

Assuring patient safety through regulation

A review of our work, September 2009

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1. Foreword

The value and failures of regulation have been much exposed to public view this last year. With a new council, new legal powers and a new sense of direction the Council for Healthcare Regulatory Excellence is determined to play a leading part in future debates on regulatory improvement and reform.

We aim to develop right touch regulation in healthcare. We need to find just the right balance of standard setting, professional development and revalidation which will help knowledgeable, talented, creative professionals to thrive. We need to find simpler ways for remediating or eliminating dangerous practice or bad behaviour.

Right touch regulation means doing more with less. We have already started to reduce the burden of our performance reviews on the regulators by addressing ourselves more clearly to outcomes. In making a judgement on how they perform we seek more insight with less oversight, we aim to ask less but understand more.

Right touch regulation will mean always asking ourselves what risk we are trying to regulate. To be proportionate and targeted in regulating that risk or to find ways other than regulation to promote good practice and safety.

Right touch regulation will mean anticipating the future. Healthcare is a rapidly changing global market. Technical innovations, changes in practise, mobility of patients and professionals, healthcare challenges such as hospital acquired infection or the 'flu' pandemic all test our ability to reassess risk and respond precisely. Regulation itself must be agile, anticipatory, and innovative if it is to keep pace with developments in healthcare and support, not stifle improvements.

We seek to apply these standards to ourselves; to be right touch in our ways of working, to do no more than is necessary for the outcome we want, to support and encourage good practice and to be an independent voice for patients and the public in the regulation of health and social care.

'Our approach is clear; regulation must always justify itself in the public interest. Regulation that is excessive, pointless or wasteful does not promote the public good. Over regulation undermines professionals and infantilises the public, under-regulation allows incompetence and dishonesty to prosper.'

Harry Cayton
Chief Executive, Council for Healthcare Regulatory Excellence

Harry Cayton has been Chief Executive of CHRE since August 2007. He worked for 22 years in the voluntary sector as Director of the National Deaf Children's Society, then Chief Executive of the Alzheimer's Society before being appointed National Director for Patients & the Public at the Department of Health in 2002. He is Chair of the National Information Governance Board for Health & Social Care, Advisor to The Health Foundation, Macmillan Cancer Support and National Voices and a Trustee of Comic Relief.

2. Summary

- 2.1 The Council for Healthcare Regulatory Excellence promotes the health, safety and well-being of patients and other members of the public in the regulation of health professionals. We scrutinise and oversee the work of the nine regulatory bodies that maintain the registers of health professionals.
- 2.2 We share good practice and knowledge with the regulatory bodies, conduct research, and introduce new ideas about regulation to the sector. We monitor policy in the UK and Europe and advise the four UK government health departments on issues relating to the regulation of health professionals. We are an independent body accountable to the UK Parliament.
- 2.3 We promote good practice in the regulation of health professionals in five main ways:
 - We review the performance of the regulatory bodies annually to identify areas where regulators are doing well and where they can improve
 - We audit initial stages of the regulatory bodies' fitness to practise procedures and examine final decisions made by them about whether health professionals are fit to practise. In some cases we refer final decisions to Court where we believe that such decisions are unduly lenient
 - We conduct research, share learning with regulatory bodies and hold events to explore ways of understanding and managing new challenges
 - We advise the Secretary of State for Health and health ministers in Northern Ireland, Scotland and Wales on matters relating to the regulation of health professionals
 - We keep up to date with European and international policies to improve policy decisions on UK regulation of health professionals. We inform colleagues in other countries of the outcome of our good practice projects that might be relevant to them.

3. Health professional regulators

- 3.1 The nine health professional regulatory bodies that we oversee were established to protect and promote the safety of the public. They do this by setting standards of behaviour, education and ethics that health professionals must meet. The regulators keep registers of health professionals who are fit to practise in the UK. They can remove health professionals from their register and prevent them from practising if they consider this to be in the interest of public protection.

3.2 The nine health professional regulators are:

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

4. 2008/09 – working to ensuring patient safety through regulation

- 4.1 In 2008/09 we worked with a range of stakeholders, including patient and public representatives, to scrutinise and improve health professional regulation in the interests of patients, the public and others.
- 4.2 Five organisational objectives identified in our *Strategic Plan 2008/09 – 2010/11* provide the basis for our work. This document sets out our achievements against each of these objectives.

Identifying and spreading good practice through high quality scrutiny and performance review of the regulatory bodies

- 4.3 Our oversight and scrutiny of the regulators has a focus on protecting patients and the public. We check that decisions made by regulators on the fitness to practise of health professionals protect the public. We review the regulators' work, ensuring that they carry out their statutory responsibilities. We also identify the strengths and areas for improvement in each of the regulators' performance.

Reviewing the regulators' final decisions on fitness to practise cases

- 4.4 Each regulator has a fitness to practise process for handling complaints made by patients, employers or the public about individual health professionals. We scrutinise the regulators' final decisions about the fitness to practise of their registrants, referring final decisions to court if we consider them too lenient and where it is necessary to do so for public protection. In 2008/09 we reviewed 1,370 such fitness to practise cases.

Working with regulators to improve regulation

In 2007/08 we were asked by the Minister of State for Health in England to report on the Nursing and Midwifery Council (NMC). Our findings, set out in a special report published in June 2008 raised concerns about the NMC's fitness to practise processes, their management of cases and the quality of customer service for people involved in fitness to practise proceedings. With our input, the NMC created an action plan to address these issues. We delivered six training sessions to assist NMC staff and supported them in reaching improvements in their fitness to practise cases.

'With CHRE's help we have agreed how we should measure our performance, and have now begun to report using the new measures. They are much more meaningful and transparent and offer a holistic view, including information about the experience of those who are using our service.'

Ian Todd, Director of Fitness to Practise, Nursing and Midwifery Council

Auditing the initial stages of regulators' fitness to practise processes

- 4.5 The Health and Social Care Act 2008 gave us new powers to audit decisions made by the regulators at initial stages of fitness to practise cases. This is where regulators decide whether a complaint about a health professional should proceed to a fitness to practise hearing. This audit aims to assess whether the regulators' decision-making processes are effective and if the interests of patients and the public are protected. This report will be published in early 2010.

Our annual performance review of the nine health professional regulators

- 4.6 We review the way regulators carry out their functions and statutory responsibilities, checking that they promote patient and public protection in their work. Our review identifies and shares good practice with the regulators. We also identify strengths and areas for improvement in each of the regulators' performance
- 4.7 We measure the regulators' performance against a set of standards that covers their standards and guidance, registration, fitness to practise, education and training, governance and external relations.
- 4.8 In 2008/09 we found that all the regulators had carried out their statutory responsibilities and were focused on promoting the health, safety and well-being of patients and other members of the public. However we also identified that the quality of regulation and level of protection for the public still varies amongst regulators
- 4.9 For the first time this year we reported on the performance of the health professional regulators to the four UK parliaments.

4.10 We try to review and refine our process every year. In 2008/09 we held meetings with patients and the public. We took into account feedback received at these meetings, which indicated that we appeared to be too reliant on a regulator's self-assessment of its performance. We have since written to a large number of organisations who we considered had an interest in how the regulators performed, using these responses to further test and challenge the regulators' self-assessments.

Sharing learning points with the health professional regulators

4.11 We encourage continuous improvement in regulation by sharing learning points identified in our scrutiny work. Whilst the vast majority of final stage fitness to practise cases that we review do not get referred to the courts, this work helps us to give useful feedback to the regulators on their decisions and processes.

CHRE's performance review – a benchmark for good practice

'The performance review gives us the opportunity to find out about the good practice emerging from the other regulators. We welcome the change to a standards-based approach, which CHRE has used in the last two performance review cycles. This is a lot more rigorous and useful to us as a regulator as it means we can benchmark ourselves against the standards.'

Duncan Rudkin, Chief Executive, General Dental Council

Using a balanced approach to working with the regulators

'I welcome CHRE's move from focusing purely on scrutiny of fitness to practise cases to areas where, by working with the regulators, CHRE adds value in the interests of patients. CHRE's willingness and determination to work in collaboration with the regulators means that the relationship is complimentary, not adversarial.'

Finlay Scott, Chief Executive, General Medical Council

Anticipating change, adapting and responding to the changing needs of health professionals

4.12 We promoted the term 'agility' as a sixth principle for good regulation. Examples below show how we have responded where appropriate to ensure that the message on patient protection is always considered in health professional regulation.

- **Commission on Scottish Devolution**

4.13 We responded to Sir Kenneth Calman's Commission on Scottish Devolution, an independent review of devolution in Scotland. The Commission's final report included our view that continued UK-wide health professional regulation is the most effective and efficient method of maintaining consistent standards of professional practice.

Advanced practice

The Department of Health (DH) report *A High Quality Workforce: NHS Next Stage Review* asked us to review the issue of advanced practice amongst health professionals. This was to determine whether development of health professionals' roles posed any risks to patient safety.

'The key findings from the report support a risk-based approach to future regulatory body activity. This is important when the drive towards a more proportionate approach to regulation in healthcare is at the forefront of policy making. The role of governance at a local level will play an essential part in responding to calls for proportionality.'

Audrey Cowie, Professional Adviser - Regulation and Workforce Standards, Scottish Government Health Directorates

- **Amendments to legislation in the interests of patient protection**

4.13 The Department of Health asked us to identify and prioritise the regulators' aspirations for future changes, particularly their governance structures and fitness to practise procedures. Our report in April 2009 included the recommendation that legislation should be implemented to enable regulators to progress plans for revalidation in the interests of public and patient protection. Revalidation requires professionals to periodically demonstrate that they remain up-to-date and fit to practise.

- **NHS Constitution**

4.14 In October 2008 we responded to a consultation on the *NHS Constitution* which sets out core values and principles for the NHS in England. Our response highlighted areas where the role of professional regulation could be clarified and where public awareness of the regulators' roles could be promoted. It suggested areas where the content of the constitution and the regulators' own standards might be better aligned to offer clarity for professionals and the public.

- **Data misuse/data security**

4.15 In light of increased awareness about risks in storing personal data, the Department of Health asked us to provide advice on how regulators can promote the secure use of patients' personal data to their registrants. Our report, published in July 2009, found that confidentiality and security of patients' data is a core value in the regulators' codes and standards. Some regulators provide additional guidance for professionals to ensure risks to patients' data are managed. We emphasised the importance of different forms of data storage, the risks and access issues that are associated with such forms of storage.

- **Legal Services Board**

- 4.16 We responded to a Legal Services Board consultation on regulatory independence. We supported their aim to make the regulation of legal services more independent and drew parallels between developments in health professional regulation and those being considered in the legal field.

Working with other countries to improve regulatory practice

- 4.17 We respond to European Union (EU) proposals to ensure that issues affecting health professionals or those with implications for public protection are considered. As well as submitting our responses to European policy consultations, we liaise with the Department of Health's international division where our views have been incorporated into wider government responses to the EU. We responded to the draft directive on patient's rights in cross-border healthcare, Europe-wide discussions on health issues and advice to different regulatory fields.

Regulatory Reform Committee

In March 2009 we submitted evidence to the House of Commons Regulatory Reform Committee. This committee examines draft legal reform in order to remove the legislative burden and to promote better regulation. Our concept of agility was quoted in the committee's report.

'...the Council for Healthcare Regulatory Excellence argued for inclusion of a further objective of in the regulatory agenda, that of "agility" – a state of readiness to respond to change. We agree that the financial crisis has demonstrated the need for regulators to be more adaptable and anticipating.'

Extract from the House of Commons Regulatory Reform Committee's ninth report of sessions 2008/09, Themes and Trends in Regulatory Reform.

Communicating effectively with all our stakeholders

- 4.18 Electronic communications have become increasingly important in keeping stakeholders informed of what we do. We introduced interactive website features such as our online surveys and discussions in 2008.

We launched an electronic newsletter and other channels for stakeholders to keep in touch with our work and deliver regular feedback. We continue to make advances in our work with patients and the public, professionals in the field of health, care and regulation and decision-makers in government and Parliament.

- **Working with patients and the public**

- 4.19 We listen to patients and the public when proposing ways by which patient safety can be promoted by health regulators. We set up our Public Stakeholder Network in March 2009, a community that is kept informed of our projects, consultations, discussions and events on a regular basis.

- 4.20 We believe that patients and the public are our partners and involvement with patients and patient representative groups is built into the work of all our teams.
- 4.21 In autumn 2008 we held public meetings in the four UK countries to present results of our performance review of the regulators. These meetings helped us to refine our proposals for working better with patients and the public in all four countries.

Working with the regulators' patient and public groups to promote patient and public involvement in health regulation

As well as promoting patient and public involvement within our own organisation, we belong to other patient and public groups such as the UK Health and Social Care Regulators' Public and Patient Involvement Group. This group reviews the regulators' public involvement policies and strategies.

'There's a strong push from the Department of Health to make patient and public involvement part of the regulators' everyday thinking, and that's what we're working towards. We value CHRE's contribution because whilst the individual regulators work with the public on their own profession-specific issues, CHRE enables public input at a wider and more strategic level.'

Martin Caple, Chair, UK Health and Social Care Regulators' Public and Patient Involvement Group

- 4.22 We work with health-related charities and regional patient groups. For example, we have developed good relations with National Voices and Local Involvement Networks (LINKs) in England, the Community Health Councils in Wales and other regional groups. We aim to extend this work with regional networks, particularly in Northern Ireland and Scotland in 2009/10.
- 4.23 We ran public consultations and discussions through our website during the year on:
- The proposed process for auditing the initial stages of fitness to practise processes
 - Our draft Welsh Language Scheme
 - Our draft three year strategic plan.

Working with professionals

- 4.24 We have increasingly been aware of professionals, including those in health professional regulatory bodies, who wish to be notified of our work in advance, as do members of our Public Stakeholder Network. In August 2009, we launched a Professional Network and have since received an encouraging number of registrations from professionals in the health sector, registrants of the professional health regulators and from wider regulatory sectors.

Engaging with policy and decision makers

4.25 We liaise with and regularly advise the Department of Health in England, the Northern Ireland Assembly, the Scottish Government and the Welsh Assembly Government on matters related to health professional regulation. We respond to direct commissions from the Secretary of State for Health in England and health ministers in Northern Ireland, Scotland and Wales. Regular meetings with the four governments facilitate discussions on topics of relevance to the individual countries, making us aware of country-specific issues to be considered in our work.

- **Providing advice to those who wish to develop and improve regulation**

4.26 Our expertise in health professional regulation enables us to advise others who aim to improve their regulatory functions. In 2008/09 we offered advice to a number of other organisations and facilitated a seminar series to stimulate debate and to exchange knowledge and experience. These series were attended by people from the fields of health, care and regulation.

Other ways in which we work to maintain the interest of patients

- **Quality assurance of undergraduate health education**

4.27 As part of their role to protect patients and the public, regulators set standards for education and training for those wishing to become health professionals. The government's report *A High Quality Workforce: NHS Next Stage Review* asked us to review processes that the regulators used to ensure that education providers meet these standards. We investigated whether the regulators' processes enabled them to ensure health professionals are trained to a level of competence that means they are safe to practise. The review looked at the health regulators' processes and those used in other fields, such as social care and architecture. The findings are available on our website.

4.28 As a result of this project we are working with regulators and other stakeholders to review and refine our standards for good regulation relating to quality assurance of education. Our work is intended to lead to changes demonstrating good practice and ensuring that patient and public safety is at the forefront of our quality assurance processes.

- **Registrants' health and the regulatory bodies**

4.29 Before being registered as a health professional, applicants must satisfy the regulators' registration requirements to show that they are fit to practise. One of these requirements relates to applicants' health. In 2007 the Disability Rights Commission, now part of the Equality and Human Rights Commission, identified health requirements as a barrier to people with impairments and long-term conditions pursuing careers in a number of regulated professions.

4.30 The Department of Health asked us to provide advice on this in relation to the health professional regulators. In our final report we put forward the view that professionals' health should be considered only in relation to their fitness to practise. We made several recommendations to ensure that health professionals and students with disabilities are not prevented from registering with a regulatory body or practising in their field.

- **Bringing our stakeholders together to exchange views from different areas of expertise or backgrounds**

4.31 We held a public conference in March 2009 to determine how partnerships between all parties: patients, the public, professionals, employers, regulators, education and government, could be developed to meet healthcare challenges, now and in the future.

Providing other forums for debate

In February 2009 we held a high level symposium to discuss future trends in health and regulation. Discussions included how complex regulatory systems could interact, how regulation could learn lessons from crises and how we can become more agile and better anticipate future developments.

During the year we held two seminar series. The topics discussed included the role of regulation in child protection, sexual boundaries between patients and health professionals and the issue of whistle-blowing.

'The seminars worked well because there were lots of contributions from healthcare professionals and those outside the health field. It was interesting to hear about different approaches to regulation from different industries and settings.'

Barbara Wood, Chair, Academy of Royal Colleges Patient/Lay Group

5. Our plans for 2009/10

5.1 Our Council is reviewing our strategic plan which will set the direction for our work for the next three years. We are increasingly moving from self-regulation by health regulators to an inclusive model of regulation based on a shared partnership between professionals, patients and the public.

Refining our scrutiny of the regulators

5.2 We will develop ways to use information from our scrutiny work for a risk-based approach in future years. We will focus our resources on areas where risk to patients and the public is the highest.

5.3 In 2009/10 we will be undertaking a revision of the performance review standards and process with input from the regulators, patients and the public and other stakeholders.

Broadening our knowledge base

5.4 During the coming year we will continue expand our understanding of regulation issues and the environment in which we work. Several areas for further research were identified by this year's performance review process and our scrutiny of the regulators which include:

- How regulators' registers of health professionals can contribute towards public protection
- Private prosecutions of people who use protected titles but are not registrants of relevant regulatory bodies
- Whether results of student fitness to practise procedures should be shared with their prospective regulatory body
- The role of regulators in ensuring that people with disabilities receive high quality healthcare
- Whether a registrant's response to a complaint should be shared with complainants in the initial stages of a fitness to practise case.

We are in the process of finding an academic partner to establish an international repository of information with respect to approaches to regulation worldwide.

Widening our engagement with stakeholders

5.5 In 2008/09 we laid the groundwork for increased involvement with stakeholders.

In the coming year we will focus on recruiting members to our Public Stakeholder Network and Professional Network.

5.6 In spring 2010 we will hold meetings with patients and the public in the four countries to increase mutual understanding and to strengthen our partnerships with patients and patient representative groups.

5.7 We will invite some members of our Public Stakeholder Network to audit our external communications in spring 2010.

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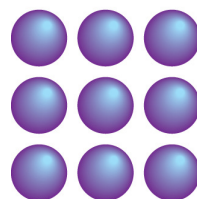
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