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Effective Board Governance of Care

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# Effective Board Governance of Care

## 1. Aims/Objectives:

1. To identify the types of governance activities undertaken by hospital Trust Boards with regard to ensuring safe care in their organisation.

2. To assess the association between particular hospital Trust Board oversight activities and patient safety processes and clinical outcomes.

3. To identify the facilitators and barriers to developing effective hospital Trust Board governance of safe care.

4. To assess the impact of external commissioning arrangements and incentives on hospital Trust Board oversight of patient safety.

5. On the basis of findings relating to points 1 to 4, to make evidence-informed recommendations for effective hospital Trust Board oversight and accountability, and Board member recruitment, induction, training and support.

Underpinning these specific project aims are a number of clear supporting objectives:

1. To undertake a review of the theoretical and empirical literature relating to hospital Board oversight of patient safety and scope the potential threats to patient safety associated with the latest NHS system reforms.

2. To carry out case studies in four areas to assess the impact of Board governance and external commissioning practice and incentives on patient safety processes and outcomes.

3. To undertake a national survey of hospital Board oversight of patient safety and link these survey data to routine data on patient safety processes and outcomes.

## 2. Background:

The NHS is widely acknowledged as providing some of the best health care in the world, with the vast majority of patients receiving care which is safe and effective. However not all care is as safe as it could be and although estimates vary, there is growing evidence to suggest that about one in ten patients admitted to hospital may be harmed as a result of their care. This harm is not limited to minor events but is often serious, including, major iatrogenic disability, hospital acquired infection and avoidable deaths. As well as human suffering, financial costs are significant with prolonged hospital stays alone costing £2 Billion per year (National Audit Office, 2008). In response to evidence of widespread harm there has been concerted effort to make health care safer and numerous initiatives and significant resources are being invested in developing strategies to improve patient safety. However, change has proved difficult to effect and the optimal mix of strategies remains unclear (Braithwaite, 2010). What limited evidence exists on Board roles and impacts in terms of patient safety and service quality originates from the USA, where several recent studies have investigated the relationship between particular governance practices and guality processes and clinical outcomes (the key findings from recent US research studies are summarised in Appendix 1). However, a degree of caution is required in attempting to extrapolate recommendations for effective governance to the NHS context. First, hospitals in the USA operate within a very different economic and political environment which will necessarily impact on the relative priorities and objectives of boards. Second, all these studies are based on large scale questionnaire surveys, and although providing an overview of broad patterns and trends in Board practice they nevertheless fail to capture fully the messy internal processes and behavioural dynamics through which Board governance is actually played out and which are best explored through more interpretive and gualitative research designs. Finally, these studies focus on the more generic topic of 'service quality' rather than the more narrowly defined topic of patient safety. Thus, in the NHS context, significant gaps remain in our understanding of Board governance and the organisational processes through which safe care is accomplished and sustained in

hospital settings. In particular we lack a full understanding of what Boards actually do in relation to promoting patient safety. So for example, how do Boards attempt to embed and sustain a culture of safety throughout the organisation? What information (hard and soft) do Boards review on a regular basis to determine whether they are providing safe care? What is the impact of external commissioning arrangements and incentives on Board oversight of patient safety? And how do Boards respond to adverse events, seek to learn from them and put systems in place to prevent them recurring? Above all we have little robust evidence on how different Board practices actually impact on patient safety processes and outcomes. Moreover, it is clear that hospital Boards do not act in a vacuum, but operate in a complex and at times (especially now) rapidly changing environment. Commissioners and strategic oversight agencies such as the Care Quality Commission also have a role in shaping the debates and practices of hospital Boards, and it is important to understand these contingencies if we are to better design not just safe organisations but safer systems. Against this background the proposed study therefore aims to address these and related questions and generate empirical evidence on the associations between Board practice and patient safety processes and outcomes with the aim of improving Boards' understanding and accountability for patient safety practice. We will build on previous work originating from the USA as well as our own closely related research:

• In depth qualitative investigations of Board dynamics exploring instrumental and symbolic practices (Freeman and Peck, 2007).

• National surveys of hospital Board activity in relation to patient safety (Dr Foster 2009).

• Quantitative and qualitative studies on the relationship between hospital Board cultures and hospital quality and performance (Davies et al, 2007; Freeman and Peck, 2009; Mannion et al, 2005a,b; Mannion et al 2009c; Mannion et al 2010).

• Quantitative studies of the implementation of clinical governance (Freeman and Walshe, 2004; Freeman, 2003).

• Approaches to measuring and assessing patient safety cultures in healthcare organisations (Davies et al, 2000; Scott et al, 2003; Mannion et al, 2007, 2009a, 2009c; Konteh and Mannion, 2008; Linsley and Mannion, 2009).

• The role and impact of commissioning arrangements and external incentives on hospital behaviour (Mannion, 2008; Mannion and Davies, 2008; Mannion et al 2008, Mannion et al, 2009b).

## 3. Need:

NHS hospital Boards are ultimately responsible for the safety of the care provided by their organisation but there have been increasing concerns over the ability of Boards to effectively discharge their duties in this regard. Such concerns are clearly expressed in the recent House of Commons Health Committee report on patient safety:

"There is disturbing evidence of catastrophic failure on the part of some senior managers and Boards in cases such as Mid Staffordshire NHS Foundation Trust. While other Boards are not failing as comprehensively, there is substantial room for improvement" (House of Commons, 2009, p.6). Common factors identified by Health Care Commission investigations into recent service failures include: a lack of responsibility from 'Board to ward' for patient safety; an excessive focus on the meeting of centrally-set targets and delivering service reconfigurations at the expense of ensuring quality and safety; a lack of literacy and competency among directors in patient safety matters; the inability of Chairs and other non executives to hold executive directors accountable for the delivery of safe care; not having robust processes in place to gather relevant soft intelligence and hard data to make informed decisions about safety; and a failure to act proactively to identify risks to safe care, rather than responding only following an adverse event. The latest national survey of hospital Trust Boards in England undertaken by Dr Foster found that 9% of hospital Trusts do not discuss clinical outcomes and 10% do not have patient safety as a constant item on their Board agenda. Moreover, up to 17% of hospital trusts do not discuss safety with commissioners (Dr Foster, 2009). Recently completed SDO reports also highlight the need for more research into current systems of Board governance in NHS Trusts (McKee et al 2010; Storey et al, 2010). Taken together these issues and concerns suggest that the governance of safety issues by hospital Boards is

not all that it could or should be and that there is a need for a stronger evidence base to inform Board behaviour and decision making. Against this background our research fills a knowledge gap that is timely given the priority given to improving patient safety in the NHS. The study will analyse and distil a wide range of theoretical and empirical literature to develop a better conceptual and practical understanding of Board governance of patient safety. Building on this, our empirical work will provide new evidence on the inter-linkages between Board practices and patient safety processes and outcomes, with the ultimate objective of improving the effectiveness of hospital Board behaviour and decision making in relation to promoting patient safety.

## 4. Methods:

### Setting / context

Given the diversity of views and approaches to understanding Board Governance of patient safety, and the intrinsic complexity of any relationships between Board governance and patient safety processes and outcomes, we propose to adopt a multi-method approach, integrating a national quantitative survey of Board practice and national performance datasets on patient safety processes and outcomes with intensive case study methods and qualitative approaches to explore Board dynamics and the governance of patient safety in four hospital Trusts. This will allow us to examine these relationships in both breadth and depth. To ensure that the study is grounded in the latest empirical work and new threats to patient safety associated with the latest system reforms, we will undertake a prior scoping study to inform the empirical work.

### (a) Scoping study

In a fast changing policy context, there is a need to identify and contextualise broad literatures related to the governance of patient safety, especially in times of organisational / system transition. Our approach combines database searches and literature review with interviews of leading policy advisors / commentators (n = 10) to identify emergent challenges and threats to patient safety which will inform our empirical work. Full details are given in the 20-page outline of research.

(b) National analysis of Board practice and patient safety

To capture the breadth of associations between Board practice and patient safety we will conduct a national quantitative survey based on the annual Dr. Foster Hospital Guide Questionnaire which has been completed since 2001 and uses a standardised format approved by The Review of Central Returns (ROCR). The national survey of hospital trusts in England will also include the Board Self Assessment Questionnaire (BSAQ) to be completed by hospital Board members (executive and non executive). Analyses will explore statistical associations between Board activity and patient safety processes and outcomes; descriptive statistics will be obtained for each relevant survey question and multivariate analysis undertaken to explore differences in Board activity and patient safety processes and outcomes. This will be done by linking the main questionnaire and BSAQ data with hospital administrative data including the Secondary User Service Commissioning Data Set (SUS-CDS) and the NPSA's patient safety incident reports. Data analysis is further detailed in the 20-page outline of research.

### (c) Case Studies

We will utilize a comparative case-study design across multiple study sites, to generalise theoretically from within and between cases (Yin, 1994). Cases will be selected on the basis of performance trajectory over the last 3 years on a range of safety / quality indicators selected from the Dr. Foster database, including measures of death rates, compliance with NPSA guidelines, and incident reporting. We will work with four case study sites:

• two hospital Trusts with a 'downward' performance trajectory as indicated above;

• two hospital Trusts with an 'upward' performance trajectory as indicated above

Our focus is to explore (a) how the management and governor Boards hold the organisation

accountable to patient safety / risk ['conformance']; (b) how they strategically respond to patient safety events ['performance']; and (c) the context of the health economy within which the acute case study sites are operating. Full details of our theoretical framework are included in the 20-page document.

#### (a) Conformance:

- Non-participant observation of management and governor board meetings (n-32 (x4 each of Management and Governor Boards x4 sites). Analysis will follow the framework developed by Hajer (2004) to reveal the ability (or otherwise) of governors / managers to ensure action. Full details of the analytic framework are available in the 20-page supporting document. - Semi-structured interviews (n=80 [20 x4 sites]) with representatives from each tier of governance (governor, management board) to explore participants' experience of Board meetings relating to patient safety issues. Informed by our theoretical framework, we will inductively analyse data to explore participants' self-understanding and follow up issues revealed during observation data and documentary analysis of board meeting minutes relating to performance and conformance.

- Semi-structured interviews (n=40 [10x4 sites], sampled from clinical / corporate / combined governance committees, directorate managers, patient representatives and lead clinicians, to explore the impact of board discussions on practice. Within each case study we will focus on one of two specific 'tracers' related to patient safety activity and follow how this is dealt with from Board to ward. The tracers are: how the hospital deals with implementation of actions around Rapid Response Reports; and Patient Safety Alerts.

#### (b) Performance:

- In addition to the observation and interviews in 1 and 2 above, we will undertake semistructured interviews (n = 40 [10x4 sites]) in response to emerging critical incidents. We will follow how each case study site deals with a patient safety incident, from 'Board to ward', drawn from the typology of categories listed in the 'Learning from Serious Incidents' national framework. The exact sample depends upon Trust governance arrangements and will include management, clinical and patient representation. This will enable us to explore in real-time board reactions to events; the ability of the Boards to mobilise action in the face of difficulties; to identify the 'reach' of proposed actions into the wider organisation; and explore the impact of interventions.

### (c) Context:

- Interviews with key staff from commissioners related to the governance of patient safety (n= 20 [5 x 4 sites]) will be triangulated to generate a '360 degree' understanding of the dynamics in each health care economy. These will focus on the governance of patient safety across care pathways for the two 'tracer' activities.

## 5. Contribution of existing research:

The study aims to fill important gaps in our understanding of Board governance of safe care. In particular there is an urgent need for better information and evidence about what Board practices are associated with better patient safety processes and outcomes. The proposed research will contribute directly to policy and practice and also inform future research within NIHR. Specifically we will identify and classify Board governance and practice with regard to patient safety; explore the associations between Board governance activity and patient safety processes and outcomes; examine the facilitators and barriers to developing effective Board governance for patient safety; and investigate how external policy drivers and incentives (e.g. Payment by Results; Quality Accounts; CQUIN) are influencing Board governance with espect to patient safety. The research is fundamentally focussed on engaging with Boards in NHS organisations to examine how they are meeting their responsibilities to commission and deliver safe care and, as such, they are a key audience for the project. However, we expect that our findings will be of interest to a wide audience of policy makers, managers, professional groups, patient and carer representatives and academics, and the dissemination strategy will be tailored to meet the information needs of each group.

### Outputs and activities will include:

a plain language executive summary;

• a short document detailing the key findings and implications for Hospital Board governance [proj ref] [CI surname] protocol version: [xxxx] [DDMMMYYYY]

targeted specifically at Board members in hospital Trusts in England

a final report to SDO specifications, suitable for peer review;

• research papers in practitioner and academic journals;

• presentations to key stakeholder audiences and conferences;

• a programme of interactive learning events (throughout the lifetime of the project) arranged with and through the SDO Network.

# 6. Plan of Investigation:

*Months 1-4:* seek ethical approval followed by R&D approval; pull together advisory group; undertake lit review elements of scoping study: select case study sites drawing on secondary data.

*Months 5-8:* Negotiate access to case study sites; conduct scoping interviews (n = 10) with key informants; design of national survey data collection instruments; selection of tracer conditions for case-studies.

*Months 9-12:* Begin fieldwork case-study sites; interviews with wider health economy stakeholders; advisory group meeting

*Months 13-16:* undertake national survey and data analysis; ongoing case study data collection and analysis

*Months 17-20:* Ongoing case study data collection and analysis, informed by data from the national survey

*Months 21-24:* Interviews with staff to explore conformance; ongoing case study data collection and analysis; advisory group meeting

*Months 25-28:* interviews with staff to explore performance; ongoing case study data collection *Months 29-32:* Case study data analysis

Months 33-36: Drafting of final report; dissemination of findings

# 7. Project Management:

The applicants between them have considerable experience of large and complex research projects funded by NIHR other funders and conducting collaborative research with practitioners and policy makers. As PI for the study, Mannion will take full responsibility for managing the project and provide overall academic direction and leadership. He will be an active participant in key aspects of the research, overseeing, and coordinating the fieldwork and participating in the data analysis, and ensuring integration across the various strands of study. He will be the formal link person between the HSMC and the Dr Foster teams and coordinate the specialist inputs of team members. Freeman will take prime responsibility for supervising the Research Fellow recruited for the study on a day to day basis and hold weekly meetings to assess progress. Barbour will be responsible for the successful execution of the Dr Foster phase of the project, managing the overall work stream using the Prince 2 methodology.

## 8. Service users/public involvement:

The involvement of key stakeholders, including representatives of patient groups, Board level managers, non executives and clinical governance staff, is integral to this research and provides the focus of our case study work. We will interview patient representatives in our case study fieldwork with tracer conditions, and ensure public involvement on the advisory Board through the appointment of Peter Mansell who is a UK representative of 'Patients for Patient Safety' and Director for patient experience and public involvement at the NPSA <a href="http://www.who.int/patientsafety/patients\_for\_patient/regional\_champions\_euro/en/index.html">http://www.who.int/patientsafety/patients\_for\_patient/regional\_champions\_euro/en/index.html</a>

# 9. References:

- 1. Arksey H and O'Malley L (2005) Scoping Studies: towards a methodological framework, *International Journal of Social Research Methodology* (8) 1,pp 19-32
- 2. Braithwaite J and Coiera E (2010) Beyond Patient Safety Flatland, *Journal of the Royal Society of Medicine*, 103, pp219-225.
- 3. Chambers N and Cornforth C (2010) The role of corporate governance and Boards in organisational performance, in Walshe K and Harvey G (eds) *From Knowing to Doing: Connecting Knowledge and Performance in Public Services*, Cambridge University Press, Cambridge
- 4. Chambers N and Higgins J (2005) *Building a Framework for Developing Effective NHS Boards* Centre for Public Policy and Management, University of Manchester
- 5. Cornforth, C. (ed.) (2003) *The Governance of Public and Non-profit Organizations: What Do Boards Do?* London: Routledge.
- Davies C et al (2005) Links between Governance, Incentives and Outcomes: a Review of the Literature National Co-ordinating Centre for NHS Service Delivery and Organisation R & D
- 7. **Davies H**, Nutley S, **Mannion R** (2000) Organisational culture and quality of health care, *Quality in Health Care*, 9:pp111-119
- 8. Davies H, Mannion R, Jacobs R, Powell A and Marshall M (2007) Exploring the relationship between senior management team culture and hospital performance *Medical Care Research and Review* 64(1) pp46-65
- Davies H. and Mannion, R. (2000) Clinical governance: striking a balance between checking and trusting, in Smith, P. (ed.) *Reforming Health Care Markets: An economic perspective*, Buckingham: Open University Press, pp 247-267.
- Davies H, Nutley S, Walter I. Why 'knowledge transfer' is misconceived for applied social research. *Journal of Health Services Research & Policy* Vol 13 No 3, 2008: pp188–190
- 11. **Dr Foster** (2009) The Good Hospital Guide 2009, how safe is your hospital? Dr Foster, London.
- 12. Eisenhardt K (1989) Building theories from case study research, *Academy of Management Review*, 14, pp532-550.
- 13. Emslie S (2007) Exploring the factors that measure the performance of Boards of directors of NHS Foundation Trusts and the association between board and organisational performance, MSc dissertation, Department of Management, Birkbeck College, University of London.
- 14. Ferlie, E.F., L. Ashburner and L. Fitzgerald (1994). *The Non-executive Director and the Board Some Evidence from the NHS.* Centre for Corporate Strategy and Change, University of Warwick.
- 15. Francis, R (2009) *The Mid Staffordshire Foundation Trust Inquiry*, The Stationary Office, London
- Freeman T (2003), Measuring progress in clinical governance: assessing the reliability and validity of the Clinical Governance Climate Questionnaire |(CGCQ), Health Services Management Research, 16(4): 234-50
- 17. Freeman T and Walshe K (2004) Achieving progress through clinical governance? A national study of health care managers perceptions in the NHS in England, *Quality and Safety in Health Care*, 13: 335-43
- 18. Freeman, T., and Peck, E. (2007) Performing governance: a partnership board dramaturgy. *Public Administration* 85(4):907-929.
- 19. Freeman, T. and Peck, E. (2009) Culture made flesh: discourse, performativity and materiality. In J. Braithwaite, P. Hyde and C. Pope (eds.) *Culture, climate and teams in health care organizations*, pp. 31-41 Basingstoke: Palgrave
- 20. Garrat, B (1996) 'The Fish Rots from the Head the Crisis in our Boardrooms: Developing the Crucial Skills of the Competent Director', London: Harper Collins Pubs.
- Hajer, M. (2004) Setting the Stage: A Dramaturgy of Policy Implementation. Amsterdam School for Social Science Research Working Paper 04/06. Amsterdam: University of Amsterdam.
- 22. Hajer, M. (2005) 'Setting the Stage: A Dramaturgy of Policy Deliberation', *Administration and Society*, 36, 6, 624 – 47.
- 23. Healthcare Commission (2009) Safe in the Knowledge: How do NHS trust Boards ensure safe care for their patients? Healthcare Commission, London.

- 24. House of Commons Health Committee (2009) Patient Safety 6<sup>th</sup> report, House of Commons.
- 25. **Huehns T** and Fletcher M. (2010) <u>Patient safety research in the UK and beyond: 10</u> years of research and policy to make health care safer. Journal of Health Services Research and Policy 15: 87-91.
- 26. Institute of Medicine (2001) *To Err is Human: Building a safer health system*, Institute of Medicine, Washington DC.
- 27. Jha A and Epstein A (2010) Hospital Governance and Quality of Care, *Health Affairs*, 29, pp182-187
- 28. Jiang J et al (2008) Board Engagement in Quality: findings of a survey of hospital leaders, *Journal of Healthcare Management*, 53:2 pp234-245
- 29. Jiang H et al (2009) Board oversight: any differences in process of care and mortality, *Journal of Healthcare Management*, 54 (1) 15-29.
- Joshi M and Hino S (2006) Getting the Board on Board: engaging hospital Boards in quality and patient safety, *Joint Commissioning Journal on Quality and Patient Safety* (4) 179-187.
- 31. Kennedy I (2001) Learning from Bristol: Public Inquiry into Children's heart Surgery at the Bristol Royal Infirmary 1984-1995, The Stationary Office London
- 32. Konteh F and **Mannion R** (2008) Clinical governance managers views on culture and culture change, *Clinical Governance: an International Journal*, Vol 13, (3) pp200-207.
- 33. Learmonth M (2001) NHS Trust Chief Executives as Heroes? *Health Care Analysis*, Vol 9 (4) pp417-436.
- 34. Lee S-Y D et al (2008) An Empirical Taxonomy of Hospital Governing Board Roles Health Services Research 43:4 pp-1243.
- 35. Lincoln Y.S. & Guba E.G. (1985) Naturalistic Inquiry. Sage, Beverly
- 36. Linsley P **Mannion R** (2009) Risky hehaviour and patient safety: a critical culturist perspective, *Journal of Health Organisation and Management, Vol* 23(5) pp494-504.
- McDonagh K and Limbdenstock R (2006) Hospital Governing Boards: A Study of Their Effectiveness in Relation to Organisational Performance *Journal of Healthcare Management* 51(6) 377-89
- 38. McKee L (et al) Measuring and assessing organisational culture change and creating safe places for patients and staff, London: SDO
- 39. McKenzie J (2001) Perform or else: from discipline to performance London: Routledge
- 40. McNulty, T. and A. Pettigrew (1999) 'Strategists on the Board', *Organization Studies*, 20, 1, pp47 74.
- 41. **Mannion R**, Konteh H, et al (2007) *Measuring and Assessing Organisational Culture in the NHS*, London, SDO.
- 42. **Mannion R** (2008) The evolution of general practitioner purchasing in the English NHS: continuity, change and future challenges, *International Journal of Health Services,* Vol 38, (4) pp 717-730.
- 43. **Mannion R** and **Davies , H** (2003) A principal-agent perspective on clinical governance in Kernick, D (ed) *Getting Health Economics into Practice*, Oxford, Radcliffe Medical Press, pp. 67-78, 2002.
- Mannion R, Davies H, Marshall M (2005a) Cultural attributes of 'high' and 'low' performing hospitals, *Journal of Health Organization and Management* 19(6):pp431-439
- 45. **Mannion R**, **Davies H** and Marshall M (2005b) *Cultures for Performance in Health Care*, Buckingham, Open University Press,
- 46. Mannion R and Davies H (2008) Payment for performance in health care, *British Medical Journal*, 303: pp 306-308,
- 47. **Mannion R**, Marini G and Street (2008) A Implementing Payment by Results in the NHS: the role of incentives and information, *Journal of Health Organisation and Management* 22(1) pp79-88, 2008
- 48. **Mannion R,** Konteh F, **Davies H** (2009a) Assessing organisational culture for quality and safety improvement: a national survey of tools and tool use, *Quality and Safety in Health Care* (18) 153-156.
- Mannion R, Street A (2009b) Managing activity and expenditure in the new NHS market: evidence from South Yorkshire. *Public Money and Management*. 29(1):pp27-34.
- 50. Mannion R, Harrison S Jacobs R Konteh F, Walshe K, Davies H (2009c) From

cultural cohesion to rules and competition: the trajectory of senior management culture in NHS hospitals, 2001-2008, *Journal of the Royal Society of Medicine*, 102(8)332-336

- 51. Mannion R, Davies H, I, Harrison S et al (2010) 'Changing management cultures and organisational performance in the NHS, London: SDO
- 52. National Audit Office (2008) Patient Safety, The Stationary Office, London
- 53. NHS (2003) Governing the NHS: a guide to NHS Boards, London: NHS
- 54. NHS (2006a) The integrated governance handbook, London: NHS
- 55. NHS (2006b) The intelligent commissioning board, London: NHS
- 56. NHS (2010) The healthy NHS board: principles for good governance, London: NHS
- 57. Ovretveit J (1998) Comparative and cross-cultural health research: a practical guide, Abingdon: Radcliffe Medical Press
- 58. Pahl, R. and J. Winkler (1974) 'The Economic Elite: Theory and Practice', in P.J. Stanworth and A. Giddens (eds), *Elites and Power in British Society*. Cambridge: Cambridge University Press
- 59. Peck E (1995) 'The Performance of a NHS Trust Board: Actors' Accounts, Minutes and Observation', *British Journal of Management*, 6, 135-156.
- 60. Peck E, Perri 6, Gulliver P and Towell D (2004) Why do we keep meeting like this? The board as ritual in health and social care *Health Services Management Research* 17 pp100-109
- Scott T, Mannion R, Davies H, Marshall M. (2003) The quantitative measurement of organizational culture in health care: what instruments are available? *Health Services Research*, 38: 923-45,
- 62. Silverman D (ed.) (1997) *Qualitative research: theory, method and practice*, London: Sage
- 63. Simon H. (1997) Administrative Behaviour: a Study of Decision-making Processes in Administrative Organizations, 4th edn. New York: The Free Press.
- 64. Stiles P (2001) 'The Impact of the Board on Strategy: an Empirical Examination', *Management Studies*, 38, 5, pp627 50.
- 65. Storey J, Holti R, Winchester N, Green R, Salaman G, and Bate P. (2010) The intended and unintended outcomes of new governance arrangements within the NHS, London: SDO
- 66. Vaughn L (2006) Engagement of Leadership in Quality Improvement Initiatives, Journal of Patient Safety, 2 (1)pp 2-9
- 67. Winkler J (1975) 'Company Directors ... or Corporate Knights? ', *The Director*, 27, 1, 85 7.
- 68. Yin R (1984) Case study research design and methods, Beverley Hills, Sage.
- 69. Yin R (1999) Enhancing the quality of case studies in health services research, Health Services Research, 34: pp1209-1224.

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