



# Emerging hybridity: Comparing UK healthcare regulatory arrangements

**DOI:**  
[10.1108/JHOM-06-2016-0109](https://doi.org/10.1108/JHOM-06-2016-0109)

**Document Version**  
Accepted author manuscript

[Link to publication record in Manchester Research Explorer](#)

**Citation for published version (APA):**  
Furnival, J., Walshe, K., & Boaden, R. (2017). Emerging hybridity: Comparing UK healthcare regulatory arrangements. *Journal of Health, Organization and Management*. <https://doi.org/10.1108/JHOM-06-2016-0109>

**Published in:**  
Journal of Health, Organization and Management

**Citing this paper**  
Please note that where the full-text provided on Manchester Research Explorer is the Author Accepted Manuscript or Proof version this may differ from the final Published version. If citing, it is advised that you check and use the publisher's definitive version.

**General rights**  
Copyright and moral rights for the publications made accessible in the Research Explorer are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

**Takedown policy**  
If you believe that this document breaches copyright please refer to the University of Manchester's Takedown Procedures [<http://man.ac.uk/04Y6Bo>] or contact [uml.scholarlycommunications@manchester.ac.uk](mailto:uml.scholarlycommunications@manchester.ac.uk) providing relevant details, so we can investigate your claim.





**Emerging hybridity: Comparing UK healthcare regulatory arrangements**

Journal:	<i>Journal of Health Organization and Management</i>
Manuscript ID	JHOM-06-2016-0109.R2
Manuscript Type:	Original Article
Keywords:	Regulation, Quality Improvement, Quality Assurance, Hybridity, Quality

SCHOLARONE™  
Manuscripts

## Emerging hybridity: Comparing UK healthcare regulatory arrangements

### ABSTRACT

#### *Purpose*

Healthcare regulation is one means to address quality challenges in healthcare systems and is carried out using compliance, deterrence and/or improvement approaches. The four countries of the United Kingdom (UK) provide an opportunity to explore and compare different regulatory architecture and models. The aim of this paper is to understand emerging regulatory models and associated tensions.

#### *Methodology*

This paper uses qualitative methods to compare the regulatory architecture and models. Data was collected from documents, including board papers, inspection guidelines and from 48 interviewees representing a cross-section of roles from six organisational regulatory agencies. The data was analysed thematically using an a priori coding framework developed from the literature.

#### *Findings*

The findings show that regulatory agencies in the four countries of the UK have different approaches and methods of delivering their missions. This study finds that new hybrid regulatory models are developing which use improvement support interventions in parallel with deterrence and compliance approaches. The analysis highlights that effective regulatory oversight of quality is contingent on the ability of regulatory agencies to balance their requirements to assure and improve care. Nevertheless, they face common tensions in sustaining the balance in their requirements connected to their roles, relationships and resources.

#### *Originality/Value*

1  
2  
3 The paper shows through its comparison of UK regulatory agencies that the development and  
4 implementation of hybrid models is complex. The paper contributes to research by  
5 identifying three tensions related to hybrid regulatory models; roles, resources and  
6 relationships which need to be managed to sustain hybrid regulatory models.  
7  
8  
9

10  
11  
12 *Keywords*

13  
14 Regulation; Quality; Quality assurance; Hybridity; Compliance; Quality improvement;  
15

16 *Article Classification:* Research paper  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Emerging hybridity: Comparing UK healthcare regulatory arrangements

### 1.0 INTRODUCTION

In the four countries of the United Kingdom (UK) different healthcare regulatory arrangements have developed, which provides an opportunity to study emerging hybrid healthcare regulatory models.

The purpose of this paper is:

- To understand and analyse healthcare regulatory models within the UK
- To identify regulatory model developments
- To understand the tensions related to the development of hybrid regulatory models

The paper is organised as follows: first, the background outlines relevant regulatory theoretical concepts. Second, the method and scope of the paper is detailed. Third, the current regulatory architecture and models are detailed. This outlines an emerging trend towards the use of hybrid regulatory models. Three tensions identified from the use of hybrid regulatory models are described in the findings and discussion. The paper concludes by outlining the contribution of the work.

### 2.0 HEALTHCARE REGULATION

Regulation can be defined as ‘sustained and focused control exercised by a public agency over activities which are valued by a community’ (Selznick, 1985, p363). Regulation arises for several reasons, including the need to adjust for market failures, unequal bargaining power, critical goods shortages or moral hazards (Feintuck, 2012), where the consumer pays indirectly for services or to reduce discrimination and further social solidarity (Prosser, 2006). Healthcare regulation addresses stakeholders’ demands for improved performance. Walshe (2003b) describes three main aims of regulation: improvement, assurance and accountability together with three regulatory models: compliance, deterrence (Reiss, 1984)

1  
2  
3 and responsive (Ayres and Braithwaite, 1992). Deterrence models assume that organisations  
4 are ‘amoral’ (Bardach and Kagan, 1982) and will deliberately break rules, thus compliance  
5 must be enforced. In contrast, compliance models assume organisations will seek to comply  
6 with regulatory requirements if they can, and focus on persuasion and encouragement rather  
7 than formal or punitive enforcement.  
8

9  
10 Responsive regulation emphasises the combination of both ‘deterrence’ and ‘compliance’  
11 models (Ayres and Braithwaite, 1992; 2007). This flexible model allows regulatory agencies  
12 to choose their approach depending on performance or risk levels (Parker, 2013). Regulatory  
13 intervention escalates (or de-escalates) through a hierarchy as performance changes. This  
14 form of regulation assumes that trust-based models will improve care more effectively (Ayres  
15 and Braithwaite, 1992; 2007). It is more suited to organisations and sectors seeking long-  
16 term improvement but it is challenging to sustain with large numbers of organisations.  
17

18  
19 In this paper, a responsive regulatory model is described as a ‘hybrid’ model, and the term is  
20 used to refer to a regulatory agency that uses a combination of deterrence and compliance  
21 models.  
22

23  
24 McDermott et al. (2015) describe hybrid regulatory agencies who simultaneously use  
25 compliance and deterrence models to support performance improvement, ‘hybridity’ is a  
26 concept widely used to describe organizational responses to changes in governance (Skelcher  
27 and Smith, 2015) and it is argued that it may support the reconfiguration of organisational  
28 models as circumstances change, accommodating multiple demands and developing new  
29 ideas (Miller et al., 2008; Borys and Jemison, 1989). However, hybridity may also lead to  
30 the disruption of existing professional communities and identities (Smith, 2014), unstable  
31 organisations which may fracture under sustained pressure (Denis et al., 2015). Fischer and  
32 Ferlie (2013) argue that regulatory regimes consist of various values, norms and instruments  
33 that cannot be readily combined. It is sometimes argued that structural separation may be  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 needed to manage the tensions that arise (Kippist and Fitzgerald, 2009; McDermott et al.,  
4  
5 2015). Nevertheless, hybrid models can produce stable states and can improve performance  
6  
7 relative to traditional models (Miller et al., 2008). This paper suggests that hybrid regulatory  
8  
9 models may be more effective in producing improvement, but also more complex to design  
10  
11 and implement and difficult to sustain.

12  
13  
14 There are three main regulatory processes: direction, detection and enforcement. Direction  
15  
16 defines standards and removes systemic barriers through the provision of external policy  
17  
18 impetus. Detection refers to the measurement and monitoring of performance. Enforcement  
19  
20 is central to regulation and covers the methods used to educate, persuade, influence and force  
21  
22 behavioural change (Hutter, 1989; Walshe and Shortell, 2004).

23  
24  
25 Regulation provides valuable feedback supporting improvement and requires high standards  
26  
27 of performance to be maintained which otherwise they may not be (Gunningham, 2012).

28  
29  
30 Despite this, it is often critiqued. Flodgren et al. (2011) finds a lack of effectiveness, other  
31  
32 problems include high costs (Ng, 2013), inflexibility (Brennan, 1998), tunnel vision,  
33  
34 (Mannion et al., 2005), inhibiting innovation (Stewart, 1981), provider capture (Boyd and  
35  
36 Walshe, 2007), ritualistic and bureaucratic compliance (Braithwaite et al., 2007), a short term  
37  
38 focus (Walshe, 2003b), loss of autonomy (Donabedian, 1988) and generating fear (Berwick,  
39  
40 2013).

41  
42  
43 Recognising the limits of deterrence and compliance regulatory models, alternative  
44  
45 supportive and more contingent models using professionalism and improvement support are  
46  
47 increasingly proposed (Ham, 2014). These models are intended to ensure healthcare systems  
48  
49 can deliver high performance and can be viewed as a variation or development of responsive  
50  
51 regulation. However, there are few studies (e.g., McDermott et al., 2015) analysing the  
52  
53 impact and influence of these emerging models. This paper contributes through comparative  
54  
55 analysis of healthcare regulatory agencies across the UK.  
56  
57  
58  
59  
60

### 3.0 METHODOLOGY

This paper focuses on the six UK organisational regulatory agencies: Care Quality Commission (CQC), Monitor, Trust Development Authority (TDA) in England [1] and Healthcare Inspectorate Wales (HIW), Healthcare Improvement Scotland (HIS) and the Regulatory and Quality Improvement Authority (RQIA) in Northern Ireland. Hospital-based care is the main area of focus for this paper, since it accounts for the majority of healthcare expenditure in the UK and all four countries oversee this healthcare area.

The study identified and analysed healthcare policy documents from each devolved country that included information related to regulatory purpose, strategy, and results. Following permission to process after ethical review, the directors of policy or regulation within each regulatory agency were contacted to discuss organisational participation within the study. All six agencies agreed, and a cross-section of employees were interviewed. The interviewees held roles including board-level executives and inspectors, with a mixture of clinical and non-clinical backgrounds from each regulatory agencies. Participation was voluntary and confidential. The interviews took place between October 2014 and April 2015.

The study used a semi-structured interview process based on the documentary analysis (Thomas, 1993). Questions included ‘what is the aim and purpose of this agency?’, and ‘what types of interventions do you use and why?’ Testing of the questions took place through five pilot interviews. Interviewees were provided with copies of the transcripts to allow for any clarifications. The use of interviews allowed complex, subjective and sometimes contradictory data to be collected from participants that could not be gathered from other approaches. The data collected from interviews and documents was analysed iteratively on NVivo data analysis software, using an a priori coding template developed from the literature. This was used to compare the current regulatory architectures, models and



1  
2  
3 aims and supported the organisation and interpretation of data through the identification of  
4  
5 themes.

#### 6 7 8 **4.0 RESULTS** 9

10 The results are presented in two sections; the first section introduces the landscape of  
11 regulatory architecture in the UK. An overview of the six regulatory agencies is provided in  
12 table 1. This architecture comparison is used to identify the regulatory models in use and  
13 development, showing that hybrid regulatory models are emerging. The second section  
14 details three tensions arising from the emergence of hybrid regulatory models.  
15  
16  
17  
18  
19  
20  
21  
22  
23

24 Table 1: Agency comparison  
25  
26  
27

##### 28 *The UK regulatory architecture* 29

30 HIS was established in 2011. It combines a number of predecessor Scottish organisations.  
31 Its aim and purpose is to advance improvement in healthcare in Scotland, and to support  
32 providers to deliver safer, more effective and more person-centred care. HIS does not review  
33 social care services; a separate inspectorate oversees this.  
34  
35  
36  
37  
38  
39 HIW was established in 2004 and it is a unit of the Welsh Assembly Government. It has  
40 wide-ranging responsibilities including inspection of health boards and trusts, the regulation  
41 of independent healthcare providers, general practices, pharmacies and dental practices. Like  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

RQIA was established in 2005. It is the main scrutiny body in Northern Ireland's care system  
and provides independent assurance about the quality of health and social care services.

In England, the regulatory architecture is more fragmented and there are areas of overlap.

There are three main healthcare provider regulatory agencies, the CQC, TDA and Monitor.

The CQC was formed as a single integrated regulatory agency in 2009 from a merger of

1  
2  
3 predecessor organisations. CQC's purpose is to ensure health and social care services  
4 provide people with high quality care and to encourage improvement (Care Quality  
5 Commission, 2013).  
6  
7  
8

9  
10 The English National Health Service (NHS) has been pursuing a policy to develop  
11 Foundation Trusts (Walshe, 2003a), which have more independence from the Department of  
12 Health provided a number of criteria is met. Monitor is the sector regulator of Foundation  
13 Trusts in England, a non-departmental public body of the Department of Health, established  
14 in 2004, The TDA is a special health authority of the Department of Health set up following  
15 the Health and Social Care Act in 2012. It provides the oversight, scrutiny, and performance  
16 management of non-Foundation Trusts on behalf of the Department of Health and develops  
17 them into Foundation Trusts. The TDA does not have formal regulatory powers.  
18  
19  
20  
21  
22  
23  
24  
25  
26

27 All the regulatory agencies were established from 2004 onwards with the most recent being  
28 the TDA in 2012. All, excepting the TDA, have seen growth in their scope since  
29 establishment. This has often followed emerging quality failures, for example in  
30 Lanarkshire, Scotland, (Healthcare Improvement Scotland, 2013b). All four countries have  
31 held inquiries into cases of poor care, which have affected scope, responsibilities and the  
32 regulatory model used (table 2).  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42

43 Table 2: Impact of responses to quality issues on regulatory agencies  
44  
45  
46

47 It is not clear how the agencies choose the processes they use to discharge their regulatory  
48 responsibilities but often this seems to be in reaction to national and political context rather  
49 than through a deliberative process. This suggests that the regulatory agencies are path-  
50 dependent in how they deliver their regulatory aims of improvement, assurance and  
51 accountability, reacting to the external environment rather than making an explicit choice of  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 regulatory model. The paper analyses the specific goals and regulatory models of each  
4  
5 agency. Table 3 analyses the documents and interviews to compare regulatory goals and  
6  
7 models, and shows that there are three 'hybrid' regulatory agencies. Agencies demonstrate  
8  
9 aspects of several regulatory models making model categorisation challenging to complete.  
10  
11 The term 'hybrid' is used to illustrate an emergent responsive regulatory approach whereby  
12  
13 regulatory agencies are primarily using enforcement methods that comprise of improvement  
14  
15 support through direct action that is tailored contingent on organisational circumstances and  
16  
17 performance. The remaining agencies described methods that remained invariant, regardless  
18  
19 of organisational circumstances and because the enforcement methods used did not include  
20  
21 the provision of improvement support.  
22  
23  
24

25  
26 Table 3: Agency goals and models  
27  
28

29  
30 *Tensions within hybrid models*  
31  
32

33 The analysis highlights a tension caused through the combination of assurance, accountability  
34  
35 and improvement goals:  
36

37  
38 *"We're part of the architecture that can make organisations simply focus on the*  
39  
40 *problem of today, ... [whereas] organisations need to find that balance between*  
41  
42 *addressing today [and] tomorrow", (Interviewee F, TDA).*  
43

44  
45 *"...it's quite clear that we're there to scrutinise and to regulate, but we're also there*  
46  
47 *to try to help improvement... it isn't always easy to fit the two together", (Interviewee*  
48  
49 *H, CQC).*

50  
51 *"[NHS] Boards are saying actually don't confuse us. You can't come in with an*  
52  
53 *inspection hat on and then an improvement one", (Interviewee C, HIS).*  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 This paper identifies three themes from this tension between compliance and improvement  
4 support within emerging hybrid models - regulatory role, resources and relationships – and  
5  
6 we now discuss each in turn.  
7  
8

9  
10  
11  
12 Regulatory roles

13  
14 Interviewees and documents describe a tension between the roles of assuring the public of  
15  
16 safe, quality care and improving care.  
17

18  
19 *“Quality care cannot be achieved by inspection and regulation alone. The main*  
20 *responsibility for delivering quality care lies with [those that provide], arrange and*  
21 *fund local services”, (Care Quality Commission, 2013).*  
22

23  
24 *“The Berwick report (2013) highlights the vital role that ‘intelligent inspection’ plays.*  
25 *However, this cannot stand alone and must be combined within a system of*  
26 *improvement”, (Healthcare Improvement Scotland, 2014).*  
27

28  
29 *“We’re very clear what our role is when we go in and our role is not to run the trust*  
30 *or run a piece of work”, (Interviewee A, TDA).*  
31

32  
33 *“They’re their own problems, because if we solve it for them, then they haven't*  
34 *worked it through, and I couldn't solve it”, (Interviewee A, RQIA).*  
35

36  
37 Some agencies are concerned that delivering improvement activity compromises their ‘role’  
38  
39 to conduct objective detection. Interviewees also raise concerns regarding accountability  
40  
41 should the improvement support not lead to the expected outcomes.  
42  
43

44  
45 *“there is a danger of conflict, that we mark our own homework... a hospital [could]*  
46 *say, but you’ve been working with us on this so the failure is also partly yours”,*  
47  
48 (Interviewee A, Monitor).  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3       *“When trusts aren’t performing, there is a lot of pressure in the system, to say...to*  
4       *almost indicate that it’s wilful. It’s almost as if they’re failing for reasons which they*  
5       *should be able to stop”*, (Interviewee C, TDA).  
6  
7

8  
9  
10       *“We don’t make standards because it would be an uncomfortable place to be, to be*  
11       *the regulator and review against your own standards”*, (Interviewee E, RQIA).  
12  
13

### 14 15 16       Resources

17  
18       The choice of regulatory approach has important ramifications for planning and execution, as  
19       it affects the type of resources (e.g. information technology versus clinical skills) and  
20       experienced staff that are needed by the regulatory agency, and influences the financial  
21       resources available for other regulatory tasks. Compliance models for example, need more  
22       inspectors whereas hybrid models need more improvement facilitators. This makes the  
23       choice of regulatory model more path-dependent and slow to change. Analysis suggests that  
24       that relatively few employees may have improvement skills or experience within regulatory  
25       agencies. Shortages need addressing through development, recruitment and investment.  
26  
27

28       *“We had no resources to take it forward”*, (Interviewee B, HIS).  
29

30       *“We’ve got quite a big, sort of, issue about needing to invest in our staff...you can’t*  
31       *just outsource...we just don’t have the time and need some supplemental space to be*  
32       *able to really engage with [improvement]. So, it is quite a big challenge for us”*,  
33       (Interviewee A, CQC).  
34

35       *“There [is] a challenge to find people of those skills”*, (Interviewee B, HIW).  
36

37  
38       It is clear from the interviews and documents that some regulatory staff resist the  
39       development of hybrid models. This may be due to the lengthy period and costs of  
40       developing skills, or to disagreements regarding the regulatory aims and concerns regarding  
41       local accountability.  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3        “[I wonder] how knowledgeable the inspectors are around improvement methodology  
4  
5        because you can’t judge it unless you know what you’re looking for... I think the  
6  
7        inspectors lack the improvement methodology understanding... we don’t have the  
8  
9        special advisors either”, (Interviewee C, CQC).

10  
11        “ We haven’t got anything like the number of people working within Monitor that have  
12  
13        the [improvement] experience they’d need... some people would say, this isn’t a job  
14  
15        for a regulator”, (Interviewee F, Monitor).

16  
17        “RQIA has limited capacity [...] to encourage service providers to continuously  
18  
19        improve”, (Regulation and Quality Improvement Authority, 2015a).

20  
21  
22  
23        Regulatory agencies report pressures linked to resources and describe a trade-off required  
24  
25        between detection and enforcement activities and the resources available.

26  
27        “...we would have to think carefully about whether our time’s better spent doing  
28  
29        [improvement work] or another inspection somewhere else”, (Interviewee B, HIW).

30  
31        “...with regulation, you have to prioritise, if we were regulating everybody it  
32  
33        wouldn’t have any impact and [we] wouldn’t have enough resources”, (Interviewee  
34  
35        B, Monitor).

### 36 37 38 39 40        Relationships

41  
42        Interviewees comment on their need to maintain effective working relationships with  
43  
44        organisations and to establish trust and openness to assure the public that their assessments of  
45  
46        care quality are fair, trustworthy and accurate. However, interviewees acknowledge the risks  
47  
48        of negative reporting, noting that detection and enforcement together with tough media and  
49  
50        political scrutiny can develop destabilising effect on organisations and associated  
51  
52        relationships.  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3           *"...if you establish good ongoing relationships outside the inspection regime then it's*  
4           *less about you coming in and more about the team that the hospital knows..."*,  
5  
6  
7           (Interviewee C, CQC).

8  
9  
10           *"...You're still having that professional distance as a regulator but you get to know*  
11           *the chief exec... and they get to know you..."*, (Interviewee F, HIW).

12  
13           *"the approach of some providers might be... they're a regulator so I don't want to go*  
14           *near them whereas some of our best relationships with trusts are ...coming to us very*  
15           *early for advice"*, (Interviewee B, Monitor).

16  
17  
18  
19  
20  
21           However, analysis of documents indicates that agencies believe that enforcement action, both  
22           punitive and supportive, must be transparent to prevent against regulatory capture to maintain  
23           public trust in 'independent and objective' regulators.

24  
25           *"HIW will report clearly, openly and publicly on the work that we undertake in order*  
26           *that citizens are able to access independent and objective information on the quality,*  
27           *safety and effectiveness of healthcare in Wales"*, (Healthcare Inspectorate Wales,  
28           2014a; Healthcare Inspectorate Wales, 2014b).

29  
30           *"By publicly reporting our findings, we provide assurance to the public that*  
31           *standards are being met, or that action is being taken where improvements are*  
32           *needed"*, (Healthcare Improvement Scotland, 2013a).

33  
34  
35  
36  
37           These two contrasting perspectives, of confidentiality and openness, can be difficult to  
38           reconcile.

39  
40           *"There is an inherent tension with that confidential, closed-doors enquiry support*  
41           *with the requirements for us as a body about public accountability and*  
42           *transparency"*, (Interviewee G, HIS).

43  
44  
45  
46  
47           Finally, external stakeholders such as the media may use information differently, hindering  
48           relationship development, mutual trust and care improvement in some circumstances. Those

1  
2  
3 providing care may be concerned that information disclosure may deter honest discussion of  
4 problems due to these stakeholders (Berwick et al., 2003).  
5  
6  
7

## 8 **DISCUSSION AND IMPLICATIONS**

9  
10 This paper describes how regulatory agencies in the four countries of the UK have different  
11 organisational remits, scope, approaches and methods of delivering their mission. The  
12 analysis suggests that effective regulatory oversight relates to the ability of regulatory  
13 agencies to balance the requirements to assure and improve care. Hybrid regulatory models  
14 are emerging in response, such as the approach taken by HIS, Monitor and the TDA. Hybrid  
15 regulatory models have to balance multiple identities which can create conflicts linked to  
16 roles and identities, resources and relationships. But hybrid organisations are sometimes  
17 described as unstable and may fracture and revert to dominant roles and identities under  
18 sustained pressure (Denis et al., 2015). Hybrid regulatory agencies need to find ways to  
19 manage the identified tensions to sustain the balance of their requirements to assure and  
20 improve care.  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34

35 Hybrid regulatory models require a range of resources in order to deliver improvement  
36 support as well as to provide assurance. Hybrid regulatory models require the regulatory  
37 agency to be able to differentiate between organisations and tailor regulatory interventions  
38 accordingly. For example, do all organisations require improvement support or only those  
39 who have poor performance or high risk levels, or is pro-active improvement support offered  
40 to all organisations regardless of performance to prevent future poor performance? How  
41 should this be prioritised? It might be argued that regulatory agencies seeking to use hybrid  
42 regulatory models need to do more to articulate their underlying improvement model  
43 (Davidoff et al., 2015).  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53

54  
55 There remains a risk that high levels of intervention and support for improvement could  
56 jeopardise the trustworthiness of the regulator as an independent assessor, strain relationships  
57  
58  
59  
60



1  
2  
3 and blur roles and accountabilities. Moreover, if the main motivation within organisations for  
4  
5 improvement derives from external regulation, organisations may exert less effort into  
6  
7 implementation (Piening, 2011). This could inhibit healthcare organisations from investing  
8  
9 and developing long-term improvement capability of their own, leading to a dependence on  
10  
11 external improvement support from the regulatory agency and increasing their resource  
12  
13 requirements.

14  
15  
16 Instead of providing high levels of ongoing intervention and support for improvement,  
17  
18 healthcare regulatory agencies could strengthen their approaches to assure and improve care  
19  
20 by focusing on the development of improvement capability as well as seeking to ensure  
21  
22 compliance with standards and performance within regulated organisations. This could help  
23  
24 to ensure that regulatory agencies are supporting the development of more proactive  
25  
26 approaches to the improvement of quality without directly doing improvement work for or to  
27  
28 organisations, allowing regulatory agencies to benefit from the advantages of hybridity whilst  
29  
30 limiting some of the risks outlined above.  
31  
32

### 33 34 35 **CONCLUSION**

36  
37 Effective healthcare regulation requires recognition of the inherent tensions between the  
38  
39 regulatory aims of improvement, accountability and assurance. Hybrid regulatory models are  
40  
41 emerging within UK regulatory agencies to assure and improve care, and these use direct  
42  
43 improvement support for organisations to supplement other regulatory interventions. This  
44  
45 paper identifies that the development of hybrid models is complex and emergent. There are  
46  
47 three key areas of challenge linked to roles, resources and relationships when developing and  
48  
49 sustaining hybrid models. This paper contributes to research by presenting findings  
50  
51 furthering the understanding and emergence of hybrid models in healthcare regulation.  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 [1] Since this research was completed the TDA and Monitor have been merged with the  
4 operational name of NHS Improvement, though the underlying legislation which created  
5 them has not been revised, so they still exist statutorily as two separate organisations.  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## REFERENCES

- 1  
2  
3  
4  
5 Ayres, I. & Braithwaite, J. (1992) *Responsive regulation: Transcending the de-regulation*  
6 *debate*. New York: Oxford University Press.
- 7 Bardach, E. & Kagan, R. (1982) *Going by the book - The problem with regulatory*  
8 *unreasonableness - A Twentieth Century Fund report*. Philadelphia, USA: Temple  
9 University Press.
- 10 Berwick, D. (2013) A promise to learn - A commitment to act. Improving the safety of  
11 patients in England. London: National advisory group on the safety of patients in  
12 England.
- 13 Berwick, D. M., James, B. & Coye, M. J. (2003) Connections between quality measurement  
14 and improvement. *Medical Care*, 41(1), I-30-I-38.
- 15 Borys, B. & Jemison, D. B. (1989) Hybrid arrangements as strategic alliances: Theoretical  
16 issues in organizational combinations. *Academy of management review*, 14(2), 234-  
17 249.
- 18 Boyd, A. & Walshe, K. (2007) Designing regulation: a review. A review for the Healthcare  
19 Commission of the systems for regulation and their impact on performance in seven  
20 sectors, and a synthesis of the lessons and implications for regulatory design in  
21 healthcare. Manchester, UK: Manchester Business School.
- 22 Braithwaite, J., Makkai, T. & Braithwaite, V. (2007) *Regulating aged care: Ritualism and the*  
23 *new pyramid*. Cheltenham, UK: Edward Elgar Publishing Ltd.
- 24 Brennan, T. A. (1998) The role of regulation in quality improvement. *The Milbank Quarterly*,  
25 76(4), 709-731.
- 26 Care Quality Commission. (2013) Raising standards, putting people first. Our strategy for  
27 2013 to 2016. London: Care Quality Commission.
- 28 Davidoff, F., Dixon-Woods, M., Leviton, L. & Michie, S. (2015) Demystifying theory and its  
29 use in improvement. *BMJ Quality & Safety*, 0:1-11. doi:10.1136/bmjqs-2014-003627.
- 30 Denis, J. L., Ferlie, E. & Van Gestel, N. (2015) Understanding hybridity in public  
31 organizations. *Public Administration*, 93(2), 273-289.
- 32 Department of Health. (2012) Transforming care: A national response to Winterbourne View  
33 Hospital. London: Department of Health.
- 34 Donabedian, A. (1988) Quality assessment and assurance: Unity of purpose, diversity of  
35 means. *Inquiry: the Journal of Health Care Organization Provision and Financing*,  
36 25(1), 173-192.
- 37 Donaldson, L., Rutter, P. & Henderson, M. (2014) The right time, the right place: An expert  
38 examination of the application of health and social care governance arrangements for  
39 ensuring the quality of care provision in Northern Ireland. Belfast.
- 40 Feintuck, M. (2012) Regulatory rationales beyond the economic: In search of the public  
41 interest. In: Baldwin, R., Cave, M. & Lodge, M. (eds.) *The Oxford Handbook of*  
42 *Regulation*. Oxford: Oxford University Press.
- 43 Fischer, M. D. & Ferlie, E. (2013) Resisting hybridisation between modes of clinical risk  
44 management: Contradiction, contest, and the production of intractable conflict.  
45 *Accounting, Organizations and Society*, 38(1), 30-49.
- 46 Flodgren, G., Pomey, M. P., Taber, S. A. & Eccles, M. P. (2011) Effectiveness of external  
47 inspection of compliance with standards in improving healthcare organisation  
48 behaviour, healthcare professional behaviour or patient outcomes. *Cochrane database*  
49 *of systematic reviews*, (11).
- 50 Francis, R. (2013) Report of the Mid Staffordshire NHS Foundation Trust public inquiry.  
51 London, UK: Crown.
- 52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 Gunningham, N. (2012) Enforcement and compliance strategies. *In: Baldwin, R., Cave, M. &*  
4 *Lodge, M. (eds.) The Oxford Handbook of Regulation.* Oxford: Oxford University  
5 Press.
- 6 Ham, C. (2014) Reforming the NHS from within. Beyond hierarchy, inspection and markets.  
7 London: The King's Fund.
- 8 Healthcare Improvement Scotland. (2013a) Annual report 2012-2013. Edinburgh: Healthcare  
9 Improvement Scotland.
- 10 Healthcare Improvement Scotland. (2013b) A rapid review of the safety and quality of care  
11 for acute adult patients in NHS Lanarkshire. Edinburgh: Healthcare Improvement  
12 Scotland.
- 13 Healthcare Improvement Scotland. (2014) Driving improvement in healthcare. Our strategy  
14 2014-2020. Edinburgh: Healthcare Improvement Scotland.
- 15 Healthcare Inspectorate Wales. (2014a) Annual report 2013-2014. Cardiff: Healthcare  
16 Inspectorate Wales.
- 17 Healthcare Inspectorate Wales. (2014b) Healthcare Inspectorate Wales operational plan  
18 2014-2015. Merthyr Tydfil: Healthcare Inspectorate Wales.
- 19 Hutter, B. M. (1989) Variations in regulatory enforcement styles. *Law & Policy*, 11(2), 153-  
20 174.
- 21 Kippist, L. & Fitzgerald, A. (2009) Organisational professional conflict and hybrid clinician  
22 managers: The effects of dual roles in Australian health care organisations. *Journal of*  
23 *Health Organization and Management*, 23(6), 642-655.
- 24 Kirkup, B. (2015) The report of the Morecambe Bay investigation. London, UK: Crown.
- 25 Mannion, R., Davies, H. & Marshall, M. (2005) Impact of star performance ratings in English  
26 acute hospital trusts. *Journal of Health Services Research & Policy*, 10(1), 18-24.
- 27 Marks, R. (2014) An independent review of the work of Healthcare Inspectorate Wales. The  
28 way ahead: to become an inspection and improvement body. Main report. Cardiff.
- 29 McDermott, A. M., Hamel, L. M., Steel, D. R., Flood, P. C. & McKee, L. (2015) Hybrid  
30 healthcare governance for improvement? Combining top-down and bottom-up  
31 approaches to public sector regulation. *Public Administration*, 93(2), 324-344.
- 32 Miller, P., Kurunmäki, L. & O'Leary, T. (2008) Accounting, hybrids and the management of  
33 risk. *Accounting, Organizations and Society*, 33(7-8), 942-967.
- 34 Monitor. (2014) Monitor's strategy 2014-17. Helping to redesign healthcare provision in  
35 England. London: Monitor.
- 36 Ng, G. K. B. (2013) Factors affecting implementation of accreditation programmes and the  
37 impact of the accreditation process on quality improvement in hospitals: a SWOT  
38 analysis. *Hong Kong Medical Journal*, 2013(19), 434-436.
- 39 Parker, C. (2013) Twenty years of responsive regulation: An appreciation and appraisal.  
40 *Regulation & Governance*, 7(1), 2-13.
- 41 Piening, E. P. (2011) Insights into the process dynamics of innovation implementation.  
42 *Public Management Review*, 13(1), 127-157.
- 43 Prosser, T. (2006) Regulation and social solidarity. *Journal of Law and Society*, 33(3), 364-  
44 387.
- 45 Regulation and Quality Improvement Authority. (2015a) Board Papers January 2015. Belfast:  
46 Regulation and Quality Improvement Authority.
- 47 Regulation and Quality Improvement Authority. (2015b) Corporate Strategy 2015-2018.  
48 Belfast: Regulation and Quality Improvement Authority.
- 49 Reiss, A. J. (1984) Selecting strategies of social control over organisational life. *In: Hawkins,*  
50 *K. & Thomas, J. M. (eds.) Enforcing Regulation.* Boston, MA: Kluewer-Nijhoff.
- 51 Selznick, P. (1985) Focusing organizational research on regulation. *In: Noll, R. G. (ed.)*  
52 *Regulatory policy and the social sciences.* CA, USA: University of California Press.
- 53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 Skelcher, C. & Smith, S. R. (2015) Theorizing hybridity: institutional logics, complex  
4 organizations, and actor identities: The case of non-profits. *Public Administration*,  
5 93(2), 433-448.
- 6 Smith, S. R. (2014) Hybridity and nonprofit organizations: The research agenda. *American*  
7 *Behavioral Scientist*, 58(11), 1494-1508.
- 8 Stewart, R. B. (1981) Regulation, innovation, and administrative law: A conceptual  
9 framework. *California Law Review*, 69(5), 1256-1377.
- 10 Thomas, R. J. (1993) Interviewing important people in big companies. *Journal of*  
11 *Contemporary Ethnography*, 22(1), 80-96.
- 12 Trust Development Authority. (2014) Delivering for patients: The 2014/15 accountability  
13 framework for NHS Trust boards. London: Trust Development Authority.
- 14 Walshe, K. (2003a) Foundation hospitals: a new direction for NHS reform? *Journal of the*  
15 *Royal Society of Medicine*, 96(3), 106-110.
- 16 Walshe, K. (2003b) *Regulating healthcare. A prescription for improvement?* Maidenhead,  
17 UK: Open University Press.
- 18 Walshe, K. & Shortell, S. M. (2004) Social regulation of healthcare organizations in the  
19 United States: developing a framework for evaluation. *Health Services Management*  
20 *Research*, 17(2), 79-99.
- 21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

Table 1: Agency comparison

Country and population	Name	Staff (WTE)	Expenditure
Scotland: 5.3M	Healthcare Improvement Scotland (HIS)	329	£20M (14/15)
Wales: 3M	Healthcare Inspectorate Wales (HIW)	59	£3M (14/15)
Northern Ireland: 1.8M	Regulatory & Quality Improvement Authority (RQIA)	152	£7.6M (13/14)
England: 53M	Care Quality Commission (CQC)	2681	£240M (14/15)
England: ~149 Foundation Trusts (FTs)	Monitor	532	£72.3M (14/15)
England: ~ 90 Non-Foundation Trusts (non-FTs)	Trust Development Authority (TDA)	315	£65M (14/15)

Table 2: Impact of responses to quality issues on regulatory agencies

Agency	Issue	Response	Impact
HIS	High Mortality Rates at NHS Lanarkshire	Review of NHS Lanarkshire (Healthcare Improvement Scotland, 2013b).	Leading to development of new scrutiny approach - 'Quality of Care Reviews'.
HIW	Care concerns at Abertawe Bro Morgannwg University (ABMU) Health Board and wider concerns about effectiveness of HIW.	Trusted to Care Independent Review (Andrews and Butler, 2014); HIW Review (Marks, 2014)	Independent review of concerns at ABMU and the Welsh Health and Social Care Committee review of HIW in 2013. Followed by a formal review of HIW (Marks, 2014).
RQIA	Incidents at Belfast Health and Social Care Trust and Northern Care Health and Social Care Trust.	Instigated reviews by RQIA of the Trusts. The Minister in parallel initiated a review of the Northern Irish health and social care system (Donaldson et al., 2014)	The review of the health and social care system found that RQIA had little visibility and the healthcare system needed to strengthen its approach to improving quality.
CQC	High Mortality Rates and patient neglect at Mid-Staffordshire NHS Foundation Trust, similar failings in care at Winterbourne View and Morecambe Bay FT.	The Mid Staffordshire Inquiry (Francis, 2013) Morecambe Bay Inquiry (Kirkup, 2015) Winterbourne View (Department of Health, 2012)	Development of new inspection approach based on the NHS England reviews of high mortality trusts conducted in response to the Francis Inquiry.
Monitor	As CQC	As CQC	Change in role following 2012 Health and Social Care Act.
TDA	As CQC	TDA did not exist during the time of these issues; however, the impact of them influenced the design of the organisation.	Established following 2012 Health and Social Care Act.

Table 3: Agency goals and models

Agency	Documentary data	Interview data	Agency model
HIS	“We are the national healthcare improvement organisation for Scotland, established to advance improvement in healthcare” (Healthcare Improvement Scotland, 2014)	“...a blend of approaches: so we have the scrutiny, assurance, we have the clinical expertise ... independent fair and objective assessment ... [and] ...support improvement efforts” (Interviewee G, HIS) “[we]... help providers in Scotland to improve their improvement capability (Interviewee A, HIS)	Hybrid
HIW	“Our purpose is to provide independent and objective assurance on the quality, safety and effectiveness of healthcare services, making recommendations to healthcare organisations to promote improvements” (Healthcare Inspectorate Wales, 2014).	“we go out and inspect and we find ...an organisation is meeting the standards... then we wouldn't seek improvement ...beyond that (Interviewee B, HIW) “we are not an improvement agency, but we should be operating in a way which supports improvement” (Interviewee D, HIW)	Compliance
RQIA	“The most important priority for RQIA is to make sure that our inspection systems and processes convey clearly to the public how well a service is performing in respect of the... minimum standards” (Regulation and Quality Improvement Authority, 2015).	“We provide assurance... about the quality of services” (Interviewee D, RQIA) “our primary role is to question them, to challenge them early, and then they can then start making... improvements” (Interviewee A, RQIA)	Compliance
CQC	“We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve” (Care Quality Commission, 2013)	“We monitor, we inspect and we regulate and make sure that these services meet the fundamental standards” (Interviewee CQC D) “it's very clear in the CQC that we're not improvement facilitators, we're regulators” (Interviewee C, CQC)	Compliance
Monitor	“[We set] a required standard that all NHS providers must meet... [We] control the risk that foundation trusts, once authorised, fall back below the required standard. If they do, we take remedial action... We will focus in particular on the capabilities that drive long-term performance” (Monitor, 2014)	“where trusts fail to deliver certain minimum standards... [we] work with those trusts to ensure that they improve their position and restore themselves to ... that minimum standard” (Interviewee A, Monitor) “[Our] mandate is basically to improve the capability of FTs” (Interviewee G, Monitor)	Hybrid



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49

Agency	Documentary data	Interview data	Agency model
TDA	“The TDA oversees NHS trusts and holds them to account... while providing them with support to improve” (Trust Development Authority, 2014)	“[Trusts] know that they are being held to account for their performance but they also know that they will get support and help and development rather than just being criticised”. (Interviewee G, TDA) “[Our role is] supporting oversight of our Trusts, ...[and] that have asked for some support because they feel that they need to make some improvements” (Interviewee E, TDA)	Hybrid