



ETHICS FOR HEALTHCARE REGULATORS: ENHANCING COMPLIANCE WITH THE SEVEN PRINCIPLES OF PUBLIC LIFE

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Contents

.....	0
1. Scope and Purpose of the Report	2
Summary and Recommendations	3
2. The Six Healthcare Regulators	6
2.1 The Care Quality Commission (CQC).....	6
2.2 Healthwatch England (HWE).....	9
2.3 The Professional Standards Authority for Health and Social Care (PSA)	10
2.4 The General Medical Council (GMC).....	11
2.5 The Nursing and Midwifery Council (NMC)	11
2.6 The Human Fertilisation and Embryology Authority (HFEA)	12
3. Key Challenges in Healthcare Regulation	13
3.1 Complexity of Healthcare Provision and its Organisation	13
3.2 Budgetary Constraints.....	14
3.3 Regulatory Complexity.....	14
3.4 Principles and Values	15
4. Enhancing Compliance with the Seven Principles of Public Life	23
4.1 Principles-Based, Goals-Driven Healthcare Regulation	23
4.2 Adopting Best Practice in Internal Governance.....	26
4.3 Encouraging Reflexivity in the Use of Expert Advice	26
4.4 Patient Involvement.....	33
4.5 Compliance, Enforcement and Sanctions Activities	36
5. Conclusion.....	39
Annex: The Seven Principles of Public Life.....	40

1. Scope and Purpose of the Report

This report deals with the ethical standards adopted by regulators within the healthcare sector. It has been commissioned by the Committee on Standards in Public Life. The meaning of 'ethical standards' for this purpose is based on the Seven Principles of Public Life: - selflessness, integrity, objectivity, openness, accountability, leadership and honesty (the Seven Principles).

While the report provides recommendations on healthcare regulation in general, within that, six healthcare regulators were chosen for particular examination. These are:

- The Care Quality Commission (CQC)
- Healthwatch England (HWE)
- The Professional Standards Authority for Health and Social Care (PSA)
- The General Medical Council (GMC)
- The Nursing and Midwifery Council (NMC)
- The Human Fertilisation and Embryology Authority (HFEA)

This report focuses on NHS healthcare provision, although its contents will have wider application to healthcare funded through other means such as insurance or private funding.

The geographical extent of the report is England but its recommendations may be of interest to healthcare regulators in other countries.

Summary and Recommendations

*'The most effective regulation comes from a mixture of principles-based standards (developed by a process involving patients, carers and the public) and technical specifications where appropriate, supported by an inspection regime with true experts who are able to apply thoughtful judgement and the right actions in response.'*¹

This report suggests that key features distinctive to the healthcare arena pose particular challenges to regulators in relation to their compliance with the Seven Principles. These are:

- The complexity of healthcare provision and its organisation;
- Budgetary constraints on healthcare provision;
- The complexity of healthcare regulation; and
- A plethora of principles and values said to apply to and guide healthcare provision and its regulation.

Such challenges threaten the ability of regulators to maintain a reputation of coherent and consistent regulation, with consequent implications for their own legitimacy and credibility, and for their ability to achieve their regulatory goals. The report therefore makes recommendations about how these challenges can be overcome:

¹ National Advisory Group on the Safety of Patients in England, *A Promise to Learn, A Commitment to Act: Improving the Safety of Patients in England*, (August 2013) 30.

- Given the complexities of the fields in which they operate, healthcare regulators require high levels of expertise, knowledge and skill if they are to operate in a way which upholds the Seven Principles.
- Healthcare regulators are guided by a variety of principles and values in their work, and thus are engaged in Principles-Based Regulation (PBR) (either on its own or in combination with other regulatory approaches).
- PBR is most effective when it uses a core goal or goals to assist in the application and interpretation of relevant principles. Healthcare regulators should be encouraged to agree on a unified goal of their activities.
- Healthcare regulators should recognise that the primary goal of their activities is to ensure quality of care and patient safety. (Other goals will relate to the individual regulator's remit).
- Regulators should assess their internal governance structure and processes to ensure they are consistent with best practice, and communicate with each other in this regard to learn from exemplary approaches.
- Healthcare regulators cannot fulfil their duty to comply with the Seven Principles if they act in isolation. They must, and do, collaborate with experts to inform their decision-making, ensuring that it is based on an accurate account of relevant factors. This must be done in a reflexive manner on the part of both regulator and advisor so that the process does not fall prey to vested interests and so that there is room for consideration of wider patient and societal concerns.

- Regulators should communicate with each other on best practice in obtaining information from and engaging with patients as part of achieving their regulatory goal of ensuring quality of care and patient safety. Such contributions need to be managed by expert regulators which are able to encourage reflexivity in this engagement whilst recognising the distinctive challenges for patients to contribute to regulatory processes. Regulators should put in place mechanisms to require and enable them to demonstrate how patient information has been used to achieve the regulatory goal.
- Healthcare regulators should communicate on the appropriate enforcement approach for the healthcare sector so that those working in the sphere are subject to a consistent approach. In the spirit of regulatory collaboration, a multi-agency exploration of best practice in compliance, enforcement and sanctions (CES) should be undertaken which recognises the potential for regulatees to be subjected to a form of “multiple jeopardy” in CES terms, with many healthcare regulatees falling under the scrutiny of numerous regulators.

The aims of healthcare regulation and the regulated activities can only be realised if the application of the relevant regulation, like the activities it governs, is truly collaborative. These recommendations are intended to avoid the dangers of a restriction of regulators’ ability to encourage compliance which a lack of legitimacy may engender, whilst enhancing opportunities to achieve the regulatory goal of quality of care and patient safety.

In order to achieve its goals, and in light of the complexities and distinct features of the healthcare sector, PBR must be implemented and applied by a knowledgeable, accountable regulator. No matter how narrow or broad the remit of the healthcare regulatory agency, the inherent complexity of the subject matter over which they have oversight, together with the area’s capacity to generate controversy, means that such regulators must possess high

levels of expertise both in relation to their understanding of the subject matter and to the application of the relevant regulatory method (in this sector, PBR).

2. The Six Healthcare Regulators

Six healthcare regulators have been selected for particular examination. These are:

- The Care Quality Commission (CQC)
- Healthwatch England (HWE)
- The Professional Standards Authority for Health and Social Care (PSA)
- The General Medical Council (GMC)
- The Nursing and Midwifery Council (NMC)
- The Human Fertilisation and Embryology Authority (HFEA)

These regulators were chosen on the basis that they oversee a comprehensive range of healthcare activities, from the provision of healthcare services, to healthcare professionals' behaviour, to medical research. They are examples of regulators at different stages of development, from the long established GMC, to the more recently formed CQC. They have a variety of accountability relationships, some with each other and others with external parties.² The Department of Health can actively intervene in the activities of certain regulators seen to be under-performing, while others are required to provide annual accountability reports.

2.1 The Care Quality Commission (CQC)

The CQC is the independent regulator of health and adult social care in England. Established under the Health and Social Care Act 2008, its purpose is 'to make sure health and social care services provide people with safe, effective, compassionate, high-quality care', and to

² For analysis of regulators' relationships with bodies to which they are accountable, see Black J, 'Calling Regulators to Account: Challenges, Capacities and Prospects', *LSE Working Paper 15/2012*.

encourage improvement in care services.³ It achieves this by registering, monitoring and inspecting services to make sure they meet the fundamental standards of quality and safety set by the CQC.⁴ It has a range of enforcement powers from the issuing of warning notices, to suspension or cancellation of registration, to prosecution.⁵ It publishes all inspection reports, including performance ratings, on its website, to help individuals make choices about their care.⁶ It is a large organisation which employed around 2681 full time equivalent staff as at 31 March 2015.⁷

The CQC is a non-departmental public body, sponsored by the Department of Health to which it is accountable for its performance and value for money. The CQC's remit was extensive from its inception, and has continually expanded since that time. For example, in October 2014, it started a regime to inspect every GP practice in England by April 2016; while in April 2015, it became responsible for monitoring the financial sustainability of the most difficult to replace care providers.⁸ Each expansion of its remit represents significant challenges in recruitment and development of relevant regulatory skills and knowledge. The scale of its remit has been said to have been underestimated by the Department of Health.⁹

In its short life it has been subjected to extensive review and criticism of its strategy, performance and leadership including by the National Audit Office,¹⁰ the Public Accounts

³ Care Quality Commission, *About Us: What We Do and How We Do It*, http://www.cqc.org.uk/sites/default/files/documents/20131108%206657_CQC_Aboutus_A5_Web%20version.pdf 2

⁴ These standards can be accessed at <http://www.cqc.org.uk/content/fundamental-standards>

⁵ For further detail about their enforcement approach see <http://www.cqc.org.uk/content/enforcement-policy>

⁶ Care Quality Commission, *About Us: What We Do and How We Do It*, note 3 above, 2

⁷ National Audit Office, *Care Quality Commission: Capacity and Capability to Regulate the Quality and Safety of Health and Adult Social Care*, HC 271 Session 2015-16 22 July 2015

⁸ National Audit Office, *A Short Guide to the Department of Health* (July 2015) Regulation and Oversight of Health and Social Care

⁹ National Audit Office, *Care Quality Commission: Capacity and Capability to Regulate the Quality and Safety of Health and Adult Social Care*, note 7 above, [4.8]

¹⁰ Ibid. See also <https://www.nao.org.uk/report/the-care-quality-commission-regulating-the-quality-and-safety-of-health-and-adult-social-care/>

<https://www.nao.org.uk/wp-content/uploads/2015/03/Making-a-whistleblowing-policy-work.pdf>

<https://www.nao.org.uk/wp-content/uploads/2015/06/Putting-things-right.pdf>

<https://www.nao.org.uk/wp-content/uploads/2015/10/Impacts-case-studies-2014.pdf>

Committee,¹¹ the Department of Health¹² and the Health Select Committee. Failings in care at the Mid Staffordshire NHS Foundation Trust, Winterbourne View and University Hospitals of Morecambe Bay NHS Foundation Trust highlighted significant failings in the CQC's regulation of the sector. The Department of Health has been closely involved in developing the CQC's new regulatory approach and in monitoring the organisation through regular accountability and finance meetings but intends to reduce its operational oversight in the future.¹³ It is not yet clear how the CQC's accountability, efficacy and efficiency will be structured after this happens.

In 2011 and 2012 the CQC was found not to have provided value for money. In March 2012, the Committee of Public Accounts reported that the Commission was a long way off becoming an effective regulator. The Commission has been working under a three-year transformation programme between 2013 and 2016 to address these criticisms.¹⁴ The CQC's executive leadership has also undergone significant reform and now includes the chief executive, three chief inspectors, a director of strategy and intelligence and director of customer and corporate services.¹⁵ The Commission's board has nine non-executive members who bring experience from a wide range of sectors. This combination of executive and non-executive members is said to help it to improve effectiveness and accountability.¹⁶

¹¹ Public Accounts Committee, *The Care Quality Commission: Regulating the Quality and Safety of Health and Adult Social Care*, Seventy-eighth Report of Session 2010–12, HC 1779

¹² Department of Health, *Performance and Capability Review of the Care Quality Commission* (February 2012) <https://www.gov.uk/government/news/performance-and-capability-review-of-the-care-quality-commission>

¹³ National Audit Office, *Care Quality Commission: Capacity and Capability to Regulate the Quality and Safety of Health and Adult Social Care*, note 7 above

¹⁴ *Ibid* [2]

¹⁵ *Ibid* [4.2]

¹⁶ *Ibid* [4.4]

2.2 Healthwatch England (HWE)

HWE is a committee of the CQC, working as an independent partner with it.¹⁷ It describes itself as ‘the national consumer champion in health and care’.¹⁸ Its purpose is to ‘understand the needs, experiences and concerns of people who use services and to speak out on their behalf.’¹⁹ Its vision is to achieve ‘a society in which people’s health and social care needs are heard, understood and met’.²⁰

HWE is supported in its work by local Healthwatch (LHW) groups situated across each of the 152 local authority areas. LHW gather information about people’s experiences of health and social care and represent their views to local providers, as well as providing information on services to local people. LHW are commissioned directly by local authorities and are independent organisations. HWE works with this network, gathering information on services, promoting and supporting good practice standards and informing national partners of matters of particular concern, such the challenges in navigating the NHS complaints system²¹. HWE has a relatively small staff²² while LHW consists of 800 staff members and 5400 volunteers.²³

HWE’s statutory powers extend over key national organisations such as NHS England, the Care Quality Commission, Monitor and each local authority in England, which are required to respond publicly in writing and to justify decisions queried by HWE.²⁴ HWE also has recourse to advise the Secretary of State for Health. These powers enable them to ‘ensure the voice of the consumer is strengthened and heard by those who commission, deliver and

¹⁷ It was established under s45 C(2) of the Health and Social Care Act 2008 as inserted by Health and Social Care Act 2012.

¹⁸ Healthwatch England, *Annual Report 2014-2015*, http://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/annualreport_final.pdf, 4

¹⁹ Healthwatch England, *Strategy 2014-2016*, http://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/healthwatch-england-strategy_2014-2016.pdf Section 2

²⁰ Healthwatch England, *Annual Report 2014-2015*, note 18 above, 6

²¹ Healthwatch England, *Suffering in Silence: Listening to Consumer experiences of the Health and Social Care Complaint System*, (October 2014) <http://www.healthwatch.co.uk/resource/our-report-complaints>.

²² <http://www.healthwatch.co.uk/our-staff-0>

²³ Healthwatch England, *Annual Report 2014-2015*, note 18 above, 7

²⁴ Healthwatch England, *Strategy 2014-2016*, note 19 above, Section 6

regulate health and care services'²⁵ and are therefore an important mechanism of accountability in health and social care.

HWE is governed by a Committee which sets its strategy, provides scrutiny and oversight, approves necessary policies and procedures and ensures compliance with rules applying to Arm's Length Bodies. The Committee comprises a Chair, appointed by the Secretary of State for Health, and 12 Committee members appointed by the Chair.²⁶ It negotiates funding directly with the Department of Health. The Chair of HWE is a Board Member of the CQC.

2.3 The Professional Standards Authority for Health and Social Care (PSA)

The PSA promotes the health, safety and wellbeing of patients, service users and the public by raising standards in the regulation and registration of people working in health and care. It is an independent body, accountable to Parliament through providing reports and evidence to the Health Committee.

The PSA oversees nine health and care professional regulators and reports annually to Parliament on their performance. As part of this oversight it conducts audits and investigations on fitness to practise cases, and can appeal their outcomes to court if sanctions applied are unduly lenient and it is in the public interest to do so. The PSA conducts research and advises the four UK governments on improvements in regulation. It also accredits voluntary health and care occupational registers to improve consumer protection and raise standards.

The PSA has been responsible since July 2012 for advising the Privy Council on the quality of the process which health and care professional regulators use to recommend candidates for appointment as chairs and members of their councils, assessing whether the process is fair,

²⁵ Healthwatch England, *Annual Report 2014-2015*, note 18 above, 6

²⁶ Healthwatch England, *Annual Governance Statement 2014-2015*, http://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/healthwatch_england_annual_governance_statement_201415.pdf

transparent and open, whether it inspires confidence, and whether it ensures all selection decisions are based on evidence of merit.²⁷

2.4 The General Medical Council (GMC)

The primary purpose of the GMC is to ensure public safety. Its overarching functions are to set the standards of behaviour, competence and education that doctors must meet; deal with concerns from the public about professionals who are unfit to practise because of poor health, misconduct or poor performance; and keep a register of doctors who are fit to practise including setting the requirements for revalidation.²⁸

The governing body of the GMC is the Council. It is responsible for the overall control of the organisation, ensuring that it is properly managed by the Chief Executive and team and that the organisation fulfils its statutory and charitable purposes. Council members are also the trustees of the GMC, which is a registered charity. The Council comprises 6 lay and 6 medical members, all appointed following an independent appointments process.

2.5 The Nursing and Midwifery Council (NMC)

The NMC is the independent regulator for nurses and midwives in England, Wales, Scotland and Northern Ireland.²⁹ Its overarching purpose is to protect patients and the public effectively and efficiently.³⁰ To this end it sets standards of education, training, conduct and performance. It maintains the register of nurses and midwives eligible to practise, oversees revalidation of such registration, and takes action in cases of alleged substandard practice.

The NMC is accountable to the public through Parliament. It is also a registered charity and the Council members are also the Charity trustees. As such Council members are required to

²⁷ PSA response to CSPL Questionnaire.

²⁸ Law Commission, Scottish Law Commission Northern Ireland Law Commission (LAW COM No 345) (SCOT LAW COM No 237) (NILC 18 (2014)) *Regulation of Health Care Professionals; Regulation of Social Care Professionals in England* (Cm 8839 2014) [1.7]

²⁹ It was established in 2002 under the Nursing and Midwifery Order 2001

³⁰ Nursing and Midwifery Council, *Strategy 2015-2020: Dynamic Regulation for a Changing World* https://www.nmc.org.uk/globalassets/sitedocuments/annual_reports_and_accounts/strategy-2015-2020.pdf

act in accordance with Charity Commission guidance and to ensure that the NMC works for the public benefit in all its activities.

2.6 The Human Fertilisation and Embryology Authority (HFEA)

The HFEA³¹ is a licensing body which oversees the use of human embryos and gametes in research and treatment throughout the UK. It has long-standing experience of dealing with some of the most contentious issues in healthcare research and drawing on the contributions of a broad spectrum of experts and stakeholders in doing so.

The HFEA has two main functions. Its executive function involves the issuing of licences for research and treatment and the carrying out of inspections to ensure that the terms of these licenses are being complied with. In its advisory role it offers guidance to practitioners on proposed or ongoing work, advises the Government on specific issues arising, including their ethical implications, and contributes to policy formation.

³¹ Established under the Human Fertilisation and Embryology Act 1990

3. Key Challenges in Healthcare Regulation

There are a number of distinctive aspects of the healthcare arena which affect the ability of its regulators to comply with the Seven Principles:

3.1 Complexity of Healthcare Provision and its Organisation

Healthcare regulation oversees a plethora of activities including treatment provision, service commissioning, research, training and professional revalidation. Undertaking such activities requires a vast range of often extremely specialised skills and knowledge to be possessed by regulatees. All of this takes place on a massive scale. The NHS is the fifth largest employer in the world³², with its employees having contact with more than 1.5 million patients, families and carers every day.³³

The challenges of providing healthcare on such a scale have been exacerbated in recent years by fundamental changes to the organisational structure of the NHS and the way in which its services are commissioned, funded and provided. The Health and Social Care Act 2012 underpins the current organisation of the NHS. It implemented a number of key organisational changes including clinically led commissioning, increased patient involvement in care, renewed focus on public health, streamlining of arms-length bodies and allowing healthcare market competition in the best interests of patients.³⁴ The integration of health with social care provision and oversight adds significantly to this complexity.

³² McCarthy N, 'The World's Biggest Employers', *Forbes*, (23 June 2015) <http://www.forbes.com/sites/niallmccarthy/2015/06/23/the-worlds-biggest-employers-infographic/#2217d2d651d0>

³³ NHS England, *Understanding the New NHS: A Guide for Everyone Working and Training within the NHS*, (26 June 2014) 4

³⁴ Ibid. See also NHS Five Year Forward View (October 2014) <https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf>. For an overview of quality in care provision in England, see Care Quality Commission, *State of Care 2014/15* HC 483 (2015) <http://www.cqc.org.uk/content/state-care-201415>

3.2 Budgetary Constraints

The NHS operates under significant budgetary pressure. While the Department of Health received a 1% increase in real terms in its budget in the four years preceding July 2015, 40 NHS foundation and 26 NHS trusts reported deficits in 2013-14 and it is estimated that the mismatch between resources and patient needs will reach £30 billion per annum by 2020-21.³⁵ A 2015 government commitment to increase funding by £8 billion a year by 2020-21 therefore still means that the NHS has to make significant and ongoing efficiency savings. NHS providers and commissioners ended 2015/16 with an aggregate deficit of £1.85 billion, the largest in NHS history and triple that of the previous year.³⁶

3.3 Regulatory Complexity

Healthcare regulators must comply with a number of generic requirements in their role, such as ensuring that they carry out their functions in compliance with 'better regulation principles'³⁷, and the Regulators' Code³⁸. As with regulators of any other sector, they engage in a wide variety of regulatory functions including policy development; compliance, enforcement and sanctions activities (including standards setting); and the development and application of guidance and advice.

However, the complexity and challenges of healthcare itself are duplicated by that of its regulation, which has been described, in reports highlighting failings in healthcare, as 'bewildering in its complexity and prone to both overlaps of remit and gaps between

³⁵ National Audit Office, *A Short Guide to the Department of Health* (July 2015) Key Facts

³⁶ Dunn P et al, The King's Fund, *Deficits in the NHS 2016* (July 2016)

³⁷ s21(2) Legislative and Regulatory Reform Act 2006 i.e. that they are carried out in a way which is transparent, accountable, proportionate and consistent and that they are targeted only at cases in which action is needed.

³⁸ Created under s22 of the Legislative and Regulatory Reform Act 2006, and which came into effect on 6 April 2014. This is 'a flexible, principles based framework for regulatory delivery that supports and enables regulators to design their service and enforcement policies in a manner that best suits the needs of [their regulatees]'³⁸ with a focus on 'transparent and effective dialogue and understanding between regulators and those they regulate'³⁸ Department for Business, Innovation and Skills – Better Regulation Delivery Office, *Regulators' Code* (April 2014) p2

different agencies.’³⁹ Mirroring ongoing organisational flux of healthcare provision, amendments to its regulation are ongoing.⁴⁰ It is not the purpose of this report to make recommendations as to how to reform this complex web.⁴¹ Rather, it is intended to provide guidance as to how to optimise compliance with the Seven Principles within that context.

3.4 Principles and Values

While maintaining their own ethical standards in compliance with the Seven Principles, healthcare regulators must also be aware that this sector is distinctive in its resort to other ethical principles and values which are intended to guide healthcare provision and its regulation. The first stimulus for the embedding of such values was the placing of key principles at the core of the NHS itself. These are that it:

- Meets the needs of everyone;
- Is free at the point of delivery; and
- Is based on clinical need, not ability to pay.

These three principles remain key to the NHS and have been expanded upon by the *NHS Constitution for England* which sets out seven key principles to guide all work within the NHS:

- Providing a comprehensive service available to all;

³⁹ National Advisory Group on the Safety of Patients in England, *A Promise to Learn, A Commitment to Act: Improving the Safety of Patients in England*, (August 2013) 30. Regulatory complexity has also been noted in Francis R, *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (February 2013) and Law Commission, Scottish Law Commission Northern Ireland Law Commission (LAW COM No 345) (SCOT LAW COM No 237) (NILC 18 (2014)) *Regulation of Health Care Professionals; Regulation of Social Care Professionals in England* (Cm 8839 2014)

⁴⁰ For example, the Healthcare Safety Investigation Branch began to investigate patient safety incidents from April 2016 <https://www.gov.uk/government/groups/independent-patient-safety-investigation-service-ipsis-expert-advisory-group>

⁴¹ Berwick made recommendations about how healthcare systems and professional regulators should streamline their activities and called for an independent review of structures and the regulatory system by the end of 2017: National Advisory Group on the Safety of Patients in England, *A Promise to Learn, A Commitment to Act: Improving the Safety of Patients in England* (August 2013)

- Access to NHS services is based on clinical need, not an individual's ability to pay;
- Aspiring to the highest standards of excellence and professionalism, including in the leadership and management of its organisations (including putting respect, dignity, compassion and care at the core of how patients and staff are treated);
- Putting patients at the heart of everything it does;
- Working across organisational boundaries and in partnership with other public, private and voluntary organisations in the interest of patients, local communities and the wider population;
- Providing best value for taxpayers' money; and
- Being accountable to the public, communities and patients that it serves.⁴²

These key principles are underpinned in the Constitution by the NHS Values:

- Working together for patients;
- Respect and dignity (including an aim to foster a spirit of candour and a culture of humility, openness and honesty);
- Commitment to quality of care;
- Compassion;
- Improving lives; and
- Everyone counts (involving fairness in resource allocation and treating everyone with equal respect).⁴³

⁴² *NHS Constitution for England*, (July 2015) 3-4

⁴³ *Ibid*

A second stimulus for the implementation of principles, wider ethical principles and values in the work of the NHS has been scandals in healthcare treatment which have emerged periodically throughout its lifetime. Such scandals have impacted on public trust in health and social care provision and its regulation. Organ retention scandals at Bristol and Alder Hey, and the activities of serial killer GP Harold Shipman have led to in-depth inquiries recommending reform of the regulation of human tissue removal, retention and use⁴⁴ and of professional regulation of doctors⁴⁵. More recently failings in care at the Mid Staffordshire NHS Foundation Trust, Winterbourne View Hospital and University Hospitals of Morecambe Bay NHS Foundation Trust have led to inquiries identifying causes for failings and making recommendations for improvements, including suggesting values and principles which should be adhered to in order to prevent reoccurrence of failings in care.⁴⁶ One of these, the Duty of Candour, has now been placed on a statutory footing.⁴⁷

The adoption of ethical principles and values to guide healthcare provision is replicated by its regulators, for example, the CQC cites its values as

- ‘Excellence – being a high-performing organisation;
- Caring – treating everyone with dignity and respect;
- Integrity – doing the right thing;
- Teamwork – learning from each other to be the best we can.’⁴⁸

⁴⁴ *The Royal Liverpool Children’s Inquiry Report*, HC 12 2000-1 (January 2001).

⁴⁵ Smith J, *Fifth Report Safeguarding Patients: Lessons from the Past - Proposals for the Future* (December 2004) <http://webarchive.nationalarchives.gov.uk/20090808154959/http://www.the-shipman-inquiry.org.uk/fifthreport.asp>

⁴⁶ Francis R, *The Mid Staffordshire NHS Foundation Trust Inquiry Report* (February 2013) <http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.midstaffspublicinquiry.com/>; Department of Health, *Transforming Care: A National Response to Winterbourne View Hospital* (December 2012) <https://www.gov.uk/government/publications/winterbourne-view-hospital-department-of-health-review-and-response>; Kirkup B, *Morecambe Bay Investigation Report* (March 2015) <https://www.gov.uk/government/publications/morecambe-bay-investigation-report>;

⁴⁷ Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

⁴⁸ Care Quality Commission, *Building on Strong Foundations: Shaping the Future of Health and Care Quality Regulation* (October 2015) 2

Its key principles, embedded in its Code of Conduct, are based on the Seven Principles and are:

- Act solely in terms of public interest and not to gain financial or other material benefit for themselves, family or friends.
- Not place themselves under financial or other obligation to outside individuals or organisations that might seek to influence them in the performance of their duties.
- Carry out duties and make choices based on merit. This includes making appointments, awarding contracts, and recommending individuals for reward and benefits.
- Be accountable for their decisions and actions and be open to any scrutiny that is appropriate.
- Be open and transparent about decision making and actions they take, providing clear reasons for their decisions, and only restrict information when public interest clearly demands.
- Declare any private interests relating to their duties and take steps to resolve any conflicts arising through the CQC Conflict of Interest declaration process. Any potential conflict of interest should be discussed with the line manager in the first instance.
- Lead by example, and behave in line with all the principles above at all times.
- Act in a manner that protects and enhances CQC's reputation and professionalism. CQC should not be brought into disrepute through any individual's action or behaviour.

HWE's mission is to champion consumer issues in healthcare by

- 'Listening hard to people, especially the most vulnerable, to understand their experiences and what matters most to them

- Influencing those who have the power to change services so that they better meet people's needs now and into the future
- Empowering and informing people to get the most from their health and social care services and encouraging other organisations to do the same
- Working with the Healthwatch network to champion service improvement and to empower local people'.⁴⁹

HWE's work is informed by its values which are that it is

- Inclusive,
- Influential,
- Independent,
- Credible and
- Collaborative.⁵⁰

HWE has identified eight consumer principles which 'are the expectations we promote on behalf of people through all our work':

- Being listened to;
- A safe, dignified and quality service;
- Access;
- Being involved;
- Essential services;

⁴⁹ <http://www.healthwatch.co.uk/our-values-and-behaviours>

⁵⁰ Ibid

- Information and education;
- Choice;
- A healthy environment.⁵¹

It also places diversity and inclusion, whether of staff or members of the public, at the heart of its work.⁵²

The PSA is committed to being

- Independent;
- Impartial;
- Fair;
- Accessible; and
- Consistent.⁵³

The GMC's four core organisational values are:

- Excellence - we are committed to excellence in everything that we do.
- Fairness - we treat everyone fairly.
- Transparency - we are honest and strive to be open and transparent.
- Collaboration - we are a listening and learning organisation⁵⁴

The NMC's values are that it will

⁵¹ Healthwatch England, *Annual Report 2014-2015*, note 18 above, 11

⁵² Healthwatch England, *Strategy 2014-2016*, note 19 above, section 4

⁵³ See PSA response to the CSPL Questionnaire at [31].

⁵⁴ <http://www.gmc-uk.org/about/11564.asp>

- Be accountable (including being well governed and acting openly and transparently);
- Be fair (including acting with integrity);
- Learn and improve (using evidence to do so);
- Be collaborative;
- Be dynamic;
- Remember we are only as good as our people;
- Provide value for money.⁵⁵

The HFEA's principles which inform every part of its Code of Practice for those undertaking working under its remit are:

- Treat prospective and current patients and donors fairly, and shall not discriminate against them unlawfully;
- Have proper respect for the privacy, confidentiality, dignity, comfort and well being of patients and donors;
- Have proper respect for the special status of the embryo when conducting licensed activities;
- Take proper account of the welfare of any child who may be born as a result of the licensed treatment provided by them and any other child who may be affected by that birth;
- Provide prospective and current patients and donors with sufficient, accessible and up-to-date information in order to allow them to make informed decisions;
- Ensure that patients and donors have provided all relevant consents, before any licensed activity is undertaken;

⁵⁵ Nursing and Midwifery Council, *Strategy 2015-2020: Dynamic Regulation for a Changing World*, note 30 above, 6-7

- Conduct all licensed activities with proper skill and care and in an appropriate environment, in accordance with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring;
- Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for purpose;
- Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice;
- Maintain proper and accurate records and information about all licensed activities;
- Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately;
- Ensure that all licensed research that they undertake meets proper ethical standards, and is only undertaken where there is both a clear scientific justification and no viable alternative to the use of embryos;
- Conduct all licensed activities with proper regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK. including:
 - maintaining up to date awareness and understanding of legal obligations;
 - responding promptly to requests for information and documents from HFEA; and
 - co-operating fully with inspections and investigations by HFEA or other agencies responsible for law enforcement or regulation of healthcare.

We can see therefore that the regulation of healthcare in England takes place in a context of organisational turmoil and financial pressure, in a sector which is innately complex. Its provision and regulation are distinctive in their recourse to guiding ethical principles and values.

4. Enhancing Compliance with the Seven Principles of Public Life

Compliance by healthcare regulators with the Seven Principles will provide a number of benefits both to them and to the sector more generally. As set out below, it will increase regulators' legitimacy, thus enhancing the likelihood of compliance; it will avoid the risks of regulatory capture; and it will enhance regulators' capacity to facilitate achievement of the regulatory goal of ensuring quality of care and patient safety. In light of the distinctive complexities and challenges of the healthcare arena, recommendations are made here to encourage healthcare regulators to go beyond mere formal acknowledgment of the Seven Principles but rather to embed them more deeply in their activities to ensure that these benefits are achieved.

4.1 Principles-Based, Goals-Driven Healthcare Regulation

The highlighted regulators describe and define their regulatory approaches in different ways. For example:

- The CQC's 2013-16 strategy introduced a revised regulatory approach to focus on ensuring people received safe, effective, compassionate and high-quality care by well-led providers. This consists of 'intelligence led, expert, rigorous inspections and ratings of services.'⁵⁶ It uses a combination of statistical information and reports of patients' experiences of care to target regulatory interventions.⁵⁷
- The PSA advocates 'Right Touch regulation', based on the principles of better regulation and with the addition of a requirement of agility.⁵⁸

⁵⁶ Care Quality Commission, *Building on Strong Foundations: Shaping the Future of Health and Care Quality Regulation* (October 2015) 3

⁵⁷ Ibid, 9. The effectiveness of this approach in ensuring quality of care and value of money is yet to be established according to National Audit Office, *Care Quality Commission: Capacity and Capability to Regulate the Quality and Safety of Health and Adult Social Care*, HC 271 Session 2015-16 (22 July 2015)

⁵⁸ Professional Standards Authority, *Right Touch Regulation- Revised* (October 2015).

- The NMC uses ‘dynamic regulation’.⁵⁹ This requires them to ‘develop our use of evidence from data analysis and research to anticipate future trends and ensure our regulatory work responds to this challenging environment.’⁶⁰
- The HFEA deploys Principles-Based Regulation (PBR).⁶¹ Under section 8(1)(ca) of the Human Fertilisation and Embryology Act 1990 (as amended) it is required to ‘maintain a statement of the general principles which it considers should be followed (i) in the carrying-on of activities governed by this Act, and (ii) in the carrying-out of its functions in relation to such activities’.

Despite this range of regulatory approaches, it is nevertheless evident that principles and values form a core part of each of their approaches and thus of the regulation of healthcare. Such principles and values are an important part of the provision of compassionate healthcare. The recommendations made here are therefore based on enhancing compliance with the Seven Principles by healthcare regulators who are engaged (either exclusively or in conjunction with other regulatory approaches) in Principles-Based Regulation (PBR).

PBR regimes are based on ‘mutuality, trust and responsibility’, encouraging and enabling regular discussions between the regulator and others as to the aim and application of relevant principles⁶². Such communication is said to enhance⁶² the willingness of regulatees to comply with well-informed regulation⁶³ and enable the identification of those who are not conforming to agreed values. It may also promote collaboration and co-operation amongst professionals and help to obtain the trust and support of the public⁶⁴ with a resulting improvement in overall standards of health. Regulators’ experience of the use and interpretation of principles must be communicated to other healthcare regulatory agencies

⁵⁹ Nursing and Midwifery Council, *Strategy 2015-2020: Dynamic Regulation for a Changing World*, note 30 above

⁶⁰ *Ibid*, 4

⁶¹ For in depth analysis of this approach to regulation, see Devaney S, *Stem Cell Research and the Collaborative Regulation of Innovation* (Routledge 2014) and Black J, ‘Forms and Paradoxes of Principles Based Regulation’, (LSE working paper 13/2008).

⁶² Black J, LSE Working Paper 13/2008.

⁶³ Baldwin R and Cave M, *Understanding Regulation – Theory, Strategy and Practice* (Oxford: Oxford University Press, 1999), 40.

⁶⁴ See Shamoo AE and Resnik DB, *Responsible Conduct of Research*, (Oxford: Oxford University Press, 2003).

in the hope that a co-ordinated approach to the application of principles, including the Seven Principles, will develop over time.

PBR allows the regulator to focus its own mind, as well as the minds of those over whom it presides, on underlying communal goals and values, enhancing the likelihood of achieving such goals. The particular principles guiding individual healthcare regulators' work may justifiably differ, reflecting their differing purposes and remits. However, given that regulatees will fall under the remit of a number of different regulators, and that this occurs within the same healthcare setting, a mutual overarching goal will increase the chances of cohesive regulation, the achievement of regulatory goals, and compliance with the Seven Principles.

The report of the National Advisory Group on the Safety of Patients in England (the Berwick Report)⁶⁵ summarised lessons learned and identified changes required as a result of the failings in healthcare and its regulation at Mid-Staffordshire. Its recommendations are intended to guide an NHS which reduces patient harm by placing an ethic of learning and improvement at its core⁶⁶. The Berwick Report states, 'All leaders concerned with NHS healthcare [including regulators] ... should place quality of care in general, and patient safety in particular, at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support.'⁶⁷ It further states that 'safety and quality stand the best chance when all of the drivers in the system – financial incentives, policies, regulatory strategies, use of competition, commissioning decisions, training, and organisational and professional norms – point in the same direction.'⁶⁸ This report echoes that position. Healthcare regulators should recognise that the goal of their activities is to ensure quality of care and patient safety.

⁶⁵ National Advisory Group on the Safety of Patients in England, *A Promise to Learn, A Commitment to Act: Improving the Safety of Patients in England*, (August 2013)

⁶⁶ Recommendation 1 and the Overarching Goal of National Advisory Group on the Safety of Patients in England, *ibid*, 14

⁶⁷ *Ibid*, Recommendation 2.

⁶⁸ *Ibid*, 30.

4.2 Adopting Best Practice in Internal Governance

Continued improvements in regulators' approaches to their own internal governance have and continue to take place. For example, in recent years structural reforms have been instituted where necessary to ensure that Boards are relatively small and include significant lay membership.⁶⁹ The healthcare regulators reviewed have implemented the Seven Principles within their organisations, typically through Codes of Conduct which apply to individuals working for and with them. Many supplement their Codes of Conduct through additional policies and procedures including appraisals. The NMC and HFEA provide particularly good examples of values-based performance review procedures which serve to further embed the Seven Principles in the working life and behaviours of their members.

Regulators should assess their governance structure and processes to ensure they are consistent with best practice, (such as holding board meetings in public; embedding effective audit procedures and risk reviews; and making declarations of interest public). It would be helpful for regulators to communicate with each other on this point in order to benefit from examples of enhanced processes engaged in by, for example, the NMC⁷⁰ and the insights on governance arrangements recommended by the PSA.⁷¹ Such communication would also help embed the communal regulatory goal and ensure compliance with and consistent understanding and application of **all Seven Principles**.

4.3 Encouraging Reflexivity in the Use of Expert Advice

The regulators considered here tend to have adopted good practice in the constitution of their boards, ensuring that they are not overly large or predominated by members who represent regulatees' interests. This allows for a formal injection of views from outside the regulated group in an attempt to avoid conflicts of interest or an inability to remain

⁶⁹ Professional Standards Authority, *Fit and Proper? Governance in the Public Interest* (March 2013) and *Board Size and Effectiveness* (June 2011)

⁷⁰ See the NMC's response to the CSPL questionnaire.

⁷¹ See PSA reports *Good Practice in Making Council Appointments: Guidance for Regulators Making Appointments Which are Subject to Section 25C Scrutiny* (October 2014); *Fit and Proper? Governance in the public interest* (March 2013); *Standards for members of NHS boards and Clinical Commissioning Group governing bodies in England* (November 2012 & November 2013); *Board size and effectiveness* (June 2011).

disinterested. Regulators seek the advice of a variety of types of experts, whether external specialists requested to advise on a particular issue; individuals such as patients with experiences of engagement with a certain provider or treatment; or internal members appointed due to relevant experience or knowledge. The term 'expert' is used here to cover all of these categories of contributor to the regulatory endeavour.

In drawing on the input of experts, more must be done to enhance compliance with the principles of **integrity, objectivity, leadership and accountability**. Without this, the perception of regulators as having the right and capacity to oversee the activities of their regulatees, known as regulatory legitimacy, may be undermined. Such acceptance is a key element in efforts to influence compliance⁷² and thus achieve the regulatory goals of quality of care and patient safety.

Healthcare regulators have, rightly, tended to exhibit a level of 'epistemic modesty',⁷³ i.e. an overt acknowledgement that they do not themselves possess all the knowledge required to regulate effectively, but must draw on the knowledge of experts to provide the high levels of technical understanding required for this role. Such expertise is drawn on, for example, by the CQC which, depending on the inspection context, populates its inspection teams with clinical specialists and/or 'Experts by Experience' i.e. patients and carers.⁷⁴

Drawing on experts' views enables regulators to appreciate why practitioners or researchers are taking particular steps; to determine whether these comply with regulatory requirements; and to offset the imbalance of knowledge between themselves and their regulatees. The danger of the influence of such highly specialist knowledge however is that it may undermine both **accountability** through discouraging debate and discussion;⁷⁵ as well

⁷² Black J, 'Constructing and Contesting Legitimacy and Accountability in Polycentric Regulatory Regimes' (2008) *Regulation and Governance* 148; Casey D and Scott C, 'The Crystallization of Regulatory Norms' 2 (2011) *Journal of Law and Society* 38(1) 88.

⁷³ Perez O, 'Responsive Regulation and Second-Order Reflexivity: On the Limits of Regulatory Intervention' *UBC Law Review* 44(3) (2011) 743–778 at 745.

⁷⁴ <http://www.cqc.org.uk/content/planning-inspection>

⁷⁵ Abraham J, 'Scientific Expertise and Regulatory Decision-making: Standards, Evidential Interpretation and Social Interests in the Pharmaceutical Sector' in Edmond G (ed) *Expertise in Regulation and Law* (Aldershot: Ashgate, 2004) 52.

as **integrity** and **objectivity** by narrowing the frame of inquiry to a particular specialism⁷⁶ leading to ‘regulatory capture’ of the agency by regulatees who are able to sway its determinations in favour of their own interests.⁷⁷ Regulators will be unable to provide a convincing account of the legitimacy of the experts on whom such reliance is placed where such experts stray into influencing policy or even lobbying, which in turn can undermine claims to legitimacy on the part of the agency itself. To avoid this, regulators must adopt *reflexivity* in drawing on such expertise. This requires that they identify and implement conditions for the provision of expert contributions which encourage expert participants actively to reflect on the belief systems on which their views are based, and on whether and if so how these should be adjusted in light of the views of others⁷⁸.

Reflexive governance further requires

‘that actors have the capacities and the competencies to participate in and contribute to social learning; that they communicate and interact in relational and deliberative ways; that they engage in and learn from experimentation through collaborative forms of joint enquiry; and that their learning is informed by cognitive processes entailing the adjustment and redefinition of frames, representations and collective identities.’⁷⁹

There are two aspects of the resort to expert advice in healthcare regulation which require an application of reflexivity in order to overcome an innate vulnerability to regulatory capture. The first is the science used in the process of advising, while the second (which builds upon the first) is the expert status of the advisors themselves.

The application of healthcare treatments depends upon scientific research for its development. Such research is greatly influenced by a plethora of external factors including

⁷⁶ Jasanoff S, ‘(No) Accounting for Expertise?’ *Science and Public Policy* 30(3) (2003) 161.

⁷⁷ Baldwin R and Cave M, *Understanding Regulation – Theory, Strategy and Practice* (Oxford: Oxford University Press, 1999), 20.

⁷⁸ de Schutter O and Deakin S, ‘Reflexive Governance and the Dilemmas of Social Regulation’ in de Schutter O and Deakin S (eds) *Social Rights and Market Forces: Is the Open Coordination of Employment and Social Policies the Future of Social Europe?* (Brussels: Bruylant, 2005).

⁷⁹ Laurie G, ‘Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law’ *Human Genetics* 130 (2011) 347–356.

available funding and facilities, political priorities and personal and career goals. From its inception therefore, scientific inquiry is socially constructed in that it can reflect the influences and biases of those with the power to affect these factors.⁸⁰ This process of construction is compounded where scientists as experts are required to apply such knowledge to the process of regulation. Such expertise is 'transgressive': it must first relate scientific knowledge to the particular context under consideration and then must communicate this contextual knowledge to those who do not have such knowledge or expertise themselves.⁸¹ Such communication inevitably involves "boundary setting" which Jasanoff describes as follows:

Experts arrive at a consensus in part by demarcating, or framing, the domains that they consider relevant to the problem at hand, or simply as tractable to analysis. What lies within the perimeter of expert competence tends to be labelled 'science' or 'objective' knowledge; what lies outside is variously designated as values, policy or politics. Yet, the very act of performing this 'boundary work' is laden with value judgments and reflects the limits of the experts' knowledge, training and imagination.⁸²

This process then depends not on epistemic strengths, but rather on 'social processes of persuasion and contestation',⁸³ i.e. it is socially constructed. Those who wish to persuade a regulator that a particular approach should be adopted may draw on a variety of different sources of evidence and argument in order to do so, including anecdotal and clinical trial evidence,⁸⁴ economic analysis and even moral argument.

Advisory science is

⁸⁰ Jasanoff, S. (2003) note 76 above, 160. For analysis of the impact of this on the process of scientific peer review, see Edmond G, 'Judging the Scientific and Medical Literature: Some Legal Implications of Changes to Biomedical Research and Publication' *Oxford Journal of Legal Studies* 28(3) (2008) 523.

⁸¹ Nowotny H, 'Transgressive Competence: The Narrative of Expertise' *European Journal of Social Theory* 3(1) (2000) 5–21.

⁸² Jasanoff S (2003), note 76 above, 160

⁸³ Rifkin W and Martin B, "Negotiating Expert Status: Who Gets Taken Seriously" *IEEE Technology and Society Magazine* 16(1) (1997) 31.

⁸⁴ Abraham J, note 75 above.

“co-produced,” in the sense that both advisors and advisee seek a symbiosis whereby advisees pose questions that advisers can answer, and advisers provide answers that have the air of scientific authority and are couched in a form that is convenient, relevant and useful to their clients.’⁸⁵

Both healthcare regulators and their scientific advisors are required to exercise ‘judgment in the face of uncertainty’.⁸⁶ However, their mutual interest in the reduction of the appearance of uncertainty, driven by the desire of both to maintain credibility,⁸⁷ actually poses the danger that their legitimacy is undermined. Healthcare regulators must therefore be alive to the need to ensure that such influences, values etc are made explicit.

The social construction of science expertise for regulation also extends to the status of expert advisors themselves,⁸⁸ who have been described as ‘persons possessing analytic skills grounded in practice and experience, rather than as truth-tellers with unmediated access to ascertainable facts’.⁸⁹ Healthcare researchers and practitioners can influence regulatory activities in their capacity as experts by acting either as policy framers, prompting regulators to consider a particular issue, or as regulatory advisors within a formalised regulatory structure.

Policy framing can occur in response to a variety of stimuli, whether on the expert’s own initiative through a prompting of regulatory decision-making (e.g. by developing scientific methods which have implications for the regulator if they were to be used in humans;⁹⁰ or by publicly indicating that they wish to undertake certain work in the future)⁹¹ or through

⁸⁵ Weiss C, “Scientific Uncertainty in Advising and Advocacy” *Technology in Society* 24(3) (2002) 378.

⁸⁶ Jasanoff S, ‘Judgment Under Siege: the Three-Body Problem of Expert Legitimacy’ in Maasen S and Wingart (eds) *Democratization of Expertise? Exploring Novel Forms of Scientific Advice in Political Decision-Making* (2005) *Sociology of the Sciences Yearbook*, 24, 211.

⁸⁷ Weiss, note 85 above, 379.

⁸⁸ The constructed nature of science for policy opens the door for experts in other arenas, e.g. patients, to contribute to decision-making, Bijker WE, Bal R and Hendriks R, *The Paradox of Scientific Authority: The Role of Scientific Advice in Democracies* (Cambridge MA: MIT Press, 2009).

⁸⁹ Jasanoff S (2005) note 86 above, 211.

⁹⁰ For example through the creation of Dolly the sheep, the world’s first cloned mammal.

⁹¹ For an account of the merits of having ‘stakeholders’ (i.e. regulatees) involved in governance in the medical sphere particularly in contributing to policy being formed through evidence-based decision-making, see Weimer DL, ‘Stakeholder Governance of Organ Transplantation: A Desirable Model for Inducing Evidence-based Medicine?’ *Regulation and Governance* 4 (2010) 281–302.

responding to a public consultation; or in response to a more directed call for contributions, for example where the regulator asks its own sub committees or particular experts to advise on a specific matter.

The healthcare regulators considered in this report provide examples of internal advisory groups which assist them in relation to regulatory decision making.⁹² Healthcare regulators must draw on expert evidence from within their own advisory committees and might rightly be criticised for any failure to do so. Such canvassing of views lends legitimacy to any resulting decision, demonstrating a utilisation of available knowledge resources in decision making. However, under the guise of their expertise, members of these committees are ‘free to serve in widely divergent professional capacities: as technical consultants, as educators, as peer reviewers, as policy advocates, as mediators, and even as judges’.⁹³

In advising healthcare regulators therefore, experts engage in a hybrid activity which spans both ‘*knowing* and *deciding*’⁹⁴ while drawing both on the knowledge they bring from their discipline area as well as from other social, ethical and political areas of discourse.⁹⁵ It has been argued that ‘[e]xperts are generally best qualified to assess the opportunity for scientific progress, while broadly representative laymen in close consultation with experts may be best qualified to assess societal need’.⁹⁶ However, the socially constructed nature both of healthcare knowledge itself and the role of advisors on its regulation ‘rules out the possibility of drawing sharp boundaries between facts and values or claims and context’⁹⁷ and requires regulation in this area to include an engagement by experts in multi-faceted

⁹² For example, HFEA, Committees and Papers, <http://www.hfea.gov.uk/140.html>; GMC, *Council and Other Governance Groups*, http://www.gmc-uk.org/about/Council_and_other_governance_groups.asp

⁹³ Jasanoff S, *The Fifth Branch: Science Advisors as Policy Makers* (Cambridge, MA: Harvard University Press, 1990) 237.

⁹⁴ Maasen S and Weingart P, ‘What’s New in Scientific Advice to Politics?’ in Maasen S and Weingart P (eds) *Democratization of Expertise? Exploring Novel Forms of Scientific Advice in Political Decision-Making* (2005) *Sociology of the Sciences Yearbook*, 24, 1-19, 7.

⁹⁵ Jasanoff (2005), note 86 above, 221.

⁹⁶ Brooks H, ‘The Evolution of Science Policy’ in Smith BLR and Barfield CE (eds) *Technology, R&D, and the Economy* (Washington, DC: The Brookings Institution, 1995).

⁹⁷ Jasanoff (1990), note 93 above, 230–231.

deliberation⁹⁸ based on a reflexive understanding of ‘the interlinkages that bind diverse practices, institutions and networks of diverse actors together’.⁹⁹

Experts should be encouraged to justify their advice to regulators on a variety of grounds, but in doing so must be explicit about their reasons and be reflexive in this role, indicating whether their views are purely knowledge-based, or providing views about wider social and ethical issues, thus entrenching their role as policy framers. The optimal approach for such experts is the ‘honest broker of policy alternatives’, who provides comprehensive information about all choices to facilitate decision-making by the regulator on the basis of their guiding goals and principles.¹⁰⁰ Reflexive ‘honest brokers’ must ‘clarify the implications of their knowledge for action and ... provide such implications in the form of policy alternatives to decision-makers who can then decide among different possible courses of action’.¹⁰¹

Healthcare regulation can often take place within a context of uncertainty and contestation, both in relation to knowledge about healthcare and its future capabilities, and in relation to the ethical and social context within which it will be provided. Within such a context, healthcare experts’ views on science and medicine must be recognised as just one facet of regulatory decision making. In displaying **leadership**, regulators ‘need not claim that the position adopted is in line with everyone’s interpretation’¹⁰² but will facilitate greater levels of legitimacy where they have accessed relevant information and used it appropriately. As stated by the PSA,

‘the most successful regulators have shown that while clinical input is essential at various stages of the regulatory core functions, the job of regulating does not itself require clinical skills, training, or registration as a health or care professional. It requires people who have the relevant skills to undertake regulation and provide

⁹⁸ Jasanoff (2005), note 86 above, 219–220.

⁹⁹ Nowotny (2003), nte 81 above, 152.

¹⁰⁰ Pielke RA, *The Honest Broker* (Cambridge: Cambridge University Press, 2007)

¹⁰¹ Ibid.

¹⁰² Brownsword R, ‘So What Does the World Need Now? Reflections on Regulating Technologies’ in Brownsword R and Yeung K, *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes*, (Hart: Oxford and Portland, Oregon, 2008).33.

organisational management with dedication and competence whether they are health or care professionals or not.¹⁰³

Concerns have been raised that the influence wielded by scientific experts falls outside of ‘many of the safeguards of classic administrative decision-making’.¹⁰⁴ It is on the basis of the dangers of a lack of **accountability, integrity** and **objectivity** to which this may give rise that it is also recommended here that the approaches advocated above must be formalised by requiring expert advisors (whether responding to consultations or acting as a member of an advisory committee) to adhere to the requirements of an explicit code of practice to guide their contributions. Numerous such codes already exist¹⁰⁵ which support the above approach.

It is both impossible and undesirable for the roles of expert advisors in the healthcare regulation area to be restricted to that of purely medical or scientific matters as this would undermine efforts to draw on important and relevant ethical and other approaches in the pursuit of the regulatory goal. Therefore, an expert management of such contributions is required to ensure compliance with the Seven Principles.

In all their activities, healthcare regulators, their committees and advisors must have regard to the principles/goals guiding the work and its regulation (and advice to government on policy formation), in order to lend a level of thoroughness and participation to the development and application of the law. This must be done in a reflexive and knowledgeable manner.

4.4 Patient Involvement

We have seen above that collaboration between the regulator and healthcare experts is vital in maintaining the legitimacy of the healthcare regulatory regime. But the regulation of

¹⁰³ Professional Standards Authority, *Fit and Proper? Governance in the Public Interest* (March 2013) [6.4]

¹⁰⁴ Jasanoff (1990), note 93 above, 229

¹⁰⁵ For example, Government Office for Science, *Code of Practice for Scientific Advisory Committees* (2011).

healthcare is even more widely collaborative than that¹⁰⁶, with contributors at a variety of levels from regulators (and their accounting bodies) to experts to practitioners to patients all playing a key role. Such collaboration has implications for the principles of **accountability** and **openness and transparency**.

The six regulators considered here all recognise the need for and benefits of a collaborative approach to healthcare regulation. The CQC has explicit strategies to work with other regulators and organisations that manage and oversee the health and social care system to respond to failings in standards of quality and safety; with Healthwatch England to identify poor care; and with individuals, community groups and voluntary organisations in evaluating care.¹⁰⁷

HWE work with other organisations at national and local levels to highlight care-related issues and formulate strategies to deal with them. For example, in relation to making complaints about care, at a national level, HWE has developed *My Expectations for Raising Concerns and Complaints: A Consumer-Led Vision of Good Complaints Handling* with the Parliamentary and Health Service Ombudsman and the Local Government Ombudsman.¹⁰⁸ This is being used by the CQC as part of its inspection regime. On a local level they worked with the Citizens Advice to develop tools to help the public navigate the complaints system, and made these available to local Healthwatch; provided local Healthwatch with resources to enable them to raise awareness of complaints problems in their areas and drive local change; and developed a set of standards that provide a vision for what a good complaints advocacy service should look like, and shared them with local Healthwatch.¹⁰⁹ HWE has agreements in place with the Department of Health, the Care Quality Commission, the Local Government Association, NHS England, Monitor and the Trust Development Authority

¹⁰⁶ For further analysis of collaborative regulation, see Devaney S, *Stem Cell Research and the Collaborative Regulation of Innovation* (Routledge 2014) and Prosser T, *The Regulatory Enterprise* (2010)

¹⁰⁷ Care Quality Commission, *About Us: What We Do and How We Do It*, note 3 above, and *Plan for engaging the Public in Our Work* <http://www.cqc.org.uk/content/our-plan-engaging-public-our-work-2015-16>

¹⁰⁸ (November 2014) http://www.ombudsman.org.uk/data/assets/pdf_file/0010/28774/Vision_report.pdf

¹⁰⁹ Healthwatch England, *Annual Report 2014-2015*, note 18 above, 15

setting out how they will collaborate to achieve improvements in care. They also work with members of the public, voluntary and community sectors and health and social care sectors.

A central theme of the NMC's strategy is partnership and collaboration, which they recognise is key to achieving their regulatory aim of protecting the public.¹¹⁰ With the GMC it has published a *Joint Statement on Professional Values*¹¹¹. The GMC is committed to collaborating with other professional regulators to promote good medical practice¹¹² and has established a system to liaise with patients during their investigations.¹¹³ The HFEA recognises that part of its role includes liaison with other regulators, the Department of Health, and other patient and professional stakeholder groups.¹¹⁴

Healthcare regulators 'should share all data on quality of care and patient safety that is collected with anyone who requests it, in a timely fashion, with due protection for individual patient confidentiality'.¹¹⁵ Information shared in the attempt to achieve the regulatory goal should include 'the perspective of patients and their families; measures of harm; measures of the reliability of critical safety processes; information on practices that encourage the monitoring of safety on a day to day basis; on the capacity to anticipate safety problems; and on the capacity to respond and learn from safety information.'¹¹⁶

Particular care has to be taken in drawing on the contributions of patients and their families and carers. The requirement for patient involvement in healthcare is well recognised, with the Berwick Report stating that '[p]atients and their carers should be present, powerful, and involved at all levels of healthcare organisations from wards to the boards of Trusts' as well as in healthcare regulation.¹¹⁷ This is reflected in the NHS Five Year Forward View which argues 'for a more engaged relationship with patients, carers and citizens so that we can

¹¹⁰ Nursing and Midwifery Council, *Strategy 2015-2020: Dynamic Regulation for a Changing World*, note 30 above

¹¹¹ NMC and GMC, *Joint Statement on Professional Values* (July 2012) http://www.gmc-uk.org/Professional_values_joint_statement_August_2012.pdf 49744505.pdf

¹¹² <http://www.gmc-uk.org/about/partners.asp>

¹¹³ http://www.gmc-uk.org/concerns/the_investigation_process/26018.asp

¹¹⁴ <http://www.hfea.gov.uk/8275.html>

¹¹⁵ National Advisory Group on the Safety of Patients in England, *op cit*, 28.

¹¹⁶ *Ibid*, Recommendations 7 and 8, 27.

¹¹⁷ *Ibid*, Recommendation 3, 18.

promote well-being and prevent ill health'.¹¹⁸ Such involvement is 'an essential asset'¹¹⁹ in the collaborative attempt to ensure patient safety and quality of care.

Focusing on consumer advocacy bodies across all sectors, Black states that 'irrespective of any legal requirement that regulators take their views into account, consumer panels have to be afforded sufficient recognition by the regulator such that the regulator really does take note of what they say, and does not just 'go through the motions' of appearing to listen but in practice disregarding them.'¹²⁰ In the healthcare setting, patients should be afforded recognition as 'experts' in their own care.

Regulators should communicate with each other on best practice in obtaining information from and engaging with patients as part of achieving their regulatory goal of ensuring quality of care and patient safety. Such contributions need to be managed by expert regulators which are able both to encourage reflexivity in such engagement whilst recognising the distinctive challenges for patients to make their voice heard. Regulators should put in place mechanisms to require and enable them to demonstrate how contributions by patients have been used to achieve the regulatory goal.

4.5 Compliance, Enforcement and Sanctions Activities

The potential for a failure in the application of compliance, enforcement and sanctions (CES) activities to undermine confidence in a regulatory regime which relies on flexibility and specialist knowledge was demonstrated in the case of the CQC's early failings. In the application of healthcare regulatory approaches, a 'responsive' regulatory approach¹²¹ which supports and reflects the regulatory goal of ensuring quality of care and patient safety is required. This approach is 'the use by regulators of mechanisms that are responsive

¹¹⁸ *NHS Five Year Forward View* (October 2014) 2

¹¹⁹ National Advisory Group on the Safety of Patients in England, *op cit.*

¹²⁰ Black J, 'Calling Regulators to Account: Challenges, Capacities and Prospects', *LSE Working Paper 15/2012*, 32

¹²¹ Nonet P and Selznick P, *Law and Society in Transition: Towards Responsive Law* (New York: Octagon Books, 1978).

to the context, conduct and culture of those being regulated'¹²². Compliance with the law can be encouraged through a variety of techniques including prosecution, education, advice, persuasion and negotiation,¹²³ forming a 'regulatory pyramid' which begins at its base with persuasion, uses multiple regulatory mechanisms to complement each other and provides the capacity for escalation to more serious forms of sanction if persuasion proves ineffective.¹²⁴ The effectiveness of the pyramid is said to be in the knowledge that non-compliance with 'polite requests' will lead to escalation up the enforcement pyramid.¹²⁵

It is important in the healthcare field to ensure that the relationship between regulator and regulatee can survive the imposition of escalating sanctions, both in order that the regulatory goal has every chance of being achieved, and that the regulator can continue to rely on specialist advisors as regulatory collaborators. Thus, 'every escalation up the pyramid should also indicate a path to de-escalation'.¹²⁶ The regulator must test the actions of the regulatee against the regulatory goal of quality of care and patient safety as well as the principles and values which guide their work. The regulatory system's contents and penalties for non-compliance must be easily understood with appropriate support for compliance being provided by the regulator¹²⁷ as well as a sensitive use of its enforcement powers in a context in which caring and learning from error are central.

It can only fulfil these tasks appropriately if it retains effective communication with regulatees about the justifications for their actions, with the agency's participation in such discussions being enhanced by the input of knowledge and views of other contributors in relation to the scientific, ethical and other issues at play. In addition, those staff members who engage in CES activities must possess 'excellent communication and relational skills in

¹²² Healy J and Braithwaite J, 'Designing Safer Health Care Through Responsive Regulation' *Medical Journal of Australia* Supplement 184(10) (2006) S56-S59, S56.

¹²³ Baldwin R and Cave M, note 77 above, 96–97.

¹²⁴ Healy J and Braithwaite J, note 122 above, S56.

¹²⁵ *Ibid* at S56–S57.

¹²⁶ *Ibid* at S57.

¹²⁷ Better Regulation Task Force, *Scientific Research: Innovation with Controls* (January 2003) Annex C.

order to convey a complex set of messages about the threat of regulatory enforcement and the possibility of cooperation in a contextually sensitive way'.¹²⁸

Responsive regulation 'values trust, transparency and professionalism',¹²⁹ important qualities in dealing with regulatees whose professional status is highly significant both to them and to their patients. If regulators are not aware of the motivations of regulatees, where results show that the latter have complied with conditions, the regulator does not know whether this is because true compliance has occurred, or whether this has meant a reduction in performance in unassessed areas; whether compliance has occurred in name but not in spirit; or whether there has been active manipulation of results to conceal non-compliance.¹³⁰ This is important in a sector in which cultural behaviours including bullying and failure to report failings in care have endangered patients' health and well-being.¹³¹ Responsive regulation accepts that different regulatees have differing motivations for compliance, or indeed there may be a variety of motivations spurring on the actions of one regulatee¹³² but that a regulator which is aware of the pressures and concerns which the regulatee works under, and has an effective dialogue with them about these, can use, or threaten to use, sanctions which are responsive to those concerns.

Given the wide variety of regulators which have oversight over healthcare, discussions should take place between them all in relation to identifying the appropriate enforcement approach so that those working in the sphere are subject to a consistent approach. In the spirit of regulatory collaboration, a multi-agency exploration of best practice in CES should be undertaken. Healthcare regulators also must be aware of the potential for regulatees to be subjected to a form of "multiple jeopardy" in CES terms with many regulatees falling under the scrutiny of numerous regulators.

¹²⁸ Ibid at 394.

¹²⁹ Healy J and Braithwaite J, note 122 above at S56.

¹³⁰ Bevan G and Hood C, 'What's Measured is What Matters: Targets and Gaming in the English Public Health Care System' *Public Administration* 84(3) (2006) 522-533, 524.

¹³¹ Francis R, *The Mid Staffordshire NHS Foundation Trust Inquiry Report* (February 2013)

¹³² Lehmann Nielsen V and Parker C, 'Testing Responsive Regulation in Regulatory Enforcement' *Regulation and Governance* 3 (2009) 378.

5. Conclusion

Healthcare regulators are making continuous efforts to improve the quality of their oversight of the sector. They do so in challenging circumstances. The sector is beset by organisational and regulatory complexity as well as severe budgetary constraints. This report has made a number of recommendations as to how healthcare regulators can enhance their own compliance with the Seven Principles of Public Life while contributing to the regulatory aims of improving quality of care and patient safety.

Annex: The Seven Principles of Public Life

1. Selflessness

Holders of public office should act solely in terms of the public interest.

2. Integrity

Holders of public office must avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them in their work. They should not act or take decisions in order to gain financial or other material benefits for themselves, their family, or their friends. They must declare and resolve any interests and relationships.

3. Objectivity

Holders of public office must act and take decisions impartially, fairly and on merit, using the best evidence and without discrimination or bias.

4. Accountability

Holders of public office are accountable to the public for their decisions and actions and must submit themselves to the scrutiny necessary to ensure this.

5. Openness

Holders of public office should act and take decisions in an open and transparent manner. Information should not be withheld from the public unless there are clear and lawful reasons for so doing.

6. Honesty

Holders of public office should be truthful.

7. Leadership

Holders of public office should exhibit these principles in their own behaviour. They should actively promote and robustly support the principles and be willing to challenge poor behaviour wherever it occurs