The role of risk in regulatory policy

A review of the literature

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professional standards authority

About the Professional Standards Authority

The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and voluntary registration of people working in health and care. We are an independent body, accountable to the UK Parliament.

We oversee the work of nine statutory bodies that regulate health professionals in the UK and social workers in England. We review the regulators' performance and audit and scrutinise their decisions about whether people on their registers are fit to practise.

We also set standards for organisations holding voluntary registers for people in unregulated health and care occupations and accredit those organisations that meet our standards.

To encourage improvement we share good practice and knowledge, conduct research and introduce new ideas including our concept of right-touch regulation.[1] We monitor policy developments in the UK and internationally and provide advice to governments and others on matters relating to people working in health and care. We also undertake some international commissions to extend our understanding of regulation and to promote safety in the mobility of the health and care workforce.

We are committed to being independent, impartial, fair, accessible and consistent. More information about our work and the approach we take is available at www.professionalstandards.org.uk.

[1] Professional Standards Authority (2015) *Right –touch regulation*. [online] Available at http://www.professionalstandards.org.uk/policy-and-research/right-touch-regulation

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1. Introduction

1.1 This review of the literature on risk in regulation has been carried out as part of a wider project to revisit and refresh *Right-touch regulation* in light of people's experience of applying it in practice. The main purpose of this review is to develop our understanding of risk in the context of *Right-touch regulation*, and to use this knowledge to improve our ability to evaluate the risk of harm.

1.2 In the five years since we published *Right-touch regulation*, we have observed that there is no common understanding of the term 'risk' or of the concept of risk-based regulation. We have been told that assessing risk presents serious challenges and yet we, along with many others, remain convinced that it is the best approach to making decisions about what and how to regulate.

1.3 Our review of the literature is an attempt to glean a more sophisticated understanding of this area using some of the key writings on risk and regulation. This exercise has involved searches for literature on risk assessment, risk management and risk in regulation in NHS Open Athens, Google and Google Scholar. Because of financial limitations on access to academic journals, our searches could not be described as exhaustive, but we are confident that our review covers the main topics of debate in this area.

1.4 We begin our paper by looking at the development of risk ideas in public and regulatory policy, before setting out some examples of risk models; in the final sections, we consider some of the benefits, challenges and limitations of designing regulatory regimes on the basis of risk.[2]

[2] In our work on professional regulatory policy, we have found it helpful to make a conceptual distinction between different types or levels of regulatory decision-making:

- Level 1: these are the highest-level decisions, generally made by governments about who or what to regulate, and under which regulatory model (design phase)
- Level 2: these are the mid-level decisions, generally made by regulators, about which regulatory levers to use, and how (design phase)
- Level 3: these are the lowest-level decisions, generally made by regulators, about applying regulatory powers to individual regulated entities (implementation/application phase).

Our guidance, *Right-touch regulation*, is intended to apply to Tiers 1 and 2, but we have found that the literature on risk-based regulation covers all three types of decision. For the purposes of this review, we have therefore included literature that looks at all three tiers.

2. The rise of risk-based approaches in regulation

2.1 We will begin by looking at the evolution of risk-based approaches in recent government thinking and regulatory policy in the UK. For this we will look at how regulation has evolved over the last 30 years or so, and how risk ideas gained ground as a response to increased levels of state control.

Background

2.2 The 1980s and 1990s witnessed an expansion of regulation in the UK, and with it the emergence of an anti-regulatory movement in industry, and business. It has been suggested that this was a reaction to the growth of what Majone in 1994[3] christened the '*regulatory state'*, described later by Hood *et al.* as a '*new institutional and policy style […], in which government's role as regulator advances while its role as a direct employer or property owner may decline through privatization and bureaucratic downsizing*.'[4] A crude illustration of this[5] is the intensive programme of privatisation that was instigated in the 1980s and 1990s in the UK, with, for example, British Rail, British Telecom, and state-run water, gas, and electricity companies all being privatised over this period. To ensure that these industries continued to provide public services and operate competitively, regulatory bodies were set up – they now exist in the shape of the Office of Rail Regulation, Ofcom, Ofwat, and Ofgem.

2.3 Successive Conservative Governments responded to the criticism of over-regulation with a number of attempts to de-regulate, including the de-regulation of the London Stock Exchange – also known as the Big Bang – in 1986, [6] and the Deregulation and Contracting Out Act of 1994.[7] More recently the Coalition Government has also tried to tackle the perceived problem with *its Red Tape Challenge* and consequent Deregulation Act 2015.

2.4 In addition, these two decades witnessed the emergence of a drive to modernise and render more efficient the way government and public services made and implemented policy. The movement was inspired by private sector management practices, and is sometimes referred to as New Public Management (NPM).[8] Accounts of NPM – which was not by any means confined to the UK – vary, but a number of characteristics are common across these accounts. Among them are:

- Performance auditing
- Accountability for performance

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[3] Giandomenico Majone. 1994. *The rise of the regulatory state in Europe*. West European Politics, Vol. 17, Iss. 3, 1994.
[4] Hood C., Rothstein H., and Baldwin R. 2001. *The Government of Risk – Understanding Risk Regulation Regimes.* Oxford University Press.
[5] Our examples.
[6] http://www.londonstockexchange.com/about-the-exchange/company-overview/our-history/our-history.htm
[7] http://www.legislation.gov.uk/ukpga/1994/40/contents
[8] Hood C. 2002. Encyclopedia entry on New Public Management in *The Encyclopaedia of the Social and Behavioral Sciences*. Elsevier. Available at: http://christopherhood.net/pdfs/npm_encyclopedia_entry.pdf.

- Improved regulation
- Privatisation
- Strategic planning and management, and
- Competition.[9]

2.5 It is in this context that risk-based approaches really started to gain traction. They were seen as providing an objective and transparent means of making policy decisions, allocating resources, resolving conflicts between competing interests,[10] and (mostly through audit) accounting for performance.[11]

Risk in regulation

2.6 The Health and Safety Executive (HSE) was something of a pioneer in the field of risk-based regulation. In 1988, it published a report entitled *The Tolerability of Risk from Nuclear Power Stations*,[12] which set out in explicit, technical, and sometimes blunt terms its approach to regulating risk in the nuclear sector. It explained that:

> *'to tolerate a risk means that we do not regard it as negligible or something we might ignore, but rather as something we need to keep under review and reduce still further if and as we can. For a risk to be 'acceptable' on the other hand means that for purposes of life or work, we are prepared to take it pretty well as it is.'*

2.7 The report states that the less tolerable a risk, the more, proportionately, employers should spend to address it. What we see emerging here is the principle of risk-based proportionality, which has become central to modern regulatory thinking.

2.8 Government-led initiatives to introduce risk ideas in regulation are generally considered to have taken shape much later. In 1997, the Better Regulation Task Force – a government body set up to reduce and control the burdens of regulation on business – devised five principles for improving regulation which have since become embedded in thinking on regulatory policy in all sectors: proportionality, accountability, consistency, transparency, and targeting. The

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[9] Gruening G. *Origin and theoretical basis of New Public Management*. Elsevier, International Public Management Journal 4 (2001) 1–25. Available at: https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=10&cad=rja&uact=8&ved=0CHAQFjAJ&url=http%3A%2F%2Fwww.researchgate.net%2Fprofile%2FDavid_Hulme%2Fpublication%2F233034883_Public_Management_Reform_Im_Developing_Countries%2Flinks%2F00b4952f8ad7d92a04000000.pdf&ei=TvrYVPCAFM6f7gaz54H4Dw&usg=AFQjCNF8I-5hGVJV-0UwRyzcqHbLRH1ziw

[10] Bridget M. Hutter. March 2005. *The Attractions of Risk-based Regulation: accounting for the emergence of risk ideas in regulation.* ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.

[11] For an account of the rise of the audit culture in the UK and its links to the regulatory state, see: Michael Moran. 2002. *Review Article: Understanding the Regulatory State*. British Journal of Political Science 32, 391–413. Cambridge University Press.

[12] Health and Safety Executive.1988. *The Tolerability of Risk from Nuclear Power Stations.* HMSO. Available at: http://www.onr.org.uk/documents/tolerability.pdf

2003 follow-up publication *Principles of Good Regulation*[13] expanded on these concepts:

- **Proportionality**: 'regulators should only intervene when necessary. Remedies should be appropriate to the risk posed and costs identified and minimised'
- **Accountability**: 'regulators must be able to justify decisions, and be subject to public scrutiny'
- **Consistency**: 'Government rules and standards must be joined up and implemented fairly'
- **Transparency**: 'regulators should be open, and keep regulations simple and user-friendly'
- **Targeting**: 'regulation should be focused on the problem, and minimise side effects'.

2.9 It is clear that risk-based approaches, in theory at least, can play an important role in the application of all five of these principles. They are integral to determining proportionality and provide a rationale for decisions about resource allocation and regulatory action. They also help to ensure that these decisions are consistent, enable greater transparency by demonstrating what lies behind the decisions, and provide the evidence to enable regulators to target problem areas.

2.10 The government push for better risk management in regulation was formalised in the *Modernising Government*[14] White Paper published by the New Labour Government in 1999. The plan set out a number of improvements that were needed in policy-making, including '*avoiding imposing unnecessary burdens*' and '*improving the way risk is managed*'. It explained that:

> *'Where government considers it right to regulate it will do so, but regulation for its own sake is too often seen as an easy answer, without proper consideration being given to better ways of achieving the outcome. We will base our decisions on a careful appraisal of the benefits any measure seek to achieve, the costs it entails and the cumulative burden of regulation on business. In doing so, we will give business and other interested parties a proper opportunity to contribute.*
> *[…]*
> *Government is often criticised for intervening too much to protect people from some risks, while failing to protect them sufficiently from others. Much government activity is concerned with managing risks, in the workplace, in what we eat and in protecting the environment. We need consistently to follow good practice in policy making as we assess, manage and communicate risks.'*

[13] Better Regulation Task Force. 2003. *Principles of Good Regulation.* Available at: http://webarchive.nationalarchives.gov.uk/20100407162704/http:/archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf
[14] HM Government. 1999. *Modernising Government*. HMSO. Available at: https://www.wbginvestmentclimate.org/uploads/modgov.pdf

2.11 The government's position on risk in regulation was developed in greater detail through the landmark Hampton review[15] of 2005. The review's aim was to *'identify ways in which the administrative burden of regulation on businesses can be reduced, while maintaining or improving regulatory outcomes.'* It set out a number of principles (known as the 'Hampton Principles'), including that:

> '*regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources on the areas that need them most*.'

2.12 The Hampton Principles were subsequently enshrined in the *Regulators' Compliance Code*.[16]

2.13 Precisely what impact these reforms have had on regulation is unclear. Hutter commented in 2005[17] that there was little clarity at that time about the '*precise ways in which ideas of risk [had] permeated regulatory debates and approaches*', and cited two government reports suggesting that the impact had been patchy at best. We have not found any more recent literature in the course of this review that surveyed the impact of risk ideas in regulation.

2.14 Whatever their impact, risk ideas appear still to be central to government policy on regulation. The financial crisis of 2008 provoked a review of prevailing regulatory approaches, particularly in the financial sector. In 2009, in the aftermath of the crisis, the Regulatory Reform Committee of the House of Commons made the following recommendation in its report on *Themes and Trends in Regulatory Reform:*[18]

> *'In future, analysts and commentators must avoid confusing risk-based regulation and so-called "light-touch" approaches. Risk-based "right-touch" regulation remains a valid approach provided there is: (a) diligence in understanding risk; (b) a willingness to accept some degree of failure (albeit that in certain sectors there must be maximum effort to eliminate failure); (c) an awareness that risk assessments, with their tendency sometimes to lead to a false sense of security, should be subject to appropriate challenge; and (d) the willingness to be intrusive rather than light-touch when appropriate. At this stage in the debate, better balance is required in order to ensure an effective delivery of the regulatory reform agenda.'*

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[15] Philip Hampton. 2005. *Reducing administrative burdens: effective inspection and enforcement.* HMSO. Available at: http://webarchive.nationalarchives.gov.uk/20121212135622/http://www.bis.gov.uk/files/file22988.pdf

[16] HM Treasury. 2006. *Implementing Hampton: from enforcement to compliance*. HMSO. Available at: http://webarchive.nationalarchives.gov.uk/20130129110402/http://www.hm-treasury.gov.uk/d/hampton_compliance281106.pdf

[17] Bridget M. Hutter. March 2005. *The Attractions of Risk-based Regulation: accounting for the emergence of risk ideas in regulation.* ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.

[18] The Professional Standards Authority, or Council for Healthcare Regulatory Excellence as it was then, submitted evidence to the Committee for this Inquiry. It is available here: http://www.publications.parliament.uk/pa/cm200809/cmselect/cmdereg/329/329ii.pdf

2.15 The Regulators' Code,[19] which superseded the Regulators' Compliance Code mentioned above, continues to require that regulators take a risk-based approach and focus on the areas of greatest identified risk. The Coalition Government's policy on the regulation of the health and care workforce[20] drew heavily on the related concepts of risk and proportionality. The financial crisis appears not to have discredited risk-based regulation in the eyes of the government and Parliament at least.

2.16 In conclusion, risk-based regulation emerged in part as a response to the growth of the government's own regulatory footprint but also in response to pressure from business for de-regulation. It has been central to all recent regulation improvement initiatives. Having survived several changes of government, it is now heavily embedded in government and other regulatory policy thinking in the UK. But what is risk, and what does risk-based regulation look like?

[19] Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300126/14-705-regulators-code.pdf

[20] Department of Health. 2011. *Enabling Excellence - Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers*. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216580/dh_124374.pdf

3. Defining risk

3.1 In order to understand and discuss the concept of risk-based regulation, we need to understand what is meant by risk.

3.2 The Oxford English Dictionary[21] gives two meanings of the word 'risk' that are relevant here:

i. The possibility that something unpleasant will happen, and
ii. A person or thing causing a risk or regarded in relation to a risk.

3.3 Under these definitions, the term means the possibility of something bad happening, as well as the cause of that bad thing. This ambiguity is borne out in the literature. The HSE gave us a third meaning – they defined risk as '*the chance that something adverse will happen'*, but also acknowledged that risk is often used to describe both '*the chance and the consequences taken together'*.[22] In other words, risk can be the possibility of a bad thing happening, the cause of the bad thing, and the bad thing itself. Malcolm Sparrow talks about the '*overlap and ambiguity between the meaning of "*risks*" and other undesirable commodities like "*problems*" and "harms"*'.[23] He states that in general 'risk *seems prospective and not very likely*. Problem *seems more current and certain*.' He describes a problem as a risk that has materialised.

3.4 In the London School of Economics (LSE) journal, *Risk and Regulation*, Anette Mikes explains that even in the world of risk management there are fundamental disagreements about the meaning of risk.[24] For example, the Committee of Sponsoring Organizations of the Treadway Commission (COSO),[25] an influential thought leader in the field of enterprise risk management, regards risk as negative, with risks and opportunities presented as opposites.[26] The International Organization for Standardization (ISO), on the other hand, consider risk to be a neutral concept, describing it as '*the effect of uncertainty on objectives – positive and/or negative'*.[27] Under this definition, risk management is about managing uncertainty and dealing with the consequences. While this definition appears to run counter to the prevailing understanding of the term, it is one that has gained some momentum in the field of risk management.

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[21] Ed. Catherine Soanes and Angus Stevenson. 2006. *Concise Oxford English Dictionary, Eleventh Edition*. Oxford University Press.
[22] Health and Safety Executive. 1998. *The Tolerability of Risk from Nuclear Power Stations*. HMSO. Available at: http://www.onr.org.uk/documents/tolerability.pdf.
[23] Malcolm K. Sparrow. 2008. *The Character of Harms: Operational Challenges in Control*. Cambridge University Press. p10.
[24] Anette Mikes. Winter 2012. *The Struggle to Codify Risk Management.* Risk and Regulation, Winder 20112 edition. ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.
[25] The Committee of Sponsoring Organizations of the Treadway Commission. More information is available here: http://www.coso.org. Accessed 30/03/15
[26] COSO. 2004. *Enterprise Risk Management – Integrated Framework, Executive Summary.* Available at: http://www.coso.org/documents/coso_erm_executivesummary.pdf
[27] See ISO Guide 73:2009. Available at: https://www.iso.org/obp/ui/#iso:std:iso:guide:73:ed-1:v1:en. Accessed 02/03/15.

3.5 It is important at this point to make a distinction between what we will call regulatory risks, and what Rothstein *et al.* term institutional risks.[28] The former are risks to society created by the regulated entities. The field of health and care professional regulation is concerned with reducing the risks posed by health and care professionals to patients, service users, and the public – those are the regulatory risks. Institutional risks, on the other hand, are those that threaten the organisation itself and its objectives. Rothstein *et al.* write that risks such as enforcement failures, liabilities and damage to reputation are '*an inherent feature of regulation, in so far as they arise from the inevitable complexities, conflicts and puzzles of regulatory activity.'*

3.6 The Rothstein paper also argues that good practice in risk-based regulation is often characterised as '*the assessment and management of the bundle of issues usually termed 'business risks' associated with delivering regulatory objectives.'* This suggests that for a regulator, business (institutional risk) should be aligned with regulatory risk, i.e. the regulatory objective to reduce the risk of harm should be the primary institutional objective. This is reflected, for example, in the work of the Solicitors Regulation Authority, whose regulatory objectives are set out in its legislation and form the basis of the risk framework. This framework '*outlines how [they] operate and oversee risk-based regulation through [their] risk management process, risk governance and the organisational culture required to embed a risk-based approach'*.[29] However, as we discuss in our closing chapter, conflicts can arise between regulatory and business objectives, particular when there is a risk of reputational damage.

3.7 Taking this into account, it is our view that in the context of this review, 'risk' should be used to describe the likelihood of harm occurring, while 'harm', a term used by Sparrow, should be used to describe the adverse consequences that regulation is meant to prevent or reduce. So when we talk about risk in this paper, unless we are quoting a publication where it may have a different meaning, we mean 'risk of harm'. Similarly when we discuss risk-based approaches to regulation, we are talking about those that identify and respond to a risk of harm. We also use the term 'hazard', which Charles Vincent describes as the conditions or events that can lead to or contribute to this harm.[30]

3.8 In health and social care, harm is the adverse consequences that a patient or service user may suffer as a result of interacting with health or social care services. Research carried out as part of this project[31] suggests that 'harm' should have a broad meaning covering both the physical and the psychological impacts of poor care.

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[28] Henry Rothstein, Phil Irving, Terry Walden, Roger Yearsley. 2006. *The risks of risk-based regulation: Insights from the environmental policy domain.* Environment International 32 (2006) 1056-1065. Elsevier.

[29] See the SRA website page on the SRA Risk Framework: http://www.sra.org.uk/risk/risk-framework.page#start

[30] The Health Foundation, January 2015. *Safer Clinical Systems: evaluation findings. Health Foundation summary and analysis*. Available at: http://www.health.org.uk/sites/default/files/SaferClinicalSystemsEvaluationFindings_InBrief.pdf. Accessed 21.07.15.

[31] Research Works. July 2015. *The Professional Standards Authority for Health and Social Care: Research with patients and service users on assuring the quality of health and care professionals through Right-touch regulation*. Available at: www.professionalstandards.org.uk

3.9 In conclusion, risk is a term with a number of related meanings. It is often used ambiguously to mean an adverse event, the chances of that event happening, and the event itself. In this review, we are using it to mean the likelihood of a harm occurring. With this in mind, we can go on to consider what risk-based regulation might involve.

4. Understanding risk-based regulation

4.1 What is meant by 'risk-based regulation' and what does it look like? These are the two questions we will address in this chapter.

Assumptions

4.2 As with 'risk', there is no universal understanding of the term 'risk-based regulation'. In their paper on the risk-based regulation of doctors, [32] Lloyd-Bostock and Hutter describe it as '*a cluster of tools and characteristics rather than a clearly defined and coherent method*.' They suggest that an '*ideal type*' of risk based-approaches would include the following characteristics:

> '*Commitment to a risk-based philosophy, belief in the anticipation and manageability of risk (in contrast with a more traditional emphasis on retrospective learning), a more holistic view of regulation and risk management in which public and private sources of regulation co-exist, integrated approaches to regulating risks which conceptualize risks as interrelated, and the formalization of regulation/risk management through the employment of technical risk-based tools emerging out of economics'*

4.3 This paragraph is of particular interest because it sets out what could be considered prerequisites for the adoption of a successful risk-based approach. The first two clauses here describe the belief system that a government or organisation needs to embrace if it is going to adopt risk-based regulation. In our view, the most fundamental of these beliefs is that some risks are more tolerable than others, and that it is possible to define what is tolerable and what is not.

4.4 Closely tied to this is the idea that it is not possible to remove all risks completely because resources are always limited – in the real world there is no such thing as zero risk of harm. Governments and regulators must choose to address certain risks over others. Lloyd-Bostock and Hutter address this further on in their paper, when they discuss the problem of acknowledging that a certain level of risk is tolerable while maintaining the confidence of the public.

4.5 The second belief is that risk can be predicted and managed based on these predictions. This raises a basic philosophical question about whether we can predict the future based on our observation of past events (known as *inductive reasoning*[33]). But of greater interest here is the more practical question of whether we can know enough about both the past (circumstances, behaviour) and the future to predict the circumstances in which harm is likely to occur in the future – and to develop a regulatory response that reduces the likelihood of it occurring.

4.6 The points about a holistic view of risk and risk-management, and about integrated approaches to interrelated risks ('*a more holistic view of regulation and risk management in which public and private sources of regulation co-exist,*

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[32] Lloyd-Bostock S.M., and Hutter B.M. 2008. *Reforming regulation of the medical profession: The risks of risk-based approaches.* Health, Risk & Society, Feb 2008; 10(1); 69-83. Routledge.

[33] As opposed to *deductive* reasoning which is based on irrefutable logical truths. The British philosopher David Hume (1711-1776) asserted that induction was flawed because there was no certainty that the future would resemble the past.

integrated approaches to regulating risks which conceptualize risks as interrelated'), echo the view set out in *Right-touch regulation* about the importance of the contributions of different agencies to providing high-quality healthcare. This is about recognising the complexity of the situations that give rise to risks and lead to their becoming reality, and the multiplicity of the agencies that can and should be responsible for addressing these risks.

4.7 The final part of this paragraph ('*the formalization of regulation/risk management through the employment of technical risk-based tools emerging out of economics')* picks up on the points we made in the opening chapter about how risk ideas were heavily rooted in management techniques from the private sector. To explain the link between regulatory development and '*the social handling of risk*', Hood *et al.* quote Michael Power who talks about the rise of the '*audit society*'. This audit society responds '*to risk and regulatory failure by "greater investment in* formal*,* generalizable[34] *systems of control rather than by developing non-standard capabilities for action on informal sources of intelligence."*'[35] In another of Hutter's publications,[36] she explains that risk-based approaches entail, at a minimum, '*the use of technical risk-based tools, emerging out of economics (cost-benefit approaches), and science (risk-assessment techniques).*' This formalisation of risk assessment and risk management through transferrable techniques is central to risk-based regulation. At its heart is the assumption that a risk can be measured or quantified, meaning it is possible to measure it objectively in a way that enables the comparison of different instances of measurement. Often, this involves the use of two metrics – potential impact and likelihood.[37]

4.8 But risk-based regimes are based on a further assumption. Measuring or quantifying risk may be useful for the task of comparing different hazards and prioritising for resource allocation, but it does not provide the information that a government or a regulator needs in order to understand whether and how the risk could be addressed or managed. For this, a qualitative assessment is needed – risk-based approaches assume that a risk can be described or qualified and the hazards identified. This is linked to the point above about the predictability of risk.

4.9 This idea of qualitative assessment is at the heart of much of Sparrow's thinking: his book *The Character of Harms* focuses on how regulatory agencies can understand and respond to the many different types of harm.[38] He talks about '*scrutinizing the harms themselves, and discovering their dynamics and dependencies*'[39] so that they may be '*sabotaged'* by exploiting identified

[34] Our emphasis.
[35] Hood C, Rothstein H, Baldwin R. 2001. *The Government of Risk – Understanding Risk Regulation Regimes.* Oxford University Press.
[36] Bridget M. Hutter. March 2005. *The Attractions of Risk-based Regulation: accounting for the emergence of risk ideas in regulation.* ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.
[37] Lloyd-Bostock S.M., and Hutter B.M. 2008. *Reforming regulation of the medical profession: The risks of risk-based approaches.* Health, Risk & Society, Feb 2008; 10(1); 69-83. Routledge.
[38] Malcolm K. Sparrow. 2008. *The Character of Harms: Operational Challenges in Control*. Cambridge University Press.
[39] Malcolm K. Sparrow. 2008. *The Character of Harms: Operational Challenges in Control*. Cambridge University Press. p27.

vulnerabilities. In his view, it is this preemptive striking that is the main task of the regulator, and not the punitive or remedial action that is taken after the fact.

Understanding risk-based regulation – how it works

4.10 We do not propose to look at this question in detail as it is a vast discipline. However, there are some broad themes that are worth considering in the context of this overview. One way of conceptualising a risk policy framework is through process. This is an area where institutional risk management and regulatory risk management models overlap – although there are some differences as we will see further on.

4.11 In his chapter for the 2010 OECD Review of Regulatory Reform, titled *Risk and Regulatory Policy – Improving the Governance of Risk,*[40] Gregory Bounds explains that most models operate as a risk-policy cycle in three phases:

i. **Risk assessment**: this involves 'framing and forecasting the probability and consequences of identified hazards'.
ii. **Risk management**: 'aims to design and implement actions and remedies to address risks through a consideration of potential risk treatments and selection of the most appropriate.'
iii. **Review and evaluation**: closes the policy loop through ex post evaluation.

4.12 The joint 2010 publication *A structured approach to Enterprise Risk Management (ERM) and the requirements of ISO 31000*[41] argues that most models involve the '7 Rs' of risk management, which fit into Bounds' three phases:

- recognition or identification of risks *(Bounds' phase 1*[42]*)*
- ranking or evaluation of risks *(1)*
- responding to significant risks *(2)*
- resourcing controls *(2)*
- reaction planning *(2)*
- reporting and monitoring risk performance *(2–3)*
- reviewing the risk management framework *(3)*

4.13 There is a wide range of methods for assessing risk. Klinke and Renn[43] developed a classification of different approaches to riskassessment:

- risk-based approaches emphasise the use of quantitative data with probability and severity ratings, and exposure limits;

[40] Gregory Bounds. 2010. *Challenges to Designing Regulatory Policy Frameworks to Manage Risks.* Chapter 1 of Risk and Regulatory Policy – Improving the Governance of Risk. OECD 2010.
[41] The Association of Insurance and Risk Managers, The Public Risk Management Association, and The Institute of Risk Management. 2010. *A structured approach to Enterprise Risk Management (ERM) and the requirements of ISO 3100*. Available at: https://www.theirm.org/media/886062/ISO3100_doc.pdf
[42] Our interpretation of what fits into which of Bounds' phases is in *italics*.
[43] Andreas Klinke and Ortwin Renn. 2002. *A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies.* Risk Analysis, Vol. 22, No. 6, 2002. Available at: http://josiah.berkeley.edu/2007Fall/NE275/CourseReader/6.pdf

- precaution-based approaches identify points of uncertainty in a process or situation, using quantitative data, and adapt the process to eliminate the uncertainty;
- discourse-based approaches are useful where there is ambiguity about the risks in a particular setting; they employ more qualitative methods to develop an understanding of risks and how they should be managed.

4.14 The first category, which the literature suggests is the most prevalent, has been referred to as the science-based approach, because of its reliance on data and probabilities. Covello and Merkhofer, writing on risk assessment in 1993,[44] developed the following definition of risk assessment, which gives some idea of the level of quantification that a scientific risk assessment methodology may aspire to:

> *'a systematic process for generating a probability distribution or similar quantification that describes uncertainty about the magnitudes, timing or nature of possible health or environmental consequences associated with possible exposure to specified substances, processes, actions or events.'*

4.15 The precautionary approach as set out by Klinke and Renn[45] was developed as an alternative to risk-based approaches, and as the label suggests, is more risk averse. In contrast, the discourse-based approach is not associated with scientific uncertainty. Instead, it is used where there is a lack of public acknowledgement of a risk, or where a risk is understood by the public to be more serious than it is.

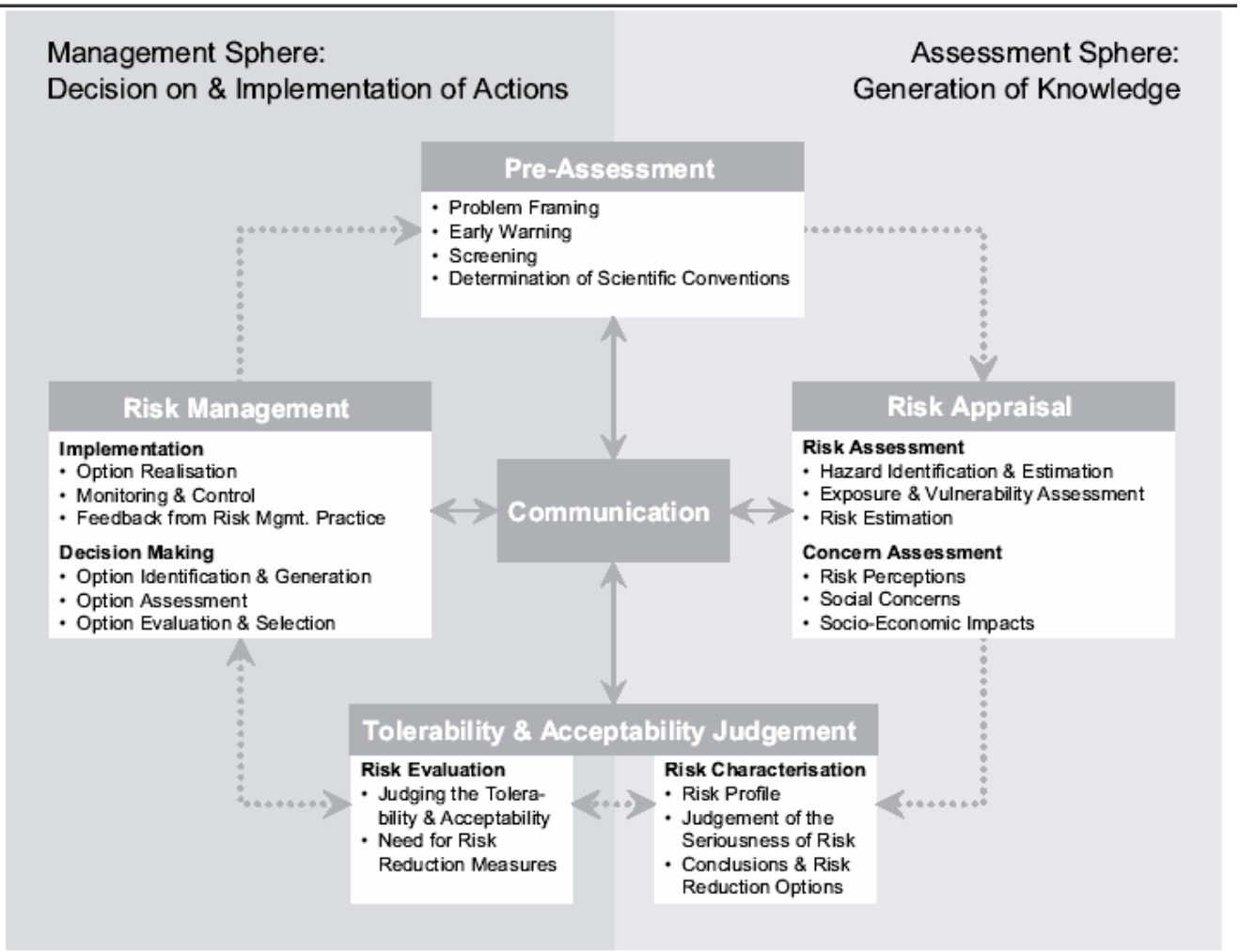
4.16 The International Risk Governance Council (IRGC) model of risk governance[46] presented in the paper by Gregory Bounds fleshes out the assessment phase.

[44] V.T. Covello, M.W. Merkhofer. 1993. *Risk Assessment Methods: Approaches for Assessing Health and Environmental Risks*. Plenum Press, New York. IS

[45] Andreas Klinke and Ortwin Renn. 2002. *A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies.* Risk Analysis, Vol. 22, No. 6, 2002. Available at: http://josiah.berkeley.edu/2007Fall/NE275/CourseReader/6.pdf

[46] A version of this flowchart and short summary are available here: http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeconaf/183/183we14.htm

Figure 1: The IRGC Risk Governance Framework



4.17 Here, the assessment phase is broken down into 'pre-assessment', 'risk appraisal' which is broken down into risk and concern assessment, and 'tolerability and acceptability judgement' which consists of characterising the risk.

4.18 This model expands on the stages of the process that relate to decisions about the tolerability of a risk, which the IRGC described in written evidence to the Lords Select Committee on Economic Affairs as the most '*controversial'*.[47] It also emphasises the fact that decisions about risk management should be based not only on what it calls '*scientific'* assessments, but also on consideration of the social and economic impacts, and on value judgements about what risks society can tolerate.

4.19 *A structured approach to Enterprise Risk Management (ERM) and the requirements of ISO 31000*[48] breaks the response phase down into four

[47] From evidence submitted in 2006. Available at: http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeconaf/183/183we14.htm

[48] The Association of Insurance and Risk Managers, The Public Risk Management Association, and The Institute of Risk Management. 2010. *A structured approach to Enterprise Risk Management (ERM) and the requirements of ISO 3100*. Available at: https://www.theirm.org/media/886062/ISO3100_doc.pdf

possible courses of action (or inaction) – the '4 Ts': tolerate, treat, transfer, or terminate.

4.20 Bounds offers a slightly different range of options:

- risk avoidance (proscription, prohibition)
- reduction (licensing, codes and standards, enforcement and compliance strategies),
- retention (accepting loss through self-insurance, or retention of responsibility for functions within government) and
- transfer (compulsory insurance, privatisation, public private partnerships).

4.21 Unlike the ERM model, Bounds does not include a termination option. This perhaps reflects the fact that in the regulatory context, regulators and governments are rarely – if ever – in a position to eradicate a risk completely. Instead, they find themselves in the business of *treating* (to use the ERM categorisation) or more specifically *reducing* (to use Bounds' phrase) the risks of harm. Some corporate or institutional risks, on the other hand, could feasibly be completely removed.

4.22 Not mentioned in either of these two models, but with its place in both the design and the evaluation phases is the assessment of risk tradeoffs. Risk tradeoff, also known as 'risk versus risk' or sometimes 'health versus health', refers to the emergence or exacerbation of one risk (the ancillary risk) resulting from the introduction of measures to control another (the primary risk). This phenomenon has given rise to the discipline of risk tradeoff analysis,[49] which, according to Rascoff and Revesz writing in 2002, '[transformed] the practice of regulation'.[50] Sparrow gives the following example of a risk tradeoff:

> *'[…] many Americans, in the months following 9/11 eschewed flying and drove their cars long distances instead. Between October and December 2001 the extra highway miles resulted in an estimated 1,000 additional road deaths.'* [51]

4.23 It is not possible to evaluate the impact of a regulatory approach without looking for these types of unintended consequences, and considering whether they themselves are tolerable, or whether they undermine the benefits of addressing the primary risk.

4.24 A final element of risk-based approaches which we have yet to address is risk communication. Bounds believes it to be '*fundamental to the entire risk policy cycle.*'[52] It is described as playing a part in identifying and assessing risks, helping to educate the public when choosing between risks (especially in a 'risk tradeoff'),[53] getting buy-in and achieving consensus among those affected by

[49] John D. Graham, Jonathan Baert Wiener, 1995. *Risk vs. Risk.* Harvard University Press.
[50] Samuel J. Rascoff and Richard L. Revesz, 2002. *The Biases of Risk Tradeoff Analysis: Towards Parity in Environmental and Health-and-Safety Regulation*. The University of Chicago Law Review. Vol. 69, No. 4 (Autumn, 2002), pp. 1763-1836. Available at: http://www.jstor.org/stable/1600618
[51] Malcolm K. Sparrow. 2008. *The Character of Harms: Operational Challenges in Control*. Cambridge University Press. p10.
[52] Gregory Bounds. 2010. *Challenges to Designing Regulatory Policy Frameworks to Manage Risks.* Chapter 1 of Risk and Regulatory Policy – Improving the Governance of Risk. OECD 2010.
[53] Gregory Bounds. 2010. *Challenges to Designing Regulatory Policy Frameworks to Manage Risks.* Chapter 1 of Risk and Regulatory Policy – Improving the Governance of Risk. OECD 2010.

the decision, and linking the concerns of the public and the regulatory processes.[54]

A conceptual model

4.25 All these models describe the process of developing and operationalizing risk-based regimes. A different, more conceptual description is offered by Hood *et al.*, [55] who describe risk-regulation regimes as having three main components:

- information gathering
- standard setting, and
- behaviour modification.

4.26 The *Information gathering* phase consists of collecting information to detect and assess risks, often through varied methods. However, what data is used and how it is collected is a vexed question, and as Hood *et al*. explains, is often the subject of criticism when regulation comes under public and political scrutiny.

4.27 Risk-based regulation is based on judgements about what levels and types of risks are acceptable, and out of these judgements emerge standards – these decisions constitute the *standard setting* phase. In the words of Hood *et al.*, *standard setting* allows a distinction to be made between '*more or less preferred states of the system*.' In their view, this is the part of the system on which most writing on risk in regulation focuses. They state that standards may be set using scientific methods, bargaining between interested parties, or simply '*stab-in-the-dark activity*' – and are in practice often the result of a combination of some or all the above.

4.28 Hood *et al.*, crediting Andrew Dunsire[56] note the distinction between '*homeostatic*'[57] and '*collibration*'[58] approaches. Homeostatic approaches consist of '*setting a threshold level or maximum to be observed*' – here the regulating body makes a judgement about what level of risk is acceptable. A collibration standard, on the other hand, is necessary when there are competing or contradictory 'goods' (such as cost savings and benefits). It sets a standard in which responsibility for resolving the tension between these opposing forces is delegated to the regulated entity, in a way that could be described as a combination of state-run regulation and self-regulation. Decisions about what is an acceptable level of risk are made on a case-by-case basis by those to whom regulation applies. The question of which of these two methods to employ (homeostatic or collibration) is described as a '*pervasive design issue in risk-regulation*'. [59]

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[54] Henry Rothstein, Phil Irving, Terry Walden, Roger Yearsley. 2006. *The risks of risk-based regulation: Insights from the environmental policy domain.* Environment International 32 (2006) 1056-1065. Elsevier.
[55] Hood C, Rothstein H, Baldwin R. 2001. *The Government of Risk – Understanding Risk Regulation Regimes.* Oxford University Press.
[56] Andrew Dunsire. 1993. *Manipulating Social Tensions: Collibration as an Alternative Mode of Government Intervention*. Max-Planck-Institut für Gesellschaftsforschung, MPIFG Discussion Paper 93/7. Available at: http://www.mpi-fg-koeln.mpg.de/pu/mpifg_dp/dp93-7.pdf
[57] Homeostasis is defined as 'the maintenance of a dynamically stable state within a system' (Oxford English Dictionary).
[58] Collibration is defined as 'weighing together; comparison' (Oxford English Dictionary).
[59] Hood C, Rothstein H, Baldwin R. 2001. *The Government of Risk – Understanding Risk Regulation Regimes.* Oxford University Press. p 26.

4.29 The third and final component of risk-based regulation is *behaviour modification*, which Hood *et al*. describe as *'highly problematic'.* Attempts to influence behaviour can lose sight of the intention behind the standard-setting (the four-hour waiting time target for hospital A&E departments could be one such example), or modify behaviour in ways that are unforeseen and produce the '*reverse of the intended effect'.*[60]

4.30 One of the major debates on the subject of behaviour modification relates to the relative merits of deterrence versus compliance regimes. Deterrence regimes rely on the application of sanctions or penalties to the few to encourage compliance of the many. Compliance regimes on the other hand are based on a more collaborative relationship between regulator and regulated, with an emphasis on '*diplomacy, persuasion, or education'.* Recent research by Gerry McGivern *et al.*[61] dealt with some of these themes in a report on the dynamics of regulation of osteopaths in the UK. The research identified a tendency for registrants who had been through the fitness to practise process to disengage from the profession, making them more likely to be subject to further complaints. The findings support a more '*relational approach to actively engaging with the osteopathy profession, which we suggest is leading osteopaths to frame osteopathic regulation and complying with [the standards] in more constructive professional terms'*. Most regulators probably use both methods though not necessarily to greatest effect.

4.31 Although there are many different models of risk based regulation, they display some common characteristics:

- They are based on a number of assumptions about regulation and the extent to which risks can be assessed;
- They tend to follow a standard cycle of risk assessment, design, application and review; and
- They consist of three key elements: information gathering, standard setting, and behaviour modification.

4.32 Taking into consideration these shared characteristics, we will now take a closer look at the appeal of risk-based approaches.

[60] Hood C, Rothstein H, Baldwin R. 2001. *The Government of Risk – Understanding Risk Regulation Regimes.* Oxford University Press. p 27.

[61] Professor Gerry McGivern, Dr Michael Fischer, Dr Tomas Palaima, Zoey Spendlove, Dr Oliver Thomson and Professor Justin Waring. February 2015. *Exploring and explaining the dynamics of osteopathic regulation, professionalism and compliance with standards in practice Report to the General Osteopathic Council*. Available at: http://www.osteopathy.org.uk/news-and-resources/document-library/research-and-surveys/dynamics-of-effective-regulation-final-report/

5. The benefits of risk-based approaches to regulation

5.1 The previous chapter gave an overview of some of the key characteristics of risk-regulation regimes. Keeping these in mind, we will now examine some of the literature that deals with the benefits of risk-based regulation.

5.2 We alluded to a number of benefits of risk-based regulation in our opening chapter. It is apparent from the impact of the Hampton Report and of the Better Regulation Commission in the 2000s, that 'risk-based regulation' and 'better regulation' became somewhat synonymous in the eyes of the UK Government and many others. Let us examine more closely why they became so popular.

5.3 In his paper for the 2010 OECD Review of Regulatory Reform, Gregory Bounds puts forward three key benefits of these approaches:

- 'it contributes to regulatory efficiency by targeting the approaches of the regulator to allocate resources where risk is greatest'
- 'it can assist in providing defensible rationale for decision making, that can withstand external challenge from the courts, or potentially the media,' and
- 'it can systematically improve decision making processes by providing new evidence and insights into potential risk.'[62]

5.4 Taking these in turn, the first of these benefits is economic, financial and social. Where resources are limited, decisions must be made about how to use them to best effect. Regulation is there to reduce the likelihood of adverse events occurring – it therefore appears legitimate for regulators to target the higher risk areas, and make conscious decisions not to use up valuable resources on the low risk areas.

5.5 But it is not just a matter of the resources expended by a government or a regulator: regulation imposes restrictions and burdens on regulated entities and markets, which can have a range of negative effects. Arguments about the over-regulation of businesses harming the economy are well rehearsed,[63] but there is also the possibility of over-regulation causing unnecessary social harms (often as unintended consequences). For instance, the quality of healthcare provision may be adversely affected if staff are distracted from their core responsibilities by the bureaucracy that is generated by regulatory requirements. It is therefore in the wider public interest to use only the regulatory force that is needed to control the level of risk. The landmark Hampton Report of 2005[64] focused on risk-based regulation as a means of

[62] Gregory Bounds. 2010. *Challenges to Designing Regulatory Policy Frameworks to Manage Risks.* Chapter 1 of Risk and Regulatory Policy – Improving the Governance of Risk. OECD 2010. p 28.
[63] See for example this report produced by the Swedish Agency for Growth Policy Analysis, *The Economic Effects of the Regulatory Burden*. p8. Available at: http://ec.europa.eu/enterprise/policies/industrial-competitiveness/competitiveness-analysis/seminars/files/bbs_falkenhall_report_en.pdf
[64] Philip Hampton. 2005. *Reducing administrative burdens: effective inspection and enforcement.* HMSO. Available at: http://webarchive.nationalarchives.gov.uk/20121212135622/http://www.bis.gov.uk/files/file22988.pdf

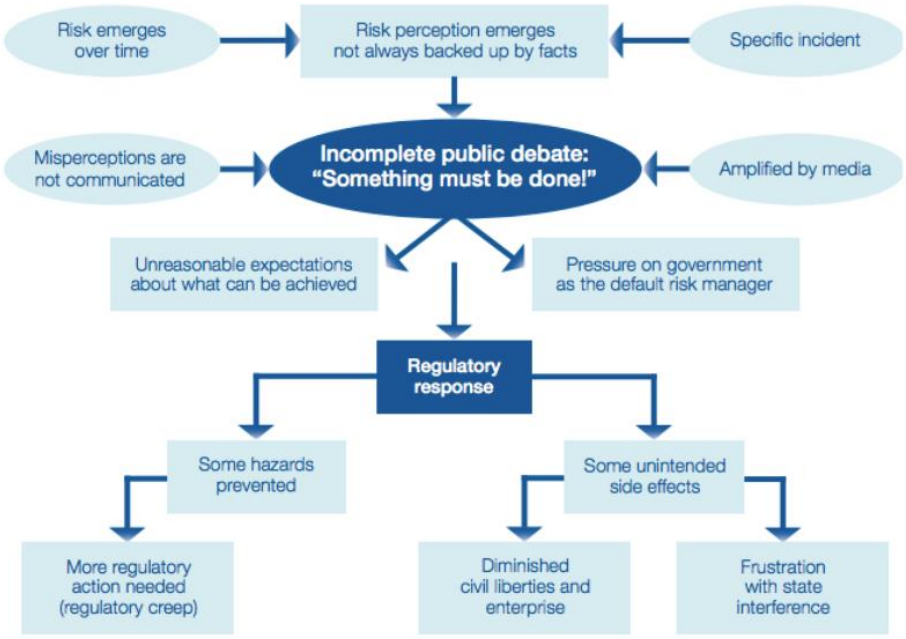
reducing regulatory burdens and reducing the unintended consequences of poorly designed regulatory regimes.

5.6 This first benefit is closely linked to the second – a risk-based framework provides what is considered by most to be a defensible rationale for allocating resource and imposing restrictions and burdens on the regulated. This relates to the Hood *et al.* idea of *standard setting*:[65] regulators must define what is acceptable and what is not, which risks or harms can be tolerated and which cannot. As Julia Black puts it in her paper on the risk-based regulation of financial services,[66] the Financial Services Authority's (FSA) adoption of a risk-based regime enabled it '*to answer its critics: to say why it did what it did, and equally as important, why it did not do what it did not do.*' Bounds believes this to be particularly useful to multi-sector regulators '*where not all policy problems within the regulator's domain will necessarily require equal or like treatment.'*[67]

5.7 Bounds refers to the need for a defence that may stand up to challenge in court and to trial by media. Such a defence will also be useful for negotiating or resolving conflicts between different interest groups.[68,69] Hutter believes that the main attraction of risk-based approaches is their '*apparent objectivity and transparency'*. In theory at least, a risk-based approach is one that can withstand challenge because it is based on the incontrovertible principle that regulation should target areas of high risk, and on the belief that it is possible to measure and compare risks objectively in order to determine which ones to target. In 2006, the Better Regulation Commission published its report *Risk, Responsibility and Regulation – Whose risk is it anyway?*[70] in which it argued that the UK Government faces undue pressure from the media and the public to manage all risks. The following diagram taken from the report summarises the argument.

[65] Hood C, Rothstein H, Baldwin R. 2001. *The Government of Risk – Understanding Risk Regulation Regimes.* Oxford University Press.
[66] Dr. Julia Black. 2004. *The Development of Risk Based Regulation in Financial Services: Canada, the UK and Australia, A Research Report*. ESRC Centre for the Analysis of Risk and Regulation. London School of Economics and Political Science. Available at: https://www.lse.ac.uk/collections/law/staff%20publications%20full%20text/black/risk%20based%20regulation%20in%20financial%20services.pdf
[67] Gregory Bounds. 2010. *Challenges to Designing Regulatory Policy Frameworks to Manage Risks.* Chapter 1 of Risk and Regulatory Policy – Improving the Governance of Risk. OECD 2010. p 25
[68] Hood C, Rothstein H, Baldwin R. 2001. *The Government of Risk – Understanding Risk Regulation Regimes.* Oxford University Press.
[69] Bridget M. Hutter. March 2005. *The Attractions of Risk-based Regulation: accounting for the emergence of risk ideas in regulation.* ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.
[70] Better Regulation Commission. 2006. *Risk, Responsibility and Regulation – Whose risk is it anyway?*. Available at: http://webarchive.nationalarchives.gov.uk/20090609003228/http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/risk_res_reg.pdf

Figure 2: The Regulatory Response to Risk (Better Regulation Commission)



5.8 The Better Regulation Commission saw risk-based regulation as a way of resisting the pressure to respond to every problem and crisis with new or increased levels of regulation. But for it to have this power, it must be visible to the outside world – this gives rise to a further benefit, which is that of transparency. In being open about the basis on which decisions about whether and how to respond to a risk, governments and regulators can resist the push from and perhaps even manage public expectations about what it should be regulating.

5.9 Bounds' third benefit is perhaps less immediate: he believes that an approach based on risk will lead to systematic improvements in decision making because it provides *'new evidence and insight into risks'*. This is possible thanks to the information gathering activity that is an essential component of risk-based regulation, according to Hood *et al.*[71] It also relates to the policy cycles we looked at in the previous chapter, where systematic pre-implementation risk assessment and post-implementation review stages are intended to improve the quality of the regulatory framework over time.

5.10 In addition, it becomes apparent from looking at the websites of regulatory agencies that have adopted risk-based approaches that they go hand-in-hand with aspirations to improve consistency in decision-making.[72] On a basic level, if two different groups of entities were to present the same level of risk, the decision about whether or not to act would be the same for both; or the same

[71] Hood C, Rothstein H, Baldwin R. 2001. *The Government of Risk – Understanding Risk Regulation Regimes.* Oxford University Press.

[72] See for example, the New South Wales Government *Guidance for regulators to implement outcomes and risk-based regulation*, available at: http://www.dpc.nsw.gov.au/__data/assets/pdf_file/0010/164782/QRS_Outcomes_and_Risk_Based_Regulation_Guidelines_-_July_2014_-_Web.pdf; the description of the risk framework of the Solicitors Regulatory Authority: http://www.sra.org.uk/riskframework/; a recent newsletter from the Australian Health Practitioner Regulation Agency: http://www.ahpra.gov.au/Publications/AHPRA-newsletter/April-2015.aspx

problem arising several years apart would elicit the same regulatory response, if the threshold for action had remained the same.

5.11 Finally, in his OECD paper Bounds also explains how risk-based methods can help to measure the performance of a regulatory agency and increase accountability. He believes they can reveal the sources of success and failure of regulatory policies, thereby moving away from a situation in which a regulator may be rewarded or punished for effects that may be unrelated to its actions. This drive for objective performance measurement and the possibilities for increased accountability that it creates are part and parcel of the modernising government agenda.

5.12 In summary, the benefits described here align with the better regulation principles by promoting a proportionate, accountable, transparent, targeted, and consistent approach to regulation.

6. Challenges and limitations of risk-based regulation

6.1 The preceding chapter describing the benefits of risk-based approaches to regulation may be a statement of the obvious for many. However, we will see in the following paragraphs that risk-based approaches also present significant challenges. The critiques of risk-based regulation are numerous and can be complex and technical – as we have done in the rest of this report, rather than looking at the technical detail, we have attempted to cover the broad challenges that may be faced by the different phases of a typical risk-based model.

6.2 Following the financial crash of 2008, risk-based regulation became the subject of much criticism. In the words of Julia Black, '*the reputations of four broad categories of regulatory approach and technique have suffered heavy casualties: principles based regulation, risk based regulation, reliance on internal management and controls, and market based regulation.*'[73] The Financial Services Authority (FSA), which was the UK banking regulator from 1997 to 2010, described itself as risk-based.[74] After the crash of 2008, it was strongly criticised for having been too '*light-touch*',[75] a term that has become associated with ineffectual risk regulation.[76]

6.3 Coincidentally, it was shortly after the financial crash that the full scale of the – now well-documented – failings at Mid-Staffordshire NHS Foundation Trust was revealed in a 2009 report by the Health Care Commission (HCC).[77] The HCC, its successor body the Care Quality Commission (CQC), and Monitor, the economic regulator for NHS Foundation Trusts were all heavily criticised for failing to take action.[78]

6.4 In this section, we will look at the key challenges faced by those seeking to use risk-based regulation, many of which were brought into focus by the financial crash and the failings at Mid-Staffs. The discussion is presented under two headings reflecting to two main phases of the risk framework: risk assessment and risk management.

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[73] Professor Julia Black. 2010. *The Rise, Fall and Fate of Principles Based Regulation*. LSE Law, Society and Economy, Working Papers 17/2010.London School of Economics and Political Science. Available at: http://www.lse.ac.uk/collections/law/wps/WPS2010-17_Black.pdf

[74] Dr. Julia Black. 2004. *The Development of Risk Based Regulation in Financial Services: Canada, the UK and Australia, A Research Report*. ESRC Centre for the Analysis of Risk and Regulation. London School of Economics and Political Science. Available at: https://www.lse.ac.uk/collections/law/staff%20publications%20full%20text/black/risk%20based%20regulation%20in%20financial%20services.pdf

[75] See Financial Times article by Brooke Masters, Chief Regulation Correspondent, ***Regulator's 'light touch' led to failure***. Available at: http://www.ft.com/cms/s/0/2bf14c52-24ce-11e1-bfb3-00144feabdc0.html#axzz3aZvjpagG

[76] See the comments of the Commons Regulatory Reform Committee on 'light-touch' and 'risk-based' regulation, paragraphs 21-27. Available at: http://www.publications.parliament.uk/pa/cm200809/cmselect/cmdereg/329/32906.htm

[77] Health Care Commission. 2009. *Investigation into Mid Staffordshire NHS Foundation Trust, March 2009.* Available at: http://webarchive.nationalarchives.gov.uk/20110504135228/http://www.cqc.org.uk/_db/_documents/Investigation_into_Mid_Staffordshire_NHS_Foundation_Trust.pdf

[78] See Final Report of the Mid-Staffordshire NHS Foundation Trust Inquiry. Available at: http://www.midstaffspublicinquiry.com/report

Risk assessment

6.5 We begin with a broad question about the validity of risk assessment methodologies. Criticisms appear to focus mostly on the quantitative, (pseudo-) scientific nature of risk assessment. Bounds refers to extensive debate about '*the technical construction of scientific procedures for assessing risk and uncertainty.*'[79] Lloyd-Bostock and Hutter explain that the quantitative nature of most risk assessments tends to simplify problems, and disguise '*the full complexity of risks*'.[80] Rothstein *et al.* argue that risk-based regulation '*asks questions of science, which science is not in a sufficiently advanced state to answer'*, and that this creates scope for '*regulatory uncertainty and conflict*'.[81] Questions about whether risk-assessment is fit for purpose go hand-in-hand with concerns that it gives an impression of greater scientific accuracy and objectivity than it can possibly guarantee.[82,83]

6.6 In practice, the level of sophistication required to identify a risk is likely to vary considerably from one context to the next, but what these quotes highlight is perhaps the principal challenge for risk assessment – how to develop tools that are sufficiently sophisticated to reflect the complexity and ambiguity of real life.

6.7 Risk assessment breaks down into a number of different tasks. Firstly, whether it is at the design phase or the implementation phase, regulators and governments need to access information that will, once analysed, reliably indicate the areas of greatest risk, the nature of those risks, and their variations over time. Lloyd-Bostock and Hutter talk about the reliance on '*good data, sound assumptions, and the quantifiability of information.*'[84] The question of what data is needed is fraught with complexity, because it requires an understanding of the predictors of risk. In the wake of Mid-Staffs, the Healthcare Commission was criticised for focusing on data that showed '*providers' apparent performance in relation to standards, most of which focused on the presence of theoretical systems, not on real achievements and outcomes for patients'*.[85] Building on work carried out by the Healthcare Commission before it, the CQC has developed a data set to help them identify higher-risk healthcare providers, the Quality and Risk Profile (QRF), which they acknowledge will need to constantly evolve.[86] Its effectiveness has yet to be established.

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[79] Gregory Bounds. 2010. *Challenges to Designing Regulatory Policy Frameworks to Manage Risks.* Chapter 1 of Risk and Regulatory Policy – Improving the Governance of Risk. OECD 2010

[80] Lloyd-Bostock S.M., and Hutter B.M. 2008. *Reforming regulation of the medical profession: The risks of risk-based approaches.* Health, Risk & Society, Feb 2008; 10(1); 69-83. Routledge

[81] Henry Rothstein, Phil Irving, Terry Walden, Roger Yearsley. 2006. *The risks of risk-based regulation: Insights from the environmental policy domain.* Environment International 32 (2006) 1056-1065. Elsevier

[82] Lloyd-Bostock S.M., and Hutter B.M. 2008. *Reforming regulation of the medical profession: The risks of risk-based approaches.* Health, Risk & Society, Feb 2008; 10(1); 69-83. Routledge

[83] Henry Rothstein, Phil Irving, Terry Walden, Roger Yearsley. 2006. *The risks of risk-based regulation: Insights from the environmental policy domain.* Environment International 32 (2006) 1056-1065. Elsevier

[84] Lloyd-Bostock S.M., and Hutter B.M. 2008. *Reforming regulation of the medical profession: The risks of risk-based approaches.* Health, Risk & Society, Feb 2008; 10(1); 69-83. Routledge

[85] The Mid Staffordshire NHS Foundation Trust Public Inquiry. 2013. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Executive summary. Available at: http://www.midstaffspublicinquiry.com/sites/default/files/report/Executive%20summary.pdf

[86] CQC. 2011. Developing quality and safety indicators in QRPs for NHS trusts – What clinicians and professionals told us at engagement events, January 2011. Available at: http://www.cqc.org.uk/sites/default/files/documents/20110117_cqc_qrp_report_final.pdf

6.8 For health and care professional regulators, the easiest option is to look for data that will identify risky groups of practitioners – in other words, the characteristics of an individual that reliably predict future lapses in behaviour or competence. The predictability of behaviour is a vast topic, and not one we can consider in any detail here. Of particular note, however, is a study by Professor David Wilson and Dr Elizabeth Yardley of characteristics common to '*contemporary nurse healthcare serial killers*'.[87] The authors claim that their research identifies '*a potentially useful checklist which, with revisions, could contribute towards preventative strategies and interventions*.' This type of study could yield valuable insights for use by employers, education providers, regulators and the police. The challenge in developing and applying these types of red flag methodologies is to find criteria that capture as few false positives as possible while nevertheless identifying those people who genuinely present a risk.

6.9 Furthermore, this type of approach assumes that harm arises out of factors relating only to the practitioner in question.[88] The reality is that mistakes, poor practice, and perhaps less obviously deliberate harm are caused by a combination of factors relating both to the practitioners and to the systems and environments in which they operate. A different or complementary approach might therefore be to look at the points in a patient's journey where risks are heightened, and the reasons for this heightened risk.[89]

6.10 The second challenge, which is inextricably linked to the first, is how to collect the data that is needed. Lloyd-Bostock and Hutter explain that proactive, tailor-made methods of data collection are time-consuming[90] and costly to the data provider. On the other hand, reactive methods that piggy-back on other collections may not provide the data in a usable form. Both require a thorough assessment of the quality and reliability of the data, and an understanding of the '*social and organizational processes whereby it enters the database.'* Inevitably, what data is available will shape what is used, because governments and regulators are reluctant to increase the regulatory burden by requiring regulated bodies to collect yet more pieces of information.[91]

6.11 Health and care professional regulators have a ready source of data about the risks presented by the group they regulate, in the shape of their own fitness to practise data. However, this is often difficult to analyse, because it is collected primarily for registration and case management purposes.[92] In addition, it is '*extremely unlikely to be representative of risks*' because '*patients tend to report*

[87] Yardley E., and Wilson D. 2014. *In Search of the 'Angels of Death': Conceptualising the Contemporary Nurse Healthcare Serial Killer*. J. Investig. Psych. Offender Profil., doi: 10.1002/jip.1434

[88] Lloyd-Bostock S.M., and Hutter B.M. 2008. *Reforming regulation of the medical profession: The risks of risk-based approaches.* Health, Risk & Society, Feb 2008; 10(1); 69-83. Routledge.

[89] Elizabeth van Rensen. June 2015. *Using video reflectivity for engaging health care professionals in practice improvement*. Building the evidence base of professional regulation: an international perspective Health and Care Professions Council conference, Amsterdam.

[90] See for example: http://www.communitycare.co.uk/2014/03/02/care-homes-face-paperwork-industry-damages-quality-care/

[91] See for example the Coalition Government's 'Red-tape Challenge': http://www.redtapechallenge.cabinetoffice.gov.uk/home/index/ Accessed 28.05.15

[92] See for example Chapter 9 of the research into risks in dentistry carried out for the General Dental Council (GDC). It explains some of the challenges that would need to be overcome if the GDC were to use it to identify risks. Europe Economics. October 2014. Risk in Dentistry, Report for the General Dental Council. Available at: https://www.gdc-uk.org/Newsandpublications/research/Documents/Risk%20in%20Dentistry.pdf. Accessed 22.07.15.

dissatisfaction in areas where they feel competent', and because '*a system relying on complaints coming forward has significant blind spots*.'[93] Lloyd-Bostock and Hutter refer to several pieces of research indicating that patients are unlikely to realise that they have been at risk, and even less likely to report it. In addition, the way a professional regulator selects which cases can proceed to an investigation undoubtedly contains biases. These biases are likely to skew the data on risks, particularly as '*psychological theory would predict that routine decision-making strategies will develop where similar decisions are repeatedly made. A circularity can develop, so that more and more information is gathered about certain kinds of incident whilst others remain off the radar.'* [94]

6.12 Data quality is a crucial factor – information provided may not be reliable, particularly where it is collected through self-assessments carried out by regulated bodies. Self-assessment introduces two potential flaws: firstly, the requirements for data collection may be interpreted differently across the range of regulated entities; secondly, data may be manipulated to give a false positive impression – especially if it affects a regulator's decision about performance. A witness at the Mid-Staffs Inquiry suggested that '*gaming'* of the information collected for the regulator was common practice not just within the hospital but across the NHS.[95] In addition, there may not be enough data to analyse if the sample size is small[96] – this is a problem likely to be encountered by smaller regulators.

6.13 Analysing and interpreting the data also presents difficulties. Klinke and Renn talk about 'ambiguity' to denote '*the variability of (legitimate) interpretations based on identical observations or data assessments*.' They argue that this may come from '*differences in interpreting factual statements about the world.'* Rothstein *et al.* give an example of this in their paper on risk-based regulation in the environmental policy domain,[97] which illustrates how using different software packages to analyse data about contaminated land produces different conclusions about where the risks lie.

6.14 Furthermore, even if one can be confident about what the risks are, identifying their causes is a complex task.[98] Klinke and Renn argue that complexity is a key challenge for risk assessment, where complexity is '*the difficulty of identifying and quantifying causal links between a multitude of potential candidates and*

[93] Lloyd-Bostock S.M., and Hutter B.M. 2008. *Reforming regulation of the medical profession: The risks of risk-based approaches.* Health, Risk & Society, Feb 2008; 10(1); 69-83. Routledge.
[94] Lloyd-Bostock S.M., and Hutter B.M. 2008. *Reforming regulation of the medical profession: The risks of risk-based approaches.* Health, Risk & Society, Feb 2008; 10(1); 69-83. Routledge.
[95] See page 51 of the witness statement of Dr. Heather Wood, available at http://www.midstaffspublicinquiry.com/sites/default/files/transcripts/Tuesday_10_May_2011_-_transcript.pdf. Accessed 28.05.15.
[96] Bridget M. Hutter. March 2005. *The Attractions of Risk-based Regulation: accounting for the emergence of risk ideas in regulation.* ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.
[97] Henry Rothstein, Phil Irving, Terry Walden, Roger Yearsley. 2006. *The risks of risk-based regulation: Insights from the environmental policy domain.* Environment International 32 (2006) 1056-1065. Elsevier.
[98] Bridget M. Hutter. March 2005. *The Attractions of Risk-based Regulation: accounting for the emergence of risk ideas in regulation.* ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.

specific adverse effects.'[99] In a study of risk management practices at the Department for the Environment, Food and Rural Affairs (DEFRA) and the English University sector, Huber and Rothstein go so far as to suggest that '*in many cases, the absence of actuarial evidence or well-understood causal mechanisms hindered the challenge function of risk assessment.'* Risk ideas were meant to change existing ways of working, but problems with data collection and difficulties assessing interdependencies '*meant that risk assessment was often at best a qualification of existing understandings […]*'.[100] Rothstein and Downer suggest that '*by casting subjective judgements in the idiom of objectivity, […] risk-based practices could even create an unjustified illusion of coherence and consistency in predicting future adverse policy outcomes.'*[101]

6.15 All of the above challenges can create what Klinke and Renn label '*uncertainty'*, referring to statistical variation, measurement errors, ignorance, and indeterminacy, which together reduce '*the strength of confidence in the estimated cause and effect chain*.' [102]

6.16 We explained in the preceding chapter that risk assessments have psychological, social, and cultural dimensions. There is a large body of literature looking at how risks are perceived and judged, and what makes some more tolerable than others. We saw that the IRGC model explicitly incorporates risk perceptions and social concerns into its risk appraisal phase. [103] Phipps *et al*. talk about the '*need to consider not just the technical knowledge that contributes to a risk assessment, but also the social and political views that are represented within it.'* [104] This statement touches on a key challenge for risk-based regulation: how to incorporate these subjective elements into an approach that appears to draw its value primarily from its objectivity.

6.17 The term 'ambiguity' used by Klinke and Renn to describe the possibility of the same data being analysed in different ways, also denotes '*differences in applying normative rules to evaluate a state of the world.'* [105] This subjectivity is exposed at the point in the process where a decision is made about whether the risk that has been identified is tolerable or not, i.e. whether it meets the threshold for action. This, Lloyd-Bostock and Hutter argue, is a moral and

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[99] Andreas Klinke and Ortwin Renn. 2002. *A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies.* Risk Analysis, Vol. 22, No. 6, 2002. Available at: http://josiah.berkeley.edu/2007Fall/NE275/CourseReader/6.pdf

[100] Michael Huber and Henry Rothstein. 2013. *The risk organisation: or how organisations reconcile themselves to failure.* Journal of Risk Research.

[101] Henry Rothstein and John Downer. 2012. *'Renewing DEFRA': Exploring the emergence of risk-based policymaking in UK Central Government.* Public Administration Vol 90, No. 3, 2012 (781-799)

[102] Andreas Klinke and Ortwin Renn. 2002. *A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies.* Risk Analysis, Vol. 22, No. 6, 2002. Available at: http://josiah.berkeley.edu/2007Fall/NE275/CourseReader/6.pdf

[103] A version of this flowchart and short summary are available here: http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeconaf/183/183we14.htm

[104] Denham L. Phipps, Peter R. Noyce, Kieran Walshe, Dianne Parker and Darren M. Ashcroft. 2011. *Risk based regulation of healthcare professionals: What are the implications for pharmacists?* Health, Risk & Society; vol 13, No 3, May 2011, 277-292. Routledge.

[105] Andreas Klinke and Ortwin Renn. 2002. *A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies.* Risk Analysis, Vol. 22, No. 6, 2002. Available at: http://josiah.berkeley.edu/2007Fall/NE275/CourseReader/6.pdf

political decision, and it is arguably the most controversial point in the entire process.[106]

6.18 The standard risk-assessment model considers potential impact and likelihood – but how much weighting should be given to each? Should a low likelihood-high impact risk take precedence over a high likelihood-low impact risk? Bounds evokes the problem of public perception tending to overestimate low probability events, such as floods, and underestimate higher probability events such as car accidents[107] – undoubtedly the portrayal of events in the media plays a role here. In fact, as Spiegelhalter suggests, neither a cluster of aviation tragedies nor a cluster of cyclist deaths in London should of itself change our understanding of the risks involved in either flying or cycling. Despite our emotional reaction to these awful tragedies, over the long term it would be unusual if we did not occasionally experience such clusters, and the fact is that in aviation at least there has been *'a clear decline in the rate of accidents over the last 40 years*'.[108]

6.19 These public perceptions can add a political dimension to a decision, and as a consequence, '*risk-based regulation may go beyond the need to ensure that the most important regulatory objectives are delivered, to take into account the competing rational needs of regulatory organisations to manage their own business risks.'*[109] In other words, the organisational risk (most likely reputational) and the regulatory risk may not be aligned, and the organisation may decide to deal with the former at the expense of the latter.

6.20 The 1988 Health and Safety Executive paper on the risks presented by nuclear power stations[110] is an example of a clear statement of risk tolerance – with the risks presented as the number of deaths per head of population. This is perhaps an approach that would be considered unpalatable in the modern-day context, but it illustrates a dilemma faced by governments and regulators alike: how to retain public confidence in both the public service in question and its regulators, while admitting that there is a risk to the public, however minimal. [111] Risk-based strategies assume that honesty is the best policy, but if they damage the credibility of regulation, they can have an adverse effect on its effectiveness. Lloyd-Bostock and Hutter argue that this is particularly difficult for the regulatory body for doctors in the UK, the General Medical Council (GMC). It needs to retain the confidence of both the public it exists to protect and the professionals it regulates, while being transparent about the fact that it is prepared to tolerate a certain level of risk to the public. This can be a difficult balance to strike.

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[106] From evidence submitted in 2006. Available at: http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeconaf/183/183we14.htm

[107] Gregory Bounds. 2010. *Challenges to Designing Regulatory Policy Frameworks to Manage Risks.* Chapter 1 of Risk and Regulatory Policy – Improving the Governance of Risk. OECD 2010.

[108] David Spiegelhalter. July 2014. *Another tragic cluster – but how surprised should we be?* www.understandinguncertainty.org

[109] Henry Rothstein, Phil Irving, Terry Walden, Roger Yearsley. 2006. *The risks of risk-based regulation: Insights from the environmental policy domain.* Environment International 32 (2006) 1056-1065. Elsevier.

[110] Health and Safety Executive.1988. *The Tolerability of Risk from Nuclear Power Stations.* HMSO. Available at: http://www.onr.org.uk/documents/tolerability.pdf

[111] Lloyd-Bostock S.M., and Hutter B.M. 2008. *Reforming regulation of the medical profession: The risks of risk-based approaches.* Health, Risk & Society, Feb 2008; 10(1); 69-83. Routledge.

Risk management

6.21 Once proposals have been drawn up for responding to a risk, they will need to be evaluated to determine whether they are worth implementing. This is where the concept of proportionality and cost-benefit (also known as cost-utility, or cost-effectiveness) analyses come into play – do the potential gains offered by a regulatory solution outweigh the costs? Some argue that cost–benefit analyses are inherently biased against the introduction of new regulatory measures. Writing in 1981, Ashford summarised the limitations of cost–benefit analyses as follows:

- '*There are important differences between economic regulation and environmental, health, or safety regulation that must not be overlooked.*
- *Costs are easier to express than benefits, but their quantifiability makes them no more certain or reliable*
- *Benefits include improved quality of life and good health as well as positive economic side-effects, but they defy accurate estimation and their recipients are not a well-organized lobbying group*
- *The comparison of costs and benefits is beset by serious methodological difficulties and requires the analyst to make value-laden assumptions; yet cost-benefit analysis appears, deceptively, to be a neutral technique*.'[112]

6.22 Although written over 30 years ago, these points may still be valid. In *Trust, Assurance and Safety*,[113] the then Secretary of State for Health, Liam Donaldson, laid down the following challenge:

> *'Empirical information on the prevalence of death, injury, disability and mental distress caused by inadequate professional competence or malicious, discourteous or abusive conduct is not available. Even if it were, it would be difficult to cost. What price do we put on the benefits of patients' peace of mind and public confidence? How do we cost lives scarred by grief in families who have lost those they love? Can we measure the frustration and anxiety of health professionals enmeshed unnecessarily in national professional regulatory procedures? How do we measure the costs of a sense of having been unjustly treated? Would the costs and burdens of accurately collecting these data be justified? These are not sentimental points, but ones that recognise the difficulties of capturing quantitatively the intangible dimensions of issues that sit at the heart of healthcare regulation*.'

6.23 Ackerman and Heinzerling dismiss cost–benefit analyses on the grounds that they can lead to absurd conclusions: they can provide a justification based on financial or economic benefits for policies that have serious negative impacts on people's lives.[114] At the more moderate end of the scale, Hutter believes that

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[112] Nicholas A. Ashford. 1981. *Alternative to cost-benefit analysis in regulatory decisions*. Annals of the New York Academy of Sciences. Volume 363, Management of Assessed Risk for Carcinogens pages 129–137, April 1981

[113] Department of Health. 2007. *Trust, Assurance and Safety – The regulation of health professionals in the 21st Century.* Crown Copyright.

[114] Frank Ackerman and Lisa Heinzerling. May 2002. *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*. University of Pennsylvania Law Review. Vol. 150, No. 5 (May, 2002), pp. 1553-1584

cost–benefit analyses tend to favour the subjects of regulation (businesses in particular) because the costs are much easier to calculate than the benefits, and because '*indirect costs and benefits are rarely considered.*'[115]

6.24 Various methodologies for quantifying benefits have emerged over the years. Quality-adjusted life years, or QALYs were developed in the 1970s as a health outcome measurement unit that combines duration and quality of life.[116] They are still in common use in matters relating to healthcare – for example the National Institute for Health and Care Excellence (NICE) uses QALYs to calculate the benefits of a particular drug or treatment.[117] Disability-adjusted life years (DALYs), which were based on the QALY, are primarily a measure of disease burden. Other models include the Willingness to Pay (WTP) model which is used mostly in environmental policy, and the Adult Social Care Outcomes Toolkit (ASCOT) for measuring outcomes in adult social care. The fact that there are competing methodologies could be viewed as problematic in itself – they yield different results, and therefore produce different answers to the question of whether the benefits outweigh the costs.

6.25 Implicit in the cost–benefit question is the matter of the indirect impacts and costs that may be created by regulatory action – it is almost inevitable that in tackling one harm, another is created or exacerbated. Assessing risk tradeoffs, or 'unintended consequences', as these ancillary risks are sometimes called in public policy, presents a challenge. In theory, regulatory impact assessments are designed to pick up on these sorts of impacts.[118] But identifying and quantifying them is likely to be at least if not more complex than for the primary risk, because they are numerous and are not the primary object of study. Some may be obvious, others may be less so, particularly those that relate to human behaviour.[119] By way of an example, a study of social workers carried out after the introduction of statutory regulation of this group found that some had changed their behaviour in ways that undermined the purpose of regulation, and would have been both hard to predict and difficult to tackle.[120] Rascoff and Revesz argue that risk tradeoff assessments are flawed because they focus only on the negative side-effects, and that ancillary benefits should also form part of the overall assessment.[121] They go on to suggest that without any

[115] Bridget M. Hutter. March 2005. *The Attractions of Risk-based Regulation: accounting for the emergence of risk ideas in regulation.* ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.
[116] Franco Sassi. 2006.*Calculating QALYs, comparing QALY and DALY calculations*. Health Policy and Planning. (2006) 21 (5): 402-408. Available at: http://heapol.oxfordjournals.org/content/21/5/402.full
[117] For an explanation of how NICE uses QALYs in cost-benefit analyses, see https://www.nice.org.uk/proxy/?sourceurl=http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectivenessTheQALY.jsp
[118] For an illustration of how regulatory impact assessments were used in the UK under the Blair Government, see the 2001 NAO guidance, *Better Regulation: Making Good Use of Regulatory Impact Assessments*. Available at: http://www.nao.org.uk/wp-content/uploads/2001/11/0102329es.pdf
[119] John D. Graham, Jonathan Baert Wiener, 1995. *Risk vs. Risk.* Harvard University Press.
[120] Lel Meleyal. March 2014. *Reframing conduct: The impact of regulation on social work registrants* (Paper). Professional regulation in health and social care: interdisciplinary insights, Professional Standards Authority conference. Windsor.
[121] Samuel J. Rascoff and Richard L. Revesz, 2002. *The Biases of Risk Tradeoff Analysis: Towards Parity in Environmental and Health-and-Safety Regulation*. The University of Chicago Law Review. Vol. 69, No. 4 (Autumn, 2002), pp. 1763-1836. Available at: http://www.jstor.org/stable/1600618

consideration of beneficial side-effects, it is hard to make a compelling case for regulation.

6.26 Finally, there is the vexed question of whether risk-based strategies, once adopted are successful in reducing risks. According to Bounds,[122] risk-based regulation makes it easier to hold regulators to account for their performance. In Hutter's view, however, the difficulty of determining what actions are responsible for an apparent improvement makes it almost impossible to draw any conclusions about regulatory performance.[123] This is echoed in research carried out by Oliver Quick into the impact of professional regulation in health on the behaviour of health and care professionals – Quick determined that the behaviour of professionals was influenced by a large number of external factors, with professional regulation featuring some way down the list.[124]

6.27 Rothstein and Downer[125] suggest that risk-based approaches, while appearing to enhance transparency and accountability, are in fact a form of defensive risk management. They do this '*by reframing and making explicit the expectations and limitations of decision-making'*. In other words, a regulator or government may meet its targets within the boundaries defined by a risk-based strategy – but this may fall short of what they might reasonably be expected to achieve.

6.28 In addition to the methodological objections to risk-based approaches, risk-based regulation faces a number of strategic challenges. Bounds talks about the difficulty of dealing with the interrelated nature of many risks – this is because responsibility for managing risks is usually fragmented across the different parts of government. He also evokes some of the challenges created by the political context in which regulation operates: crisis situations frequently lead to knee-jerk responses that are not in line with risk-based policy; solutions are devised before a risk has been properly assessed. [126] This highlights the fact that governments and regulators operate in a highly complex, political environment, and risk-based strategies may struggle to stay on course. But as we saw in the preceding paragraphs, risk-based tools can also be used to suit political and institutional agendas.

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[122] Gregory Bounds. 2010. *Challenges to Designing Regulatory Policy Frameworks to Manage Risks.* Chapter 1 of Risk and Regulatory Policy – Improving the Governance of Risk. OECD 2010.
[123] Bridget M. Hutter. March 2005. *The Attractions of Risk-based Regulation: accounting for the emergence of risk ideas in regulation.* ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.
[124] Oliver Quick. May 2011. *A scoping study on the effects of health professional regulation on those regulated, Final report submitted to the Council for Healthcare Regulatory Excellence*. Available at: http://www.professionalstandards.org.uk/docs/default-source/psa-library/110516-literature-review.pdf?sfvrsn=0
[125] Henry Rothstein and John Downer. 2012. *'Renewing DEFRA': Exploring the emergence of risk-based policymaking in UK Central Government.* Public Administration Vol 90, No. 3, 2012 (781-799)
[126] Gregory Bounds. 2010. *Challenges to Designing Regulatory Policy Frameworks to Manage Risks.* Chapter 1 of Risk and Regulatory Policy – Improving the Governance of Risk. OECD 2010.

7. Conclusion

7.1 As the literature shows there are advantages to risk-based approaches for regulation. They provide a defensible, common-sense justification for the deployment of limited resources, and for the burdens that regulation places on its subjects. Their continuing popularity suggests that they have proved useful to decision-makers and have retained their credibility, despite the difficulty of applying them correctly in all circumstances.

7.2 In fact, both the principles underpinning risk ideas and their utility remain largely undisputed. What is questioned, however, is their capacity to take into account the complexity of real life, and their apparent objectivity, which some believe can be used to mask the moral and political dimensions of decisions about risks.

7.3 In the conclusion of her paper on the emergence of risk ideas in regulation, Bridget Hutter wrote the following:

> *'[…] the devil is in the detail of technical, legal and political implementation and the risks that tools will be too literally and slavishly believed in. It is important that those using risk-based approaches fully understand their limitations.'* [127]

7.4 This is a fitting message on which to conclude this review. We should be under no illusions that implementing risk-based approaches is a simple task. Anyone seeking to use them should do so in full cognisance of the challenges and pitfalls described in this paper. Nevertheless, methodological and other types of obstacles will have be overcome, as risk ideas still represent the most rational and sustainable approach available.

[127] Bridget M. Hutter. March 2005. *The Attractions of Risk-based Regulation: accounting for the emergence of risk ideas in regulation.* ESRC Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics.

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