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Citation for final published version:

McDermott, Aoife M. , Hamel, Lauren M., Steel, David, Flood, Patrick C. and McKee, Lorna 2015. Hybrid healthcare governance for improvement? Combining top-down and bottom-up approaches to public sector regulation. *Public Administration* 93 (2) , pp. 324-344. 10.1111/padm.12118

Publishers page: <https://doi.org/10.1111/padm.12118>

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**Acknowledgements:** This research was funded by Health Research Board Award HRA\_HSR/2010/26. We note that the views expressed within this article are the authors' own. We acknowledge the advisory role of Professor Noel Whelan, member of our steering committee, and helpful comments from our editors, anonymous reviewers, Malcolm J. Beynon, Rhys Andrews, Paula Hyde, Dimitra Petrakaki, and the convenors and attendees of SWG 6 in EGOS 2013 in Montreal, on an earlier version of this paper.

# Hybrid healthcare governance for improvement? Combining top-down and bottom-up approaches to public sector regulation

## Abstract

Improving healthcare governance is an enduring challenge for policy-makers. We consider two national healthcare regulators adopting novel ‘hybrid’ regulatory control strategies in pursuit of improvement. Hybrids combine elements usually found separately. Scotland and Ireland’s regulators combine: (1) top-down formal regulatory mechanisms deterring breaches of protocol and enacting penalties where they occur (e.g. standard-setting, monitoring, accountability); and (2) bottom-up capacity building and persuasive encouragement of adherence to guidance by professional self-determination, implementation and improvement support (e.g. training, stimulating interventions). We identify socio-historical contextual factors constraining and enabling regulatory hybridity, whether and how it can be recreated, and circumstances when the approaches might be delivered separately. Using our findings, we develop a goal-oriented governance framework illustrating distinct, yet complementary, national and local organizational roles: (1) ensuring the adoption and implementation of best-practice, (2) enabling and (3) empowering staff to adapt and add to national mandates and (4) embedding cultures of improvement.

**Keywords:** • hybrid • healthcare • improvement • governance • regulation • international •

## Introduction

Public sector improvement is an enduring challenge, and healthcare improvement is a particular concern (Francis, 2010; Keogh, 2013). A high-quality and efficient healthcare service can help enhance the quality and longevity of life, and balance public finances. To sustain system-wide healthcare quality, the recent Berwick report (2013) suggests that a top-down focus on regulatory conformity needs to be complemented by bottom-up investment in the improvement capacity of health service staff, with the objective of generating responsive ‘learning organizations’. Top-down approaches to attaining public management goals adopt a rational, control orientation, limiting discretion (Schofield, 2001). However, the requirement to ‘translate’ and adapt national goals to fit local contexts (Ansari et al., 2010; van Gestel and Nyberg, 2009), and to add to national agendas in the light of local challenges (McDermott et al., 2013), is increasingly recognized. Such bottom-up approaches require the development of local improvement capacity – to identify context-specific requirements for change, to gain appropriate support and resourcing, and to implement required amendments (*ibid.*). Competing models of regulation embody these differing approaches to achieving policy goals. On the one hand is a preference for deterrence approaches, with a preventative orientation, and enforcement through directives, targets, sanctions and regulatory escalation. On the other, is a dependence on more persuasive methods, with an emphasis on capacity building and encouragement - developing employees’ focus on quality, stimulating local quality initiatives, and building improvement skills. Ayres and Braithwaite (1992: 21) describe this tension as knowing ‘*When to punish; When to persuade*’?

Scotland and Ireland’s healthcare quality improvement efforts are respectively supported by single national regulatory organizations, namely Healthcare Improvement

Scotland (HIS) and the Health Information and Quality Authority (HIQA). Both organizations are unusually configured to deliver improvement through a hybrid of top-down deterrence and bottom-up persuasive approaches. These are often presented as dichotomous, meaning their combination has been omitted from regulatory typologies (see Grabosky and Braithwaite, 1986). HIS and HIQA's 'mixing' contrasts with the regulatory pyramid's approach, which treats them as alternatives (c.f. Ayres and Braithwaite, 1992). In adopting both approaches, these organizations internalize longstanding tension within the public sector between top-down control through governance and regulatory performance management regimes, and enabling bottom-up improvement and innovation by empowering staff (c.f. NESC, 2012; Newman, 2001). Previous work has identified how these approaches have resulted in competition between overlaid norms and assumptions within regulated institutions, potentially making them hard to reconcile (Ayres and Braithwaite, 1992; Newman, 2001). However the potential benefits of such combinations are reflected in Ayres and Braithwaite's assertion (1992: 25) that '*The trick of successful regulation is to establish a synergy between punishment and persuasion*'.

In this article, our focus is on whether and how the regulators combine the two approaches to generate a new 'hybrid' form of regulation. Hybrids are composite phenomena produced by elements usually found separately (Fischer and Ferlie, 2013). We follow Reed (2011) in considering hybrid control systems as extending top-down formal regulatory strategies to encompass more dispersed, normative and internalised forms of influence. In organizational terms, hybrids represent a combination of two modes of organizing that achieve a degree of stability (Fischer and Ferlie, 2013). Hybridity often occurs in ambiguous domains (Noordegraaf, 2007), and can therefore be dynamic (Miller et al., 2008). Fischer and Ferlie (2013) identify three potential outcomes from hybridity: complementarity between elements that can result in synergistic benefits and added value (of particular interest to us,

following Ayres and Braithwaite, 1992); tensions that can be managed and; escalating contest and contradiction where paradigms interact but lack commonality. Our study exposes the complexities of trying to combine and reconcile what could be perceived as dichotomous regulatory approaches. In undertaking our analysis of regulatory hybridity, we begin to address calls to consider new ways of regulating (Parker, 2013), in particular those that support proactive improvement and innovation (Berwick, 2013; Braithwaite, 2013; Gunningham and Sinclair, 1998). We also address calls for insight into the conditions that shape and limit ‘ready hybridization’ (Fischer and Ferlie, 2013), and begin to clarify situations in which hybridity may - or may not - be beneficial (c.f. Pache and Santos, 2013)

The article is structured in four parts, beginning with a brief overview of theory relating to the role of governance and regulation in achieving healthcare improvement. Second, we detail our methods. Third, through documentary and interview analysis, we chart the historical establishment of hybrid regulation in Scotland, and the emergent hybridization process in Ireland. Comparison provides insight into specific aspects of socio-historical context that can mitigate contradictions or exacerbate competition between top-down deterrence and bottom-up persuasive approaches to improvement. Last, we consider whether regulatory hybridity leads to synergistic benefits, beyond those perceived to result from the independent pursuit of these strategies. On the basis of our findings, we develop a four quadrant integrative governance framework, to support improvement. We adopt a goal-orientation that contrasts with previous biases to process (c.f. Ayres and Braithwaite’s, 1992; Grabosky and Braithwaite, 1986). We illustrate distinct yet complementary national and local organizational roles: (1) ensuring the adoption of best-practice, (2) enabling and (3) empowering employees to adapt and add to national mandates, and (4) embedding a culture of improvement. This provides a potentially useful framework in considering national and

local responsibility for top-down and bottom-up approaches, whether or not hybrid regulation is being pursued.

## **Building on previous theory**

### **Health systems governance for improvement**

Health systems governance encompasses ensuring that healthcare organizations assure and improve the quality of their services (Francis, 2010). Regulation is one important national aspect of governance, defined as *‘the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour modification’* (Black, 2002: 26). In short, Black characterises regulation as an *‘intentional, systematic attempt at problem-solving’*. Kingsford Smith (2002) also emphasises the pluralist, intentional, and relational nature of regulation, which can be pursued using an array of techniques, individually, in configuration or in escalation, to help solve problems. HIS and HIQA are structured to enhance improvement capacity via simultaneous pursuit of top-down deterrence approaches on the one hand and bottom-up persuasive engagement on the other. These have traditionally been alternated in pursuit of ‘responsive regulation’ (Ayres and Braithwaite, 1992).

### **Transcending top-down deterrence and bottom-up persuasive regulatory approaches: From responsive to hybrid regulation?**

Ayres and Braithwaite coined the term responsive regulation to capture *‘how the implementation of quality standards is encouraged by a balance of sanctions and supports’*

(NESC, 2012: xiii). Responsive regulation aims to overcome the limits of top-down rule-based regulation via a central regulator and bottom-up self-regulation by professionals and service providers. The combination of these approaches is often depicted as a regulatory pyramid, where self-regulation and voluntary approaches provide a broad base, with command and control approaches - and their associated sanctions - at the narrow apex. Responsive regulation is premised on initial cooperative dialogue and assumption of virtue (Gunningham and Sinclair, 1998), the (potentially naïve) assumption that parties are willing and able to communicate to resolve problems (Parker, 2013), and a strategy of gradual escalation if this does not occur (Mascini, 2013). Thus the pyramid enables regulators to select whether to adopt a persuasive or punitive style in a given context (Mascini, 2013), with persuasive strategies recommended in the face of cooperation, and punitive in the face of opposition. A punitive approach should only be adopted when persuasion has failed – to enhance legitimacy (Braithwaite, 2011), and promote transparency (Ayres and Braithwaite, 1992). De-escalation is also recommended in response to cooperation (Braithwaite, 2013; Heimer, 2011). This can help to preserve relationships and trust (Ayres and Braithwaite, 1992), as regulatees tend to focus most on negative signals (Mascini and Van Wijk, 2009). In addition, following Black’s (1976) theory of law, Grabosky and Braithwaite (1986) suggest that reduced relational distance should decrease the tendency to use formal sanctions. Stringency in regulation may or may not be positive – while Grabosky and Braithwaite (1986: 217) note *‘some tendencies for closeness to be associated with a rejection of punitiveness towards industry, it may also be associated with a superior capacity to achieve substantive regulatory ends by persuasion or the give-and-take which tend to be part of ongoing relationships’*. This ‘give and take’ is a central part of responsive regulation, reflected in Heimer’s assertion (2011: 663) that responsive regulation *‘is not simply something that a regulator unilaterally does to a regulatee’*.



Like all regulatory approaches, responsive regulation encounters challenges (c.f. Braithwaite, 2013). Regulators have struggled to implement the pyramid responsively (Mascini, 2013), focusing mainly on enforcement and sanctioning strategies (Parker, 2013; Mascini, 2013). This underemphasises potential for proactive local innovation and improvement, illustrated in Braithwaite et al.'s (2007) overview of the benefits of creative space in advocating for the elderly. Indeed, Braithwaite (2013: 142) explicitly recognises the importance of practitioner innovation in his assertion that '*Regulatory theory fails when it neglects scanning widely for the experience of how practitioners solve the theoretically unsolvable*'. Similarly, Gunningham and Sinclair (1998: 413-414) note:

*'major criticisms of much conventional regulation are the lack of incentives for firms to continuously improve...[...] A key challenge for policymakers, therefore, is to ensure that regulatory solutions...[...] reward enterprises for going 'beyond compliance'.*

Attempts are made to address this issue in the 'strength-based pyramid' which adopts an appreciative orientation (described in Braithwaite et al., 2007). However, encouraging bottom-up service improvement is not novel. Policy implementation research has distinguished between those who avoid or abstain from national mandates, 'adopters' who comply, 'adapters', who make appropriate local adjustments, and 'extrapreneurs' who add extra dimensions (McDermott et al., 2013). Entrepreneurial front-line workers' distributed engagement in initiatives can provide contextualized local knowledge of what is required and how it might be achieved (*ibid*; van Gestel and Nyberg, 2009). Thus, the rationale for hybrid health system governance - encompassing top-down deterrence mechanisms to promote good practice, together with bottom-up persuasively oriented capacity building for ongoing proactive service improvement and innovation - is strong. Our case-studies are premised on organizations in which this combination is actively being pursued, enabling us to answer Parker's (2013) call for studies to consider new ways of regulating.

## Methods

### International comparison

This international study compared national approaches to supporting quality and safety in two policy contexts and four acute hospitals (our hospital level findings are reported separately). Scotland and Ireland are small, proximally located contexts that have heavily invested in health service improvement. Public service governance and improvement poses particular challenges in small contexts – although scale is mediated by other economic and socio-political factors (Cole and Stafford, 2014). Scotland’s healthcare is predominantly provided through the public National Health Service. Ireland also has a large public health service, with private provision available within the physical infrastructure of public as well as private hospitals. Both display moves towards the development of hybrid regulators. Thus they provide an appropriate context for consideration of our research questions, namely: (1) whether synergistic hybridity (displaying synergy between top-down deterrence and bottom-up persuasive approaches, with impact beyond their independent pursuit c.f. Fischer and Ferlie, 2013) has been achieved in the national regulation of healthcare quality in each context and; (2) what factors enable or constrain the emergence of hybridity. Our discussion concludes by considering what governance lessons can be derived from their experiences for other health systems.

### Data collection and analysis

Data analysis initially encompassed a comprehensive review of national policy documents. Interviews with forty-four national, strategic level respondents (twenty-two in each context) ensued. Interviews were conducted with staff from within organizations dealing with health policy, health management, the professions, and quality and safety within each health system.

Thematic interview analysis regarding the role of each regulator explored codes including: ‘role’; ‘inspection and audit’; ‘implementation focus’; ‘building capacity’; ‘innovation’; and ‘tensions’. Quotes are drawn from the full range of these respondents. Emergent analytical themes were added to the coding schedule and led to preliminary theory generation. Finally, we undertook cross-case comparative analysis. This enabled consideration of similarities and differences in the emergence and form of national regulatory regimes. It also supported theory building, positioning findings against extant literature. Figure 1 summarizes our analytic strategy.

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Figure 1

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Next, we introduce each regulator, providing an analytic chronology of their historical context. This is due to the importance of context in designing regulatory strategies and interventions (c.f. Gunningham and Sinclair, 1998) and associated implications for policy transfer.

## **Placing regulatory regimes in context: The emergence of HIS and HIQA**

### **Scotland’s evolution to hybridity: the emergence of Healthcare**

#### **Improvement Scotland (HIS)**

Healthcare Improvement Scotland (HIS) came into existence in April 2011, as a reconfiguration of NHS Quality Improvement Scotland. HIS is part of the NHS, one of eight national boards (illustrated in Figure 2). It is responsible for generating standards, supporting improvement, the regulation of the independent health sector and the inspection of public and private health organizations. Four phases of the Scottish quality movement, comprising the historical emergence of HIS, are detailed below.

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Figure 2

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*Phase 1: Compiling evidence to provide advice and guidance*

Scotland's whole-system approach to quality and safety was influenced by the 1983 Griffiths report. This led to the establishment of groups concerned with good managerial and effective clinical practice (detailed in Figure 4). Subsequently, the 1989 White Paper '*Working for Patients*' required that all hospital doctors participate in medical audit. It also saw the introduction of the Clinical Resource and Audit Group, later instrumental in the 1993 development of the Scottish Intercollegiate Guidelines Network. This medically-led multidisciplinary network became responsible for developing evidence-based clinical practice guidelines (see Harbour et al., 2011). This year also pioneered the production and publication of clinical outcomes indicators (see Scottish Executive, 2000). However, patchy coverage and a desire to link to NHS priorities influenced the emergence of a national system for quality assurance during the late 1990s (c.f. Woods and Carter, 2003).

*Phase 2: Quality assurance*

The Health Act (1999) introduced local clinical governance, defined as 'corporate accountability for clinical performance' (see Scottish Office, 1998). A focus on evidence-based clinical practice was centralized and formalized in the establishment of the Clinical Standards Board for Scotland in 1999. An aligned development was the establishment of the Health Technology Board for Scotland in 2000, to conduct technology and medicines assessments. Scotland's approach to managing health service quality via national leadership through systems and establishing and monitoring best practice became established during this time.

### *Phase 3: Implementation and improvement support*

In January 2003 concerns about fragmentation led to the consolidation of the organizations responsible for health service quality (the Clinical Resource and Audit Group, the Clinical Standards Board, the Health Technology Board and two others) to form NHS Quality Improvement Scotland (QIS). A national body, QIS was given a mandate to develop and deliver a centrally coordinated strategy for improving clinical effectiveness and the quality of health services. In 2005, SIGN became part of QIS. It later acquired an increased focus on patient and public involvement, with the creation of the Scottish Health Council within it. Subsequently, in 2008, QIS was given by the task, under the auspices of the Scottish Patient Safety Alliance, of delivering the Scottish Patient Safety Programme (SPSP). The SPSP was designed and delivered in partnership with the Institute for Healthcare Improvement (see Haraden and Leitch, 2011). Its premise is the spread and adaptation of existing knowledge to multiple settings, underpinned by the plan, do, study, act cycle.

### *Phase 4: Emergence of scrutiny and inspection*

In 2008/09 QIS introduced its 'integrated cycle of improvement' comprising (1) advice, guidance and standards; (2) implementation and improvement support and; (3) assessment, measurement and reporting (NHSQIS, 2009). In 2009 the Healthcare Environment Inspectorate (HEI) was established in QIS, to undertake at least one announced and one unannounced inspection of all acute hospitals across NHS Scotland every three years. The scrutiny aspect of QIS's role was further emphasized when QIS became Healthcare Improvement Scotland (HIS) in 2011, with the extension of HEI's remit to include the care of older people in acute hospitals and on the assumption of responsibility for inspection and regulation of independent healthcare (see Scottish Government, 2007). HIS's integrated cycle of improvement is intended to facilitate coherent quality enhancement (NHSQIS, 2008),

reflecting the Scottish Government's aim of enhancing integration of quality and safety issues set out in its Healthcare Quality Strategy (Scottish Government, 2010).

## **Ireland's ongoing evolution to hybridity: the Health Information and Quality Authority (HIQA)**

The Health Information and Quality Authority (HIQA) is an independent statutory government-funded agency. HIQA's objective, set out in legislation, is '*to promote safety and quality in the provision of health and personal social services for the benefit of the health and welfare of the public*' (DoHC, 2008). Established in 2007, it lacks HIS's major institutional legacy, although one Scottish respondent noted that interchange with senior QIS executives informed HIQA's development. HIQA's first (2008-2010) Corporate Plan (HIQA, 2008) notes its responsibility for developing, monitoring and enforcing standards; providing a comprehensive information framework; undertaking health technology assessments; reporting its work and; engaging effectively with service users, providers and policy makers. Although its' first strategic objectives didn't refer to 'capability and capacity building', this subsequently evolved as an explicit focus. During data collection, HIQA was enacting its second (2010-2012) Corporate Plan. This describes a range of roles, noting that beyond its:

*'important regulatory role, we also have essential roles in advising on health information, informing decision-making, supporting and promoting the capacity and capability of the health and social care system'*. (HIQA, 2010: 29)

The focus on developing a supportive role and enhancing improvement capacity emerged from learning and reflection on its 2007-2010 operations (HIQA, 2010). Reorganization along functional lines led HIQA's four core activities to be organized and delivered via separate directorates (regulation, supporting improvement, assessing health technologies and improving outcomes through information – see HIQA, 2013d). A Director of Safety and Quality Improvement was appointed in July 2012 (HIQA, 2012), with the Improvement Directorate responsible for:

*‘actively supporting and enabling a culture of patient safety and quality improvement across and within the health and social care system by helping to build capability and capacity in the people providing services. This will be done through the development of national standards and guidance in consultation with key stakeholders and the provision of training in quality improvement methodologies and tools’ (HIQA website, 2013a).*

HIQA’s establishment marked a large change in Ireland’s approach to achieving quality and safety in healthcare provision. Historically this was attained through professional regulation. However repeated structural reform, detailed below, has increased national coordination.

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Figure 3

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#### *Phase 1: The emergence of a centralized national health system*

In Ireland, the consistent attainment of the policy goals inherent in the 1994 and 2001 healthcare strategies was hampered by the regional administration of health service delivery. This led to a major restructuring and consolidation of the Irish health service (illustrated in Figure 3). Under the 2004 Health Act, national healthcare policy was entrusted to the Department of Health and Children (DoHC). A new body, the Health Service Executive (HSE), was established to implement policy and manage the delivery of health services across the country.

#### *Phase 2: Proactive management of quality*

The development of the HSE paved the way for the proactive management of service quality. During 2008-09 the HSE piloted and introduced a performance monitoring system for hospitals. However it is the establishment of HIQA as an external regulatory body under the 2007 Health Act that is the focus of our analysis. HIQA emerged in a tumultuous context, in the wake of major maternity (see Harding Clark, 2006) and nursing home scandals (see DoHC, 2008) that influenced its establishment. In its early days HIQA conducted a number of investigations into quality and safety concerns and published associated reports (see, for

example, HIQA, 2008a; 2009). These placed early emphasis on its investigation and inspection remit.

To support HIQA, the 2008 Health Information Bill aimed to enable health service information to be used to monitor and enhance the quality and safety of care. That same year, a report published by the DoHC (2008) made a series of recommendations to improve the quality and safety of care. HIQA's development is ongoing and it produced the 'National Standards for Safer Better Healthcare' in 2012 (HIQA, 2012), after we collected our data. As detailed later, HIQA appears to be proactively continuing and developing efforts to move beyond its initial focus on applying top-down deterrence approaches, to enhance improvement support.

## Comparing Scotland and Ireland

Like Scotland, Ireland is increasingly characterized by an explicit policy focus on measuring and managing healthcare quality; regulation by a dedicated body and; the use of audit. However, their respective historical contexts raise three differences of note. First, HIS sits within, and HIQA without, national health service structures (see Figures 2 & 3). Second, the professions have held different roles and levels of involvement in each context, with more of a longstanding professionally-led history of standards generation in Scotland (c.f. Steel and Cylus, 2012). Third, Scotland's move towards hybridity began with the provision of advice, guidance and standards, and then implementation and improvement support. The sharper focus on scrutiny, accountability and regulation emerged later. In contrast, Ireland began its journey towards hybridity with a focus on top-down deterrence mechanisms, with implementation and improvement support developed thereafter.



## Interview findings: Whether and why hybridity has emerged

Reed (2011) notes that hybridized forms of organizational control usually combine competing design principles and operational processes. Like Foucault (2003), and the ensuing ‘governmentalists’, Reed’s (2011) discussion of hybridized control systems centres on the extension of formal regulatory control mechanisms, to encompass softer, internalized forms of normative socio-psychological, cultural and discursive control. For Reed (*ibid*), the process of hybridization is one through which increasingly complex, multi-level and multi-dimensional control systems are developed. Here we consider whether HIS and HIQA can be characterized as displaying synergistic hybridity (c.f. Fischer and Ferlie, 2013) in national healthcare regulation (e.g. displaying both top-down and bottom-up strategies with evidence of impact beyond that resulting from their independent pursuit). Following Reed (2011), we note evidence of hybridity in HIS, and ongoing hybridization in HIQA. Interview findings detail the relative emphasis placed on (1) deterrence, including inspection and audit, and (2) persuasion, including attempts to support implementation, capacity building and innovation.

### Hybridity in Scotland: mitigated control, capacity-building and collaboration

HIS enacts its control orientation by generating evidence and undertaking oversight. Respondents noted that inspection and audit are a ‘*national imperative*’ that are ‘*not optional*’ (SP4). However they also noted how HIS’s role extends beyond monitoring performance against national mandates:

*...the idea is you provide the guidance, you support the implementation of it and then you check up to see whether it is being implemented and to identify gaps where you need to do something new to get things moving. (SP2)*

*...we can’t improve quality in this building but we can help people out there who actually can. (SP5)*

A number of respondents emphasized the organization’s deliberately mitigated and supportive approach, building on the principles of evidence-based medical practice:

*We avoided the use of the word inspection and in that respect the interesting question that you pick up from talking to people... QIS [now HIS] didn't have the profile that some inspectors and certainly our counterparts have across the border. (SP2)*

*...so we're not the guys who come along with a report that's going to get people in trouble[...] that we're actually sort of a helpful partner in quality. (SP5)*

*...[...] it makes sense to use evidence based interventions, it goes to their evidence based medicine. (SP8)*

In adopting this mitigated approach HIS benefits from, and builds upon, a long history of inclusive and collegiate relationships:

*...doing it in a way that engages rather than dictates so there is a far more authoritative way that England tries to do it. (SP12)*

*...on the whole still in Scotland has wanted to sort of work with clinicians and with the [specialists] and has seen them as taking a leading role in developing standards and in developing guidance and taking forward the quality and strategy issue. (SP6)*

Respondents noted that HIS utilizes a number of strategies to build implementation and improvement capacity, helping health service employees to address their own local, as well as national, improvement agendas. Interventions include: educational resources; training in data management and quality improvement methods; providing 'bundles' of tested interventions to implement locally; and the facilitation of networks to enhance peer learning and provide peer support:

*...improvement tools and skills that not only do you use in your personal life but actually you can apply to any issue you're trying to fix. (SP16)*

*...the main basket of tools if you like, is the associates of process improvement and the cycle of improvement. ...learning sets, for five or six hundred people together on the system and to work on their results...[...] the third cohort of the Scottish Patient Safety Fellowship programme...[.] the expertise and support that we have got from IHI ...that certainly made a big difference so that we have capability in frontline staff within our whole frontline, to be able to do that work for themselves. (SP20)*

Together, these interventions enhanced capability to identify problems (via data), provided some strategies to address them (using 'bundles' and improvement support) and enabled staff to apply improvement techniques to emergent issues. In this way, HIS aimed to help support individuals and collaboratives implement good practice and develop their own innovations:

*Trying to make sure that we don't stifle innovation, to be able to provide them with at least some short-term support to get going...[...] and the learning to create their own communities of innovation is what we are really trying to encourage wherever possible. (SP4)*

*...we are actually bringing together teams of people...[...] to develop their own sense of priorities and how are they going to tackle them, giving them the protected space and time to do that. (SP11)*

While respondents noted challenges in managing competing priorities, there was a sense in which the focus on mitigated control, capacity building and innovation had a shared focus on improvement and were successfully coexisting:

*I think I'll come back to what I was saying earlier on about how it's given a drive commitment and purpose. (SP13)*

*So, I think policy and improvement and quality, I think they are all entwined and very much in Scotland. (SP9)*

Some respondents provided descriptions that combined deterrence, persuasion and innovation roles, balancing top-down recommendations with being responsive to bottom-up needs:

*...our standards work and so on is around being responsive to local systems, genuinely listening to what local systems are telling us and making sure that what we deliver is a part of that and is acceptable around that. (SP21)*

*Increasingly as we identify areas of concern or poor performance – we are closing the loop and feeding that back to the local service. And proposing discussions as to how we can work with them to improve the local situation before getting to that escalation point back to Scottish government. [...] Recently we have had two examples of working with boards, where they have actually contacted us directly to say “We need a bit of help with this, can you work with us.” [...] And I think that is the way forward for us, is actually being on the end of the phone and being able to send staff out to work with the local teams. (SP4)*

*...none of this is a one trick pony so pulling together, a more integrated approach. (SP18)*

The first quote emphasises responsiveness to local needs. The second quote illustrates commitment to proactively supporting improvement, to avoid directive intervention. It also suggests health service employees' willingness to engage with the organization to address service concerns. Here we see evidence not only of a combination of regulatory activities, but of synergistic benefits between them (e.g. standards development informed by local needs and concerns; improvement support helping to avoid regulatory intervention). However we

note that tensions remain, despite aspects of complementarity and synergistic hybridity. Next we consider HIQA.

## The ongoing emergence of hybridity in Ireland: From deterrence to hybridity?

Respondents particularly emphasized HIQA's role as an independent external regulator, its relatively nascent status, and its emergent role:

*[HIQA] it's still to some extent finding its feet and navigating its way and it can't cure all and, you know, it can't isolate and identify problems and shortcomings in the long weekend. (IP4)*

*We are starting to get to grips with it. But we are still kind of forming to some extent. Storming and forming around it. (IP15)*

Despite its continued development, HIQA was described as having a deterrence orientation, with emphasis on its role in establishing standards, inspecting and auditing.

*It was always envisaged that the national standards, the standards that we had developed would provide the basis for what licensing would look like. (IP6)*

*They really have led the way in terms of audit. (IP1)*

*They have [a] lead to a lot of the kind of reactive patient safety side of quality. (IP14)* Some respondents saw this as a strong, positive driver of change. However, it was consistently noted that HIQA's initial deterrence orientation had led to somewhat tense relationships between the regulator and other organizations. One respondent described it as 'the Big Brother type' noting that 'the HIQA relationship is much less collaborative...[...] it is a somewhat tricky relationship' (IP14). Suggestions of HIQA's strained relationships with other bodies may be related to its independent position and external relationship with the health service (see Figure 3), as well as its capacity to give formal warnings, and even close institutions:

*We have [HIQA] the external regulators establishing standards and inspecting. (IP3)*

*HIQA and the powers that it has been given for unannounced inspections for, you know, for formal warnings of workplaces or care institutions, the power to close you down if you don't meet a standard. (IP4)*

Such suggestions may also reflect the difficult context in which HIQA emerged. HIQA's early history was marked by its response to a number of large-scale scandals. Respondents suggested that a focus on 'naming and shaming' may have undermined early proactive mobilisation for improvement:

*The agenda has been arising from a lot of high profile failings of care and a lot of name, blame and shame and that sort of thing. I think it is difficult to mobilize people around this because I think it has been somewhat tainted by some of the negativity arising from some of those high profile failings of care. (IP15)*

Despite HIQA's emergent focus on supporting improvement and enabling a quality-oriented culture, this role was not yet widely recognised by respondents.

*They [HIQA] can point out what's wrong, but they don't have a responsibility for making it right and managing it... the modus operandi of HIQA is such that, you know, it is the anathema of, you know, a systemic uplift, or a systemic review. It is very much individual, it named like in its inspections it names the person in charge. (IP4)*

*We would have regular meetings with [HIQA] them... Sometimes we struggle with implementation of our recommendations but we strive to do that... (IP15)*

Importantly respondents recognized that cultural change and building both the regulators' and the regulated organizations' capacity for improvement would take time.

*I think clearly any system can't just rely on an external regulator and the emphasis has to be on building strong internal mechanisms of assurance within the providers themselves and then HIQA is there then, in many ways, as a regulator, to validate those internal mechanisms of quality assurance. (IP16)*

*Having a system for external assurance around quality and safety shouldn't be seen as a substitute for having internal systems. I know certainly in terms of the discourse or dialogue that I would have been involved in, people would have sort of said – well, why are you coming along as the HSE looking for us to do this when HIQA will be doing that? (IP15)*

A further theme was the need to build role clarity and enhance coordination between the variety of bodies involved in delivering quality and safety:

*We have a Memorandum of Agreement with HIQA, we are going to have a Memorandum of Agreement with xxx because we are trying to tie up loops. (IP7)*

Indeed, one respondent (IP2) noted that an OECD Report had recommended a reduction in the number of bodies in existence – something that Scotland did early on in the development

of its improvement agenda. In summary, respondents appreciated the difficult context in which HIQA emerged, perceived standards as a natural evolution within the health system, but identified a need to clarify the distribution of roles across the organizations in the health service, and to develop explicit strategies for supporting implementation and proactive improvement and innovation (although not necessarily by HIQA itself). There was also some concern regarding the legacy of HIQA's early engagement in investigating major health service scandals, and establishing a more positive orientation. At the time of the research, HIQA was displaying a strong deterrence orientation, but with an emergent emphasis on a hybrid approach. Next, we build on these findings to address Fischer and Ferlie's (2013) call for insight into the conditions that shape or limit ready hybridization.

## **What factors enabled and constrained the emergence of hybridity in national regulatory regimes?**

Here we consider socio-historical developments enabling the development of hybridity in HIS and constraining its emergence in HIQA. We focus on differences in their contexts (receptivity, critical incidents, structure of the regulator, and potential path dependency) and development processes (building credibility, clinical collaboration and crafting mechanisms). Key phases and historical developments are summarised in Figure 4.

### **The emergence of hybridity in HIS: A crafted, collaborative approach in a receptive context**

HIS is part of NHS Scotland. It emerged in a receptive context after a near thirty year development process that amalgamated pre-existing organizations (see Figure 4). HIS therefore gained from historical investment of political attention, time, resources and clinical engagement:

*Government has taken the initiative in this and it would not have been possible for us to get as far as we've got had there not been strong support from successive ministers, successive chief executives and successive chief nursing officers and chief medical officers in particular. So there's been a very strong, central focus....[...] HIS is still a, I won't say revered institution, but a respected institution. (SP 2)*

*We have engaged the clinical community. (SP4)*

One respondent noted that Scotland lost 'ten years of issuing beautiful documents saying what should be done. And then having only minimal impact' (SP2). This served as a critical incident, leading QIS to develop a strong focus on enhancing capability before the addition of an explicit inspection focus. In fact inspection came late – twenty-five years – into Scotland's improvement efforts:

*We have got a strong set of foundations around quality and safety. It hasn't come to us; it isn't something that is new to people. We have had a strong history in clinical audit. We have had the Scottish Intercollegiate Guideline network for some considerable time. There have been some foundations to build on. This is not a countercultural approach that we are trying to take on. It builds on work that we have already done and it is an attempt to accelerate that. (SP3)*

In Scotland, the introduction of bottom-up improvement support and capacity building prior to introducing the top-down inspectorate and scrutiny role was important - helping to establish longstanding collaborative relationships, continued across the various organizational incarnations preceding HIS. The absence of negative critical incidents also gave the organization a continuous 'fair wind' as it established credibility.

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Figure 4

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### **Emerging hybridity in HIQA: Critical issues at commencement challenging collaborative relationships and capacity building**

In contrast, HIQA is an external and independent regulator, established separately to previous improvement efforts. HIQA commenced operations in a negative and challenging context. A range of critical incidents (see Figure 4) led to early emphasis on top-down deterrence

activity premised on investigation and inspection. This provided a difficult platform from which to encourage organizations to engage in proactive disclosure and improvement efforts. As Ayres and Braithwaite (1992: 26) suggest *‘To adopt punishment as a strategy of first choice is unaffordable, unworkable, and counterproductive’*. HIQA also has greater sanctioning powers than HIS, with capacity to close organizations. Its early structure may have alienated some in the clinical community. The majority of the founding board were laypersons and *‘there was a lot of angst about that’* (IP1). These factors, combined with HIQA’s lack of institutional legacy, may explain its initial struggle to build trusting, collaborative relationships with key stakeholders.

### Enabling and constraining hybridity

In evaluating the conditions that shape or limit ready hybridization, we emphasize the role of founding and historical context. Despite both organizations sharing similar objectives in not dissimilar health systems, their contexts differentially affected their initial foci. HIS and HIQA had different starting platforms – persuasion and deterrence respectively. Notably, HIS’ persuasive starting premise differs from Reed’s (2011) presumed initial focus. Further, longstanding collaborative relationships between HIS and clinicians further enhanced the social context for hybrid regulation in Scotland (Steel and Cylus, 2012). In contrast, HIQA had a more deterrence oriented initial focus, previously noted by others. Specifically, NESC (2012) note that, in the context of residential care for older people, enforcement and inspection demands limited time available for support activities. Despite *‘interest in providing supports to centres to help them meet the standards’* in that context *‘efforts to avoid a conflict of interest, the priority accorded to registration and inspection, and a lack of resources, have meant that HIQA has not concentrated on this area of work’* (NESC, 2012: 108).



However hybridity is dynamic, with potential for transition (c.f. Miller et al., 2008) requiring future research to revisit our findings. Notably, the addition of an explicit inspectorate function to HIS in 2009 may challenge existing synergy in Scotland. In contrast, HIQA documents published subsequent to data collection suggest that efforts to build capability and support improvement are gaining momentum. Its' 2013-15 Corporate Plan prioritises providing education and building capacity in quality improvement methodologies, continuing to support improvement via national initiatives, and sharing good practice and learning (HIQA, 2013). In support, it established a training collaboration with IHI in 2013 (HIQA, 2013a). These developments may reflect HIQA's assertion (2013b) that *'we have gained significant insights into not only the sectors that we monitor and regulate, but how we work and how best to engage with these sectors'*. HIQA's corporate documents, restructuring, and training partnerships are suggestive of an evolution in emphasis, enhanced investment in and promotion of improvement support and capacity building – and ongoing pursuit of regulatory hybridity.

## **Whether and how to recreate regulatory hybridity: Lessons, future research and an integrative approach to health systems improvement**

In this section we consider lessons for those considering recreating or translating regulatory hybridity into other national contexts – and note aspects of hybrid regulation requiring future research attention. First, our findings draw attention to the importance of early regulatory focus and context, and potential for subsequent path dependence. This reflects David's (1994) assertion that organizations are the carriers of history, with past experiences shaping the present via established expectations and behaviours.

Second, HIQA's experience, particularly in the light of exchange with senior HIS executives, raises questions regarding whether regulatory hybridity is replicable and scalable.

Hybridity in HIS was premised on long-term investment and the decisions and actions of key stakeholders in a unique, conducive and inimitable historical trajectory. Our analysis suggests that where replication and translation are attempted, it might be beneficial to embed bottom-up persuasive processes to enhance improvement capacity and promote collaboration with key stakeholders, before top-down accountability mechanisms are introduced. Unless well-established and embedded, bottom-up approaches may be more likely to be ‘crowded out’ where contest or contradiction arises (c.f. Fischer and Ferlie, 2013). Further, contexts where regulators are forced to use their ‘big gun’ can undermine trust and collaboration (c.f. Ayres and Braithwaite, 1992). In contrast, adopting bottom-up, persuasive and professionally-oriented approaches in the first instance may reflect Pache and Santos’s (2013) ‘Trojan horse’ approach to gaining legitimacy - helping to establish trust and collaborative approaches between stakeholders. This is important as Reay and Hinings (2009) suggest that competing logics may be reconciled and coexist where stakeholders develop mechanisms of collaboration.

Third, this paper has considered the factors influencing whether and why regulatory hybridity (combining top-down deterrence and bottom-up persuasive approaches) emerged in two national contexts. However, our research is premised on a snapshot in time, and perceptions of interviewees rather than evidence of improvement. Future research should consider whether regulatory hybridity is sustainable, given increasing demand for tough inspection; the leadership requirements associated with combining the two approaches – within regulating and regulated organizations; and the impact of regulatory hybridity on quality improvement processes and outcomes.

Next, in the light of challenges in achieving hybrid regulation, we question whether this is desirable, and present an integrative framework to guide the combination of top-down and bottom-up approaches to health systems governance for improvement. In so doing, we

are mindful that hybridized control systems are often ‘*contested terrains*’ (Reed, 2011: 60), offering professional elites delegated control overlaid by ‘panoptican’ type forms of surveillance (*ibid*). This creates challenges for national and local levels ‘*to co-ordinate effectively their control strategies and practices in ways that sustain coherent narratives of change and innovation*’, with ‘*an underlying process of ‘hybridization’ in which control management becomes even more precarious and contingent*’ (Reed, 2011: 57). Our framework is integrative, in following Reed’s (2011) concern with aligning national and local control strategies to sustain a clear improvement focus. Specifically, we suggest that the culture and capability of local organizations may affect the most appropriate national governance approach (e.g. a single hybrid regulator or otherwise) to supporting improvement.

### **Towards an integrative governance framework for health systems improvement**

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Figure 5

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Organizations risk undermining consistency in performance when undertaking adaptation and improvement (Denis and Forest, 2012). Efforts to create hybrid health service regulation in Scotland and Ireland attempt to address this by encouraging employees in regulated organizations to adopt, adapt and add to best practice (c.f. McDermott et al., 2013), in line with Berwick’s (2013) call to generate responsive ‘learning organisations’. Our closing findings from Scotland – suggestive of mutual support between national and local agendas, and between standards, implementation capacity and innovation (potentially leading to refined standards) – are attractive. Coupled with hybridity’s emphasis on synergistic benefits, this might make a hybrid regulatory approach seem normative. Yet our findings suggest that hybridity may be hard to recreate, as ‘*there is no such thing as an ahistorical optimal*

*regulatory strategy*’ (Ayres and Braithwaite, 1992: 101). In particular, while having both roles evident in regulatory systems may be desirable, complementarity may be difficult to achieve within a single organization (c.f. Fischer and Ferlie, 2013). Where there is potential for one approach to get ‘crowded out’, imbuing separate national organizations with responsibility for top-down and bottom-up approaches to improvement could enhance clarity and focus – and promote longevity. It could also help to avoid conflicts of interest within regulators, and regulatory capture (c.f. Grabosky and Braithwaite, 1986, NESC, 2012). There is also a need to explicitly recognize the role that local health service delivery organizations (e.g. hospitals, social care organizations) play in supporting improvement (c.f. Berwick, 2013; Denis and Forest, 2012). This has previously been captured in the concept of ‘enforced self-regulation’, where individual organizations propose their own regulatory standards (c.f. Ayres and Braithwaite, 1992). Building on our findings, Figure 5 details distinct yet complementary national and local organizational roles. It provides a framework for identifying potential national improvement support roles to deliver together in pursuit of hybrid regulation (e.g. combining top-down and bottom-up national supporting roles) or to be pursued via independent organizations. It also identifies supporting local organizational roles. Discussion suggests that local stage of development may affect what is appropriate nationally.

Quadrant 1 illustrates a top-down role for a national organization in *ensuring* the adoption of evidence-based best practice, drawing upon a range of potential deterrence oriented accountability mechanisms, such as standards, scrutiny and inspection. Evaluating performance using such mechanisms requires collation of performance information, ‘*an essential prerequisite for continuous improvement*’ (Gunningham and Sinclair, 1998) – although we note the IHI’s differentiation between information for judgement, and information for improvement (Haraden and Leitch, 2011). The investment required in

compiling and sharing best-practice evidence, as well as engaging in scrutiny to ensure its adoption makes it appropriate for a top-down national organization to lead this role.

Quadrant 2 identifies a persuasion oriented capacity building role for a national organization, to *enable* employees to engage in bottom-up improvement activities, including adapting national agendas. Quadrant 2's focus on education and training enables action on the basis of performance information. Although potentially counterintuitive for a bottom-up approach, the need to spread improvement capacity across the system means the centralized provision of change resources and training – as well as networks to spread learning – is appropriate. Importantly, like the provision of information, Gunningham and Sinclair (1998) suggest that education and training complement other regulatory instruments. However, our findings suggest that, in certain circumstances, their delivery might beneficially be separated from deterrence mechanisms - introducing the idea that interventions' institutional home (separate or shared), as well as their content and sequence (c.f. Gunningham and Sinclair, 1998), may affect their compatibility.

Quadrant 3 notes the important persuasive organizational role in *empowering* employees to utilize their bottom-up improvement capacity in their own organizations – adding to national efforts via trial and error and innovative problem-solving, and sharing findings from local evaluation efforts. Creating such a supportive climate for service-improvement requires attention to sharing best practice information, and developing local leadership (McDermott and Keating, 2012).

Last, Quadrant 4 notes the importance of organizations engaging in top-down efforts to *embed* cultures of improvement, innovation and learning – via board policies and priorities, clinical governance, local improvement support units, and celebrating success. This entails a combination of potential internal deterrence and persuasive mechanisms, employed

via development of local processes and supports. Quadrant 4's focus may arise via voluntarism<sup>1</sup>, and also in response to the accountability mechanisms (performance and process standards) detailed in Quadrant 1. This is captured by Gunningham and Sinclair (1998: 433) who note that '*voluntary based measures which seek to change the attitudes of managers and the corporate culture may serve to reinforce a commitment to process based standards*'. Importantly, the culture change (encompassing behaviours and values) referred to in Quadrant 4 requires contextually sensitive interventions, such as those detailed above, to be effective (c.f. Ogbonna and Harris, 2002). While deep-rooted change to values may be difficult to achieve, behavioural compliance is more widely feasible (*ibid*), and may be captured via performance monitoring mechanisms.

Building on our findings and following Gunningham and Sinclair (1998), Figure 5 details a range of complementary regulatory instruments (accountability premised on process and performance standards; information; education and training and; voluntarism), tailored to specific goals, and notes the potential for these to be delivered via alternative configurations of national and local organizations. Importantly, our findings and this framework suggest that the regulatory functions in Quadrant 1 (Ensuring) and Quadrant 2 (Enabling) might be delivered via a single or separate national organizations – in response to contextual circumstances previously detailed. We have suggested that, if being combined in a single national regulator, it may be beneficial for the bottom-up 'Enabling' approach inherent in Q2 to be embedded in the organization before the top-down focus on 'Ensuring' in Q1 is introduced. Following Berwick (2013) and Denis and Forest (2012), the model also recognises a role for local organizations (e.g. hospitals; social care organizations) in supporting improvement (e.g. Q3, Q4). Where local organizations have yet to embed cultures

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<sup>1</sup> Gunningham and Sinclair (1998) note voluntarism and self-regulation overlap to a significant extent. However, the main distinction is that self-regulation typically involves industry level groups while voluntarism focuses on individual organizations self-regulating their members

of improvement, a focus on ‘Ensuring’ (Q1) via top-down formal regulation may help develop local organizational systems and processes (e.g. Q4). In contexts where Q1’s top-down focus is likely to receive particular emphasis (e.g. in the foundational or early stages of regulatory systems, or in response to critical incidents), it may be constructive to deliver this separately to the bottom-up focus on Enabling inherent in Q2. In health services where local cultures of improvement are well embedded (e.g. Q4) and where staff are commonly empowered to engage in improvement efforts (e.g. Q3) it may be easier to combine top-down and bottom-up approaches in a single national regulator - as Q1’s focus on Ensuring is less likely to be enacted in a punitive form. Thus, implicit in our framework is a suggestion of a variety of contextually responsive ways of achieving the policy goal of continuous proactive improvement. Previously detailed caveats in recommending hybrid regulatory control as the single ‘best way’, a focus on contextual responsiveness, and a concern with aligning national and local focus, lead us to adopt the language of integration rather than hybridity in describing the framework.

Our findings have addressed calls for insight into the factors affecting hybridization, detailed the merits and challenges of regulatory hybridity, and provided an integrative governance framework to help select an appropriate regulatory strategy in a given context. While we note potential for hybridity to develop over time, we suggest that, in the absence of a receptive context, collaborative stakeholder relationships, adequate time or resources, or where an early deterrence orientation is required, it may be advisable to separate out national regulatory responsibility for top-down and bottom-up approaches to improvement. Our integrative model of health systems governance details specific national and organizational roles in achieving ongoing improvement – answering calls for policy design strategies to encourage organizations to go beyond regulatory compliance.

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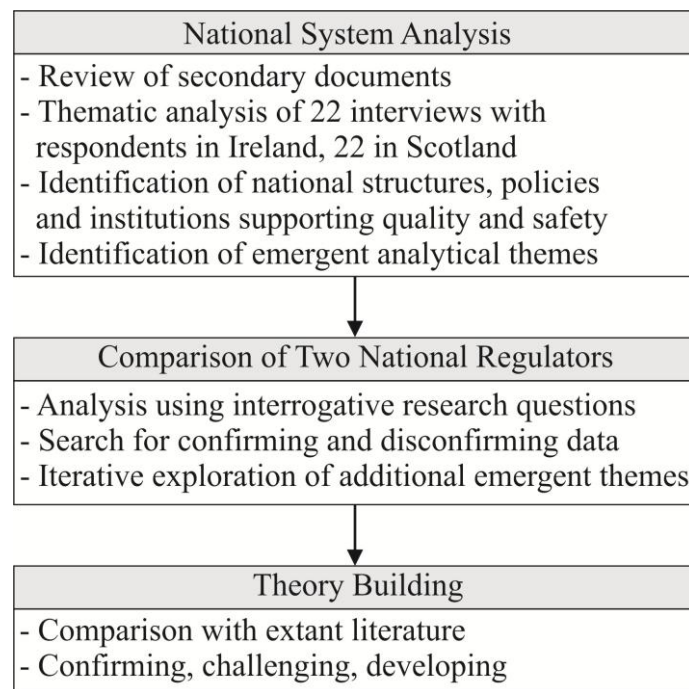
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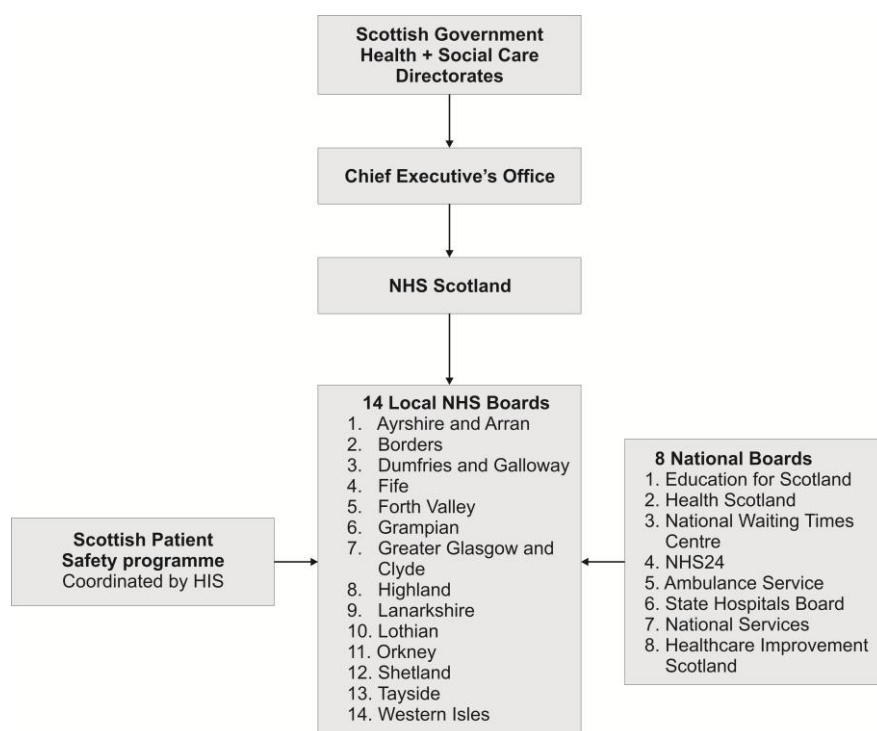
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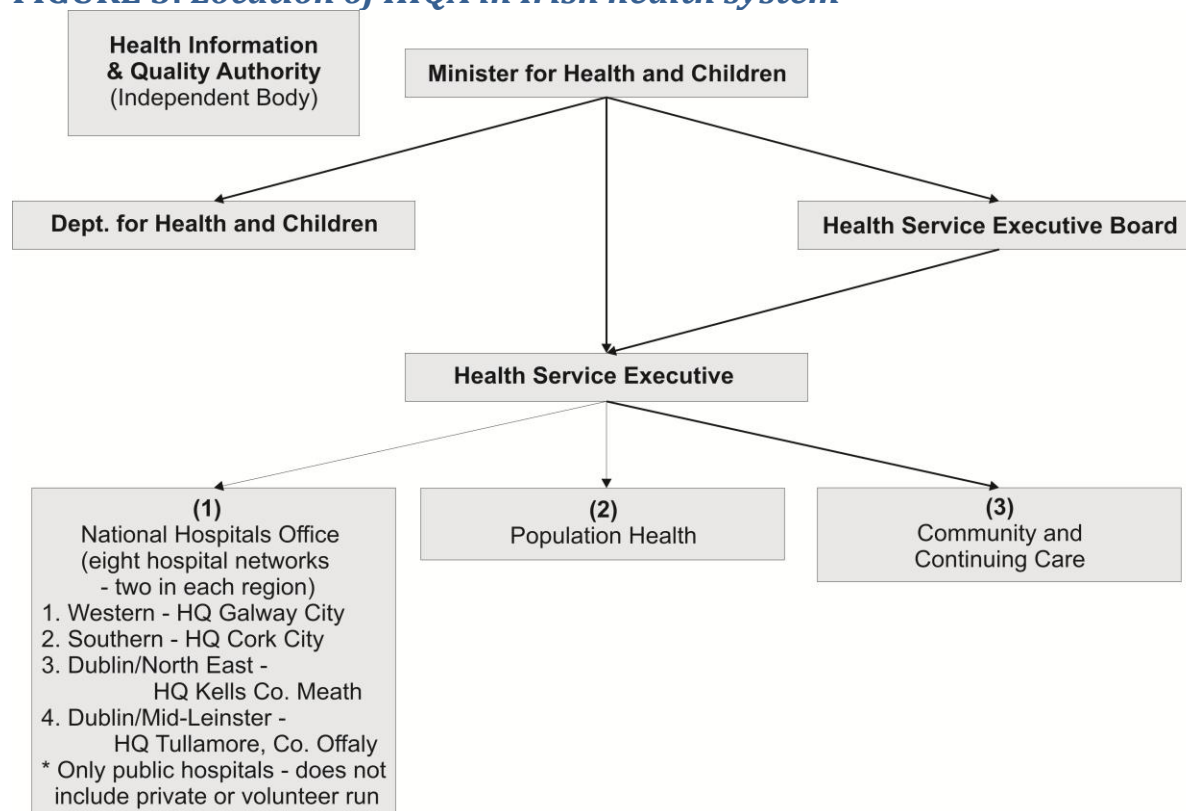
**FIGURE 1: *Overview of analytic strategy***



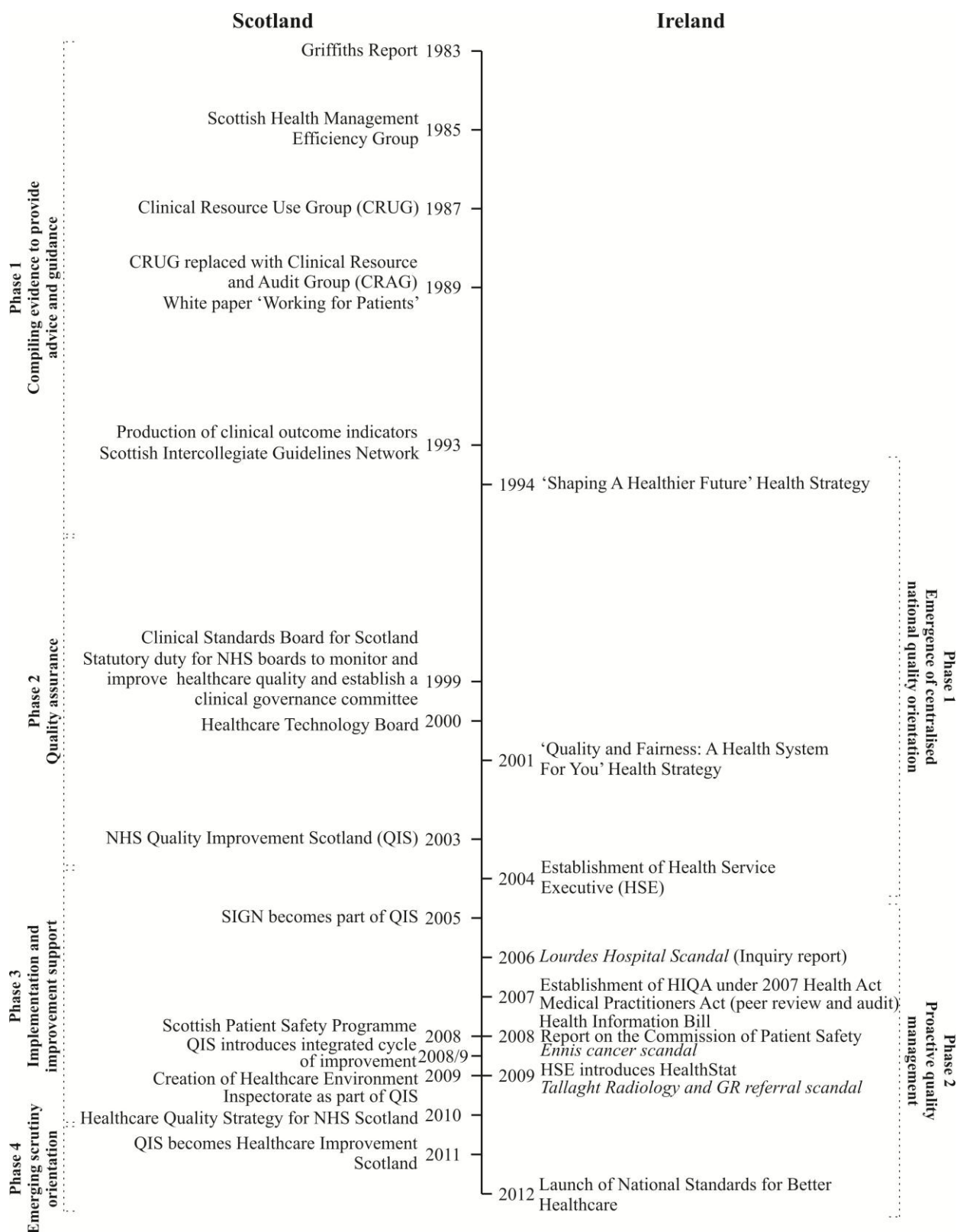
**FIGURE 2: Location of HIS in Scottish health system**



**FIGURE 3: Location of HIQA in Irish health system**



**FIGURE 4: Historical timeline leading to HIS and HIQA**



**FIGURE 5: Integrative governance model**

