negotiation to determine the broad time frame for the visit. The visiting process for optometry courses takes approximately 30 weeks from the initial letter from GOC to the education provider through to the final report (week 26) and the provision of an action plan by the education provider (week 30)

In 2008 the GOC also undertook a review of the QA visit process to ensure that the process remained fit for purpose and wherever possible the GOC was able to utilise existing quality assurance reports and processes to obtain the information it requires and to reduce the burden of the accreditation process on both the institutions and the regulator.

The outcome of the review was a decision to introduce an annual monitoring scheme, which would enable the GOC to gain data, monitor progress and be informed on any proposed changes to optics programmes on an annual basis.

The new process requires each institution to submit an annual monitoring form in which they must provide details of progress against the conditions and recommendations of the previous visit, notification of any changes (or proposed changes) to the programme structure, content, assessment methods etc or to staffing and resourcing, student progression and achievement data and clinical records.

This will allow the quinquennial visits to be much more focused on the areas of risk, on clinical patient experience, supervision and areas identified for improvement or change. The length of visits themselves will be reduced from four to two days. The annual monitoring forms for the years proceeding a visit will be used as pre-visit information for the panel, together with additional feedback collected from employers, supervisors and patients via questionnaires which will be sent to these groups in advance of a visit and the responses will be collated into a meaningful report to assist the Panel.

This new scheme is being piloted in February 2009 with full roll out to all Optometry programmes planned for Autumn 2009. Roll out will then be extended to dispensing programmes in early 2010 following full panel visits to all dispensing courses in 2009.

### **General Osteopathic Council**

The GOsC accredits ten providers of osteopathy courses to ensure they meet the minimum standards required to produce osteopaths who are safe and competent to practise. The standards that must underpin osteopathy courses are:

- Standard of Proficiency –the standards of osteopathic practice expected of registrants and the level to be attained by a graduating osteopath.
- Code of Practice – requirements in relation to conduct and ethics to be observed by osteopaths and the level expected of graduating osteopaths.

- Osteopathy Benchmark Statement – an educational benchmark developed and published in conjunction with the QAA, outlining the expected standards of delivery of education.

If a course meets these standards, then it is awarded a 'Recognised Qualification' (RQ) which generally lasts for a period of between one and five years, although in practice new courses are approved for one to two years. The initial award of an RQ is based on a report of a team of specialist reviewers, who review the course documentation and visit the institution to gain any necessary evidence. The visit generally lasts three days and takes account of teaching (clinical and theory), as well as including interviews with staff, students and reviews of patient feedback where possible. This process is repeated at the point where an RQ is due to expire, in order to renew the accreditation.

The GOsC contracts with the QAA to undertake the review, the visit and production of an evaluative report. The QAA trains specialist reviewers, both lay and osteopaths, selects teams to conduct RQ reviews and produces reports which are considered by both the GOsC Education Committee and Council before a final recommendation on course accreditation is made to the Privy Council (which has final say on the approval of osteopathic courses).

The review team in recognition and renewal reviews will normally consist of a Review Coordinator, two specialist osteopath visitors and one lay visitor. In advance of the review, QAA will communicate to the GOsC the suggested composition of the review team. Providers to be reviewed will have the opportunity to comment on suggested review team composition. Responsibility for the appointment of visitors rests with the GOsC.

In addition to the RQ reviews conducted by the QAA, the GOsC also requires institutions offering osteopathic courses to submit an annual report to the Council, outlining any significant changes to the course provision, providing statistics on student and patient profiles and answering any specific areas of interest that the GOsC may have. The GOsC also include site visits as part of their monitoring reviews.

### **Health Professions Council**

The HPC standards of proficiency (SOPs) are threshold standards for safe and effective practice that all registrants must meet. They include both generic elements, which all registrants must meet, and profession-specific elements. These standards play a central role in how to gain admission to and remain on the Register and thereby gain the right to use protected title(s).

HPC's Standards of Education and Training (SET) are the standards that an education programme must meet in order to be approved as an education provider for any of the 13 professions overseen by HPC. These generic standards ensure that anybody who completes an approved programme meets the standards of proficiency and is therefore eligible for admission to their profession's Register. The standards cover:

- the level of qualification for entry to the Register;
- programme admissions;
- programme management and resources;
- curriculum;
- practice placements; and
- assessment.

All courses will be visited as part of the initial approval process, but there is no structured visit schedule thereafter. Programmes are awarded 'open-ended approval' subject to satisfactory ongoing monitoring. Both annual monitoring and major change processes may trigger a new approval visit.

Visits are coordinated and managed by the HPC. The HPC visit panel is normally made up of one education executive and two visitors, at least one of whom is from the same part of the Register as the profession with which the programme is concerned.

Once approved, the HPC monitor programmes annually on a two year cycle. It involves two different processes of monitoring submissions – audit and declaration. Declaration forms are submitted to the Education & Training Committee for ratification. Audit forms are reviewed by an HPC visitor from the same part of the register, and preferably one involved in the initial approval visit. Following this, additional information may be requested.

The annual monitoring process draws heavily on the education providers' existing documentation and is guided by previous QA activity. Each academic year, programmes that were approved by HPC in the prior academic year, or are currently going through the approval process, will not normally be subject to annual monitoring.

Once an assessment has been made, visitors can make the following recommendations:

- the programme continues to meet standards
- there is insufficient evidence to show how the programme continues to meet standards and a visit is required to gather evidence to show how the programme meets the SETs and SOPs and, if required, place conditions on ongoing approval
- additional information is required in order for the visitors to make their recommendation

The major change process considers significant changes to a programme and the impact of these changes in relation to standards. Any change that significantly alters how SETs and SOPs are met should be reported to the HPC who make a decision on the most appropriate course of action. HPC can decide to assess the impact of a change using the annual monitoring, major change or approval processes at this stage. If the major change process is used, education providers are asked to map the impact of the change against the SETs. This is assessed alongside previous reports by visitors and recommendations are sent to the Education and Training Committee.

### **Nursing and Midwifery Council**

The NMC currently approve 84 programme providers across the UK. These offer over 1100 approved programmes covering pre-registration nursing and midwifery, return to practice for all three parts of the register and post registration qualifications, including specialist community public health nursing, teacher programmes and non-medical prescribing.

The NMC base their annual monitoring on a range of identified risks to quality education and requires all education providers to show they are accurately controlling those risks, which include:

- Resource inadequacy
- Inadequate safeguards for monitoring student conduct

- Inadequate governance of practice learning
- Failure to provide learning opportunities of a suitable quality
- Unreliable conformation of achievement
- Failure to incorporate essential skill clusters or address required learning outcomes
- Failure of internal QA systems to provides assurance against NMC standards

The NMC contract out their QA operations to two suppliers: HLSP in England, Scotland and Northern Ireland and Healthcare Inspectorate Wales (HIW).

Approval/re-approval events for programmes take place every five years; risk-based monitoring events for providers take place annually. Programme approval/re-approval is undertaken jointly between the NMC, an approved programme provider and other stakeholders, which will normally include the placement providers and commissioners of the programme, as well as students, users and carers. If a programme is approved subject to conditions, these must be completed before the programme is allowed to run. Any recommendations identified will form part of subsequent annual monitoring.

Annual monitoring is the process by which the NMC seeks assurance that approved programmes continue to be delivered in accordance with NMC standards, that key risks to public safeguarding are controlled. Underpinning this quality assurance event is the production of an annual report by programme providers. The annual monitoring event itself takes place over one to three days and from the information gathered the managing reviewer's hypotheses of risk is tested, a collective judgment is reached and a draft evidence based report on the programme(s) is developed. The NMC uses a Red Amber Green approach to reporting as an effective method of reporting outcomes and risk control. Feedback on the process is then provided to (and requested from) the education provider. A final report is then submitted to the NMC. Monitoring reports are concise (1-3 pages) and consist of a summary of key findings which addresses the extent to which key risks are controlled.

A provider is awarded one of the following grades:

- Outstanding: Exceptionally and consistently high performance with examples of effective practice which is innovative and worthy of dissemination and emulation by other programme providers.
- Good: The element/programme enables students to achieve stated learning outcomes without need for specific improvements.
- Satisfactory: The element/programme enables students to achieve stated learning outcomes but improvement is needed to overcome weaknesses.
- Unsatisfactory: Exceptionally low performance. The element / programme makes a less than adequate contribution to the achievement of stated learning outcomes. Significant and urgent improvement is required to become acceptable.

The overall outcomes of monitoring activity in 2007-08 resulted in providers being placed in one of the following categories for monitoring in 2008-09:

- Programme providers with well-developed risk control: these are asked to carry out a self-assessment for one year, using the same reporting format as the NMC's reviewers (31 providers)
- Programme providers with acceptable risk control: these are considered to be managing acceptably and are subject to a standard 2-day visit (33 providers)

- Programme providers with weaker levels of risk control; these will be subject to a 3-day visit. Visits to these institutions will be carried out early in the academic year to allow time for a re-visit if required (20 providers)

Under normal circumstances approved institutions can undertake improvement and enhancement of NMC approved programs through their own internal processes. NMC must be notified however, and all programme modifications and developments must be reported in the Annual Report. Where modifications introduce more significant changes to approved programs it may be necessary for NMC reviewers to participate in the programme provider's internal processes in order to provide assurance of continued compliance with the relevant NMC standards.

### **Pharmaceutical Society of Northern Ireland**

The PSNI adopts the RPSGB system of quality assurance of undergraduate education in Northern Ireland. From September 2009 there will be two schools of pharmacy in Northern Ireland.

Having assessors with specific knowledge of Northern Ireland legislation (e.g. Medicines Act 1968, Pharmacy Northern Ireland Order 1976) and practice (e.g. emerging cross border service and regulation issues, Northern Ireland specific services such as the Minor Ailment Scheme etc) on the accreditation panels of Northern Ireland Pharmacy Schools enables changes in practice specific to devolved areas to be reflected in the quality assurance process.

### **Royal Pharmaceutical Society of Great Britain**

There are 22 undergraduate schools of pharmacy in the United Kingdom.

The RPSGB accredits all UK MPharm degrees and successful completion of a course allows a pharmacy graduate to apply for preregistration training. The accreditation process is different for new and existing schools, although the underlying principles are the same: it is evidence based, involves peer review and is cyclical. New schools are required to submit a business plan and detailed syllabus in advance of students entering the course: the school is then visited in each of the first four years of delivery of the MPharm; only then is full accreditation given. Once a new school becomes an existing school it is reaccredited quinquennially. Accreditation can be suspended or withdrawn (by Council) if there are concerns about the standard of an MPharm.

Accreditation panels have a range of expert practitioners from the main pharmacy sectors, plus lay visitors whose remit is patient safety and public protection.

UK MPharm degrees are designed with reference to the Society's Indicative Syllabus, which has 51 items under the following broad headings:

- The Patient
- Medicines: drug action
- Medicines: the drug substance
- Medicines: the medicinal product
- Healthcare systems and the roles of professionals
- The Wider Context

As a framework around which MPharm degrees are designed, the RPSGB has defined 50 criteria, all of which need to be met by providers (except one, the use of inter-professional learning, which is recommended). The first five relate to EU requirements, the sixth to minimum entry standards for English Language and Mathematics (GCSE grades A-C or equivalent), seven-31 outline graduate outcomes (the nearest thing to competencies the Society uses) and the remainder, 32-50, deal mainly with the academic infrastructure supporting delivery.

A condition of accreditation is that annual reports on student progress and resources available for the course are submitted to the RPSGB. Furthermore, when course changes are substantial, the RPSGB should also be informed. Generally changes are dealt with by staff, if the proposed change is reasonable and it does not substantially affect accreditation and the institution is informed as soon as possible. If changes are so substantial that the MPharm alters drastically, a full accreditation event would have to be arranged. If there are concerns about the standard of an MPharm, accreditation can be suspended or withdrawn.

## Annex 2

### European standards for the external quality assurance of higher education<sup>1</sup>

2.1 Use of internal quality assurance procedures: External quality assurance procedures should take into account the effectiveness of the internal quality assurance processes described in Part 1 of the European Standards and Guidelines.

2.2 Development of external quality assurance processes: The aims and objectives of quality assurance processes should be determined before the processes themselves are developed, by all those responsible (including higher education institutions) and should be published with a description of the procedures to be used.

2.3 Criteria for decisions: Any formal decisions made as a result of an external quality assurance activity should be based on explicit published criteria that are applied consistently.

2.4 Processes fit for purpose: All external quality assurance processes should be designed specifically to ensure their fitness to achieve the aims and objectives set for them.

2.5 Reporting: Reports should be published and should be written in a style, which is clear and readily accessible to its intended readership. Any decisions, commendations or recommendations contained in reports should be easy for a reader to find.

2.6 Follow-up procedures: Quality assurance processes which contain recommendations for action or which require a subsequent action plan, should have a predetermined follow-up procedure which is implemented consistently.

2.7 Periodic reviews: External quality assurance of institutions and/or programmes should be undertaken on a cyclical basis. The length of the cycle and the review procedures to be used should be clearly defined and published in advance.

2.8 System-wide analyses: Quality assurance agencies should produce from time to time summary reports describing and analysing the general findings of their reviews, evaluations, assessments etc.

### European standards for external quality assurance agencies

3.1 Use of external quality assurance procedures for higher education: The external quality assurance of agencies should take into account the presence and effectiveness of the external quality assurance processes described in Part 2 of the European Standards and Guidelines.

3.2 Official status: Agencies should be formally recognised by competent public authorities in the European Higher Education Area as agencies with responsibilities for external quality assurance and should have an established legal basis. They should comply with any requirements of the legislative jurisdictions within which they operate.

3.3 Activities: Agencies should undertake external quality assurance activities (at institutional or programme level) on a regular basis.

3.4 Resources: Agencies should have adequate and proportional resources, both human and financial, to enable them to organise and run their external quality assurance

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<sup>1</sup> European Association for Quality Assurance in Higher Education, 2009. *Standards and guidelines for quality assurance in the European higher education area*, 3rd edition. Available at: [http://www.enqa.eu/files/ESG\\_3edition%20\(2\).pdf](http://www.enqa.eu/files/ESG_3edition%20(2).pdf) [Accessed 20 May 2009]

process(es) in an effective and efficient manner, with appropriate provision for the development of their processes and procedures.

3.5 Mission statement: Agencies should have clear and explicit goals and objectives for their work, contained in a publicly available statement.

3.6 Independence: Agencies should be independent to the extent both that they have autonomous responsibility for their operations and that the conclusions and recommendations made in their reports cannot be influenced by third parties such as higher education institutions, ministries or other stakeholders.

3.7 External quality assurance criteria and processes used by the agencies: The processes, criteria and procedures used by agencies should be pre-defined and publicly available. These processes will normally be expected to include:

- a self-assessment or equivalent procedure by the subject of the quality assurance process;
- an external assessment by a group of experts, including, as appropriate, (a) student member(s), and site visits as decided by the agency;
- publication of a report, including any decisions, recommendations or other formal outcomes;
- a follow-up procedure to review actions taken by the subject of the quality assurance process in the light of any recommendations contained in the report.

3.8 Accountability procedures: Agencies should have in place procedures for their own accountability.

## Annex 3

### World Health Organization / World Federation of Medical Education Guidelines for Accreditation define a number of essential elements<sup>1</sup>

- Authoritative mandate
- Independence from governments and providers
- Transparency
- Predefined general and specific criteria
- Use of external review
- Procedure using combination of self-evaluation and site visits
- Authoritative decision
- Publication of report and decision

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<sup>1</sup> Karle, H, 2008. *World Federation for Medical Education Policy on International Recognition of Medical Schools' Programme*. Ann Acad Med Sing 37:1041–1043