Building a culture of openness across the healthcare system

From transparency through learning to improvement?

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Lay summary

The public inquiry into the quality of care at Stafford Hospital in the 2000s highlighted issues at several levels of the National Health Service (NHS) that allowed problems to persist and go undetected for a long time. Many of these issues related to the ‘openness’ of the NHS: its willingness and ability to identify, acknowledge, and learn from failings in the quality of care. Following the public inquiry, the government introduced a large number of policies that, in various ways, attempted to promote a culture of openness across the NHS in England. This report presents the findings of a policy evaluation study, commissioned by the Department of Health Policy Research Programme, that sought to examine how the policies are working in practice: whether they are affecting attitudes and behaviours; whether and how they are being used to encourage positive changes; and the extent to which the experiences of patients and staff of certain aspects of openness are changing through time.

Our study included four sub-studies, using a range of research methods to address these questions. They were:

- interviews with senior managers and clinicians in NHS organisations in England (including organisations providing different kinds of care), and with people outside the NHS with insights into work to promote openness inside the NHS (such as representatives of regulatory organisations, not-for-profit organisations interested in patient safety, and clinical-negligence solicitors);
- a survey of senior managers in NHS organisations about the changes in policy and how they are being put into practice;
- analysis of data from annual surveys of NHS staff and patients (including patients in acute hospitals, and patients receiving mental health care in the community), to examine how experiences of different aspects of openness are changing, for better or worse, through time;
- more detailed qualitative research in six NHS organisations (three acute hospitals, two mental health and community healthcare organisations, and one ambulance service), using interviews to explore with staff, patients and families how three policies relating to openness are being put into practice.

Our work was guided by advisory groups including patients, carers, academics, NHS staff, and others with experience of this area.

Across our sub-studies, we found evidence that organisations had made extensive efforts to implement the policies, and to try to ensure that they made a difference to openness. Senior staff in some organisations worked to go beyond compliance with policies ‘on paper’, and to try to spread an ethos of openness across their organisation. Data from the annual surveys suggested that for NHS staff, and for people in acute hospitals, experiences of openness may have improved noticeably since the publication of the public inquiry. For users of community mental health services, however, our analysis suggests that experiences may in some cases have become worse.

We encountered some impressive and innovative approaches to encouraging staff to learn from mistakes, to be open with colleagues and patients, and to speak up about concerns. However, these approaches may be more effective in some places than others, and need to be accompanied by work to address poor behaviour where it exists. Our findings suggest that the policies were easier to implement in some organisations than others. Some participants suggested that the policies were designed to fit acute hospitals, and were more difficult to put into practice in other organisations that see different kinds of patients, and are more dispersed. Culture and behaviour around openness varied markedly between different units in the same organisations.

We identified several requirements for improving openness: high quality administrative systems; flexibility and sensitivity in implementing policies; integrating those policies into the wider mission and mainstream work of organisations; and continuous learning and improvement from implementing the policies. It is important to avoid the impression that the policies are time-limited “projects”. To achieve progress, organisations need to invest in openness, including adequate resourcing, work to bring

together insights from different initiatives, efforts to ensure that openness is relevant to the everyday work of staff, and—above all—sustained and unerring determination to learn from failure and success alike.

Executive summary

The independent and public inquiries into the shortcomings in the quality of care at Mid Staffordshire NHS Foundation Trust over several years in the 2000s offered sobering lessons for the National Health Service (NHS) as a whole. They identified deficiencies in the management and organisation of the trust, and in wider systems of NHS governance and regulation, that allowed the problems to go unacknowledged and unresolved for so long. The public inquiry attributed these deficiencies to a wider "institutional instinct"[1] in the NHS for opacity and intransigence rather than openness and learning. In response to the public inquiry and other reviews of quality, safety and culture in the NHS, the government introduced a wide range of policies. Common to many of them was a focus on promoting a 'culture of openness': a health service that proactively identifies problems of quality and safety, informs those affected by them without reluctance, and seeks systematically to learn from them to inform improvement.

Several of these policies have been subject to evaluation or other research. The aggregate impact of the policy changes on attitudes, culture and behaviour in the NHS around openness also merit attention, however. Through its Policy Research Programme, therefore, the Department of Health and Social Care invited proposals for a policy evaluation to examine the nature and extent of change in the culture of the NHS since publication of the public inquiry, perceptions of the policies and their impact, and how these policy changes have worked in various contexts, including barriers to impact, unintended consequences, and mechanisms that support improvements. This report presents findings from the evaluation commissioned by the Policy Research Programme, which took place between February 2017 and October 2019, and was led by researchers at the University of Leicester, in collaboration with colleagues from the universities of Sheffield and Cambridge.

Methods

The study sought to address three research questions:

1. How do senior managers and clinicians in organisations providing NHS services understand policies relating to openness and translate them into specific norms, expectations and practices in their organisations?
2. Are staff and patients' views on openness, knowledge of performance, and experiences of giving voice to concerns changing through time, for better or worse?
3. Are provider organisations' efforts to increase openness resulting in real changes in staff values, attitudes and actions at the 'sharp end' of care and in patients' opportunities and experiences around openness—and what features contribute to success?

To address these research questions, the study team undertook four connected workpackages (WPs) over 32 months, and sought to synthesise their findings to provide practice- and policy-relevant insights. The workpackages included:

- qualitative interviews with senior stakeholders in and around the NHS involved in policy implementation, about the degree to which the initiatives offered clarity of direction, offered a coherent programme, or conflicted with each other and with the wider policy context (WP1) (addressing the first research question);
- a survey of executive-level leaders of NHS provider organisations on the implementation of policy initiatives, including the structures and processes adopted for delivering policies and their relationship with improved openness (WP2) (addressing the first research question);
- a longitudinal analysis of key questions from NHS annual staff and patient surveys relating to various aspects of openness, looking to examine whether there has been any change in the direction or pace of change since the publication of the public inquiry, broken down by organisation types (WP3) (addressing the second research question);

- case studies of six diverse NHS provider organisations: in each organisation, qualitative interviews were conducted with staff at the blunt and sharp ends, and with patients and family members affected by efforts to improve openness. Interviews focused on three particularly pertinent policy initiatives (the statutory Duty of Candour, the investigation of serious incidents, and the Freedom to Speak Up programme), examining the extent to which they appear to be resulting in change in attitudes, behaviours and experiences (WP4) (addressing the first and third research questions).

The study team was guided by a patient and public involvement group and a professional advisory group comprising academics, NHS staff, and others with experience of this area. The full report presents findings from across the four workpackages over nine chapters.

Results

Telephone interviews with senior stakeholders (WP1)

In total, 51 participants were interviewed, including individuals from a wide range of organisations including acute hospital trusts, community and mental health services trusts and ambulance trusts, and individuals from outside NHS provider organisations with experience of and insight into openness policies. Findings are presented in detail in Chapter 3.

- Broadly, there was a warm reception for policies around openness among participants in this workpackage. They considered that the problems that affected Stafford were unlikely to be unique to the trust, and saw merit in many of the policies that had been introduced. They also stressed the importance of an approach to implementing the policies that went beyond mere compliance, sought alignment with wider organisational priorities and mission, and attempted to ensure that openness was not seen as ‘just another’ top-down imperative with little relevance at the ‘sharp end’ of care.
- The policies were seen to present a significant administrative overhead, in terms of the need for well functioning arrangements for discharging new responsibilities, the task of monitoring them, and the need to demonstrate compliance to regulators and other external authorities. At times, this was seen to conflict with an approach to policy implementation that was true the ethos of openness, and sensitive to the needs of individual patients and families. For example, in relation to the Duty of Candour, there was concern that requirements around timing and format of disclosures would ensure that disclosures were made, but at the cost of sensitivity and judgement about exactly how and when (see section 3.5.1).
- While these (relatively senior) participants were clear about the importance of openness, they identified challenges in making this imperative relevant to colleagues at the sharp end, delivering care on a day-to-day basis. Some discussed ‘black spots’ in their knowledge of practice and performance in their organisations that caused them anxiety. Especially given day-to-day pressures in a resource-constrained NHS facing increasing demand, it could be difficult, participants reported, to impress upon their colleagues the importance of lessons from an event that seemed exceptional, extreme and—increasingly—a matter of historical interest rather than present-day relevance (see section 3.5.2).
- Events that had occurred within their own organisations were often more easily cast as imperatives for change. In several organisations, efforts to improve quality, safety and openness had predated formal policy prescription. There was a sense that these organisations were at something of an advantage in implementing policy, though sometimes policy prescriptions could be difficult to graft onto existing efforts. In relation to the Duty of Candour, for example, some participants recounted how their organisations had previously introduced local-level policies to encourage openness with patients and families when things went wrong, which then proved non-compliant with the process, timescale or reporting requirements of the statutory Duty when it was introduced (see section 3.5.3).
- Past events could also cast a long shadow over present efforts to secure openness. In many

organisations, participants reported that poor treatment of those who had seek to be open (for example, by identifying errors or speaking up about concerns) informed widely entrenched beliefs about the safety or otherwise of being open. Mere words on the part of organisational leaders offering reassurance about the importance of openness could do little to change such views, particularly given wider and more recent events across the NHS (for example high-profile prosecutions for gross negligence manslaughter) that could reinforce the view that openness was a disposition that carried many risks and few benefits for an individual (see section 3.5.4).

- Particularly though not exclusively outside the acute sector, many organisations were geographically dispersed and culturally heterogeneous, and this presented distinctive challenges for senior clinicians and managers looking to secure a culture of openness across their organisation. Some units were particularly isolated, with the attendant risk of 'organisational enclaves' where highly localised, and potentially problematic, cultures might emerge. There was also a sense that for community and mental health services trusts in particular, differences in clinical focus, patient pathways and organisational structure made it challenging to implement openness policies (see section 3.5.5).
- Participants identified a wide range of approaches that, they felt, had helped to ensure that policy implementation went beyond compliance and could begin a move towards a more open culture. These approaches varied in their specifics, but common features included ongoing and visible commitment to the agenda of openness at a senior level, efforts to share the burdens and benefits of openness across the (clinical) sharp end and (managerial) blunt end of the organisation, and celebrating the improvements that openness could bring (see section 3.5.6).

Survey of executive leaders on the impact of policy interventions (WP2)

The survey was stymied by a weak response rate, although at least one response was received from 30% of acute provider trusts and 38% of mental health and community health services trusts. Results are presented in detail in Chapter 4.

- Respondents to the survey had varying views on the impact of a range of openness initiatives, with those that were mandatory, associated with significant resourcing implications or organisation-wide in their focus seen as more impactful than those that were not. Overall, respondents indicated that the initiatives had had a positive impact on their organisations, though there were somewhat more mixed views on the effect of the policies on the likelihood of litigation (see section 4.1).
- Respondents were asked specific questions about the Duty of Candour, the Freedom to Speak Up programme, and the Serious Incident Framework. Many agreed that the Duty of Candour had improved communication between patients and staff, and that the presence of Freedom to Speak Up Guardians encouraged staff to voice concerns. Responses suggested that resourcing and commissioners' expectations posed challenges in implementing the Serious Incident Framework, and that clarity of policymaker and regulator expectations could be improved for the Duty of Candour. The survey suggested a wide range of approaches to recruiting, resourcing and managing Freedom to Speak Up Guardians (see section 4.2).
- Respondents were largely positive about the culture around speaking up in their organisations, a finding that contrasts with other sources of evidence on this issue. In relation to a question on their own ability to raise concerns about quality and safety, respondents were largely confident that they knew whom to approach outside their organisation about such concerns, but were less certain that their concerns would be taken seriously (see section 4.3).

Secondary analysis of NHS survey data (WP3)

Analysis covered the NHS National Staff Survey (2006-2017), the NHS Acute Inpatient Survey (2004-2016) and the NHS Community Mental Health Service User Survey (2007-2017). Longitudinal statistical methods (piecewise and interrupted latent growth curve analysis) were adopted to determine any change in response to survey questions relating to matters of openness since the time of the public inquiry (2012/2013). Results are presented in detail in Chapter 5.

- For the Staff Survey, there was a positive increase in the rate of change after the publication of the report of the Mid Staffordshire public inquiry in matters relating to communication between managers and staff, and in the fairness and effectiveness of incident-reporting procedures. Where rates of improvement slowed or levelled off, this appeared to be due to a ‘ceiling effect’ where no further improvement was possible.
- Similarly, for the Inpatient Survey, the general trend was positive, with increases at a faster rate during the period after the publication of the public inquiry. Specifically, from 2013, satisfaction with the amount of information given to patients in the emergency department about their condition or treatment increased at a faster rate; patients’ satisfaction with their involvement in decisions about their care and treatment also increased more sharply.
- For the Mental Health Service User Survey, the pattern of change was rather different. Patients continued to report better access to care consultations, though at a slower rate of increase after 2013. However, levels of satisfaction indicated in other questions relating to openness deteriorated: patients felt less listened to, believed they were not given enough time to discuss their care, and felt treated with less respect and dignity compared to previous years (see sections 5.3 and 5.4).

Case studies of six diverse NHS provider organisations (WP4)

Based on the findings of workpackages 1, 2 and 3, the research team identified three ‘tracer issues’ selected to exemplify openness policies and the challenges involved in their implementation: the statutory Duty of Candour, the investigation of serious incidents, and the Freedom to Speak Up programme. In WP4, they explored these through interviews in six case-study organisations with diverse functions, histories, existing cultures around openness, populations and organisational structures. They included three acute hospital trusts, two community and mental health services trusts (one including a secure forensic mental health unit), and one ambulance service trust. Across the six case studies, 88 interviews were conducted (70 with members of staff; 18 with patients and family members). Findings from the case studies are presented in detail in Chapters 6 and 7.

- Organisations varied in the quality of their systems for administering the initiatives on a day-to-day basis. Each policy required coordination across diverse staff groups, timely discharge of responsibilities, and clear documentation and monitoring; the existence of both high-quality information systems and a broader socio-technical infrastructure was essential to ensuring they were carried out effectively. High-quality administration also underpinned an approach to implementation that was sensitive to the needs of those affected (patients, families and staff). On its own, however, it was not enough: it also required sensitivity and flexibility to ensure that compliance with the letter of policies did not override the personal preferences of those involved (see section 6.2).
- While participants identified some areas of resistance to the introduction of openness policies, such resistance generally pertained to the challenges of implementation (and sometimes the personal burden that a disclosure or the expression of a concern presented) rather than to principled opposition to the changes in the roles and relationships of professional staff implied by the changes. However, there appeared to be areas of all six organisations that seemed intransigent to efforts to improve openness. Sometimes these could be characterised as ‘fiefdoms’, where dominant individuals used the power they had accrued through hierarchical position or personal connections to encourage sycophancy, punish dissent, and silence concerns (see sections 6.3 and 7.4).
- Participants identified many benefits of using approaches to disclosing incidents and conducting investigations that were thorough, involved those affected extensively, and sought to derive learning for improvement. These benefits included important insights (particularly when they were integrated with other sources of knowledge about organisational performance), reconciliation with patients and families (and a claimed concomitant reduction in litigation proceedings), and wellbeing of staff, who also appreciated the learning and closure that could come from disclosure and investigation. In contrast, where disclosure and investigation were mishandled, the result

could be anger, antagonism and opposition, with initial good will and a sense of common purpose forfeited (see sections 6.4 and 6.5).

- A wide range of approaches to implementing Freedom to Speak Up was in evidence in the case-study organisations, including not just variable levels of protected time for Guardians, but also varying degrees of 'in kind' investment in the programme. On the whole, Guardians were occupied not only with 'case management' work where individuals had approached them with concerns, but also with the task of promoting openness and detecting areas where openness seemed problematic—though this was more challenging for Guardians who lacked organisational support (see sections 7.1 and 7.2).
- The concerns that were raised with Guardians were often not readily identifiable as issues of quality and safety, but related to a wide range of other issues affecting staff and organisations. The work of the Guardian the involved helping colleagues to make sense of the concerns that they had, sometimes investigating them, providing emotional support, and helping them to find their way through systems that sometimes seemed Byzantine (see section 7.3).
- Overall, key findings from the case studies included the importance of coherence across the policies, and between the policies and wider organisational missions. This required work beyond implementation, and often long-term commitment: those case-study organisations with more 'mature' cultures around openness, and with a longer record of action and investment in initiatives to promote openness, seemed to have achieved greater success in affecting attitudes and behaviours (see section 7.5).

Discussion, conclusion and implications

Synthesis of findings from across the workpackages suggests several overarching implications. These are discussed in detail in Chapter 8, and distilled in Chapter 9.

- **Functional administrative systems** are a necessary, but not a sufficient, condition for effective and compassionate realisation of the policies, and for efforts to seek to derive wider organisational learning that might inform improvement. Such systems require extensive investment, and involve not just sophisticated information management systems, but a wider socio-technical system with clear definition of and synergy between people in different roles in organisations. Organisations that lacked such an infrastructure faced challenges in implementing policies optimally, responding to the preferences and needs of staff, patients and families flexibly, and maximising learning from the knowledge that derived from investigations, concerns and other sources (see section 8.2.1).
- However, **flexibility and sensitivity** are also needed if systems are to run in a way that is compassionate as well as efficient. Across the openness initiatives examined in the case-study organisations, 'coldly efficient' systems that ground away inflexibly, giving no quarter to the needs of those involved, could give the impression that efforts to advance openness were about no more than feeding a bureaucracy, adding insult to (literal) injury. The work of disclosure, investigation and speaking up is about more than the documents, pathways and processes that describe it: doing it right requires judgement, flexibility, discretion, and sometimes even working around formal procedures and protocols (see section 8.2.2).
- It is important to **integrate openness policies into the wider organisational mission** to avoid the impression that such initiatives are separate, temporary, or contradictory to the objectives of high-quality care. This means both ensuring integration of the learning and insight that accrues from openness initiatives (often through functional administrative systems), and symbolic work to place openness front and centre of organisations' priorities. Where organisations failed to do this, for example through 'bolt-on' procedures or through failure to invest in Freedom to Speak Up or other programmes, openness could appear to staff to be no more than a fad, or an exogenous mandate followed reluctantly. Work is therefore required to translate openness into a day-to-day activity, and not something reserved for extreme or rare events (see section 8.2.3).
- In many organisations, implementation of the policies relied to a great extent on the **good will**

and discretionary effort of staff. This stock of good will is not inexhaustible. Particularly where the benefits of openness are not evident to staff at the sharp end, there is a risk that it will be depleted. As a result, NHS staff may feel neglected, exploited or disenfranchised; support for staff as they undertake the challenging and sometimes emotionally fraught business of openness is important (see section 8.3.1).

- Many approaches to achieving openness followed the principles of organisational development: they viewed the policies as a potential means of enhancing organisational effectiveness by acting on the behaviour of staff members, in a way that would also contribute to their own development as individuals. However, there are **limits to the power of approaches based on organisational development** to achieve improvement. Most notably, the existence of ‘fiefdoms’ controlled by domineering individuals in case-study organisations suggests that such approaches must be underpinned by robust mechanisms for detecting and evidencing persistent poor behaviour, and unerring organisational commitment in addressing it (see section 8.3.2).
- The policies introduced since the publication of the Mid Staffordshire public inquiry have focused to a greater extent on the role of staff in improving openness than **the role of patients and families**. For example, and despite the notable role of patients and families in uncovering poor quality at Stafford and elsewhere, the Freedom to Speak Up programme is oriented exclusively towards staff, with no parallel opportunities for patients and families to express concerns (beyond those that already existed prior to the inquiry). Some organisations have taken the initiative in seeking to elicit concerns from patients and families, but overall there is a risk that this important source of knowledge continues to be overlooked (see section 8.3.3).
- Finally, all of this must be underwritten by an ethos of **continuous learning and improvement**: efforts to ensure that approaches to fostering openness are themselves subject to an ethic of reflection, learning and improvement. The achievements of case-study organisations with functional administrative systems or a more mature culture around openness had not arisen by accident: they were the product of long-term, persistent prioritisation, investment and learning. Avoiding the impression that openness policies are discrete, time-limited ‘projects’ is thus crucial. So too is work to act on tangible systems, processes and routines that are seen to work effectively, efficiently and fairly. Practical steps arising from deeply held values and commitments seemed more productive than trying to intervene in a somewhat nebulously defined ‘culture’. Case-study organisations that had achieved more mature cultures around openness appeared to have done so through by focusing on high-quality systems, infrastructure and support for the work of clinical and non-clinical staff across the blunt and sharp ends (see section 8.2.4).

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List of abbreviations and acronyms

A&E	accident and emergency
AvMA	Action Against Medical Accidents
BME	black and minority ethnic
CCF	Central Commissioning Facility
CCG	clinical commissioning group
CHS	community health services
CQC	Care Quality Commission
FLO	Family Liaison Officer
FTE	full-time equivalent
FTSU	Freedom to Speak Up
GP	general practitioner or general practice
HR	human resources
HSIB	Healthcare Safety Investigation Branch
IT	information technology
LGM	latent growth curve modelling
LINk	Local Involvement Network
NHS	National Health Service
NHSE	NHS England
NHSI	NHS Improvement
NIHR	National Institute for Health Research
NMC	Nursing and Midwifery Council
OD	organisational development
PGCM	piecewise growth curve model
PPI	patient and public involvement
QC	Queen’s Counsel
RCA	root cause analysis
REC	Research Ethics Committee
WP	Workpackage

1. Introduction

> "For all the fine words printed and spoken about candour, and willingness to remedy wrongs, there lurks within the system an institutional instinct which, under pressure, will prefer concealment, formulaic responses and avoidance of public criticism." (Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Volume 1[1])

It is now more than a decade since details began to emerge about severe and sustained shortcomings in the quality of care at Mid Staffordshire NHS Foundation Trust over several years in the 2000s.[2,3] The problems themselves, the consequences for patients, and the circumstances that allowed these problems to continue unchecked for so long were all the subject of widespread attention and reflection.

This included two judicial inquiries, both led by Sir Robert Francis, QC. The first (independent) inquiry focused in particular on the managerial and clinical arrangements within the trust that precipitated the problems, and failed to address them.[4] The second (public) inquiry extended scrutiny to the wider governance of care provided in the English National Health Service (NHS).[5] It exposed systemic failings, particularly around regulatory oversight, systems of incentives, and confusion over accountability, that were not unique to Mid Staffordshire. Rather, Francis suggested, the disaster of Mid Staffordshire was a symptom of an "institutional instinct"[1]—a wider culture—that was oriented towards opacity and defensiveness. When things went wrong, the public inquiry suggested, the NHS's inclination was not to learn, but to hide. Consequently, Francis concluded, "a fundamental culture change is needed."[5] He called for greater openness ("the proactive provision of information about performance, negative as well as positive") and candour ("the volunteering of all relevant information to persons who have, or may have, been harmed by the provision of services, whether or not the information has been requested, and whether or not a complaint or a report about that provision has been made") across the NHS.[6]

The public inquiry offered nearly 300 recommendations,[6] with implications across the NHS, from the 'sharp end' (where care is delivered) to the 'blunt end' (of management, regulation and policy).[7] The government accepted the findings of the inquiry,[8] and commissioned the National Advisory Group for the Safety of Patients in England, chaired by Donald Berwick, to undertake further work to translate the recommendations into action.[9] It also set up several further, parallel reviews, including an examination of 14 other acute hospital trusts that seemed, according to standardised mortality data, to be negative outliers in quality and outcomes,[10] and a review of attitudes and behaviour around speaking up about concerns across the NHS.[11]

Following these reviews, two further government papers set out the policy agenda. Responding to the findings of the National Advisory Group,[9] the review of care in 14 trusts[10] and four other independent reviews, *Hard Truths* proposed a wide-ranging programme of interventions designed to address several of the deficits identified in Mid Staffordshire.[12] A year later, *Learning not Blaming*[13] presented the government's response to the *Freedom to Speak Up* review,[11] the Public Administration Select Committee's report on clinical incident investigation,[14] and an investigation into maternity care at University Hospitals of Morecambe Bay NHS Foundation Trust[15]—where problems of opacity, poor communication and failure to learn, similar to those of Stafford, were implicated in the deaths of 11 babies and one mother.

The calls for a more open culture contained in the inquiries and reviews that followed Mid Staffordshire were not unprecedented. Professional and organisational cultures in healthcare had been the subject of academic interest and policy action for some time, with links made between openness, learning and patient safety within and beyond the NHS.[16,17] The 2000s saw several initiatives in English healthcare oriented towards fostering openness, for example around open disclosure,[18] alongside wider efforts to improve quality and to promote more patient-centred, less paternalistic approaches to delivering healthcare.[19–22]

Further failures in health and social care, contemporary and historic, served to underscore the consequences of systems and cultures that bred opaque organisations. Besides the tragedies of Morecambe Bay,[15] major problems were documented in residential care for people with learning disabilities at Winterbourne View,[23] in respite care at Gosport War Memorial Hospital,[24] and in the entire organisational culture of NHS Highland.[25] A common theme across all was opacity. In each case, individuals with varying degrees of power and authority were aware of problems early on in their gestation; and in each case, it took a long time, and external intervention from outside the organisation or even beyond the NHS system, for this knowledge to give rise to action.

It is in this longer-term and wider organisational context, then, that the government's response to the events at Stafford should be understood. *Hard Truths* and *Learning not Blaming* both set out policy interventions designed to address the specific causes of the problems identified. But both also framed these interventions in terms of a broader need for wholesale 'cultural change' in the NHS.

> "Together the responses to the Inquiry's recommendations seek to build and strengthen a culture of compassionate care, looking to an NHS future in which world class leaders working with highly skilled and caring staff consistently strive to improve the care they give to patients."[12]
>
> "These changes are necessary, but they are insufficient on their own to secure the consistency of experience and reliability of care that patients should be able to take for granted and that staff are striving to provide. The remaining critical component is culture, in the context of financial sustainability. Since the publication of the Public Inquiry report, the NHS has undoubtedly made progress in strengthening its culture, but a great deal more remains to be done."[13]

Along with other government initiatives following Stafford, *Hard Truths* and *Learning Not Blaming* heralded the introduction of a wide range of policies and initiatives. These were diverse in nature and objectives, and included:

- changes to the organisation and inspection regime of the Care Quality Commission (CQC), trialled and refined through the review of 14 trusts;[10,12]
- the introduction of the statutory Duty of Candour, requiring all NHS provider organisations to promptly inform and apologise to patients and their families when something goes wrong;[12,26]
- the 'Sign Up to Safety' campaign and the Q Fellows community, which seek to secure organisational and individual commitment to improving quality and safety, and to link interested practitioners through campaigns and networks;[27]
- regional patient safety collaboratives, funded by the government, with a range of objectives around quality and safety, defined nationally and locally;[12,28]
- the Freedom to Speak Up programme, including the designation of Freedom to Speak Up Guardians in each NHS provider organisation, to promote and support staff with concerns in giving voice to them;[11,13]
- revisions to the framework for investigating serious clinical incidents, and the subsequent creation of the Healthcare Safety Investigation Branch (HSIB);[13,29,30]
- the Fit and Proper Persons Test, which requires NHS organisations to undertake rigorous checks on the suitability of candidates for executive and non-executive director roles.[12,31]

Several of these initiatives have been subject to separate evaluation,[32–34] and others are subject to ongoing research endeavour, for example through studies currently funded by the National Institute for Health Research (NIHR). However, given the ambitions set out for these interventions collectively, their aggregate impact on the culture of the NHS also merits attention. Thus in 2016, the Department of Health Policy Research Programme invited tenders for research on "how the culture has changed since publication of the Francis report with regard to openness," including "how policies announced since Francis […] were perceived, and […] their effect within this wider picture," and "how the 'post-Francis' changes have worked in different contexts, considering possible barriers to improvement, unintended consequences, and the mechanisms that support improvements." The research was to "contribute to an understanding, from a local to a system perspective, as to whether and how the culture of the NHS has become more open and transparent as a result of the Government's response to the Francis recommendations."[35] This report presents findings from the study commissioned following this tendering process, which took place from February 2017 to October 2019.

The premise that inquiries and governments' responses to them are capable of bringing about cultural change is, of course, itself a contestable one. There is a long history in the NHS of inquiries following scandals of care, but with patch long-term impact.[36,37] Moreover, organisational culture itself is a contested entity. Sometimes defined as "the way things are done around here,"[38] culture covers the routine, taken-for-granted aspects of organisational life: the things that come so naturally, it is difficult to conceive of any other way of doing them, including values, beliefs and expectations.[39] Culture consists of "clear and consistent values, interpretations and or assumptions that are shared on an organization wide basis."[40] Such values and beliefs, and the practices they inform, can therefore be very hard to shift.[38,41] Culture is often embedded both in individuals' ways of thinking and in organisations' systems and processes; both can be resistant to efforts to change them. Culture reproduces itself as those systems and processes operate, and as new people brought into an organisation are inculcated into incumbent ways of perceiving and thinking.[42] In this light, rather than something that an organisation *has*, culture might be better understood as something the organisation *is*.[43]

But culture can also be variegated. Analyses of organisations, including healthcare organisations, have tended to challenge the notion of a uniform organisational culture. Different professional groups and different units within organisations can have rather different (sub)cultures: different sets of assumptions; different ways of relating to each other and carrying out their work; even different languages.[44–48] Problems of culture may also appear rather different at different hierarchical levels of an organisation: what might be diagnosed as a 'cultural issue' by senior managers at the blunt end might seem to have more to do with issues of resourcing, organisational structure or poor systems for those at the sharp end of care.[49,50]

Together, these findings from past studies point to the challenges of any attempt at cultural change, whether driven 'top-down' or 'bottom-up', and whether comprising a single unified change programme or multiple complementary interventions oriented towards change. In summarising the rationale underlying his 290 recommendations, Francis foregrounded the aim of fostering "a common culture shared by all in the service of putting the patient first."[5] Given the lessons of the literature summarised above, however, we can expect the interventions introduced into the NHS since the public inquiry to be inconsistent and complex in their impact on culture—and not necessarily uniformly positive.

This study, therefore, aimed to examine the impact of a number of post-Francis policy interventions on attitudes, behaviour and culture around openness, at various levels, among various groups, and in various types of provider organisation in the NHS. We sought to provide a robust, detailed and actionable assessment of the current state of cultures in the NHS relating to openness and how this is changing through time, and the degree to which policies have given rise to changes in norms, attitudes, practices and behaviour. Using qualitative and quantitative methods and a range of sources of data, we aimed to address the following connected research questions:

1. How do senior managers and clinicians in organisations providing NHS services understand policies relating to openness and translate them into specific norms, expectations and practices in their organisations?
2. Are staff and patients' views on openness, knowledge of performance, and experiences of giving voice to concerns changing through time, for better or worse?
3. Are provider organisations' efforts to increase openness resulting in real changes in staff values, attitudes and actions at the sharp end of care and in patients' opportunities and experiences around openness—and what features contribute to success?

To answer these questions, we undertook four connected workpackages (WPs) over 30 months. The first three, which took place during the first half of our study, comprised:

- qualitative interviews with senior stakeholders in and around the NHS involved in policy implementation, about the degree to which the policy initiatives offered clarity of direction, offered a coherent programme, or conflicted with each other and with the wider policy context (WP1) (addressing the first research question);
- a survey of executive-level leaders of NHS provider organisations on the implementation of policy initiatives, including the structures and processes adopted for delivering policies and their relationship with improved openness (WP2) (addressing the first research question); and
- a longitudinal analysis of key questions from NHS annual staff and patient surveys relating to various aspects of openness, looking to examine whether there has been any change in the direction or pace of change since the publication of the public inquiry, broken down by organisation types (WP3) (addressing the second research question).

The final workpackage (WP4), which took place during the second half of our study, sought to build on the insights provided by the first three workpackages—for example in its focus, and in sampling. It involved case studies of six diverse NHS provider organisations. In each organisation, qualitative interviews were conducted with staff at the blunt and sharp ends, and with patients and family members affected by efforts to improve openness. Interviews focused on three particularly pertinent policy initiatives (‘tracer issues’), examining the extent to which they appear to be resulting in change in attitudes, behaviours and experiences. This workpackage sought to address the first and third research questions.

The study involved researchers from the universities of Leicester, Sheffield and Cambridge.

1.1. The structure of this report

This report provides high-level findings from each workpackage, identifies key cross-cutting issues, and highlights areas that NHS policymakers, managers and senior clinicians might fruitfully focus further effort on if the good intentions contained in the post-Francis policies are to translate into enduring impact on organisational cultures.

Eight further chapters follow this introduction. In Chapter 2, we set out our methods for the four workpackages, and provide information on study governance and oversight. Chapters 3, 4 and 5 present findings from WP1, WP2 and WP3 respectively. Chapter 6 introduces the six organisational case studies in which we undertook work for WP4, and presents findings from two of the tracer issues that guided our inquiry in these sites. We cover findings from the third tracer issue from WP4 in Chapter 7. Chapter 8 presents a synthesising discussion of key themes from across the workpackages, highlighting particularly persistent and pertinent findings, and seeking to tackle the question—alluded to above—of whether and how policy interventions of this kind might, in aggregate, have some enduring impact on NHS cultures. Finally, in Chapter 9, we highlight some of the most pressing implications of our research for policymakers and others charged with the responsibility of engendering change and promoting openness in the NHS, and discuss the strengths and limitations of our study.

For completeness, the report also includes a comprehensive suite of appendices including items such as research tools, supplementary analyses and outputs published or in development from this study so far. It is not necessary to read these appendices to understand and interpret the main body of the report.

2. Methods

We undertook a mixed-methods study of the implementation and impact of selected policies introduced following publication of the *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry.*[5] We aimed to evaluate (i) the current state of cultures in the NHS relating openness, transparency and learning, including change over time and variation across settings, and (ii) how far specific policies, introduced since the publication of the Francis inquiry, had resulted in changes in norms, attitudes, practices and behaviour in relation to openness, transparency and learning. This involved a programme of linked workpackages using mixed methods and primary and secondary data to answer three research questions:

1. How do senior managers and clinicians in organisations providing NHS services understand policies relating to openness and translate them into specific *norms, expectations and practices* in their organisations?
2. Are staff and patients' views on openness, knowledge of performance, and experiences of giving voice to concerns changing through time, for better or worse?
3. Are provider organisations' efforts to increase openness resulting in real changes in staff *values, attitudes and actions* at the sharp end of care and in patients' opportunities and experiences around openness—and what features contribute to success?

Our study comprised four workpackages which aimed between them to answer these research questions. The first three workpackages focused in particular on initiatives, attitudes and trends: they sought to provide a relatively high-level overview of what was being done in the NHS to translate policy initiatives into practice, the views of stakeholders on the value or otherwise of such initiatives, and the trends apparent in various indicators of openness over time. Data collection and analysis for these three workpackages (WP1, WP2, WP3) took place between July 2017 and April 2018.

The final workpackage sought to focus on actions, experiences and consequences: it examined the realisation of policies in practice in NHS organisations, how these were experienced by staff, patients and families, and with what consequences for the prospects for openness. Data collection drew on findings from the first three workpackages to inform in-depth examination of whether and how organisations' efforts to translate policy into practice were affecting experiences of openness. The final workpackage took place between March 2018 and July 2019. Analysis of data from the final workpackage and integration and synthesis of findings across workpackages to inform this final report continued through to October 2019.

We present the methods for each workpackage in turn, and then describe the broader governance of the study, along with wider forms of dissemination beyond this report. Note that in the interests of clarity, we use different labels for the workpackages in this report from those used in the original research proposal. The senior-stakeholder interviews (WP1) were referred to as WP1a; the national survey of board-level executives (WP2) was referred to as WP1b; the secondary analysis of NHS surveys of staff and patients (WP3) was referred to as WP1c; and the organisational case studies (WP4) were referred to as WP2a and WP2b.

2.1. Telephone interviews with senior stakeholders (WP1)

The first workpackage sought to provide insight into the reception for calls for openness arising from the Francis inquiry,[5] the National Advisory Group[9] and the Department of Health,[8,12,13,27] and for specified policies relating to openness, as detailed in the Policy Research Programme's commissioning brief.[35] It thus sought in particular to answer our first research question.

For this workpackage we focused our attention on relatively senior individuals within NHS organisations, as well as wider stakeholders in government, regulatory organisations, law and civil society. We were interested both in these individuals' interpretations of the mandate from government, and in their sense of the extent to which the wide range of policy initiatives that had followed Francis offered a coherent and actionable package of interventions through which to achieve cultural change around openness.

We sought to understand whether current systems and processes to implement policies relating to openness were perceived by senior leaders to provide clarity of direction or, conversely (given complex and overlapping accountability, regulatory and oversight arrangements[49]), they were seen to compete or conflict. We sought to examine how senior managers and clinicians in NHS organisations have responded to the imperatives for change by discussing with them how they had gone about implementing the initiatives and activities, and their associated 'theories of change'[51]—how and why they expected this work to produce the hoped-for improvements in openness.

We planned to conduct 60 telephone interviews, using a quota-sampling approach to recruit participants in approximately the following numbers:

- 20 representatives of acute trusts;
- 15 representatives of mental and community health service trusts;
- five representatives of ambulance service trusts;
- 10 representatives of non-NHS organisations providing NHS services; and
- 10 wider stakeholders, including civil servants; senior leads in NHS England and CQC, to provide commissioning and regulatory perspectives).

Within the first four categories, participants were recruited through a combination of random, purposive and snowball sampling approaches. We sought to obtain a sample that was broadly representative of NHS provider organisations as a whole, and included a wide range of experiences—in particular, including organisations that appeared better and worse placed to realise policies around openness, based on publicly available data and our own knowledge of organisations' histories.

We approached a randomly generated selection of acute trusts (20), community and mental healthcare trusts (10) and ambulance trusts (five). In parallel, we purposively sampled four organisations that had experienced problems with openness, as indicated by regulatory intervention and/or media coverage. We asked participants to suggest others (from their own or other organisations) who might fruitfully comment on the issues raised in the interviews. Finally, we asked our professional advisory group (see section 2.5) to suggest individuals within or beyond their organisations who might be able to offer insights relating to our research questions. Wider stakeholders—who included policymakers and representatives of regulatory, third-sector and medico-legal organisations—were identified purposively in consultation with the professional advisory group, with snowball sampling again supplementing this initial list.

Ethical approval was given by the University of Leicester's College of Life Sciences research ethics committee; approval to undertake the study in NHS organisations was granted by the Health Research Authority (HRA) on 27 June 2017 (reference 18/HRA/0084).

Interviews took a semi-structured format, with open questions and prompts that sought to provoke wider discussion of the challenges of translating policy into practice and achieving cultural change around openness. All participants were provided with written information on the study, were given the opportunity to ask questions, and provided written consent to participate. The topic guide (see Appendix A) was informed by the Policy Research Programme brief, reviews of the academic literature on transparency, learning and culture, and by discussions with our professional advisory group and patient and public involvement (PPI) advisory group. Interviews covered participants' understanding of the relevant policies, including their views of the policy goals, the clarity and unity of direction they provided, and the incentives and disincentives they offered to increase openness. We ultimately interviewed 51 participants in this workpackage (see Chapter 3). Interviews averaged 40 minutes and were audio-recorded and transcribed verbatim.

Data analysis was based on the constant-comparative method,[52] building on ‘sensitising concepts’ (initial indications of what may be important) from the existing policy and academic literature. Assisted by NVivo (version 11) qualitative data analysis software, interview transcripts were read independently by two members of the research team, who coded the data for high-level themes derived from the evaluation brief and academic literature, and themes identified inductively from close reading of the data. Codes were modified, developed and amalgamated as more data sources were incorporated and analysis proceeded. Coding was accompanied by ongoing discussion among the research team. Emergent findings fed into the development of the national survey of board-level executives (WP2) (see section 2.2), and into the focus and sampling of WP4 (see section 2.4).

Findings from WP1 are presented in Chapter 3.

2.2. National survey of board-level executives in provider organisations (WP2)

To complement and build on the insights developed through interviews with senior stakeholders (WP1) and further answer research question 1, we developed a short survey aimed at senior executives within NHS organisations on the implementation of a range of post-Francis policy initiatives relating to openness. We sought in particular to identify and characterise the range of structures and processes that organisations were putting into place for delivering on their responsibilities to be open, and the challenges they were facing as they sought to put policies into practice.

The survey instrument was developed through a stepwise process. This involved (i) reviewing the literature to identify candidate constructs and question forms, (ii) several rounds of prioritising and forming of key questions within the research team, (iii) consultation and piloting with the study’s stakeholder advisory group, and (iv) finalisation of the agreed questions and formatting for electronic and postal distribution.

First, we conducted a search of the literature on key areas of relevance to the project (attitudes towards policy initiatives, organisational values, organisational openness, candour, organisational learning (acquisition, distribution, interpretation and integration), organisational change, giving voice, acting on concerns, communication). One member of the research team identified and reviewed academic papers and survey instruments, primarily from the organisation and management literature, and presented them for discussion within the team. These papers and instruments provided important indicators of the kinds of constructs used to examine this area, but the questionnaire tools identified were of limited direct use, since they were designed primarily for intra-organisational use, to examine employees’ perceptions of these issues, and in some cases compare them with those of managers.

Next there followed several rounds of construct and question definition, formation and refinement. Starting initially with a large number of potential areas of interest and approaches to operationalising in survey form, we progressively reduced these, using issues arising from WP1, issues raised by our professional advisory group and PPI advisory group (see section 2.5), and policies identified in the commissioning brief as a reference point. We sought to ensure that the survey: (i) was as focused as possible on these key issues; (ii) focused on those issues best suited to multiple-choice survey questions; (iii) focused on those areas that senior managers would be well placed to address; and (iv) minimised length and overlap in questions to ensure it could be completed swiftly (in 10 minutes or less) and without reference to sources that might not be immediately available to respondents.

The final round of this process gave rise to a candidate set of questions presented in an appropriate format. This set of questions was circulated to professional advisory group members, who were asked to attempt to complete the survey (where they were in professional roles similar to those of the target respondents), and comment on the content and format of the survey as a whole and specific questions. Feedback from advisory group members was then collated and incorporated into a final version of the survey. The final version of the survey, which comprised 14 questions including binary and categorical questions, Likert scales and a small number of open-ended questions, is provided in Appendix B. The survey included questions relating to specific policies including:

- the statutory Duty of Candour;
- the revised Serious Incident Framework;
- Freedom to Speak Up Guardians;
- Sign Up to Safety;
- patient safety collaboratives;
- the Fit and Proper Persons Test;
- the Q Community (formerly the Q Fellows and 5000 Safety Fellows).

Additionally, the survey also included a range of wider questions, including the general implementation challenges associated with the policies, the challenge of openness across professional and hierarchical boundaries, influences on speaking up, executives' own views on speaking up, the board's role in openness, and the contribution of patients and families to openness initiatives.

We engaged Wilmington Healthcare (formerly Binley's) to administer the survey. Wilmington were able to draw on a large database of potentially relevant respondents, from a range of NHS provider organisations and independent-sector providers of NHS services. From this database, four groups were identified as being particularly relevant, and so were chosen as the sampling frame for the survey: chief executives; medical directors; directors of nursing; and leads for risk, governance and safety. The survey was distributed electronically and by post to individuals with contact details in the database on 19 January 2018. The survey remained open until 16 February 2018; regular reminders were issued to those contacted. Disappointingly, the survey yielded a very low response rate—in part due to the very large sampling frame, which turned out to include a number of redundant, irrelevant or duplicate contact details (see Chapter 4 for further details).

Results from the survey (including postal and electronic responses) were collated and cleaned in a Microsoft Excel spreadsheet, and were examined using descriptive and some analytical statistical methods. Survey results also fed into the focus of and sampling for WP4 (see section 2.4). Key results from WP2 are presented in Chapter 4.

2.3. Secondary analysis of NHS surveys of patients, service users and staff (WP3)

Annual surveys have taken place in the NHS since 2003 (for staff) and 2004 (for acute inpatients and community mental health service users), offering an opportunity to explore perceptions of openness over several years. To complement the cross-sectional perspectives offered by WP1 and WP2 and address our second research question, we deployed a longitudinal research design to draw on these annual surveys to identify changes and trends through time, and in particular whether there was a noticeable change in the direction or pace of change after the publication of the Mid Staffordshire public inquiry.

We used data from the NHS National Staff Survey (2006-2017), NHS Acute Inpatient Survey (2004-2016) and NHS Community Mental Health Service User Survey (2007-2017). Longitudinal statistical methods (piecewise and interrupted latent growth curve analysis) were adopted to determine any change in response to survey questions relating to matters of openness since the publication of the *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*.[5]

Historical data were gathered from the UK Data Service (ukdataservice.ac.uk) and recent data from the Survey Coordination Centre based at Picker Europe (www.nhsstaffsurveys.com and

Year	Questionnaires sent out	Questionnaires returned	Response rate	Number of trusts
2007	291,843	157,667	54%	392
2008	289,919	159,691	55%	360
2009	289,277	157,450	54%	387
2010	311,098	167,736	54%	390
2011	250,000	134,967	54%	365
2012	203,188	101,169	50%	259
2013	416,313	203,028	49%	264
2014	603,937	255,150	42%	289
2015	722,811	298,817	41%	296
2016	948,640	414,330	44%	316
2017	1,067,266	478,872	45%	309

Table 1: Response rates for NHS staff survey 2007-2017

Year	Questionnaires sent out	Questionnaires returned	Response rate	Number of trusts
2004	142,432	88,308	62%	169
2005	136,937	80,793	59%	164
2006	136,769	80,694	59%	166
2007	135,623	75,949	56%	165
2008	134,415	72,584	54%	165
2009	133,362	69,348	52%	161
2010	132,696	66,348	50%	161
2011	133,704	70,863	53%	161
2012	126,480	64,505	51%	156
2013	127,435	62,443	49%	156
2014	125,709	59,083	47%	154
2015	176,843	83,116	47%	149
2016	176,932	77,850	44%	149

Table 2: Response rates for NHS acute inpatient survey 2004-2016

www.nhssurveys.org). As individual responses were not tracked across years, changes over time were analysed at the trust level and data aggregated to the organisational level.

The NHS National Staff Survey (hereafter the ‘staff survey’) runs on an annual basis from April to March. All NHS healthcare organisations are invited to participate, including acute trusts, ambulance trusts, community trusts and mental health/learning disability trusts. Data from the staff survey were sourced from 2007 to 2017. Each year a random sample of staff in each trust are invited to participate in the survey. Up until 2015 the minimum sample size permitted was 850; this increased in 2016 to 1250. Response rates for each year can be found in **Error! Reference source not found.**. Only trusts that remained unchanged as organisations for the duration of the study were included in the longitudinal analysis: trusts which merged were excluded. Of the original sample, over the 12 years of study, 244 organisations remained by 2017. The staff survey includes over 150 questionnaire items, including 38 ‘key findings’. The key findings represent aggregates of individual survey items based around a theme.

The NHS Acute Inpatient Survey (hereafter the ‘inpatient survey’) is conducted each year within acute care. Data were sourced from 2004-2016. Trusts identify up to 1250 adult patients who were discharged from hospital in the July of each survey year (prior to 2015, trusts were asked to identify 850 patients). Trust unable to attain the required sample size are permitted to sample back as far as January. Fieldwork takes place between August and January. Response rates can be found in **Error! Reference source not found.**. Over the 13 years of analysis, 144 organisations remained unchanged throughout.

Data from the NHS Community Mental Health Service User Survey (hereafter the ‘mental health survey') were sourced for years for 2007-2017 (excluding 2009, when no survey was conducted). NHS mental health services include combined mental health and social care trusts, foundation trusts and community healthcare social enterprises that provide mental health services. Patients aged 18 years and over, who had received specialist care or treatment for a mental health condition, and were not current inpatients, are eligible for participation. Each trust selects a random sample of 850 service users who had received specialist care or treatment between September and November. Fieldwork takes place between February and June. Response rates for each year can be found in **Error! Reference source not found.**. Over the 13 years of analysis, 54 organisations remained unchanged throughout.

Year	Questionnaires sent out	Questionnaires returned	Response rate	Number of trusts
2007	41,842	15,900	38%	69
2008	41,014	14,355	35%	68
2009		No survey conducted		
2010	53,746	17,199	32%	66
2011	52,852	17,441	33%	65
2012	49,619	15,878	32%	61
2013	46,552	13,655	29%	57
2014	46,552	13,500	29%	57
2015	41,650	11,695	29%	52
2016	49,300	13,254	28%	58
2017	47,600	12,139	26%	58

Table 3: Response rates for NHS Community Mental Health Service User Survey 2007-2017

For analyses of all three surveys, Becker's recommendations were observed when selecting which control variables to include because of their relevance to the outcome measures.[53] Different trusts have different priorities; therefore controlling for trust type is necessary. Trusts were divided into four broad categories: 'Acute' (including acute, acute specialist trusts and combined acute and community), 'Mental Health/Learning Disability' (comprising combined mental health/learning disability and combined mental health/learning disability trusts), 'Ambulance' and 'Community'. Organisations classified as 'other' were not included in the analysis due to insufficient numbers to make comparisons. Trust type comprised categorical data which were 'dummy coded' for inclusion in the models; the control variable 'Acute' served as the comparator group.

The trusts included in the analysis represented all areas of England. For the purposes of this study, we used four overarching regions: 'Midlands' (East Midlands, East of England, and West Midlands), 'North' (Yorkshire and the Humber, North East, and North West), 'South' (Wessex, Thames Valley, Kent, Surrey and Sussex, and South West) and 'London' (North West London, South London North, Central and East London). Region consisted of categorical data which were dummy coded before inclusion in the models. 'London' served as the comparator group.

Trust size was included as larger organisations may have greater access to resources that can buffer against the negative effects of demand. Trust size is measured as the full-time equivalent staff (FTE) employed by each trust (gathered from the NHS staff survey advice centre). Trust size consists of continuous data.

Item from the survey were selected for analysis prospectively, prior to data collation and analysis. Drawing from the questions as phrased in the 2013 surveys, we first identified a preliminary list of items from each survey dataset with some relevance to three key concepts defined in the report of the Mid Staffordshire public inquiry:[5]

- openness: "enabling concerns to be raised and disclosed freely without fear, and for questions to be answered";
- transparency: "allowing true information about performance and outcomes to be shared with staff, patients and the public"; and

- candour: “ensuring that patients harmed by a healthcare service are informed of the fact and that an appropriate remedy is offered, whether or not a complaint has been made or a question asked about it.”

At this stage, we took an inclusive approach, including items with any potential relevance in the longlist, and so it comprised some 131 items (17 key findings from the staff survey; 51 individual questions from the staff survey; 38 questions from the inpatient survey; and 25 question from the mental health survey). The list was then reviewed by four members of the research team, with a view to identifying a parsimonious subset of items that related most closely to the notion of openness as described in the commissioning brief and the public inquiry,[5,35] and addressed through the policy interventions that followed. This incorporated, for example, openness among staff (as covered by interventions such as Freedom to Speak Up[11]), openness about errors (as covered by the Duty of Candour[26] and efforts to improve the quality of incident investigations[29]), transparency and candour with patients (as covered by the Duty of Candour[26], as well as broader initiatives seeking to encourage proactive sharing of information and performance data with patients and the public[12]), and the psychological safety experienced by staff and patients in relation to communicating ideas and concerns. Together, the team members progressively reduced the longlist to a much shorter selection of candidate variables, reviewing the longlist independently at first and then together. Ultimately, the agreed list included 10 primary variables (survey questions directly related to the aspects of openness, transparency and candour noted above) and 18 secondary variables (items whose connection to openness was more indirect or peripheral). The number of years’ data used varied by question. Some questions were introduced more recently and/or were modified. For the staff survey, the included items relating to contribution to decisions and improvements, response to errors and incidents, and acting on concerns of patients. For the inpatient and mental health surveys, selected items related to receiving understandable answers, quality of information about care and treatment, and opportunities for feedback.

The full final list of primary variables included was as follows:

- Quality of communication between managers and staff (staff survey key finding);
- Opportunity for staff to contribute towards improvements in the workplace (staff survey key finding);
- Fairness and effectiveness of incident reporting procedures (staff survey key finding);
- Information provided about condition or treatment provided while in the emergency department (inpatient survey);
- Involvement in decisions about care and treatment (inpatient survey);
- Availability of someone on the hospital staff to talk to about worries and fears (inpatient survey);
- Did the person you saw listen carefully to you? (mental health survey);
- Were you given enough time to discuss your needs and treatment? (mental health survey);
- Review of care over 12 months (mental health survey);
- Treatment with respect and dignity (mental health survey).

The secondary variables included were:

- Experiences of discrimination (staff survey key finding);
- Provision of equal opportunities (staff survey key finding);
- Positive organisational evaluations (would recommend the trust as place to work) (staff survey key finding);
- Team discussion of its effectiveness (staff survey individual question);
- Quality of team communication (staff survey individual question);
- Doctors discussing patients as if they were not there (inpatient survey);
- Nurses discussing patients as if they were not there (inpatient survey);
- Responsiveness to calls for assistance (inpatient survey);
- Explanation of risks and benefits of an operation or procedure (inpatient survey);

- Explanation of what an operation or procedure would involve (inpatient survey);
- Explanation of what to expect to feel after an operation or procedure (inpatient survey);
- Explanation of how the operation or procedure had gone (inpatient survey);
- Provision of written information on recovery before leaving hospital (inpatient survey);
- Provision of information on monitoring danger signals post-discharge (inpatient survey);
- Opportunity to give views on the quality of care (inpatient survey);
- Provision of information on how to complain to the hospital (inpatient survey);
- Involvement in decisions about medicines (mental health survey);
- Medications review in the last 12 months (mental health survey).

As a result of changes to the wording of some questions, each item was reviewed to ensure the underlying construct (the focus of measurement) remained the same. Where we observed significant changes, items were excluded from analysis up until the year where the difference had been identified. Position (and possible change in position) of questions across years was captured to control for priming effects of surrounding questions. The response options (Likert scale, binary or categorical) of each item were checked to ensure consistency across years. Where response options significantly changed, preventing direct comparisons across years, such items were excluded from analysis up until the year where the difference had been identified.

At least five years' data, overlapping 2012 and 2013, and including two or more years' data before and after 2012 (i.e. covering, at a minimum, the period 2010-2014) were required for each item of interest. In a number of cases the data available extended the minimum parameters: some items ranged from 2007-2017 for the staff survey, 2004-2016 for the inpatient survey and 2007-2017 for the mental health survey.

The objectives were examined using Latent Growth Curve modelling (LGM),[54] using Mplus (version 8). This allowed modelling of staff and patient survey outcomes over time. For each outcome, models ranging from eight to 13 years (depending upon available data) were adopted. After controlling for relevant trust-level variables (trust size, type and region), both the intercept (the starting level) and the slope (rate of change over the period of interest) were predicted for each of the staff and patient survey variables of interest.

Indices were used to explore model fit. Traditionally, reported fit statistics used in LGM include the comparative fit index, with acceptable levels of fit being above 0.95,[55] and the root mean square error of approximation with a cut-off of ≤ 0.05 for close fit.[56] Analysis involved testing for the optimal growth shape based on the data. The acceptance of the subsequent (more complex) model was determined by the rejection of the previous model based on failure to meet the absolute fit criteria. A summary of model progression is given below.

- Baseline model:
  - *Model 1: Growth curve with random intercept and fixed slope:* The baseline model assumes a single linear relationship, where starting scores vary across trusts (random intercepts) and rates of change remain the same (fixed slopes).
- Piecewise models:
  - *Model 2: Piecewise growth curve with random intercept, fixed piecewise slopes with break at 2012 and 2013:* Before choosing a piecewise alternative the linear (baseline) model needs to be rejected. Piecewise growth curve models (PGCM) are used when the underlying growth process is not linear and is hypothesized to consist of phasic developments connected by a turning point (i.e. at 2012 or 2013). Model 2 retains the same freedoms and constraints as Model 1 but with a turning point at 2012 for Model 2a and 2013 for Model 2b.
  - *Model 3: Piecewise growth curve with random intercepts, fixed slopes for the first piece of the growth curve, random slopes for second piece:* Building upon the previous model, random slopes, which allow for different rates of growth across trusts, are introduced to the second piece of the growth curve (representing change from 2012 onwards for Model

    3a and 2013 onward for Model 3b).
  - *Model 4: Piecewise growth curve with random intercepts, random slopes for first and second piece of the growth curve:* Constraints imposed in Model 3 are removed as random slope effects are introduced to the first part of the growth curve that allow for different rates of growth across trusts (pre-2012 for Model 4a and pre-2013 for Model 4b).
  - *Model 5: Piecewise growth curve with random intercepts, random slopes for first and second piece of the growth curve, plus controls:* To search for the optimal growth trajectory, we analysed a series of conditional PGCMs (i.e. with covariates: trust type, region and size) and continued to change the shape of the growth curve with turning points at 2012 for Model 5a and 2013 for Model 5b.
  - The Wald test was used to test for a significant difference between the mean of the first and second slope of the piecewise growth curve, statistically significant at conventional levels: $p < 0.05$; $p < 0.01$; $p < 0.001$.
- Interrupted models:
  - *Model 6: Interrupted time series with random intercepts, random slopes for first and second piece of the growth curve, plus controls:* PGCMs assume continuous change following a turning point - however this is not always the case. Change may be temporary before a trajectory returns to its original path, or takes a different direction. Accordingly we tested for the possibility of an interrupted time series between 2012 and 2013 for Model 6a and 2013 and 2014 for Model 6b.

Findings from these analyses are presented in Chapter 5.

2.4. Organisational case studies of ‘openness in action’ (WP4)

Between them, our first three workpackages focused on the reception of post-Francis initiatives at the blunt end of the NHS, and on the high-level impact of the initiatives on various proxies for openness as experienced by staff and patients through time. Complementing and building on this analysis of initiatives, attitudes and trends, our fourth workpackage sought to examine the work done to translate policy initiatives into action in NHS organisations, how this was experienced by patients, families and staff at the sharp end, and the extent of evidence for any aggregate impact on culture and behaviour around openness.

We sought in particular to ensure that we collected data from those involved in ‘delivering’ the policies: raising and listening to concerns; making disclosures about harm or receiving them; using various forms of intelligence to unearth potential problems or secure learning and improvement. We aimed to ensure that we went beyond the accounts of individuals in relatively senior positions in organisations. Such individuals provide enormously valuable but necessarily partial perspectives on policy translation: while they may seek to provide frank and thorough descriptions of work to promote openness, their accounts are subject to various biases, and should not be relied on alone for empirical insight.[57]

One well established means of overcoming the limitations of interview accounts is the collection of naturally occurring data through ethnographic or other observational methods.[58] However, given the focus and research questions of this study, use of ethnographic methods was not feasible. Many aspects of openness are characterised by infrequent, unpredictable occurrences (e.g. enacting the Duty of Candour; expressing or acting on concerns), rendering direct observation difficult. Ethical challenges in an area of great sensitivity, and an unpredictable observer effect, compound these problems. Our selected approach therefore relied instead on the collection of further qualitative interview data, but involving a wider range of participants (notably sharp-end practitioners, and patients and family members), and viewed through the lens of purposively selected, comparative organisational case studies.

Ethical approval was given by the National Research Ethics Service North West – Greater Manchester (East) Research Ethics Committee (REC); approval to undertake the study in NHS organisations was granted by the HRA on 6 December 2017 (reference 17/NW/0719), and subsequently amended as participating organisations were confirmed.

2.4.1. Case-study selection

As analysis of data collected for WP1, WP2 and WP3 proceeded during early-to-mid-2018, we began to identify issues of analytical consequence that went beyond the initial brief and existing literature. These included, for example, the importance of intra-organisational variation (WP1—see section 3.5.5), the variety of approaches to arrangements for appointing Freedom to Speak Up Guardians and prioritising their workload (WP1 and WP2—see sections 3.3 and 4.2), and a seemingly rather divergent pattern of implementation and impact in different types of organisation (WP1 and WP3—see sections 3.5 and 5.3). Additionally, our findings suggested that some of the post-Francis initiatives were particularly strong candidates for more in-depth data collection, because of their reported impact (see section 4.1) or because of the challenges and opportunities they afforded to those enacting them (see sections 3.5 and 4.3). These findings informed our sampling of organisations, and our identification of three 'tracer issues'—foci for data collection that encapsulate key themes of analytical interest, and thus act as an anchor for fieldwork[59]—which guided our sampling and data collection in WP4.

Our original plan was to sample between four and six organisations in WP4, securing variation in characteristics likely to be significant in influencing the approach taken to improving openness and its likely success.[60] We were particularly keen to include at least one or two organisations that appeared to be taking promising, innovative approaches to openness. In the event, our sample was at the top end of this range, and included six case-study organisations (three acute trusts, two community and mental health services trusts, and one ambulance trust) with a range of trajectories around openness (see section 6.1 for details). This decision was informed in particular by our finding from WP1 of the importance of local stimuli to change, which some participants suggested were at least as important as the national impetus (see sections 3.5.3 and 3.5.4). Our sample in WP4 thus included trusts that, judging by their recent history, might be seen as organisations where openness was very far from routine—but where great efforts had also been put into achieving change. With varying degrees of emphasis, we examined the implementation of our three tracer issues (the statutory Duty of Candour, the investigation of serious incidents, and the Freedom to Speak Up programme) in each of the six organisations.

Candidate organisations for inclusion in WP4 were identified in the course of interviews for WP1, through discussions with our professional advisory group, and through informal discussions with NHS staff, academics and others at conferences and other events attended by members of the research team. Recruiting sites proved to be a complex and sometimes tortuous process. In part, this was due to some of the (sadly) familiar challenges in the research governance oversight and approval process. However, the focus of the research presented an added complication.

The process varied between organisations, but typically, our initial contact would be with an individual in a middle or senior management position with some responsibility for quality, safety or risk, who was enthusiastic at the prospect of inclusion in the study. Such individuals, however, were of course not be able to make a decision to participate unilaterally, and therefore required time to discuss with colleagues in various roles, and seek to locate a colleague with the authority to sign off involvement. This could be a time-consuming process in itself, and sometimes it would uncover individuals who were rather less keen for their organisation to be involved in the study—requiring further explanation and negotiation.

In consequence, although the involvement of the first case-study organisation was agreed in January 2018, the final organisation was not recruited until January 2019. In the interim, we spent much time approaching numerous other organisations with a view to involvement, including detailed discussions and provisional agreement of participation with individuals from two organisations (one acute trust, one non-NHS provider of NHS services) which ultimately did not come to fruition. In consequence, the time we had to undertake fieldwork varied between case-study sites; this is reflected in the numbers of interviews ultimately undertaken in each. The complexities of the process of agreeing organisational participation—including the disparate ways in which responsibility for the openness ‘portfolio’ was arranged between organisations, and the varied attitudes towards participating in a research study of this nature—provide in themselves some insight into the challenges of openness.

2.4.2. Participant recruitment

Once participation had been formally agreed by organisations’ management, and research-governance approval had been obtained from their research and development offices, recruitment of individual participants proceeded through two routes. We began by seeking to recruit a small number of senior-level staff with remits around openness in general, and/or the three tracer-issue policies. Relevant individuals were identified by local collaborators and through snowball sampling. These individuals provided an overview of the organisation’s approach to policy implementation, and of associated local initiatives that supported or supplemented the nationally driven initiatives. They also provided a sense of the history and topography of the organisation: its sub-units; areas of perceived strength and weakness; significant events of the past that might explain attitudes and initiatives in the present. The topic guide for these interviews is provided in Appendix C. This knowledge informed our second route to recruiting participants.

A key consideration for this second route, given the sensitivities of the topics covered, was a process that was (and was seen to be) completely independent of the organisation. We wished to ensure that senior managers were not involved in the recruitment process, and that they would have no way of knowing who had been approached, who had agreed to participate, or who had declined. Simultaneously, of course, it was not possible for the organisation to disclose contact details of potential participants to the research team without their permission.

We took several steps to minimise the potential for inadvertent disclosure and maximise participants’ confidence in the process, including a verbal (not written) consent process. The overall approach taken to recruiting participants through this second route (as approved by the REC) therefore involved the following steps:

1. Organisations were asked to distribute a standard-form message to groups of potential participants (staff or patients), using appropriate mailing lists or, in some cases, more far-reaching media, such as newsletters. Potential participants included, for example, individuals who had been involved in the disclosure of a serious incident, individuals who had contacted the Freedom to Speak Up Guardian, or individuals in a particular organisational unit.
2. The standard-form message included brief details about the study, and provided a URL for a secure website specific to the group of potential participants (hosted on onlinesurveys.ac.uk), where any individual interested in learning more about the study could leave their details (an e-mail address or phone number, including non-work contact details if preferred).
3. Individuals who left their details were contacted with more information about the study. In the event, all individuals provided an e-mail address. They were sent a short e-mail, including a participant information sheet as an attachment. The information sheet provided more details, stressed the confidential nature of the study, and explained the steps taken to ensure that no-one in the organisation would know whether an individual participated. Individuals who were still interested were asked to contact a researcher to arrange a date and time for a call.
4. Upon being called, participants were given the opportunity to ask questions about the study. If they were happy to proceed, the interview began.
5. At the start of the interview, after audio-recording had begun, the researcher read a statement about the study to the participant which replicated the content of a written consent form. The participant was asked to confirm orally that s/he had understood, and consented to be interviewed. The interview then proceeded.

In some instances, participants suggested others who might wish to be involved. Participants were asked to encourage them to express an interest in participation via the secure site (per the second step above). Therefore some snowball sampling may have occurred; however, due to the nature of the process, it is not possible to know what proportion of participants received the standard-form message directly, and what proportion heard about the study through an existing participant.

2.4.3. Interviews and analysis

The format for interviews conducted via this route varied by participant, but in general took the form of a narrative interview,[61,62] taking as a starting point the event (e.g. incident of harm; disclosure; decision to speak up; investigation) that had led to their experience of one or more of the tracer issues. The interviewer invited participants to tell the story of 'what had happened to them'. As participants recounted their experiences, where appropriate, the interviewer asked questions to elicit more information about the background, the process and the consequences. The topic guides for these interviews, which differ slightly for staff participants and patient or family member participants, are provided in Appendix C. Across both recruitment routes, interviews averaged 50 minutes in length.

In each site, across both routes to recruitment, we aimed to interview between 14 and 21 members of staff, and between six and 10 patients and family members. Given our intention to include between four and six case-study sites, this would have resulted in a total sample size of between 80 and 186 (56–126 members of staff, and 24–60 patients and family members). In practice, just as organisational-level case-study recruitment had proved challenging in places, so too was it difficult to recruit individual participants. There was less time to recruit participants in organisations that were confirmed as case-study sites later on; some organisations were much more willing or able than others to identify appropriate contact lists and send the standard-form message; and there were palpable differences within and between organisations in participants' sense of the safety of participating in the study. As a participant in one case-study site put it when discussing recruitment to the study, "people don't want to do something that will fuck up their career." More generally, as others have noted, in a pressured NHS, it is increasingly difficult for staff at the sharp end to find time to undertake things that are perceived as non-essential, including participation in research.[63] Ultimately we undertook 88 interviews—exceeding our minimum target case study size (albeit spread across six organisations rather than four), but falling well short of the maximum. Interviewees were spread unevenly across case-study sites, and some groups of participant were better represented than others. Notably, we recruited only 18 patients or family members, falling short of our minimum target of 24. Further details of the sample are provided in Chapter 6.

All interviews were audio-recorded in full and transcribed by a professional firm, with which a contract including clauses regarding confidentiality was in place. Potentially identifying words or phrases were removed in the course of transcription. A similar process to that described for WP1 (section 2.1) was used for analysis, but with particular attention to the structure, content and internal logic of participants' narratives.

We drew on the constant-comparative method,[52] building on the ideas and concepts developed in the analysis of earlier workpackages. Assisted by NVivo qualitative data analysis software, one researcher led analysis of the data, coding for high-level themes developed *a priori* and themes identified inductively from close reading of the data. A particular focus for coding and analysis was the longitudinal connections described by participants: how things described earlier in their narratives led to things they described later, and how later events affected their interpretation and understanding of earlier ones. Codes were modified, developed and amalgamated as more data sources were incorporated and analysis proceeded. Coding was accompanied by intensive discussion between two members of the research team, including two lengthy analytical debriefing sessions which were themselves audio-recorded and transcribed to inform further analysis, and more intermittent discussion with other members of the team.

Analysis from WP4 is reported in Chapter 6, which introduces the case-study sites and presents findings relating to the Duty of Candour and serious incident investigations, and Chapter 7, which presents findings relating to the Freedom to Speak Up programme, and key overarching themes.

2.5. Guidance, governance, formative feedback and dissemination

The study proposal, written in response to the Department of Health Policy Research Programme's invitation to tender, was peer reviewed, and revised in light of reviewer comments. The research team, comprising the five authors of this report, were supported in the study by a PPI advisory group, and a professional advisory group, as well as by colleagues from the Department of Health and Social Care and the NIHR Central Commissioning Facility (CCF). Over the course of the study, each group met in person on three occasions, with ad hoc contact in between meetings with members when advice on particular issues was sought.

The PPI advisory group began with six members, each of whom had experience of issues relating to openness. For example, one had experiences of raising concerns with a clinical commissioning group (CCG) about changes in service provision and eligibility criteria, and another contributed to the development of the Freedom to Speak Up Guardian role at his local acute trust, and was involved in the selection process. The group was supplemented by one further member, recruited through the newsletter of the charity Action Against Medical Accidents (AvMA), though she was not able to attend any meetings in person.

The professional advisory group comprised members who could offer a wide range of clinical, healthcare management, academic and wider stakeholder perspectives. It included:

- the Director of Safety and Risk at a large acute hospital trust;
- a clinical academic involved in the development and day-to-day running of a national audit and the publication of clinician- and trust-level outcomes;
- the Medical Director of a mental health and community health services trust;
- the Director of Medical Education at an acute teaching trust, with an interest in developing learning and improvement from understanding of individual and system error;
- the commissioning lead for mental health in a CCG (also a general practitioner);
- the chief executive of a local Healthwatch organisation;
- an epidemiologist with a particular interest in the use of data on quality and safety;
- a senior manager at a national patient safety charity.

Counsel was sought from both groups throughout the study, particularly at strategic points such as when sampling decisions were required. The professional advisory group played a key role in particular in the development and piloting of the survey for WP2 (section 2.2). Members of both groups commented on interim reports, and were invited to the study dissemination event (see below). Members of both groups were offered (and in most cases accepted) small payments for their time, as well as reimbursement of expenses. For the avoidance of doubt, responsibility for any accuracies and omissions in this report and other outputs from the study belongs to the authors alone.

Throughout the study, we maintained close contact with the Department of Health (later Department of Health and Social Care), via contacts at the NIHR CCF. We presented an interim report to colleagues at the Department of Health in mid-2018, highlighting key findings from the first three workpackages, and obtaining a steer for the focus of the fourth. We met again with Department of Health and Social Care colleagues in July 2019, providing overview findings, discussing the format of the final report, and discussing supplementary routes to dissemination (beyond the report itself and papers in academic journals) with a view to maximising the reach and impact of the study, particularly among those involved in the commissioning, management and delivery of NHS care. Two early such dissemination activities were a summary of innovative approaches to openness (submitted separately and also include in this report as Appendix D), and a dissemination event held in Birmingham on 30

September 2019, entitled ‘Openness in action’. We hope to make a fully formatted, public-oriented version of Appendix D available in due course, along with other outputs oriented towards NHS managers, clinicians, patients and families.

The dissemination event included presentations on the study and its findings, presentations from managers and clinicians around the NHS about the challenges of developing a culture of openness and their innovative work to address this, and a discussion panel including presenters, researchers and members of our professional advisory group. Our proposal included plans for two or three such events and a total of 60 attendees, but it proved difficult to secure repeat presentations from individuals outside the research team. Therefore we held one, larger, event. Some 123 individuals were invited to attend, 72 registered, and 54 attended the event.

We circulated a brief evaluation survey to those who attended after the event. Feedback was very positive: 79 per cent of those who responded stated that the event met their expectations “very much” (16 per cent selected “somewhat” and five per cent “a little”), and 74 per cent said that the event was “very useful” for them (21 per cent said it was “somewhat useful,” and five per cent were “unsure”). Free-text comments indicated that participants appreciated “meeting like-minded people and having 'common sense' qualified by research,” and that the event offered a “great opportunity to understand and follow through on the findings with practical insights from across the NHS.” We also offered to present our findings to relevant groups in each of our WP4 case-study organisations; two of the six organisations took up this offer.

Several academic outputs from the study are in various stages of completion. Those that have been fully drafted and submitted for consideration by journals (or in one case published) are included as appendices—see Chapters 3 and 5 for further details.

3. Results: Telephone interviews with senior stakeholders (WP1)

WP1 involved telephone interviews with senior stakeholders in and around the NHS in England. The primary objective of this workpackage was to answer the research question ‘How do senior managers and clinicians in organisations providing NHS services understand policies and translate them into specific norms, expectations and practices in their organisations?’ We sought to examine whether current systems and processes to implement policies relating to openness are perceived by senior leaders to provide clarity of direction or, conversely (given complex and overlapping accountability, regulatory and oversight arrangements[49]), they are seen to compete, conflict or fail to cohere, with each other or with the wider policy and regulatory environment. We sought to understand how senior managers and clinicians in and around a variety of healthcare organisations have responded to the imperatives for change by generating an account of the initiatives and activities undertaken in provider organisations, and their associated ‘theories of change’[51]—how and why they are expected to produce the hoped-for improvements in openness.

Full details of the methods used for this workpackage can be found in section 2.1, which includes details of our approach to sampling, recruitment and analysis. Interviews were carried out between July 2017 and January 2018. They lasted, on average, 40 minutes. All interviews were audio-recorded and transcribed, verbatim, in full.

In total, we interviewed 51 participants, in a variety of middle and senior management roles in NHS organisations, and in other bodies with a stake in the issue of openness in the English NHS, including regulators, not-for-profit organisations, and law firms. Details of the backgrounds of participants can be found in Table 4. The number of participants fell slightly short of our target sample size of 60; we ceased recruiting new participants early as theoretical saturation became evident in our data set—that is, analysis of our data was no longer producing new conceptual categories as further data were collected.[52] Compared with the intended profile of our sample (see section 2.1), we slightly under-recruited from acute providers and ambulance trusts, and slightly over-recruited from community and mental health service trusts and wider stakeholders, who—despite or perhaps because of their greater distance from the provision of NHS care—offered a wide range of perspectives on the issues covered. Despite protracted efforts, we were able to secure participation from only one non-NHS provider of NHS services.

In this chapter, we present our findings first in terms of key initiatives introduced by central government following the report of the Mid Staffordshire public inquiry[5] and the responses to it.[8,9,12,13,27] We then seek to describe participants’ responses to the policy initiatives in aggregate, and their collective impact on practice and culture around openness in NHS organisations. Where appropriate, we distinguish between the views of sub-groups of participants—for example where those in the mental and community health service sector appeared to differ from those in the acute sector. Data and analysis from the telephone interviews also feed into our focus in WP4 on ‘openness

Participant’s organisation	Number
Acute trusts	17
Community and mental health trusts	17
Ambulance trusts	3
Non-NHS providers of NHS services	1
Other organisations (regulators, policy bodies, commissioners, third-sector organisations, law firms)—‘Commentators’	13
Total	**51**

Table 4: Backgrounds of participants in telephone interviews (WP1)

in action' (Chapters 6 and 7)—i.e. the sense of how openness is encouraged, supported or undermined in NHS organisations on a day-to-day basis, among patients, carers, clinicians and other NHS staff. We synthesise our findings across the blunt and sharp ends of the NHS in Chapter 8.

Of the initiatives we discussed in interviews (see Appendix A), the introduction of mandatory (e.g. Freedom to Speak Up Guardians) and statutory (e.g. Duty of Candour) initiatives, and changes to regulators' inspection regimes, attracted most comment. It is on these changes, and their positive and negative consequences for openness, that we focus most closely in this chapter.

Our findings suggest that policy efforts to encourage joined-up systems of oversight, intelligence and regulation are welcomed by senior stakeholders, and the need to normalise openness is widely held to be an important aspiration. Many participants cited Francis as a driver for change, but some indicated that change in their organisations had predated Francis, often as a response to a local incident that highlighted the need to improve (a theme that also proved important in some of the case-study organisations in WP4—see section 6.1). For these participants, a 'local' imperative of this kind presented a more powerful motivator to change than national-level drivers that might appear more remote to staff. Wider stakeholders perceived a difference between organisations that were taking their responsibilities around openness seriously, and those that saw them more as an exercise in compliance. Concerns were also raised by some participants that some elements of the policies failed to take into account organisational differences; it was felt that a 'one size fits all' approach, modelled on an acute service provider, had been the dominant model at the planning stage. This meant that for those in, for example, community and mental health service trusts, there were challenges in fitting regulatory requirements to their own organisation.

Findings from WP1 feature in two publications from our study: on the evidence for the impact of post-Francis initiatives on culture in the NHS broadly[64] (Appendix E, published); and on the realisation of the role of the Freedom to Speak Up Guardian (Appendix F, currently under review). These papers provide more focused examinations of some of the key foci of this part of the study.

3.1. The statutory Duty of Candour

Introduced in 2014 for acute trusts and 2015 for other healthcare provider organisations in response to recommendation 181 of the Francis public inquiry,[6] the statutory Duty of Candour places an obligation on organisations to be open with patients and families on occasions when it is discovered that patients have suffered moderate harm, severe harm or death in consequence of an unintended or unexpected incident during their care. The duty is set out in Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.[26] Supplementing the professional duty of candour already incumbent upon healthcare professionals, the statutory Duty introduces criminal liability for organisations that fail to comply. It also introduces expected standards for disclosures to patients and family members, pertaining for example to the timing of the disclosure, how it should be made (including an apology—"an expression of sorrow or regret in respect of a notifiable safety incident"), and how it should be documented.[26] Concerns have been expressed by some about the potential for discharging the Duty of Candour in a way that prioritises defensiveness or compliance over the needs of the patient or family member—a "box ticking approach [that] devalues the apology"[65]—and for the disclosure and reporting requirements associated with the Duty to encourage organisations or healthcare staff, deliberately or subconsciously, to 'downgrade' their assessments of the level of harm sustained in the course of their care.[66] There is also some evidence of rather mixed levels of compliance with the Duty of Candour, for example in relation to maternity care.[67]

3.1.1. Implementation

Broadly, the introduction of the Duty of Candour was welcomed by participants in our telephone interviews. At the level of senior management, it was seen as setting out a reasonably clear framework for responding to incidents, and was viewed by our participants—many of whom had executive responsibility for areas such as patient safety, learning and governance—as placing openness squarely on the agenda of organisations' boards.

"There are some grey areas, but I think it is quite a clear policy around what we need to be doing. So it gives us a framework to work within, from a Duty of Candour perspective anyway." (Participant 15, Acute trust)

"Certainly we're now very conscious of Duty of Candour, and we have set timescales around how we comply with the Duty." (Participant 30, Community and mental health services trust)

Particularly early on in the implementation of the Duty of Candour, participants noted that there had been concerns about the relationship between an apology and an organisational or personal admission of error or guilt. By and large, however, there was a sense from our participants that such concerns were diminishing, in part due to concerted efforts around training and awareness-raising, led by organisations themselves and by others, such as medical defence associations (providers of indemnity insurance)—as well as national information campaigns.[68]

> "You might find a situation where people felt that if you offered an apology too early, you're actually admitting guilt. And so [with] the Duty of Candour [it] was, I think, necessary to clarify what the process should be. That was very, very helpful. And I don't think that has been received at all badly, certainly in our service." (Participant 22, Community and mental health services trust)

> "People know what it means. People realise that apologising is not admitting guilt, but it is possible to apologise for an event. Unlike in the past when there was an incident of any kind, that you would contact the trust solicitor if you felt that you needed to and the first thing [they] will say: 'Do not apologise'." (Participant 20, Community and mental health services trust)

> "There was almost a culture of being taught not to say sorry, because that was an admission of guilt and it wasn't what we did. And it's trying to be two people, the professional nurse rather than human being. But I think that's changing, or changed in the last three or four, four, five years." (Participant 37, Ambulance trust)

For some participants, then, there was a sense that the Duty of Candour was itself helping to shift staff perceptions of norms around appropriate communication with patients, giving them licence to be a little more candid in their discussions. As we see below, however, it would be premature to suggest that such a shift constituted a cultural change.

By and large, participants indicated that awareness of the Duty of Candour, and when it applied, was strong in their organisations. Many described how their organisations had provided extensive training and information sessions for staff when the Duty of Candour was introduced—in part, they acknowledged, because of the legal requirement, and because of its place in the CQC's regulatory regime.

> "We did an awful lot of Duty of Candour awareness sessions, and we set out to train every member of staff in what Duty of Candour was. So we did a big awareness campaign, and it's a message that is reiterated at all team meetings, at team brief, which is our organisational mechanism for face-to-face communication with the exec team. I think, to be fair, it was here, we had to implement it. But I think we just picked it up and ran with it to be honest. And certainly now staff's awareness of it has picked up when we do all our CQC mock inspections; we have posters up around the trust around it." (Participant 6, Acute trust)

But there was much variation in between, and sometimes within, organisations in the way that they had interpreted and acted upon the Duty beyond awareness-raising. One participant compared the enactment of the Duty in two units in a single organisation:

> “I’ve never seen such an honest and open response to the client’s complaint, in accordance with the Duty of Candour, that has gone a huge way to bringing the parties together, has reduced the litigation process and everything that goes with that. And it was a really, really good example of the benefits that can be gained from the Duty of Candour, and restoring the patient and clinician relationship. Within that same trust, within a different department—the maternity ward—[there was a serious incident resulting in an infant] resuscitated with brain injury. And I have just literally been given the serious untoward incident [report], which is a single-page document. That is complete and utter shambolic attempt to deal with a serious untoward incident and the Duty of Candour that follows from that.” (Participant 40, Commentator – medical negligence solicitor)

Participants found that implementing the Duty was operationally challenging. Systems for tracking and monitoring disclosures were required, as was coordination with wider processes, including incident investigation (see Section 3.2). Efforts to ensure that the Duty of Candour was incorporated into routine processes and practices appeared to be more advanced in some organisations than others. Some participants were able, for example, to describe the integration of the Duty of Candour into their technological infrastructure, which helped to ensure timely disclosures, compliance with documentary requirements, and clear lines of oversight within the organisation. In some cases a sophisticated socio-technical infrastructure was in place to ensure identification, actioning and documenting of disclosures, with roles and teams dedicated to the process.

> “Duty of Candour is now mandated, so it’s a mandated field within our incident reporting that has to be confirmed that the Duty of Candour has been met and conversations been happening. We’re a high-reporting organisation, so that helps from that particular perspective. And actually what we’re now doing as part of our significant events, anything that meets the threshold in terms of a significant event requiring investigation, is that all of those incidents have an exec lead and an operational lead, and the exec lead takes on an element of that Duty of Candour [disclosure].” (Participant 7, Acute trust)

> “How it’s put into practice in this organisation is obviously any clinical incident would go onto Datix. Those are all screened, obviously. And so therefore anything that meets the threshold, […] so where moderate harm or above has been done, then my team would coordinate that quite closely within this organisation. So the formal Duty of *Candour* process is monitored by my patient safety team, and we will ensure that contact is made with the right appropriate person, depending on the situation. We will ensure that the Duty of Candour one letter goes out, and we screen all those and see them all before they go out.” (Participant 30, Community and mental health trust)

Yet as others noted, incorporation into processes did not necessarily equate to integration into an ethos of patient-centred care. The Duty of Candour—similar to other initiatives (see sections 3.2 to 3.4, and section 3.5.1, and also the findings of WP4 in Chapters 6 and 7)—risked becoming an exercise in bureaucracy, driven by the logic and requirements of compliance and reporting (for example, to provide evidence of activity for CQC inspections) rather than by a will to openness. In itself, the Duty—along with the requirements around timing and reporting—represented an intervention that could indeed be implemented rather mechanistically. This meant that effort was needed to balance accountability requirements with patient-centredness, particularly where patients’ needs and preferences might not automatically be best served by the default approach to disclosure.

> “People are so focused on the figures and the pressure, and filling in spreadsheet and templates. So I think we’ve created a lot of additional work, and that seems to sit different in different places in different levels of the organisation. And so we’re doing all the returns. It would just be really nice to think that everybody just understood it and knew it was important. […] People reel off, ‘We need to do this that and the other about Duty of Candour’, and I’m thinking, ‘But that should be the norm’. We should communicate so well with our patients and families that we don’t have to talk about Duty of Candour and

> tick a box; we should know that when something's happened it's a normal part of the process that we do something about it and tell the family." (Participant 16, Acute trust)

> "There's too many organisations that have used it as a tick box. So they send a standard letter to a family member, and the language, the vocabulary that's used in the letter isn't really an apology, it's a token gesture of meeting a statutory requirement. So I think the principle's right, and some organisations have got it right, but I think there are some organisations that have got it very wrong." (Participant 48, Commentator – national arm's length organisation)

Participants found that extensive work was needed beyond simple implementation if their efforts were to have a chance of initiating cultural change among their colleagues.[64] Participants within NHS organisations, often with experience of more than one, similarly highlighted how organisational culture could mediate the impact of the policy. Where organisations had already been seeking to embrace the spirit of the Duty of Candour prior to its introduction, it might be a somewhat more straightforward task.

> "Before Duty of Candour came out we had a Being Open policy. And then we just adapted the Being Open policy to put other legal bits in around the Duty of Candour. They'd always worked that way, since I came in 2011. So that was part of our risk management strategy, about being open, and that true learning and just, no-blame culture, that that's the way we work. So it was already there, so actually it was nothing new to put anything extra in to do it, apart from making sure that we had the evidence that those conversations have been had within that timescale of 10 days." (Participant 1, Acute trust)

We explore the efforts that senior stakeholders described to move from a 'compliance-driven' to an 'ethos-driven' approach to putting initiatives into practice in section 3.5.6, and this is a core theme of WP4 (Chapters 6 and 7).

3.1.2. Specific challenges in implementing the Duty of Candour

In seeking to ensure that the Duty of Candour was seen as more than an exercise in compliance, participants described a number of challenges. First, the language, legal requirements and accountability arrangements could themselves get in the way of what participants viewed as a more patient- and family-centred realisation of the Duty. Participants noted a particular tension between allowing staff to make disclosures their own way, sensitive to the wishes of patients and family members and personalised in their choice of delivery and phrasing, and the need to demonstrate formally that all the requirements of a Duty of Candour disclosure had been met. There might be particular problems where patients or family members expressly declared their wish to be treated differently, or where following the statutory timescale might risk adding insult to injury.

> "Francis has brought some more formal language to things we were probably already doing. And in some ways that language is unhelpful, if you're talking Duty of Candour rather than saying sorry. How staff translate that into a more meaningful way, and the sense of a more bureaucratic, 'got to evidence to the CCG that we've done this Duty of Candour' thing, rather than being really in the moment clinically with people, saying we're sorry this has happened. [...] It's that whole 'if it's not written down it hasn't happened'. And again, Duty of Candour's a prime example, where we'll have had great conversations with families, who say 'Just please don't send me a letter, I don't want it'. And then we feel that we have to have an e-mail trail to prove that we've thought about it." (Participant 31, Community and mental health services trust)

> "I think the timescale issue is another issue that's caused the tick box, especially that first apology within 10 days, and then the letter. I just think organisations have had to

> implement it in a way that suits them, which might not suit the patient." (Participant 48, Commentator – national arm's length organisation)

Organisations sought to tread a balance between giving staff liberty to communicate with patients in their own way and ensuring that disclosures included the requisite content.

> "Everybody's got a slightly different style, but we [...] now have a template that they use, which basically guides them through." (Participant 11, Acute trust)

Second, although participants felt (as noted above) that awareness of the Duty of Candour was generally good among their staff—including the recognition that apologies did not in themselves amount to admissions of guilt that could make staff vulnerable to disciplinary or legal action—they did nevertheless note that some staff groups remained sceptical. Some staff felt that regardless of the legal situation, making a disclosure of this kind was not their responsibility. Participants also noted, again, that the language around the Duty of Candour, and a perception among colleagues at the sharp end that it was something that was being imposed from above, could provoke anxiety. No amount of reassurance about the protections afforded to staff could entirely assuage such fears, especially in an environment in which—it was perceived—acts of candour could be subsequently used against clinical staff, by professional regulators or in criminal courts.[69]

> "I think that actually by frightening people, by saying this is a statutory Duty of Candour, doesn't necessarily lead people to being more open. I think we just need to make sure that people are being open and they don't feel that it's because there's a penalty attached if they're not." (Participant 19, Community and mental health services trust)

Participants noted occasional debates among staff about who would be landed with the task of making a disclosure: it was a difficult process for many, notwithstanding the provision of training. For staff making a disclosure in line with the Duty, there was a major time burden on top of the emotional burden such staff were often contending with: as Participant 28 (Community and mental health services trust) put it, "fulfilling duty of candour properly is very time-consuming in itself."

Third, on a much more mundane level, there were practical difficulties in determining when the Duty of Candour applied. Participants noted that the process of determining that moderate (or worse) harm had occurred was not straightforward. Different clinicians would make different judgements around the thresholds. Assessing psychological harm could be particularly challenging. Determining how long-lasting the impact of harm would be was difficult. And sometimes, harm would manifest long after the events that precipitated it had taken place, making causation and responsibility difficult to identify.

> "I know it's in black and white, but that is very open to interpretation I think. And I think organisations even struggle with what does and doesn't meet that formal threshold at times." (Participant 28, Community and mental health services trust)

Participants did not suggest any conscious or conspiratorial effort to systematically downgrade assessments of harm—for example with a view to defending organisational reputation, avoiding the risk of litigation, or concealing problems from patients. They did, though, note that judgements could vary, particularly at the border between low and moderate harm. We return to this point in more detail in Chapter 6.

Fourth, participants noted that challenges could arise in discharging the Duty of Candour where patients came to harm in more complex care settings. While responsibility and accountability for the care of acute inpatients undergoing discrete episodes of treatment was comparatively straightforward, where patients were cared for in the community, perhaps with multimorbidity and with the involvement of multiple teams, identifying and responding to harm could be much more difficult. Some participants described disputes between organisations about how and when to make disclosures under the Duty of Candour. Moreover, where there was multi-agency involvement, coordination with organisations outside the healthcare system (not subject to the Duty of Candour, and with their own policies around data sharing, safeguarding, investigation, and being open with clients) was far from straightforward, for example in timing of and approach to disclosure, and in investigating the causes of harm.

> "Because of course we overlap with, from a mental health perspective, other organisations, with local authorities, potentially with police, with GPs. And of course you can't always give—you don't, as an individual organisation, always have the answers. And depending on how those other organisations approach Duty of Candour, very much depends on how you're able to deliver that yourself, when you've got multiagency type things going on." (Participant 28, Community and mental health services trust)

Fifth, and finally, participants based in mental health and community health services trusts in particular noted challenges around the Duty of Candour when patients did not wish for details of their diagnosis or treatment to be disclosed to family members. In cases where patients had died while under the care of mental health teams, participants might face legal and ethical quandaries about how much should be disclosed and to whom.

> "It's that whole thing, isn't it: families are complicated, and if somebody has made a decision not to share their information with their family while they were alive, but then have passed away. So we have had that a couple of times. And again I think it's that thing of you have to deal with each case on its individual merit. And it has created quite a lot of internal discussion and debate around what the best course of action is. [...] So we do have a Mental Health Act and legislation department, so they'll often give us the legal bit. And we also use our information governance teams. But also we are then mindful of involving the clinicians who've been involved in that patient's care, because often they are able to articulate what that patient's perception was of that family relationship, and what the impact may well be. And then it just tends to be a discussion, making sure that we're complying with the law and the Data Protection Act, but at the same time, making sure that we are honouring the patient's wishes as far as possible." (Participant 29, Community and mental health services trust)

The challenges of operationalising the Duty of Candour in an ethically defensible and legally compliant way in mental health trusts in particular, and non-acute settings more broadly, exemplified a broader sense among some participants that the policy interventions post-Francis had been modelled on the acute care setting, with little consideration for how they might be put into practice elsewhere. We return to this theme later on.

3.1.3. The Duty of Candour and litigation

There is some debate over whether disclosures made under the statutory Duty of Candour are likely to increase or reduce the likelihood of litigation. Handled well, openness with patients and families might satisfy them that organisations are taking their concerns seriously, and reduce the likelihood of litigation—reflecting the experiences of communication-and-resolution programmes elsewhere.[70] Indeed, one of the prospective measures of success listed by NHS Resolution in its inaugural five-year strategy is "a drop in the number of 'frustration' claims which have only been made because of a failing earlier in the process, such as lack of candour."[71] On the other hand, disclosures might also have the effect of making an error more visible to patients and family members, encouraging litigation.[72] For the purposes of this report, we are concerned less with the relative validity of such assertions, and more with their impact on the views of those responsible for implementing and enacting openness—and how this affected their approach to putting the Duty of Candour into practice.

Board-level staff members who responded to our survey (WP2—see section 4.1) expressed mixed views about the relationship between the Duty of Candour and the likelihood that patients and family members' would pursue legal action against NHS organisations. By and large, participants in telephone interviews took the view that the introduction of the Duty of Candour in itself was unlikely to have a direct bearing on litigation, for better or worse.

> “I don’t think it’s affected it at all. I would say that if people are going to litigate they’re going to litigate, with or without the Duty of Candour. So I haven’t seen an increase.” (Participant 24, Community and mental health services trust)

Where there was a sense that the Duty of Candour might interact with litigation was in the approach to its implementation, and the supporting activities that surrounded it. Again, several participants noted that their organisations had already begun initiatives in the spirit of openness when things went wrong before 2014, and that these seemed to be helping to avoid unnecessarily adversarial interactions with patients and family members.

> “I don’t know if that’s directly linked to Duty of Candour, but a lot more of our complaints we’ve managed to tag through local resolution. So let’s just meet, let’s sit in a room, have a chat through, meet the consultant, meet the nursing team, whoever, and chat through, and recognise the fact yeah, we could have done this better, and actually next time we’ll do this. So I think what we’ve seen, particularly in the last 12 months, is that far more of our complaints are resolved at local resolution. [...] And I think actually what that then does, it takes away any air of suspicion, it takes away any air of actually what are they hiding here, I need to put in a complaint or, ‘I need to take to litigation, because actually I’ve uncovered this issue and so what else are they not telling me?’” (Participant 7, Acute trust)

Accounts from patients and family members in WP4—reported in Chapter 6—suggest how the appearance of defensiveness or opacity might easily result in a sense of confrontation that could rapidly take on its own momentum, and come to govern interaction between healthcare organisations and families when things went wrong.

3.2. Incident investigation

While not introduced in direct response to the Francis inquiry, changes to the serious incident investigation framework were made in 2015,[29] following a report from the CQC that found inconsistencies and deficits in the way that many organisations were carrying them out.[30] The revisions to the framework included efforts to ensure openness (including involvement of patients and family members) and secure learning—though there is some evidence to suggest that compliance with the obligation to involve patients in the process is inconsistent.[67] A 60-day timeframe for the completion of serious incident investigations was also introduced, with a view to securing learning promptly and simplifying the monitoring of progress. Further guidance has been provided on involving families when patients die in the course of care from NHS organisations, emphasising the need to provide clear and accurate information sensitively, and involve family members on an equal footing in investigation processes, from setting the terms of reference forward.[73] Serious incidents involving harm to patients would also typically require disclosures under the statutory Duty of Candour, and participants in our study often discussed the two areas in tandem.

Some time after data collection for WP1 was completed, NHS England made further changes to the framework for investigating serious incidents,[74] following a review of how the process was working in practice. The newly introduced Patient Safety Incident Response Framework incorporated changes to the expected timeframe for investigations, as well as modified guidance for involving patients and families in the process. The views expressed by our participants predate this change, and relate to the implementation of the 2015 framework.[29]

Respondents to our survey (WP2) indicated that the Serious Incident Framework had been one of the more challenging aspects of policy to implement, with 70% reporting that resourcing issues were ‘somewhat’, ‘very’ or ‘extremely’ challenging, and nearly half stating that commissioners’ expectations were ‘somewhat’, ‘very’ or ‘extremely’ challenging (section 4.2). Participants in the telephone interviews described how the serious incident reporting process was at risk of becoming somewhat driven by bureaucracy, with components associated with particular standards, targets and deadlines prioritised over others, sometimes in ways that undermined the goal and spirit of openness policies.

> "You have different requirements. So we've got the operational NHS contract requirement that within 10 working days you should be informing the relevant person that an incident has occurred. Then if it's a serious incident you have 60 days to investigate and develop an action plan. And then obviously there's a requirement after that to then inform the patients and families. So that, there's no real deadline to that. And that's the bit that can sometimes slip." (Participant 15, Acute trust)

The approach taken to managing the serious incident investigation process varied substantially between organisations. Some trusts had taken on responsibility centrally, seeking to standardise and optimise the process, lead training to create a cadre of highly skilled investigators among their staff, provide oversight from non-executive directors with a view to securing consistency, timeliness, and rapid learning across the organisation from investigations that were undertaken. Others remained much more piecemeal in their approach to incident investigation.

> "It's interesting how different organisations manage it. And one of the things I come across, linking in with people that deal with serious incidents from a number of organisations, is I am constantly surprised by how differently people do manage the process. And how differently: some trusts do really leave services just to get on with it. Which I always find quite sad really, because actually, you might have some poor service that's never had to deal with anything like this before." (Participant 28, Community and mental health services trust)

Participants not employed by NHS provider organisations noted variation across NHS trusts, particularly in relation to the overall investment made in ensuring high-quality investigations—exemplified, for instance, in the approach taken to training. Despite the Serious Incident Framework's stipulation that investigations be undertaken by those with sufficient training, often in practice this amounted to "a couple of hours' training, left to get on with it in an office on their own, and it's not root cause analysis methodology" (Participant 48, Commentator – national arm's length organisation).

Besides training, other key challenges included coordinating between the groups that needed to be involved in the investigation process (including those outside healthcare organisations such as coroners' courts), and resourcing investigations more broadly. Similar to their experience of the Duty of Candour (section 3.1.2), participants in community settings noted the difficulties of undertaking investigations where care provision crossed sector or organisational boundaries, and different organisations had different approaches to investigation—and different propensity to receive and act upon learning. Coordination and integration of response were especially problematic. Accordingly, the possibility existed that problems at the interfaces of organisations—noted, of course, to be a particular site of risk, for example in relation to discharges and other transfers of care[75]—would go under-analysed and unaddressed.

> "Often what you find in our investigations is some of our recommendations may well be in relation to other agencies, but we end up having to take those recommendations out, because they've not been part of the investigation, so how can we make recommendations for another organisation, which would be wrong for us to do. Because it's fine if an incident happened within our organisation and didn't affect any other agency, but if you think about some patients who might have moved between social care, acute and community services, there are probably issues in relation to transition between each different agency, referral routes and patient pathways, that actually we could learn a lot from an incident." (Participant 29, Community and mental health services trust)

There was a keen sense among several participants that the resource available to undertake investigations was not always deployed optimally: organisations continued to seek to spread the resource too thinly, and in consequence undertook a large number of investigations of variable quality, that resulted in at best mixed learning and impact on systems, processes, training and behaviour. Participants who were not based in NHS provider organisations also suggested that, as with Duty of Candour disclosures, the quality of investigations could vary, between and within organisations. They noted particular variation in the degree to which patients and families were effectively involved in the process.

> "If there's an investigation that will follow on the back of [a Duty of Candour disclosure], [patients or family members] should be involved in developing the terms of reference, they should have a meeting with the person that's leading the investigation, to hear what their side of the story is. Because their record of events should feed into a timeline, so that investigation team can have a full look at what happened. But we rarely see that done in a really effective way." (Participant 44, Commentator – national arm's length organisation)

> "The quality of investigations is very definitely variable. I think the question is: are either the patients or the relatives being informed, and are they being informed in a way that is open, at the same time trying to be mindful of what one is actually saying to a patient? So if they have got the wrong dose of a drug, and if that has caused harm, how do you get that across to the patient in a way that is bearable to both parties?" (Participant 45, Commentator – national arm's length organisation)

Where patients and family members were effectively involved, participants reported that this could be beneficial to the process, as well as helping to rebuild damaged relationships with those affected.

> "[During an investigation into a fall,] one of my team went and spoke with the family, and the family said, 'Well all the bells are removed out of the reach of patients, and they're taped up, so nobody can ring any bells at night'. And we never knew that. And so we went in to check, and you could see, because there were sticky marks all around the bells, where nursing staff had taped them up because they didn't want to be disturbed, and that's the reason why the patient fell. So families give you greater insight into how things were managed." (Participant 25, Community and mental health services trust)

> "The feedback we've had from the patients is involving me has helped me, you've helped me grieve or reach closure, which has been really quite powerful. So they're the examples where we've got it really nailed on and it's been really good." (Participant 13, Acute trust)

Some participants reported how their organisations had sought to synthesise insights from the investigations they and other organisations had undertaken, to identify patterns and address underlying risks. A participant from a community and mental health services trust, for example, described how learning around deaths among people with learning disabilities in NHS care had given rise to efforts to reduce incidence of pneumonia, and ensure prompt intervention. Others described going beyond the stipulations of the Serious Incident Framework to close the feedback loop and make maximum use of the learning obtained.

> "Every serious incident will have a root cause analysis. Every serious incident will have an after-action review, and that will be led by one of the corporate clinical teams, so that we can get a lessons learnt out of it. And then we do have regular, both webinars and seminar days for matrons, that are based around lessons learned, and I would bring in, I don't know, CQC or a lawyer, or if there was a trend or something like that." (Participant 38, Non-NHS provider organisation)

Many participants were able to give examples of investigations that had been done well, and where multiple benefits had accrued: reconciliation with patients and families; reflection and learning for individual clinicians; improved systems and processes at the organisational level and beyond.

The sense from participants overall, however, was that under the regime that prevailed at the time of this part of our study (mid-to-late 2017 and early 2018), organisations struggled to achieve high-quality investigations consistently—and some organisations were failing to undertake high-quality investigations, led by appropriately trained staff with sufficient, dedicated capacity, at all. Bureaucratic requirements could help to ensure that minimum standards were upheld, but often they could translate into a box-ticking exercise, such that some organisations risked meeting the requirement but missing the point:[76] complying with expectations about what should be investigated and how promptly, but failing to derive learning to improve quality and avoid similar incidents in future.

The revisions to the NHS's approach to investigating serious incidents in England that have taken place since our data collection account for some of these concerns, and acknowledge that NHS organisations tended to "struggle to deliver" the expectations set out in the Serious Incident Framework. There is a welcome emphasis in the *NHS Patient Safety Strategy*, for example, on the quality of investigations over their quantity, as well as on national standards around training.[74] The introduction of HSIB as a body to scale incident investigation and learning to the national level also seeks to maximise the value derived from investment in investigation, with a focus on potential as well as actual harm and on the scope for system-wide learning.[77]

Our findings suggest that to achieve improvement from investigations at a local level, adequate resourcing will be crucial, but so too will an emphasis on learning. Descents into formalising and process-driven behaviours aimed at demonstrating compliance should be avoided. The new Patient Safety Incident Response Framework offers both flexibility (for example around timescales and around the approach to involving patients and families) and standardisation (for example around training requirements and informing relatives) that are to be welcomed in view of our findings about the problems of the earlier regime. Attention is also required, however, to the approaches taken by organisations to hearing and applying the lessons of investigations, particularly when they have implications for how they work together across organisational boundaries.

3.3. Freedom to Speak Up Guardians

A troubling finding of the Mid Staffordshire public inquiry was that there was some awareness of poor-quality care at the time, but that people with concerns felt unable to speak up about them—and those in positions of power ignored or otherwise failed to act on concerns that did reach them.[5,78] Following the publication of the inquiry's findings, its chair Sir Robert Francis led *Freedom to Speak Up*,[11] a review of attitudes towards speaking up across the NHS that involved, among other things, a survey and confidential submissions from NHS staff on their experiences of raising concerns.

A central recommendation of the review was the introduction of a new role—the Freedom to Speak Up Guardian—in every NHS provider organisation. Guardians were to act as a confidential point of contact for people with concerns, offer a conduit to ensure that concerns were dealt with appropriately, provide training and support for a culture of openness across organisations, and report to boards about trends and progress in culture and behaviour around speaking up. Alongside the Guardian role itself, the review also recommended clear structures for raising and escalating concerns within organisations, better training, and support for 'whistleblowers' seeking alternative employment after raising concerns in their own organisations.

The government accepted many of these recommendations, including requiring every NHS provider organisation to appoint a Guardian as "a genuinely independent figure" to encourage the raising of concerns. It also established a National Guardian, hosted by the CQC, as "a key leader in a national renewal and reinvigoration of an open and learning NHS culture."[13] Guardians are key informants for the CQC in its new 'Well-led' inspections (see also section 3.4).[79]

3.3.1. Implementation

As with the statutory Duty of Candour (section 3.1.1), we found little dispute among participants about the desirability in principle of Freedom to Speak Up Guardians, notwithstanding the fact that they were an additional, unfunded, demand on organisations' resources. The potential of a role dedicated to promoting a culture of speaking up, and with accountability to senior figures within the organisation, was welcomed by participants. The role's potential coordinating function, tying up 'loose ends' following the formal or informal expression of concerns and ensuring an appropriate response, was seen as valuable.

> "She follows them through the whole process, she follows through to make us account for responding to them properly. She will tell me if she's got something in a service, about a service, she doesn't think it's right, and response isn't right or the response isn't happening. And I think that's absolutely invaluable, because that's helping us get in a better state about tidying up staff concerns in the organisation where they've not been properly addressed through other methods." (Participant 27, Community and mental health services trust)
>
> "She knows her way around really; she's quite sensitive with things. But actually we've had her [come] to a number now of senior meetings, or she will approach me now about how to address something. But to some extent it's operating on the edge of our awareness as well, in terms of she's raising things that actually we might have been a little bit conscious of, or maybe things we weren't conscious of at all." (Participant 12, Acute trust)

The approach taken to implementing the role varied greatly, for example in terms of: the process for identifying and appointing Guardians; the background of those appointed; and the amount of time dedicated to the post.

Some of the participants themselves acted as Freedom to Speak Up Guardians in their roles; most were involved in the recruitment and/or management of these roles in some capacity. Recruitment processes varied from those that were fully open, inviting applications within and outside the organisation, to more bespoke appointment processes that involved identifying a handful of candidates seen as eligible and negotiating with them personally. In a few cases, participants related cases of appointments to the Guardian role that they saw as entirely inappropriate, given their positions of authority, their potential to subdue voice, and the message these appointments gave about the value placed on decisions by sharp-end clinicians to speak up.

> "In the trust I used to work for—they were one of the last to recruit a Freedom to Speak Up Guardian, and it was literally just bolted onto the Director of Nursing, who is the worst person you could have as a Freedom to Speak Up Guardian." (Participant 21, Community and mental health services trust)
>
> "They left it rather last minute in some [organisations], and some have appointed HR directors, which really isn't in the spirit of Freedom to Speak Up." (Participant 9, Acute trust)

Few organisations had a single, full-time Guardian; some had multiple Guardians (often based in different sites, and/or with different professional backgrounds) whose FTE contribution exceeded a single full-time post. This reflects surveys undertaken by the National Guardian's Office since our data collection,[80] and the findings of our own survey (section 4.2). Participants discussed the trade-off between having a junior role-holder with a greater commitment, or having a part-time Guardian who also occupied a more senior role in the organisation, and was thus potentially better placed to facilitate speaking up and ensure that concerns were heard.

Sometimes, individuals were expected to take on the responsibilities of the Guardian role on top of their existing duties, without protected time. Indeed, despite the expectation set out in the *Freedom to Speak Up* review,[11] a survey by the National Guardian's Office found that 51% of the 234 responding Freedom to Speak Up Guardians had no ring-fenced time.[81]

A fundamental challenged faced by participants in the implementation of the Guardian role was its position within and interface with other parts of their organisations' infrastructure for reporting concerns. The *Freedom to Speak Up* review suggested that the ‘branding’ of the role—in terms of its name and purpose—be consistent across NHS organisations, “so that those who move between organisations know immediately where to go for help.”[11] Similar to their experiences with the Duty of Candour (section 3.1.1), however, some organisations had already sought to act upon the recommendations arising from the Mid Staffordshire public inquiry, and had made investments in systems, roles and processes for encouraging voice, prior to the policy response. The Duty of Candour required organisations to undertake specific, time-bound processes, which could—albeit with some difficulty—be superimposed or grafted onto existing approaches. The expectations around Freedom to Speak Up, however, seemed in some ways to pose a greater challenge to organisations. A particular concern was in ensuring that the new role simplified systems for voice, rather than introducing new complication. An associated challenge was ensuring that it did not contradict or risk undermining existing mechanisms for voice.

> “My only concern is that it encourages people perhaps to side-line some of the other mechanisms by which they could resolve issues. So some of our—I would say most of our Freedom to Speak Up reports at the moment are things that really should have been—they’re not really whistleblowing, if you know what I mean: they’re issues that really could have been resolved somewhere else. [...] I think for me, in terms of the real serious whistleblowing issues, then I absolutely support Freedom to Speak Up Guardians’ role in that, because I do think that there’s—staff need that confidence. But I do think it runs the risk, like anything, of people deliberately circumventing.” (Participant 36, Ambulance service trust)

Some participants were particularly concerned about the potential of the new role, paradoxically, to undermine existing arrangements and expectations around speaking up. Guidance around implementation of the Freedom to Speak Up Guardian role from NHS Improvement suggests a particular role for Guardians in assisting people with concerns where they feel their supervisors or managers have not responded to them appropriately.[82] Some participants suggested, however, that Freedom to Speak Up Guardians risked offering a parallel pathway to voice that staff could turn to prematurely, thereby compromising healthy, open relationships between managers and their staff that encouraged speaking and listening.

More broadly, in common with the other initiatives discussed, some participants were concerned that the accountability arrangements for Guardians—and particularly the data-collection burden—risked creating distortion or distraction from the key purpose. Particularly acute for this initiative was the question of what should be taken to constitute ‘success’. As with other measures, such as levels of incident reporting, how to interpret a rise in concerns was open to debate; participants suggested that much of the low-level activity of Guardians would evade measurement, and that some of the potentially greatest benefits of the role might thus be devalued.

> “I’ve spoken to a few Speak Up Guardians, and I think we’ve all been taken a little bit by surprise by the pace at which that agenda has actually developed, to the point where I think I’ve said this before, to me, it’s becoming an industry again, within an industry. It might be missing the point.” (Participant 33, Community and mental health services trust)

> “I do feel the administration has been put round the role of the Guardian, it’s becoming a very bureaucratic exercise, and diluting what it's about. When it was launched back in October, it was a really positive launch. But there were indications then that it was going to become something that—OK, I'm sorry if it's my cynicism of the NHS, but in terms x initiative has to then be counted and double-counted, and monitored, and it then is a distraction from what it's actually about. [...] The requirement for more-or-less standard records to be kept about not only the nature of the concern, but the characteristics of the person raising the concern. The demographics, but equally whether that person was satisfied. And I think sometimes it's not always appropriate to say, ‘Are you happy with

> the approach that I've taken?’ at that particular point in time!” (Participant 22, Community and mental health services trust)

Some participants noted a broadening since the introduction of the role of the variables that organisations and Guardians themselves were expected to measure; they highlighted a risk that the bureaucratic responsibilities of the role might increasingly crowd out the practical and relational work it involved, particularly given the fact that, in the main, these were not full-time roles.

3.3.2. Realising the value of the Guardian role

Despite the challenges, the Guardian role was highly valued by many participants. Indeed, it was in the relatively routine work of Guardians that participants tended to see the most value. There was a sense from interviewees that, at least in the aftermath of the Mid Staffordshire public inquiry, they had made some progress in setting up systems that would help them to identify major problems in the quality and safety of healthcare. Efforts at national level, such as the review of mortality rates that informed the work of the review of quality at 14 hospitals,[10] had been replicated locally in the organisations of many participants, with renewed efforts to analyse metrics, reporting rates and other routinely available indicators of quality to identify areas of risk and prompt more detailed investigation as necessary. But while participants tended to be confident in the ability of such approaches to identify major hazards, aberrations and problems in the making, they were conscious that not all problems were visible to such issues.

> “Sometimes you get very longstanding management teams within a specific directorate, [and] they can stop hearing. [...] And people as a consequence feeling they can’t speak up: it’s not the norm. Everything’s alright because nobody’s said anything.” (Participant 27, Community and mental health services trust)

> “My perception is that we’re probably doing a lot better than other places, but you don’t know what you don’t know. If staff are reluctant to come to anybody and raise their concerns, how do you know that? How do you benchmark it?” (Participant 6, Acute trust)

In this light, a particularly important role for Guardians was less collection of and advocacy for specific concerns, and more their much more informal work in traversing the organisation and collecting ‘soft intelligence’ about culture, behaviour, relationships and quality. As part of their efforts to promote a culture of openness and spread awareness of available avenues for voice, Guardians had the opportunity to build relationships with people all over the organisation, and gain a much more implicit sense of where all was well, and where things might be awry. Particularly in diffuse organisations, with multiple sites and potentially diverse managerial approaches and cultures (see also section 3.5), the interpersonal relationships that Guardians developed and the corridor conversations in which they participated were especially important. Guardians could get a sense of the relative openness of different parts of the organisation, informing organisational-level surveillance and governance processes, and picking up a sense of problems in the making.

> “There are pluses on that, because you do have those working relationships with the staff and the board, and we do get to see things from the inside. [...] I can walk onto a ward and know most of the staff by name, because our turnover’s quite low. It takes me sometimes quite a long time to go between meetings because you stop and have conversations in the corridor. So I think in terms of the approachability, I think it works.” (Participant 7, Acute trust)

A more extended analysis of this potential role for Freedom to Speak Up Guardians is developed in one of our outputs from the study (Appendix F).

Many participants described the benefits of Guardians who built on their insider knowledge of the organisation to develop trusting relationships and offered an informal conduit for those who had concerns, but who for various reasons—not least their own uncertainty about their validity—did not wish to take them up formally. Participants also, though, highlighted some of the downsides that could come with a role that was very firmly located within an organisation. Most obviously, where relationships were dense and people had prior alliances and personal obligations that might not be obvious to the individual considering speaking up, the risks of speaking up might continue to outweigh the potential benefits for those with concerns.

> "In terms of the approachability, I think it works. But I also think sometimes that is a little bit of a hindrance, if someone thinks, 'Well I want to raise something anonymously'. I think there is sometimes that element around, 'Well I'm not sure to raise that because it will get back to the individuals'." (Participant 7, Acute trust)

More broadly, the formal relationship of dependence between Guardians and their organisations was also seen as potentially problematic. While policy emphasised the independence of the role,[13] and steps had been taken to strengthen Guardians' autonomy (such as the relationship with the CQC and the introduction of the National Guardian's Office), several participants noted that their status as employees risked compromising perceptions, at least, of the independence of the role. Some of their organisations had taken steps to mitigate this, for example by introducing a line of accountability from the Guardian to a relatively independent senior figure (such as the trust secretary or a non-executive director), or by contracting with an external organisation to host the Guardian or provide alternative routes for voice. Nevertheless, some participants expressed disappointment at how the role had been realised in most organisations, and suggested that this would do little to make people who had previously been reluctant to speak up more likely to do so.

> "We've found more [concerns] have come through external routes. Which I think says something about the role of the Guardian. [...] It could have been strengthened [by making the role] totally independent. And I know some people are employed in a substantive role, [...] but they're still paid by that organisation, and they still account to chief exec, or the chair, or directors, who sometimes have a vested interest not to make some changes." (Participant 22, Mental health services and community health services trust)

At a more general level, moreover, the extent to which the introduction of a new role in big organisations would do much to address the major structural impediments to voice was doubtful. The deterrents to voice in organisations inside and outside healthcare have been well studied,[83–85] and as Attree puts it,[86] speaking up remains a "high risk:low benefit act," given the high likelihood of negative formal or informal repercussions, and the relatively remote prospect of change or improvements resulting from it. As we explore in more detail below (section 3.5), moreover, the legacies of past responses to acts of openness, such as speaking up—from inaction to retaliation—could cast a long shadow over claims of a new openness.

We consider the contribution of the Freedom to Speak Up programme in further detail in our organisational case studies in Chapter 7. An ongoing evaluation of the implementation and impact of the Freedom to Speak Up Guardian in the English and Welsh NHS, led by Cardiff University, will be completed in late 2020.

3.4. The new Care Quality Commission inspection regime

Both the CQC and its predecessor, the Healthcare Commission, were criticised in the Mid Staffordshire public inquiry. Their standards and criteria, their approach to inspection, their response to what they found in the trust, and their coordination with other organisations in the regulatory landscape were among the areas found wanting.[5]

The CQC adopted a new approach to the inspection and rating of providers of healthcare in the wake of the report of the public inquiry, seeking to develop “a more targeted, responsive and collaborative” model of inspection and reporting,[87] drawing on the principles of risk-based regulation set out in the Hampton report.[88] Among other things, this included: “an intelligence-driven approach to regulation”[87] that involved more targeted and risk-based approach to inspection (piloted in the identification of 14 hospitals with higher-than-expected standardised mortality ratios[10]) and support; the definition of a new domain for inspection and rating—‘Well-led’; and greater reliance on a broader range of sources of evidence, including use of unannounced inspections to gain greater insight into the quality of care as provided on a day-to-day basis.[87] Implicit in much of this new model is a more continuous relationship with trusts, with a view to improvement as well as inspection, and less reliant on punitive, episodic encounters.

Additionally, the CQC was given the power to prosecute healthcare organisations under criminal law, with a view to addressing a gap identified by Francis between the responsibilities of the CQC and the Health and Safety Executive, which at the time of the disaster at Mid Staffordshire neither had been willing to fill. In 2017 the CQC completed its first successful prosecution of Southern Health, which was fined £125,000.[89] Further corporate and individual cases have followed, most recently of a nursing home provider and its former manager.[90] The Commission has also sought to move towards inspections that reflect newly emerging integrated models for organisation and delivery of care developed since the NHS *Five Year Forward View*,[91] such as integrated care systems, though this was not a major feature of our interviews.

Most people we interviewed made some comment on the CQC’s new regime. Several identified a tangible evolution in the CQC’s approach to inspection and its broader relationship with healthcare organisations, largely for the better. Participants noted that a more mature, adult-to-adult relationship between trusts and regulator presented risks, but could be made to be work effectively if care was given to how it would operate.

> “I think historically what we were seeing were 60, 70 inspectors turn up at the front door, crawl over everything, ask for lots of data on the day, and write a report. And I suppose our argument on those elements were actually how much can you do in that short period of time—and actually it is very subjective. Whereas I think with the new process, it feels far more inclusive. So obviously we’ve now got far more regular relationship meeting with the CQC, so again it’s that open, no surprises. So I meet them every six weeks, so they know the organisation; the fact then that the inspectors that know the organisation then turn up unannounced, so we’ve got them as the core inspectors today and tomorrow. Then the triangulation with NHS Improvement, because obviously NHS Improvement know us well as well, and then the ‘Well-led’. It may come back to bite me, and it will come down to actually what we see in terms of the report at the end of it, but it feels like what we will get at the end of this is probably a far more reflective report.” (Participant 17, Acute trust)

> “I think our last report did some of this, it takes a really holistic view of an organisation. And really tries to understand the challenges that each organisation’s facing. And within the NHS I don’t think that a hospital is a hospital is a hospital.” (Participant 13, Acute trust)

Participants found that regional CQC leads, with dedicated responsibility for a set of organisations, were helping to facilitate this more continuous and open relationship. Several described helpful discussions with their leads that helped to set the tone for inspections by providing context, and could be fruitful in ensuring that the insights of the regulator could be used towards improvement efforts.

> “I do have to have a relationship now with the CQC, and I’ve spoken to [one] on the phone. I think that will help that new relationship. I know the inspector for [area] was saying it’s a new working for them as well. And it’s quite difficult in some respects, because you’re going to become more friendly with your local trusts, but you’re still

> having to keep those professional boundaries in place. I think it will be really good in some ways, because they will be able to do unannounced inspections. I think that's really important for patients' trust. I think in a way a lot of staff would prefer that, because having been in the NHS, been through CQC inspections, the amount of preparation that goes into a CQC inspection, it never feels quite right to us either." (Participant 7, Acute trust)

> "Our relationship leads from CQC will come in and ask our opinion on things. And we'll share what we're doing, and so on. So it—I think it is changing. [...] Because of the role I do, I see all of the regulators as critical friends." (Participant 36, Ambulance services trust)

The focus on the 'Well-led' domain was largely welcomed, as was the commitment to greater reliance on the insights of staff at the sharp end of care, patients and carers, which were seen to provide inspectors with insights into the health of organisational culture. The provision of regular 'insight reports' by the Commission between inspections, offering analytics, profiling and benchmarking against other organisations, was especially welcomed by some participants as an addition that made the CQC's contribution to improvement more useful on an ongoing basis.

Several participants indicated that their experiences suggested that the quality of inspections and inspectors could vary. Many participants felt strongly that there was inconsistency in the Commission's approach, with some inspectors and even whole regions seen as more lenient than others. Inspectors not currently employed by healthcare organisations were seen as sometimes espousing views of appropriate care that were not realistic or viable. Those who were employed elsewhere were sometimes seen as lacking understanding of differences in organisational set-up. Some participants recounted experiences of whole inspection reports (and ratings) being coloured by the impression of a single investigator, who in turn had relied on just one or two experiences or conversations. While the reduction in the scale of inspections was welcomed, participants felt that it brought with it the risk of relying even more heavily on individual inspectors, encounters and discussions that might be atypical of the usual quality of care—for better or worse.

> "We get inspected at times by people that make comparisons to their own organisations, without understanding the logistics of a particular organisation and the environment that you're in. And on two previous inspections I've been criticised for not providing female psychiatric intensive care. But I'm not commissioned to provide it. So if I'm not commissioned to provide it, how can I? I think some of the people that lead inspectors have not got the experience or the skills to communicate at an executive strategic level." (Participant 30, Community and mental health services trust)

> "The enormity of having 50 inspectors turn up to your site for four days, and trying to keep everyone operational and trying to keep staff kind of calm. And what I mean by that is our staff were really up for being inspected, but it is an extra pressure, isn't it, on top of their day job, to think well I'm going to do this and maybe the inspectors will turn up to the ward, what are they going to ask me, all those kind of anxieties. So it does feel more manageable. [...] What worries me with the new process is that if they chose the wrong area to go and look at, you know, you could hit the jackpot and have four areas that are all doing brilliantly, but you could have the other four core services that are not doing quite so well." (Participant 14, Acute trust)

Participants understood the rationale for the more risk-based approach to inspection, for the 'Well-led' domain and for the unannounced inspections. Generally they welcomed the prospect of a more focused inspection regime, in place of a periodic, intensive visits involving legions of inspectors that many saw as overwhelming. This welcome was tempered by the continued sense that, regardless of the appropriateness of the focus or the breadth of sources of evidence deployed, the outcomes of inspections would still inevitably be affected by luck—and that more targeted inspections could risk missing well rated units that were seeing sharp declines in performance, or were becoming complacent.

Perhaps the most acute challenge identified by participants was how to reconcile the (inevitably imperfect) validity and reliability of ratings—and the need for transparency in communicating them to stakeholders, particularly commissioners, patients and the public—with the demoralising potential of a rating that fell short of expectations. Several participants highlighted the crudeness of a four-point rating system. Some expressed doubts about the transparency of ratings ("their rating formula is so complex, that unless you work in the darkened room with the CQC" it is opaque—Participant 30, Community and mental health services trust). Judgements at the thresholds between ratings, they argued, would always be marginal, yet the consequences of falling one side or the other of the boundary could be immense—particularly between 'Good' and 'Requires improvement'. For all the efforts to improve the validity of inspections, including diversifying the sources of evidence and relying to a greater extent on unannounced inspection, participants still felt that inspectors could still be dazzled by "smoke and mirrors" when they visited.

> "The way that inspections have been done in the past is wide open to misinterpretation, and so much rests on it. Some organisations I know have not had the appropriate assessment, or not had the right score at the end of the day, because it's based on a parachute-drop inspection that might take a few days. There's always an element of grey around the edges with these things, and hopefully they get it right. I just think that the implications of getting it wrong far outweigh the robustness of the process, if that makes sense. So it's too easy to get it wrong. [...] If you get it wrong and the organisation scores more lowly than it ought to have, it can be quite devastating. It can have serious implications for some individuals. And for me that's dangerous." (Participant 26, Community and mental health services trust)

Notwithstanding the changes following Francis, CQC inspection results remained high-stakes for those in senior positions. A poor rating was described as having potentially huge consequences for the morale of staff across the organisation. Accordingly, participants described continued efforts by organisations to play the inspection 'game'. Indeed, the possibility of an unannounced visit meant that further efforts were made in some organisations to 'prep' staff for the questions they were likely to be asked, along with efforts to ensure that inspectors did not interview staff members less likely to toe the organisational line.

As noted above in our discussions of the Duty of Candour, the investigation of serious incidents, and Freedom to Speak Up, there was a clear sense among some that accountability brought with it a temptation to undertake measures that would secure paper compliance while failing to address the real-world objective. Similarly, when a disappointing verdict from the CQC was announced, participants recounted that the profundity of the reputational consequences would orient organisations towards defensiveness rather than learning—or even towards victimisation of those seen as 'culpable' for the poor rating.

> "What I see from the organisation side is they go in to defence mode when the report comes through for factual accuracy. So you get a group of people saying, 'That isn't how it works round here, that's wrong'. And actually that's what they found out on the day, that's what, what people said. [...] The other thing I've seen is when somebody blew the whistle to the CQC, instead of focusing on what the issue was, they were trying to work out who'd done it. I thought was dreadful. That really saddened me, that we were seriously still in that culture of trying to work out who blew the whistle, rather than immediately looking to see what risks we've got and what can we do to prevent it happening." (Participant 16, Acute trust)

More broadly, one of the key issues identified by Francis in the Mid Staffordshire public inquiry[5]—that of the clutter of regulatory organisations, and associated potential for both gaps in coverage and 'priority thickets' full of competing efforts to assess the same thing[49]—remained problematic for some participants. Talk of greater coordination between, for example, the CQC and NHS Improvement was reported by some interviewees to have failed to materialise.

> "If I had to make a comment at all, it's just that regulation is very burdensome. Not because of any individual regulator, but because when you've got the NMC, the CQC, NHSE, NHSI, all wanting the same assurance, but in different ways, becomes really, really burdensome. There's one thing that I think would make life a lot easier, it's if everybody agreed on one way of reporting. One lot of information that everybody shares. That would make it so much easier." (Participant 11, Acute trust)

Again, here, there was a palpable sense that the burden of bureaucracy associated with the regulatory regime risked crowding out the underlying regulatory purpose. For organisations that had received less-than-favourable reviews from inspectors, the potential for multiple, parallel interventions, well meaning but with bureaucratic overheads and accountability expectations that were poorly aligned, could be overwhelming.

> "We're in a period of very, very heavy regulation for us. So we've got an assessment with NHSI in early November, we've got the CQC, we're in the new regime, we're part of that, so we know we've got an unannounced inspection coming up, and we've got our 'Well-led' inspection at the end of November. We've got a very heavy period for us of regulation. It's all overlapping. And we've also had CCG, we've had a validation day with them, and it's all been within a period of three months." (Participant 15, Acute trust)

> "Regulation is becoming much more comprehensive so there is a beast to be fed, which is hard for organisations. Particularly the closer to the bottom you are, the more requests there are, and the more you almost need two parallel lives: one actually doing the improvement and one feeding the beast." (Participant 3, Acute trust)

3.5. The policies in aggregate: their impact on openness

As explained in Chapter 1, our objective in this workpackage (and in the study as a whole) was not to seek to evaluate the value or impact of any one of the policies according to its direct objectives, but rather to examine the relationship of the policies to the broader ambition of achieving 'cultural change' around openness in the English NHS. Their impact in aggregate—including both their cumulative effect, and their interactions with one another for better or worse—is therefore of particular interest for our study. In this section we identify a number of themes that cut across the policies and initiatives introduced since the Mid Staffordshire public inquiry, and discuss the implications of these for the kind of culture change around openness proclaimed as an objective in policy documents.[27] We summarise these themes in 5.

A published output from this study considers some of these challenges in further detail; it can be found in Appendix E.

3.5.1. Bureaucracy and implementation

Despite its often negative connotations, bureaucracy—including mundane processes such as explicit guidance, process management, documentation of activity and accountability—is vital to the effective implementation of any policy or initiative in any organisation.[92] But the 'dark side' of bureaucracy is also well documented. It can give rise to problems that range from 'rent-seeking behaviour' on the part of bureaucrats by incentivising them to extend their control without adding value,[93] to deepening the gaps between the world of the document and the world of real-life practice. Paper compliance might mask everyday shortcuts, workarounds and deviations while bureaucratic accountability and monitoring systems continue to provide a potentially misleading view.[94]

In the case of the initiatives discussed in these telephone interviews, a common refrain was that the

Theme	Key points	Section
Bureaucracy and implementation	• Significant administrative burden was associated with implementing the policies (without support or extra resourcing nationally) • The data-collection burden in particular was seen as heavy, and there was some concern about the uses to which such data might be put • Some felt that the need to follow regulations to the letter and document the process could result in inflexible processes, insensitive to patients and carers' preferences	3.5.1
The gap between the blunt end and the sharp end	• Participants—relatively senior within their organisations—noted the relevance of the policies to their work, sensing that many of the issues that beset Stafford could have affected their organisation • They felt, however, that this sentiment was not shared by sharp-end staff, for whom the Mid Staffordshire Inquiry was an increasingly distant memory • Pressures at the sharp end meant that some could see issues in quality of care as issues inherent in day-to-day work, rather than tractable issues subject to concern, openness and action	3.5.2
Variations in prior progress and approach	• Many participants suggested that existing practice varied greatly between organisations: some had already made much progress ahead of policy change, while others lagged behind • Organisations that had already acted ahead of policy were seen as more likely to be receptive environments for further change • However, early action also brought downsides—for example prior changes that did not quite match policies that were subsequently introduced could necessitate further, resource-consuming change	3.5.3
The long shadow of the past	• Negative responses to openness on the part of organisations or individuals in the past could cast a long shadow over the present • Signals in the wider system in the present, too, suggesting that openness was punished rather than valued, could have a chilling effect • Dissonance between formal support for openness, and experience, memory, or even hearsay suggesting that openness is not valued, could make staff very doubtful about the safety of being open	3.5.4
Inter- and intra-organisational variation	• Many of the policies were seen as being based on the template of a relatively integrated, singular organisation, such as an acute trust • Organisations diverging from this template, such as mental health trusts and multi-site organisations, could be less culturally coherent: accordingly, change could be more challenging • Tailored approaches to intervening in such organisations, based on insights and intelligence gathered from across the organisation, were seen as crucial to policy implementation	3.5.5
Overcoming the implementation gap	• Ensuring that action was informed by insight from across the organisation was seen as crucial, including 'softer' forms of intelligence and quantitative data on processes and outcomes • Showing the benefits that could arise from efforts to improve openness was seen as crucial to engaging staff at all levels and making the policies seem like more than a bureaucratic burden • Work to ensure that responsibility for the burdens of openness fell to the blunt end as well as the sharp end could further help to encourage engagement and overcome scepticism about initiatives	3.5.6

Table 5: Cross-cutting themes in the implementation of openness policies

bureaucratic work accompanying them created significant burdens. Given that the initiatives carried little or no extra resource, the administrative overhead was significant. Moreover, in some cases, participants saw it as expanding: with the Freedom to Speak Up Guardians, for instance, there was a sense that the data-collection expectations were increasing, with a view for example to monitor and address the accessibility of Guardians to groups known to be under-represented in speaking up, or particularly vulnerable to victimisation.[11]

Many participants expressed dismay at the scale of the administrative demand that accompanied the initiatives, particularly where it focused on demonstrating compliance with timescales and undertaking data-collection exercises that required the setting up of dedicated new systems and processes. There were qualms about the uses to which data would be put, the risk of misinterpretation of high or low levels of activity, and the potential for such information to be used punitively or to incentivise behaviour in ways that could have unintended consequences. Some participants commented on how a preoccupation with documentation might be at the expense of a sincere, reflective effort to put the policies into practice in a way that would prize openness and learning, and be sensitive to the preferences of patients and families.

> "They will be covering themselves by giving strict legal interpretation [of the Duty of Candour], they will be telling the various people this is what you must be doing in order to fulfil the statutory obligation. They will not be approaching [...] it from a patient safety perspective. And then if nobody's doing that then there's a complete gap and we're losing the whole purpose as to what the Duty of Candour's meant to do. So it's just seen as an extra layer of administration." (Participant 40, Commentator – medical negligence solicitor)

Such concerns are to be expected with any new system designed to ensure implementation and monitor and compare progress in realising the aims of a new policy. Often, they are well founded.[95] But more than this, our findings indicate particular concerns that, in an area as delicate as openness, the will to accountability through data might actually undermine the overarching objectives of the policies. In relation to the Duty of Candour, for example, there was concern that requirements around timing and format of disclosures would ensure that disclosures were made, but at the cost of sensitivity and judgement about exactly how and when—and discretion about whether and how to follow up with families who had declared that they did not wish to receive further communication. Similarly, with Freedom to Speak Up, some participants questioned the value and appropriateness of collecting data on the views and characteristics of those approaching the Guardians, often from a position of anxiety and vulnerability—and perhaps with worries about identification and how data about them might be used. As we discuss in more detail below (section 3.5.5), participants working in mental health and community health services trusts struggled in particular with following instructions for implementation that they felt had been designed around the template of an acute hospital organisation, and which did not transfer easily to more diffuse settings and less episodic care delivery.

It is, of course, challenging to get the balance right between appropriate accountability for implementation of policies in a taxpayer-funded service, and appropriate discretion in implementation by managers and clinicians whose autonomy is to be valued and who are sensitive to local contingencies. The trade-offs involved in achieving this balance were noted by participants in relation to the CQC's new regulation model, which they felt sacrificed the (perhaps false) assurance of a highly standardised, extremely intensive approach to inspection in favour of a more risk-driven and more dialogical approach. Participants acknowledged the dangers of missing problems that this shift might bring, but largely welcomed it as an approach that sought to move towards working with, rather than ruling over, NHS organisations. In other areas, however, they worried that an excessive preoccupation with compliance and monitoring might work against the spirit of the initiatives.

3.5.2. The gap between the blunt end and the sharp end

By design, the telephone interviews discussed in this chapter focused on the views of individuals in relatively senior positions in and around NHS provider organisations. The case study work we describe in chapters 6 and 7 provides insights into how these policies are experienced by patients, carers and clinicians at the sharp end of care. Nevertheless, participants did comment on the challenges of implementing the policies in a way that would overcome the gap between senior stakeholders—relatively well versed in the post-Francis policies—and sharp-end clinicians, who might not be quite so aware of the report and its recommendations.

Participants tended to report that they welcomed the attention to openness and cultural change heralded by the policies. A commonly expressed view was that ‘Stafford could have happened here’. Several discussed ‘black spots’ in their knowledge of their organisations that caused them anxiety. However, participants suggested that the significance of Mid Staffordshire might be much less self-evident to sharp-end colleagues.

> “In terms of openness, certainly the trajectory is that we are very open at executive level. I’m not sure that we are that open below there.” (Participant 20, Community and mental health services trust)

Rather, at the sharp end of NHS organisations, much of the activity around openness might be indistinguishable from other changes in organisational policy, and could be perceived as just more top-down interference for no good reason. A particular challenge was in parts of organisations that had issues around openness, reflection and transparency (see section 3.5.5). But across organisations, while at a senior level the lessons of Stafford were seen as a “wake-up call” (multiple participants) and something that “could happen everywhere if I’m honest” (Participant 25, Community and mental health services trust), Stafford was seen as something sharp-end staff tended to perceive as unique, distant, and increasingly, something that happened in the past.

The sense among sharp-end staff that Stafford lacked pertinence to their day-to-day work was compounded, participants said, by their increasing busyness in a health system affected by increases in demand without comparable increases in resourcing, and the sense that sub-optimal care had become normalised as a result. More broadly, whereas the relevance of Stafford was plain to those in senior positions, for those at the sharp end it was much easier to rationalise poor or suboptimal care as a necessary mechanism for coping with the demands of the job.

> “We know there’s things missed because people are too busy, rather than people are negligent. But I think what we’ve become quite good at is normalising that.” (Participant 16, Acute trust)

Ironically, the extensive media coverage and soul-searching within government and the senior strata of the NHS might have served to heighten the sense that Stafford was something exceptional and unique—and thus with limited relevance to their own practice. The egregious acts documented by Francis might, participants suggested, appear to have limited relevance to everyday forgivable shortcuts and imperfections[96] that those at the sharp end used to get by. In section 3.5.6 we discuss the efforts undertaken by participants to bridge this gap.

A slightly different issue, raised by several participants, was a sense among staff at the sharp end that their own efforts and wellbeing were being neglected in the rush to openness. For many (see section 3.5.4), there was concern that the NHS remained a punitive place, and that fine words about just cultures and about the benefits of openness were not borne out in practice. For some of their colleagues at the sharp end, participants reported, the attention to Stafford and the flurry of policy and action that had followed did a disservice to existing efforts, denigrated staff, and gave rise to an impression that “we look after staff far worse than patients” (Participant 42, Commentator – organisational development consultancy).

3.5.3. Variation in prior progress and approach

As noted in section 3.5.2, for many participants, the policies that followed from Francis—at least in principle—were welcome. Some had proactively processed and responded to the independent[4] and public[5] inquiries and surrounding commentary,[9] and sought to learn lessons ahead of the formal policy response.

> "It probably was a catalyst for change. Without it, I'm not sure that many organisations would have been inclined to change some of their approaches. And as I mentioned, probably ours included. Because I think there was always a feeling that we were inclusive, we were open, and we were transparent." (Participant 21, Community and mental health services trust)

Participants found that these attempts to progress in advance of policy change could represent both a blessing and a curse. There was a sense from many that the work to change systems, processes and behaviour that they had already begun could help to pave the way for the initiatives introduced from 2014 forward. Participants not employed by NHS provider organisations observed divergence in the way policies were received among organisations; those that had already acted to make change were seen as more receptive environments for an approach to implementing the Duty of Candour, Freedom to Speak Up and other initiatives in a way that focused on spirit rather than letter.

> "[I know] a trust in [area], where every single board member is a Freedom to Speak Up ambassador. And they've also got a Guardian, and the board are absolutely bought into it. And then we've got another trust, that I won't name, where one of the executives calls the Guardian the 'freedom to sneak up guardian'." (Participant 43, Commentator – national arm's length organisation)

In many cases, moreover, they were able to meld the initiatives they had already introduced with the new policies passed down from the national level.

At the same time, however, some participants found that the work they had already done to seek to foster openness in their organisations was less readily compatible with the requirements subsequently introduced by policy. In relation to the Duty of Candour, for example, some recounted how their organisations had previously introduced local-level policies to encourage openness with patients and families when things went wrong, but then proved non-compliant with the process, timescale or reporting requirements of the statutory Duty when it was introduced. Participants acknowledged that this was an occupational hazard of innovation, but were also frustrated at the lack of flexibility in the implementation requirements (see also section 3.5.1). At least with non-statutory requirements, there may be a case for greater discretion, or a variant of the 'earned autonomy' bequeathed to foundation trusts,[97] among organisations that have consistently demonstrated their commitment to openness, perhaps based on the CQC's 'Well-led' assessments.

3.5.4. The long shadow of the past

A common thread in interviews was the way memories of responses to openness in the past could bear upon dispositions towards openness in the present. The events of Stafford could seem remote (section 3.5.2), yet people's recollections of what had happened in their own organisation had very strong resonance—even where the events in question had occurred many years ago, and memory had been subject to the distortions of time. Formal organisational responses and the informal responses of peers alike had sometimes marked effects on voice, reflection and transparency; accounts of retaliation could become organisational folklore and cautionary tales about the folly of openness. They could even cross boundaries between organisations, and propagate the idea that the NHS as a whole was not safe for people who were open.

> "I have an example of somebody who spoke up in a previous organisation and had their tyres slashed, and as a result they didn't want to take the chance. So people do bring their experiences from previous organisations to the one they work at." (Participant 5, Acute trust)

> "One of my team raised a concern to the previous chief executive, and was told not to bring a problem to the table. He didn't want to hear. Nurses have described situations where they've raised concerns and been told that if they don't like working here they can find somewhere else to work. And I think what that does then is it has an impact over time, it starts to become the norm. People start to accept there's no point in raising a concern because nothing will happen, and you'll just feel that you're a troublemaker." (Participant 11, Acute trust)

Such challenges are well documented in the literature within and outside healthcare.[86,98–101] What our findings highlight, though, is the scale of the challenge that will be faced in any efforts to reverse such entrenched, even institutionalised, beliefs. Where formal policy conflicts with personal experience, or even with widely known myths about what happens in practice, the downsides to a behaviour already ridden with risks become magnified. Moreover, some participants highlighted the chilling impact of more recent events, such as high-profile gross negligence manslaughter cases against doctors such as David Sellu and Hadiza Bawa-Garba, and associated action by the General Medical Council.[69]

A key implication is the need for patience, persistence and caution in any expectation that policy changes will translate into a culture of greater openness. Patience and persistence are required because any change will take time, and because if implicit understandings of the propriety and safety of speaking up are to be shifted, the validity of the new understanding must be repeatedly reinforced.[83] Caution is required because a conflict between proclamation and reality may renew people's cynicism, and reaffirm their view that their organisations are places where, whatever senior managers might claim, being open is a dangerous choice.[98]

3.5.5. Inter- and intra-organisational variation

We noted in relation to some of the initiatives covered in sections 3.1 to 3.4 that participants based in community and mental health services trusts reported some difficulties in adapting the policies to their organisations. A prevalent view was that the policies were designed around an acute template, and that seeking to apply them in other settings was challenging, and could even give rise to unintended consequences.

> "This is the bit that I suppose we struggle with, the diktat around—so we've all got one of these people [Freedom to Speak Up Guardians], and whether it's the right thing for your organisation didn't really matter, it was a national diktat, this is what you've got to do. And I think if you're in an acute trust it's slightly easier perhaps, because you're all on one site. Whereas our staff are all dispersed across the county. So people respond to an acute issue and then try to transpose it across the whole of the NHS." (Participant 25, Community and mental health services trust)

The differing profile of illnesses (particularly among people with mental health conditions), and their consequences in terms of pathways, timescales, locations, multidisciplinary team involvement and multi-agency involvement, were seen as key to this challenge. Notably, our secondary analysis of national staff and patient survey data (Chapter 5) highlights disparate trends in the trajectory of key indicators of openness in the acute physical and community mental health sectors. Community and mental health trusts also tended to be more diffuse organisations, both geographically and culturally. Often, they were composed of units that had complicated and divergent histories in terms of their organisational identity and affiliation—for example, inpatient mental health units alongside community health facilities that would, until the deepening of the purchaser-provider split in the late 2000s, have been hosted by primary care groups or trusts.[102] Understanding the divergent challenges across such heterogeneous organisational units, let alone achieving uniform improvements in openness or changes in culture, represented an enormous challenge.

Some participants in acute hospitals, too, faced similar difficulties. Several of these organisations were also spread out geographically, and mergers of trusts—as well as broader moves towards closer working within sustainability and transformation partnership areas—could bring together organisational units with little in common, and with variable degrees of identification with and connection to the organisational centre. This created difficulties for participants in their knowledge of the performance, culture and challenges faced in different parts of their organisations. It also meant that uniform approaches to addressing those challenges were unlikely to work.

> "The fact that people aren't reporting the things I expect them to, what's that about? Or are things fine and dandy? It's really difficult to tell." (Participant 16, Acute trust)

Moreover, isolation from the wider organisation could itself create the potential for opacity and poor practice, in ways that were difficult to detect.

> "We've done a lot of investment in terms of our community teams, because obviously the challenges there are also that they're integrated. [...] They may touch base in the morning, but actually that's it then until the next day. And some teams, particularly out-of-hours, they're like ambulance crews, they'll turn up, two of them doing outreach at night, meet up, get in a car and that's it for the night. It's making sure they have the same opportunities, have the same culture as other elements." (Participant 17, Acute trust)

The upshot of these challenges were that participants felt it important to invest in 'intelligence-gathering' devices that could provide them with assurance that, at the very least, they would become aware of incipient problems reasonably promptly. This was among the latent benefits identified for Freedom to Speak Up Guardians, and wider networks of champions or advocates for speaking up (section 3.3.2; Appendix F). There remained a concern, however, that some parts of their organisations remained resistant to oversight, and posed particular challenges when proclaiming the virtues of a more open culture.

The small number of interviews we undertook with staff in ambulance trusts offer an interesting coda to this analysis. Operating on a region-wide basis, ambulance trusts were in some ways perhaps the most diffuse of all, prone to the development of 'organisational enclaves' where highly localised, and potentially problematic, cultures might emerge. On the other hand, participants reported, the more hierarchical culture that tended to predominate in ambulance trusts—arising from their organisation as a responsive, '999' emergency service, more akin to the police or fire brigade than other healthcare organisations—tended to be conducive to greater top-down direction. But participants perceived that it also created an environment where there was a greater risk of bullying, with authority gradients that would discourage speaking up.

3.5.6. Overcoming the implementation gap

Even as they discussed the size of the challenge they faced in translating the policies into something that might, given time, result in a move towards a more open culture, participants in the interviews offered useful reflections on the strategies that seemed helpful in overcoming some of the issues described above.

At a basic level, participants were clear that what was required was more than policy implementation and monitoring. Quite apart from its potential to create paper compliance and completely fail to secure the benefits of openness expected from the policies, it would also leave staff at the sharp end of care disengaged. Rather, implementation would be an ongoing exercise that required regular reassertion and renewal, exemplifying commitment to and prioritisation of openness through alignment with other activities and policies.

> "It's almost like a loop, you're like, 'OK, this week we have to focus on that, next week we have to focus on that'. And I think staff feel that. If we've got this message that you're important, patient safety's ultimately important, we want to look after you so you can look after patients, and then all our emphasis is on, I don't know, an overtime ban, then they feel that: they feel that conflict and it doesn't feel very authentic." (Participant 36, Ambulance services trust)

> "It's no good just doing it once, then thinking the job is done. It's got to become ingrained. And if senior staff are doing walkabouts around the hospital, load of them just walking around and not listening to people, [they're wrong]—they've got to listen to people and then act on it." (Participant 45, Commentator – national arm's length organisation)

First of all, this meant developing connections with the diversity of units where care was delivered, with a view to understanding the challenges and issues faced—particularly the more remote or isolated units discussed in section 3.5.5. Formal interventions such as patient safety walkrounds were sometimes mentioned,[103] as was the importance of much more informal day-to-day communication across organisational levels, that could provide the 'soft intelligence' that can evade capture through formal reporting mechanisms.[78]

> "The most important bits around openness and transparency, where the greatest success has been, [are] just by the executive team—so me and my colleagues—out in the patch, walking, understanding the issues, meeting the staff, so we can see the problems that they're facing. I think that's the biggest change." (Participant 25, Community and mental health services trust)

Within this general frame, second, participants suggested that work was needed to show how openness would result in benefits, as well as burdens, for staff at the sharp end. Fixing problems as they were identified could represent a quick win: something that could be done at little expense, could have direct benefits for safety and quality, and demonstrate to sharp-end staff a willingness to respond to their concerns.[104] An important corollary of this was demonstrating that senior staff at the blunt end were willing to take their fair share of the burden, too.

> "I think what our staff have seen is an organization that puts its money where its mouth is. If I'm working of a weekend I'll be in. And they see that we hear. One of the things that our nurses recently said is, 'If you put bank staff onto weekly pay, I'd do more bank shifts', because we're short-staffed like everybody else. And it cost money to do that, but we've done it, and all of a sudden our bank shift fill rate has improved. So we do listen to our staff, and we try wherever possible to heed what they're saying and listen. And I think listening's really important." (Participant 11, Acute trust)
>
> "We've done other things where they said, 'This is not right', [and] we've bought a piece of kit. So whenever we go around, we have a little pot of money that we can actually go into and say, 'Well this is to help get it sorted'. So I think people recognize that we want to go out there and hear." (Participant 1, Acute trust)

Third, and related, participants highlighted the importance of persistently asserting the importance of openness, seeking to challenge the view that the lessons of Stafford were not relevant here (section 3.5.2). Among other things, this meant active effort to promote the advantages of openness as an everyday disposition, something that could assist units in improving the quality of their care in small ways, rather than just an imposition in reaction to wrongdoing.

> "[This] organisation's approach is it doesn't matter what the concern is, we'd much rather people talk about it, through whichever process they want to talk about it, and share a problem. [...] The culture element requires almost constant massaging, constant reinforcement that we want, and it's good to talk about things: actually it's not about admitting defeat or saying your own practice is poor. This is actually the right thing we should be doing for patients, colleagues, the system." (Participant 17, Acute trust)

Participants acknowledged that achieving this kind of cultural change would be a long-term process, but, as suggested in section 3.5.4, it was one where dogged persistence, and consistency in word and deed, might ultimately help to precipitate a shift in culture.

3.6. Conclusion

Our telephone interviews with senior stakeholders in and around the NHS surfaced challenges and opportunities associated with several of the policy initiatives introduced following the publication of the Mid Staffordshire public inquiry. Participants focused their discussion on those policies that they felt had been most salient in their organisations; this reflects the views expressed in the wider survey of senior stakeholders (Chapter 4) of which policies had been most impactful. At the collective level, participants also provided important reflections on the challenges of policy implementation, and particularly of the work they had to do in translating and orchestrating the policies within their organisations to secure the maximum likelihood of impact on culture.

We return to some of these insights in our synthesis and discussion of the study as a whole in Chapters 8 and 9. The findings from WP1, particularly around the policies that participants felt had been most consequential, informs our choice of tracer issues in the case study-based work described in Chapters 6 and 7.

3.6.1. Limitations

By design, this part of the study aimed to capture the views and experiences exclusively of relatively senior staff in and around the NHS. It does not directly include the views of staff at the sharp end or of patients and carers. Participants reported their own experiences of the reception to the initiatives of their sharp-end colleagues, but interpretation of these comments should be guided by the indirect nature of these data.

Sampling was informed by the approach set out in section 2.1, which sought to combine the merits of a randomised approach to sampling with a more focused, theoretically informed approach that sought to ensure representation of organisations that had faced publicised issues with openness in the past. By and large we were successful in achieving this, and our confidence in the validity and transferability of our findings is bolstered by our sense that theoretical saturation had been achieved.[52] However, we sampled fewer ambulance service trusts than we intended, and far fewer non-NHS providers of NHS services (only one), despite protracted efforts. The transferability of our findings to these organisations is therefore less clear. It is also plausible that participants (and perhaps organisations) who were more sympathetically inclined towards the policies were more likely to agree to be interviewed than those sceptical or indifferent to them.

As an interview-based study, the data collected in WP1 are subject to the usual limitations of this approach, most notably social-desirability bias, whereby participants tend to give answers that they feel the interviewer, or society at large, would see as proper. Our topic guide and the approach taken to interview, which sought to avoid leading questions, provide assurances of confidentiality, and probe for more detailed comment, offer some mitigation here, while the diversity of views expressed about the policies offers some reassurance that participants were not reticent in expressing their opinions.

4. Results: Survey of executive leaders on the impact of policy interventions (WP2)

To complement the qualitative interviews undertaken with senior stakeholders in and around the NHS discussed in Chapter 3, we developed, executed and analysed a cross-sectional survey designed to examine reception of and attitudes towards openness initiatives in a larger sample of similarly senior NHS staff. Details of the design, development and piloting of the survey can be found in section 2.2.

The survey was developed and piloted in the summer and autumn of 2017, with data collected in early 2018. The survey itself is included as Appendix B. Due to challenges in sourcing contact details for senior executives in both NHS organisations and private- and third-sector organisations providing NHS services, we commissioned Wilmington Healthcare (formerly Binley's) to undertake the survey on our behalf, using their own comprehensive list of senior contacts in healthcare organisations. This covered chief executives, medical directors, directors of nursing, and executive leads for quality, governance and safety. The sampling frame was very broad, often including multiple contacts for each organisation concerned (and in some cases, multiple e-mail addresses for single individuals).

While the sampling frame was comprehensive in terms of the numbers of organisations and roles within them covered, the validity of the contacts provided was mixed. Further challenges were

	n (%)
Respondents and organisations	
Total individual participants	112
Unique organisations represented	84
Roles of respondent	
Chief executive	29 (25.9%)
Medical director	24 (21.4%)
Director of nursing	24 (21.4%)
Executive lead for quality, governance, safety or similar	35 (31.3%)
Organisation types	
NHS acute trust	46 (54.8%)
NHS community and mental health services trust	27 (32.1%)
NHS ambulance services trust	1 (1.2%)
Non-NHS organisation providing NHS services	10 (11.9%)
Respondent's time in current post	
Less than one year	9 (8.0%)
Between one and three years	24 (21.4%)
Between three and five years	26 (23.2%)
More than five years	44 (39.3%)
No response	9 (8.0%)
Size of organisation	
Less than 1500 FTE staff	14 (12.5%)
1500-2999 FTE staff	10 (8.9%)
3000-4999 FTE staff	34 (30.4%)
5000-9999 FTE staff	40 (35.7%)
10,000 or more FTE staff	4 (3.6%)
Don't know or no response	10 (8.9%)

Table 6: Profile of survey respondents (WP2)

experienced in executing the survey due to the time of year (it was open at a time when the NHS was experiencing acute ‘winter pressures’), and possibly due to IT-related issues and cautions in the aftermath of the ‘WannaCry’ cyber-attack on the NHS, which had occurred six months earlier.

The survey was open for a four-week period, from 19 January to 16 February 2018. In total, 112 responses were received from 1837 unique contacts. Thus the overall response rate was very low—9% for NHS organisations, and 6% overall. The survey did achieve coverage (at least one response received) of 30% of NHS acute provider trusts, and 38% of community and mental health services trusts, but caution is clearly needed in interpreting the findings. To gain a sense of the likely representativeness of this sample, we compared the overall ratings provided by the CQC to responding organisations (the sample) with the profile of ratings for all core acute and mental health provided by NHS provider organisations (the population) as at 31 July 2018,[105] using a chi-square test (Appendix G). We found a significant difference between the observed and expected distributions (p=0.03); organisations rated ‘Good’ were under-represented in the sample, while organisations rated ‘Requires improvement’ were over-represented. Notably, the sample contained not a single trust with a rating of ‘Inadequate’ at the time of the survey. The overall profile of respondents to the survey is presented in **Error! Reference source not found.**.

Findings from the survey are presented here primarily using descriptive statistics. Additionally, given the notable finding from WP1 that participants in community and mental health services trusts found implementation of the policies more challenging than their counterparts in acute hospitals (see section 3.5.5), we also selectively used chi-square tests to test the null hypothesis that there was no significant difference between responses from the two trust types. Where other relationships appeared to exist in the data, we also undertook non-parametric tests to examine whether these differed significantly from a situation of no differences between groups. Caution is needed when interpreting these findings, as no specific hypotheses were derived in advance and therefore the results are indicative only. For transparency, results of tests performed are reported, whether significant or insignificant at the 5% level; our analyses are reported in Appendix G.

4.1. The overall impact of the policy initiatives

Participants in the survey were asked to rate the impact of seven new policies, introduced directly or indirectly in consequence of the Mid Staffordshire public inquiry and public debate that followed, on a five-point Likert scale, from ‘no impact’ to ‘very significant impact’. The views of participants on the relative impact of these initiatives (Figure 1) largely reflects their relative scale and resourcing implication, with mandatory, organisation-wide changes such as the statutory Duty of Candour and the revised Serious Incident Framework seen as most impactful, while more marginal and/or voluntary schemes like Sign Up to Safety were seen to have had less of an impact. The Fit and Proper Persons Test prompted the most divergent range of responses, and was seen as having had a very significant impact by just under 20% of respondents, but little or no impact by over 40%. This divergence perhaps reflects wider disquiet about the inconsistent way in which the Test was being applied. The Kark Review of the Fit and Proper Persons Test recently found that while it was being applied effectively for clear-cut issues, it was much less useful in making finer decisions about the appropriateness of directors.[106]

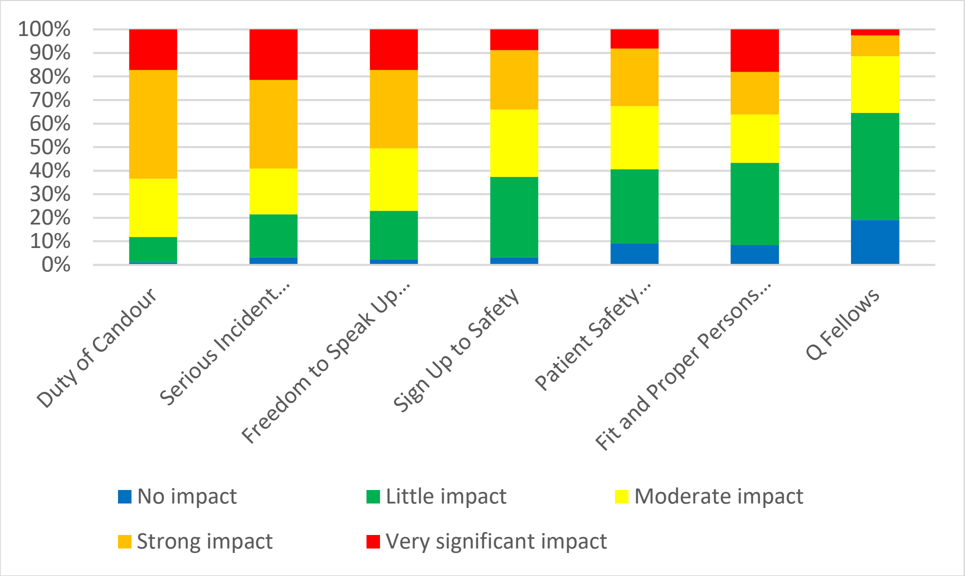

Figure 1: Perceived organisational impact of seven openness initiatives

Overall, participants tended to consider that the initiatives covered in the survey had, in the round, had a positive impact on organisations. Across all organisation types, 78% of those responding agreed or strongly agreed that ‘Taken together, the policy measures [above] have begun to increase the openness of staff in my organisation about concerns about patient safety’ (Figure 2). Comparing the distributions for acute and community and mental health services trusts, we found no significant difference (p=0.69) (Appendix G). On the question of the relationship between the reforms as a whole and the likelihood of litigation (‘Taken together, the policy measures […] increase the likelihood of litigation (e.g. negligence claims) against my organisation’), respondents were a little more divided (Figure 3). While 42% of those responding disagreed or strongly disagreed with this statement, 29% agreed or strongly agreed—suggesting that participants in our telephone interviews were more optimistic on this issue (WP1—section 3.1.3) than many of their peers.

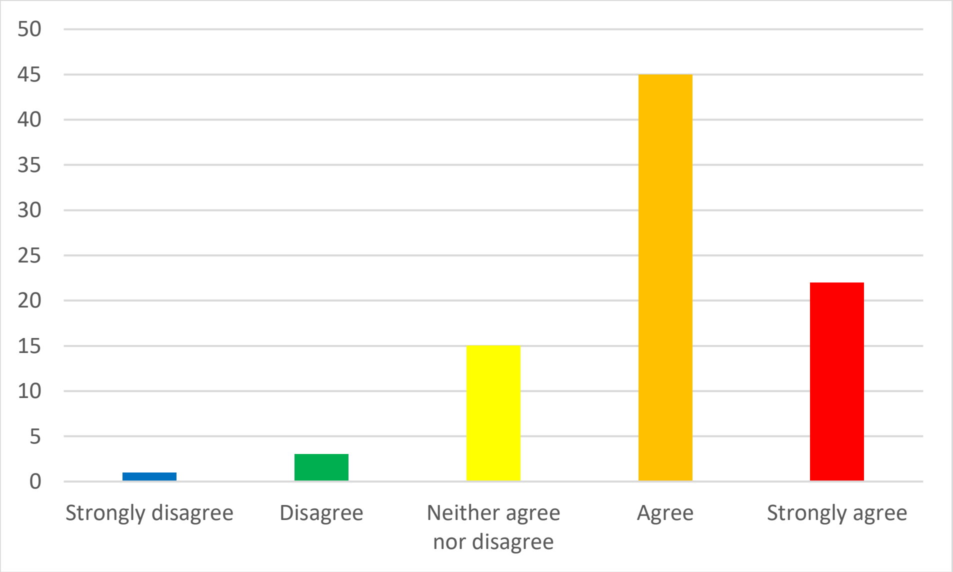

Figure 2: Response to 'Taken together, the policy measures […] have begun to increase the openness of staff in my organisation about concerns about patient safety’

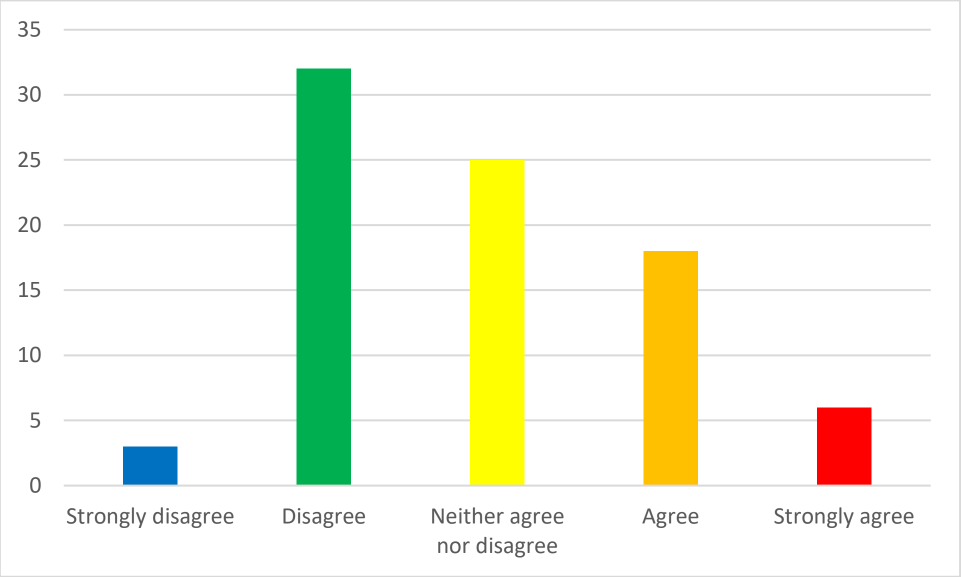

Figure 3: Response to 'Taken together, the policy measures […] increase the likelihood of litigation (e.g. negligence claims) against my organisation'

4.2. Specific initiatives

We asked survey respondents for their views on the impact of the Duty of Candour and the introduction of Freedom to Speak Up Guardians in relation to certain objectives, informed both by the stated aims of these two initiatives,[11,13,27] and by our early analysis of data from telephone interviews (sections 3.1 and 3.3). Reflecting the views expressed in the telephone interviews, respondents in the survey were largely positive about the potential of the statutory Duty of Candour to improve patient-staff communication, and of Freedom to Speak Up Guardians to help colleagues to voice concerns about colleagues (Figure 4), with a clear skew towards agreement in both cases—particularly for the Duty of Candour. Comparing responses from respondents located in acute trusts and community and mental health services trusts on these questions, we found a significant difference in neither case (p=0.784 and p=0.790, respectively) (Appendix G).

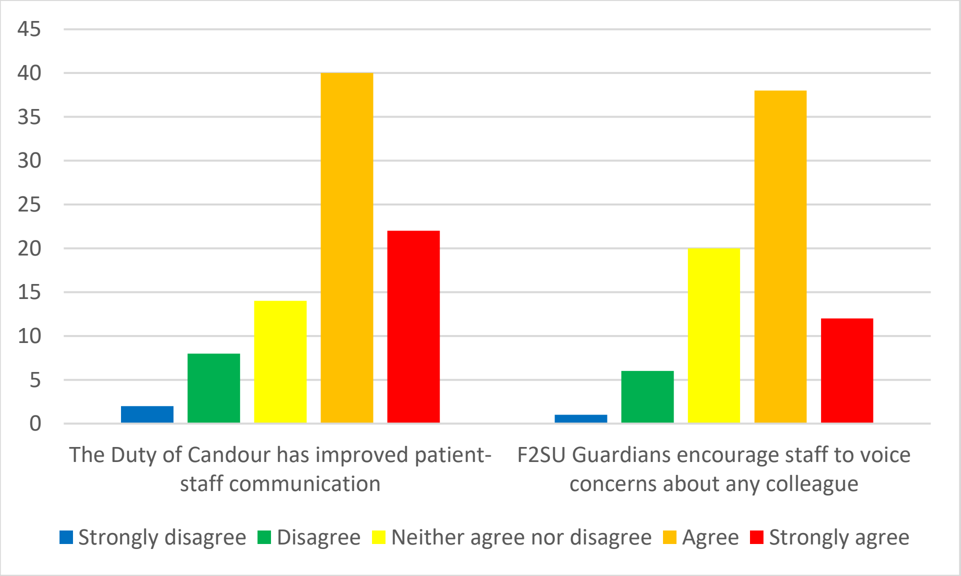

Figure 4: Reponses to 'The Duty of Candour has helped to improve patient-staff communication following incidents' and 'The introduction of [FTSU] Guardians has started to encourage employees to voice concerns about colleagues of any grade or profession'

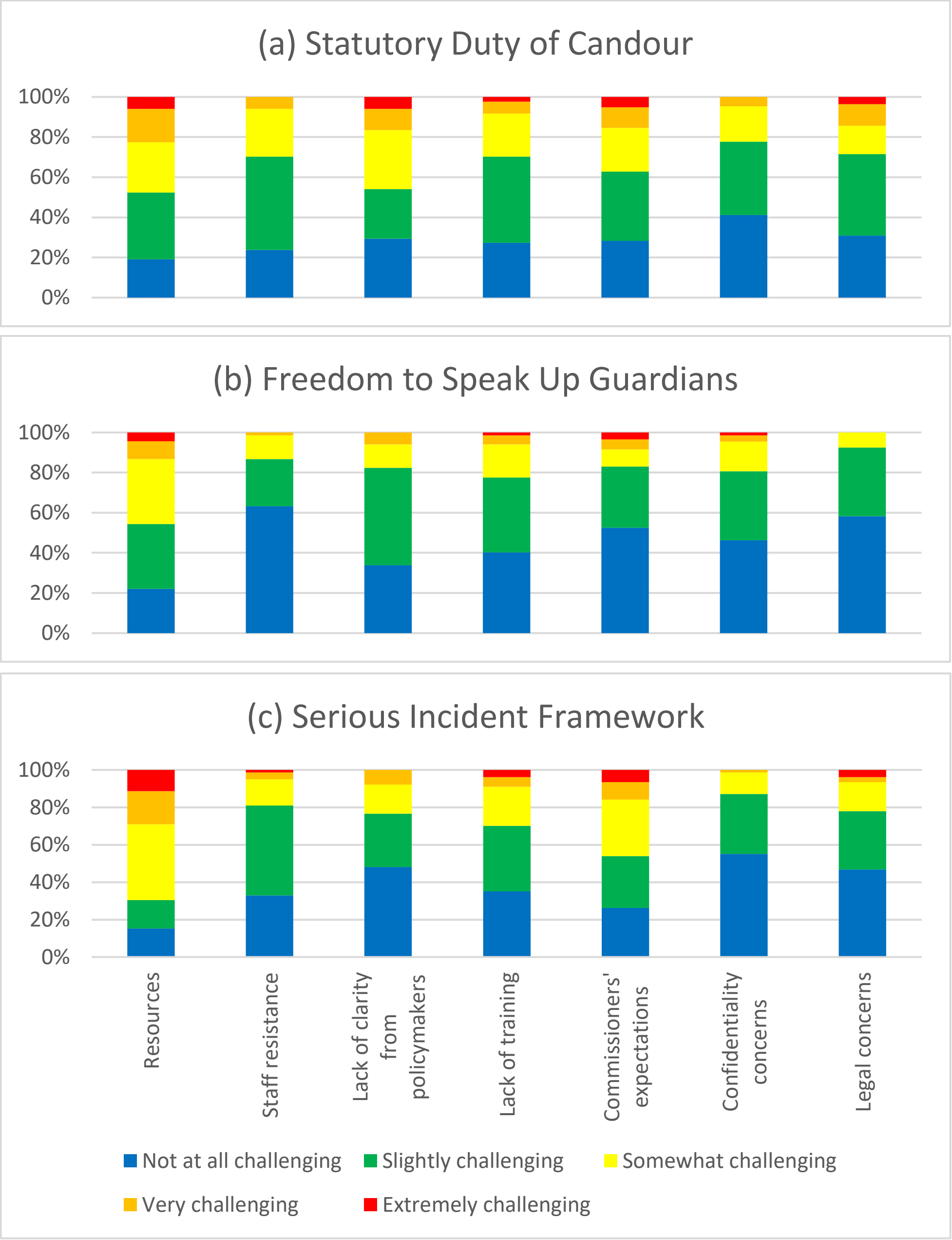

Figure 5: Views on implementation issues across three openness initiatives

The survey also asked about the range of challenges involved in implementing the statutory Duty of Candour, the Freedom to Speak Up Guardians, and the Serious Incident Framework. For each initiative, respondents were asked to describe the degree of challenge posed by a range of issues, on a scale from ‘Not at all challenging’ to ‘Extremely challenging’. Figure 5 presents results from these questions, comparing responses across the three initiatives. Of note is the particularly high proportion (70% of those responding) who found ‘Resources’ at least ‘Somewhat challenging’ in implementing the Serious Incident Framework. This compares to figures of 48% for the Duty of Candour and 46% for the Freedom to Speak Up Guardians. Similarly, 46% of respondents found managing ‘Commissioners’ expectations’ ‘Somewhat’, ‘Very’ or ‘Extremely challenging’, compared to 37% for the statutory Duty of Candour and 17% for Freedom to Speak Up Guardians. A comparison of the distributions of responses on these two issues across the three policies was statistically significant at the 5% level both for ‘Resources’ ($p<0.001$) (with the Serious Incident Framework the most challenging) and for ‘Commissioners’ expectations’ ($p < 0.001$), with expectations around the

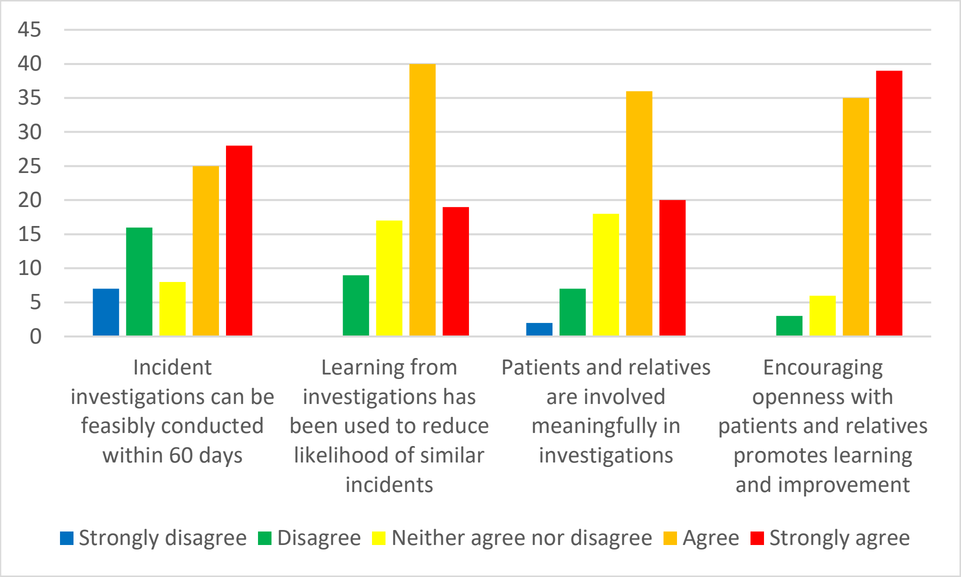

Figure 6: Views on structures for learning and involving patients and families

Freedom to Speak Up Guardians seen as less challenging (Appendix G). Also perhaps noteworthy are the 46% of respondents who found 'Lack of clarity from policymakers and regulators' 'Somewhat', 'Very' or 'Extremely challenging' in relation to the Duty of Candour, compared to only 18% for the Freedom to Speak Up Guardians and 23% for the Serious Incident Framework. Again, we sought to assess the strength of this apparent difference in the distributions statistically, and found a significant (p<0.001) difference between the distribution between the three policies; lack of clarity around the Duty of Candour was seen as more challenging than for the other two policies (Appendix G).

We asked respondents questions about the structures in place for achieving openness in their organisations, relating in particular to learning from incidents and involving families and carers in the process. Again we used a Likert scale to assess respondents' agreement with a series of statements about processes in place and how effectively they were working. Results are presented in Figure 6. Reflecting the responses presented in Figure 5, and the views expressed by telephone interview participants in section 3.2, a fairly sizeable minority (24%) of respondents disagreed or strongly

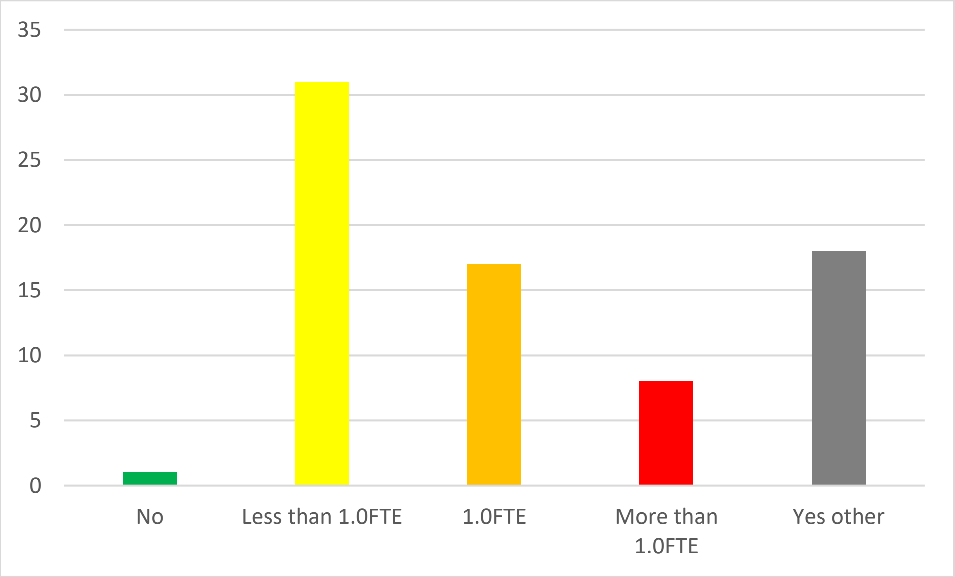

Figure 7: Responses to 'Has your organisation appointed one or more Freedom to Speak Up Guardians? If so, what is the full time equivalent (FTE) time allocated to these duties?'

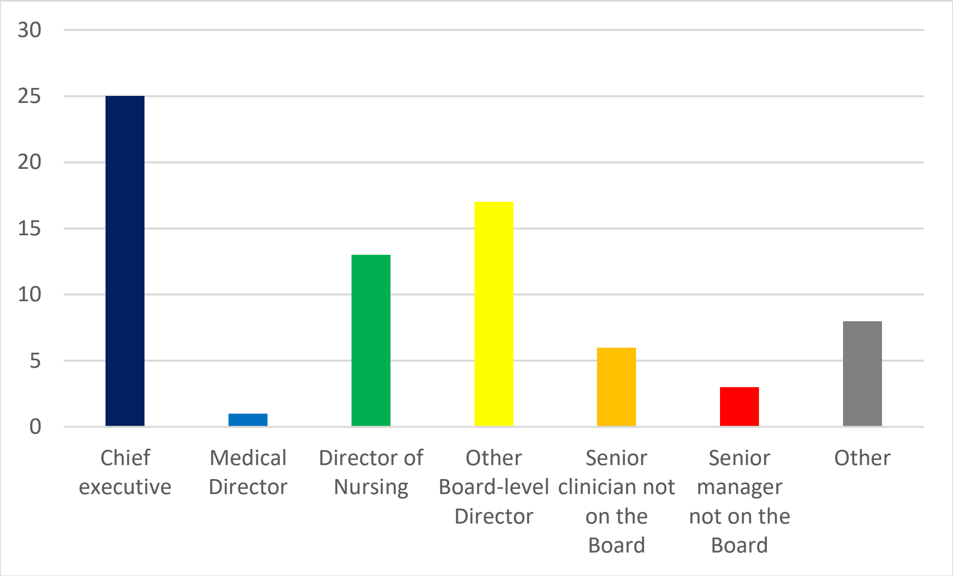

Figure 8: Responses to 'Who receives and handles concerns referred by the Freedom to Speak Up Guardian(s)?'

disagreed with the assertion that ‘It is feasible for my organisation to undertake internal investigations into all serious incidents that are identified within 60 days’. There was a much more positive skew in responses to the other three questions, with particularly emphatic agreement with the statement that ‘Encouraging openness with patients and carers when things go wrong is a strategy that promotes learning and improvement within a healthcare organisation’.

Finally in terms of questions relating to specific initiatives, we asked a series of questions about the implementation of the Freedom to Speak Up Guardian role. These were prompted in part by emergent findings from our telephone interviews that suggested that the role was not being realised as a single, full-time individual, but rather in a wide variety of fractional roles undertaken by multiple members of staff—including, sometimes, in addition to existing duties, without having a proportion of their time set aside (section 3.3.1). Participants reported various arrangements for allocating Guardian duties (Figure 7), with the majority (55%) of those indicating an FTE commitment choosing the ‘Less

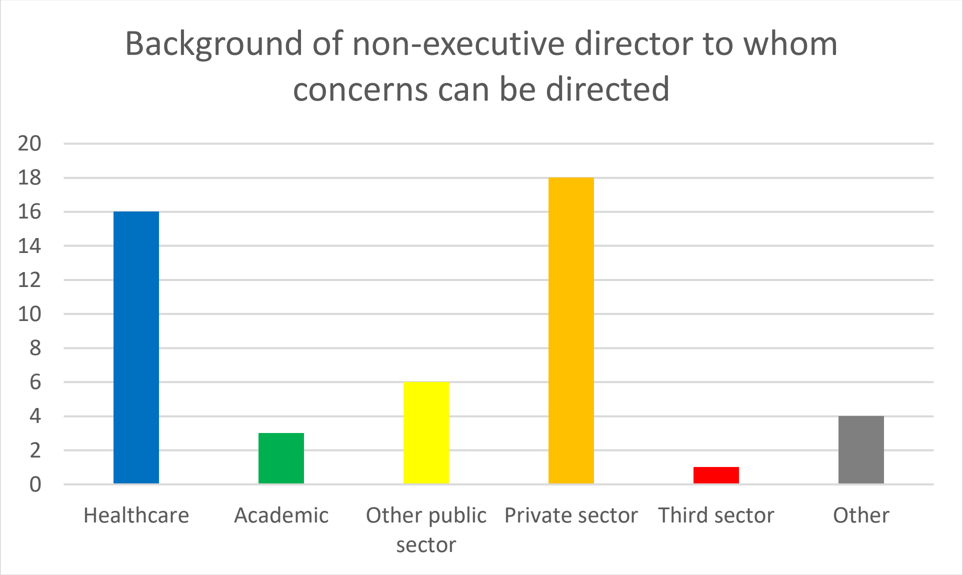

Figure 9: Responses to ‘What is the professional background of the nominated non-executive director to whom the Freedom to Speak Up Guardian(s) and others can refer concerns?’

than 1.0 FTE' option and a further 30% reporting a commitment of '1.0 FTE'. Eighteen participants gave a response of 'Yes – other'. Their free-text commentary was coded, and in the majority of these cases respondents reported that the role was fulfilled by either a single individual without dedicated FTE (6), or multiple individuals without dedicated FTE (11). One other respondent who selected 'Yes – other' indicated that their organisation contracted with an external body for its Freedom to Speak Up Guardian. Our findings here largely mirror those of the National Guardian's Office,[81] which found that half of Guardians have no dedicated time for their role, while 70% have less than a day a week—though it does not provide figures for the cumulative FTE of multiple Guardians in a single organisation.

The majority of respondents indicated that a board-level senior member of staff was responsible for handling referrals of cases made by the Freedom to Speak Up Guardian (77% of those giving an answer) (Figure 8), in line with the recommendation of the *Freedom to Speak Up* review that the Guardian have "direct access to the CEO and the board when needed."[11] In some cases (34%), this was indeed the chief executive her/himself. Sir Robert Francis also recommended the designation of a non-executive director who "works closely with the Freedom to Speak Up Guardian to act as a conduit through which information is shared with the board."[11] Of those responding to our question on this point, 67% reported that such a non-executive director had been identified, seven per cent said that they had not, and 25% did not know. Those who said that a non-executive director had been designated were asked to select the background of the director; Figure 9 presents responses to this question (those reporting other indicated in free text that non-executive directors from more than one of the sectors indicated fulfilled this role).

4.3. Culture and behaviour within organisations

The final set of questions in the survey related to respondents' perceptions of attitudes towards openness and learning in their organisations, and their sense of their own ability to raise concerns externally, as senior members of their organisations (particularly in light of well documented issues faced even by executives when speaking up about issues to external authorities[107]).

We asked respondents for their views on the extent to which staff members in their organisations were deterred from speaking up due to concern about the potential negative repercussions, indicated via a Likert scale. We also asked questions about the extent to which they considered hierarchy and

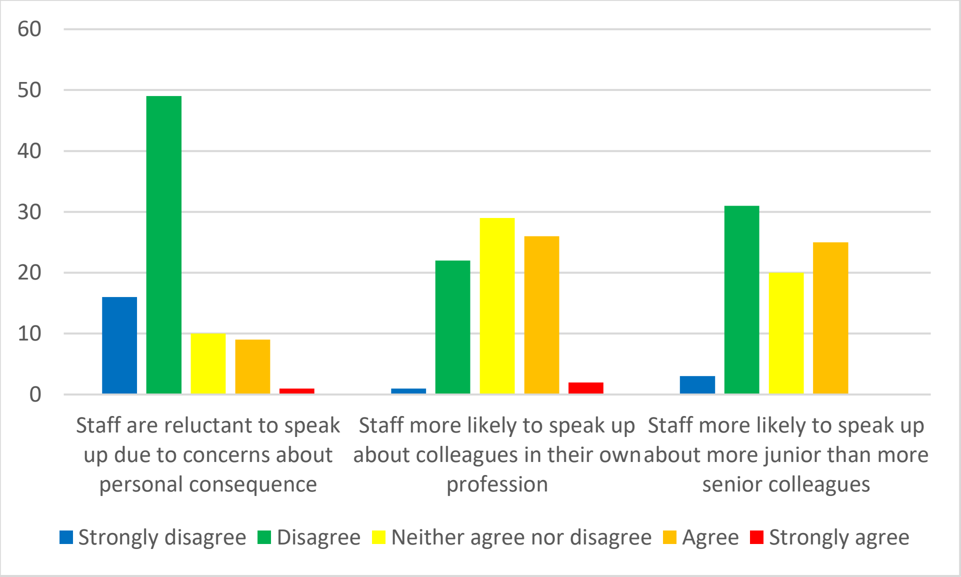

Figure 10: Views on influences on speaking up behaviour among colleagues

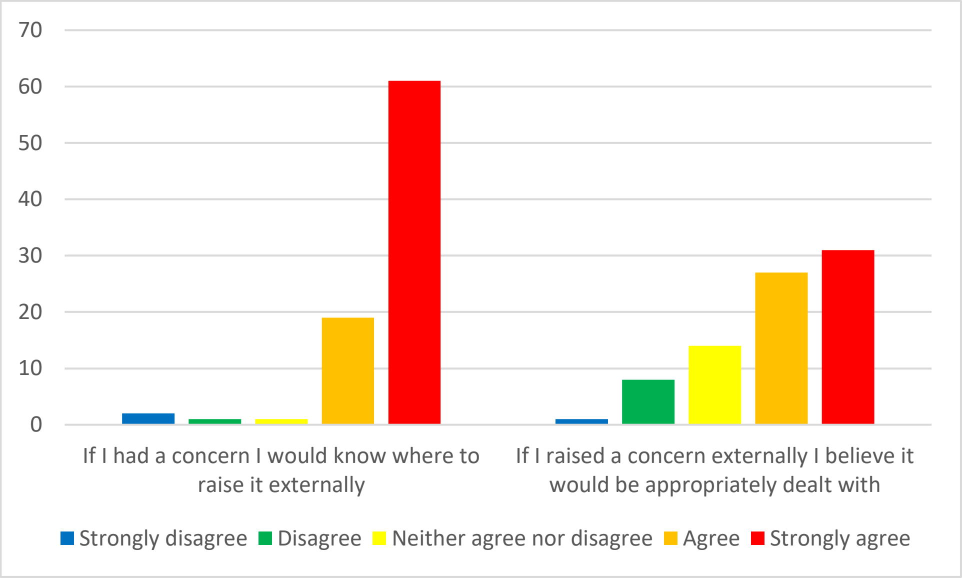

Figure 11: Views on raising concerns outside an organisation as a senior leader

professional affiliation to affect staff members' proclivity to speak up, again using Likert scales. Results are presented in Figure 10. A strong majority (76%) of those responding disagreed or strongly disagreed with the proposition that 'Employees in my organisation are reluctant to speak up about concerns about patient safety because they worry about potential negative consequences for themselves'. A comparison of the distributions for acute trusts and community and mental health services trusts using a chi-square test showed them to be similar (p=0.134) (Appendix G). Respondents were more divided in their responses to statements that 'Employees in my organisation are more likely to voice concerns about colleagues in their own professional group than in others' and 'Employees in my organisation are more likely to voice concerns about colleagues who are junior to them than about colleagues who are senior to them'.

Finally, we asked respondents about their sense of their own ability to speak up outside their organisations, if they had concerns about quality or safety. Responses to these questions are presented in Figure 11. The majority of respondents stated that they were very confident about whom they could approach with a concern, with 73% strongly agreeing with the statement 'If I had a concern about the quality and safety of care in my organisation that could not be dealt with internally, I would know which external body to raise it with'. Only three per cent disagreed or strongly disagreed. Responses to the statement 'If I raised a concern about quality and safety of care in my organisation with an external body, I am confident that it would be dealt with appropriately' were more mixed, however. The majority agreed or strongly agreed, but 28% of those who responded to this question disagreed or were unsure.

4.4. Conclusion

Though stymied by a low response rate, our survey nevertheless offers some interesting insights, broadening some of the analysis developed in Chapter 3 and highlighting some of the divergent challenges involved in the implementation of initiatives relating to openness.

The overall response to the survey suggests, similar to the findings from the telephone interviews, that the policy measures are by-and-large being welcomed by senior leaders within the NHS. Leaders also indicated that many of the measures were having an impact, though only for the Duty of Candour and the Serious Incident Framework (among the seven initiatives included in the question) did a clear majority of respondents report a 'Strong' or 'Very significant' impact. Initiatives that were optional, or to be found at the margins of organisations, such as the patient safety collaboratives and Q Fellows, were seen as much less impactful in respect of the goals of openness.

Respondents also tended to report that their organisations were places were already environments where staff had few anxieties about speaking up. This is a surprising finding, in the light of both the data from our telephone interviews (see section 3.5.4 in particular) and the findings of other research, which suggests that reticence about speaking up for fear of retaliation remains common—not least the surveys of staff conducted as part of the *Freedom to Speak Up* review.[11] Three explanations present themselves for this finding. One is response bias: as we note above, our sample did not appear to be representative in terms of their CQC rating (with acute and community and mental health services trusts rated 'Inadequate' at the time of the survey unrepresented), and it is plausible that respondents come from organisations that are more conducive than average to expressions of voice. A second explanation is that the results have been affected by social-desirability bias, such that respondents felt obliged to express more favourable views of their organisations than they really felt. The third, more concerning, explanation is that our results reflect a difference of perceptions between senior clinicians and managers at the blunt end of care, and 'rank-and-file' clinicians and other staff at the sharp end. Some support for this interpretation is perhaps offered by our telephone interviews, with senior staff noting something of a perception gap between sharp-end and blunt-end staff about the implications of Stafford and the salience of policies designed to improve openness (section 3.5.2).

Findings from the survey highlight challenges of implementation, particularly in relation to three of the highest-profile policy initiatives: Duty of Candour; Freedom to Speak Up Guardians; and the revised Serious Incident Framework. There was evidence in our data that the Serious Incident Framework was particularly problematic in relation to its resource implications (financial and in terms of staff capacity), and in terms of commissioners' expectations; nearly a quarter of respondents felt that the 60-day limit that then prevailed for the completion of serious incident investigations was unrealistic. Subsequent changes to the framework that, *inter alia*, relax this requirement are to be welcomed. There was very strong agreement with the notion that openness with patients and families helped to secure environments in which learning from mistakes was valued.

To this extent, and noting again the potential for social-desirability bias, the calls for greater family involvement in the new Patient Safety Incident Response Framework appear to be pushing at an open door in terms of executive support. Compared with the Serious Incident Framework and the Freedom to Speak Up Guardians, though, respondents felt that more clarity was required on the implementation of the Duty of Candour. This perhaps reflects findings from our telephone interviews that suggested in at least some organisations that a very risk-averse, compliance-oriented approach to implementation of the Duty has predominated (sections 3.1.1 and 3.5.1). In line with the qualitative analysis of our telephone interviews (section 3.3) and the findings of other research,[81] the results of our survey suggest that the Freedom to Speak Up Guardian function is being realised in various ways. This may assist in ensuring that groups in different positions in hierarchies and professional networks are able to access a Guardian. They also suggest, however, that in a substantial number of organisations, the equivalent of less than one full-time position is committed to the Guardian role—with no protected time at all in some.

Responses to the questions about participants' views on their own opportunities to speak up externally perhaps also deserve comment. There was a skew to the right in the distribution of answers to both questions—on where to raise a concern, and whether it would be dealt with appropriately (Figure 11)—but respondents were somewhat more ambivalent in their responses to the latter question. While the data from our telephone interviews indicates that some senior stakeholders are positive about the more mature relationships they now have with CQC inspectors following changes to the inspection regime (section 3.4), evidence from elsewhere suggests that (despite rhetoric around decentralisation and rationalisation of regulatory oversight) NHS leaders continue to have performance-oriented relationship with regulatory and commissioning bodies[108–110] that may suppress candour about the problems faced. Moreover, well publicised cases in the recent past where senior staff found difficulty in raising concerns with outside bodies[107] may remain prominent in the consciousness of current leaders, similar to the cautionary tales that we suggest may have an important impact on willingness to speak up at the sharp end (section 3.5.4).

While participants in the telephone interviews suggested that organisation type was an important mediator in their ability to implement some of the policies effectively (section 3.5.5), we were unable to find statistical support for a difference in the views of survey respondents from acute trusts and community and mental health trusts.

4.4.1. Limitations

The survey went through a careful, iterative and transparent process of development, including piloting with our professional advisory group. However, the response rate to our survey limits our confidence in its findings, and the results presented above should be interpreted with caution. Comparing the CQC ratings of the organisations from which respondents were drawn with the national profile of CQC ratings at the time suggests that the sample may not be representative, and notably no members of organisations rated ‘Inadequate’ responded to the survey. More broadly, as with any survey instrument, it is subject to reporting biases. In particular it should be noted that given its status as part of a Department of Health-commissioned study, respondents may have had qualms about whether to respond and about the responses they gave, even though assurances were given that results would be reported anonymously and in aggregate.

5. Results: Secondary analysis of NHS survey data (WP3)

Annual surveys have taken place in the NHS of staff since 2003. Patients, including acute inpatient and community mental health service users, have been surveyed annually since 2004. Several questions included in the surveys can be seen to relate to openness, and so these longitudinal datasets offer an opportunity to explore perceptions of openness over several years. WP3 sought to identify a complement of appropriate questions that had been posed consistently through rounds of the survey, with a view to identifying trends and changes—particularly since the publication of the Mid Staffordshire public inquiry.[5] Our research question was: are staff and patients' views on openness, knowledge of performance, and experiences of giving voice to concerns changing through time, for better or worse?

Full details of the methods for this secondary analysis are provided in section 2.3. In brief, a longitudinal research design was applied using data from the NHS National Staff Survey (2006-2017), NHS Acute Inpatient Survey (2004-2016) and NHS Community Mental Health Service User Survey (2007-2017). Longitudinal statistical methods (piecewise and interrupted latent growth curve analysis) were adopted to determine any change in response to survey questions relating to matters of openness since the time of the public inquiry (2012/2013).

We present our analysis and findings for each survey below, distinguishing between the primary and secondary variables identified *a priori* by the research team. We present each analysis in turn. Analyses covered individual survey items and, for the NHS National Staff Survey, 'key findings': aggregates of individual survey items based around a theme (see section 2.3). Appendix H provides supplementary information, including:

- tables showing the statistical summary details of each model tested.
- plots showing the actual change of variables over time.
- analysis for a small number of variables was omitted due to a lack of convergence of the models. We detail both those where the lack of convergence could be attributed to a change in the measurement used, and those where was for other reasons.

We discuss the implications of our results for the research question, and relate them to the wider study. Key findings are also picked up in Chapter 8. Findings from WP3 also feature in an output from our study comparing the results of the staff and patient surveys across physical and mental health (Appendix I).

5.1. Primary variables

5.1.1. National Staff Survey key finding: Good communication between managers and staff

Collected between 2008 and 2017, this is the percentage of employees who agreed or strongly agreed with at least three of the following four statements:

- senior managers here try to involve staff in important decisions;
- communication between senior management and staff is effective;
- I know who the senior managers are here;
- senior managers act on staff feedback.

In general, ratings of quality of communication between managers and staff increased from 2008-2017 (ranging on average from a minimum of 26.0% to a maximum of 33.5%). Between 2008 and

2013 this increase represented growth of 0.2% per annum. There was a slight decrease between 2013 and 2014 (significant at $p < 0.01$) of -0.1%. Rates of growth returned to a positive trajectory of 0.8% per annum between 2013 and 2017: a non-significant ($p > 0.1$) increase compared to previous years.

The intercept (starting mean at 2008) was lower for ambulance trusts than acute trusts with a difference of -14.8% ($p < 0.001$), indicating that perception of communication between managers and staff was initially better in acute care than in the ambulance service. All regions had lower starting means than London; the difference was -6.6% in the Midlands ($p < 0.001$), -4.4% in the North ($p < 0.001$) and -5.1% in the South. Trusts with more employees had a lower starting mean that those with fewer staff (organisational size, $Z=-0.40$, $p < 0.01$), indicating that communication was initially felt to be better in smaller organisations. Prior to 2013, rates of positive change in communication increased with organisational size ($Z= 0.10$, $p < 0.01$). Post-2013 rates of positive change in communication were faster in the South of England by 0.6% ($p < 0.05$) than in London.

5.1.2. National Staff Survey key finding: Can contribute towards improvements

Covering the period 2008-2017, this is the percentage of employees who agreed or strongly agreed with at least two of the following three statements:

- there are frequent opportunities for me to show initiative in my role;
- I am able to make suggestions to improve the work of my team/department;
- I am able to make improvements happen in my area of work.

Opportunities for staff to contribute towards improvements in the workplace increased between 2008 and 2017 (ranging on average from a minimum of 61.6% to a maximum of 70.2%). The period of growth began with an initial increase of 1.0% per annum between 2008 and 2013. This increase continued, but at a slower rate of 0.7% per year, between 2013 and 2017. There were no significant differences in rates of growth previous to or following 2012 and 2013; however there was a period of stagnation between 2013 and 2014 ($p < 0.05$).

In 2008, the survey suggests that ambulance trusts provided fewer opportunities than acute trusts for staff to contribute towards improvements in the workplace (a difference of -24.6%, significant at $p < 0.001$), while mental health trusts offered slightly more opportunities than acute (a difference of 5.7%, significant at $p < 0.001$). Such opportunities were also less frequent in all other regions compared to London, with a difference of -5.6% in the Midlands ($p < 0.001$), -4.8% in the North ($p < 0.001$) and -3.9% in the South ($p < 0.001$).

Prior to 2013, rates of change on this key finding followed a slow negative trend in mental health compared to acute trusts (a difference of -0.5%, $p < 0.001$), whilst rates of change were faster in the Midlands (by 0.5%, $p < 0.01$) and the North of England (by 0.4%, $p < 0.05$) than London. Post-2013 positive change was faster in the South of England (by 0.4%, $p < 0.05$) than in London.

5.1.3. National Staff Survey key finding: Fairness and effectiveness of incident reporting procedures

This scale (included from 2007 to 2017) measures: the extent to which staff are aware of the procedures for reporting errors, near misses and incidents; the extent to which they feel that their trust encourages such reports, and then treats the reports fairly and confidentially; and the extent to which the trust takes action to ensure that such incidents do not happen again.

Participants were asked to indicate (on a five-point Likert scale ranging from 1, ‘strongly disagree’, to 5, ‘strongly agree’) the extent to which they agreed or disagreed with the following statements:

- my organisation treats staff who are involved in an error, near miss or incident fairly;
- my organisation encourages us to report errors, near misses or incidents;
- my organisation treats reports of errors, near misses or incidents confidentially;

- my organisation blames or punishes people who are involved in errors, near misses or incidents;
- when errors, near misses or incidents are reported, my organisation takes action to ensure that they do not happen again;
- we are informed about errors, near misses and incidents that happen in the organisation.;
- we are given feedback about changes made in response to reported errors, near misses and incidents.

The average of participants' responses to the seven statements produced the key finding score.

There was an overall increase in ratings of the fairness and effectiveness of incident reporting procedures between 2007 and 2017 (ranging on average from a minimum of 3.36 to maximum of 3.73). Between 2007 and 2013, this increase averaged 0.02 scale points per year; it continued at a faster rate between 2013 and 2017, with an average annual increase of 0.06 scale points. The difference in rate of change pre- and post-2013 was significant at $p < 0.001$.

In 2007 mental health ($Z=-0.05$; $p < 0.001$) and ambulance trusts ($Z= -0.35$, $p < 0.001$) had a lower starting mean than acute trusts on indicators that measured the fairness and effectiveness of incident reporting procedures. Pre-2013, the rate of improvement on this measure was faster for mental health trusts ($Z=0.01$, $p < 0.001$) and slower for ambulance trusts ($Z=-0.01$, $p < 0.01$) than acute trusts. Organisations with more employees increased at a faster rate than those with fewer (Organisational size, $Z=0.001$; $p < 0.01$).

Post-2013, rates of improvement on this measure were faster for ambulance trusts ($Z=0.02$, $p < 0.001$) than acute and slower in the North of England ($Z=-0.01$, $p < 0.05$) than in London.

5.1.4. Acute Inpatient Survey: While you were in the A&E Department, how much information about your condition or treatment was given to you?

This item (analysed for the period 2005-2016) examines experiences of the provision of immediate treatment to people who are seriously injured in an accident or who are suddenly taken seriously ill, and how much information they are given about their condition or treatment while in the emergency department. This item is measured as a percentage ranging from zero (I was not given any information about my treatment or condition) to 100% (I was given the right amount of information about my treatment or condition).

Between 2005 and 2016, survey resulted indicated an upward trend in the amount of information given by A&E staff to patients (ranging on average from a minimum of 80.83% to a maximum of 83.58%). Between 2005 and 2013, this increase averaged 0.29% per year. Between 2013 and 2014 there was a slight decrease of -0.06% ($p < 0.001$), before returning to a positive trajectory between 2013 and 2016 of 0.75% per year—a significant increase ($p < 0.01$) compared with the pre-2013 trajectory.

There were no significant differences in intercept by region or organisation size. Likewise, there were no significant differences in rates of growth on either of these control variables pre- or post-2013.

5.1.5. Acute Inpatient Survey: Were you involved as much as you wanted to be in decisions about your care and treatment?

This item, covering the period 2004-2016, relates to the extent to which patients felt they were involved in care and treatment decisions relative to their preferences. This item is measured as a percentage ranging from zero (no involvement) to 100% (full involvement). Findings ranged on average from a minimum of 70.33% to a maximum of 75.07%.

There was an increase between 2004 and 2013 by an average of 0.39% per year, which continued at a slightly faster rate between 2013 and 2016, at an average of 0.78% per year. The difference in rate of change pre- and post-2013 was significant at $p < 0.01$.

In 2004, the extent to which patients were involved in decisions about their care and treatment was higher (on average) in the North (by 2.86%, $p < 0.05$) and South of England (2.66%, $p < 0.05$) than in London. Pre-2013, all regions had a slower rate of improvement on this item than London (Midlands -0.18%, $p < 0.05$; North -0.18%, $p < 0.05$; South Z= -0.20%, $p < 0.05$). There were no significant differences post-2013 by region or organisation size.

5.1.6. Acute Inpatient Survey: Did you find someone on the hospital staff to talk to about your worries and fears? (2004-2016)

This item, analysed from 2004 to 2016, considers whether patients had access to someone on the hospital staff whom they could talk to about any anxieties they had about their care. This item is measured as a percentage ranging from zero (no) to 100% (yes, definitely). Findings ranged on average from a minimum of 56.59% to a maximum of 61.50%.

Overall, there was a decrease on this item between 2004 and 2012 by an average of -0.10% per year; however, between 2012 and 2016, despite some fluctuations, there were also signs of recovery ($p < 0.05$) averaging 0.23% per year.

In 2004, all regions offered more opportunities than London for patients to discuss their concerns: the Midlands by 3.73% ($p < 0.01$); the North by 5.99% ($p < 0.001$); and the South by 4.13% ($p < 0.01$). Pre-2012, there were no significant differences in the rate of change on this variable by region or organisation size. However, post-2013, all regions experienced negative growth on average (the Midlands by -0.56% ($p < 0.01$), the North by -0.60% ($p < 0.01$) and the South by -0.45% ($p < 0.05$)) compared to London.

5.1.7. Community Mental Health Service User Survey: Did the person or people you saw listen carefully to you?

Relating to the interactions that occur between patients and health and social care workers, this item (covering the period 2007-2017) considers whether community mental health service users feel listened to when discussing their care needs. It is measured as a percentage ranging from zero (no) to 100% (yes, definitely). Findings ranged on average from a minimum of 81.47% to a maximum of 88.29%.

It should be noted that while the response option has remained the same over the years, the wording to the question has altered somewhat:

- pre-2010, participants were asked to think of their psychiatrist when answering the question;
- for 2010-2013, participants were asked to choose from a list of health and social care workers (one of the options being a psychiatrist) when responding to the question;
- for 2014-2017, participants were asked to contemplate the question in relation to their interactions with a wide range of health and social care workers (not just one) from the perspective of the service more broadly.

While it is not customary to present longitudinal analysis based on data that has been affected by changes to the wording of the question on different data points, this finding is presented for narrative purposes, since we believe it reflects the changing nature of mental health services—with the primary point of contact no longer necessarily a psychiatrist.

There was an increase on this variable from 2007 to 2013 by an average of 0.32% per year. After this, however (and up until 2017), there was a significant decrease ($p < 0.001$) at an average of -1.92% per year, suggesting patients may not feel as listened to as they once did.

There were no significant differences in intercept by region or organisational size. Likewise, there were no significant differences in rates of growth on either of these controls variables pre- or post-2013.

5.1.8. Community Mental Health Service User Survey: Were you given enough time to discuss your needs and treatment?

This item (2007-2017) considers whether service users feel they are given sufficient time to discuss their mental health needs when interacting with health and social care workers. This item is measured as a percentage ranging from zero (no) to 100% (yes, definitely). Findings ranged on average from a minimum of 75.47% to a maximum of 83.09%.

As with the previous question where participants are asked to consider whether they felt listened to when discussing their care needs, this question has been subject to same changes. Initially participants were asked to think of their psychiatrist as the main unit of analysis when answering the question, and in later years they were asked to think more broadly in terms their experience of the service generally. These finding are therefore presented for narrative purposes only.

There was an increase from 2007 to 2013 by an average of 0.32% per year. After this (and up until 2017) there was again a significant decrease ($p=.001$) at an average of -1.77% per year, suggesting patients are becoming less satisfied with the amount of time available to discuss their care needs.

In 2007, patients receiving care in the North of England were more satisfied with the amount of consultation time available to them (by 3.33%, $p < 0.001$) than those in London. Pre- and post-2013, there were no significant differences in rates of growth on this variable by region or organisational size.

5.1.9. Community Mental Health Service User Survey: In the last 12 months have you had a formal meeting with someone from NHS mental health services to discuss how your care is working?

This question (considered for the period 2007-2017) investigates whether service users have attended a formal meeting to review their care with someone from NHS mental health services in the past year. This item is measured as a percentage ranging from zero (no) to 100% (yes). Findings ranged on average from a minimum of 55.11% to a maximum of 73.86%.

There was an increase between 2007 and 2013 by an average of 1.80% per year. There was then a significant increase ($p < 0.01$) at a rapid rate from 2013-2014 by 3.23%. From 2013-2017 the increase continued but at a slower rate, by an average of 0.52% per year—a significant deceleration ($p < 0.001$) compared to previous years.

In 2007, service users in the Midlands said they had fewer opportunities to discuss their care than those in London (as indicated by a -7.02% difference, significant at $p < 0.05$). Pre- and post-2013, there were no significant differences in rates of growth on this variable by region or organisational size.

5.1.10. Community Mental Health Service User Survey: Overall in the last 12 months, did you feel that you were treated with respect and dignity by NHS mental health services?

In contemplating their overall experience, this question (2007-2017) asks patients to consider whether they feel they were treated with respect and dignity. This item is measured as a percentage ranging from zero (no) to 100% (yes, always). Findings ranged on average from a minimum of 83.01% to a maximum of 92.82%.

There was a decrease between 2007 and 2013 of an average of -0.05% per year. This continued but at a faster rate of -6.55% ($p < 0.001$) between 2013 and 2014. Between 2013 and 2017 there was still a decrease but at a slower rate of -0.38% per year—a slight, non-significant ($p > 0.1$) worsening compared to the 2007-to-2013 timeframe.

In 2007, perceptions and experiences of respect and dignity were higher in all other regions (by 2.51% in the Midlands, $p < 0.001$; by 2.57% in the North, $p < 0.001$; and by 1.86% in the South, $p < 0.01$) than in London. Pre- and post-2013, there were no significant differences in rates of growth on this variable by region or organisation size.

5.2. Secondary variables

5.2.1. National Staff Survey key finding: Suffered discrimination in last 12 months

Covering the period 2009-2017, this is the percentage of staff who say that they had experienced discrimination from patients / service users, their relatives or other members of the public, and/or from colleagues or managers in the last 12 months.

Overall experiences of discrimination were reported to have increased between 2009 and 2017. Findings ranged on average from a minimum of 7.5% to a maximum of 13.7%. There was an increase from 2009-2012 by an average of 0.9% per year. From 2012 to 2017 there was still an increase, but at a lower rate of 0.2% per year—reflective of a levelling-off effect. The difference in growth either side of 2012 was significant at $p < 0.001$.

In 2009, mental health and ambulance staff said they experienced higher levels of discrimination that those working in acute care (mental health staff by 1.10%, $p < 0.01$; ambulance staff by 6.1%, $p < 0.001$). Staff in all other regions experienced lower levels of discrimination than those working in London (the Midlands by -3.7%, $p < 0.001$; the North by -4.9%, $p < 0.001$; the South by -3.9%, $p < 0.001$). Levels of discrimination were initially higher in larger organisations ($Z= 0.20$, $p < 0.001$) than those with fewer employees.

Between 2009 and 2012, discrimination in mental health and ambulance trusts was reported to have increased at a higher rate than in acute trusts (mental health trusts by 0.30%, $p < 0.01$; ambulance trusts by 1.1%, $p < 0.001$). Rates of change fell at a decreased rate in all other regions compared to London (the Midlands by -0.4%, $p < 0.01$; the North by -0.7%, $p < 0.001$; the South by 0.5%, $p < 0.01$). Between 2012 and 2017, mental health trusts experienced negative growth of -0.2% ($p < 0.05$) compared to acute trusts where levels discrimination where higher.

5.2.2. National Staff Survey key finding: Trust provides equal opportunities to staff

This is the percentage of staff who said that their trust acts fairly with regards to career progression/promotion, regardless of ethnic background, gender, religion, sexual orientation, disability or age (analysed for 2008-2017).

There was an overall downward trend in perceptions of equal opportunities between 2008 and 2017. Findings ranged on average from a minimum of 84.3% to a maximum of 89.0%. There was a decrease from 2008-2012 by an average of -0.7% per year. From 2012 to 2017 this decrease continued at a rate of -0.8% per year. The difference in growth either side of 2012 was significant at $p < 0.05$.

At the intercept (2008), equality of opportunity was seen as poorer in mental health (by -1.8%, $p < 0.001$) and ambulance trusts (by -14.8%, $p < 0.001$) than in acute trusts, but better in community trusts (by 5.2%, $p < 0.01$).

Equal opportunities were seen as greater in all other regions compared to London (the Midlands by 4.3%, $p < 0.001$; the North by 5.9%, $p < 0.001$; the South by 4.9%, $p < 0.001$). As organisation size increased, equality of opportunities worsened ($Z=-0.20$, $p < 0.05$).

Prior to 2012, views of equal opportunities within mental health services improved at a faster rate (0.5%, $p < 0.001$) than acute care, while proceeding at a negative rate within the ambulance service (-1.4%, $p < 0.001$).

Equal opportunities in the Midlands and the North of England transpired at faster rate (of 0.4%, $p < 0.05$) than those in London. Post-2012, rates of change were higher for ambulance trusts than acute trusts (by 0.9%, $p < 0.001$) and higher in the South of England (by 0.5%, $p < 0.01$) than in London.

5.2.3. National Staff Survey key finding: Would recommend trust as place to work

Staff are asked whether they thought care of patients and service users was the trust's top priority, whether they would recommend their trust to others as a place to work, and whether they would be happy with the standard of care provided by the trust if a friend or relative needed treatment. We considered this key finding from 2009 to 2017, and it was measured on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).

Overall, staff's perceptions of their organisation improved. Findings ranged on average from a minimum of 3.50 to a maximum of 3.75. Between 2009 and 2012, changes in perceptions contributed to an average increase of 0.02 scale points per year. This increase continued, albeit at a slightly slower rate of 0.01 scale points per year, between 2012 and 2013, before returning to improvement at a rate of 0.02 scale points per year between 2012 and 2017. The difference in growth between 2012 and 2013 was significant at $p < 0.01$ compared to prior and future years.

At the outset (2009) employees' positive perceptions of their organisation was lower for mental health ($Z=0.16$, $p < 0.001$) and ambulance ($Z=0.40$, $p < 0.001$) trusts than acute. Perceptions were also more negative in all regions compared to London (Midlands $Z=-0.15$, $p < 0.001$; North $Z=-0.11$, $p < 0.01$; South $Z=-0.16$, $p < 0.001$) and in larger organisations (organisation size, $Z=-0.01$, $p < 0.05$).

Prior to 2012, ambulance trusts experienced negative growth ($Z=-0.04$, $p < 0.05$) compared to acute; this trend reversed post-2012 ($Z=0.04$, $p < 0.01$). Also, subsequent to 2012, rates of growth on this variable were higher in the Midlands ($Z=0.02$, $p < 0.05$) and the South of England ($Z=0.03$, $p < 0.001$) than in London.

5.2.4. National Staff Survey other item: The team I work in often meets to discuss the team's effectiveness

This section (and section 5.2.5) presents some individual staff survey items (not captured by the key findings above) relevant to the issue of openness. These items relate specifically to employees' views about their job, and are located in the 'Your job' section of the staff survey.

The first scale (covering the period 2010-2017) assesses the extent to which staff feel they work in a team where team members meet often to discuss the team's effectiveness. Possible scores range from 1 (strongly disagree) to 5 (strongly agree). Responses ranged on average from a minimum of 3.44 to a maximum of 3.48.

Overall, ratings increased between 2010 and 2013 by 0.02 scale points per year. This pattern was followed by a decrease between 2013 and 2017 of -0.01 scale points per year. The difference in change either side of 2013 was significant at $p < 0.05$.

In 2010, staff in mental health ($Z=0.24$, $p < 0.001$) and community ($Z=0.29$, $p < 0.001$) trusts reported more opportunities for teams to meet to discuss their effectiveness than acute trusts, whilst such opportunities were seen as fewer by ambulance trust staff ($Z=-0.73$, $p < 0.001$). All regions reported lower scores on this variable compared to London (Midlands $Z=-0.09$, $p < 0.001$; North $Z=-0.05$, $p < 0.05$; South $Z=-0.06$, $p < 0.01$). Such opportunities were also seen as fewer within larger organisations ($Z=-0.01$, $p < 0.05$).

Between 2010 and 2013, rates of growth of this variable were lower among ambulance ($Z=-0.05$, $p < 0.001$) and community trusts ($Z=-0.04$, $p < 0.05$) than acute trusts—both showing a negative trajectory.

Post-2013 until 2017, ambulance trusts ($Z=-0.028$, $p < 0.01$) experienced more negative growth than acute trusts. Trusts in the Midlands (Z=0.015) experienced more positive growth than those in London.

5.2.5. National Staff Survey other item: Team members have to communicate closely with each other to achieve the team's objectives

This item (2010-2017) relates to the extent to which teams agree that communication within their team allows them to achieve their objectives. Measured on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), responses on average ranged from a minimum of 3.89 to a maximum of 3.96.

Overall, there was a general upward trend between 2010 and 2012 of 0.03 scale points per year. Between 2012 and 2017 this upward trend continued at a slower rate at 0.01 scale points per year. Between 2012 and 2013 the rate of change was significantly lower ($Z= 0.00$, $p < 0.05$) than in the years previous to or subsequent.

In 2010, mental health trusts scored higher on this variable ($Z= 0.05$, $p < 0.001$) than acute trusts, while ambulance trusts scored lower ($Z=-0.32$, $p < 0.001$). There were no significant difference in rates of growth on this variable between 2010 and 2012 by trust type, region or organisation size.

Post-2012, rates of change on this variable grew at a negative rate among ambulance trusts ($Z=-0.03$, $p < 0.001$) compared to acute trusts. Rates of change developed at a negative rate within the North of England ($Z=-0.01$, $p < 0.05$) compared to London.

5.2.6. Acute Inpatient Survey: Did doctors talk in front of you as if you weren't there?

This item (covering the period 2004-2016) explores patient-doctor interactions and whether patients feel dismissed during consultations in the emergency department. This item is measured as a percentage ranging from zero (yes, often) to 100% (no). An upward trend on this item is indicative of an improvement (no is the positive stem). Responses ranged on average from a minimum of 83.27% to a maximum of 86.27%.

Overall, there was an improvement in patient-doctor interaction overtime as measured by this item. Positive responses to this question increased at an average rate of 0.17% per year up until 2013; after this and up until 2016 the rate of change increased to 0.62%. The difference in growth either side of 2013 was significant at $p < 0.05$.

In 2004, positive experiences of doctor-patient dialogue were higher in the North (by 3.18%, $p < 0.001$) and South of England (by 2.70%, $p < 0.01$) than in London. Positive interactions were less frequent in larger organisations ($Z=-0.35$, $p < 0.001$). Pre-2013, there were no significant differences in rates of change on this variable by region and organisational size. Post-2013 rates of improvement were higher in the Midlands (by 0.35%, $p < 0.05$) and North of England (by 0.36%, $p < 0.05$) than in London.

5.2.7. Acute Inpatient Survey: Did nurses talk in front of you as if you weren't there?

This item (2004-2016) explores patient-nurse interactions in the emergency department, and whether patients feel dismissed during consultations. This item is measured as a percentage ranging from zero (yes, often) to 100% (no). An upward trend on this item is indicative of an improvement (no is the positive stem). Responses ranged on average from a minimum of 86.71% to a maximum of 89.53%.

Responses to this question followed a mostly positive trend. Between 2004 and 2012 there was a slight increase in patient-nurse dialogue of 0.12% per annum; this decreased to some extent between 2012 and 2013 by -0.02% (a difference statistically significant at $p < 0.05$ compared to past and future years), before returning to a positive trajectory of approximately 0.61% per annum up until 2016.

In 2004, perceptions of nurse-patient dialogue were better in the Midlands (by 3.45%, $p < 0.001$), North (by 5.12%, $p < 0.001$) and South of England (by 5.34%, $p < 0.01$) than in London. Positive interactions were less frequent in larger organisations (Z=-0.20, $p < 0.001$). Rates of change were lower in the South of England by -0.14% pre-2012 ($p < 0.05$) and by -0.28% post-2012 ($p < 0.05$). There were no significant differences by organisation size.

5.2.8. Acute Inpatient Survey: How many minutes after you used the call button did it usually take before you got the help you needed?

This item (2004-2016) assesses the speed with which patients' calls for assistance are met, and is measured as a percentage ranging from zero (I never got help when I used the call button) to 100% (0 minutes / right away). Responses ranged on average from a minimum of 60.91% to a maximum of 68.17%.

Responses to this question prior to 2012 followed a period of decline (-0.56%) followed by recovery (0.34%). The difference in growth either side of 2012 was significant at $p < 0.01$.

At the intercept (2004) scores on this variable were higher in the North of England (by 5.93%, $p < 0.001$) compared to London. Pre-2012, the North of England experienced negative growth by -0.28% ($p < 0.05$). This pattern continued post-2012 by a rate of -0.34% ($p < 0.05$) (again compared to London). There were no significant differences by organisation size.

5.2.9. Acute Inpatient Survey: Beforehand, did a member of staff explain the risks and benefits of the operation or procedure in a way you could understand?

This question (2005-2016) aims to determine whether patients are informed of, and understand, the risks and potential benefits of their operation or procedure. This item is measured as a percentage ranging from zero (no) to 100% (yes, completely). Responses ranged on average from a minimum of 88.30% to a maximum of 89.80%.

Responses followed an initial period of minor fluctuation (2005-2012), representing an average annual increase of 0.06%. This was followed by a more rapid improvement between 2012 and 2016 of approximately 0.28% per year. The difference in growth either side of 2012 was significant at $p < 0.05$.

At the intercept (2005) scores on this variable were higher on average in the North (by 1.51%, $p < 0.05$) and South of England (by 1.44%, $p < 0.05$) compared to London. Pre- and post-2012, there were no significant differences in rates of growth on this variable by organisational size or region.

5.2.10. Acute Inpatient Survey: Did a member of staff explain what would be done during the operation or procedure?

Measured as a percentage ranging from zero (no) to 100% (yes, completely), this item (analysed for the period 2005-2016) considers the extent to which patients feel they are fully informed about their operation or procedure. Responses ranged on average from a minimum of 84.40% to a maximum of 86.05%.

Overall, there was an improvement over time in responses to this item. From 2005 to 2013 there was an annual increase of 0.17%, followed by an increase of 0.49% per year between 2013 and 2016. The difference in growth either side of 2013 was significant at $p < 0.001$.

There were no significant differences in intercept by region or organisation size. Pre-2013 rates of improvement decreased with organisational size (Z=-0.02%, $p < 0.05$). Post-2013 rates of improvement were lower in the South of England (by-0.37%, $p < 0.05$) than in London.

5.2.11. Acute Inpatient Survey: Were you told how you could expect to feel after you had the operation or procedure?

This item (2005-2016) considers whether patients are informed how they should expect to feel after an intervention. It is measured as a percentage ranging from zero (no) to 100% (yes, completely). Responses ranged on average from a minimum of 69.64% to a maximum of 73.08%.

There was an increase through time in positive responses to this question. Between 2005 and 2016 this increase averaged 0.37% per year; from 2013 to 2016 this increase represented 0.98% per annum. The difference in growth either side of 2013 was significant at $p < 0.05$.

At the intercept (2005) scores on this item were higher in the North of England (by 2.84%, $p < 0.01$) than in London. Pre-2013 rates of improvement decreased with organisation size (Z=-0.03%, $p < 0.05$). Post-2013 rates of improvement were lower in the North of England (by -0.52%, $p < 0.05$) than in London.

5.2.12. Acute Inpatient Survey: After the operation or procedure, did a member of staff explain how the operation or procedure had gone in a way you could understand?

This item (covering the period 2005-2016) represents the percentage of patients (ranging from zero (no) to 100 (yes completely)) who feel they are told how their procedure had gone in a way that they can understand. Responses ranged on average from a minimum of 75.61% to a maximum 79.85%.

There was an increase over time in positive responses to this question. Between 2005 and 2012 this represented a 0.42% annual increase; this was followed by a slower increase between 2012 and 2013 of 0.09% (a statistically significant difference in rate of change compared to past and future years by $p < 0.05$), before returning to faster rate of 0.88% between 2012 and 2016.

There were no significant differences in intercept by region or organisational size. Pre 2012 rates of improvement decreased with organisational size (Z=-0.03%, $p < 0.05$). There were no significant differences in rates of growth post-2012.

5.2.13. Acute Inpatient Survey: Before you left hospital, were you given any written or printed information about what you should or should not do after leaving hospital?

This item (2007-2016) represents the proportion of respondents who were given written or printed information about their post-hospital aftercare. This item is measured as a percentage ranging from zero (no) to 100% (yes). Responses ranged on average from a minimum of 61.28% to a maximum of 69.18%.

Overall responses to this question showed an increase followed by a decrease, suggesting access to written or printed information has gone into decline. Between 2007 and 2012 there was an annual increase of 1.68%, which continued but at a slightly slower rate between 2012 and 2013 of 1.17% (a statistically significant difference compared to past and future years at $p < 0.01$). Between 2012 and 2016, there was a decreased at an annual rate of -1.49% per year.

There were no significant differences in intercept by region or organisation size. Pre-2012 rates of improvement were lower in the Midlands (by -0.83%, $p < 0.05$) than in London. There were no significant differences in rates of growth post-2012.

5.2.14. Acute Inpatient Survey: Did a member of staff tell you about any danger signals you should watch for after you went home?

This item (2004-2016) represents the proportion of patients who report being told how they should be vigilant after leaving hospital. This item is measured as a percentage ranging from zero (no [I was not told]) to 100% (yes, [I was told] completely). Responses ranged on average from a minimum of 49.40% to a maximum of 54.16%.

Between 2007 and 2012 there was an annual increase of 0.84%. This continued but at a slightly slower rate between 2012 and 2013 of 0.34% (a statistically significant difference compared to past and future years at $p < 0.05$), and continued at an increased rate of 0.54% per year between 2012 and 2016.

At the intercept (2004), scores on this item were higher in the North of England (3.56%, $p < 0.05$) than in London. Pre-2012 rates of improvement were lower in the Midlands (-0.41%, $p < 0.05$) than London. There were no significant differences in rates of growth post-2012.

5.2.15. Acute Inpatient Survey: During your hospital stay, were you ever asked to give your views on the quality of your care?

This item (2005-2016) covers the extent to which patients are invited to give feedback on their views on the overall views of the quality of care they received. This item is measured as a percentage ranging from zero (no) to 100% (yes). Responses were much poorer on this measure than most others, ranging on average from a minimum of 6.15% to a maximum of 21.27%.

Longitudinal responses to this question started with an increase which was followed by a decrease. Between 2005 and 2012 there was an average annual increase of 1.87%; this increased rapidly between 2012 and 2013 by 5.41%, before moving to a slight downward trajectory of -0.63% per year until 2016.

At the intercept (2005), scores on this item were lower in the Midlands (by -2.86%, $p < 0.001$), North (by -2.29%, $p < 0.01$) and South of England (by -3.21%, $p < 0.001$) compared to London. Pre-2012, rates of improvement were lower in the North (by -0.73%, $p < 0.001$) and South (by -0.75%, $p < 0.001$) compared to London. There were no significant differences in rates of growth, by region or trust size, post-2012.

5.2.16. Acute Inpatient Survey: Did you see, or were you given, any information explaining how to complain to the hospital about the care you received?

This measure of patient experience (covering the period 2007-2016) relates to whether patients know how to complain (if needed) about the care they receive. In 2012, the phase “were you given” was included in the question; prior to this, survey participants were only asked to consider whether they had *seen* such information. This wording change may have implications for the pattern of responses. Responses ranged on average from a minimum of 21.48% to a maximum of 41.98%.

Overall awareness of complaint procedures as indicated by this item decreased over time. Between 2007 and 2013, there was an annual decrease of -1.66%; between 2013 and 2016 this accelerated to -1.71%. The difference in rate of change either side of 2013 was significant at $p < 0.001$.

In 2007, initial scores on this variable were lower in the South of England (by -4.70%, $p < 0.05$) than in London. Pre-2013 rates of improvement were lower in the North of England (by -1.11%, $p < 0.05$) than London. There were no significant differences in rates of growth, by region or trust size, post-2013.

5.2.17. Community Mental Health Service User Survey: Were you involved as much as you wanted to be in decisions about which medicines you receive?

This question (2007-2017) asks patients whether they were involved as much as they wished in medication decisions, and is measured as a percentage ranging from zero (no) to 100% (yes, definitely). Responses ranged on average from a minimum of 60.39% to a maximum of 72.99%.

Responses followed a positive trajectory between 2007 and 2013, with an average increase of 1.75% per year. Between 2013 and 2017, there was a slight downward trend averaging -0.88% per year. The difference in growth either side of 2013 was significant at $p < 0.01$.

There were no significant differences in intercept by region or organisation size. Likewise, there were no significant differences in rates of growth on either of these control variables pre- or post-2013.

5.2.18. Community Mental Health Service User Survey: In the last 12 months, has an NHS mental health worker checked with you about how you are getting on with your medicines?

This question, analysed for the period 2010-2017, assesses whether patients are supported in their use of medications. This item is measured as a percentage ranging from zero (no) to 100% (yes). Responses ranged from a minimum of 76.89% to a maximum of 88.35%.

Whilst growth on this item generally remained consistent between 2010 and 2017, a significant deviation should be highlighted at 2013. Between 2012 and 2013 there was an increase of 3.82% compared to past and future years (significant at $p < 0.01$); this increase was followed by a rapid decrease between 2013 and 2014 of -2.23% (also significant at $p < 0.01$), after which time scores returned to pre-2013 levels or thereabouts.

There were no significant differences in intercept by region or organisation size. Similarly, there were no significant differences in rates of growth on either of these control variables pre- or post-2012 and 2013.

5.3. Summary of findings

We find that for some indicators of various aspects of openness selected prior to analysis, there was a discernible change in trajectory when comparing trends over time before and after the publication of the report of the Mid Staffordshire public inquiry in 2013.[5] For almost all questions identified as primary measures of interest in the National Staff Survey, there was a positive increase in the direction or rate of change after publication. For primary measures of interest identified in the Acute Inpatient and Mental Health surveys, however, the picture was more mixed: while the general trend in the measures from the Acute Inpatient Survey was positive, for the measures from the Mental Health Survey it was negative. For secondary measures, the pattern of changes was also more mixed, with some evidence of positive changes, but other variables where the change seemed to be non-existent or negative.

The summary presented here assume a general pattern of growth in the direction of the trajectory stated, unless specified otherwise.

5.3.1. Primary variables

A noticeable change was observed in Staff, Inpatient and Mental Health Service User Survey data in the rate and sometimes the direction of change after the publication Mid Staffordshire public inquiry in 2013.

For Staff Survey variables relating to openness, there was a positive increase in the rate of change after the publication of the Francis report in matters relating to communication between managers and staff, and in the fairness and effectiveness of incident-reporting procedures. Where rates of improvement slowed or levelled off, this was most likely due to a ‘ceiling effect’ where no further improvement was possible.

The general trend for the Inpatient Survey was positive, with increases at a faster rate during the second period. Specifically, from 2013, satisfaction with the amount of information given to patients in the emergency department about their condition or treatment increased at a faster rate; patients’ satisfaction with their involvement in decisions about their care and treatment also increased more sharply.

For the Mental Health Service User Survey the pattern of change was rather different. Patients continued to report better access to care consultations (as indicated by whether they had attended a meeting to discuss their care in the last year), though at a slower rate of increase after 2013. However, levels of satisfaction indicated in other questions relating to openness deteriorated: patients felt less listened to, believed they were not given enough time to discuss their care, and felt treated with less respect and dignity compared to previous years.

5.3.2. Secondary variables

For items from the National Staff Survey, there was a mixture of effects, with some improvements slowing after 2012/2013 and some picking up in pace. Employees' views on their likelihood of recommending their trust as a place to work, and on close communication with their team to achieve common objectives, both improved after 2012, but at a slower rate than previously. Conversely, staff reported having experienced slightly more discrimination in last 12 months compared to previous years, and felt that equal opportunities had worsened (2012). A decline was also observed in how often teams met to discuss their effectiveness (2013).

For the NHS Acute Inpatient Survey, positive and negative changes were observed after 2012 and 2013. Post-2012, patients' calls for assistance were more quickly responded to; pre- and post-operative communication regarding the risks and outcomes of a procedure was more comprehensible to patients; patients were better informed of the warning signs to be aware of following discharge from hospital (though this rate of increase slowed after 2012); patients felt nurses were more respectful (and less dismissive) of them during discussions. On the other hand, patients had less access to written or printed information concerning their aftercare, and were less likely to be invited to give feedback on the quality of care they received. Post-2013, patients felt that doctors were more respectful (and less dismissive) of them during consultations, and felt better informed about what would happen during an intervention and how they could expect to feel afterwards. Conversely, patients said they were less likely to be given information explaining how to complain (if necessary) about the care they received.

Change in measured covered by the NHS Mental Health Survey comes into effect from 2013 (no significant changes were identified in 2012). The likelihood of receiving a medication review to check how they were getting on with new medications decreased after a peak in 2013, and service users were less satisfied with the involvement they had in decisions about the medications they received.

5.4. Conclusion

Our longitudinal analysis of data from the staff survey, acute inpatient and mental health surveys suggests that for some indicators of various aspects of openness selected *ex ante*, there was a discernible break when comparing trends over time before and after the publication of the Mid Staffordshire public inquiry,[5] consistent with the notion of a 'Francis effect'. This change often predates the introduction of formal policies, but as noted in section 3.5.3, in many organisations efforts to address various aspects of openness predated national-level policy implementation.

The apparent divergence in the trajectories and rates of change, as evidenced by differences in the experiences of patients and service users in acute care and community-based mental health, deserves some comment. Recent commentary has noted an entrenched inequality in perceptions, resourcing and funding between physical and mental health,[111] and policymakers have committed in the *Long Term Plan* to achieving 'parity of esteem' between physical and mental health services.[112] Ensuring that patients feel able to discuss their conditions and raise concerns about care is an important component of ensuring high-quality care, but this analysis suggests a worrying and sustained trend for several indicators as assessed by mental health service users. As we note in our analysis of telephone interviews with senior stakeholders (section 3.5.5), there is a perception that many of the measures that have been introduced since the Mid Staffordshire public inquiry have been modelled around the template of an acute hospital organisation. Interviewees suggested that this related to differences in both organisational form and client group, with the more sustained, less episodic care trajectories of mental health service users compared to patients in acute hospitals resulting in the need for different approaches to openness when it comes to, for example, disclosures under the Duty of Candour. Similar disparities between the two sectors may be at play in relation to the more day-to-day components of openness covered in the Acute Inpatient and Community Mental Health Service User surveys, around issues such as the time available for discussions about care, decision-making and medication. Finding space for openness and dialogue in such processes is clearly fundamental to positive experiences of care; it is also challenging in resource-constrained environments.

5.4.1. Limitations

In interpreting the analyses presented in this chapter, we cannot presume any direct causal effect between the Francis report and these changes. There is no control group, and various other significant changes affected the NHS in England at a similar time (most notably the introduction of the Health and Social Care Act,[113] which had significant consequences for the organisation of care across the NHS). However, the findings are largely consistent with the hypothesis that at least some aspects of the experience of both staff and patients were linked to changes resulting from analyses and policies following Mid Staffordshire, including but not limited to the public inquiry.

6. Results: Openness in action: the Duty of Candour and incident investigations (WP4)

In our final workpackage, we used qualitative methods to take a closer look at the realisation of three openness-related policies in a range of case-study sites, sampled for their organisational diversity. We sought to address our first and third research questions: ‘how do senior managers and clinicians in organisations providing NHS services understand policies and translate them into specific norms, expectations and practices in their organisations?’ (also addressed through WP1 and WP2, Chapters 3 and 4); and ‘are provider organisations’ efforts to increase openness resulting in real changes in staff values, attitudes and actions at the sharp end of care and in patients’ opportunities and experiences around openness—and what features contribute to success?’.

Our approach was qualitative. As many aspects of openness are characterised by infrequent, unpredictable occurrences (e.g. enacting the Duty of Candour; ‘blowing the whistle’; expressing or acting on concerns), direct observation is very difficult. Given the challenges of studying instances of openness as they occur, we relied on interview accounts with both senior and junior staff, and with patients and carers affected by openness initiatives. Data collection took place from March 2018 to July 2019. A full account of our methods is provided in section 2.4.

Findings from workpackages 1 and 2 (see Chapters 3 and 4) suggested that various organisational characteristics might be relevant to how policies played out on the ground in provider organisations. Accordingly, we sampled six case study sites purposively, with a view to capturing diversity in these characteristics, broadly following a maximum-variation sampling strategy[60] with a view to permitting cross-case comparison,[57,59] and thus insight into the role of these characteristic in influencing openness. Seemingly consequential variables included provider type (acute care, mental health and community healthcare, ambulance service—see sections 3.5.5 and 5.1.1-5.1.3), size of organisation (with larger organisations posing a greater implementation challenge, but smaller organisations potentially suffering from isolation—see sections 3.5.1, 3.5.4 and 3.5.5), and the variety of approaches to arrangements for appointing Freedom to Speak Up Guardians and prioritising their workload (see sections 3.3 and 4.2). We also sought to account for other variables that seemed intuitively likely to influence openness, such as CQC rating, board stability, and position in the ‘Learning from mistakes league’,[114] a ranking system compiled by Monitor and the Trust Development Agency based on indicators of effectiveness of incident-reporting procedures, staff confidence in reporting unsafe clinical practice, and the proportion of staff who feel able to contribute towards improvements. We included trusts with troubled episodes from the past and those that had implemented impressive, locally designed, novel programmes to promote or facilitate openness, identified by participants in WP1.

The six case-study sites we recruited included three acute trusts, two community and mental health service trusts (one including high-secure forensic mental health services), and one ambulance service trust. Table 7 presents an overview of the characteristics of the case-study sites. It will be noted that although varied, they do not reflect the full range of the wider population in all the variables. For example (and similar to our experience with WP2—see Chapter 4), we were unable to recruit any trust rated by the CQC as ‘unsatisfactory’.

Across the six case-study sites, we undertook a total of 88 interviews (Table 8). While this exceeded our minimum overall expected sample size, it fell well short of our maximum target (see section 2.4); moreover, there was notable variation in the numbers of interviews recruited in each case study site. For example, we only recruited 18 patients and carers, against a minimum target of 24. Although in our sampling strategy we took different approaches to recruiting senior-level staff and staff in middle-

	Case A	**Case B**	**Case C**	**Case D**	**Case E**	**Case F**
Type of trust	Teaching / acute; urban and rural catchment	Community and mental health; urban and rural catchment	Community and mental health, including secure facility; urban catchment	Ambulance trust serving a wide region	Acute, covering a large rural area	Teaching / acute; largely urban catchment
Size: employees	10,000-15,000	5000-10,000	Fewer than 5000	Fewer than 5000	5000-10,000	More than 15,000
Size: population served	1-2 million	1-2 million	0.5-1 million	Over 2 million	1-2 million	Over 2 million
Number of sites	Three main hospital sites	Three directorates / over 100 sites	Around 100 sites	Split into three divisions; c. 50 stations serving c. 15 hospitals	Three hospital sites, plus community sites	Merged organisation composed of multiple pre-existing trusts
CQC rating	Requires improvement	Requires improvement	Requires improvement	Good	Good	Not yet inspected
Tenure of chief executive	Five years or more	Two to four years	Two to four years	Two to four years	Less than two years	Newly formed organisation
Learning from mistakes league	Poor reporting culture	Good reporting culture	Poor reporting culture	n/a	Significant concerns	n/a
Maturity of openness culture (see section 6.1)	More mature	Mixed	Less mature	Mixed	More mature	Less mature

Table 7: Characteristics of case study sites (WP4)

management or blunt-end roles (see section 2.4.2), many participants in practice had roles that cut across these categories. Therefore we do not make this distinction in in Table 8, or in presenting our findings in this chapter and Chapter 7.

We focused our fieldwork and analysis by selecting three tracer issues,[59] which appeared, based on our analysis in WP1, to exemplify some of the key challenges and conundrums in openness. These were the statutory Duty of Candour, the investigation of serious incidents, and the Freedom to Speak Up programme. Between them, these three issues covered a range of activities relating to openness, and covered its impact on practitioners at the sharp end, and patients and families too, including both disclosures when things go wrong, and the degree to which various groups are involved in identifying problems and contributing to learning.

	Case A	Case B	Case C	Case D	Case E	Case F	**Total**
Staff	11	8	12	9	22	8	70
Patients and carers	7	2	2	0	7	0	18
Total	**18**	**10**	**14**	**9**	**29**	**8**	**88**

Table 8: Breakdown of participants (WP4)

The Duty of Candour and the Freedom to Speak Up programme are both mandatory: the Duty is enforced in legislation and Freedom to Speak Up is a contractual obligation. However, both can be treated by provider organisations as exercises in compliance or—as envisioned in policy[27]—as tools to engender culture change. By exploring how these initiatives played out in practice, using them as points of comparison between sites, and gathering the perspectives of staff at the blunt end, staff at the sharp end, and patients and carers, we sought to gain insight into the broader culture of openness in each site.

The current chapter continues with a more detailed overview of the six case-study sites and their positions at the time of our research, particularly in terms of how their recent organisational history had contributed to a situation where openness had been subject to varying degrees of organisational attention and financial investment. The rest of this chapter then presents our findings in relation to the implementation of the Duty of Candour and the (linked) implementation of obligations to investigate and learn from serious incidents. Chapter 7 presents findings relating to Freedom to Speak Up, and considers overarching messages from the case-study sites about the challenge of translating all three policies into sustainable influences on organisational culture. In Chapter 8, we bring our findings together from across the workpackages, and provide a high-level discussion of their key implications.

6.1. The six case-study sites and their organisational trajectories

It became apparent early on in the course of our data collection, and particularly from participants who worked at a senior level in the organisations and/or had been employed in them for some time, that they diverged in the prevailing state of their cultures around openness.

As noted in Chapter 1, culture is a contested concept, comprising taken-for-granted assumptions and behaviours.[39,40] It is perhaps better understood as something an organisation *is* than an attribute amenable to direct modification. It is also likely to be inconsistent within an organisation: multiple subcultures may coexist that defy the notion of a unified, singular organisational culture.[38] Nevertheless, our sense from the preliminary interviews with more senior stakeholders, identified directly via local collaborators or through snowball sampling (see section 2.4.2), was that some organisations had managed to raise consciousness around the need for openness, learning and improvement to a much greater extent than others, often prior to the advent of the post-Francis policies. This reflected the national picture portrayed to us in WP1 (section 3.5.3).

More ‘mature’ organisations in terms of openness demonstrated greater prior progress in features such as well developed systems of oversight and intelligence, communications systems with reach across the organisation, and investments in processes and roles with a focus on identifying and addressing problems. As we continued interviews through the second recruitment route (messages sent by the organisations to relevant lists of staff, who were invited to contact the research team if they were interested in participating—see section 2.4.2), these inter-organisational differences remained apparent. While this did not mean that experiences of the openness initiatives were universally more positive in these organisations, it was clear that they had had more success in positioning openness as an organisational priority.

For this reason, it is important to distinguish between what we term a *mature* culture around openness, and assessment of the degree to which a culture is positive or functional. Some researchers have documented improvements in culture in organisations, sometimes measured longitudinally using validated instruments.[115,116] The maturity of culture as we conceptualise it does not imply that a positive culture is experienced more-or-less consistently across an organisation; rather, it is something that resides primarily at the blunt end. However, it was often recognised by others outside the blunt end, in the form of sustained organisational commitment, even if it had not (yet) translated into a change in culture across the organisation and at the sharp end.

Maturity of culture of openness seemed to be due in part to the history, geography and function of the organisation. First, as the label would suggest, maturity of culture was in part a consequence of time, but also of the degree to which the policy agenda had local resonance. Earlier high-profile incidents or scandals that had affected case-study organisations *directly* appeared to have acted as catalysts to action in these organisations.[50] Subsequently they found themselves at something of an advantage as the post-Francis initiatives began to trickle down. Since they had already begun to initiate similar processes due to endogenous influences, they found that capacity, understanding and skills were already in place to implement nationally driven programmes. Sometimes, this could pose challenges: for example, there was a struggle for some sites to implement the Freedom to Speak Up programme in a way that complemented, rather than overlapped confusingly, with existing initiatives (cf. section 3.3.1). More often, it aided both the technical work of implementation, and the process of engaging staff. Second, case-study sites that were less dispersed and fragmented seemed better able to maintain and communicate a coherent sense of organisational identity and unified mission. The two mental health and community healthcare trusts (Cases B and C) were at something of a disadvantage here, as the sector had been subject to numerous rounds of reorganisation and restructuring in preceding years.[102,117]

Together, these experiences could leave organisations in a position where they appeared readier for change. They became more ‘receptive contexts’, to deploy Robert and Fulop’s development of a concept originally coined by Pettigrew et al.[118,119] Besides the structural influences on change (such as external inquiries, critical inspections or enforced changes in management), this also encompassed psychological and even emotional influences.[119] For example, as we discuss in more detail below (sections 6.1.4 and 6.1.5), participants in Cases D and E commonly referred to their regret about the scandals that had affected those organisations some years before, or even guilt by association—and a concomitant determination to contribute to learning from it and improving. It was clear, therefore, that the organisations’ histories prior to the introduction of post-Francis reforms had an important influence on the ways in which those reforms were implemented and understood. These histories manifested in different ways, and included a mixture of sharp breaks with the past (for example, new leadership teams brought in with a mandate for change, to provide direction that had been lacking) and continuities (the collective memories of staff, patients and communities, and a determination not to squander the organisational learning that had been acquired so painfully). This is not to say that the experiences of patients, families and staff in organisations with more mature cultures of openness were consistently better. However, it does provide helpful analytical purchase on many of the findings we present in this chapter and the next. We therefore offer the following brief summaries of these prior organisational trajectories.

6.1.1. Case study A

Case A was a large acute trust serving a mixed urban and rural catchment. Improvement work in this organisation had been ongoing for several years, but happened gradually rather than in direct response to the impetus of a ‘scandal’. Embedding openness was an aim that was clearly articulated aim by more senior staff interviewed; they also emphasised the need for ongoing effort and investment in systems and processes. The organisation had a coherent and well developed programme of improvement, and a stable history. Case A had invested in a full-time Freedom to Speak Up Guardian role, supported by director-level staff. The Guardian role was seen here as complementing extensive existing work to improve surveillance and prospective monitoring of risks to quality and safety, including efforts to gain ‘softer’ forms of intelligence that might be assimilated and triangulated with other sources to enable ‘trouble’ to be detected proactively. We characterise Case A as one of the organisations with a more mature culture around openness in our sample.

6.1.2. Case study B

Case B was a community and mental health services trust, serving a diverse population. Its work was typical of the diversity of functions of this type of trust, and was distributed across more than 100 sites. Senior-level participants in the study claimed that openness had long been a strategic-level concern; several also articulated in detail how the introduction of the statutory Duty of Candour was instrumental in further advancing the focus on openness, and in placing it on the board's agenda. There was also a growing programme of joint work around openness, communication and joined-up care with the area's acute provider. Consequently, staff members already engaged in openness work had found increasing and sustained financial and logistical support for their efforts from the organisation. Case B employed a part-time (0.6FTE) Freedom to Speak Up Guardian. We characterise Case B as one of the organisations with a mixed culture around openness in our sample.

6.1.3. Case study C

The second community and mental health services organisation in our sample, Case C, similar to Case B, was large and sprawling. Unlike Case B, however, it also had a high-secure forensic mental health facility with its own distinct subculture—viewed by some senior staff as in some ways more akin to a prison than a healthcare unit, and by its nature rather closed off from the rest of the world. Despite its lower number of sites, moreover, there was a greater level of unit-level autonomy in this organisation than in Case B, reflected not only in subcultures and identifications, but also in information systems, which had proven difficult to integrate across the organisation. The Freedom to Speak Up role in this organisation was part of the portfolio of a high-level, advisory member of staff who worked in the trust for several days a month, and included the role within these days. The Guardian was supported by three Freedom to Speak Up 'champions' who occupied junior, non-clinical roles; there were plans to recruit more champions but at the time of data collection these had not yet been fulfilled. We characterise Case C as one of the organisations in our sample with a less mature culture around openness.

6.1.4. Case study D

Case D was the sole ambulance services trust in our sample. By its nature, it was something of a fragmented organisation, with many small units distributed across a wide region, and relatively little cross-unit interaction except at the very senior levels of the organisation. Moreover, senior-level participants described how historically, ambulance trusts had more in common with the other '999' emergency services (such as the police and fire brigade) than with other NHS providers. They were characterised by 'command and control' structures, governed by clear and regulated channels of communication and hierarchy. In common with other ambulance trusts, Case D was making attempts to move towards less militaristic structures with a view to mitigating the negative consequences of steep authority gradients (reflected in the weaker scores in the National Staff Survey for ambulance trusts on indicators such as communication and contribution to improvement—see sections 5.1.1 and 5.1.2). Senior staff acknowledged that any change would take time, however. The trust had been the subject of some media attention in relation to its response to serious incidents and communication with patients (in common with Case E below). Blunt- and sharp-end interviewees discussed a shared sense of shame and regret, and saw these incidents as a prompt for a subsequent organisation-wide improvement programme, with a particular focus on supporting patients and families. This programme had informed the implementation of the Freedom to Speak Up programme in the organisation, with learning shared between the two. The Freedom to Speak Up Guardian here did not have a dedicated time allocation. The distinctive background of this organisation, and the combination of innovative efforts to make the culture more open and its enduring command-and-control structure, leads us to characterise Case D's culture around openness as mixed.

6.1.5. Case study E

Case E was an acute trust that was relatively small in its staff size and patient catchment, but geographically distributed owing to the largely rural area it served. It had been subject to regulatory and media attention in the recent past due to problems of quality and outcomes. As in Case D, staff here who were in post at the time of this attention found it chastening, and discussed in interviews their sense of guilt and shame by association. A new leadership team, appointed after these events but before the implementation of the post-Francis policies, had led an organisation-wide improvement programme. This included, among other things, heavy investment in systems and processes for supporting the rapid identification of problems and investigation of incidents, and concerted efforts to rebuild trust with staff and patients. When the Duty of Candour and Freedom to Speak Up went live, the organisation had been able to assimilate these policies relatively easily into its existing processes, aided by the size of the organisation and the shared desire to put events of the past behind it. An early adopter of the Freedom to Speak Up programme, Case E employed a part-time (0.6FTE) dedicated Guardian. We characterise the culture around openness in Case E as one of the more mature among our sample.

6.1.6. Case study F

Case F was the product of a recent merger of several formerly independent acute trusts, with disparate ratings by the CQC and other external authorities. This had made it one of the largest NHS organisations in England. Senior-level interviewees felt that this meant it was starting a new journey towards both building a unified culture, and harmonising systems, processes, and expectations across its constituent parts. For example, each of its predecessor organisations had taken its own approach to implementing Freedom to Speak Up, and leaders in the new organisation had decided to redesign and relaunch the programme. The Guardian was a respected former clinician in one of the predecessor organisations, supported by a network of champions drawn from all sections of the workforce, including several representative of groups with protected characteristics. Given its recent formation and the sense from the (limited number of) staff we interviewed that it is having to develop its approach to openness anew, we characterise the culture around openness in Case F as one of the less mature among our sample.

6.2. Implementation and compliance challenges

The prior trajectories of the case-study organisations had a palpable impact on the approach taken to implementation in all three of the tracer issues we examined (the Duty of Candour, the investigation of serious incidents, and Freedom to Speak Up). There was notable variation, for example, in the approaches taken implementing the Duty of Candour and the requirements for undertaking investigations into serious incidents. Ensuring timely and effective delivery of both obligations was greatly assisted by a sophisticated socio-technical infrastructure. In other words, both the technical systems for recording and monitoring disclosures and investigations, and the social processes in place around them to orchestrate and coordinate the work of the range of members of staff involved, were crucial to their management.[120]

The degree to which these requirements were in place, and adequate for the job, varied among sites. Where sophisticated systems for managing the Duty of Candour and incident investigations were in place, these often reflected a history of attention and investment, born of a more mature culture of openness (and, as discussed in section 6.1, often with its origins in a local incident or scandal that had shaken the organisation out of a position of complacency). For example, in Site E, incidents requiring disclosure under the Duty and/or resulting in investigations were tightly managed through an information-management system and weekly meetings coordinated by board-level executives, in which timelines were agreed and actions monitored. This system predated the introduction of the Duty of Candour, but provided a ready-made implementation vehicle, which both ensured effective discharge of the Duty and minimised the extra bureaucratic burden associated with implementation—improving reliability and reducing resistance.

> “We started our patient safety summits about four-and-a-half years ago. So Duty of Candour wasn’t out at that point, so it just became part of what we did as the business for the patient safety summit. So the process was already there, and the Duty of Candour could be easily added onto it, just as we could do with other things, if, as and when other things get added. People are quite open to doing things differently now in the organisation. You ask them to do something and they’ll just say ‘Yeah, OK’. [...] RCA,

> Duty of Candour, learning to improve or learning lessons, all part of one process. That is all part of incident-management processes and people have to send the letter that's gone out of the Duty of Candour, as part of the investigation. So that all gets tied in—each incident's got a number attached to it, the rapid reviews, the staff reflections if that's what we've asked for, or if we've asked for the minutes of the meeting where they've discussed this so that we can prove that they've actually had the discussion with the wider team, the Duty of Candour, anything like that." (Non-clinical staff, Case E)

Some other sites had undertaken work to integrate the Duty of Candour and the investigation process into existing incident reporting and management systems, offering oversight of all the information regarding an incident as it passed through different reporting channels.

> "Datix is but one method and I know other trusts have opted for others. The reason we do it is, one, it's there, we've got the tool anyway but two, it's a warehouse for everything. So if I've got an incident which is also a complaint, which is also a claim, which is also an inquest, which is also Duty of Candour, I just have to look into one warehouse and I get all of that data out." (Non-clinical staff, Case A)

In other sites, however, such integrated systems did not exist, or were not fully exploited. Case C's approach to oversight, for example, afforded fewer opportunities for supporting openness. In contrast to the integrated approach of Case E, here the approach to monitoring disclosures under the Duty of Candour had been limited by what existing systems could support.

> "We would have had a staff member who had breached [by disclosing the incident to an inappropriate person] without knowing that he was doing it, because there's no way of flagging it on the electronic records system." (Clinical staff, Case C)

Large-scale redesign of the existing system, similar to the steps taken in Case E some years earlier, would likely have been disruptive and would require significant investment. Moreover, the large size and sprawling nature of Case C meant that systems had been developed on a directorate-by-directorate basis, and there was resistance to a whole-organisation approach. In consequence, investigations were conducted within directorates and then information was fed into the organisation's governance department who then managed the dissemination of learning. This process, participants in Case C confided, was prone to unreliability.

> "So the way it works—whether it works well I don't know—the governance team will then draft a vignette, because otherwise it's just, no-one's going to read the whole, the whole report, not everybody, so they'll draft a vignette. That vignette is then fed back to the different teams, and it goes from top, so there's a senior management team, then there's a clinical team, then there's a local—everybody has about a thousand meetings, I find! It filters down, so, eventually the ground-floor staff will have it." (Non-clinical staff, Case C)

The development of effective systems to support this complex process, then, appeared important, and participants made it clear that the complexities of the process—including compliance and reporting requirements, and the need to ensure that patients and families were kept informed and learning was disseminated—required sophisticated administration that was much more evident in some cases than others.

6.2.1. Adhering to the letter of the law

Ensuring that organisations were enacting the Duty of Candour as expected by government and regulators was not straightforward. Apart from the requirements around timescales and reporting, participants described grey areas and ambiguities that they encountered. As reported in earlier chapters, our survey of board-level executives found concerns about the clarity of policymakers' expectations and the scope of commissioners' expectations for the Duty of Candour and serious incident investigations respectively (section 4.2). Our interviews with senior stakeholders, meanwhile, highlighted some of the challenges in putting the Duty of Candour into practice. These were particularly notable in non-acute settings, where levels of harm were often a matter of subjective judgement, sources of harm might be more diffuse, and the legal duty to disclose errors to relatives when patients had died could jar with prior commitments to confidentiality (section 3.1.2).

Building on these insights from WP1 and WP2, participants in the case studies identified similar difficulties, and elaborated on some of the challenges. In enacting openness, they faced real dilemmas when it came to making decisions about when, how and with whom to engage. There were relatively straightforward cases, where the cause of harm was obvious, the nature and degree of harm was immediately apparent, and the individuals to whom disclosures should be made were readily identifiable. In such cases, decisions about disclosure and about instigating an investigation followed a reasonably linear pathway. However, in many cases, things were more complicated. For example, careful judgements had to be made when patients had died or where they lacked capacity, temporarily or indefinitely.

> "You've got to be very clear about who you can engage with because it could be a potential abuser, it could be a perpetrator—you've got to be very, very careful. So that might be something that's worth considering from your perspective about when it's relevant not to engage with a next-of-kin or a patient around capacity and around the potential conflict with the criminal justice system, those kind of things." (Clinical staff, Case B)

Sometimes there were more prosaic difficulties in identifying the appropriate person to whom to disclose in the event of serious harm or death.

> "We've got somebody else who died in A&E, there's no next—there was a friend. No next of kin, but there was a friend listed on 'Related people'. And [he] said, 'I'm only a friend. He hasn't got any family I know of so there's no one to contact'. [...] I mean it obviously doesn't stop the RCA process. Because that goes ahead no matter what. The lessons that are there to be learned. It's the contact. That is quite difficult." (Non-clinical staff, Case A)

> "Sometimes, we only have a telephone number of a brother, and we might have numbers, telephone numbers for people, but we don't have any addresses, we don't, or might have just a name. On our records, and that's, I find that quite difficult, knowing how to open that conversation up. That's not easy." (Clinical staff, Case B)

Moreover, some forms of harm presented more obviously than others. There was a sense from some participants that healthcare staff tended to draw on narrow biomedical ideas when categorising harm, with judgements about whether a disclosure and investigation were warranted made according to a very narrow frame of reference (despite the fact that psychological harm is explicitly included in Regulation 20[26]). Indirect consequences tended to be excluded from the determination of harm, even though from the perspective of patients and their families, they could be very grave.[70]

> "A pressure ulcer, in the grand scheme of things you'd think well, you know—we haven't took the wrong leg off. It's a pressure ulcer. But then I spoke to somebody's daughter last week, and her mum's got a pressure ulcer, because according to the RCA she had a pressure ulcer elsewhere, and the nurses concentrated on that. And then didn't really monitor her heels. She got a grade two, she was discharged, and now she's bedbound, because she can't step out onto her heel. She's now bedbound and extremely poorly. Huge quality-of-life loss, and she's got 24-hour carers. The daughter's moved in with her." (Clinical staff, Case E)

> "I'm still waiting for Duty of Candour, but it'll happen; it'll be interesting to see what happens when I get my records through and I start reading them. And that was the other thing I said to them, the other thing, I think, with any Duty of Candour, or, or Guardian,

> it's just, I said to them, 'You are seeing me just as a patient, you're not seeing me as [Name] the wife, [Name] the grandmother, [Name] the daughter. I've got a mother who's got Alzheimer's. I care for my grandson'. I said, 'All you're interested in is me lying in a bed, but you don't realise why I'm challenging you is, actually, I need to get out, because I've got people who are dependent on me'. So I'm not being arsey for the sake of it: I'm arsey because I actually need to get well to go home. And they look at you, and you sit there thinking, 'Haven't you been taught anything in your medical career, that we're not just bodies?'" (Patient/carer, Case E)

Similarly, participants in both acute and mental health settings noted, for example, the challenge of identifying psychological harm, which would not necessarily be immediately apparent. This posed problems not just of identification, but also of attribution, responsibility, and timeliness of disclosure.

> "That concerns me that, OK, we are looking at a snapshot of 60 days following the incident, and this draft report will be finalised and presented to the trust, lessons will be learned. But what happens I don't know for argument's sake in 12 months' time if [name] finds himself with post-traumatic stress, or flashbacks?" (Patient/carer, Case E)

Challenges of this nature added to the burden involved in undertaking the Duty of Candour and incident investigation, and made it more difficult to discharge both responsibilities in a manner that was respectful, sensitive and responsive to patients and families. Decisions about what was eligible and whether and how the processes should proceed were not always simple. Moreover, and in line with the findings from WP1 (section 3.1.2), the categorisation of harm itself was also seen as something of a challenge.

Since the introduction of the Duty of Candour, the level of reporting of moderate or serious harm has declined, even as the reporting of incidents overall has increased[66]—with suggestions that this might indicate 'gaming' of categorisations. We found no evidence to suggest that incidents were being routinely or deliberately unreported, or 'de-rated', in the interests of organisational reputation. Participants did, however, note that the construction of an incident as an occurrence of harm, and its severity, was often not clear cut or simple matter of the objective application of unambiguous criteria.[121] Further, there was a sense from some participants that the sheer burden of responsibility falling upon the person who made a call that an incident met the threshold for a disclosure under the Duty might deter them from making that judgement. In other words, this was less a matter of deliberate suppression of an incidence of harm, and more about avoiding a process that could come at a high price for the individual—though the appearance and the consequences were similar.

> "A lot of maybe lower-band nurses or nurses that don't want to get involved, they might put a patient safety incident in. They may not, because it's a lot of paperwork if you do, it's not easy." (Non-clinical staff, Case E)

In section 7.3, we note that a similar logic could pervade decisions (not) to speak up about concerns. In both cases, the difficulties of making judgements, and the personal burden in terms of time and stress for the individual making them, could serve as deterrents to openness. Effective administration of the initiatives—including things like training, IT support, and decision trees—could reduce but not eliminate this challenge.

6.2.2. Embracing the spirit of the law

There were many other challenges in implementing the Duty of Candour and undertaking incident investigations—and doing so in ways that were sensitive to the particularities of individual cases, and that did not run counter to the intentions of the policies. These challenges varied in the extent to which they could be addressed through high-quality administration, provision of training and development, or the exercise of informed judgement by individual practitioners. Questions around issues of cognitive impairment and capacity in patients, for example, were seen as amenable to being addressed through the development of local organisational policies, and the effective dissemination of associated guidance to clinicians.

> “So things like ventilated patients or patients with dementia or patients without capacity what you do in those circumstances, the timeliness of that and so [on], we provided the training.” (Non-clinical staff, Case A)

Other challenges lent themselves less well to uniform policies, and continued to require judgement from individual practitioners if the Duty of Candour was to be discharged both efficiently and sensitively. This could mean adjusting the frequency or the nature of contact depending on patients and families’ preferences; it could mean going beyond the minimum requirements of the Duty and seek to show genuine concern and compassion, driven by more than mere legal obligation.

> “We are taking that as one of our values and being open and transparent across the board, and I think that’s where we go above and beyond, and don’t just try to tick the box. If we think that a family should know about something then we’ll definitely make sure that they do and it’s not going on behind their back. Because really it only takes five, 10 minutes on a phone call from a member of staff to say, ‘I’m glad that that person’s on the mend and we’re happy that things didn’t go really bad. But just to let you know we feel like we could have done this a little bit better and we’re going to look that briefly and see what we could do better for somebody else and make sure it doesn’t go worse next time’.” (Non-clinical staff, Case D)

In a similar vein, some case-study sites were much more willing than others to be flexible in their approach to incident investigations. As far as the Serious Incident Framework allowed, there were differences both in the criteria used to select incidents for investigation (with some sites tending to orient towards potential for learning, prevalence and consequences for practice, rather than just severity of actual harm), and in the approach adopted to investigating.

> “RCA as a template works for some things but other things we need to be doing things differently. And it is about the learning. [...] And actually if you look through, I don't know, like all our pressure ulcer incidents, I bet your bottom dollar they will be the same action, and actually if those actions are being implemented, it’s not making a difference, so actually we need to do something different. [...] So then we agreed, it’s like ‘Let’s have a conversation’, so a session was set up.[...] And the conversations, we've been having those conversations in CHS [community health services] and one thing is very much around your behaviours and the language you use with staff and how you describe things and all of that.” (Non-clinical staff, Case B)

Similarly, participants in some case-study sites were much more readily able to describe the ways in which they responded to patients and families’ needs when it came to involving them in the incident-investigation process. Again, evident here was a consciousness of the need to interpret a general principle—that patients and families have a right to be involved in developing terms of reference for investigations, and for the process to be conducted with respect and transparency—in a way that accounted for variability in individual patients and families’ preferences.

> “There’s a vast range of patients that we deal with and it does vary in terms of what involvement people want. Most of our serious incidents involve patients with mental health needs and sadly a lot of those involve death or serious injury, so quite often then we’re relating to families. And families, in general, do want to be involved in the process, and someone goes out to see the family, or if it is a patient, the patient. The investigator normally sits with the person, whether it’s a family member or the patient themselves, and talks through the Duty of Candour process. We give them information on it and make sure that we get any questions that they want answered as part of the investigation. And then those are put into the terms of reference as well to the investigator. And then when the investigation has been signed off by commissioners, someone personally goes

> and takes that investigation report back to that patient or family, if they want it. Not everybody does. Some people just—particularly where we've had people that have made things like suicide attempts and not taken their own life, quite often those patients are like, 'I want to leave it there, I don't want to relive the whole thing'." (Non-clinical staff, Case B)

In Case D, following a widely publicised serious incident, extensive investment had gone into the development of a role providing support for families affected by a serious incident for the duration of the investigation process. Providing information, support, signposting and liaison with the organisation, this role was seen as converting the principles of openness into something that could operate in a patient- and family-centred way, responding to the needs and preferences of patients and families as they evolved through time.

Following the spirit of the law, therefore, required judgements made in good faith. At times, this necessitated human intervention to make sure that pathways and processes addressed both reporting requirements and the particularities of the case. Even where they had effective administrative arrangements in place to ensure the timely delivery of disclosures and investigations, organisations that failed to support the need for judgement, sensitivity and flexibility risked implementing policies in a way that was 'coldly efficient': apparently discharging their responsibilities effectively, but neglecting the personal preferences or emotional needs of patients and families.[122] We discuss this theme further in the next section; later on (section 6.5), we examine how this could give rise not only to upset, but also to relationships between organisations and patients and their families characterised by confrontation, defensiveness and resentment.

6.2.3. Aligning the letter and the spirit

'Coldly efficient' implementation of the initiatives could be found where adequate administrative support for the Duty of Candour and incident investigations was in place, but practitioners or organisations did not consistently put them into practice with sensitivity or flexibility.[65] One participant discussed her variable experience of the initial verbal disclosure of harm under Regulation 20.[26]

> "She was taking a leaflet in. She went, 'Oh, I need to go and do this Duty of Candour with them', and I was sat right outside the door so I could hear everything. And it just felt like it was very—it was as if she was reading a script and it just came across really strange. And it just felt as if it was very much a tick-box exercise, that's exactly what it felt like. So it was done, but I felt the way it was done and the timing was pretty poor. And I was told that [the family] were very angry and upset and then obviously she went in and did the Duty of Candour and they were still as angry and upset afterwards." (Clinical staff, Case E)

Instances of this kind were not unique to organisations where the culture of openness seemed less mature. It did, however, seem that an absence of attention to providing training and support to sharp-end staff involved in the Duty made it more likely that they would view disclosures as a process to be undertaken to serve the bureaucracy, rather than an ethical obligation to patients and families. While there was much variation within organisations, some patterns were evident at the organisational level. Participants in Case B, for example, identified a tension between the organisation's approach to implementation of the Duty of Candour and their own sense of candour as the right thing to do.

> "So personally, I feel as a trust, we've approached the Duty of Candour like it's a duty. So we have a duty and therefore we have rules and therefore we audit those rules and to check whether we've implemented them and are working to the Duty of Candour. Whereas actually, I see the Duty of Candour as totally and utterly our responsibility to be open and transparent, so I feel that Duty of Candour effectively applies to everything, not the category of serious incident or when harm has been done or whatever. We should be encouraging our staff to have conversations with patients and relatives when something has happened and we should be encouraging our staff to involve patients and relatives in

> identifying the solution." (Clinical staff, Case B)

Elsewhere, participants felt that the organisational approach was more in keeping with the spirit of the policy.

> "We actually live the whole Duty of Candour and openness, rather than just ticking a box to just say we've complied with the regulation, but actually it doesn't mean anything." (Non-clinical staff, Case D)

Equally, variation was evident in most organisations, relating in part to the frequency with which staff encountered the Duty of Candour, and in part to the degree to which the complications described in section 6.2.2 applied, such as more complex cases where determination and attribution of harm were not straightforward.

> "So it's out in the areas where people have had less exposure to Duty of Candour that we've had some interesting comments come back and we've then had to remind people of their duty and we've sent them the policy and advised them to take the online course. So yes, there are areas where people are less candid. And I think, particularly inpatients, it's part of the bread and butter of what they do every day, whereas some of the outpatient areas and some of the more with little teams, it's not necessarily part of their culture, their everyday processes, they have to be reminded to do it." (Non-clinical staff, Case B)

Organisations had taken steps to equip staff with the skills at least to discharge the Duty of Candour according to the letter of the law, and in some cases to assist them with fulfilling its spirit. Most had provided training on what was required, and had sought to reassure staff that apologies would not expose them to the risk of retribution, sometimes in association with medical defence unions or professional associations. Some went further, seeking to integrate values into staff development work.

Despite reassurances about legal risk, the requirement in the Duty of Candour for "a genuine apology" posed notable challenges to organisations and staff. Quite apart from any issues of liability, finding a way to phrase apologies that was—and appeared to be—sincere, even as it was mandated, was difficult.[123] Some participants spoke of hesitancy to write a letter with such profound significance for the recipients; others described how their efforts to apologies in writing to patients and families had been Bowdlerised by their own organisations' legal departments. From organisations' perspectives, written apologies drafted under Regulation 20 by staff at the sharp end varied markedly in style and standard. Participants thus described a delicate process of trying to quality-assure the Duty of Candour while giving staff making the disclosure rein to put their reflections into words. In Case A, for example, quality and safety leads had produced a template letter with a view to striking this balance.

> "People were troubled by putting it in writing to the family or the patient. And getting the wording of that right. What we have done is a number of template letters, so my team did those and made them available. So on Datix you can just select a number of template letters but really make it personal, but to give them an idea. And I was a bit ambivalent about that at the beginning because I don't like formulated things; I like a much more—writing, you know, it comes from the heart and you say what you think. But people didn't know where to start and they were worried that they were saying the wrong thing or not saying it in the right way, and by showing them template letters they got it a bit more. And so people don't always use the template letters, but they know the gist of what they're trying to do so. That really has worked quite well. But that took us a good year and more for people to get comfortable with putting something in writing." (Non-clinical staff, case A)

Others described ongoing efforts to press upon colleagues the need to view these obligations as more than compliance exercises, similar to the work described by senior stakeholders in WP1 in section 3.5.6. This included a range of more and less formal approaches, including training, role-modelling and examples of best practice, all of which sought to press home the message that the

Duty of Candour and incident investigations, if seen as ethical obligations, could have benefits for patients and families, staff and organisations. We discuss these benefits in more detail in section 6.4.

6.3. ‘Resistance’

Across all organisations, participants reported resistance to both the Duty of Candour and the incident-investigation process. In contrast to the practical difficulties encountered in implementing the initiatives and discussed in section 6.2.1, this arose from more fundamental concerns about the policies and their implications for professional practice. Two distinct sets of concerns were especially apparent: those premised on a more traditional construction of the proper relationship between clinicians and patients; and those arising from suspicions that the openness agenda was more about blame than about learning—suspicions which in many cases had been borne out in the past.

The first set of concerns, which pertained to a potential conflict between the Duty and existing notions of medical professionalism, was not particularly prominent in our data, and was only found in participants’ accounts of their colleagues’ behaviour: it was not a view to which any participant claimed to subscribe herself or himself. Nevertheless, some participants did stress that it remained a prominent disposition among some of their colleagues. They noted that some clinicians saw the Duty of Candour as a challenge to their professional autonomy, and in conflict with their understanding of their duty towards their patients. This appeared to reflect a residual tension between traditional paternalistic notions of medicine and more recent ideas around shared decision-making, co-production and patient-centred care.[124] Some participants noted that this form of resistance was less evident amongst staff who had come into the professions more recently.

> “Those who still believe that ‘I am genuinely trying to do my best and I am their doctor and I’ll tell them what I think they need to know’, and the people who are of that ilk tend to come to it harder. For some people that isn’t how they were trained. It isn’t how they were schooled. It isn’t how they were nurtured for the first 25, 30 years of their career, so asking them to jump fences is quite an ask.” (Non-clinical staff, Case A)

Such individuals, participants suggested, were more likely to remain impervious to efforts to instil the spirit of openness: the best that could be hoped for was grudging compliance with the letter. While not seen as prevalent in any organisation, their influence could be disproportionate to their numbers. In Chapter 7, we consider the parallel phenomenon of organisational fiefdoms dominated by individuals with authority derived from longevity, connections or personality that could have a profound influence on the inclination towards openness of those around them (section 7.4). What the two phenomena have in common is that they illustrate that some issues around openness are likely to be resistant to nearly any policy or regulatory intervention to increase openness.[72] Only the passing of time, or exceptionally concerted and coordinated organisational action,[101] is likely to address such intransigent issues.

Much more common in our dataset was apprehension about the Duty of Candour and (particularly) the investigation of serious incidents founded in the second set of concerns—that there might be hidden agenda behind the impulse towards openness, with potentially undesirable consequences for staff. Though the term was used by participants, ‘resistance’ is perhaps not the most appropriate way to construct this position. It did not imply any opposition to the ideas of openness, candour and learning in principle, but it did involve deep-rooted scepticism that the policy initiatives were primarily about advancing these values. And often, such scepticism was born of experience. As described in section 3.5.4, the past could cast a long shadow, and both personal experience and organisational lore could create implicit assumptions about organisations’ (or policymakers’) intentions that a change in policy alone could not shift.

> “I think it’s that sad historic culture of investigations and incidents. Our culture at [Case B] is nothing like that anymore, there’s no blame, there’s no nothing. But I think it’s when professionals are a bit vulnerable as well. Rather than being where you are now,

> they sometimes go to places of hurt from. And it's so difficult to do work like that. Yeah, I think that's what makes them reluctant to do it." (Non-clinical staff, Case E)

> "I feel that's a very similar situation with the Duty of Candour and the raising concerns type thing within the NHS, is that occasionally something will get raised and everyone will pat you on the back, or something else will get raised and someone will get selected and thrown under the bus. And there's no predictability about it." (Clinical staff, Case F)

It was not just organisations' motives that were under suspicion. The wider medico-legal environment, too, infused the talk of many participants. The recent case of Hadiza Bawa-Garba was perceived by junior doctors as an exercise in apportioning blame, and as demonstrating inconsistency between the message from policy and educators and the behaviour of the wider system.[69] Clinical staff were not alone in suggesting that cases of this sort could have a chilling effect on candour.

> "She wasn't negligent or criminal: she just made a mistake. And they took her to court. All the transparency in the world, all the attempts in the world to have transparency, will be destroyed by that." (Patient/carer, Case E)

Junior- and senior-level participants reported that cases like Dr Bawa-Garba's influenced their own approach to candour in the course of investigations, and the advice they gave to colleagues who had made mistakes. The potential for contributions to organisational learning to spill into the domain of the legal—with very different terms of reference and personal risks—cast a shadow over openness.

> "I feel deeply uncomfortable about telling people to limit their reflective, but I'm also—if I'm sensible—telling them to limit their reflection. You know: 'Don't admit culpability in your reflection. Only do it post hoc, completely. Wait until the end of the investigation, then you reflect'. Which are all reasonable things, but I feel, actually, if they want to reflect now, and then it turns out they reflected wrongly because they learnt something else, that's OK, but it can't be now, because it's been distorted by the potential for it to be drawn into a different process." (Clinical staff, Case C)

Even without the shadow of the past or anxieties about the medico-legal environment, fears about the risks of openness could pervade staff's dispositions towards the Duty of Candour and the investigation of incidents. Across organisations, participants from more senior backgrounds acknowledged the need to move away from punitive processes and to emphasise learning over blame (while emphasising the need for a just culture rather than a no-blame culture[125]). But this commitment did not always filter into the enactment of the processes themselves, particularly in organisations with a less mature culture of openness, or where the sheer size and spread of the organisation meant that efforts to change practice were slow or inconsistent. Participants in Cases B and F, for example, found that the incident-investigation process remained one that appeared punitive and adversarial from the perspective of members of staff implicated.

> "It wasn't done in a 'OK, this situation has happened. Can you just describe to me your thought process? Can you think of any other way that you may have managed this?' But it wasn't that way, it was: 'Well you did this, why did you do that? And well, the guidelines says this so why didn't you follow the guidelines?' [...] Which I found less supportive." (Clinical staff, Case F)

"I think there is still quite a heavy blame culture within the organisation. I don't think it's necessarily something that—I think it's a fallout of the system rather than actually that's how people in the system want it to work." (Non-clinical staff, Case B)

Regardless of the success of organisations in orienting their serious incident investigation processes towards learning and accountability rather than blame, the format was such that it would, almost inevitably, leave looming questions that staff would fill with their own answers. Due process and confidentiality were vital parts of a robust and fair incident-investigation system, but meant that staff on the fringes could leap to their own conclusions. In section 7.3 we note a similar tension between discretion and openness that could pose a challenge to staff's willingness to raise concerns; addressing this tension was a notable challenge for organisations.

> "If there is, say, a member of staff in that team or that ward, area, that's being investigated, because the details of that investigation won't be told to other people, people formulate their own stories and their own narratives around it and think, 'Actually, this happened because he only just raised a concern, and now that he raised this, look what's happened to him, so we best not do anything!' [...] People feel that it's different for different people, which it isn't in reality, but I think when someone sees, 'Oh, one person has been suspended, but this person just got moved', they don't think of the reasons behind it. So that's why I'm trying to develop information, so that they are aware that these are the circumstances where we would move people, and this is why you would suspend—the different rationales for it all." (Non-clinical staff, Case B)

Internal communications—including not just the 'how-to' of openness policies, but also an explanation of the process—was thus an important part of organisations' strategies in seeking to ensure that the discretion and confidentiality that necessarily surrounded investigations did not aggravate staff scepticism.

6.3.1. Overcoming resistance

Senior-level participants across case-study sites were aware of these kinds of fears among their colleagues.

> "I think we need to have more of a nurturing environment because we are in the caring profession, but I think nurses, doctors don't feel particularly well cared for themselves." (Clinical staff, Case F)

They noted, however, that policy and regulatory levers on their own were of limited use in ensuring that resistance did not result in obligations evaded or satisficed. In particular, they cautioned against taking assurance or seeking comfort[49] from paper-based compliance exercises, which could simply reflect processes discharged with cold efficiency.

> "I think from an organisational point of view, it becomes a tick-box exercise, that Duty of Candour's been done. And it's not a tick-box thing! It is more of a culture based approach to how you approach the care with your patients." (Non-clinical staff, Case C)

> "We might pat ourselves on the back and say, 'Yes we're meeting Duty of Candour as per statutory requirement and we've not had breaches', but in actual fact, looking at it, we know that there's places that do this really well, places that do it less well, places where they follow the letter but the spirit is probably a bit lagging." (Non-clinical staff, Case A)

The impetus for overcoming resistance and trying to secure an approach to implementation of the policies that embraced the spirit as well as the letter of the law, then, needed to be found elsewhere. As discussed in section 6.1, in some organisations an internal impetus had given rise to sustained attention to openness and improvement. In some cases, it had come from constructively critical engagement with commissioners. Commissioners themselves fell outside the scope of this study, but participants in the six provider organisations described mixed experiences of the contribution of commissioners to developing a culture of openness, for example in their attitude towards serious incident investigations. At their best, engaged and intelligent commissioners could firmly encourage provider organisations to focus on openness and consider how best to harness it for learning and improvement.

> "We had a 'Being open' policy for several years which, if I'm perfectly honest, was one of those that sat on a shelf on most wards. And after Mid Staffordshire and then all the Duty

> of Candour guidance came out, there was a sudden flow of activity within our executive team because there are obviously timescales around when we needed to have policies in place and those needed to be good policies, etc. And, at the same time, it awoke our commissioners to start asking us questions about how transparent and candid we were with our patients. [...] There are certain fractions in the organisation that believe that the commissioners over-scrutinise and to what end, and are they using it as a stick to beat us with. But there are other people, myself included, who believe that having a positive relation with your commissioners as the people who do scrutinise us and we do provide assurance to is one of our ways of measuring whether we're doing the right thing." (Non-clinical staff, Case B)

In contrast, participants in other organisations found that commissioners used their influence less wisely, and could risk reinforcing the sense of highly personalised risk, and concomitant tendency towards opacity, that staff often felt.

> "It's a constant discussion around how our incident investigations are run. And they're really analysed and re-analysed, in high-level detail, and often when the organisation's already signed it off, there will be this expectation from one of the commissioners to somehow re-do it. And of course you can't re-do something that you've done. [...] It's very easy to say, 'These things should have stopped it'. So it's hindsight bias now and if that is determining how we're reviewed all the time, it makes people resistant to sharing problems. [...] That has a really detrimental impact on the people who are doing the work, because I think it makes them overly defensive and guarded, and it creates a perverse incentive, again, for being closed, and that's a problem then, because you're reinforcing the issue that you're trying to prevent." (Clinical staff, Case C)

6.4. Doing candour and learning well: the benefits

Perhaps the strongest case for an approach to the Duty of Candour and incident investigations that did seek to marry the letter and the spirit of the law was the benefits that could accrue, across organisations, if done successfully. Despite their relatively recent introduction, participants at various levels of organisations suggested that their efforts to make best use of the Duty of Candour and serious incident investigations towards learning and improvement were reaping benefits. In some cases their views were supported by analyses of audits and other internal documents; in others they were the result of personal experience. Three sets of benefits in particular were claimed; each was dependent on an approach to implementation that was based on a well developed administrative infrastructure, and on efforts to ensure sensitivity, flexibility and responsiveness in each case.

The first set of benefits derived from the greater organisational insight produced by more consistent recording of harm that efforts to implement the Duty of Candour could precipitate. This, alongside focused and thorough investigation of incidents, and intelligence from other sources of intelligence (such as those discussed in Chapter 7), could be marshalled towards better vigilance and responsive action. Perhaps more important, however, was the renewed emphasis on investigating and understanding harm, making use of available information, and acting promptly.

> "What we have asked ourselves is, 'Were the actions taken reasonable? Would we see this coming again? How has the landscape changed in terms of Candour, the Freedom to Speak Up, openness, behaviours? [...] What behaviours are reasonable?' Both at corporate level and in the specialty, because there has been noise about [speciality]. And what it has taught us in part is that you listen to everything. It might be you investigate it and there's really very little substance behind it. But you listen to everything and you triangulate everything. [...] If we'd triangulated the trainee survey, the 'Learning from deaths' process and the medical examiner, the Freedom to Speak Up and concerns raised, the noise in the service and any Duty of Candour things, I think we'd be in a different place earlier than we were then." (Non-clinical staff, Case A)

In other words, taken in aggregate, and used as tools to inform high-quality processes and a culture of openness as well as processes to be followed individually, these policies offered a means to vigilance, intervention and, potentially, the prevention of harm.

> “Clinical incidents reporting has gone up steadily. Our level of harm has gone down and that’s what you would expect to see at the moment, so the other thing that happens is then you get a really good sense of what’s happening in the organisation. So you might say, ‘That’s the second incident that we’ve had’, or, ‘We’ve had a run of grade-two pressure ulcers, what’s that about?’ And so we’ll do a thematic review.” (Clinical staff, Case E)

Second, participants reported that where the Duty of Candour had been implemented in a sensitive way focused on the needs of patients and families, they had seen a reduction in litigation and complaints. Some could point towards downward trends in claims, although causality is of course difficult to establish definitively. Others described cases which, they felt, would have resulted in legal action had there not been effective disclosure, communication and ultimately reconciliation between the organisation and the affected family. Again, the policy-level focus on openness had, it was felt, given rise to channels of communication that at least some organisations had not previously attended to. But again, yielding the benefits of these opportunities relied on more than simply discharging the Duty of Candour efficiently.

> “What we have found is five years ago we had a number of complaints that were upheld by the ombudsman. Our numbers of complaints reduced significantly and so has the number that have been upheld—touch wood—I can't remember the last one that was upheld, because what we can demonstrate every time that we have been open and honest and we shared the learning.” (Non-clinical staff, Case E)

> “Last week I contacted a husband whose wife had died three, four months ago. I contacted him last week, to say we just need to disclose. And he said, ‘Well there are lots of questions I’ve got’. I thought well, what would he have done with that? If I hadn’t have rung him, what would have happened after that? Would he have put a complaint in? Because he’d got lots of valid questions.” (Non-clinical staff, Case A)

> “When you put it all together, we haven’t actually invested a lot of money in these changes, but we’ve actually saved a lot of money as a result of these changes, i.e. litigation, reduction in incidents.” (Non-clinical staff, Case D)

Third, and relatedly, participants discussed the benefits of resolution and reconciliation for patients and families as an end in itself—and, concomitantly, the benefits for staff that could follow. Once again, this arose much more from the social and technical infrastructure that organisations had put in place, than from the mere act of disclosure or involvement in investigations itself.

> “So one of the vital things that we do at the end is meet with family [...] and go through the [investigation] report with them, word for word, and read it to them to make sure that they can answer or ask any questions, and we can answer them so they’re not left feeling left in the lurch and they just have this cold big chunk of paper. I think it’s valuable that we really work with them and make sure that it closes the doors for them as well, allows them a bit of closure.” (Non-clinical staff, Case D)

When patients who had been harmed or their relatives expressed gratitude for candour, or stated that their faith in the system had been restored, it could also be restorative for staff who had often suffered some psychological harm themselves.[126]

> “This patient end up in cardiac arrest and the patient died. [...] It was very difficult: he was too frail and his wife was also very frail. I went in and talked to her. I thought I

> should tell her. Of course it was a difficult time for her but at the same time she should know the truth, and I told her and she hugged me. I was emotionally—I felt like crying. [...] She hugged me and she wrote a letter, thanking me for being honest and nice to her. And sorry, I'm getting a little bit emotional as well. I still remember. The thing is that being truthful, being honest and open: I strongly, strongly believe there is really, really big value [in it]." (Clinical staff, Case A)

6.5. Doing candour and learning badly: the consequences

Some participants found, then, that disclosures, and ongoing communication with patients and families as investigations proceeded and further details came to light, could indeed achieve the reconciliation vaunted in the literature following a serious incident.[127] Even if disclosures and associated processes did not ultimately lead to the outcome that families and patients wanted, they did at least demonstrate organisational willingness to be accountable and to seek to learn.

> "I think it's assuring for people, that people know that things aren't being swept under the carpet. Some action's been taken, that people do know what's happened to you, so, it's not just a case of 'Oh, something happened to me on the ward, the sister knew but nobody higher than that ever knew'. They're assured that people have known: it has been talked about." (Non-clinical staff, Case A)

In contrast, a disclosure or investigation process managed poorly could convey precisely the opposite impression. Partial, insincere or poorly coordinated approaches to disclosure and involvement could give the sense that practitioners or organisations were being selective in their approach to openness, that the full picture was being deliberately withheld, or that the organisation simply did not care.

Many patients and family members who participated in interviews could attest to exactly this kind of experience. At best, this could give rise to the impression that the Duty was being treated as no more than a duty: discharged reluctantly, compliantly, even officiously. This is not to say that organisations did not see serious incidents as opportunities for learning. But in prioritising improvement and learning, they could appear indifferent to the needs of patients and families.[128] Participants described processes that felt like ongoing exercises in box-ticking, leaving patients and families with the impression that disclosure and apology were no more than events that needed to take place to populate a form.

> "It's not really got a great deal of substance to it. There is many sorrys and you know, yes, invite us to speak to the trust—they can invite us. Whether we would go or not I don't know, but if we go will he get an apology or will it be us giving them—in fact I just hit my own nail on the head there. I feel as though we are giving them everything they need for their investigation, but they are not giving to us what we need to close it." (Patient/carer, Case E)

At worst, poorly managed disclosure processes and shortcomings in communication around investigations, complaints and the interactions that followed could position patients, families and sometimes members of staff as adversaries in an oppositional process. Participants described lengthy, wearisome interactions with organisations that could drag on for months and years. Impersonal and bureaucratic processes involving multiple parts of organisations, characterised by the appearance—at least—of evasiveness, half-truths, deceit and legalistic language, could leave participants drained and disillusioned. Common to such narratives was the sense that processes began in a spirit of good faith and optimism, which was quickly sucked away as organisations defaulted to positions of defensiveness. This led to processes that were adversarial rather than inquisitorial in style. Not surprisingly, participants sometimes went on the attack in response, often moving away from investigations that seemed to be falling short of their collaborative promise, and towards more formal approaches such as complaints and legal action (for example "'frustration' claims,"[71] to coin a phrase used by NHS Resolution).

> "My complaint did not fit the form. I imagine for most people, at that point, they give up. Because it was one of those deliberately boxy things where you had binary choices and it was very reductive: it stripped it right down. So I filled it in, but then it said, 'Would you like to leave notes?', so I left—they bloody hate me, because I was like, 'Yes, I would like to write *War and Peace* actually'. [...] And then they sent me another message a few days later saying, 'We have now allocated a caseworker to your case'. [...] I'm almost certain that they will look into my case on the basis of the really useless form and go, 'We can't see anything here'. At which point I will go again. Because I'm not having it. So that's the next hurdle that most—if people got through the first one, that's the next one they'll fall down at. I have no expectations, other than at this point my sole reason for living is to make [staff member]'s life more difficult. Because I'm now at the point where I'm like you have really, really upset me." (Patient/carer, Case A)

> "They mistakenly thought that they could squash us and we might go away. But we didn't, and we became quite troublesome really. Which is why we're very much personae non gratae at our trust, without a doubt. [...] It definitely feels like that when you've got the whole of the NHS against you, basically. But to be quite honest the only thing that's in my favour is I've absolutely nothing to lose, except some money. And I'm very willing to go to the extremes this time, because they will not want to stand up in court and answer the questions that will be asked. Even if I have my day in court, that will make me feel a little bit better about what's happened. But at the end of the day what we have to know is that we did the right thing." (Clinical staff, Case E)

Striking in such descriptions was the way 'coldly efficient' administrative processes could leave patients, family members and staff with the sense that these processes were not collaborative exercises in learning and improvement, but battles to be won or lost. This did not seem to be because organisations deliberately sought to construct them in this way, but because their approach to disclosure and to the involvement of participants in the investigation process failed to demonstrate support, empathy, and honesty.

> "So yes, that's really it. I mean I'm not a normal member of the public for your Duty of Candour thing, because now it's really on vengeance lines for me, but this is what I said to them at the end of my meeting. I said, 'The thing that strikes me the most is that you have stripped me and women like me of our dignity'." (Patient/carer, Case A)

6.6. Conclusion

Along with Freedom to Speak Up, which forms the principal focus of the next chapter, the implementation of the Duty of Candour and the investigation of serious incidents formed our 'tracer issues' through which we sought to examine the extent to which organisations' efforts to increase openness were giving rise to changes in attitudes and experiences. Our findings paint a mixed picture, some of which might be explained by the differential progress made on their journeys towards openness by the six case-study organisations. While there was only limited resistance to the vision of openness espoused in policy and to the initiatives put forward to achieve it, there was variation in way policies had been put into practice. We suggest that this variation had real consequences for staff's approaches to undertaking these duties, and in staff and patients' experiences of the outcome. In particular, we note that both effective administration and flexibility were crucial to ensuring that duties were delivered, and delivered in ways that reflected the spirit as well as the letter of the policies. We pick these themes up in Chapters 8 and 9.

7. Results: Openness in action: Freedom to Speak Up (WP4)

In this chapter we continue our presentation of findings from the six organisational case studies covered by WP4. The principal focus of the chapter is the third of our tracer issues: the implementation of Freedom to Speak Up (and particularly the role of Freedom to Speak Up Guardians) in the organisations. Towards the end of the chapter, in section 7.5, we take a step back to consider the potential impact of the policies in aggregate, and the conditions and actions that might contribute to the realisation of the cultures of openness envisaged by Francis and by those who conceived of the policy interventions.[5,8,9,27]

Alongside the Duty of Candour and the use of serious incident investigations to foster openness and learning as considered in Chapter 6, the Freedom to Speak Up programme appeared from WP1 and WP2 (Chapters 3 and 4) to be a particularly prominent and promising aspect of the portfolio of policies introduced following the Mid Staffordshire public inquiry. As discussed in section 3.3, the *Freedom to Speak Up* review recommended the introduction of a new role—the 'Freedom to Speak Up Guardian'—in every NHS provider organisation.[11] Guardians are to act as confidential points of contact for people with concerns, offer a conduit to ensure that concerns were dealt with appropriately, provide training and support for a culture of openness across organisations, and report to boards about trends and progress in culture and behaviour around speaking up. Our analysis of the telephone interviews conducted in WP1 indicated that approaches to implementing the role vary across NHS organisations, driven in part by the need to add the Guardians to systems already in place to encourage voice, and ensure complementarity rather than duplication. Senior stakeholders also expressed concerns about the reporting and monitoring burden facing Guardians (section 3.3.1), and about the extent to which the Guardian role is (and is perceived to be) independent of existing organisational hierarchies (section 3.3.2). They did, however, see potential for the role in offering insights into parts of the organisation that evaded scrutiny through more formal mechanisms, and in helping to anticipate problems in the making (section 3.3.2; see also Appendix F).

This chapter builds on the findings from our earlier workpackages about the realisation of the Guardian role, and its fit with organisations' wider infrastructures to support voice, with data from those involved in implementing the role, Guardians themselves, and several participants who had themselves approached Guardians or otherwise attempted to speak up. Since the Freedom to Speak Up programme is largely oriented towards staff, interviews with patients do not feature in this chapter.

7.1. Implementing and promoting Freedom to Speak Up

Interviewees in WP1 described a variety of approaches to implementing the Guardian role, while in WP2 a wide range of levels of FTE funding for Guardians was reported (section 4.2). Other national-level surveys also indicate that organisations vary widely in the level of dedicated support for Guardians.[81] While English NHS provider organisations were mandated to appoint Freedom to Speak Up Guardians, ring-fenced funding was not provided, and there was little specification of the size or scope of the role beyond this. The case-study organisations reflected this variability in their own implementation of the Guardian role. Across cases, the time allocated to each Guardian role varied from a single full-time appointment, down to an unspecified and unprotected contribution (see also sections 6.1.1 to 6.1.6). Approaches to recruitment also varied, with some advertising the post openly (internally or externally) and others appointing to the role without advertising. Cases A, B and E had constructed the Guardian role as a discrete post, with protected time of between 0.6FTE and 1.0FTE. These were among the case-study sites that appeared to exhibit more mature openness cultures (see section 6.1) and, correspondingly, had been swift to respond to the requirement to appoint a Guardian. Their choice of a single-Guardian model reflected the original conceptualisation of the role.[11,13,82]

The Guardians in Cases C and D enacted the role alongside their existing roles in the trust voluntarily, with allocation of time to Freedom to Speak Up duties not formally protected. In practice, the Guardian in Case C had around three days a month to dedicate to these duties, but also enjoyed the support of three Freedom to Speak Up ‘champions’—advocates for speaking up elsewhere in the organisation, recruited with a view to extending organisational reach and distributing responsibilities for promoting speaking up more broadly.[80] The Guardian in Case D, the ambulance services trust, had no protected time for these duties, but declared confidence that the organisation, by merit of its existing openness culture, would support her in managing the demands of her workload. (Case D adopted a similar approach, with apparent success, in supporting families during the course of investigations of serious incidents—see section 6.2.2.) The programme in Case F, meanwhile, was being reconfigured in response to the recent merger of multiple large organisations. Here too, given the size of the new trust, the optimal approach was seen to involve a ‘networked’ model that devolved much of the responsibility for promoting a culture of openness and encouraging voice to champions, with a single individual—senior, but without dedicated time for the role—appointed as Guardian.

While the varying models and their corresponding resource implications might be interpreted as reflecting differential commitment to the Freedom to Speak Up programme, other considerations also influenced the approach to implementation. These included the need to complement the existing apparatus in place within organisations to provide opportunities for voice, as discussed in section 3.3.1, and quandaries about whether a smaller contribution from a more senior individual would be more or less valuable than a larger contribution from someone more junior. In Case F, the decision to appoint a retired clinician the role had been made quite consciously: this position was seen to achieve the clout associated with seniority, without the potential compromise that came with entanglement in internal line-management structures. Similar trade-offs were described elsewhere.

> “It provides somebody who is fairly well defined as being independent of trust processes but nevertheless, it’s sufficiently integrated to make those processes work when they should. Quite a bit does depend on the individual. I’m fortunate, perhaps, in being old and ugly, and I’ve been around a long time, and so I feel reasonably empowered to ensure that people in the trust take action where it’s needed.” (Non-clinical staff, Case F)

> “You either have people who are so junior, they don’t really get the access, or you get me, who is so senior that I’m very cautious. And I want to do everything as informally as is possible and talk to people, and then talk in a very softly, softly way.” (Non-clinical staff, Case C)

There was recognition, nevertheless, that from the perspective of staff at the sharp end, the sense of seniority and power might overshadow the perception of independence. More work, then, was needed to ensure that awareness of and engagement with the programme spread through the tendrils of the organisation.

Where organisations had indeed devoted scarce financial resources to the Guardian role, moreover, staff read signs of commitment to putting the principles of openness into practice. Investing in the role was important symbolically and materially, and meant that Guardians were able to spend time traversing the organisation and making themselves known.

> “It does show commitment to the whole agenda and I've got resources available to me, within reason, and the board and the exec team are very open to suggestions and things. When I took the role, it was described to me as going to be 80 per cent about getting out and seeing people in terms of raising the profile about raising concerns. And probably 20 per cent actually face-to-face speaking to individuals who wanted to raise concerns.” (Non-clinical staff, Case B)

Support for the role, however, was not just about funding dedicated sessions or providing budgets.

The ‘in kind’ support provided by organisations was seen as crucial to generating awareness of Freedom to Speak Up, and in presenting the programme as a meaningful initiative rather than an exercise in compliance. Some promotional work about Freedom to Speak Up had been done at the national level by the CQC and the National Guardian’s Office, but work to publicise the programme at the local level was also needed. There was a stark difference here in the experiences of Guardians who were supported in their organisations in this work, and those who found themselves alone in seeking to advance the Freedom to Speak Up agenda. Typically, those Guardians with protected time also found that they enjoyed the support of their organisations in other ways, too.

> “My team [the organisation’s risk and governance department] started to work more closely with [Guardian] to make sure that she’s getting the exposure that she needs as well.” (Non-clinical staff, Case B)

These organisations made active efforts to integrate Freedom to Speak Up into wider organisational processes. This in turn could make it clear that efforts to promote voice were not a ‘bolt-on’ or ‘optional extra’ or adjunct to the main business of healthcare, but an integral part of their work. For example, Case B had included an introduction to the Guardian into key organisational processes, such as staff induction. This required not just sufficient time for Guardians, but also organisational interest and support for reconfiguring processes.

> “I go to every induction, including the student nurses, nursing associates and junior doctors. I go to team meetings: so I targeted each individual directorate, introduced myself to the director, explain what I wanted to do and then found out the matrons, so that I could get invited to team meetings to make sure that I was engaging with staff as far and wide as possible. Just raising awareness about the role—it was my passion that it was about seeing a face rather than just a brand, and knowing that there’s just another mechanism by which people can speak up. I always give the background around the Francis report and use that as the hook to say, ‘This actually refers to us’.” (Clinical staff, Case B)

In Case D, notwithstanding the lack of protected time, efforts had been made to support the Guardian in raising awareness and providing routes to voice that would cut across the diffuse organisation.

> “Through August, September, [Guardian] is spending some time with our clinical care managers who manage both the patient transport services and our frontline emergency care services, so our 999 services, is trying to spend some time with them, and trying to meet with staff to try and get the message out there on a face-to-face basis. We’ve had promotional campaigns through our weekly staff e-mail, through our monthly or bimonthly newsletter for staff; we’ve got posters that should be up in every station, we’ve got leaflets that go out in our induction course and in our statutory and mandatory training course for all staff.” (Non-clinical staff, Case D)

In contrast, without the financial and in-kind support of organisations, the burden of spreading the word fell solely upon Guardians (and sometimes champions), and made for a daunting task.

> “Any sort of profile-raising has to be through social media. CQC, they took my photograph round to all the sites and all the walls, and every time I went on the ward I saw myself—disconcerting! But it is very, very difficult. A lot of it I have to do over the phone. I’ve got a lot [of contact] recently because the CQC, they raised the profile. But I probably don’t get more than about five or six in the quarter.” (Non-clinical staff, Case C)

> “I can’t do it without the [champions]. When people really start using them, as I hope they will more and more, that will be particularly useful. I just can’t cover the territory effectively enough, I see everyone who wants to see me, but it’s very time-consuming, and I’m not—apart from being a screensaver!—I’m not that visible on some of the other sites.”

> (Non-clinical staff, Case F)

National-level support for the roles was viewed as patchy by Guardians and others involved in the Freedom to Speak Up programme. Again, participation in the support opportunities offered could be difficult for those with limited time to devote to the role; some organisations were also reluctant to provide support for travel or accommodation costs. The National Guardian's Office organised engagement and training events, but Guardians needed sponsorship from their employers to attend. Some participants felt that the Office was rather London-centric in its orientation, which could further deter participation.

> "I have done some work with the National Office, but they wanted to train me to train other Freedom to Speak Up Guardians. But that to me isn't an advantage to the trust here, because there was a big cost to us to accommodate me in London for two days. [...] So I didn't go because of that, and it was taking me out of the trust for too long." (Clinical staff, Case E)

In some areas, Guardians had taken it upon themselves to organise 'bottom up', by forming regional communities of practice[129] where they could share experiences and tips for how to put their emergent role into practice.

More generally, Guardians in the case-study sites described an ambivalent relationship with the National Guardian's Office. They sometimes framed it as remote from, and out of step with, their own experiences of the role and its challenges in practice. Some were troubled by the Office's approach to performance measurement, which was based primarily on Guardian-reported numbers of contacts. Some questioned the value of such an approach, and suggested that it was open to gaming. Further, participants raised concerns about the way these figures were interpreted, and translated into a proxy for openness. A low number of contacts could mean concerns were not being raised with the Guardian—but *were* being raised successfully and appropriately addressed through other channels. Participants in cases with lower numbers of contacts felt that this could negatively affect perceptions of the organisation and the Guardian's performance.

> "There's some trusts that have a huge number of Freedom to Speak Up cases, and ours is relatively low level. It's difficult to interpret the numbers. [...] But when I look at the ones that have got really high ones, it makes me think, 'Actually, are people just going to the Guardian direct, rather than talking to their line managers about issues and getting stuff resolved as a matter of course?' Because the things that get picked up and resolved at the line manager level won't feature in the statistics that go to the National Guardian's Office." (Non-clinical staff, Case D)

More broadly, as we see in section 7.2, this approach to measurement and monitoring failed to capture the mainstay of the Guardians' day-to-day activity in practice.

Together, these issues with the coordinating, performance-management and promotional role of the National Guardian's Office meant that many Guardians and their colleagues were more inclined to orient towards local efforts to promote and empower the role. They were less inclined to subscribe to the nationally consistent model, with uniform branding and standardised points of contact, that Francis envisaged in recommending the 'Guardian' nomenclature.[11]

For all these efforts, local and national, to promote the role of the Guardian and the value of speaking up more broadly, it should be noted that even in those case-study sites that dedicated extensive resources and support to the Freedom to Speak Up programme, knowledge appeared patchy. Even with organisational support, Guardians remained small groups of individuals in very large organisations.

> "There needs to be a little bit more promotion about Freedom to Speak Up Guardians, on exactly what they do. Because I don't think people know. People don't seem to know who

> they are or what they do, what they’re there for. So I think they need to raise awareness of that.” (Non-clinical staff, Case E)

7.2. The Guardian role in practice

Participants, including Guardians themselves, described a wide range of functions for the role. The most prominent largely reflected three of the functions imagined for Guardians in the *Freedom to Speak Up* review and other blueprints.[11,82,130] First, the role involved a large ‘signposting’ component for staff who were unsure of the nature of what they were reporting, or what—given the choice of available reporting channels—to do with it. Guardians could offer an informal space in which staff could discuss their issue and, with the help of the Guardian, make an informed decision about whether and where to report it formally. Second, participants highlighted the importance of an ‘ambassadorial’ role for Freedom to Speak Up Guardians. This involved seeking to promote the virtue of speaking up about concerns, taking an active role in spreading the word about how to speak up, and emphasising that the organisation would value and take seriously the issues raised. Here, the Guardians with dedicated time for the role were obviously at a distinct advantage.

Third, participants highlighted an important role for Guardians in understanding what was happening across their organisations. Building on some of the points made in WP1 (section 3.3.2), participants described how the Guardian could detect ‘weak signals’ that might be the precursors to serious trouble,[131] or that, in aggregate, indicated something perhaps already wrong. Used wisely, the intelligence offered by Freedom to Speak Up Guardians could be synthesised with other data to provide early warnings of where all might not be well.

> “It’s the really little, small, just fragmented pieces of—for want of a better word—kind of badness. Where each individual incident—I have people coming to me and go, ‘Oh, it just sounds really petty’, or, ‘It sounds really silly’. But when you add it all up together it’s actually not petty or silly at all. It’s actually quite a bad situation sometimes.” (Clinical staff, Case A)

Similar to the way that participants described aggregating data from the Duty of Candour and incident investigations to anticipate bigger issues that were on the horizon (section 6.4), insights from Guardians could provide a valuable prospective resource. Again, this required considerable effort—and thus funded time and capacity—from Guardians. In common with the Duty of Candour and incident investigations, it also required a well integrated, functional infrastructure for collating and coordinating the intelligence provided. In case-study organisations where the overarching safety culture seemed less mature and systems of oversight were less effectively integrated, the goal of triangulating intelligence could be hampered.

> “We have BME [black and minority-ethnic] networks, through staff committee, and trade unions. So the question is, there’s clearly a lot of intelligence being gathered. So who has oversight of all of this? In terms of patient safety concerns, it would be our Director of Nursing and our Medical Director. In terms of staff concerns, me, really, I guess! [...] I think it's a challenge. So, if a concern gets raised through the Speak Up Guardian line, then it's very straightforward, so the Speak Up Guardian will speak to me, if it's related to staff, and to [colleague] if it relates to patients. With the [incident reporting] process, it's up through the line-management chain, and I think there's a big issue with making sure that we’re confident that they're all being picked up, and they're all being reviewed, and certainly that they're all being responded to, and people are getting to the outcome. I think that probably making sure that we've got a coordinated response, so that we know, other than through the executive director's conversations and discussions.” (Non-clinical staff, Case C)

Like the ambassadorial role, gathering intelligence in this way implied a heavy time commitment for Guardians. It meant extensive, ongoing work to build relationships and understanding.

Notably, then, while these activities did map on to the description of the role put forward by Francis and others, they did not include the most obviously distinctive part of the role: as a ‘case worker’ who would act to ensure that concerns were being addressed where raising them through line management structures had failed.[11,82] In this light, it is perhaps unsurprising that participants were concerned about the National Guardian’s Office’s approach to measurement and monitoring, with its focus on the number of approaches made to Guardians and their resolution (section 7.1). It simply did not reflect the predominant content of their jobs in practice. These findings also serve to emphasise the much more limited role that Guardians without protected time for their work could play. A dedicated telephone number or a ubiquitous screensaver might be helpful in guiding staff about how to escalate concerns that they felt were not being taken seriously. But they were no substitute for meeting and chatting, particularly when it came to helping staff to navigate confusing systems, acting as an ambassador for employee voice, or gathering insights into areas where troubles might be mounting.

7.3. Supporting speaking up

Although the ambassadorial part of the role of Guardians was seen as important, participants also acknowledged that it could only go so far in encouraging voice. Guardians could spread the word about openness but, mirroring our findings in WP1 (sections 3.5.2 and 3.5.6), they needed to be able to offer their colleagues clear examples of how their organisations valued openness if their message was to be heard. Alongside this, their individual-level ‘case work’—their interactions with colleagues with concerns—could also play an important part in advancing a sense that the organisation was listening, was gathering the views of staff about problems and how to solve them, and was prepared to take those views seriously.

There was some misunderstanding of the nature and scope of the Guardian role among colleagues. For example, one Guardian described how he had been asked to bring pressure to bear on their organisation to build new facilities, and others described the very wide range of issues—from the serious to the seemingly very trivial—that their colleagues brought to them. Often, the issues brought to Guardians by their colleagues were less about overt patient safety or quality issues than about more general qualms, discontentments and distractions.

> “They bring a range of problems with them, which vary from consultants whose behaviours are deeply prejudicial to patient safety, but certainly to staff wellbeing, to very junior, or people in relatively humble posts who feel they haven’t been valued by the trust or they’ve been re-banded and they didn’t think it was fair, and that sort of thing. So there’s a very big range of activities and incidents which cause people unhappiness.” (Non-clinical staff, Case F)

In such instances, Guardians could offer reassurance and personal support to people, some in vulnerable situations, whether or not their concerns ultimately turned out to merit further investigation or escalation. Participants emphasised that speaking up carried with it the potential for detriment and could engender difficult emotions. Guardians were in a position to provide informal support alongside their formal role.

> “I think that’s the most important thing, emotional support for staff, in my eyes. Because if it’s an investigation or speaking up or anything, there’s always going to be emotional stuff attached to it. So as long you’re maintaining and looking after those emotions, you’re going to get a good outcome.” (Clinical staff, Case A)

> “So I do think it was, you know, [name], the Freedom to Speak Up Guardian, who was an absolute brilliant support. If she hadn’t have been there, I—you know, I went to occupational health a month after this happened, and I told them I wished I was dead.” (Clinical staff, Case E)

A key part of this role was in mediating between the organisation and the concerned individual. Mirroring some of the key points arising from our analysis of the implementation of the Duty of Candour and the investigation of incidents (sections 6.2.1 and 6.3), people who dared to speak up could find themselves ensnared in a burdensome or 'coldly efficient' bureaucratic system. Those who had contacted Guardians appreciated their mediating role, and the way for example they could help to explain processes that might seem Byzantine.

> "Having a Freedom to Speak Up Guardian has opened the doors for an awful lot of people. And you might find an awful lot of people suddenly realise that there is somebody who can actually see the middle ground. I'm not expecting miracles, all I wanted was parity and fairness." (Non-clinical staff, Case A)

Systems for investigating complaints often had opaque rules and indefinite timelines. They often led not to resolution but to uncertainty and ambiguity. As with incident investigations, these features were to some extent and inevitable by-product of the need for confidentiality, discretion and thoroughness during the course of investigation processes (and sometimes around their outcomes, too). But just as with the Duty of Candour and the serious incident investigation process (see section 6.5), for those implicated, these characteristics were difficult to distinguish from defensiveness, obfuscation and duplicity. Guardians could make the process less impersonal, and provide reassurance that concerns were being treated seriously rather than falling into a vacuum.

> "She's just been absolutely outstanding, and she, totally professional, she feeds back—when we've raised concerns with management, we don't get any feedback from them about what's going on or what's been done to address the problems. Whereas with [Guardian], she keeps in touch with us all and lets us know what's going on and where we're up to, and making sure that we're OK." (Clinical staff, Case E)

> "We've had other cases that have come through where actually the outcome has been [that] there's been a flaw in this process, that actually the policy isn't very clear on this. And then we've been able to then fully feed back and say, 'Thanks to your feedback and raising your concern, what we've done is…'." (Non-clinical staff, Case B)

Of course, Guardians could be more candid about some matters than others. Confidentiality in relation to sensitive issues and processes that had not been concluded was essential. Their role in mediating between people and systems could also put them in a position where they had to make fine judgements about the balance between their obligation to the organisation and their obligation to the individual they were supporting. They had to tread a careful line, for example, between assuring the probity of the process and ensuring that it did not leave those involved alienated and disenfranchised. They sought to walk this line by providing informal support to those who had approached them to supplement the voids left by formal documentation of processes, and assure them that concerns were being taken seriously.

> "To be fair to the Guardian, when it did happen—[…] I have met her and we've had a discussion more on an informal basis rather than it being anything in writing. And she did say that the fact that they had had their contract terminated was because of the concern raised. And I don't think she would have said that if it wasn't true." (Non-clinical staff, Case A)

As with other policies, functional administrative support for this activity was crucial. Keeping tracks of the progress of concerns raised, following up for appropriate responses, and providing whatever feedback was possible to complainants all depended on high-quality information-management systems. As noted in sections 6.1 and 6.2, the degree to which these were present varied across case-study sites; some Guardians had to rely on their own individual administrative skills to keep on top of their caseload, with inevitable compromises in reliability.

On a one-to-one basis, then, through their 'case work', Freedom to Speak Up Guardians appeared to make an important contribution to the sense that openness was not a one-way street: that there were benefits as well as risks to giving voice to concerns, and that raising issues was not just a matter of feeding a bureaucratic beast.

7.4. Reaching the parts that others cannot?

Where Guardians were indeed resourced and empowered by their organisations to do so, there was a sense from the participants in WP4 that they were making something of a difference. This reflects the largely positive views of the contribution of Guardians expressed by senior stakeholders in our survey (sections 4.1 and 4.2)—and perhaps the incremental improvements in staff's views of reporting systems and their ability to contribute towards improvement found in our longitudinal analysis of staff survey data (sections 5.1.2 and 5.1.3). However, participants also identified limits to this capacity, at both the collective and the individual level.

First, some groups of colleagues were 'harder to reach', and/or more sceptical of the messages put forward around organisational receptiveness to employee voice. The reasons for this were largely the same as those we grouped under the heading 'resistance' in section 6.3: issues such as geographical remoteness or ingrained cynicism born of past experiences left some groups harder to convince of the merits of speaking up than others. More prosaically, there were simple practical challenges in conveying the role of the Guardian, and the opportunities to speak and be heard, to particular groups. Some staff, especially at lower grades, did not have staff e-mail accounts, and were therefore at risk of missing out on promotional materials distributed digitally.

> "A lot of the domestics, the estates people, they won't have computer access." (Non-clinical staff, Case E)

Some staff on the margins of the organisation, such as agency or locum staff—a vulnerable group, and one that is often exposed to pressured parts of the service at risk of fraying[132]—felt less able to make use of Guardians, or were even unclear as to whether they were eligible to make contact with them.

> "I wasn't offered anything like [the Guardian]. I know that they're supposed to be in the building. I wasn't really directed to them. The [staff] bank manager wanted to deal with it all." (Clinical staff, Case C)

Where case-study sites offered little protected time to their Guardians and relied instead on publicising the role via posters and e-mail campaigns, these challenges could be particularly salient.

Second, across case-study sites, participants identified the issue of what we call 'fiefdoms'. These were associated with the phenomenon described in section 3.5.5, whereby more geographically distributed organisations, with teams and units distant from each other and from the organisation's management, could develop subcultures that were immune to external influence—and which could be opaque and unhealthy. More than this, though, fiefdoms comprised groups of individuals who had come to wield significant power over their colleagues. Sometimes this was a function of their hierarchical position in the formal organisation. More often, it was based on or supplemented by their informal power: their longevity; the people they knew; the favours they were owed.

These groups exercised their power in dysfunctional ways: for example, preventing colleagues from reporting incidents or concerns; bullying and reinforcing their position by meting out forms of punishment to those who dissented; allocating more desirable shifts to sycophants while giving 'dirty work' to those out of favour. An extreme example is perhaps the overbearing influence of a cabal of midwives identified in the Kirkup report on quality and outcomes in maternity and neonatal services at Furness General Hospital.[15] Similar, if less dramatic, examples of the disproportionate negative influence of certain individuals were described in all six cases; recent literature similarly highlights the untoward impact of 'untouchables'[101] and 'divas'.[133]

> "The biggest, thorniest problems are generated by doctors, usually. Sometimes by senior nurses. But dysfunctional people in senior roles are very difficult to deal with." (Clinical staff, Case F)

Participants described how the problem of fiefdoms could have a negative impact on patient safety, but often in complex and indirect ways. In consequence, issues could remain below the organisational radar, sometimes because they were seen as too trivial to report and sometimes because they were too difficult to act upon. Sometimes, too, they might suffer from a 'credibility gap', where the events described were hard to believe and correspondingly difficult to make actionable.[134] Through time, normalisation of deviance[135] could create a vicious circle, as those subjected to inappropriate behaviours perceived organisations indifferent to their issues, or unwilling to act. For those working in fiefdoms, stress, misery and distraction from their roles would follow.

> "So it's really unnerving, whenever you've got a group of people in a position of power making it very clear that they've got a longstanding history here, any of your concerns are not going to go anywhere, they're not going to leave that room: nothing's going to act on it." (Clinical staff, Site A)

> "The comments were made because this group of people had got away with a lot of work behaviours for a long period of time, and [name] was a new Band 7 that wasn't tolerating it anymore, and was coming down on them, and making sure they were doing the job. And it was that reason that this group of people, who were close knit, didn't like it, and just decided to retaliate badly against him." (Clinical staff, Case E)

The foundations of fiefdoms were often to be found in the informal organisation. Deep-rooted friendships, or shared secrets, could create bonds between individuals in different units that were invisible to others until they stumbled across them. This made it dangerous to express concerns to others who were on the face of it independent, at least as far as the formal organisational hierarchy was concerned. The fear that individuals with long histories in the organisation would have friends in high places could in itself deter voice; sometimes individuals who did dare to speak up found themselves exposed by such relationships.

> "I was getting mixed reports of the management being complicit in this, because, obviously, they had all trained together and they were all friends, they were all colleagues and had been for 20-odd years. I can understand why, whenever you went and spoke to matron that it didn't go anywhere, didn't leave those four walls, because she was in an odd place herself, having to speak to one of her friends about [that individual's] behaviour." (Clinical staff, Case E)

> "There's a certain dynamic has developed over the years between these people. Who know a lot about each other. And go back an awful a long way. And the result of that, unfortunately, was that this person was supported by colleagues, who, who had a—well, a sort of sycophant-type relationship if you like. Where they would—basically there is no integrity there at all, it was just a case of 'I know which side my bread's buttered, and that is that. I support this person through thick and thin, regardless of what they've done'." (Clinical staff, Site E)

Sometimes, the existence of Freedom to Speak Up Guardians offered a new outlet for concerns, providing staff with confidence that there was an independent and robust mechanism through which their concerns could be routed. This was not always the case, however. Particularly where Guardians had been appointed through opaque processes or were seen as a distant individual, participants could not be certain that they too were not bound up in hidden social networks.

> "We've had a Guardian for the last two years. Again, it's all paper exercise. They want a job as a Guardian, and their line manager is not very credible." (Clinical staff, Case E)

Where they were approached with concerns about fiefdoms, Guardians offered what reassurance they could that behaviours of this kind would not be tolerated. They could also offer support to people who raised these kinds of concerns.

> "[This] has happened to me in the past when I raised issues the first time round. It was just subtle things like giving me really awful off-duty, loads of night shifts. Making me work right through the Christmas period, even though I'm part-time. Just subtle things like that, so there was some retribution. So this time round, I raised those concerns with [Guardian]. I said, 'Look, I'm really concerned that I'm going to get penalised for speaking out again'. And she just said to me, 'Well I'll keep in touch with you, and if you've any concerns about any retribution, let me know about it, so I can deal with it on your behalf'." (Clinical staff, Case E)

Nevertheless, the nature of fiefdoms—and particularly the fact that they existed in the informal organisation, and wielded their influence through subtle, devious acts—meant that the ability of Guardians to address these issues was inherently limited. Guardians could contribute to organisational intelligence about their existence and influence, but an effective response required a great deal of care, resource, and tenacity.

7.5. The policies in aggregate: the potential for cultural change?

> "Turning all this into a better world, of course, is a slightly slow process. And I think that will come." (Clinical staff, Case F)

Finally in presenting analysis from WP4, we take a step back to consider our findings in terms of the potential of policies designed to engender openness to achieve this objective. In doing so, we return explicitly to our third research question: 'Are provider organisations' efforts to increase openness resulting in real changes in staff values, attitudes and actions at the sharp end of care and in patients' opportunities and experiences around openness—and what features contribute to success?'

Recurrent themes across Chapters 6 and 7 include the finding that high-quality systems for administering the three initiatives are a necessary—but not a sufficient—condition for promoting the sense among staff and patients that an organisation's commitment to openness is sincere. Work to implement the policies flexibly and sensitively is also required, and this requires capacity, opportunity and willingness among those involved in realising the policies: including staff making disclosures under the Duty of Candour, those administering incident investigations, and Freedom to Speak Up Guardians.

A related point is the need for openness initiatives to be integrated into the wider organisational infrastructure, and not function (or appear to function) as adjuncts that have their own rationalities divorced from organisational mission. To this end, and cutting across the three specific policies covered in WP4, several case-study organisations had sought to locate them within wider organisational frameworks around openness, including declarations of mission or values, descriptions of systems and processes, and statements of standards to which colleagues behaviour would be held. These sought to bring the common themes of candour, openness and learning together in locate them explicitly at the centre of the organisation's purpose and activity.

> "The first thing is to identify that [inappropriate behaviours] exist. The second is to show that by existing, behaviours are not focused on the core business of the enterprise, for instance, looking after patients. And the third is to demonstrate that their existence is harmful to either the organisation or its core purpose, and that all takes some time." (Non-clinical staff, Case F)

Participants found varying degrees of success in their efforts to give openness primacy in this way. Important were efforts to translate behavioural standards frameworks and other such documents into tools which staff at the sharp end could make use of themselves, on a day-to-day basis. Otherwise, participants recognised, such documents risked gathering dust on shelves or being perceived as little more than branding initiatives. To make them useful, senior members of staff needed to role-model them, and to use them explicitly in influencing their colleagues' conduct, so that others felt empowered to draw on them as well. Senior staff in Case D had gone through an extensive co-production process in generating its framework, with a view to ensuring buy-in and ownership, with (they felt) some success. In Case E, meanwhile, participants discussed how a behavioural standards framework was used consistently to frame what was expected and thus, it appeared, become a functional tool that could be used in both formal and informal interactions across staff.

> "They promote it a lot at corporate induction, and it does underpin the culture. You do get people coming to raise concerns because these standards are now expected of everyone within the trust. Because it was quite a public launch, that's been quite good. And supported by the behaviour standards, but it's more a cultural thing, and there's been a big thing against [poor behaviour]: 'It's not OK to behave that way'." (Clinical staff, Case E)

Freedom to Speak Up Guardians and others located across the organisation could play an important role in encouraging and supporting staff to use frameworks of this kind to challenge maladaptive behaviours, and normalise giving voice to concerns on an informal basis, in the course of day-to-day practice,[136] as well as formally.

> "We've got behaviours framework that's in place now, which is all built by staff. So it looks at the values and says what expected behaviour is and what's exemplary behaviour against each one of the values, giving tangible examples. Staff are being encouraged to use that on a daily basis, regardless of grade and managerial structures. If you see something and somebody isn't acting in line with the values, then use the behaviours framework to say, 'Actually I'm not sure that you really are living and breathing the trust values in the way that you've acted'." (Non-clinical staff, Case D)

Inevitably, such efforts were received with more enthusiasm by some groups than others, reflecting the organisational subcultures and patterned 'resistance' discussed in sections 3.5.5, 6.3 and 7.4. Participants did, however, suggest that in general there was recognition of the insidious impact of poor behaviour and of the need to uphold good standards of conduct, bolstered by an increasing evidence base for the relationship between incivility, staff experience and patient safety.[137,138] Frameworks like this were also being incorporated explicitly into recruitment and appraisal systems, ensuring that formal processes were in line with informal socialisation, and with a view to securing long-term changes in attitudes and behaviours.

Efforts of this kind, however, needed unerring tenacity. Participants largely subscribed to the notion that cultural change was a necessarily long-term project. Persuading staff that commitment was genuine; showing that openness would not be punished; dealing with fiefdoms; inculcating positive shared values: all of these would take time. Adherence to the letter of the law could be achieved relatively quickly, if high-quality administrative processes were in place (section 6.2.1). The work needed to imbue the spirit of the law—and demonstrate that this was not a fad that would quickly be displaced by day-to-day operational and resourcing pressures—required a much longer timeframe. Participants in case-study sites with more mature cultures of openness stressed that this meant not only integrating openness initiatives into the day-to-day routines of organisations, but also into their long-term planning. In other words, realising the Duty of Candour, improving the benefit of incident investigations and supporting Freedom to Speak Up all required approaches that saw them as more than time-limited 'initiatives'. Rather, they needed to be viewed as ongoing, open-ended work tied into wider organisational objectives and aligned with organisational values. While exacting project management was necessary, it could not on its own achieve higher-level aspirations to create more open organisations. Indeed, too great a focus on implementation could frustrate these aspirations if it gave the impression that they were projects that could ever be deemed complete.[139]

> "We're doing a whole piece of work around outcome measures and it's a nightmare, it is like going through treacle, it is awful, but we've set it up and I've said, 'This is an organic process. I am not saying that by December next year you will have a suite of outcome measures'. I'm not saying any of that, it is an organic process. It's 'What do we have? What do we need to develop? What do the staff tell us? What do patients tell us? How does it look? How can we do it? What does that picture give us?' And it's building that picture, and I'm being quite assertive about that, saying, 'Don't tell me that you need all these boxes filling because it's not going to happen'. We need to work with people to do it." (Non-clinical staff, Case B)

7.6. Conclusion

Organisations in our sample implemented Freedom to Speak Up in varying ways, with different levels of resourcing and in-kind support for Guardians. These appeared consequential for the way Freedom to Speak Up was realised in practice. Notably, an approach to putting the recommendations of the *Freedom to Speak Up* review that focused solely on the most distinctive feature of the Guardian—as a point of contact for members of staff who were unsatisfied with their initial efforts to raise concerns—could fall short. Viewing the role of the Guardian primarily as one of receiving calls or e-mails from concerned members of staff meant that other important functions, notably the promotion of a culture of openness and the gathering of 'soft intelligence', could be marginalised. Guardians needed time to undertake these aspects of the role, and to foster relationships of trust across often-dispersed organisations. Even then, however, some parts of the organisation were more likely to engage with Freedom to Speak Up than others, and the fiefdoms that lurked in the corners of every case-study organisation posed particularly thorny challenges.

Across the three tracer issues, several common themes emerged. Perhaps most notable were the necessity of high-quality administration to ensure that the policies were being discharged reliably and compliantly, and to give those involved in them a clear handle on pathways that were often complicated. A second overarching theme was the need to integrate—and be seen to integrate—these policies into the mainstream activity of the organisation, so that they were not seen as side projects of low priority, or interests with a limited shelf life that would ultimately be displaced by the business as usual of resourcing, productivity and targets. Participants discussed the role of overarching frameworks relating to organisational values and behavioural expectations, and to the need to ensure that openness initiatives were aligned with other aspects of the organisational mission on an ongoing basis. We pick up these themes and others in the final two chapters of the report.

7.6.1. Limitations

While our sampling for WP4 was theoretically informed, ultimately participating organisations were self-selecting. It is plausible therefore that organisations that were more positively inclined towards the openness initiatives were included; the challenges we faced in the course of recruiting organisations (section 2.4) would support this supposition. At the level of individuals, the number of participants varied notably across case-study organisations, and in one organisation (Case F) only eight interviews took place. This may limit the validity of our findings. The number of patients and family members included fell short of our minimum target, and we did not speak to any patients or family members in Cases D and F. More generally, caveats around potential for bias associated with interview-based data collection (particularly recall bias and social-desirability bias) apply to this workpackage.

8. Discussion

Between them, the four workpackages conducted for this study over 30 months between 2017 and 2019 used a range of methods to shed light on the impact of policy changes in the English NHS since the publication in 2013 of the report of the Mid Staffordshire public inquiry.[5] In this chapter, we bring the findings of the workpackages together with a view to addressing in particular the issue at the core of our inquiry, set out in Chapter 1: whether, how, and to what extent these initiatives appear to be having an impact on cultures around openness in the NHS. We offer reflections on what our findings suggest about the challenges and opportunities proffered to the NHS for enduring change in the area of openness by the post-Francis polices and the wider current NHS context.

In doing so, we the tackle the three questions that guided our research: understanding and translation of policies by senior NHS staff, the extent to which views and experiences of openness are changing through time, and what helps in ensuring that implementation efforts produce tangible changes in attitudes, actions and experiences among patients, families and staff at the sharp end. We return to the three research questions to answer them more directly and succinctly in Chapter 9, and derive key implications for policy and practice. Here, however, we offer a broader and more reflective discussion of our findings.

8.1. The general trend: positive signs; persistent problems?

Across the board, we found evidence of support for the post-Francis policy agenda, at least at the level of the blunt end (Chapters 3 and 4). Our longitudinal analysis of annual surveys of NHS patients, service users and staff (Chapter 5) covered a wide set of variables, all chosen *ex ante* for their association with the themes of openness covered by the policies. For many, the trend over time was in a positive direction, and in several cases, there were statistically significant improvements in the direction or gradient of change in the period after the public inquiry's publication.

From the perspective of staff, experiences relevant to openness improved in several respects over time, including around communication and responses to incident reporting. Where improvements levelled off, it was in some cases due to an apparent 'ceiling effect': further improvements were difficult to achieve given existing high standards. The trajectory of the views of acute inpatients was broadly similar. But the pattern was rather different for users of community mental health services. Several indicators—including, for example, experiences of respect, dignity and being listened to—showed deterioration post-Francis. This may reflect longstanding differences between the resourcing and policy attention paid to mental health services as the 'poor relation' of NHS healthcare provision, which have only recently become the focus of sustained attention.[111,112,140] Nevertheless, that in some cases the declines in this sector have taken place so recently is noteworthy and concerning.

Besides the clinical differences between mental and physical health and illness, and the differences in diagnostic and therapeutic approaches that follow, there are indications in our data that organisational differences may also be consequential here. Significant differences in ratings between organisation types (acute trusts, mental health trusts and ambulance trusts) were evident in NHS Staff Survey responses at baseline. Mental health trusts and ambulance trusts scored more weakly on indicators that measured, for example, the fairness and effectiveness of incident reporting procedures. Moreover, both our stakeholder interviews (Chapter 3) and our organisational case studies (Chapters 6 and 7) suggested that there were challenges in putting the policies introduced after Francis into practice into non-acute provider organisations. Various influences seemed to be at play here, relating to patients' characteristics, clinical conditions, and organisational features. Where incidences, causes and consequences of harm might be relatively easy to locate in discrete episodes of care in acute organisations, participants argued that they were less readily identifiable when trajectories were more complex and took place over a longer period, often including multiple organisations. Psychological harm, though explicitly identified as within the scope of Regulation 20,[26] proved a particular challenge for those charged with identifying incidents that merited disclosure under the Duty of Candour. It was less easily measured and quantified, and could manifest at unpredictable points, sometimes long after the preceding event, making identification and attribution difficult.

Organisationally, too, community and mental health services trusts tended to be more diffuse, geographically and culturally. Over several decades, such organisations have been subject to reorganisation, disaggregation and merger to arguably an even greater extent than the rest of the NHS,[102,141,142] and this could result in organisations that lacked a sense of coherence or affiliation. For senior stakeholders in interviews, this added significantly to the challenge of policy translation. This was particularly true for the 'latent' or indirect intended functions of the policies,[143] for example around culture change. Implementing policies in ways that ensured compliance and would stand up to audit-based scrutiny was one thing, but communicating to colleagues across a diffuse organisation the intent around openness was quite another.

Mental healthcare organisations were not the only ones faced with this challenge. Ambulance trusts, and some acute trusts, also traversed multiple sites where organisational identities varied, and where there were logistical challenges in communication, managerial accountability and coordination of processes and outcomes. Larger organisations too could face difficulties in presenting a unified strategy across an expansive workforce and multiple functional units. One of our case-study organisations (Case F), a very large trust and the subject of a recent merger, appeared to exemplify some of the complexities. After controlling for other variables, participants in the staff survey felt that communication in smaller organisations was better, and that smaller organisations were better places to work.

Whether because Francis's recommendations seemed to be modelled on an 'acute template', as some participants from mental health and community healthcare backgrounds commented, or because of other forms of heterogeneity beyond core organisational function, implementation clearly posed more of a challenge in some organisations than others. Participants described difficulties in reaching the more far-flung parts of their organisations, and in forming a clear picture of where problems with openness might lie (and how policies were being received). Even within relatively modestly sized organisations located on a small number of sites, units could vary in their recent history, their local culture, and thus their receptiveness to policies.

Shortly after the publication of the Mid Staffordshire public inquiry,[5] Davies and Mannion cautioned that, given the "cultural mosaic" of many NHS organisations, "we would do well to tone down our rhetoric around culture, be cautious about the idea of cultural uniformity, and be sceptical that top-down prescriptions will bring about the desired changes."[38] Certainly, our findings suggest that the fate of the policies is in large part down to their implementation on the one hand, and down to pre-existing and enduring cultural and organisational forms on the other. To this extent, our findings reflect Exworthy and Powell's application of Kingdon's 'policy streams' framework at the local level. Just as national-level policy initiatives rest on the coming together of problems, solutions and political actors, so local-level implementation is likely to be pursued more energetically where policies appear to address recognised problems, and 'entrepreneurs' seize the opportunity to implement them.[144] Interviews with participants from outside the NHS (Chapter 3), as well as our cross-case comparisons (Chapters 6 and 7), evidenced starkly divergent approaches to implementation. Some approaches that were compliant with the letter of regulation, and would serve to achieve the declared, immediate aim of a policy—disclosure when things go wrong; new opportunities for voice and so on—seemed unlikely to do much more than this. Approaches that sought to go beyond mere compliance, seeing the immediate realisation of policy as a means to a greater end, required a much greater investment of time and effort, and sometimes needed to be tailored to the subcultures of organisational units. With Freedom to Speak Up, for example, participants described how some units—perhaps because they were more distant from the core of the organisation, or because of local events that had bred scepticism or hostility—required more attention than others.

In seeking to implement policies in ways that would secure engagement from their colleagues, senior stakeholders described the importance of matching words with deeds. This included ensuring that policies were communicated and implemented in ways that showed they were part of the organisation's mainstream business (a theme to which we return in section 8.2). It also involved seeking to show that post-Francis policies represented more than just another top-down initiative that would add to demands at the sharp end, require a show of organisational attention,[94,145] offer little benefit, and then fade away with time. Participants suggested that efforts to ensure issues raised through openness initiatives were dealt with promptly not only ensured that learning and improvement were enacted quickly, but also served as tokens of mutual commitment. They could renew the covenant between an organisation and its staff, demonstrate that this was not simply a one-way exercise in compliance that bore little relation to the day-to-day delivery of care, and mark the beginnings of a virtuous circle that would encourage people to continue to engage in openness and learning. Done well, these efforts could show that organisations valued staff, and recognised their engagement as both an antecedent to and an indicator of more open, more reflective, safer organisations.[146–148] For their part, participants at the sharp end of care in the case-study sites felt they could 'read' organisational commitment—or the lack of it—without much difficulty. Approaches to implementation that went little beyond compliance were readily recognisable, while initiatives that were resourced only to do the bare minimum—as with the Freedom to Speak Up programme in some of our case-study organisations—were far more limited in their reach and impact. Given the abiding influence of events in the past where people had suffered punishment or retaliation for openness, as well as continuing ambiguities in the wider medico-legal environment about the consequences of openness,[69] demonstrating organisational commitment seemed particularly important.[149]

Skilful implementation by local-level leaders and entrepreneurs, therefore, was key. Participants in senior-stakeholder interviews and in organisational case studies noted the importance of flexibility and sensitivity in both implementing and executing the initiatives. With the Duty of Candour, for example, participants found something of a tension between stipulations around the process that not only created a large paperwork burden, but could also incline practitioners towards putting compliance ahead of compassion towards harmed patients and families. With Freedom to Speak Up Guardians, there was concern that the performance-monitoring regime was open to manipulation and/or misinterpretation, and at any rate did not capture much of the focus of Guardians' work in practice. How best to measure the quality and safety of healthcare is, of course, a vexed question with an extensive attendant literature. Many of the challenges identified in that literature—for example around the relative value of process versus outcome measures, the risk of gaming, and the question of how to account for rare events[95,150–155]—have clear relevance to the measurement and monitoring of openness initiatives. Participants acknowledged the risk of not measuring, particularly in organisations where little more than minimal compliance had been achieved: without an audit and performance-management regime, they might not even have got this far. But they also suggested that an abundance of process measures could create its own problems.[49,154]

There was some praise for the changes made by the CQC to its inspection regime, and especially its move towards a more dialogical, continuous relationship with provider organisations, particularly those with good records and high-quality internal assurance mechanisms[88]—alongside greater use of unannounced inspections. Participants acknowledged the risks of this more risk-informed approach,[156,157] and particularly the possibility that regulators might on occasions take false reassurance from inspections that failed to offer sufficient scrutiny. But they also found the input of the CQC's new regime more instructive and supportive in their own improvement efforts. Some suggested that consistently good CQC ratings (particularly in the 'Well-led' domain) might offer more assurance that organisations are implementing policies relating to openness effectively than a large suite of measures of compliance. Given that, as noted in Chapter 1, the ambition of these policies is about their aggregate impact and not just the implementation of individual processes,[12,13] there may be a case for a greater reliance on wider-ranging assessments of organisational approach, in place of exhaustive measurement of individual processes.

Undoubtedly, then, Davies and Mannion are correct when they argue that policy implementation in itself can only ever have a limited impact on organisational culture.[38] The varied topography of the

NHS, and of individual organisations, means that impact will inevitably be uneven. The skill, judgement and capacity of those implementing policies at organisational and sub-organisational level are therefore critical. Nevertheless, our study also offers insight into features that appear consistently more conducive to embracing and realising the wider ambitions of the policies around openness than others, regardless of the influence of context.

8.2. The necessary conditions for realising openness

While not an interventional study, let alone an experimental or controlled evaluation, our study does offer some qualitative evidence of the features of organisations or approaches to implementation that may help to secure impact on the attitudes, actions and experiences of staff, patients and families. These claims derive from the careful attention we paid to mechanistic relationships between contexts, processes and outcomes in our analysis; confidence in their reliability and transferability is arguably bolstered by the breadth of our sampling, and in particular by our comparative approach to analysis of data from the six organisational case studies (Chapters 6 and 7). We highlight four high-level sets of features that seemed particularly important: functional administrative systems; flexibility and sensitivity in implementation; integration into organisational mission; and continuous learning and improvement. These are presented in the sections below and summarised in Table 9. Again, these themes are in some ways familiar from other literatures, including implementation studies and improvement research.[118,139,158–160] Moreover, as we note below, in some ways they may be seen as following from the existence of more mature cultures of openness of the kind discussed in section 6.1.

8.2.1. Functional administrative systems

First, a consistent finding across the stakeholder interviews, survey of executive leaders and organisational case studies (Chapters 3, 4, 6 and 7) was the difference that well functioning administrative systems could make. The cross-sectional survey identified a number of implementation challenges in relation to the Duty of Candour, the investigation of serious incidents and Freedom to Speak Up. While some of these were associated with ambiguity in policy, others were challenges that could be exacerbated by poorly functioning systems, or greatly mitigated by well functioning systems. Stakeholder interviews suggested a wide range of approaches to administering the policies in practice. Comparison across the six case-study organisations demonstrated some of the consequences of this variation. These included striking differences in features ranging from ease of compliance, through consistency of communication with staff, patients and families affected, to swiftness of learning and improvement.

Though sometimes maligned, there is much evidence for the importance of clearly understood pathways, proactive management of processes and sound underpinning systems and infrastructure for the effectiveness of all but the simplest of improvement interventions.[78,161–166] Even a disclosure under the Duty of Candour required coordination across multiple teams to ensure timeliness, appropriate follow-up, and effective recording. In case-study organisations with more mature cultures around openness (notably Cases A and E), there was evidence of sophisticated socio-technical infrastructures built up over several years. These sought, for example, to secure tight oversight of disclosure and investigation processes, rapid dissemination of learning internally and implementation of recommendations, and integration of different sources of organisational intelligence about concerns and risks.[162]

Systems of this kind did not arise by accident. They were the products of sustained attention and investment, and continual improvement efforts—partly in response to local crises or scandals that had shaken the organisations out of a state of complacency,[50] and perhaps had greater local resonance than events in a West Midlands hospital some years previously. They complemented, rather than replacing, continuous attention to quality, safety and risk, and the “chronic unease”[167] and “problem-sensing behaviour”[49] that were also seen as important in these case-study organisations. But there was nevertheless a palpable difference in their effectiveness and efficiency in discharging the responsibilities presented to provider organisations by post-Francis policies, and doing so in a way

Theme	Key points	Section
Functional administrative systems	• Well functioning administrative systems were crucial to executing openness policies efficiently and sensitively, and to ensuring activity was appropriately documented • There was a marked difference in the quality of administration between organisations that had invested in systems and processes over time and those that had not • Systems needed to be accompanied by proactive efforts by staff to seek out, identify and act on signals that all was not well	8.2.1
Flexibility and sensitivity	• Sometimes well administered systems could appear to be driven by nothing more than the logic of their own processes, without consideration of the needs of patients, families and others • While operating efficiently and perhaps serving the purposes of detecting problems and prompting learning, such systems could alienate patients and staff, giving rise to oppositional relationships • Ensuring that openness policies addressed the needs of all those affected by poor-quality care required much relational and adaptive work, beyond functional administrative systems	8.2.2
Integration into organisational mission	• Where openness policies had been grafted onto rather than integrated into existing organisational systems, it was often very clear to staff and others • Efforts to align openness initiatives with existing work made it clearer that openness mattered, that it was a core part of the organisation's work, and that it was here to stay • Broader organisational efforts to 'mainstream' openness, such as codes of conduct and expectations around respectful communication, were seen as enhancing this integration	8.2.3
Continuous learning and improvement	• Integrated, hiqh-quality systems and processes for encouraging openness did not occur over night: rather they were themselves a product of experimentation, failure, learning and improvement • These efforts tended to be targeted more at systems and processes to support openness, rather than an open culture itself • Participants highlighted the importance of viewing openness as an open-ended, ongoing, long-term mission rather than a time-limited to be accomplished and 'signed off'	8.2.4

Table 9: Key themes relating to the necessary conditions for realising openness

that sought to reap their indirect benefits for openness as well as addressing their immediate functions.

8.2.2. Flexibility and sensitivity

However, as the analysis of Chapters 6 and 7 indicates, functional administration of openness initiatives alone was not enough. Families, patients and staff members described the negative consequences of systems and processes that appeared bound by their own internal order, timescale and rationality. What we have called 'coldly efficient' systems that grind away inflexibly, giving no quarter to the needs or wishes of the individuals involved, gave the impression that policies to advance openness were above all about serving the system. This is not to say that such approaches to implementation were necessarily exercises in paper compliance alone. They could serve the purpose of learning and improvement, but they did so in ways that left those affected with the sense that they had been used, or even harmed further.[70,128]

Apologies to those harmed in these processes appeared less a sincere "expression of sorrow or regret"[26] than an item on a list of actions to be ticked off in sequence, let alone the reconciliatory or even transformative process that some advocates of open disclosure have suggested.[168] Narrative analysis of the interviews of patients and family members showed how this kind of experience could move them away from a desire for insight with a view to learning and prevention of future harm, towards a position where retribution or even vengeance was their main motivator. Staff members who experienced incident investigations that seemed characterised by a search for blame rather than insight described similar trajectories. Correspondingly, their interactions with organisations would move from an inquisitorial logic governed by a joint interest in learning and improvement, towards an adversarial logic, in which one side (at most) would win, and one side (at least) would lose.

Generally, this kind of conflict seemed to arise inadvertently. Some individuals outside the NHS included in the senior stakeholder interviews could point towards examples of organisations that defaulted to oppositional approaches, with legal teams always on standby. But by and large, the narratives of patients, families and sharp-end staff in the organisational case studies indicated that this shift tended to happen by accident. Both weak administrative systems and insensitive behaviour could be implicated, as could any indication that organisations were being less than candid in what they disclosed. Approaches to disclosure, investigation and learning that were beholden to inflexible pathways, timescales and forms of interaction did, however, seem to be particularly prone to vex,[122] adding insult when people were still raw from injury. Participants in case-study organisations reported approaches that sought to soften systems with a human touch while still ensuring adherence to regulatory and legal requirements, such as templates for disclosure letters that showed what was needed for compliance but also allowed staff to express sorrow, regret and empathy in their own words. In Case D, staff could volunteer to train to act as points of contact and advocates for family members after serious incidents, for the duration of what could be very challenging period for them. Blunt-end staff here suggested that this system had been successful in reducing complaint and litigation—but crucially it did so *because* it prioritised the emotional needs of families.

The broader point, perhaps, is that the work of disclosure, investigation and speaking up is much more than what can be contained within formal documents, pathways and processes. Just as the day-to-day work of patient safety involves so much more than following codified instructions,[169,170] so doing openness is laborious, messy and infused with emotion. Openness work as done exceeds openness work as imagined. Doing it right requires judgement, flexibility, discretion and the occasional workaround.[122,168,171]

8.2.3. Integration into organisational mission

A third persistent feature of more promising approaches to openness was effort to frame it as part of the mainstream of an NHS organisation's business, and avoid the impression that it was a separate or optional bolt-on. Again, this was important for both symbolic and material reasons. Symbolically, as noted above, a lack of organisational commitment to the policy agenda around openness was often crudely obvious. If a Freedom to Speak Up Guardian was a remote individual who was only ever seen on a screensaver or a poster, it was clear that this was not an initiative that featured high on the organisational priority list. But as the findings of Chapter 7 suggest, decisions to graft responsibility for Freedom to Speak Up onto existing roles without investment to protect time could also have important material consequences. Important aspects of the role (not just the 'case work' of helping individuals with concerns, but the wider work involved in fostering a culture of openness) required the devotion of time and effort, and face-to-face presence. Without such investment, there seemed little prospect of using the initiative to raise awareness of the pro-social contribution of voice, to make speaking up safer, or to gather soft intelligence about the relative safety of different organisational units. The role could be as superficial as its FTE allocation suggested.

On the other hand, work to optimise and tailor the policy initiatives, or to integrate them into the wider organisational mission, seemed to reap significant benefits. We note above (section 8.2.1) the benefits that could accrue from integrating insights from the Duty of Candour, incident investigations, Freedom to Speak Up and other initiatives noted in organisations with functional administrative systems. In addition, participants described the importance of maximising alignment between ascendant values around openness with other organisational norms, expectations and policies. This could help to make clear that the need for openness was not a fad, or an exogenous mandate followed reluctantly, and rather that it was fundamental to improvement. Participants in the senior-stakeholder interviews described how asserting the evidence base for the association between various forms of openness and patient safety[85,137,138,172–174] could help to persuade sceptical colleagues of the value of this kind of activity.

Moreover, participants in some organisational case studies described the importance of efforts to translate openness into something that was operationally useful to colleagues at the sharp end of care on a day-to-day basis. Their work here reflected initiatives that seek to positively influence communication such as 'Civility saves lives'[175] and the World Health Organization's surgical safety checklist,[176] and interventions to turn potentially abstract concepts into practically useful tools, such as values-based recruitment.[177] Interventions such as behavioural standards frameworks could be useful here, though active work was required to ensure that they were more than rarely visited webpages or documents to gather dust. This involved making them resources that colleagues felt empowered to use in routine interactions, seeking to normalise high-quality communication and respectful dialogue, regardless of professional affiliation or hierarchical position. Participants saw this as valuable because, although Freedom to Speak Up, the Duty of Candour and other policy initiatives were seen as important, they could also be seen as pertaining only to rare events and moments of high stakes. Accompanying efforts were required to normalise openness as part of everyday conduct, rather than a value to be mobilised only occasionally, and in exceptional circumstances.

8.2.4. Continuous learning and improvement

Finally, implicit throughout these sets of features was effort to ensure that approaches to fostering openness were themselves subject to an ethic of reflection, learning and improvement.[178] High-quality systems of the kind described in Chapter 6 and section 8.2.1 did not arise by accident, and were not perfected at the first time of asking. Rather they were the product of failure, learning, persistence and improvement. Indeed, participants in Cases A, D and E noted that it was discontentment with poor-quality systems or even the shame of an earlier failure that had provided the initial impetus for their sustained work to try to cultivate openness and develop their infrastructure. Participants described protracted and dogged efforts to improve systems and processes, sometimes using formal improvement approaches, and sometimes more ad hoc.

This took place at various levels. At the level of individual processes, for example, participants in Case D described how they had worked to learn from disclosures that went badly to tweak the approach in future. In Case B, effort had gone into reducing the secrecy that surrounded incident investigations, which itself had been seen to deter openness. At the level of wider systems, Case E had done much work to hone its approach to rapidly collating and disseminating learning from incidents and near misses. And at the level of integrating those systems and processes into the wider organisational infrastructure, Case A had committed extensive senior time and energy in seeking to optimise its use of various forms of intelligence to anticipate and pre-empt quality and safety issues.

As noted in Chapter 7, underlying all of these efforts was an approach to implementation that was open-ended and extended beyond individual policies. Treating the policies as discrete, time-limited implementation tasks[179] meant that their potential complementary impact as part of wider efforts to foster openness would be lost. Maintaining a journey towards openness meant moving beyond a mindset of "projectness,"[139] and embracing instead the National Advisory Group's appeal to the NHS to "continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning."[9]

An important finding across these four sets of features was that much of the work was targeted not at culture itself, but at more tangible systems, processes and routines. We noted in Chapter 1 that culture is a contested and nebulous concept. Even if agreement is reached on what it includes, the implications for changing it may remain unclear.[38,41–43] The focus of work in case-study organisations that appeared to exhibit more mature cultures around openness had been on providing high-quality systems, infrastructure and support for the work of clinical and non-clinical staff across the blunt and sharp ends. Through time, improvements in openness, whether subjectively judged or measured through various proxies, had ensued. While interventions of this kind may not on their own be sufficient to secure cultural change, they do appear to be a necessary condition.[49]

8.3. The prospects for long-term, sustained change

It is taken as given that culture change is an onerous and slow process.[38,41] It is therefore very early days in the aftermath of Mid Staffordshire for any change to manifest. The account we present in this report should be understood accordingly; data collection took place in 2017-2019, and some of the experiences described by participants in Chapters 3, 6 and 7 occurred earlier. The organisational case studies whose cultures around openness seemed most mature or advanced had both set this as a priority before mandates for policy implementation were introduced. While it may be an obvious point, it bears restating that their greatest advantage over the other case studies in the sample was the amount of time they had already devoted to the kind of work described in section 8.2 above. For Case A, this had been an ongoing priority of a relatively settled board. For Case E, a comprehensive change of organisational leadership following major lapses in quality and safety of care placed openness at the top of the organisation's agenda, where it remained at the time of our fieldwork.

However, our findings also indicate how difficult it can be to retain an unswerving focus on candour, openness and learning over time. The literature on implementation offers many examples of improvements that have been introduced with some success, before faltering or fading through time,[159,180–182] as new initiatives take their place or longstanding pressures push back. Quite apart from the pressures on resources and workload exerted by continuing increases in demand and shortages in clinical staff,[183,184] there was a sense from some senior-stakeholder interviewees that calls for openness did not always resonate at the sharp end. The events of Stafford could seem far away and (increasingly) long ago: asserting their relevance to staff feeling the pressures of day-to-day operational needs was challenging. While local stimuli to change, of the kind seen in some of the case-study organisations, could be powerful, the impact of these two could decline with time. While there was some optimism among participants that continued efforts to renew the focus on openness and to 'mainstream' it in their organisations would sustain the agenda, there were challenges. We note three in particular, presented below and summarised in Table 10.

8.3.1. The reliance on good will and discretionary effort

By and large, provider organisations had been expected to implement the policies without supplementary or ring-fenced resource from central government. Accordingly, as our stakeholder interviews, survey of executive-level leaders and case studies showed, organisations varied in the resource they invested into openness initiatives, given the opportunity costs that applied. Investing in openness of necessity mean taking resources from elsewhere, and decisions about investments by their nature involve complex and sometimes painful trade-offs. Even in case-study organisations with apparently more mature cultures around openness, however, there was a substantial reliance on input from staff over and above their core responsibilities, posing threats to sustainability.

For example, the programme introduced to much acclaim in Site D, to improve communication and relationships with patients and families during the course of investigations, relied on the voluntary contribution of staff members, who would add these duties to their own work without any protected time. Staff themselves saw the importance of the initiative, and interviewees attested to how rewarding this work could be. Work, however, was exactly what it was: work that relied on discretionary effort, and was unrewarded by the displacement of other activities or extra payment. Other initiatives elsewhere similarly relied on staff who recognised them as worthwhile, and were therefore prepared to take on their duties. In some cases (including two case-study organisations and a substantial number of NHS organisations nationally, if our survey [Chapter 4] and similar exercises[81] are to be believed), even the Freedom to Speak Up Guardian role operated in this way. Though not directly evidenced in our study, it would be unsurprising if more challenged organisations were those least well placed to improve on openness – potentially exacerbating inequalities between

Theme	Key points	Section
The reliance on good will and discretionary effort	• In the absence of extra resourcing, organisations varied in how they supported openness initiatives, but most relied at least in part on voluntary efforts from staff • In some organisations this extended to complex, challenging roles such as Freedom to Speak Up Guardians • Many participants noted increasing demands on staff and less attention to staff wellbeing • Staff's good will is a resource that risks being depleted, particularly if the burdens of initiatives are seen to outweigh their benefits	8.3.1
The limits to organisational development	• Implementation of openness initiatives was generally premised on the idea that staff are willing and able to develop their roles, behaviour and contribution, with support from the organisation • Often there exist pockets of more recalcitrant staff—such as fiefdoms ruled through fear by powerful individuals—where such an approach is likely to flounder • Supportive approaches based on principles of organisational development need to be backed up with more discipline-based approaches where poor behaviour persists through time	8.3.2
Patients, families and openness	• Despite the notable role of patients and families in exposing problems in Stafford and elsewhere, few of the policies address their potentially active role in encouraging openness • The avenues open to patients and families to raise concerns are little changed from the systems in place prior to the Mid Staffordshire public inquiry • Some organisations have sought to develop opportunities for proactive contributions from patients and carers locally; these might inform wider changes	8.3.3

Table 10: Key issues in implementing and sustaining openness policies

organisations and populations.

Of course, reliance on the discretionary effort of NHS staff, clinical and non-clinical, is not unique to these initiatives. The results of the most recent NHS Staff Survey suggest that three out of five staff work unpaid overtime every week,[185] and vocational commitment is central to the ethic of medicine, nursing and other professions.[186] Much of the labour involved in committing to openness initiatives, however, presents particular emotional demands. On an individual level, the work of disclosure, expressing concerns, speaking up about wrongdoing and seeking to learn from mistakes can be arduous.[83,84,86,126,187] Though it cannot compare to the experience of patients and immediate family members, the harm that can accrue to clinicians involved in incidences of harm—sometimes controversially called the 'second victim' phenomenon[126,188]—should not be underestimated. Francis's *Freedom to Speak Up* review and other studies document the issues that can face staff who express concerns before, during and long after episodes of voice.[11,84–86,136,189] Whether they are directly implicated in such events or more indirectly involved in facilitating voice or disclosure, there is no doubt that such processes can be taxing.

Moreover, at a collective level, a long catalogue of calls on the discretionary labour of staff will ultimately take its toll. Participants in the senior-stakeholder interviews presented in Chapter 3 indicated that good will and a sense of reciprocity fuelled this labour market. They also suggested that some organisations were better at demonstrating the benefits that could accrue from engaging in openness initiatives to their staff. In others, the impression could be that work to identify and learn from issues resulted in nothing but burden at the sharp end, in the name of unspecified benefits for senior managers, regulators, politicians or other distant stakeholders. The interviews also suggested that trust in the NHS as an employer was fragile in some organisations and among some employees.

Memories of injuries endured by people who spoke up in the past were hard to displace, and bitter experiences such as the lengthy dispute over pay and conditions for junior doctors could leave staff cynical, and less inclined to give of themselves to initiatives of dubious benefit to them. Where talk of a no-blame culture or a just culture was not matched by experiences of organisations' approaches to incident investigations (Chapter 6), the sense that openness could equate to detriment was compounded.

In short, then, the stock of good will that underpinned the implementation of these initiatives in many organisations was not inexhaustible, and in some organisations it appeared to have been depleted substantially. Senior-level stakeholders within and beyond the case-study organisations acknowledged the relationship between staff wellbeing, organisational wellbeing and quality and safety,[147,148] and in some cases noted pointedly that the NHS was at risk of neglecting its staff as it embraced openness. Given this, efforts to demonstrate the benefits that openness can offer at the sharp end as well as the blunt end are perhaps not enough. Support for staff as they undertake the challenging and sometimes emotionally fraught business of openness, is also important.[190] Research elsewhere suggests a number of promising interventions that might help to provide such support, for example Schwartz Center Rounds,[191,192] originally developed at Massachusetts General Hospital and recently evaluated in the NHS,[193] which seek to offer staff a rare space for exploring and understanding the emotional dimensions of their work.

8.3.2. The limits to organisational development

The approach to policy implementation described by many participants across the stakeholder interviews and the organisational case studies might be characterised as aligning with the principles and ethos of organisational development (OD). That is to say, they viewed the policies as a potential means of enhancing organisational effectiveness by acting on the behaviour of staff members, in a way that would also contribute to their own development as individuals.[194] Rather than forcing change upon recalcitrant members of staff, the idea is that staff themselves recognise, understand and embrace the need for change,[195] rendering organisational-level improvement more thoroughgoing and robust.

As section 8.3.1 notes, even where extensive efforts had been made in this vein to bring staff along with the organisational agenda and emphasise the breadth of benefits that would accrue, there was a sense that change was fragile. Where implementation had been driven by compliance and staff seemed less engaged, progress towards culture change seemed even more tenuous. But more than this, even in organisations that had invested heavily in roles and processes and claimed a progressive, enlightened orientation towards openness, there remained areas of the organisation that seemed impervious to the influence of the policies. These included individual clinicians with views who were characterised as outmoded or old-fashioned. More problematically, they also included groups who could wield an insidious influence on those around them.

These groups are exemplified most vividly in the fiefdoms we describe in Chapter 7. In these fiefdoms, dominant individuals created a climate of fear, bolstered by their seniority, their longevity in the organisation, or their advantageous social networks. While they might not have a direct impact on quality and safety, these individuals could provoke anxiety and doubt among colleagues, creating the conditions that were far from conducive to high-quality care. Often they evaded detection because their very existence could have a chilling effect on voice. Indirect indicators, such as high staff turnover rates or lack of engagement with organisational initiatives, offered weak signals that might alert attentive managers to their existence. The introduction of Freedom to Speak Up Guardians offered organisations another route to detecting such fiefdoms. However, participants suggested that detection was often as far as they could get. Appealing to staff affected by fiefdoms about the potential benefits of openness was futile in areas where the risks were so obviously apparent.

The existence of fiefdoms across the six case-study organisations points towards the limits of an OD-based approach. While it may be very effective in driving changes in culture that are more than superficial in large swathes of organisational units, participants' experiences suggest that it will fall flat in others. In these areas, a different approach is required, and this may require even more organisational investment and commitment. Tools such as behavioural standards frameworks (Chapter 7) and professional accountability programmes may offer a useful starting point, providing unambiguous criteria by which deficits in behaviour might be identified and required improvements specified.[196] While evaluations are rather scarce,[197] there are some examples of successful use of professional accountability programmes in the United States and Australia.[196] Where shortfalls do not improve, experience elsewhere suggests that organisations may ultimately need to resort to much more Draconian, authoritarian measures, backed by strong and effective personnel management processes.[101] Seeing such measures through will be vital and time-consuming, particularly where poor behaviours have been ignored, tolerated or even encouraged in the past.

8.3.3. Patients, families and openness

Finally, it is notable that that the bulk of the focus of post-Francis policy interventions has been on organisations (commissioners, providers and regulators) and staff. Patients and families, though acknowledged as central to concern about openness and presented as its ultimate beneficiaries, are mainly bit-part players in enacting the policies. They are the recipients of disclosures under the Duty of Candour and should be "involved and supported" in the course of incident investigations,[29] but as far as making openness happen is concerned, staff are centre-stage.

This absence is perhaps surprising, given the critical role of patients as well as staff in uncovering—and demanding action about—the problems at Stafford. The public inquiry was effusive in its praise of grass-roots campaigners, including the work of 'Cure the NHS', the group of patients and relatives led by Julie Bailey, whose mother died at Stafford.[5] Other family members have played similarly instrumental roles in pushing for action following tragic shortcomings of care elsewhere, such as James Titcombe in relation to maternity care at the University Hospitals of Morecambe Bay NHS Foundation Trust,[15] and Sara Ryan in relation to care for people with learning disabilities in Southern Health NHS Foundation Trust and beyond.[198] In contrast, Francis was rather damning of the role of the official mechanisms for patient and public involvement and scrutiny, Patient and Public Involvement Forums (until 2008) Local Involvement Networks (LINks) (after 2008), at Stafford. They were preoccupied with administrative matters and deferential towards the trust, such that "the public of Stafford were left with no effective voice—other than CURE—throughout the worst crisis any district general hospital in the NHS can ever have known."[5]

Since then, LINks have been dissolved and replaced by local Healthwatch organisations. This move, sanctioned by the Health and Social Care Act 2012,[113] was driven by the need to keep mechanisms for public involvement in line with wider changes in the organisation of the NHS rather than by their underperformance in Staffordshire. Although some Healthwatch organisations have been active in inspecting healthcare organisations and publishing reports on quality and patient experience, it is not clear that their powers leave them better equipped than LINks to hold NHS organisations to account.[199,200] Rather, it is striking that the principal mechanisms through patients and family members can raise concerns about quality and safety remain the same as they were in the 2000s: complaints mechanisms; Patient Advice and Liaison Services; discussions with the clinicians involved in their care. There has, for example, been no equivalent programme to Freedom to Speak Up oriented towards patients and families.

There was strong support in responses to our survey (Chapter 4) for the proposition that 'encouraging openness with patients and carers when things go wrong is a strategy that promotes learning and improvement within a healthcare organisation'. Participants in our case-study research noted that in some cases, their organisations had taken the initiative themselves, and sought to open their openness opportunities to patients and families. In one case-study organisation in WP4, a participant noted that the Freedom to Speak Up Guardian had received more approaches from patients than from staff members. But this left patients and family members who did have concerns somewhat beholden to organisations that might or might not offer them opportunities to speak up, and to staff members who might or might not be willing to listen. Given the importance of patients and relatives in challenging opacity in Stafford and elsewhere, there is a risk that some organisations are missing an important source of information by failing to develop openness initiatives along these lines. The experiences recounted in Chapter 6, including encounters with seemingly impenetrable and indifferent organisational units, suggest that patients and families might have a distinctive and valuable perspective on issues of quality, safety and risk. Our findings also suggested that they may sometimes conceptualise harm quite differently from staff. They may be more sensitive to problems and harms that are less apparent to healthcare staff.[201] In this light, a failure to mandate clear routes and organisational responsibilities for patients and family members wishing to raise concerns may increase the risk of problems of quality and safety going undetected for longer.

9. Conclusions and implications

In this final chapter, we return to the research questions set out at the start of the study (see Chapter 1). We summarise our findings under each question; more detailed consideration of the questions is provided in the relevant chapters, and in the overall discussion in Chapter 8. We note the strengths and limitations of the study. Finally, we highlight some of the implications of our study, including areas for consideration for policymakers and practitioners, and possible avenues for future research.

9.1. The research questions revisited

9.1.1. How do senior managers and clinicians in organisations providing NHS services understand policies relating to openness and translate them into specific norms, expectations and practices in their organisations?

We sought to address this question through WP1, WP2 and WP4 (Chapters 3, 4, 6 and 7). Senior-stakeholder interviews (Chapter 3) offered insight into the approaches taken to policy implementation across a range of provider organisations, and some assessment of the reception and response to the policy changes at the blunt and sharp ends of the NHS. The survey of executive-level leaders (Chapter 4) offered insight into the degree of traction and influence of a range of policies in NHS organisations, the approach taken to implementing policies, and the challenges of implementation they presented. Our organisational case studies (Chapters 6 and 7) allowed us to investigate efforts to translate three policies into practice in NHS organisations that varied in terms of their size, function, and prior trajectories.

Our findings suggested that organisations deployed a variety of approaches to putting the policies into practice. Participants in senior-stakeholder interviews were largely welcoming of the focus on openness. In many cases, they reported that they had already begun to make changes within their organisations in the spirit of the post-Francis policies before they became compulsory, with a view to ensuring openness across their organisations, learning from mistakes, and intervening early where problems were apparent. These senior stakeholders understood the intention of the policies as relating not just to their declared, immediate objectives, but also to a wider ambition to shift the culture of the NHS in the way envisaged by Francis. They highlighted the need for care in implementation if the impact of policies was to contribute to a change in culture around openness.

Despite the evident agreement on the goals of policies, both the survey and the interviews with participants outside the NHS highlighted variation in the implementation approaches taken between and sometimes within organisations. The role of the Freedom to Speak Up Guardian, for example, appeared to take very different forms in different organisations, while stakeholders inside and outside the NHS could attest to the differences between units within organisations in the approach taken to disclosures under the Duty of Candour. In some cases, it was hard for organisations to progress implementation, for example because of resourcing difficulties or with the variable structure and geography of organisations. Interviewees in community and mental health services organisations, for instance, found it difficult to apply some of the policies in settings that involved more diffuse units, more complex patient pathways, and different kinds of problems.

Participants suggested that ‘successful’ implementation—by which they meant something that had a chance of achieving more than paper compliance, and which might have a sustainable impact on culture and behaviour around openness—relied on skilful policy translation. This meant active work to align policy imperatives with local pressures and norms, and went far beyond simply replicating national policy expectations at a local level.[202] They highlighted in particular the need to demonstrate that openness was more than another top-down mandate that would present extra demands on staff who were already feeling pressure. They sought to show that openness could have benefits for organisations and for staff at the sharp end. Work to share the burdens and the benefits of openness was crucial here, but participants identified that the regulatory, monitoring and surveillance regime around the policies did not always support them in this regard.

Many saw the bureaucratic overhead as excessive; in some cases it was even seen as undermining the underlying objective of the policies. Compliance with timescales and reporting requirements for the Duty of Candour and for incident investigations could, it was felt, sometimes frustrate the interests or preferences of patients and families. Similarly, expectations around reporting of the activity of Freedom to Speak Up Guardians might fail to capture, or even misrepresent, the quality and focus of their work. In this vein, participants in senior stakeholder interviews welcomed the changes to the CQC's approach to inspection, monitoring and improvement. While acknowledging the potential downsides of risk-stratified regulation, they felt that the more dialogical relationship with the CQC they were experiencing offered better support for their improvement efforts. It should also be noted that changes to the framework for serious incident investigation made since data collection for this study also appear to address some of the concerns of participants,[74] though the consequences of these changes in practice remain unevaluated.

9.1.2. Are staff and patients' views on openness, knowledge of performance, and experiences of giving voice to concerns changing through time, for better or worse?

We sought to address this question through WP3 (Chapter 5), which involved secondary analysis of data collected longitudinally over several years through staff and patient surveys, with a view to identifying impact on indicators of openness over the four years following the publication of the Mid Staffordshire public inquiry.

Our analysis of National Staff Survey data suggested a broadly positive trajectory over time in relation to several indicators of various aspects of openness, selected *ex ante*. In several cases there was a positive increase in the rate of change in the period after the publication of the public inquiry (compared to the period of up to seven years before). This perhaps reflects our finding, in relation to the first research question, that many organisations had not waited for policy mandates to begin making changes to encourage openness as the nature of the problems at Stafford emerged.

Analysis of data from the Acute Inpatient Survey painted a similar picture. Broadly, inpatients' experiences of openness appeared to be on the increase, with an acceleration in improvements on several indicators in the period after Francis also apparent, or, in the case of the question about finding someone on the hospital staff to talk to, the reversal of a negative trend.

A rather different picture emerged for the indicators of openness we covered for the Community Mental Health Service User Survey, however. Some indicators levelled off from 2013, following a period of increase; others went into decline. Over the 2013-2017 period, community mental health services users said they felt less listened to, believed they were not given enough time to discuss their care, and felt treated with less respect and dignity.

As the importance of the quality of NHS mental healthcare is increasingly recognised through work to secure 'parity of esteem' across physical and mental health,[112] the divergent trajectories of users of acute inpatient and community mental health services are conspicuous. Taken together with our findings about the challenges of realising many of the post-Francis policies in non-acute settings, these results suggest perhaps that care is needed to the design or application of interventions to improve openness in mental health settings. Nevertheless, the improvements in openness from the perspective of acute inpatients and NHS staff, some of which show a significant acceleration since the publication of the Francis report, should not go unrecognised.

9.1.3. Are provider organisations' efforts to increase openness resulting in real changes in staff values, attitudes and actions at the sharp end of care and in

patients' opportunities and experiences around openness—and what features contribute to success?

We sought to address this research question through WP4 (Chapters 6 and 7), which used comparative organisational case studies to examine how three 'tracer' policies had been implemented in a range of settings, with a particular emphasis on the views and experiences of staff at the sharp end, patients and families. Although we relied on interview-based retrospective accounts of the enactment of various forms of openness, our intention here was to go beyond the necessarily partial views of individuals at the blunt end of care, with a view to understanding the extent to which the policies were being practised as intended.

We took the Duty of Candour, the investigation of serious incidents, and the Freedom to Speak Up programme as our tracer issues. They were chosen because earlier work suggested that they were the most impactful in NHS organisations, and because they exemplified some of the tensions between an approach oriented towards compliance alone and an approach oriented towards culture identified in WP1. We were interested not only in the declared, immediate objectives of the policies, but also in assessing their potential longer-term and aggregate impact in relation to openness. The six organisations we sampled varied in their function, their size, and the quality of care they provided as assessed by external authorities. They were also variable in what we termed the maturity of their culture around openness, influenced by their recent organisational history and the degree to which openness had already been a priority for organisational attention and investment.

We found notable variation in the approaches taken in case-study organisations to implementing the policies, which seemed consequential for the way they were experienced at the sharp end by staff, patients and families. All three tracer issues represented complex implementation tasks, involving multiple actors, actions and decision points, and requiring careful oversight and coordination. Consequently, implementation of these initiatives benefitted from sophisticated administrative infrastructures to ensure that things were done, but these infrastructures were much better developed in some organisations than others. In those where they were lacking, the interventions were reliant on the capacities of key individuals, such as those making disclosures or Freedom to Speak Up Guardians, to ensure coordination and timely completion of tasks. Where administrative capacity fell short, those affected by disclosures or wishing to speak up were left adrift during stressful and emotionally fraught episodes.

Administrative competence alone was not enough, however. In all six, there were parts of the organisation that openness initiatives struggled to reach, sometimes dominated by fiefdoms that could breed cultures of silence and opacity, and could thwart efforts to effect change. In such areas, the viability of an approach to openness based on the principles of organisational development seemed doubtful, and arguably a rather different approach to securing openness—and preventing harm—appeared necessary. We also found examples of 'coldly efficient' systems, which were formally compliant with legal or regulatory expectations around process and timescale, but left those affected with the sense that the whole process was about feeding a bureaucracy. This is not necessarily to say that it was seen as a paper exercise in compliance: it could well also address organisational priorities around learning and improvement. But for those most directly affected by incidences of actual harm or fears about risk of harm, the sense was of being a means to an end. This could drive increasingly antagonistic and oppositional relationships, where there had previously been a sense of common purpose.

Our findings also highlight the importance of integrating policies and objectives around openness into the mainstream organisational mission, including the extent to which it is framed as something relevant on a day-to-day basis, rather than something reserved for exceptional, high-stakes occasions such as disclosure following harm or 'blowing the whistle'. Participants described various approaches to normalising openness in this way. But in some organisations, the appearance (and perhaps the reality) was that these initiatives were marginal, and divorced from the day-to-day business of providing care. Incident investigation processes that failed to contribute to organisational learning, or

Freedom to Speak Up programmes that did not resource Guardians sufficiently to do their job well, spoke volumes about the priority ascribed to openness in these organisations.

The likely long-term success of efforts to make openness part of ‘business as usual’ is difficult to assess with confidence. If culture change is the ambition, then the policies have as yet only had a very limited window for impact. But it was also clear from participants’ accounts that it may be hard even to maintain the gains made: as the resonance of Stafford diminishes, the challenges of sustaining the primacy of openness in pressured NHS contexts may increase. Efforts to renew were important, as was asserting the local relevance of openness, for instance by using examples from within organisations that shook any complacent sense that openness had been accomplished.

9.2. Strengths and limitations

Our study has several strengths. They include the mixed-methods approach, which incorporated complementary workpackages to shed light on different policies, different approaches to implementation and their impact in different kinds of organisations, as well as a longitudinal examination of the evidence for change in experiences of openness over time. We sought throughout the study to ensure that the findings of each workpackage informed the others. We adopted robust and established approaches to study design, sampling, data collection and analysis. This included, for example, the identification *a priori* of relevant questions for analysis in WP3, the use of theoretically driven sampling approaches for WP1 and WP4, and an iterative approach to developing and piloting the survey instrument used in WP2. Our work was also enriched by the counsel of a professional advisory group and a PPI advisory group, whose expertise and experience helped to guide the direction of our study, and ensured we accounted for ongoing developments in policy and practice.

The limitations of individual workpackages are discussed in our results chapters (sections 3.6.1, 4.4.1, 5.4.1 and 7.6.1). Additionally, the study as a whole has some notable limitations.

First, it was observational: it did not involve the evaluation of individual interventions or their implementation, or the collection of data on health outcomes. Our findings in relation to the relative value of different approaches to openness should be understood accordingly, although our qualitative analysis did seek to identify plausible mechanisms by which different ways of realising openness policies gave rise to divergent consequences.

Second, by design, our study excluded primary care. Primary care accounts for the majority of healthcare contacts in the NHS, and is not immune from challenges of openness. The most recent GP Patient Survey found a year-on-year decline in satisfaction with general practice among patients.[203] While primary care was not initially the target of openness initiatives, more recently (in 2017), NHS England introduced parallel programmes in primary care (including general practice, dentistry and community pharmacy), for example Freedom to Speak Up and the requirement to appoint a Guardian.[204] Our study also considered the role of commissioning in openness only indirectly; our tentative findings here (sections 4.2 and 6.3) suggest that commissioners may have an important influence on the realisation of openness, for better or worse.

Third, and also by design, our study pertained to only to the English NHS. While some of the most widely publicised shortcomings in openness in recent years have occurred in England, and the Scottish system has been praised for its attention to quality, safety and learning,[205] there is no reason to believe that the issues identified are exclusive to England. Issues of openness have arisen in many healthcare systems around the world,[84,101,125,206] and the Scottish NHS has had its own well documented problems in recent years.[25] While the problems and interventions may well be transferable to other settings, we cannot comment directly on how the somewhat different prevailing organisational systems, funding structures and cultures in Scotland, Wales and Northern Ireland might affect their implementation.

Fourth, our study took place in an (English) NHS context that was not static. Our findings regarding the Serious Incident Framework, for example, may now be less relevant given the shifts in policy that have taken place since data collection. There are also broader shifts in the organisation of the NHS—most notably the move towards integrated care—that will be consequential for how openness is addressed in future. Exactly how such changes will influence openness is difficult to predict, although our findings around the ways that organisational mergers can disrupt efforts to foster openness, as well as on the challenges of operationalising openness across organisations governed by different social, professional and legal expectations, offer some indication of the challenges that might be faced.

9.3. Implications

While it is beyond the scope of this report to offer recommendations for policy or practice, we do identify issues raised by our research that would benefit from further attention from researchers, policymakers, regulators and senior NHS managers and clinicians.

9.3.1. Implications for research

- Given the variation in approaches to implementing policies around openness and their likely differential impact, we suggest further evaluative research on the policies and their implementation. (We note that NIHR-funded studies on, *inter alia*, the Freedom to Speak Up programme and open disclosure in maternity settings, have been commissioned.)
- This study did not cover primary care, but challenges around openness and learning likely also exist in this setting. We suggest that there may be value in a similar programme of research on initiatives that have been extended to primary care (such as Freedom to Speak Up), which might build on this study and compare findings across primary and secondary care. Research in Scottish, Welsh and Northern Irish contexts might also be of value, and help to shed light on the impact of similar and divergent policies in different system contexts.
- The existence of 'fiefdoms' across organisational case studies points towards the limitations of approaches to improving openness based on the principles of organisational development. Sometimes organisations will need to undertake alternative approaches to addressing problematic behaviours, deliberate or accidental, and these need to include recourse to disciplinary measures. The evidence base for such interventions, however, is limited.[197] Development and evaluation of approaches to managing disruptive or transgressive behaviour would be beneficial.[101]

9.3.2. Implications for policy

- Across WP1, WP3 and WP4, our findings suggest that many of the openness policies lend themselves more easily to implementation in some types of organisation than others. Most obviously, there was concern from several participants that they were not easily implemented in community and mental health services trusts, though participants in other organisations where services were distributed and patients were not typical of the 'episodic' pathways of emergency or elective acute patients expressed similar concerns. Given the concerning divergence between the experiences of acute inpatients and community mental health service users identified in WP3, we suggest that further consideration be given to openness policies and/or implementation or monitoring in these settings.
- While recognising the importance of monitoring and audit, particularly in organisations that are less well disposed to increasing openness, participants found the level and sometimes the direction of monitoring and reporting requirements relating to several initiatives burdensome, and even potentially incongruous with the goals of the initiatives. We suggest that attention be devoted to the focus and scale of reporting obligations in this field, and that consideration be given to alignment with other regulatory activities, such as the CQC's 'Well-led' domain. This might include a more risk-stratified approach to regulatory oversight, with organisations that demonstrate (to the CQC or other authorities) a lasting and sincere commitment to openness allowed more latitude in the approach they take to achieving it.

- Our findings show that organisations have varied in their approach to implementing the Freedom to Speak Up programme, as reflected in the direct support provided to Guardians through protected time, the ‘in kind’ support offered in assisting them in discharging their duties, and the scope of responsibilities allocated to the role. The role appears to have considerable potential in fostering openness beyond ‘case management’; however, further guidance, resourcing or direction may be required if organisations are to realise this potential.
- We found variability in organisations’ approaches to the investigation of serious incidents, including in relation to selection of incidents for investigation, the involvement of patients and families in the process, and the degree to which learning from investigations is valued and actioned. As the Serious Incident Framework is replaced by the Patient Safety Incident Response Framework, attention should be paid both to guidance and to fidelity in implementation.
- Determining harm for the purposes of the Duty of Candour and the identification of serious incidents poses some challenges to staff. While we found no evidence that harms are being ‘de-rated’ with a view to avoiding disclosure, there remain difficulties in identifying and attributing harm (particularly outside acute settings with clearly delimited episodes of care), some uncertainty over what constitutes moderate or severe harm, and challenges when the incidence, nature and severity of harm are not immediately apparent. Further clarification of such issues in relation to the discharge of the Duty of Candour under Regulation 20, and as the approach to implementing the Patient Safety Incident Response Framework is developed, would be valuable.
- Our findings indicate that the role of commissioners in relation to the Duty of Candour and the investigation of serious incidents can be variable, with some more oriented towards compliance and others keen to offer impetus to and support for learning. Guidance on the role that commissioners can play in supporting an effective and compassionate approach to implementation of these policies may be valuable.
- The policies introduced since the publication of the Mid Staffordshire public inquiry offer more support for openness and new means of raising concerns for staff, but initiatives that focus on patients and families are fewer. Given the importance of patients and family members in exposing and demanding attention to failures in quality of care in the past, consideration might be given to how best to ensure that patients and family members are able to voice concerns promptly. Any intervention would need to address power differentials between patients and NHS staff, and allow patients and family members alternative routes to voice if their concerns are not initially heeded. Initiatives already introduced in some NHS organisations might offer a model for such efforts.

9.3.3. Implications for practitioners

- The most promising approaches to improving openness rest on making the problem locally relevant and demonstrating that the solution will have local benefits.[50] This requires active and ongoing work to promote and maintain the importance of policies around openness, and to seek to make visible the benefits of openness and the sharp end of care.
- Developing high-quality systems for the administration of openness initiatives, and to integrate sources of intelligence across an organisation, is important to compliant and timely delivery of policy requirements, is a prerequisite for sensitive and compassionate approaches to openness, and is crucial to integrating and learning from insights about quality, safety and risk from diverse sources across an organisation.
- Approaches to implementing Freedom to Speak Up Guardians vary across organisations. Our findings indicate the importance of providing Guardians with the time and resources to embrace the breadth of their role, rather than simply being a ‘case manager’ for people who approach them with concerns. Without such investment, Guardians may appear distant, and are unlikely to be able to act as ambassadors for openness or to be able to gather intelligence about behaviour, culture and risk across the organisation.
- For some organisations, especially but not exclusively mental health, community health services and ambulance service organisations, particular challenges were posed by variable organisational subcultures, born in part of differing functions, histories, and approaches to management. Geographical distance can further complicate the challenge of managing heterogeneous contexts.

This may require different approaches to seeking to address culture and behaviour, and means that efforts to gather soft and hard intelligence about behaviour, quality and risk across the organisation (for example through Freedom to Speak Up Guardians) can be valuable.

- While our research suggests that approaches to improving openness premised on the ideals of organisational development can be successful, there are also likely to be limits to the effectiveness of such approaches. Efforts to align individual and organisational interests and motivations need to be underwritten by high-quality organisational policy and human resource management, including a commitment to address persistent poor behaviour directly and justly when necessary.
- In the course of our research we encountered outstanding examples of innovation which, while not formally evaluated through our study, appear to offer very promising approaches to fostering a culture of openness. Appendix D provides examples; we hope to make a fully formatted, publicly oriented version of this document available separately in due course.
- The success of these interventions, however, rests on organisational investment in openness, including adequate resourcing, integration of insights through high-quality systems, alignment with organisational mission to make openness relevant to the everyday practice of staff, and—above all—sustained and unerring tenacity in learning from failure and success alike.

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Appendices

A. Topic guide used for senior stakeholder interviews (WP1)

Interviews with senior managers and clinicians in organisations providing NHS services to explore how they understand policies relating to openness and how they have been translated into specific norms, expectations and practices in their organisations.

Questions will be used selectively, depending on participant and time available; further follow-up questions not specified on the topic guide may be asked as discussion develops, as appropriate. Participants will also include those in policy and regulatory roles; the same questions will be asked of these participants, though they will be rephrased appropriately (e.g. references to healthcare organisations in general rather than ‘your organisation’)

Welcome and introduction

Seek additional verbal consent to continue and to audio-record the interview. (Interviewer to note sex of participant.)

Re-cap of project and plan for interview

The interview will explore how organisations in and around the NHS are responding to policies designed to encourage openness, candour and learning.

The aim is to understand how your organisation is responding to this impetus, what is changing and the challenges and opportunities. We are interested in your perceptions, on the basis of your knowledge and experience and your position within the organisation. If you do not feel you are able to comment on any area please say so. Your identity and that of your organisation will be anonymised in any outputs from the study.

Participants

Do you have any questions before we start?

What is your present job title?

How long have you been in post/ in the organisation?

Culture in organisations

On a scale of 1-10, where 1 is bad and 10 is good, how would you rate the culture of your organisation overall in relation to openness?

- Why do you give that answer?

To what extent would you say that the behaviour of staff in your organisation reflect the values and expectations you try to set as an organisation around openness?

- How can you tell which units within your organisation have a positive culture in relation to openness?
- Conversely, what are the warning signs for units where things might not be so positive?
- What mechanisms are available in your organisation for people to raise concerns about things like quality of care, safety, professional behaviour?
- To what extent are they well utilised by staff at the ‘sharp end’?
- How is the information produced used by the organisation for learning and improvement?
- How are quality accounts constructed?

Policy changes

What if any changes would you say there have been in your organisation since the Francis inquiry, the Berwick report, and government responses? (If they have been in the organisation for long enough)

- What has helped/ hindered with this work (probe for different endogenous and exogenous factors: e.g. hierarchical compliance; threat of sanction against individual (disciplinary) or organisation (legal/regulatory); change in attitudes and understanding about openness and learning; concerns about public reputation; etc.)

There have been a number of specific initiatives that been introduced in the last few years or are planned around openness, candour and transparency. Could you tell me what impact, if any, they have had (for those introduced) or you feel they might have (for those planned), in your organisation?

- The Duty of Candour (at the level of the organisation)
    - What kinds of changes has this given rise to in your organisation?
    - How does it interact with the professional duty of candour already placed on individuals?
- Freedom to Speak Up Guardians
- Patient Safety Collaboratives, the Q Fellows network (formerly ‘safety fellows’), Sign Up to Safety
- The Friends and Family Test
- MyNHS and other publicly available provider comparison tools, and requirement to clearly publish CQC ratings
- Quality Accounts, particularly proposed changes to content to mandate providers to show how investigation and learning have informed improvement
- The Healthcare Safety Investigation Branch (formerly the Independent Patient Safety Investigation Service)
- Changes in the CQC’s approach to regulation and inspection

To what extent would you say these policies provide a co-ordinated steer to your organisation? Are there any tensions between them? (Prompt on tools around publication of data, legalistic approaches, approaches aimed at fostering culture change)

To what extent do you feel they are prioritised in your organisation given all the other current pressures on the NHS? To what extent are they prioritised in the wider system? Prompt:

- How much of a priority are they for commissioners?
- How much of a priority are they in regional transformation plans, e.g. STPs?

Change and resistance

What mechanisms are available in your organisation for people to raise concerns about things like quality of care, safety, professional behaviour?

- How were these designed/put in place
- Who was involved in the design?
- Who manages the information
- How does it feed into practice (evidence of organisational learning)
- To what extent are reporting systems well utilised?

What has helped/ hindered with this work (probe for endogenous factors- hierarchy/disciplinary/social and exogenous factors- PR/litigation worries)

Are there differences in the ways different groups of staff approach the question of candour and openness – e.g. nurses/doctors; surgeons/physicians; professional/support staff etc.?

- If so, what sorts of differences are there?
- Why do you think they have arisen and what could be done to moderate them?

How does your organisation seek to show staff, patients and carers that it takes seriously their views and concerns?

- To what extent is this successful in encouraging openness?
- Can you give me some examples of good practice from your organisation?

Have you involved patients, carers or the wider public in any of these activities? At what stage?

- If yes - how did you go about involving patients? How did it work in practice?
- Did you face any particular problems in involving patients?

What aspects of your organisational context make it easier or harder to make changes?

Closing

Are there any other aspects of your experiences to date that you would like to discuss?

Thank you for your time.

Later on in the study, we will be sampling a number of case study organisations, where we will be undertaking more detailed, focused work on the same theme [explain WS2]. Might your organisation be interested in participating in this?

B. Instrument used for national survey of board-level executives (WP2)

1. What kind of organisation are you employed by?

NHS acute hospital trust ☐
NHS community and/or mental health trust ☐
NHS ambulance trust ☐
Private / for profit provider ☐
Voluntary / social enterprise / not-for-profit provider ☐
Other (please specify) ☐

2. What is the size of your organisation in terms of total number of staff (full time equivalents)?

Fewer than 1500 staff ☐
1500-2999 staff ☐
3000-4999 staff ☐
5000-9999 staff ☐
10,000 or more staff ☐
Don’t know ☐

3. Which of the following best describes your role within the organisation?

Chief executive ☐
Medical director ☐
Director of nursing ☐
Director of quality, safety, risk or similar ☐
Other ☐

4. How long have you occupied this role?

Less than 1 year ☐
Between 1 and 3 years ☐
Between 3 and 5 years ☐
More than 5 years ☐

5. To what extent would you say the following policy measures have made an impact on the day-to-day work of frontline staff in your organisation?

	No impact	Little impact	Moderate impact	Strong impact	Very significant impact	Don’t know
Statutory Duty of Candour *The requirement that healthcare providers inform, support and apologise to patients or families if moderate or serious harm occurs in the course of care*	☐	☐	☐	☐	☐	☐
The revised NHS Serious Incident Framework *Updated guidance for NHS organisations on investigating serious incidents, requiring initial review within 72 hours and completion of investigations within 60 days*	☐	☐	☐	☐	☐	☐
Introduction of the Sign Up to Safety initiative *A campaign seeking to encourage individuals and organisations to make pledges around patient safety and support them in achieving these*	☐	☐	☐	☐	☐	☐
Introduction of Patient Safety Collaboratives *Regional bodies coordinating a range of nationally and locally driven patient safety initiatives across NHS organisations*	☐	☐	☐	☐	☐	☐
The Q Fellows initiative *A national initiative funded by NHS England and the Health Foundation to connect and support several thousand individuals with an interest in improving quality and safety*	☐	☐	☐	☐	☐	☐
Appointment of Freedom to Speak Up Guardians *Individuals in organisations who offer guidance and support for colleagues who have concerns about the quality and safety of care*	☐	☐	☐	☐	☐	☐
Fit and Proper Persons requirement for directors *The requirement that NHS bodies have robust processes to check that directors are suitable for senior management roles and have access to ongoing training and development*	☐	☐	☐	☐	☐	☐

6. To what extent do you agree with the following statements?

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Don't know
THE IMPACT OF RECENT POLICIES						
Taken together, the policy measures mentioned above have begun to increase the openness of staff in my organisation about concerns about patient safety	☐	☐	☐	☐	☐	☐
Taken together, the policy measures mentioned above increase the likelihood of litigation (e.g. negligence claims) against my organisation	☐	☐	☐	☐	☐	☐
The statutory Duty of Candour has helped to improve patient-staff communication following incidents	☐	☐	☐	☐	☐	☐
The introduction of Freedom to Speak Up Guardians has started to encourage employees in my organisation to voice concerns about colleagues of any grade or profession	☐	☐	☐	☐	☐	☐
ATTITUDES AND BEHAVIOURS OF STAFF IN YOUR ORGANISATION						
Employees in my organisation are reluctant to speak up about concerns about patient safety because they worry about potential negative consequences for themselves	☐	☐	☐	☐	☐	☐
Employees in my organisation are more likely to voice concerns about colleagues in their own professional group than in others	☐	☐	☐	☐	☐	☐
Employees in my organisation are more likely to voice concerns about colleagues who are junior to them than about colleagues who are senior to them	☐	☐	☐	☐	☐	☐
STRUCTURES FOR ACHIEVING OPENNESS IN YOUR ORGANISATION						
It is feasible for my organisation to undertake internal investigations into all serious incidents that are identified within 60 days	☐	☐	☐	☐	☐	☐
Learning from internal investigations into serious incidents has been effectively used to reduce the likelihood of similar incidents in my organisation	☐	☐	☐	☐	☐	☐

Patients, families and carers are meaningfully involved in internal investigations into serious incidents in my organisation	☐	☐	☐	☐	☐	☐
Encouraging openness with patients and carers when things go wrong is a strategy that promotes learning and improvement within a healthcare organisation	☐	☐	☐	☐	☐	☐

YOUR OWN ROLE IN SPEAKING UP ABOUT CONCERNS

If I had a concern about the quality and safety of care in my organisation that could not be dealt with internally, I would know which external body to raise it with	☐	☐	☐	☐	☐	☐
If I raised a concern about quality and safety of care in my organisation with an external body, I am confident that it would be dealt with appropriately	☐	☐	☐	☐	☐	☐

7. In implementing the <u>statutory Duty of Candour</u>, to what extent have the following issues posed challenges?

	Not at all challenging	**Slightly challenging**	**Somewhat challenging**	**Very challenging**	**Extremely challenging**	**Don't know**
Resources (financial resources and time available to staff)	☐	☐	☐	☐	☐	☐
Resistance from staff	☐	☐	☐	☐	☐	☐
Lack of clarity from policy and regulatory bodies about what is expected of your organisation	☐	☐	☐	☐	☐	☐
Lack of training within the organisation for staff affected	☐	☐	☐	☐	☐	☐
Expectations of commissioners	☐	☐	☐	☐	☐	☐
Concerns about confidentiality	☐	☐	☐	☐	☐	☐
Concerns about potential legal challenges (e.g. litigation)	☐	☐	☐	☐	☐	☐
Other (please specify)	☐	☐	☐	☐	☐	☐

8. In implementing Freedom to Speak Up Guardians, to what extent have the following issues posed challenges?

	Not at all challenging	Slightly challenging	Somewhat challenging	Very challenging	Extremely challenging	Don’t know
Resources (financial resources and time available to staff)	☐	☐	☐	☐	☐	☐
Resistance from staff	☐	☐	☐	☐	☐	☐
Lack of clarity from policy and regulatory bodies about what is expected of your organisation	☐	☐	☐	☐	☐	☐
Lack of training within the organisation for staff affected	☐	☐	☐	☐	☐	☐
Expectations of commissioners	☐	☐	☐	☐	☐	☐
Concerns about confidentiality	☐	☐	☐	☐	☐	☐
Concerns about potential legal challenges (e.g. litigation)	☐	☐	☐	☐	☐	☐
Other (please specify)	☐	☐	☐	☐	☐	☐

9. In implementing the NHS England Serious Incident Framework, to what extent have the following issues posed challenges?

	Not at all challenging	Slightly challenging	Somewhat challenging	Very challenging	Extremely challenging	Don't know
Resources (financial resources and time available to staff)	☐	☐	☐	☐	☐	☐
Resistance from staff	☐	☐	☐	☐	☐	☐
Lack of clarity from policy and regulatory bodies about what is expected of your organisation	☐	☐	☐	☐	☐	☐
Lack of training within the organisation for staff affected	☐	☐	☐	☐	☐	☐
Expectations of commissioners	☐	☐	☐	☐	☐	☐
Concerns about confidentiality	☐	☐	☐	☐	☐	☐
Concerns about potential legal challenges (e.g. litigation)	☐	☐	☐	☐	☐	☐
Other (please specify)	☐	☐	☐	☐	☐	☐

10. Has your organisation appointed one or more Freedom to Speak Up Guardians? If so, what is the full time equivalent (FTE) time allocated to these duties?

Yes – less than 1.0 FTE allocated for Freedom to Speak Up Guardian duties	☐
Yes – 1.0 FTE allocated for Freedom to Speak Up Guardian duties	☐
Yes – more than 1.0 FTE allocated for Freedom to Speak Up Guardian duties	☐
Yes – other arrangement that cannot be measured in FTE allocation (please specify)	☐
No	☐
Don't know	☐

11. Who is the individual in your organisation who receives and handles concerns referred by the Freedom to Speak Up Guardian(s)?

Chief Executive	☐
Director of Nursing	☐
Medical Director	☐
Other Board-level director	☐
Senior clinician not on the board	☐
Senior manager not on the board	☐
Other (please specify)	☐
Don't know	☐

12. Does your organisation have a nominated non-executive director to whom the Freedom to Speak Up Guardian(s) and other individuals can refer concerns?

Yes	☐
No	☐
Don't know	☐

12a. If yes to question 12, what is the professional background of the nominated non-executive director to whom the Freedom to Speak Up Guardian(s) and others can refer concerns?

Healthcare (NHS or non-NHS)	☐
Academic	☐
Other public sector	☐
Private sector (non-healthcare)	☐
Charity / third sector	☐
Other (please specify)	☐
Don't know	☐

13. Are there any particular initiatives that you have introduced locally that you feel have the potential to make a major impact on the openness of your organisation? This might include, for example:

- **Communication with patients and relatives following patient safety incidents**
- **Helping staff to feel comfortable about raising concerns**
- **Supporting staff in disclosures following patient safety incidents**
- **Improving the quality of serious incident investigations**

Please give details (and provide links if appropriate).

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14. What, if anything, could organisations such as the Department of Health, NHS England and the Care Quality Commission do to support the creation of a more open culture in your organisation?

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15. Would you be happy to be contacted about the possibility of your organisation being involved in more in-depth research on the themes included in this survey?

Yes ☐
No ☐

Many thanks for your time and effort in completing the survey – it is much appreciated.

C. Topic guides used for interviews in organisational case studies (WP4)

Three topic guides were produced for WP4; the choice of topic guide for an interview depended on (i) the route of contact, and (ii) whether the participant was a member of NHS staff, or a patient or family member (see section 2.4).

Topic guide for interviewees contacted through the first route

Interviews with senior managers and clinicians in this organisation providing NHS services to explore how they understand policies relating to openness and how they have been translated into specific norms, expectations and practices in their organisations, particularly with a view to identifying initiatives and areas for further focus.

Welcome and introduction

- *Seek additional verbal consent to continue and to audio-record the interview.*
- *Re-cap of the project and plan for the interview*

  The interview will explore how organisations in and around the NHS are responding to policies designed to encourage openness, candour and learning. The aim is to understand how your organisation is responding to this impetus, what is changing and the challenges and opportunities. We are interested in your perceptions, on the basis of your knowledge and experience and your position within the organisation. We are particularly interested in any innovative initiatives that are ongoing in your organisation around these themes, and any opportunities in your organisation for looking at these in more detail. If you do not feel you are able to comment on any area please say so. Your identity and that of your organisation will be anonymised in any outputs from the study.
- Do you have any questions before we start?

The participant

- What is your present job title?
- How long have you been in post/ in organisation [x]?

The culture in your organisation

- Generally speaking, how would you describe the culture of your organisation, as it relates to openness about issues of quality and safety?
- How can you tell which units within your organisation have a positive culture in relation to openness?
- What mechanisms are available in your organisation for people to raise concerns about things like quality of care, safety, professional behaviour?
- To what extent are they well utilised by staff at the ‘sharp end’?

Policy changes

- What, if any, changes would you say there have been in your organisation since the Francis inquiry, the Berwick report, and government responses to those?

- *Explore whether there were any local catalysts for change*
- What kinds of changes has your organisation made in response around
    - The Duty of Candour
    - Freedom to speak up (Guardians and wider efforts to foster speaking up)
    - Investigating patient safety incidents and learning from them
- Are there any particularly important or distinctive or innovative approaches you have taken in seeking to implement these recommendations (and in trying to develop a culture of openness more generally)?
    - *Probe for details, including:*
        - *description of initiative*
        - *which parts of organisation it applies to*
        - *who involved in leading and rolling out*
        - *successes and challenges in implementing*
        - *sense of impact to date*
- Are there any parts of the organisation that, you feel, have particularly embraced these initiatives?
- Are there any parts of the organisation that have been more reluctant to embrace them?

Closing questions

- As you know, we would like to gain insight into these initiatives as they are experienced by frontline staff, and patients and carers. In moving forward on this, whom should we speak to next?
    - Anyone else to interview in gathering information about these initiatives?
    - Which initiatives and areas should we focus on in seeking to recruit to interviews, and who would be well placed to assist in recruitment?
- How would you like me to refer to you in the transcript (e.g. clinician, doctor, nurse, manager etc.)?
- Is there anything else you would like to add that you think might be relevant to me?
- Thank you for your assistance.

Topic guide for interviewees contacted through the second route (staff)

Interviews with staff who have experiences of speaking up in their organisation and/or the disclosure and investigation of patient safety incidents, including under the statutory duty of candour. To explore the process of speaking up and disclosure and investigation in terms of the degree to which the process aligns with policy intentions around openness and learning, and how staff feel polices have impacted on the openness of their organisation and whether they feel that their local culture has changed as a result.

Welcome and introduction

- Thank you for contacting us and being willing to speak with me. You may stop the interview any time you wish, and you need not answer my questions if you do not wish or feel able to. Please note that your participation in this interview will not be revealed to any member of staff at your organisation. No part of the interview will be published that will enable anybody to identify you.
- *Seek verbal consent:*
    - Your consent to participate in this study is taken orally to avoid creating a written record of your participation. Will you please confirm that you have read and understood the information in the information leaflet and the oral consent to interview form, and that you give your consent to being interviewed for this study. Your response will be included in the anonymous transcript of your interview.
- This interview will explore how your organisation has responded in practice to policies and

initiatives designed to encourage openness, candour and learning. I would very much like to hear about your experiences of any aspect of these, particularly if you have one or more specific examples of speaking up about concerns, disclosing patient safety incidents to patients and carers, or involvement in incident investigations at your organisation.

Eliciting the narrative

- Do you have any specific examples of this kind of process that you would like to talk about?
- *If so:*
    - Can you talk me through what happened please?
    - *The interviewee begins telling their story; the interviewer will use non-verbal and short verbal cues as necessary to encourage the interviewee to talk freely. The interviewer will avoid interrupting with more detailed questions until there are clear signs that the interviewee has finished their story.*
- *If not, move on to Part 3 and pick up any specific examples that arise in the course of the interview as above.*

Questioning phase

- *The interviewer will ask further questions about the topics raised in the narrative.*
- *For example, in relation to speaking out about concerns:*
    - Who else was involved in making the decision to report?
    - Was it a clear cut incident or ambiguous?
    - What were the consequences for you and the other parties involved?
    - Did you receive any particular encouragement from others to speak up? Who, and in what way?
    - Did you receive any particular discouragement from others to speak up? Who, and in what way?
    - Were you aware of the organisation's policies and processes around freedom to speak up? Did these influence your decision or the way you went about pursuing your concern? In what way?
    - *Depending on when the narrative was set:* Do you think the same thing would happen today?
    - What would have helped make things easier for you?
    - What has been the impact on you, career wise and personally?
- *In relation to acts of disclosure:*
    - Who else was involved in making the decision to disclose the incident? Who else was involved in the process (e.g. professional colleagues, managers, HR, legal department)?
    - Was it a clear cut incident or ambiguous?
    - Can you remember the rough form of words you used in disclosing the incident?
    - Was it a one-of meeting or did you meet with the patient or relative more than once?
    - What were the consequences for you and the other parties involved?
    - Did you receive any particular encouragement from others to make the disclosure? Who, and in what way?
    - Did you receive any particular discouragement from others to make the disclosure? Who, and in what way?
    - What kind of support, if any, was there for you during and following the disclosure?
    - Were you aware of your professional obligations in relation to candour? Did this influence your decision or the way you went about disclosing the incident? In what way?
    - Were you aware of the organisation's policies and processes around the duty of candour? Did these influence your decision or the way you went about disclosing the incident? In what way?
    - How did the patient or carer respond to your disclosure?
    - *Depending on when the narrative was set:* Do you think the same thing would happen

    today?
  - What would have helped make things easier for you?
  - What has been the impact on you, career wise and personally?
- *In relation to incident investigations:*
  - What was it that prompted the investigation, and who made the decision that an investigation was required?
  - Who led the investigation, and who else was involved (e.g. professional colleagues, managers, HR, legal department)?
  - Were any individuals or bodies from outside your organisation involved in the investigation?
  - Were patients and carers involved in the process? If so, how?
  - Approximately how long did the investigation take?
  - To what extent did you feel that the investigation worked well?
  - To what extent did you feel it was concerned with learning for improvement?
  - Have you read the report of the investigation? If so, to what extent do you feel it fairly reflected the incident and its causes? To what extent do you feel that lessons have been learned and appropriate changes have been made following the investigation?
  - *Depending on when the narrative was set:* Do you think the same thing would happen today?
  - What would have helped make things easier for you?
  - What has been the impact on you, career wise and personally?

Generic questions

- Do you feel that your workplace is one in which people can easily raise concerns? Why? Is there anyone you wouldn't speak up to?
- Are there particular instances or situations which would make it less likely that you would raise concerns? What are they? Do you have any particular examples?
- How comfortable do you feel with raising concerns with people from different professional groups?
- How comfortable do you feel with raising concerns with people more senior than you?
- What knowledge do you have of recent changes in healthcare policy that attempt to improve openness in the NHS? *Prompt:*
  - The statutory Duty of Candour
  - Freedom to speak up and Freedom to Speak up Guardians
  - The Healthcare Safety Investigation Branch
- To what extent do you feel that these have led to tangible differences in your own organisation? Can you given any examples?
- When something goes wrong in your organisation, what are the consequences for the individuals involved?
- If you were involved in a patient safety incident, do you feel that the organisation would treat you fairly?
  - What would it do to try to learn from the incident?
  - What would it do to hold those involved to account?

Closing questions

- Is there anything else that you think might be relevant to me before I go?
- How would you like me to refer to you in the transcript (e.g. clinician, doctor, nurse, manager etc.)?
- Thank you for your assistance.

Topic guide for interviewees contacted through the second route (patients and family members)

Interviews with patients or carers who have experienced the disclosure of incidents under the statuary duty of candour process, and/or have been involved in investigations to such patient safety incidents. To explore how patients experience disclosures, whether they feel the process is adequate and appropriate in this organisation, and the degree to which the process aligns with policy intentions around openness and learning.

Welcome and introduction

- Thank you for contacting us and for your interest in speaking with me. You may stop the interview at any time you wish, and you need not answer my questions if you do not wish or feel able to. Please note that your participation in this interview will not be revealed to anyone else, including any member of staff at organisation x. No part of the interview will be published that will enable anybody to identify you.
- *Seek verbal consent:*
    - Your consent to participate in this study is taken orally to avoid creating a written record of your participation. Will you please confirm that you have read and understood the information in the information leaflet and the oral consent to interview form and that you give your consent to being interviewed for this study. Your response will be included in the anonymous transcript of your interview.
- This interview will explore how organisation x has responded in practice to policies and initiatives designed to encourage openness, candour and learning when incidents occur, and particularly how it has informed and involved patients and carers when things have gone wrong. I would very much like to hear about your experiences of this.

Eliciting the narrative

- I understand that you have a specific experience of being informed of a patient safety incident of this kind – is that correct?
- *If so:*
    - Could you talked me through what happened, please?
    - *The interviewee begins telling their story; the interviewer will use non-verbal and short verbal cues as necessary to encourage the interviewee to talk freely. The interviewer will avoid interrupting with more detailed questions until there are clear signs that the interviewee has finished their story.*
- *If not, move on to Part 3 and pick up any specific examples that arise in the course of the interview as above.*

Questioning phase

- *The interviewer will ask further questions about the topics raised in the narrative.*
- *For example, in relation to the process of disclosure:*
    - How did you feel about how the process was handled?
    - Did you receive an apology? How did you feel about this?
    - Did you feel you had the opportunity to ask questions, and to get them answered to your satisfaction?
    - How were you supported by the professionals involved, or by the organisation?
    - Was anyone else available to support you during or after the process? Did you feel that you were able access good advice about how to respond?
    - Do you think the right people were involved?
    - Who would you have liked to have been involved?
    - What has been the impact on you of the disclosure?

    - What would have helped to make the disclosure process better for you?
  - *In relation to involvement in incident investigations:*
    - How did you feel about how the process was handled?
    - To what extent did you feel that your views were taken account of during the investigation?
    - Did you feel you had the opportunity to ask questions, and to get them answered to your satisfaction?
    - How were you supported by the professionals involved, or by the organisation?
    - Was anyone else available to support you during or after the process?
    - Do you think the right people were involved?
    - Who would you have liked to have been involved?
    - Approximately how long did the investigation take?
    - To what extent did you feel that the investigation worked well?
    - To what extent did you feel it was concerned with preventing similar things happening in future?
    - Have you read the report of the investigation? If so, to what extent do you feel it fairly reflected the incident and its causes? To what extent do you feel that lessons have been learned and appropriate changes have been made following the investigation?
    - What has been the impact on you of being involved in the investigation process?
    - What would have helped to make the process better for you?

Generic questions

- In your opinion, do you think that organisation x are genuinely open?
    - *Prompt in terms of organisation as a whole and particular individuals or groups within it*
- Were some staff better than others at responding to any concerns that you might have had?

Closing

- Is there anything else that you think might be relevant to me before I go?
- *State that we will be referring to people as 'patient 1' or 'carer 1' and check that this is acceptable.*
- Thank you for your assistance.

D. Examples of innovative approaches to openness

In discussing potential outputs from the study, colleagues from the Department of Health and Social Care expressed enthusiasm for as short, accessible document highlighting some of the innovative approaches to encouraging a culture of openness we had encountered in the course of research (see section 2.5). The intended audience is policymakers; subject to approval following review of the report, we hope to make a fully formatted, publicly oriented standalone leaflet, incorporating revised language to ensure accessibility, and available to wider NHS, patient and public audiences too.

Innovative approaches to openness

Recent years have seen a wide range of policies designed to increase the openness of the NHS in England. An evaluation study, led by researchers at the University of Leicester (with colleagues from Sheffield and Cambridge), looked at their implementation in the NHS and examined the extent to which they were resulting in palpable change on the ground, in the experiences of staff, patients and families.

A key finding was the work needed by managers and clinicians in NHS organisations to ensure that the policies were put into practice in a way that made sense locally, and which made clear the potential benefits of openness to everyone affected. During the study, the researchers came across a wide range of innovative approaches to openness, some originating in the organisations they studied, some elsewhere. The examples discussed in this document include some given by research participants of their own work and experience, and others highlighted by participants as representing good practice elsewhere in the NHS.

This leaflet provides an overview of some of the innovative approaches the researchers encountered, and what it was about them that seemed to make them work. It should not be taken as an endorsement of these approaches. It is also not intended as a list of solutions, but as a set of ideas that might be useful to those seeking to enable openness in practice. Findings from the study show that to work well, they need to be part of a wider strategy that places openness at the heart of organisational mission, and invests in infrastructure and support for openness, learning and improvement.

The full report of the study was submitted in November 2019, and will undergo peer review prior to publication on the on the Department of Health and Social Care Policy Research Programme Central Commissioning Facility (CCF) website. One peer-reviewed academic paper is already available from the study.

Improving relationships between community and healthcare practice

Family Liaison officers

Family Liaison Officers (FLOs) have been deployed in the police service for a number of years, with the aim of supporting families through serious investigations. In one ambulance trust that we were told about, in consultation with a police expert, the role has been adapted to support patients and carers through investigations into serious incidents of harm, including those that meet the statutory Duty of Candour criteria.

The FLO role is designed to mediate between an NHS organisation and the patient or family affected by harm, and to advocate for the rights and wishes of the patient and family. FLOs make themselves available to answer questions about the process, to help ensure that the investigation's terms of reference incorporate the interests of the patient and family, to provide updates on progress, and to explain terminology and translate findings into plain English.

FLOs are volunteers from among the organisation's staff who undergo rigorous training to ensure they have the skills to deal with complex situations and sensitive interactions. While the role of the FLO in practice is determined by the expressed wishes of the patient or family, there are certain ground rules that govern the relationship. For example, the FLO will be available for contact during the investigation, but contact will cease when the investigation is over and the FLO has delivered and discussed report with the patient and family. FLOs' wellbeing is a priority for the organisation and efforts are made to free their time and ensure that they are not pressured to take on cases. To help maintain impartiality, FLOs are not deployed in cases relating to their own working areas.

Benefits claimed for the FLO programme include better relationships with patients and families following instances of harm, engagement of staff in a programme that is seen to benefit patients, and reduced resort to legal processes by patients and families frustrated by organisational inaction following harm.

Community involvement

NHS organisations are required to have forums and channels for patient and service user involvement. Some publish community-facing newsletters, and foundation trusts may encourage people from the local community to become trust members to influence the organisation's work.

Particularly in the aftermath of significant problems in the quality of care, one trust we heard about had made great efforts to engage the local community and involve it directly in learning from mistakes and redesigning services with patients and families at the centre. The trust drew extensively on the experiences of staff, patients and families affected directly by failings, with a view to securing a process of learning and improvement process that was authentic and genuinely influenced by those who have suffered. Continuing this process, senior managers continue to seek to engage members of the local community in change, for example by using social media not only to broadcast successes, but also to acknowledge continued shortcomings and solicit suggestions for improvement.

Involving service users in complaint handling

A mental health and community health services trust has sought to improve the quality and responsiveness of its complaints office by employing former and current service users to assist in dealing with complaints. Taking advantage of the Department of Work and Pensions' 'permitted work' scheme, it sought to provide a service that would benefit the organisation itself, the people staffing it, and the people using it. As well as being more readily able to empathise with people making complaints, the organisation found that service users were often better able to respond to complaints because of their expertise by experience. They were able, for example, to assist in the interpretation of complaints, contribute to the wording of response letters, and ensure that complaints were adequately addressed.

Improving relationships between management and staff

WalkRounds and similar approaches

NHS organisations are making increasing use of Leadership or Executive WalkRounds (an intervention developed by the Institute for Healthcare Improvement in the United States[207]) and similar interventions designed to facilitate understanding and communication between the 'blunt' and 'sharp' ends of organisations (senior managers and clinicians delivering care), and secure improvement. They involve face-to-face forums that usually take place in sharp-end settings, and seek to provide a structure for staff to surface safety concerns, ensure they are recognised and understood by senior staff, and create plans to address them.

Organisations have often developed and adapted the formula to ensure that it is well suited to their own setting, for example by reducing reliance on prescribed checklists of items to cover, or by broadening the scope of rounds to include staff morale and patient experience as well as patient safety. As well as seeking to address specific items pertaining to safety, quality, experience and morale, managers and clinicians in some organisations use forums of this kind as opportunities to engage in more informal chats with staff, getting a sense of the concerns that people have and the issues they are facing.

In ensuring that WalkRounds and similar interventions foster high-quality interactions between managers and clinicians, and are not seen as 'inspections' or 'check-ups', research has shown the importance of clearly separating them from performance-management or auditing activities.[103] While activities like spot checks and unannounced visits may have their place, they do not precipitate the kind of trust and informality that WalkRounds seek to achieve.

More broadly, senior managers involved in the research recognised the importance of building closer relationships between the sharp end and the blunt end, and WalkRounds were one of several interventions they pursued to try to improve openness. They felt that key influences on the success of such work included the approachability, visibility and understanding of blunt-end staff; strategies for increasing these features included:

- leaders undertaking occasional shifts (including clinical and non-clinical work, for example as assistants or in janitor roles) at the sharp end;
- leaders shadowing sharp-end staff as they go about their everyday business;
- leaders operating open-door policies or holding open forums;
- leaders discussing their own mistakes and what they have learned from them;
- leaders informally walking around, listening and being seen to act on issues raised by their colleagues on a day-to-day basis;
- leaders noticing and celebrating positive aspects of staff practice and behaviour.

Ensuring that they were visible, seen to take responsibility for learning and improvement, and prepared to respond to staff's concerns could help to demonstrate that openness could be beneficial at all levels of the organisation—rather than appearing as a top-down demand or distant policy priority. Small gestures could go a long way: for example, simple things like reinstating a budget for hot drinks for people on night shifts. Work to ensure that conversations about openness were normalised rather than formalised was also important: for example, offering frequent opportunities for contact between the blunt end and the sharp end, perhaps over a cup of tea, rather than limiting such contact to occasional formal meetings or formal intervention when problems arose.

Improving staff wellbeing

Schwartz Rounds

Schwartz Rounds have been adopted in many organisations. They are designed to provide a regular space where staff from clinical and non-clinical backgrounds meet to discuss the emotional aspects of working in healthcare. Their purpose is to understand the broader challenges and rewards involved in care, rather than focusing on clinical specifics, and in the process support staff in providing compassionate, high-quality care. There is some evidence for their effectiveness in improving indicators of staff wellbeing, particularly in relation to self-reported empathy and compassion, and staff perceptions of organisational support.[193]

The need to ensure that staff are taken care of was a notable theme in the research. We spoke to individuals from several organisations that had embraced Schwartz Rounds, who were strong advocates for their benefits. Ensuring that opportunities for reflection and learning of this kind existed was also seen as reflecting organisations that took staff wellbeing and its contribution to improvement seriously.

Improving interpersonal behaviours

Civility Saves Lives

The issue of unpleasant interpersonal behaviours among staff arose frequently in our research. Acts of rudeness or incivility meant that staff felt undermined, and made for miserable and stressful working conditions. There is also mounting evidence for associations between uncollegial behaviour and quality and safety outcomes.[137,138] Efforts to address this problem have gained mounting momentum and support from various quarters; one example of a coordinated effort to address ill-behaviour is 'Civility Saves Lives'.[175] As well as providing information sourced from the movement's membership, the website provides academic evidence for the link between civil behaviour among staff and improved outcomes for patients. Participants in the research valued this resource.

Behavioural standards frameworks

Changing entrenched behaviours is not easy. Some NHS organisations have introduced behavioural standard frameworks as a tool for change. Sometimes these form part of an employee's contractual obligations. Some organisations have included them in inductions for new staff, and have offered training to help colleagues draw on frameworks in their everyday work. They can offer staff with an accessible framework that makes it clear what is and what is not acceptable; if well constructed and promoted, they can offer a means by which staff can hold one another to account and address poor behaviour on a day-to-day basis.

Enforcing such frameworks where staff members consistently fall short in their behaviour towards their colleagues and patients is more challenging. Evidence from the study and from elsewhere[101] indicates the importance of unerring tenacity in upholding the expected standards consistently and uniformly. This means that they must be underpinned by high-quality HR systems, processes and personnel, with a readiness to invoke formal intervention (including disciplinary proceedings) where a member of staff's behaviour persistently falls short of the expected standards.

Encouraging speaking up and reporting

Alongside the introduction of Freedom to Speak Up Guardians, many NHS organisations have attempted innovative approaches to encouraging voice. One example that we were told about is the development of a workshop that began with a comedy performance, satirising the influences that can inhibit voice and encourage silence. The performance was followed by a confidential workshop, where could discuss their own view on and experiences of speaking up and reporting. Run every six months, the workshop has received positive feedback from colleagues in the organisation, and represents a means of encouraging conversation about something that can be very difficult to discuss.

Our study suggested that approaches to implementing Freedom to Speak Up and supporting Guardians vary markedly. Guardians with protected time, and 'in kind' support from their organisations, appear to be much better able to fulfil the breadth of the responsibilities of the role than those who have to juggle it with existing commitments.

The 'Gripes' reporting tool

In one organisation that we heard about, collaboration with a local university had led to the development of a tool oriented in particular towards junior doctors, to enable them to report events that fall short of patient-safety incidents, but which nevertheless cause concern. The 'Gripes' tool is intended to detect recurrent issues that, if addressed, would improve day-to-day working conditions, with potential indirect positive consequences for quality and safety.[208] The tool also provides extra insights into quality, safety, outcomes and risk that complement existing surveillance mechanisms.

Systems and processes

Communication and culture

A recurrent theme in the research was the challenge of enabling dialogue across the sharp and blunt ends of an organisation, with a view to creating common purpose across a unified workforce, and a clear and simple set of values to which the organisation and its staff subscribe. The sheer size of many NHS trusts can make this challenging. Staff can face ‘information overload’, and so relying on e-mails and ‘marketing’ style campaigns with leaflets and posters to try to create such a culture seems unlikely to be effective. Not all staff have access to e-mails, and finding a language that is accessible to all can be challenging.

Evidence from this study and beyond[116,209–212] suggests that the most powerful form of communication is face-to-face, and that the project of cultural change is best thought of as a social movement, spread by word of mouth and by the modelling of open behaviours by leaders and colleagues.

Information management

Many organisations continue to struggle with sourcing, monitoring and acting upon diverse sources of intelligence about performance, safety and risk. This problem is nothing new: the Kennedy report into the problems of paediatric heart surgery in Bristol noted that the organisation was “awash with data” but that these data were not aggregated, reviewed, triangulated or acted upon.[213] Notable efforts by NHS organisations to respond to such challenges include:

- adapting incident-reporting systems such as Datix to ‘warehouse’ all documents relating to incidents, disclosures and investigations, optimising use of this resource for learning;
- regular meetings to assess the progress of each incident and allocate actions to relevant member of staff, with unceasing management to ensure that processes are followed and learning is not lost;
- drawing on the work of the Freedom to Speak Up Guardian with a view to detecting low-level ‘rumblings’—“weak signals”[131]—that may be the precursors of patient-safety issues;
- triangulating hard metrics with ‘soft intelligence’[78] derived from a variety of sources;
- dedicated staff with a focus on integration of data and oversight of indicators of safety, experience and other aspects of quality of care.

E. Output: ‘Senior stakeholder views on policies to foster a culture of openness in the English National Health Service: a qualitative interview study’

This paper has been published in the *Journal of the Royal Society of Medicine* as: Martin, G.P., Chew, S. and Dixon-Woods, M. Senior stakeholder views on policies to foster a culture of openness in the English National Health Service: a qualitative interview study. *Journal of the Royal Society of Medicine* 112, 4 (2019): 153–59.[64]

Abstract

Objectives: To examine the experiences of clinical and managerial leaders in the English healthcare system charged with implementing policy goals of openness, particularly in relation to improving employee voice.

Design: Semi-structured qualitative interviews.

Setting: NHS, regulatory and third-sector organizations in England.

Participants: 51 interviewees, including senior leaders in healthcare organizations (38) and policymakers and representatives of other relevant regulatory, legal and third-sector organizations (13).

Main outcome measures: Not applicable.

Results: Participants recognized the limitations of treating the new policies as an exercise in procedural implementation alone and highlighted the need for additional ‘cultural engineering’ to engender change. However, formidable impediments included legacies of historical examples of detriment arising from speaking-up, the anxiety arising from increased monitoring and the introduction of a legislative imperative, and challenges in identifying areas characterized by a lack of openness, and engaging with them to improve employee voice. Beyond healthcare organizations themselves, recent legal cases and examples of ‘blacklisting’ of whistle-blowers served to reinforce the view that giving voice to concerns was a risky endeavour.

Conclusions: Implementation of procedural interventions to support openness is challenging but feasible; engineering cultural change is much more daunting, given deep-rooted and pervasive assumptions about what should be said and the consequences of misspeaking, together with ongoing ambivalences in the organizational environment about the propriety of giving voice to concerns.

Key words: Employee voice; organizational silence; Freedom to Speak up; organizational culture; NHS; England.

Introduction

Though the insights from the ‘front line’ or ‘sharp end’ of organizations are an important resource for detecting problems, learning and improvement, organizations often struggle to encourage ‘employee voice’ and to respond appropriately.[100] This is a particular challenge in healthcare, where the importance of speaking up about concerns has been repeatedly demonstrated. In the United Kingdom (UK), for example, the first modern inquiry into National Health Service (NHS) failings arose from concerns reported by a nursing assistant at Ely hospital in Cardiff.[214] The NHS is far from unique in experiencing these problems: similar difficulties in eliciting and making use of concerns of those at the sharp end of care have also been implicated in problems of quality and safety in health systems globally.[78]

Latterly, voice in the healthcare system has become a prominent focus of government policy.[215,216] In England, this attention has been driven in particular by a high-profile failings in care at Mid Staffordshire NHS Foundation Trust. Led by Sir Robert Francis QC, a public inquiry into events at the hospital,[5] and a more wide-ranging review of *Freedom to Speak Up,*[11] suggested that voice in healthcare organizations was inhibited by individuals’ fear of repercussions and by perceptions of futility. In response, the government declared its intention to take steps to foster openness, defined in the Francis inquiry as “enabling concerns to be raised and disclosed freely without fear, and for questions to be answered.”[5]

Some of these steps have taken a procedural form. They include initiatives such as legal protection for ‘whistleblowers’, and revisions to guidance on reporting and investigating serious patient safety incidents.[13,27] Organizations have also been mandated to appoint ‘Freedom to Speak Up Guardians’ (conduits for concerns about facilities, quality of care, or colleagues’ behaviour), and must fund the role themselves. An additional, distinctive feature of policy on openness is its emphasis on the importance of attending to the *culture* of the NHS as a whole, and the extent to which it “actively promotes the benefits of openness and transparency.”[12] “Chief Executives and Boards,” states one policy document, “should promote a culture of openness,” seeking to embed the policies by translating regulatory requirements into cultural change.[12]

The academic literature supports the notion that organizational-cultural influences have a critical impact on voice.[83,84,149] Research demonstrates the importance of features of the organizational environment in encouraging or inhibiting voice, for example the role of psychological safety in reducing fear of adverse consequences associated with decisions to speak up.[100,217,218] Studies have also identified the relevance of heuristic schemas such as ‘implicit voice theories’ about when it is appropriate to speak, which may result in self-censorship and habituated silence.[83,149] Barriers to voice, therefore, may have their roots more in an organization’s cultural cues, and in entrenched assumptions about appropriate behaviour, than in explicit policies or the dynamics of specific opportunities to speak. But how to realize a policy commitment to *cultural change* (rather than procedural implementation) of the kind necessary to address these barriers remains an important challenge, and one that we address in this article. We report findings from a recent interview-based study that sought to examine the experiences of clinical and managerial leaders in the English healthcare system who were charged with implementing the policy goals of openness.

Methods

We conducted semi-structured interviews with senior leaders (including clinicians and administrators) in English healthcare organizations, along with policymakers, representatives of regulatory bodies, and individuals from relevant medico-legal and third-sector organizations, as part of a wider mixed-methods policy evaluation.

Senior leaders were identified through a mixture of random, purposive and snowball sampling techniques. With a view to securing representativeness, a randomly generated selection of acute trusts (20), community and mental healthcare trusts (10) and ambulance trusts (five) was contacted to identify potential participants. In parallel, we purposively sampled four organizations that had experienced problems with openness, as indicated by regulatory intervention and/or media coverage. Finally, we asked participants to suggest colleagues within or beyond their organizations who might be able to offer insights relating to our research questions. Wider stakeholders—such as policymakers and representatives of regulatory, third-sector and medico-legal organizations—were identified purposively in consultation with a stakeholder reference group, with snowball sampling again supplementing this initial list.

Data collection occurred between July 2017 and January 2018. Interviews were guided by a topic guide based on a literature review and discussion among the authors, collaborators, the stakeholder reference group and a patient and public involvement group. The guide was intended to elicit participants' in-depth understanding of relevant policies, including the clarity and unity of direction they provided, the process of implementing them, and incentives and disincentives to increase openness. Interviews averaged 40 minutes, and were audio-recorded and transcribed verbatim.

Supported by NVivo 11, we used an approach derived from the constant-comparative method for analysis.[52] Interview transcripts were read independently by [Author1] and [Author2], who coded the data for high-level themes derived from the evaluation brief and academic literature, and themes identified inductively from close reading of the data. We modified, developed and amalgamated codes as we read and re-read data sources. Coding was accompanied by ongoing discussion among the authors. [Author1] then drafted an integrated analysis of the findings in relation to the research questions above, which was developed and agreed by all authors, and is presented below.

Findings

We interviewed 18 participants from acute hospitals (denoted Ac data excerpt attributions), 17 from community and mental healthcare trusts (MH), and three from ambulance trusts (Am). Participants came from 16 acute trusts and one non-NHS provider of acute services, 11 community and mental healthcare trusts, and three ambulance trusts: in total, 31 different organizations were represented. We also interviewed 13 wider stakeholders (WS), bringing the total number of interviewees to 51. NHS-employed participants largely occupied senior management positions, but also included eight Freedom-to-Speak-Up Guardians of varying seniority.

The challenge of encouraging voice

The need for greater openness was broadly acknowledged and accepted by participants. Many cited the Francis inquiry as a driver for change, but some noted that change in their organizations had started earlier, often in response to a serious local incident. Participants recognized that organizations were likely to feature "dark spots"[49] of poor performance and practice, where lack of organizational knowledge or reluctance to speak up obscured poor care.

> "My perception is that we're probably doing a lot better than other places, but you don't know what you don't know. If staff are reluctant to come to anybody and raise their concerns, how do you know that? How do you benchmark it?" (Ac06)

Though the aspiration for openness was welcomed, the challenges associated with encouraging voice were seen as daunting. Participants described fear of speaking up as having complex origins, relating to both perception and reality.

First, implicit voice theories[83] were seen as influential. Participants described how their colleagues associated speaking up sometimes with extreme consequences such as job loss or litigation, and sometimes with less dramatic but nonetheless important fears, such as difficult interactions with managers or being seen as the cause of trouble or extra work. A closed culture was seen as the natural consequence of such assumptions.

> "If people put their head above the parapet, [they fear] that they will suffer themselves, either through being isolated or victimized, or—worst-case scenario—that they would suffer by losing their job, because that has happened in places up and down the country.

> And the reputation of whistleblowing is very much [that] you're taking a risk by doing this." (MH12)

A second reported influence on a closed culture was the behaviours of leaders who either failed to listen or actively suppressed voice, inducing silence through aggression or indifference.

> "Sometimes you get very longstanding management teams within a specific directorate, [and] they can stop hearing. [...] And people as a consequence feeling they can't speak up: it's not the norm. Everything's alright because nobody's said anything." (MH10)

> "One of my team raised a concern to the previous chief executive, and was told not to bring a problem to the table. He didn't want to hear. [...] It has an impact over time." (Ac11)

Finally, participants saw closed cultures as arising when staff simply did not notice what was going wrong. In some settings, the prevailing cultural disposition—that is, the taken-for-granted beliefs and behaviours of a unit[38]—was not to question. Staff did not speak up because they did not perceive the need to do so.

> "[We had issues with] a small community hospital, completely off our radar, low level of complaints, care of older people, people not speaking up in that particular environment. So quite shocking to discover." (Ac04)

Such deficits of openness were seen as most likely to occur in isolated groups, less exposed to broader norms and inclined to be more inward-looking. Participants reported that these groups might also be among those most difficult to support in change towards openness.

Promoting openness

Participants described taking seriously the goal of promoting openness, often giving accounts of concerted organizational efforts to implement regulatory requirements and of cultural work to reshape organizational norms through strengthening of relationships and creating a narrative of collective accountability.

One set of tasks associated with realizing openness was largely procedural in nature. Participants described, for example, their work to appoint Freedom to Speak Up Guardians, and prepare clear organizational statements that explicitly encouraged voice. Achieving these procedural tasks was not straightforward, but could at least be structured and managed through clear operational plans.

> "We took the recommendations, we went through and picked out all of those that could possibly apply to a non-acute provider. And we grouped them in areas that fitted into work that we were doing, and monitored against them." (MH02)

Much more challenging were the cultural tasks of reshaping organizational norms, values and behaviours towards openness. Many of the actions described by participants appeared to target directly the challenges that they saw as contributing to closed cultures.

First, they sought to create relationships between management and staff characterized by trust and confidence. They emphasised the need for clarity and consistency about the mutual obligations and expectations of the employee-management relationship, and to reassure staff that punitive intent would play no role in responses to concerns being raised. Accordingly, they stressed the need to ensure alignment between espoused and enacted values by senior leaders.

> "There is a tentative period where people are watching whether you are going to do what you said, and I think having a set of values, that the leadership doesn't lead, is a kind of anti-value, really: it is worse than useless." (Ac03)

In particular, they sought to convince colleagues that giving voice to concerns was a worthwhile activity that would deliver benefits at the sharp end, not just in administrators' reports to their superiors. This meant efforts to establish openness as the default orientation, and to position conversations about shortcomings in care as a route to collaborative improvement rather than hierarchical accountability.

> "The most important bits around openness and transparency, where the greatest success has been, [is] just by the executive team—so me and my colleagues—out in the patch, walking, understanding the issues, meeting the staff, so we can see the problems that they're facing. I think that's the biggest change." (MH08)

Second, participants sought to create a narrative of collective accountability that both fostered a sense of being 'on the same side' and emphasised shared values. Strategies for creating and sustaining dialogue included use of Schwartz rounds (a method by which staff from all levels can reflect on the emotional aspects of their roles, with a view to legitimizing and normalizing openness). Participants also described their work to take collective ownership of problems of quality and safety, modelling openness and embracing vulnerability rather than loading responsibility onto the sharp end:

> "[Chief executive] has a blog in our intranet, and it is completely uncensored; we don't have any time lag between comments to be able to censor. Some people sail very close to the wind but nonetheless we support free expression. [...] If we hear things that make us feel uncomfortable, all good." (MH03)

Third, participants described the importance of meaningful responses to concerns. In this model, problem-solving was a key responsibility of leaders, including closing the feedback loop by ensuring that those who raised issues were informed of progress.

> "We've done other things; where they said, 'This is not right', we've bought a piece of kit. So whenever we go around, we have a little pot of money that we can actually go into and say, 'Well this is to help get it sorted'. So I think people recognize that we want to go out there and hear." (Ac01)

All in all, these efforts focused on seeking to establish willingness to speak up as the default orientation, by sharing the burdens and benefits of greater openness between the blunt and sharp ends.

Frustrating a culture of openness?

Participants were cautious about the prospects for their efforts in improving openness. Both direct experiences and shared lore about the risks of speaking up carried enduring weight, and informed implicit voice theories. Procedural interventions, they felt, might be futile in the face of deeply rooted assumptions about organizational behaviour, but even efforts to intervene in organizational culture could flounder.

> "There are certain areas where people feel more vulnerable than in others. And depending on previous experiences, even quite historical, if there's been a particularly significant event and there's been any kind of staff disciplinaries on the back of that, that legacy might still be there in a team, sometimes many years later." (MH14)

This meant that no strategy was uniformly effective. Participants found that their organizations were not homogenous with respect to openness, but varied area-by-area, team-by-team. Organizations that operated across multiple sites were seen to be at particular disadvantage in trying to inculcate a common culture that normalized openness. Just as some parts of their organizations had cultures that appeared more closed, organizational units varied in their response to efforts to breed openness.

> "We're very geographically challenged, because [Town A] and [Town B] are 45 miles

> apart. [...] To promote speaking up in everyday practice, business as usual, that's going to take a long time to embed." (Ac09)

Beyond localized 'resistance' to efforts to foster openness, a system-wide sense of vulnerability also remained, because many of the assumptions about the risks of speaking up still rang true. Whatever formal policy proclaimed, and however sincere individual organizations were in implementing it locally, the wider system still contained conflicting signals about the risks and benefits of openness. Widely publicized criminal convictions,[69] along with cases of 'blacklisting' of whistle-blowers, sustained the message that openness was not risk-free.

> "What happened recently with the paediatrician, and a couple of other cases of corporate manslaughter, or individuals: [...] those kind of cases really risk people being open and honest." (WS10)

> "If you talk to staff—and I know because staff tell me—there's still a bit of fear about being open. So however much they're reassured, there's still this belief that it may lead to being disciplined, or sanctions, or opportunities being limited." (Am01)

Furthermore, participants reported that some aspects of government policy perversely risked inhibiting openness. Alongside policies to promote voice, for example, the government had introduced a statutory 'duty of candour', obliging organizations and clinicians to acknowledge, apologize in writing for, and learn from incidences of moderate or severe harm caused to patients.[27] For those who failed to uphold this duty, punitive consequences could follow, including criminal prosecution.[26] The legalistic language surrounding the duty could, some participants argued, lend further credence to the notion that openness was being forced upon the healthcare service, with a greater focus on blame than learning:

> "To make it a criminal offence, I think, was entirely wrong. [...] Frightening people, by saying this is a statutory duty of candour, doesn't necessarily lead people to being more open." (MH02)

There was also a sense that some of the accountability requirements associated with openness risked subverting the substantive intent of the policies.

> "Each initiative has to be counted and double-counted, and monitored, and it is a distraction from what it's actually about. [...] The requirement for more-or-less standard records to be kept about not only the nature of the concern, but the characteristics of the person raising the concern. [...] It's not always appropriate to say, 'Are you happy with the approach that I've taken?' at that particular point." (MH05)

Overall, participants reported that the weight of the past, alongside ongoing developments in the present, could render their efforts at securing change fragile.

Discussion

Our findings suggest some enthusiasm for openness initiatives among senior stakeholders across the English NHS. However, many recognized the limitations of treating the new policies as an exercise in procedural implementation alone. They understood that the initiatives were hard to sell to colleagues functioning in suboptimal conditions, or who had witnessed or heard about maltreatment of colleagues who had spoken up about concerns in the past. When the prevailing understanding was that speaking up remained a "high risk:low benefit act,"[86] new procedures and the appointment of figures such as Freedom-to-Speak-Up Guardians were seen as unlikely to provide reassurance.

Accordingly, senior stakeholders sought to supplement implementation of policies and roles with a sort of 'cultural engineering' to address reticence, and assure their colleagues that giving voice to concerns would now be welcomed, not punished. They attempted to do this in ways that mapped well onto existing knowledge about leadership behaviours that empower and engage colleagues in improvement, such as senior management visibility, connecting proposed change to wider values and vision, and finding common purpose.[116,211] They sought to ensure that some of the advantages of an open culture accrued at the sharp end, and to make openness useful in addressing everyday imperfections as well as 'big-ticket' problems. Achieving this involved ongoing dialogue between the blunt and sharp ends, focused on understanding over accountability, with a view to instilling openness as the default disposition.[49,103]

Participants argued that cultural work to engage, and to share the benefits and burdens of openness, was essential in underwriting any behavioural change in relation to voice. But they also acknowledged that this approach faced its own barriers. One was the heterogeneous character of their organizations: the parts that might most benefit from efforts to improve openness were often those that were difficult to identify as problematic, difficult to reach, and difficult to influence. A second was that some characteristics of the policies risked reinforcing the view that voicing concerns was a risky activity. The monitoring activity that surrounded the Freedom-to-Speak-Up Guardians, for example, meant that preoccupation with the letter of the law might undermine its spirit, converting it into a bureaucratic display of compliance or, worse still, a punitive threat. While policy documents stressed the importance of "learning not blaming,"[13] the risk was that the very regulatory practices intended to support it might have the opposite effect.

Thus senior stakeholders understood that they needed to go beyond legalistic reassurances of protection for those who spoke up, and even beyond efforts to foster psychological safety that might embolden staff to give voice to concerns,[149] towards generating environments where the value of openness was apparent. Given the mixed signals of the wider system, however, and the diversity of experiences and expectations within organizations, our analysis suggests that participants may need to attend to creating an organizational infrastructure that might reinforce the well-meaning words intended to show that the blunt and sharp ends could both benefit from greater openness. There was little sign of the significant, programmatic investments in structured processes for support, development and intervention that research suggests have underpinned changes in organizational culture elsewhere,[101,219,220] especially for addressing the challenges of diverse micro-cultures within healthcare organizations.[38] While efforts to lead by example and ensure that benefits accrue at the sharp end are surely necessary, it is perhaps doubtful whether they are sufficient to secure sustained cultural change around openness when messages about its risks and rewards remain mixed.

For other systems looking to emulate the policies and initiatives developed in the English NHS to foster openness, our findings suggest two lessons. First, work is required to make aspirations of openness relevant to sharp-end clinicians working in pressured environments, for whom compromises and workarounds are a taken-for-granted feature of routine work, and who may see such interventions primarily as blame-allocation devices.[95] This means that actions must match words, especially in environments where initiatives purportedly intended to prompt learning and improvement have a tendency to metamorphose into tools of performance management.

Second, and more broadly, the word 'openness' is perhaps too passive a term to describe what is desired here. A major barrier to openness identified by participants was not concealment or opacity among their colleagues, but rather a kind of normalized incuriosity. Intervening in such contexts is challenging: established routines of explanation and rationalization may over time become institutionalized as legitimate ways of dealing with problems; it is difficult to disrupt these routines without the disruption itself being deemed deviant.[135,221] Open cultures therefore require active nurturing by those seeking to foster them, to imbue a state of continued, reflexive inquiry and self-questioning. This is not something that can be achieved by policy implementation alone. However, it may also require more than fine words and symbolic deeds on the part of leaders, especially given the shadow of history and the equivocal signals of the present.

Our study has limitations. Participants self-selected in their response to requests for interview. It is plausible that they represented organizations that were more forward-thinking in their approach to fostering openness; indeed wider stakeholder participants affirmed that some organizations were less advanced in implementing openness policies. Despite our partly random sampling strategy, therefore, it should not be assumed that our findings are nationally representative. Furthermore, we have only interview accounts of participants' views and of their organizations and colleagues' behaviour, and we have no measure of the impact of the approaches they saw as more or less successful.

Conclusion

Calls to improve employee voice pose challenges for senior stakeholders. While implementation of procedure is possible, engineering cultural change is daunting, given deep-rooted and pervasive assumptions about what should be said and the consequences of misspeaking, together with ongoing ambivalences in the organizational environment about the propriety of giving voice to concerns. Visible efforts to reframe the relationship between blunt and sharp ends of organizations seem a promising approach, but it is not clear that such endeavours will succeed in the absence of an infrastructure that underwrites positive words with consistent organizational action.

F. Output: ‘Uncovering, creating or constructing problems? Enacting a new role to support staff who raise concerns about quality and safety in the English NHS’

This paper has been accepted for publication in *Health* (authors: Martin, G.P., Chew, S. and Dixon-Woods, M.)

Abstract

Employee voice is an important source of organizational intelligence about possible problems in quality and patient safety, but effective systems for encouraging and supporting those who seek to speak up have remained elusive. Various interventions have sought to foster voice, including in the English NHS a new role known as the ‘Freedom to Speak Up Guardian’. We critically examine this role, in light of key issues in the framing of voice in healthcare organizations, notably the multiplicitous influences on willingness to speak, and the dominance of the notion of ‘whistleblowing’ in predominant constructions of voice. Our data are drawn from 51 interviews covering multiple sectors of the English NHS. Many managers were keen to ensure that the role focused on clearly defined problems of quality and safety. Guardians themselves, however, reported that the role was difficult to delimit so tightly. Some concerns were not, on the face of it, obviously quality- or safety-related, but they nevertheless required careful interrogation—and could yield important insights. Our analysis suggests that the role’s potential contribution might be understood less as supporting and protecting whistleblowers in demanding a response to allegations of clear-cut wrongdoing, and more as helping those with lower-level worries to construct their concerns and what to do with them. This points towards issues with the conceptualization of voice and the way it is (or is not) valued in healthcare.

Key words

healthcare quality; patient safety; speaking up; speaking out; employee voice; openness; candour; whistleblowing; Freedom to Speak Up; National Health Service (NHS); England

Introduction

Healthcare systems worldwide increasingly recognize the importance of employee voice in improving the quality and safety of the care they provide. Long acknowledged as a source of organizational intelligence across a range of industries,[100] employee voice may offer especially valuable insights about problems that are not readily detected through formal indicators.[78]. But, despite evidence that failures of voice have been implicated in crises in healthcare worldwide,[221–223] challenges in encouraging and responding to voice are widely reported within healthcare [e.g. 215] and beyond.[e.g. 149] The difficulties individuals face in raising concerns, and how these might be addressed, are the focus of a growing body of research and policy activity.

In the United Kingdom, efforts to improve voice have been driven by high-profile incidents where failure to speak up (or to listen to concerned individuals) have been implicated. Particularly notable was one the most significant disasters in English National Health Service (NHS) history—the failings at Mid Staffordshire NHS Foundation Trust, where problems of voice were endemic in the 2000s. The scandal had a profound impact on healthcare policy in England,[216] giving rise to a public inquiry [5] and corresponding responses by the government, including the commissioning of a review of culture and practice around raising concerns among healthcare professionals.[11] The review found a widespread reluctance to speak up among staff, linked to doubts about whether authorities would listen, and to concerns about retribution. It recommended several measures to foster a culture of speaking up, where “injustice to whistleblowers should become very rare indeed, [and] is redressed when it does occur.”[11] A flagship proposal from the review was the introduction of a new role, the ‘Freedom to Speak Up Guardian’, in every healthcare provider in England across the acute, mental health, community health and ambulance sectors. The Guardian role was intended “to act as an independent and impartial source of advice to staff at any stage of raising a concern, with access to anyone in the organisation, including the chief executive, or if necessary, outside the organisation.”[82]

The Freedom to Speak Up Guardian is a highly novel intervention, with no obvious parallels or precedents for the role internationally, in healthcare or elsewhere (Jones et al. in preparation). Much has been made of the role and its potential to provide guidance and support for individuals with concerns and contribute to wider cultural change about the importance of speaking up.[13] Given the ubiquity of problems of voice in healthcare systems worldwide, the Guardian role is of international interest. However, though it has received significant investment organizational and governmental investment, it has remained unevaluated. In this article, we examine the Guardian role and its potential through empirical study of the realization of the role in practice, bringing empirical evidence and theoretical insights on voice in organizations to bear on our analysis. We derive wider insights into predominant understandings of speaking up and speaking out, their implications for how voice is understood and imagined in healthcare organizations, and the consequences of this for which concerns are identified, valued, addressed and learned from.

We begin by exploring some current major themes in the literature on employee voice, noting emerging insights into influences on voice and recent analytical advances that distinguish a spectrum of heterogeneous voice behaviours. We then examine the origins of the Freedom to Speak Up Guardian role, and the form it was proposed to take in English healthcare organizations.

The dynamics of speaking and listening in healthcare

A growing literature on employee voice across multiple industries has identified a range of psychological and organizational characteristics that encourage or inhibit people in speaking up about concerns. Two strands of literature are significant in pointing towards the need for better understandings of the influences on individuals’ decisions about whether to speak up, the range of behaviours that ensue when individuals do decide to act, and the implications for any intervention seeking to foster voice.

First, a major recent theme is the psychological and organizational influences on individuals’ voice behaviour, including the complex of factors that contribute to decisions about giving voice to concerns.[e.g. 149] A common approach has been to parse these factors into attributes of the individual (candidate) speaker, and features of the organizational context in which the speaker is positioned. For example, Okuyama et al.’s[85] review finds a wealth of research devoted to identifying “the barriers and promoters of speaking up.” It distinguishes “general contextual factors” affecting a decision to speak up (such as the strength of managerial support for speaking up, and professional expectations) from “individual factors” (such as job satisfaction, sense of responsibility to patients, and confidence). In combination, these factors may render speaking up “a high-risk:low-benefit act”,[86] such that silence is a rational response. The implication is that voice might be encouraged by creating contexts that encourage and act upon on voice, and/or by endowing individuals with the inclination and ability to speak up.

This cognitive-rationalist construction of the decisions to raise concerns is, however, the subject of growing critique. Field and experimental studies demonstrate that, in any given situation, individuals draw heuristically on a range of considerations, such as their implicit understandings of whether speaking up will be deemed appropriate by a range of audiences, including managers and colleagues. For example, Detert and Edmondson [83] identify the range of 'implicit voice theories' that may guide behaviour, pointing out that these theories are often informed not by explicit cues, but by a sense that speaking up may be "wrong or out of place." Such theories may have deep roots.[224] A key corollary of this line of research is that efforts to promote voice must do more than address the formal signals conveyed by organizations about the propriety of speaking up. Indeed, mere changes to formal policy that contradict years of accumulated experience and shared lore about the consequences of voice may have exactly the opposite effect to that intended.[98]

A second, related, theme in recent literature is the contention that attempts to raise concerns are not best characterized using the binary distinction between voice and silence that has traditionally predominated. One reason for this is that, in healthcare in particular, much activity that might be the subject of concern is inherently uncertain: a matter of inevitable compromise arising from ethical trade-offs, resource limitations, imperfect information and so on.[96] Such activity may also be emergent: perhaps only rarely will a single act or event be recognized as an unambiguous imperative to speak up. What people do in response to concerns is not simple either: they may use varied tactics, including peer-to-peer communication,[136] informal concern-raising[189] and a spectrum of more formal options, often invoked incrementally.[84]

Many of these voice-related activities cannot accurately be categorized as silence,[215] but they may not be full-throated voice either. Yet, as Mannion et al.[225] discuss, policy effort and public discourse is dominated by the loudest form of voice: 'whistleblowing', defined as "the disclosure by organization members (former or current) of illegal, immoral or illegitimate practices under the control of their employers, to persons or organizations that may be able to effect action."[226] For individuals facing mundane (though nevertheless important) challenges in the ambiguous field of day-to-day clinical practice described by the likes of Bosk,[96] the world of "illegal, immoral or illegitimate practices" may have limited relevance. Their decisions about whether to give voice to concerns will be governed by very different considerations, implicit or explicit. Further, the tropes of gravity, personal sacrifice and irreversibility associated with whistleblowing cast a long shadow over all voice behaviours,[227] with the possible effect of suppressing voice in general.

The literature is clear, then, that any intervention to foster voice must seek to do more than merely provide greater opportunity to speak up, proffer administrative protections, or address only the visible aspects of organizational structures and cultures that inhibit voice. It must also be cognisant of the wider socio-cultural context that informs decisions about voice, and of the range of behaviours through which employees may raise concerns, short of the 'nuclear option' of public whistleblowing. All of these insights are relevant to understanding the institutional context in which the Freedom to Speak Up Guardian role must operate.

The Freedom to Speak Up Guardian

One of the most troubling features of the Mid Staffordshire disaster (and, as noted above, a significant driver of English healthcare policy since) was the revelation that while there was no shortage of information indicating that all was not well in the organization, those with access to this intelligence failed to act on it.[5] Characterized by some commentators [e.g. 223] as a failure of voice, and by others [e.g. 215] as a failure of listening, the implication either way was clear. At Mid Staffordshire—and perhaps in other healthcare organizations—systems and processes to ensure that informal knowledge held by those at the 'sharp end' of care was communicated and acted upon were seriously flawed.

A subsequent review of speaking up in the English NHS [11] appeared to confirm these worries. Undertaken by the lawyer who had also led independent and public inquiries into the Mid Staffordshire disaster, it found widespread reticence across the system around speaking up about quality of care, patient safety, and colleagues' behaviour, linked to a sense of futility and fear of retaliation.[11] Though framed as "a review of whistleblowing in the NHS,"[11] the report was also clear that it covered the full spectrum of voice activities "relevant to safety or the integrity of the system."[11] A survey undertaken for the review found that 30 per cent of those who had raised concerns felt unsafe afterwards, while 18 per cent of those who had not expressed a lack of faith in the system.

The recommendation to introduce the 'Freedom to Speak Up Guardian' sought to address these challenges. The review described the Guardian as "someone to whom staff can go, who is recognised as independent and impartial, has the authority to speak to anyone within or outside the trust, is expert in all aspects of raising and handling concerns, has the tenacity to ensure safety issues are addressed, and has dedicated time to perform this role."[11] Implementing the recommendation, the government mandated that each organization providing healthcare in England should appoint one or more Guardians,[13] explicitly to act as a point of contact for anyone with "a concern about risk, malpractice or wrongdoing [they] think is harming the service."[82] The roles must be funded from organizations' own resources, with Guardians' efforts coordinated by an independent national officer (later dubbed the National Guardian), with a budget of around £950,000 per annum.[228]

Notably, neither the review nor the government response offered detailed specification of the appointment, responsibilities and accountabilities of the organizational role of the Freedom to Speak Up Guardian. Introducing the role, the Secretary of State for Health described the Guardian as a "member of staff to whom other members of staff can speak if they have concerns that they are not being listened to, […] someone independent in their organisations to whom they could talk and raise their concerns" (*Hansard*, Vol. 592, Cm. 782-793, 11 February 2015). In setting out how organizations should approach implementation, the regulator NHS Improvement [82] similarly emphasised that individuals should usually approach Guardians if initial efforts to resolve concerns with line managers had failed. Guardians, it indicated, were to have "special responsibility and training in dealing with whistleblowing concerns," offering access to other paths to voice inside and outside the organization.[82] Such descriptions posit the Guardian as a 'second-line' route to voice for staff with a concern about quality, safety and colleague behaviour, to be pursued where 'first-line' acts of voice have failed. The Guardian thus acts as an "independent and impartial source of advice,"[82] sitting aloof from the compromised complex of relationships and local histories that can make speaking up difficult.

To date, beyond descriptive overviews of the role provided by the National Guardian's Office,[80,81] no research on the Guardian role has been published. Moreover, a recent literature review found that the role is largely unprecedented, in healthcare or other industries—even sectors, such as banking, vulnerable to "illegal, immoral or illegitimate practices" and corresponding whistleblowing activity (Jones et al. in preparation). It thus represents an innovative, but entirely untested, approach to facilitating voice in healthcare organizations.

Methods

We draw on data collected through a study of policy interventions to foster a culture of openness in the English NHS. We conducted semi-structured interviews with key individuals (including clinicians and administrators) involved in delivering these policies in English healthcare organizations, along with policymakers, representatives of regulatory bodies, and individuals from relevant medico-legal and third-sector organizations, as part of a wider mixed-methods policy research study.

Participants were identified through a mixture of random, purposive and snowball sampling techniques. With a view to securing representativeness, we contacted a randomly generated selection of acute trusts (20), community and mental healthcare trusts (10) and ambulance trusts (five) in England to identify potential participants. In parallel, we purposively sampled four organizations that had experienced problems with openness, as indicated by regulatory intervention and/or media coverage. Finally, we asked participants to suggest colleagues within or beyond their organizations who might be able to offer insights relating to our research questions. Wider stakeholders—such as policymakers and representatives of regulatory, third-sector and medico-legal organizations—were identified purposively in consultation with a stakeholder reference group, with snowball sampling again supplementing this initial list.

Data collection occurred between July 2017 and January 2018. We interviewed 51 stakeholders in total: 18 participants from acute hospitals (denoted Ac in data excerpt attributions), 17 from community and mental healthcare trusts (MH), and three from ambulance trusts (Am), as well as 13 wider stakeholders (WS). NHS-employed participants included 10 Freedom-to-Speak-Up Guardians of varying levels of seniority, mostly on a part-time basis as part of their wider (clinical or managerial) role, and others who had been involved in determining the scope and position of the role in their organization, and in recruitment and management of Guardians. Some job titles have been altered where they are particular to host organizations, and may be identifying. Interviews were guided by a topic guide based on a literature review and discussion among the authors, collaborators, the stakeholder reference group and a patient and public involvement group. The guide was intended to elicit participants' in-depth understanding of relevant policies, including those designed to foster voice such as the Guardian role, the clarity and unity of direction these policies provided, the process of implementing them, and incentives and disincentives to increase openness. Interviews averaged 40 minutes, and were audio-recorded and transcribed verbatim.

Supported by NVivo 11, our analytic approach was based on the constant comparative method.[52] Interview transcripts were read independently by [Author1] and [Author2], who coded the data for high-level themes derived from the evaluation brief and academic literature, and themes identified inductively from close reading of the data. We modified, developed and amalgamated codes as we read and re-read data sources. Coding was accompanied by ongoing discussion among the authors. [Author1] then reviewed all codes relating to the Guardian role, and undertook a further round of iterative, finer-grained coding based on this reading, which he used to develop an integrated analysis of the realization of the role. All three authors contributed to this analysis through further interrogation, and iterative development of the themes presented below.

Findings

We organize our findings around three themes. First, we discuss healthcare organizations' operationalization of the new role. Next, we examine the early experiences of Freedom to Speak Up Guardians themselves. We note that often the concerns voiced to Guardians differed in character from those anticipated in the role's development. Finally, we consider the implications of how the Guardians organized and focused the role in practice for its potentials and limitations in helping to make concerns about quality and safety heard. We highlight that this approach to the role suggested a rather different notion of the nature and constitution of such concerns from implied by policy and by many organizations' approaches to managing the role.

Designing and managing the Guardian role

Though some minimal guidance was available, leaders were charged with the task of designing a role for the Guardians that would work in their own organizations. Largely consistent with the role as set out by NHS Improvement,[82] they tended to cast the Guardians as a means of coordination, signposting and connectivity, with two important functions: first, raising awareness of the range of options available to those with concerns, and second, coordinating how those concerns were managed. Several participants saw the Guardian primarily as a signposter, charged with directing individuals with concerns to the right mechanisms and offices. Guardians and managers also constructed the role as crucial in ensuring that concerns were escalated to the correct level of the system, and securing an appropriate response.

> "It offers an avenue that's never existed before to raise concerns. And [...] a number of issues, they're doing quite a bit of facilitation and guiding and helping people, and also doing a bit of myth-busting as well." (Ac13: Director of Workforce)

> "People didn't know where to go. It was either, 'Well, shut up or go to the CQC

> [regulator]', or the MP [member of parliament] or whatever. Which are two very different things to do. Whereas I'm able to not just talk through the options and find a bit of a context, but also go look at the middle ground [...] so that they have more escalation mechanisms open to them should they be dissatisfied with how it's being dealt with." (Ac05: Guardian)

In a similar vein, Guardians were positioned as an independent and confidential point of contact, advising individuals who approached them of their options, assisting them in directing their concern to the appropriate authority, and identifying and addressing shortcomings in existing organizational systems.

> "It's acted as another option for people to raise concerns. [...] The Freedom to Speak Up role gives you that opportunity to raise [an issue] and discuss it with someone one-to-one and face-to-face, who—unless it's of a serious nature or a criminal investigation or ya-de-da—is able to protect that person's anonymity." (Ac06: Guardian)

> "She follows them through the whole process, she follows through to make us account for responding to them properly. She will tell me if she's got something about a service, she doesn't think it's right, and response isn't right or the response isn't happening." (MH10: Director of Nursing)

These formulations of the role were consistent with the broad policy goal of ensuring that "individuals are supported when they speak up" and that "appropriate action is taken when an issue is brought to the attention of a Freedom to Speak Up Guardian."[130]

At the same time, however, some managerial participants suggested that the boundaries of the role needed to be carefully specified and managed, not least so that it did not interfere with or undermine established channels for raising concerns. In many cases, these channels had developed in a relatively unplanned way, giving rise to a complex 'ecosystem' of routes to voice that were often tangled, ill-coordinated, and unique to each organization. Within organizations, in some units or departments a variety of routes to voice flourished and co-existed, while other areas were barren. Providing signposting and assisting in cases where first-line mechanisms for voice had failed was one thing, but there was also concern that the new role would duplicate existing procedures or create new dysfunctions by adding yet another process to an already-complex ecology. Accordingly, integrating the role into incumbent infrastructures for employee voice posed a challenge in itself.

> "There's a huge number of ways for people to raise concerns and complaints." (MH13: Deputy Chief Executive)

> "You looked at the outset, you thought, 'Well how's this going to work? How does it fit with all sorts of other things, your whistleblowing? How do you get somebody to be used in that way, to fulfil that role?'" (MH10: Director of Nursing)

Several participants sought to tightly bound the proper territory of Freedom to Speak Up Guardians in a way that mirrored official policy: "the raising of a concern relevant to safety or the integrity of the system," to use Francis's [11] phrasing. Similarly, some worried that the role could undermine cordial existing relationships between managers and staff where openness about concerns was already routine. They identified a risk of function creep, with the role straying beyond NHS Improvement's [82] emphasis on "risk, malpractice or wrongdoing," and into the domain of routine line management processes.

> "My only concern is that it encourages people perhaps to side-line some of the other mechanisms by which they could resolve issues. So most of our Freedom to Speak Up reports at the moment are things that really should have been—they're not really whistleblowing, if you know what I mean: they're issues that really could have been resolved somewhere else." (Am04: Director of Organizational Development)

> "If you've got a full-time Guardian, I don't know what they'd be doing. Without appearing to be disrespectful to that, I wonder if they're touting for business. And that's not the approach that we are taking here at all. We want our line managers to be able to respond appropriately." (Ac15: Associate Director of Governance)

Participants in executive or managerial roles accordingly sought to distinguish between what they saw as legitimate work for Freedom to Speak Up Guardians—helping those who approached them decide about whether and how to voice concerns, offering advocacy on particular issues, and raising awareness—and activity that strayed beyond this focus, and risked overriding existing mechanisms, "touting for business," or finding or even creating problems where they did not exist.

> "If they're sensible people doing a role—as long as you haven't got people who are zealots, who are looking for problems where there aren't some—I'm sure it'll be a beneficial role." (WS08: Regulatory organization representative)

> "I think for me, in terms of the real serious whistleblowing issues, then I absolutely support Freedom to Speak Up Guardians' role in that, because I do think that there's—staff need that confidence. But I do think it runs the risk, like anything, of people deliberately circumventing." (Am04: Director of Organizational Development)

For those in leadership positions, this meant identifying where the Guardian role could flourish without interfering with functional processes or upsetting the balance of the existing ecosystem, and being quite clear about whether issues fell inside or outside the Guardian's remit.

Concerns and their discontents: the role as practised

In practice, Freedom to Speak Up Guardians themselves found that the boundaries of their roles were not always easy to divine. For one thing, they had little control over the kinds of approach they received. Several Guardians interviewed found that many approaches could not readily be categorized as relating to service quality or patient safety. They instead concerned interpersonal relationships with colleagues, broadly consistent with the National Guardian's Office's [80] analysis of concerns raised across England, which found that only 32% of reported cases included an element of quality or patient safety, but 45% included an element of bullying or harassment.

> "They've been more about signposting, rather than safety issues: more about personal employment issues. I've had to signpost that. So none have come my way as whistleblowing." (MH05: Guardian)

> "I've had very few contacts in the 12, 13 months since my appointment. And when I have, it tends to be somebody disgruntled because of an individual employment issue. An HR issue." (MH16: Guardian)

Guardians indicated that they tended to support individuals who approached them with concerns that seemed to fall outside their remit, and were sometimes able to signpost to more appropriate routes through which to pursue such concerns. There was a sense among some managerial participants, however, that the role was being appropriated for purposes—particularly personnel and relationship issues—for which it was not really intended.

> "What we have got to work on is that people should be able to raise issues in their reporting line. But sadly not everybody feels they can. But at the moment my experience is that the real safety issues that people worry about, they haven't so far used the Freedom to Speak Up Guardian." (Ac02: Chief Nurse)

> "For our organization, I would say that [the Guardian] has not had the contact that she was hoping she would get. […] Most of the time it's about signposting about other things rather than about freedom to speak up." (Ac01: Director of Nursing and Quality)

Some in leadership roles thus saw personnel-related matters (and other issues not directly related to quality, safety or other matters of wider concern) as *ultra vires* for the Guardians.

Several Guardians, however, discussed their experiences of hearing concerns that appeared on first sight to relate to interpersonal dynamics among team members or grievances against superiors, but which turned out to be symptomatic of deeper pathologies—with direct or indirect consequences for quality and safety. Some Guardians noted, for example, the prerequisite of an organizational culture that was open to challenge and in which staff were valued for high-quality care.[cf. 147]

> "This isn't really the patient safety stuff. But the reason I take things on like that myself is I want to do something about it. If we're not following HR policies and procedures then we're never going to shift the culture, because there'll always be that criticism. And I just want people treated fairly." (Ac16: Guardian)

Similarly, some suggested that concerns that manifested as interpersonal or human resources-related issues might have direct consequences for quality and safety.

> "I have had quite a range. [...] People going for different positions within the trust and feeling that the job description wasn't particularly accurate. That they hadn't had relevant training for certain things. Issues, as you would expect, with harassment, bullying or discrimination. Issues with managers not allowing their staff to fully undertake the role, and as a result staff feeling a bit limited in what they can deliver for patients." (MH04: Guardian)

> "I don't turn anyone away who's suffering from bullying and harassment, because the trust has said they've got zero tolerance. [Executive director] wanted to eradicate bullying this year, which I think is a bit unlikely, unfortunately. But out of the concerns raised, it's a balance between health and safety and bullying and harassment." (Ac09: Guardian)

More broadly, Guardians found that many of the issues that colleagues brought to them could not easily be placed into a clear, well bounded category. What appeared to be specific, delimited concerns—whether about a practice or a policy or a person—often turned out to be have deeper and knottier roots. People approached Guardians both when they were unsure where to turn, and when they had concerns that were too complex, sensitive or amorphous for existing mechanisms, with their well-specified remits and terms of reference.

> "A lot of the concerns that have come my way are not about what I would term simple safety issues. [...] They're in the too-difficult box, or they're in the 'Who's going to sort it out?' box." (Ac17: Guardian)

> "I'm finding the stuff that comes my way tends to be stuff that doesn't fit in boxes, because if it did then those people would know to go to their unions or HR or their manager. [...] I do pick up anomalies. But often it's the anomalies where the big scandals come from. All this business about lessons learned et cetera et cetera, those things: the large scandals where there's the national reviews, usually they pick on processes that weren't fit for purpose." (Ac05: Guardian)

Consequently, Guardians found that they were tasked with making sense of and dealing with concerns that sometimes could not straightforwardly be dismissed, deflected to the right system, or escalated to the appropriate authority. And this meant that acting only as a passive conduit for clearly defined concerns, with responsibilities neatly demarcated from other mechanisms for voice as the high-level policy blueprint and some of their colleagues envisaged, was not viable.

Unearthing roots: maximizing the role's problem-sensing function

The most challenging—but also, potentially, the most valuable—component of some Guardians' caseload thus turned out to not to be discrete issues of the kind that could be appropriately signposted or guided through to a satisfactory conclusion, but threads that led into wider concerns in which systems, structures and past events were also implicated. And this could mean that their job was as much about co-constructing problems as sorting and directing them. When approached by individuals with issues whose shape and scope were not obvious, Guardians found that, whatever their formal terms of reference might suggest, further work was often necessary to make sense of the concern. This could often reveal more complicated issues than first apparent.

> "Because her role takes her to different wards, she was seeing the problems and thinking, 'There's something really bad going on here'. And one of the wards she particularly picked out, I wanted to see the matron, because I thought, 'Well I'll ask some questions'. I'm not supposed to investigate; I'm supposed to give things to people. But [...] I was fascinated what was going on. So I went to speak to the matron. [...] And immediately she was really defensive. [...] I sat with her for about probably an hour-and-a-quarter, hour-and-a-half in the end, and she said I'm the only person who's listened to concerns that she has and staff have about the ward." (Ac6: Guardian)

Handling such concerns effectively, Guardians felt, required active work to trace the issues presented to them and situate them within their broader organizational context. It also implied a rather different approach to the Guardian's position within the organization from that put forward by many of those responsible for implementing the role. We noted above that those in managerial roles tended to stress the need for clear demarcation from existing formal or informal routes to voice, and the policy blueprint positioned the role as an independent, second-line mechanism for concerns that had not been resolved through regular management processes. For Guardians themselves, however, a focus on independence and neutrality, and on maintaining a distance from the day-to-day commotion that faced people who might approach them, had important limitations.

> "There's a lot of previous whistleblowers who are very dismissive of Freedom to Speak Up, and they think it's a tick-box exercise. [... They] want the Freedom to Speak Up to come from outside the trust, completely independent, but I think you have an accessibility issue there. So if I had volunteers and staff who are on quite low [grades] raising concerns, I don't think they would see some non-exec who sits outside the trust as being accessible to them. And the people who've whistleblown in the past about organizations, a lot of them are ex-consultants [attending physicians], who are very confident people. [...] I don't think your average volunteer would do that, or someone who works in estates and facilities." (Ac09: Guardian)

For the more discrete, overt or egregious issues, Guardians acknowledged, independence and critical distance were important. But for concerns that were less clear-cut, or more embryonic, or where the concerned individuals were simply less powerful or less confident about what they were describing [cf. 84], something different was needed. In many cases, they suggested, the Guardian role had adapted to fulfil that function. To elicit and make sense of such concerns, they found, necessitated a proximity that would facilitate trust and understanding, and encourage colleagues to take the chance to confide in Guardians.

> "There are pluses on that, because you do have those working relationships with the staff and the board, and we do get to see things from the inside. [...] I know I can walk onto a ward and know most of the staff by name, because our turnover's quite low. It takes me sometimes quite a long time to go between meetings because you stop and have conversations in the corridor. So in terms of the approachability, I think it works." (Ac07: Guardian)

Contrary to the concerns of some managers that Guardians might intrude on others' territory or generate concerns by "touting" for business, Guardians felt that fulfilling their role effectively meant making themselves accessible, and showing themselves to be interested and engaged in the difficulties their colleagues faced. Accordingly, they saw relational dynamics as more important than procedural clarity or cold neutrality. Achieving strong relationships with their colleagues meant immersing themselves in the challenges and compromises of the clinical sharp end, not restricting themselves to a formally demarcated position in the organizational structure.

> "What I didn't want is to just be, in the perception of the people who are actually delivering the services, part of this perceived corporate bubble. [...] To speak up is to stick your head above the parapet and in order to do that, the person who you are raising the concern with, if you have seen them, if you have spoken to them or heard them speak or whatever, you have at least got that beginning of a rapport. [... You] cease to be either a person on the end of a phone, or this kind of faceless position. [...] I want to develop a rapport with people. The harder-to-reach people, you know, the BAME employees, LGBT, people with mental or physical issues, junior doctors. I have the time and the resources that enables me to target people who perhaps in previous times go under the radar." (MH04: Guardian)

Discussion

Employee voice is an important source of organizational intelligence, but effective systems for encouraging staff to speak up have remained elusive. The Freedom to Speak Up Guardian role represents a potentially promising innovation, but neither the review that recommended its creation,[11] government policy [13] nor implementation guidance [82] specified exactly how it should be operationalised. Our findings show that those responsible at organizational level for implementing the policy were eager that the role's place among existing channels for voice organizations was well-bounded. One reason for this careful boundary work was to avert the risk that it might inadvertently interfere with existing systems for speaking up, undermine other processes, or risk uncovering or even creating problems where they did not really exist. For Guardians themselves, however, such a neatly demarcated role—epitomized in the notion that they should act primarily as signposters or as a second-line mechanism when initial efforts to speak up had failed—was often estranged from the realities of the role as they put it into practice at the sharp end. The nature of the concerns brought to them frequently defied easy categorization; very few reached a threshold for whistleblowing, many were not obviously quality and safety-related, and some appeared to be signals of issues that were much more complex and wide-ranging than they first appeared.

Many parts of the Guardians' caseload turned out to not to be discrete concerns of the kind that could be readily guided through to a satisfactory conclusion, but instead were fragments of larger challenges whose totality could only initially be glimpsed. Consequently much of their activity involved active work with those who approached them, to help them construct and make sense of the hints of issues they had sensed. The Guardians' focus on the relational aspects of their work also reflects an understanding of the importance of going beyond rigid formalities, given the long shadow cast by past experiences of speaking up, and the durability of implicit assumptions about what should and should not be said.[83] If the act of speaking up is not usually the result of a conscious, rational decision-making process, then efforts to understand and influence the influences that tacitly inform people's sense of which acts of voice are appropriate will be at least as important as providing supplementary routes to voice or offering better coordination of the opportunities available. Equally, our findings show that the issues at stake in dilemmas about whether to speak do not always present themselves clearly as 'problems' that warrant disclosure: rather, like the patient safety episodes that were contorted into the shape of incident reports in Waring's [229] study, they were more diffuse, ambiguous and subject to interpretation. Such episodes can of course be readily explained away or deflected, particularly if the alternative is to construct them as 'concerns' that must be formally voiced,[84] but to do so risks missing their potential value and eroding the potential role of the Guardian as a safe haven for concerns. From this perspective, the value of the Guardian and similar roles may lie in their ability to assimilate, distil, and sometimes augment the potentially valuable intelligence that resides in ambiguous and informal voice acts.

This in turn points towards issues with the concept of whistleblowing itself. Though charged with examining "the treatment of 'whistleblowers' and their concerns," Francis [11] took care to note that (public) whistleblowing usually results from the escalation of lower-key voice behaviours, consistent research that highlights the spectrum of acts of voice between silence and whistleblowing.[e.g. 215,227] Our findings, however, suggest that whistleblowing's conceptual baggage goes beyond its association with grave, public and irreversible acts. It also assumes that the subjects of concern can be readily characterized as discrete activities that are evidently problematic, readily identifiable and probably deliberate, reflected for example in NHS Improvement's [82] reference to "concern about risk, malpractice or wrongdoing." Near and Miceli's [226] notion of the "disclosure […] of illegal, immoral or illegitimate practices […] to persons or organizations that may be able to effect action" has, as Mannion et al. [225] note, been largely taken-for-granted in the literature on employee voice within and beyond healthcare. This conceptualization of whistleblowing has evident relevance in fields such as banking, accountancy or insurance, where fraud, bribery and other deviant acts may be difficult to *detect*, but easy to *categorize* as wrongful. It is more problematic when applied to healthcare quality and safety, where—with conspicuous exceptions [e.g. 230]—catastrophic outcomes have their roots not in criminal acts, but often in decisions made in good faith in suboptimal circumstances. Where problems are more subtle, ambiguous or forgivable,[96] the decision to speak up may be equally momentous—but characterized by a different set of quandaries. In such situations, as the Guardians and some others we interviewed reported, independence or formal accountabilities may seem less important to potential speakers than the ability to understand and help make sense of the complex situations they faced.

This is not to suggest that acts of whistleblowing in the narrower sense of the term should be disregarded: on the contrary, whistleblowers' actions have been crucial in exposing persistent problems of omission or commission in several systems.[5,213,222] It is, however, to note that Guardians' contribution in supporting whistleblowers [11,13] remains as yet unproven—and indeed appears from our study and from other evidence [cf. 80] to be a relatively small component of their workload.

For the future development of the Freedom to Speak Up Guardian role, and for other healthcare systems that might seek to devise a similar intervention, our findings suggest several lessons. First, work must be done to reimagine and re-present the work of raising concerns, so that it is infused less by the connotations of whistleblowing. Voice behaviours are gradated and plural, and the subjects covered by voice may go beyond issues that are easily recognizable as safety and quality concerns. Second, given both the range of forms that voice may take and the range of issues that it may cover, limiting the remit of Guardians or similar roles to more formal acts of voice about clearly defined issues may not be the most profitable way to deploy them. If problems of healthcare quality and safety tend to have their roots in misplaced optimism or tolerance of standards that slip through time,[131] rather than in wilful acts of commission or negligence, then attention to understanding and intervening in the localized cultures that produce these traits may be a more optimal focus. Third, this implies a need for a close and embedded—rather than distant and independent—relationship between Guardians or their equivalents and their colleagues: a role that is relational rather than procedural.

While this study has important strengths, including the wide-ranging backgrounds of the interviews, the breadth of the organizations involved, and the novelty of the focus, it also has important limitations. Participants self-selected and had an interest in openness; they may not be representative of all organizations, and others may be more sceptical about the role. As an interview-based study, our analysis also rests on accounts presented by participants, which may be prone to issues such as social-desirability bias. The study also involved a relatively small number of Guardians (10); further research is required to interrogate the role, its potentials and limitations more fully.

Conclusion

The new Freedom to Speak Up Guardian role in the English NHS is rich in potential for addressing a persistent challenge for healthcare systems worldwide: inhibition of voice about quality and safety concerns. Our findings suggest, however, that to limit the role to supporting and advising those with concerns that can unambiguously be characterized as relating to quality and safety may not be the best way to exploit that potential. It was their relational work with colleagues with emergent, inchoate concerns that Guardians in this study found most fruitful, and it is this component of the role that may be most valuable for other healthcare systems looking to develop similar interventions to foster a culture in which employee voice may flourish.

G. Underlying data and analyses performed on cross-sectional survey data (WP2)

Test 1: Overall trust-level CQC ratings of sample compared to overall service-level CQC ratings of population (as at 31 July 2018)

Since trust-level ratings for the population are not readily available on the CQC website, we service-level ratings published by the CQC in its annual review of care quality for 2017-18.[105] This introduces a limitation to the analysis, since service-level distribution may differ from the trust-level distribution of the population. A χ^2 test of representativeness was performed to compare the distribution of the sample with the population, to identify possible bias in respondents' organisations' quality rating.

Rating	Population	Sample	
		Expected	Observed
Outstanding	151	4.7	5
Good	1457	45.1	36
Needs improvement	661	20.5	31
Inadequate	55	1.7	0
Total	2324		72
		χ^2 (3) = 8.98	**p = 0.030**

Test 2: Views of participants from acute and community and mental health services trusts on the overall impact of the policies on patient safety

We compared the distribution of responses to the statement 'Taken together, the policy measures […] have begun to increase the openness of staff in my organisation about concerns about patient safety' for respondents from NHS acute trusts and community and mental health service trusts, excluding non-responders and 'Don't know' responses. A χ^2 test for trend was used.

	Acute		Community and mental health	
Response	Expected	Observed	Expected	Observed
Strongly agree	9.6	8	6.4	8
Agree	24.1	24	15.9	16

Neither agree nor disagree	7.8	11	5.2	2
Disagree	1.8	1	1.2	2
Strongly disagree	0.6	0	0.4	1
Total		44		29

χ^2 (1) = 0.16 **p = 0.688**

Tests 3 and 4: Views of participants from acute and community and mental health services trusts on the impact of the Duty of Candour and Freedom to Speak Up Guardians

We compared the distribution of responses to the statements ‘The statutory Duty of Candour has helped to improve patient-staff communication following incidents’ and ‘The introduction of Freedom to Speak Up Guardians has started to encourage employees in my organisation to voice concerns about colleagues of any grade or profession’ for respondents from NHS acute trusts and community and mental health service trusts, excluding non-responders and ‘Don’t know’ responses. A χ^2 test for trend was used.

Duty of Candour

	Acute		Community and mental health	
Response	Expected	Observed	Expected	Observed
Strongly agree	9.6	9	6.4	7
Agree	21.0	21	14.0	14
Neither agree nor disagree	7.2	7	4.8	5
Disagree	4.8	7	3.2	1
Strongly disagree	1.2	0	0.8	2
Total		44		29

χ^2 (1) = 0.08 **p = 0.784**

Freedom to Speak Up

	Acute		Community and mental health	
Response	Expected	Observed	Expected	Observed
Strongly agree	6.0	7	4.0	3
Agree	20.9	20	14.1	15
Neither agree nor disagree	9.0	8	6.0	7

Disagree	3.6	5	2.4	1
Strongly disagree	0.6	0	0.4	1
Total		40		27
			χ^2 (1) = 0.07	**p = 0.790**

Tests 5, 6 and 7: The relative challenge of resources, commissioner expectations and policy clarity for the Duty of Candour, Freedom to Speak Up Guardians and the Serious Incident Framework

We compared the distribution of responses to the question to what extent have ‘Resources (financial resources and time available to staff)’, ‘Expectations of commissioners’ and ‘Lack of clarity from policy and regulatory bodies about what is expected of your organisation’ posed challenges, for the statutory Duty of Candour, Freedom to Speak Up Guardians and the Serious Incident Framework, excluding non-responders and ‘Don’t know’ responses. Friedman tests were used to ensure comparisons were made within respondents, but expected numbers of responses under the null hypothesis of no difference are shown also.

Resources	Duty of Candour		Freedom to Speak Up Guardians		Serious Incident Framework	
Response	Expected	Observed	Expected	Observed	Expected	Observed
Extremely challenging	6.2	5	5.0	3	5.8	9
Very challenging	12.4	14	10.0	6	11.6	14
Somewhat challenging	27.3	21	22.1	22	25.6	32
Slightly challenging	22.5	28	18.3	22	21.2	12
Not at all challenging	15.6	16	12.7	15	14.7	12
Total		84		68		79
			Q(2) = 18.831			**p < 0.001**

Post-hoc pairwise comparison tests reveal a significant difference (p < 0.001) between responses about Freedom to Speak Up Guardians and the Serious Incident Framework, but not other pairs. Resources for the Serious Incident Framework were seen as more challenging.

Commissioners’ expectations	Duty of Candour		Freedom to Speak Up Guardians		Serious Incident Framework	
Response	Expected	Observed	Expected	Observed	Expected	Observed
Extremely challenging	4.0	4	3.1	2	3.9	5

Very challenging	6.6	8	5.0	3	6.4	7
Somewhat challenging	16.5	17	12.5	5	16.1	23
Slightly challenging	24.2	27	18.3	18	23.5	21
Not at all challenging	26.7	22	20.2	31	26.0	20
Total		78		59		76
			Q(2) = 31.714			**p < 0.001**

Post-hoc pairwise comparison tests reveal a significant difference between responses about Freedom to Speak Up Guardians and the Duty of Candour (p = 0.001), and between Freedom to Speak Up Guardians and the Serious Incident Framework (p < 0.001). Expectations around the Freedom to Speak Up Guardians were less challenging than the others.

Regulator/policy clarity	Duty of Candour		Freedom to Speak Up Guardians		Serious Incident Framework	
Response	Expected	Observed	Expected	Observed	Expected	Observed
Extremely challenging	1.9	5	1.5	0	1.7	0
Very challenging	7.0	9	5.6	4	6.4	6
Somewhat challenging	16.6	25	13.3	8	15.1	12
Slightly challenging	28.1	21	22.5	33	25.4	22
Not at all challenging	31.4	25	25.1	23	28.5	37
Total		85		68		77
			Q(2) = 17.720			**p < 0.001**

Post-hoc pairwise comparison tests reveal a significant difference between responses about the Duty of Candour and Freedom to Speak Up Guardians (p = 0.026), and between the Duty of Candour and the Serious Incident Framework (p = 0.013). (Lack of) clarity around the Duty of Candour was seen as more challenging than the others.

Test 8: Views of participants from acute and community and mental health services trusts on the inclination of staff to speak up about patient safety

We compared the distribution of responses to the statement ‘Employees in my organisation are reluctant to speak up about concerns about patient safety because they worry about potential negative consequences for themselves’ for respondents from NHS acute trusts and community and mental health service trusts, excluding non-responders and ‘Don’t know’ responses. A χ^2 test for trend was used.

	Acute	Community and mental health

Response	Expected	Observed	Expected	Observed
Strongly agree	0.6	0	0.4	1
Agree	5.4	4	3.6	5
Neither agree nor disagree	5.4	5	3.6	4
Disagree	26.3	28	17.7	16
Strongly disagree	5.4	6	3.6	3
Total		43		29
			$\chi^2(1) = 2.24$	**p = 0.134**

H. Further details on item selection and analysis for WP3

Model fit indices and slope mean differences

Primary variables – NHS National Staff Survey (key findings)

Variable	**Model**	**X^2, Df**	**CFI**	**RMSEA**	**Wald, df**	**Slope 1 Mean**	**Mean**	**Slope 2 Mean**
Good communication between managers and staff (2008-2017) [NSSKF01]	5a	152, 97	0.98	0.05	1.76, 1	0.10%		0.70%
	6a	145, 96	0.98	0.05	5.71*, 1	0.10%	0.10%	0.70%
	5b	189, 97	0.97	0.06	2.94, 1	0.20%		0.70%
	6b	180, 96	0.97	0.06	7.70**, 1	0.20%	-0.10%	0.80%
Can contribute towards improvements (2008-2017) [NSSKF02]	5a	620, 98	0.87	0.15	0.45, 1	1.00%		0.70%
	6a	618, 97	0.87	0.15	1.90, 1	1.00%	0.00%	0.70%
	5b	612 98	0.87	0.15	0.11, 1	1.00%		0.70%
	6b	587 96	0.88	0.15	4.14*, 1	1.00%	0.00%	0.70%
Fairness and effectiveness of incident reporting procedures (2007-2017) [NSSKF03]	5a	897, 111	0.81	0.17	7.47**, 1	0.02		0.05
	6a	897, 110	0.81	0.17	0.14, 1	0.02	0.00	0.05
	5b	794, 111	0.83	0.16	13.64***, 1	0.02		0.06
	6b	786, 110	0.83	0.16	8.45**, 1	0.02	0.00	0.06

*p < 0.05; **p < 0.01; ***p < 0.001.

Primary variables – NHS Acute Inpatient Survey

Variable	**Model**	**X^2, Df**	**CFI**	**RMSEA**	**Wald, df**	**Slope 1 Mean**	**Mean**	**Slope 2 Mean**
While you were in the A&E Department, how much information about your condition or treatment was given to you? (2005-2016) [IPP01]	5a	243, 114	0.86	0.09	0.07, 1	0.27%		0.52%
	6a	242, 113	0.86	0.09	0.11, 1	0.27%	-0.00%	0.52%
	5b	241, 114	0.87	0.09	0.05, 1	0.28%		0.62%
	6b	222, 113	0.89	0.08	14.37**, 1	0.29%	-0.06%	0.75%
Were you involved as much as you wanted to be in decisions about your care and treatment? (2004-2016) [IPP02]	5a	345, 124	0.91	0.11	6.73, 1	0.31%		0.80%
	6a	345, 123	0.91	0.11	0.01, 1	0.31%	0.01%	0.80%
	5b	360, 123	0.90	0.11	9.03**, 1	0.39%		0.78%
	6b	360, 122	0.90	0.11	0.00, 1	0.39%	0.00%	0.78%
Did you find someone on the hospital staff to talk to about your worries and fears? (2004-2016) [IPP03]	5a	231, 123	0.95	0.08	8.53**, 1	-0.10%		0.23%
	6a	231, 122	0.95	0.08	0.50, 1	-0.11%	0.03%	0.22%
	5b	233, 123	0.95	0.08	4.27*, 1	-0.04%		0.15%
	6b	233, 122	0.95	0.08	0.08, 1	-0.04%	-0.01%	0.15%

*p < 0.05; **p < 0.01; ***p < 0.001.

Primary variables – NHS Community Mental Health Service User Survey

Variable	**Model**	**X^2, Df**	**CFI**	**RMSEA**	**Wald, df**	**Slope 1 Mean**	**Mean**	**Slope 2 Mean**
Did the person or people you saw listen carefully to you? (2007-2017) [MHP01]	5a	173, 77	0.41	0.15	2.95, 1	0.64%	▨	-1.72%
	6a	165, 76	0.45	0.15	9.05**, 1	0.63%	0.12%	-1.72%
	5b	206, 77	0.21	0.18	11.83***, 1	0.32%	▨	-1.92%
	6b	202 76	0.23	0.17	3.03, 1	0.34%	0.51%	-1.79%
Were you given enough time to discuss your needs and treatment? (2007-2017) [MHP02]	5a	142, 77	0.58	0.12	0.89, 1	0.73%	▨	-1.71%
	6a	141, 76	0.58	0.13	0.82, 1	-0.16%	0.07%	-0.22%
	5b	175, 76	0.36	0.15	8.30**, 1	0.32%	▨	-1.77%
	6b	175, 75	0.36	0.15	0.47, 1	0.33%	-0.16%	-1.74%
In the last 12 months have you had a formal meeting with someone from NHS mental health services to discuss how your care is working? (2007-2017) [MHP03]	5a	236, 76	0.07	0.20	4.79*, 1	2.22%	▨	1.03%
	6a	235, 75	0.06	0.20	0.51, 1	2.21%	-0.05%	1.01%
	5b	243, 77	0.03	0.20	5.16 *, 1	1.91%	▨	1.02%
	6b	231, 76	0.10	0.19	5.85**, 1	1.80%	3.23%	0.52%
Did you feel that you were treated with respect and dignity by NHS mental health services? (2007-2017) [MHP04]	5a	312, 77	0.00	0.24	0.09, 1	-0.04%	▨	-2.39%
	6a	307, 76	0.00	0.24	7.09**, 1	-0.08%	0.24%	-2.45%
	5b	323, 76	0.00	0.24	6.04**, 1	-0.39%	▨	-2.53%
	6b	250, 75	0.12	0.21	17.54***, 1	-0.05%	-6.55%	-0.38%

*p < 0.05; **p < 0.01; ***p < 0.001

Secondary variables - NHS National Staff Survey (Key Findings)

Variable	Model	X^2, Df	CFI	RMSEA	Wald, df	Slope 1 Mean	Mean	Slope 2 Mean
Suffered discrimination in last 12 months (2009-2017) [SNSSKF01]	5a	839, 81	0.75	0.20	75.56***, 1	0.90%		0.20%
	6a	836, 80	0.75	0.20	2.91, 1	0.90%	-0.00	0.20%
	5b	863, 80	0.74	0.20	1.83, 1	-0.30%		-0.20%
	6b	863, 79	0.74	0.21	0.15, 1	-0.30%	0.00	0.30%
Trust provides equal opportunities to staff (2008-2017) [SNSSKF02]	5a	208, 98	0.97	0.07	4.53*, 1	-0.70%		-0.80%
	6a	208, 97	0.97	0.07	0.56, 1	-0.70%	0.00%	-0.80%
	5b	196, 97	0.97	0.07	4.35*, 1	-0.60%		-0.90%
	6b	211, 97	0.97	0.07	0.12, 1	-0.60%	0.00%	-0.90%
Would recommend trust as place to work (2009-2017) [SNSSKF03]	5a	430, 81	0.898	0.135	0.23, 1	0.02		0.02
	6a	441, 83	0.895	0.135	6.57**, 1	0.02	0.01	0.02
	5b	432, 80	0.897	0.136	1.35, 1	0.03		0.01
	6b	440, 83	0.896	0.135	6.08*, 1	0.03	-0.00	0.01

*p < 0.05; **p < 0.01; ***p < 0.001

Secondary variables - NHS National Staff Survey (Individual items)

Variable	**Model**	**X^2, Df**	**CFI**	**RMSEA**	**Wald, df**	**Slope 1 Mean**	**Mean**	**Slope 2 Mean**
The team I work in often meets to discuss the team's effectiveness. (2010-2017) [SNSSID02]	5a	498, 67	0.91	0.17	0.66, 1	0.02		-0.00
	6a	498, 66	0.91	0.17	0.45, 1	0.02	0.00	-0.00
	5b	486, 67	0.91	0.16	4.95*, 1	0.02		-0.01
	6b	485, 66	0.91	0.16	0.33, 1	0.02	0.00	-0.01
Team members have to communicate closely with each other to achieve the team's objectives. (2010-2017) [SNSSID03]	5a	169, 67	0.96	0.08	0.08, 1	0.03		0.01
	6a	164, 66	0.96	0.08	4.44*, 1	0.03	0.00	0.01
	5b	148, 67	0.97	0.07	0.01, 1	0.02		0.01
	6b	145, 66	0.97	0.07	2.47, 1	0.02	0.00	0.01

*p < 0.05; **p < 0.01; ***p < 0.001

Secondary variables - NHS Acute Inpatient Survey

Variable	**Model**	**X^2, Df**	**CFI**	**RMSEA**	**Wald, df**	**Slope 1 Mean**	**Mean**	**Slope 2 Mean**
Did doctors talk in front of you as if you weren't there? (2004-2016) [SIP04]	5a	317, 124	0.92	0.10	2.60, 1	0.12%		0.60%
	6a	316, 123	0.91	0.10	0.56, 1	0.12%	-0.02%	0.61%
	5b	334, 123	0.91	0.11	3.99 *, 1	0.17%		0.62%
	6b	330, 122	0.91	0.11	3.37, 1	0.18%	-0.02%	0.58%
Did nurses talk in front of you as if you weren't there? (2004-2016) [SIP07]	5a	317, 124	0.92	0.10	2.60, 1	0.12%		0.60%
	6a	316, 123	0.91	0.10	0.56*, 1	0.12%	-0.02%	0.61%
	5b	334, 123	0.91	0.11	3.99, 1	0.17%		0.62%
	6b	330, 122	0.91	0.11	3.37, 1	0.18%	-0.02%	0.58%
How many minutes after you used the call button did it usually take before you got the	5a	225, 124	0.96	0.07	7.22**, 1	-0.56%		0.34%
	6a	225, 123	0.96	0.07	0.58, 1	-0.56%	0.01%	0.34%
	5b	240, 123	0.95	0.08	6.00**, 1	-0.48%		0.50%

help you needed? (2004-2016) [SIP09]	6b	237, 122	0.95	0.08	2.73, 1	-0.48%	-0.01%	0.52%
Beforehand, did a member of staff explain the risks and benefits of the operation or procedure in a way you could understand? (2005-2016) [SIP10]	5a	166, 107	0.95	0.061	4.93*, 1	0.06%	▨	0.28%
	6a	166, 106	0.95	0.06	0.75. 1	0.06%	0.02%	0.28%
	5b	173, 106	0.94	0.07	3.50, 1	0.06%	▨	0.38%
	6b	173, 105	0.94	0.07	0.66, 1	0.06%	-0.00%	0.38%
Did a member of staff explain what would be done during the operation or procedure? (2005-2016) [SIP11]	5a	183, 107	0.93	0.07	1.53, 1	0.14%	▨	0.44%
	6a	172, 106	0.94	0.06	9.49**, 1	0.14%	0.11%	0.44%
	5b	183, 107	0.93	0.07	11.47***, 1	0.17%	▨	0.49%
	6b	181, 105	0.93	0.07	1.01, 1	0.17%	0.00%	0.50%
Were you told how you could expect to feel after you had the operation or procedure? (2005-2016) [SIP13]	5a	143, 107	0.97	0.05	1.35, 1	0.36%	▨	0.78%
	6a	139, 106	0.97	0.05	3.52, 1	0.37%	-0.01%	0.81%
	5b	140, 106	0.97	0.05	5.18*, 1	0.37%	▨	0.98%
	6b	139, 105	0.97	0.05	0.71, 1	0.37%	0.02%	0.95%
After the operation or procedure, did a member of staff explain how the operation or procedure had gone in a way you could understand? (2005-2016) [SIP14]	5a	164, 107	0.95	0.06	2.25, 1	0.01%	▨	-0.08%
	6a	159, 106	0.96	0.06	4.45*, 1	0.42%	0.09%	0.88%
	5b	168, 106	0.95	0.06	2.80, 1	0.47%	▨	0.96%
	6b	165, 105	0.95	0.06	2.07, 1	0.47%	0.03%	0.95%
Before you left hospital, were you given any written or printed information about what you should or should not do after leaving hospital? (2007-2016) [SIP15]	5a	246, 75	0.893	0.12	4.42*, 1	1.74%	▨	-1.31%
	6a	234, 74	0.900	0.12	8.53**, 1	1.68%	1.17%	-1.49%
	5b	140, 75	0.959	0.08	0.29, 1	1.46%	▨	-2.06%
	6b	137, 74	0.961	0.08	2.90, 1	1.45%	0.18%	-2.11%

Did a member of staff tell you about any danger signals you should watch for after you went home? (2004-2016) [SIP16]	5a	181, 122	0.98	0.06	2.78, 1	0.85%		0.65%
	6a	174, 121	0.98	0.05	4.93*, 1	0.84%	0.34%	0.54%
	5b	170, 121	0.98	0.05	3.01, 1	0.92%		0.27%
	6b	169, 120	0.98	0.05	1.46, 1	0.91%	0.12%	0.22%
During your hospital stay, were you ever asked to give your views on the quality of your care? (2005-2016) [SIP18]	5a	658, 114	0.57	0.57	2.78, 1	2.05%		1.06%
	6a	507, 113	0.69	0.15	34.71***, 1	1.87%	5.41%	-0.63%
	5b	631, 114	0.60	0.17	0.18, 1	2.33%		-0.38%
	6b	611, 113	0.61	0.17	13.72***, 1	2.34%	0.62%	-0.44%
Did you see, or were you given, any information explaining how to complain to the hospital about the care you received? (2007-2016) [SIP19]	5a	1494, 81	0.14	0.34	90.45***, 1	-1.80%		-1.49%
	6a	1493, 80	0.14	0.35	1.24, 1	-1.78%	-0.21%	-1.47%
	5b	1501, 81	0.13	0.34	155.06***, 1	-1.66%		-1.71%
	6b	1492, 81	0.14	0.35	10.61**, 1	-1.66%	-0.32%	-1.67%

*p < 0.05; **p < 0.01; ***p < 0.001

Secondary variables – NHS Community Mental Health Service User Survey

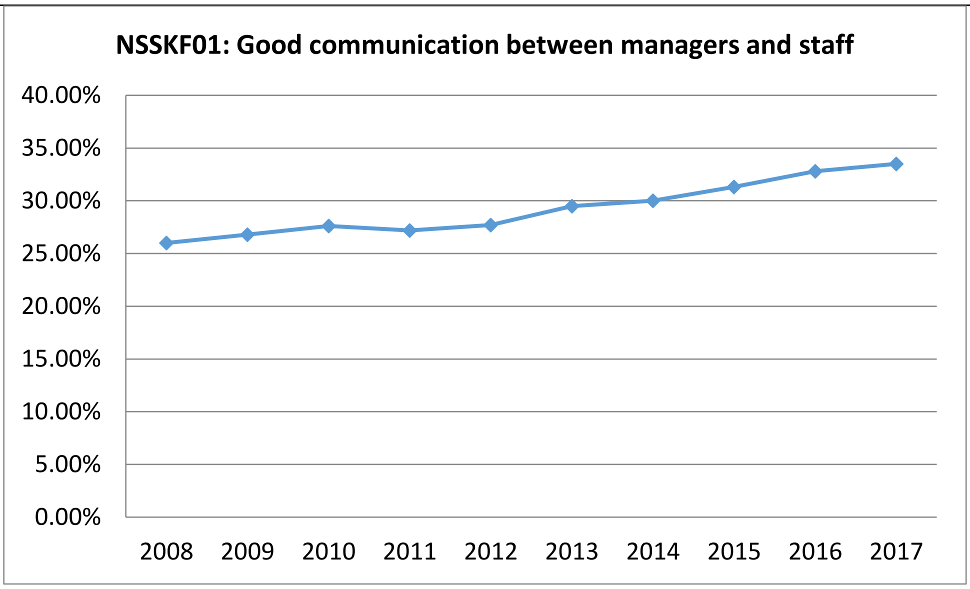
Variable	**Model**	**X^2, Df**	**CFI**	**RMSEA**	**Wald, df**	**Slope 1 Mean**	**Mean**	**Slope 2 Mean**
Were you involved as much as you wanted to be in decisions about which medicines you receive? (2007-2017) [SMHP02]	5a	212, 77	0.00	0.18	4.13*, 1	2.19%		-0.69%
	6a	212, 76	0.00	0.18	0.36, 1	2.18%	0.07%	-0.69%
	5b	258, 77	0.00	0.20	12.86**, 1	1.75%		-0.88%
	6b	258, 76	0.00	0.21	0.11, 1	1.75%	-0.05%	-0.85%
In the last 12 months, has an NHS mental health worker checked with you about how you are getting on with your medicines? (2010-2017)	5a	335, 50	0.00	0.32	1.16, 1	1.62%		-1.25%
	6a	313, 49	0.00	0.31	12.25**, 1	1.16%	3.82%	-1.79%
	5b	294, 49	0.00	0.30	0.38, 1	1.35%		-2.04%
	6b	277, 48	0.00	0.29	12.16**, 1	1.47%	-2.23%	-1.12%

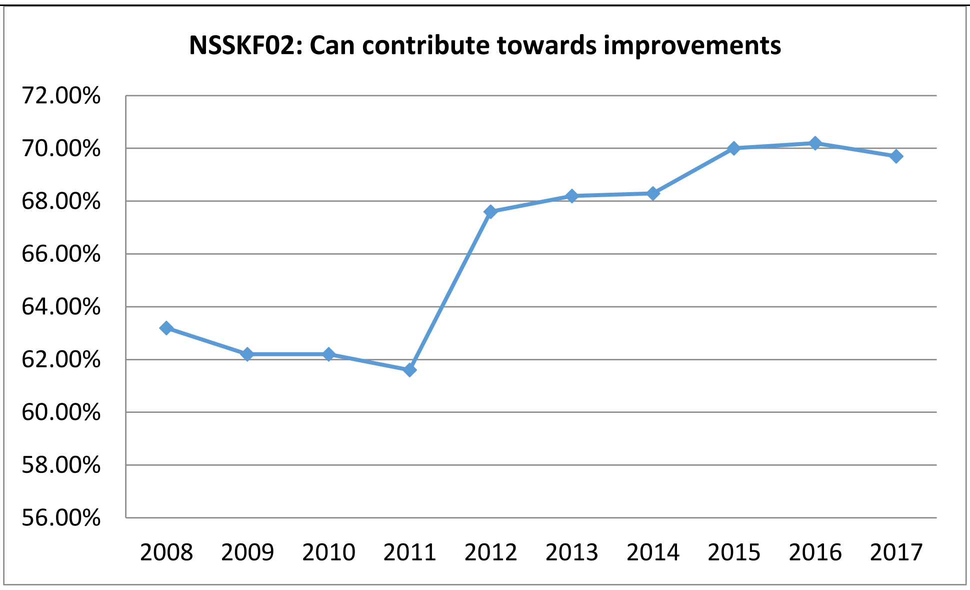
[SMHP04]								

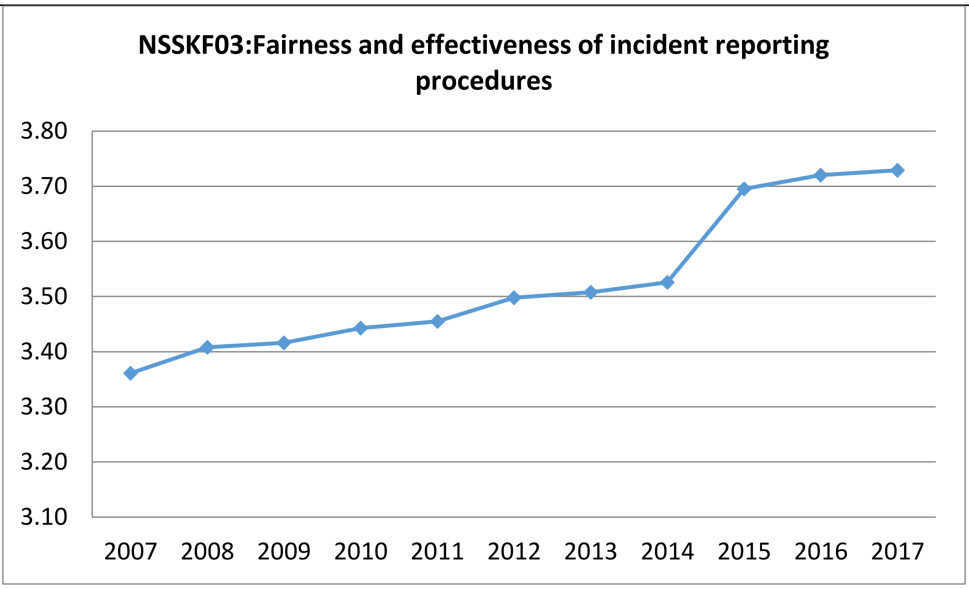
*p < 0.05; **p < 0.01; ***p < 0.001

Growth curve graphs

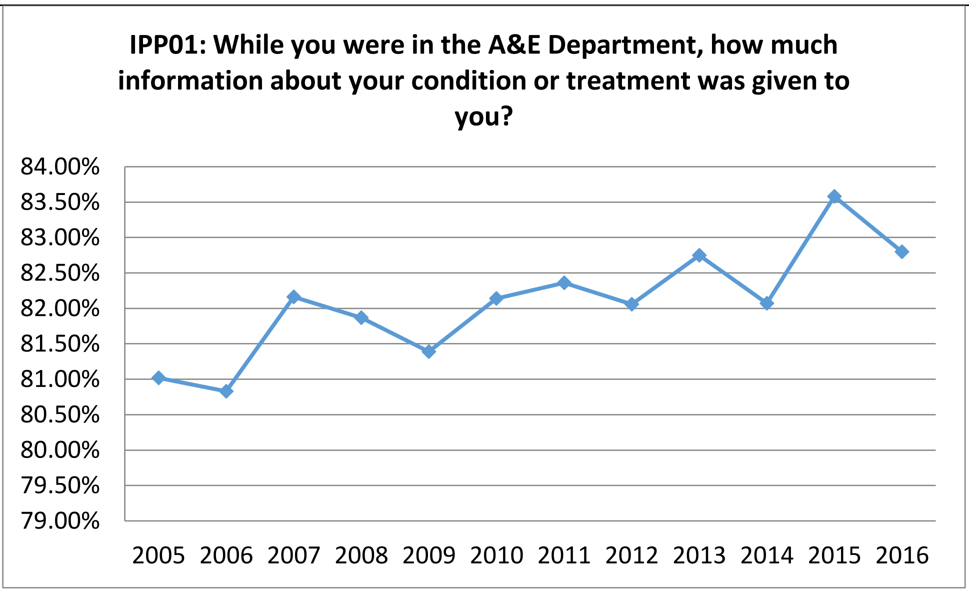
Primary variables: NHS National Staff Survey (key findings)

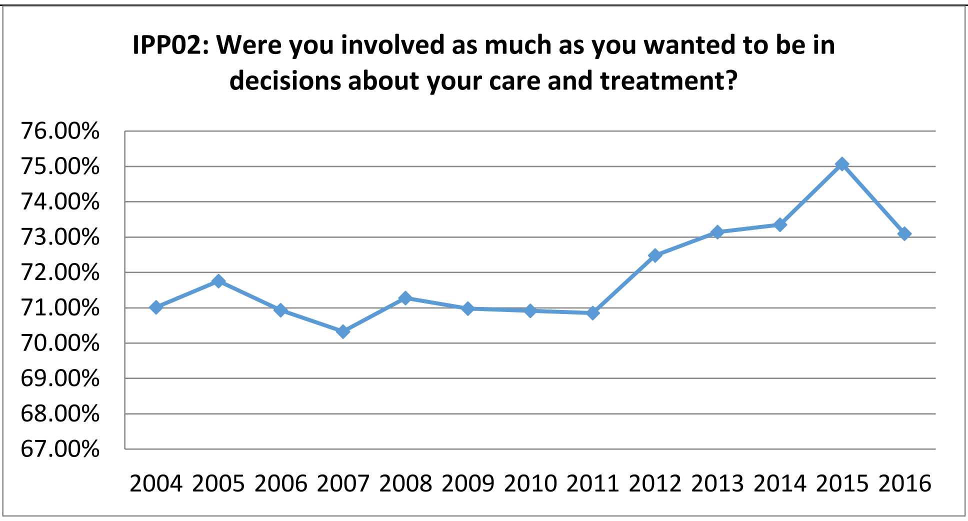


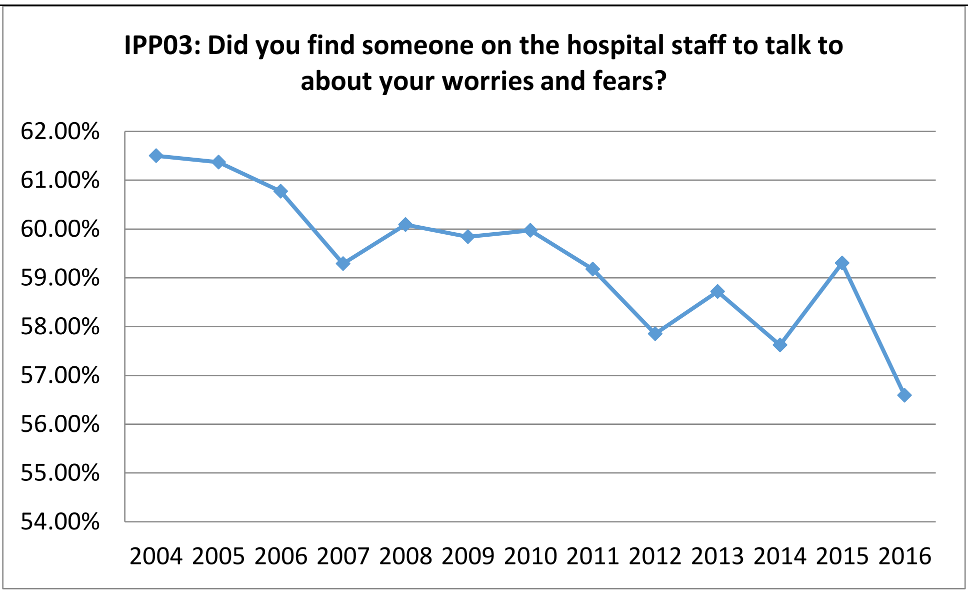




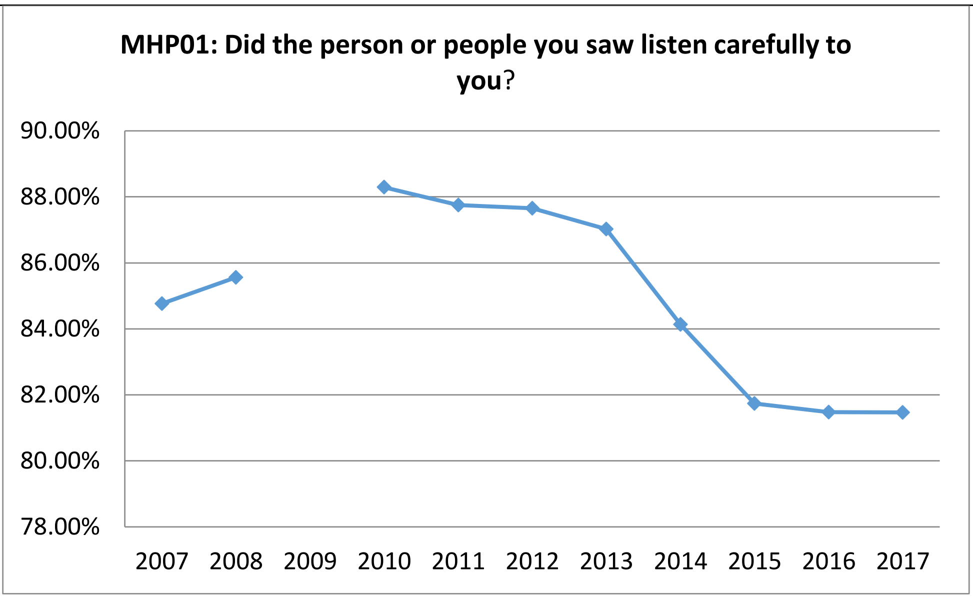
Primary variables: NHS Acute Inpatient Survey

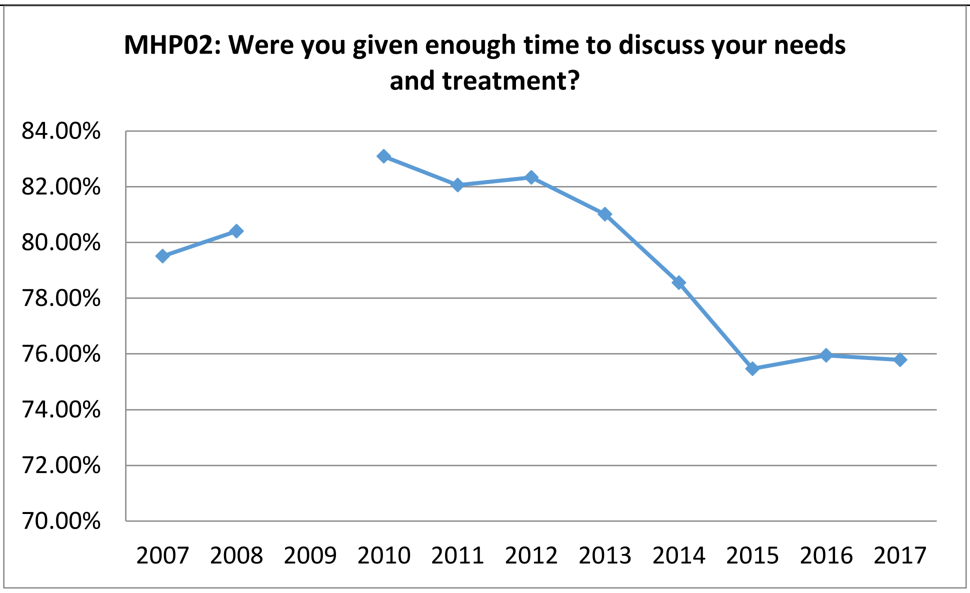


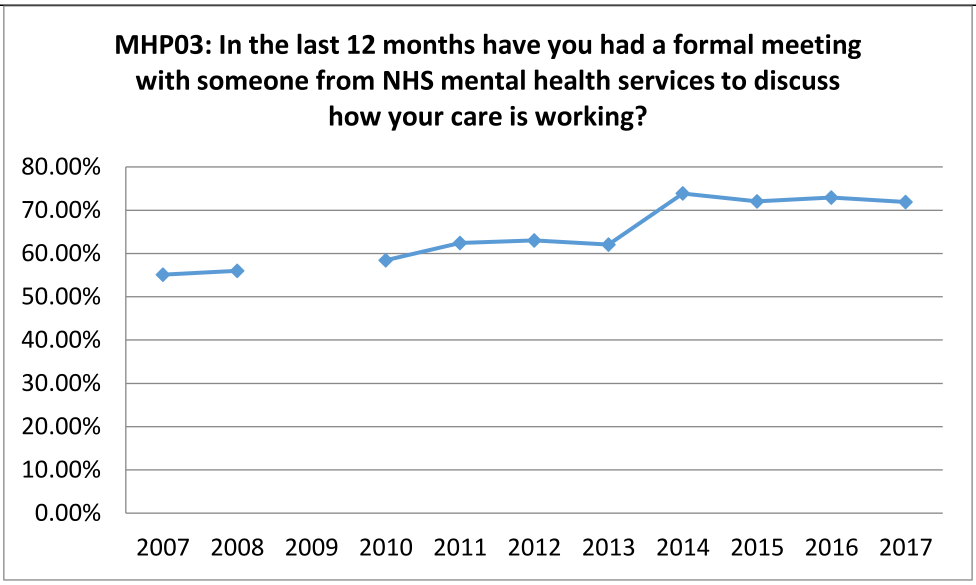

IPP02: Were you involved as much as you wanted to be in decisions about your care and treatment?
76.00%
75.00%
74.00%
73.00%
72.00%
71.00%
70.00%
69.00%
68.00%
67.00%
2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016

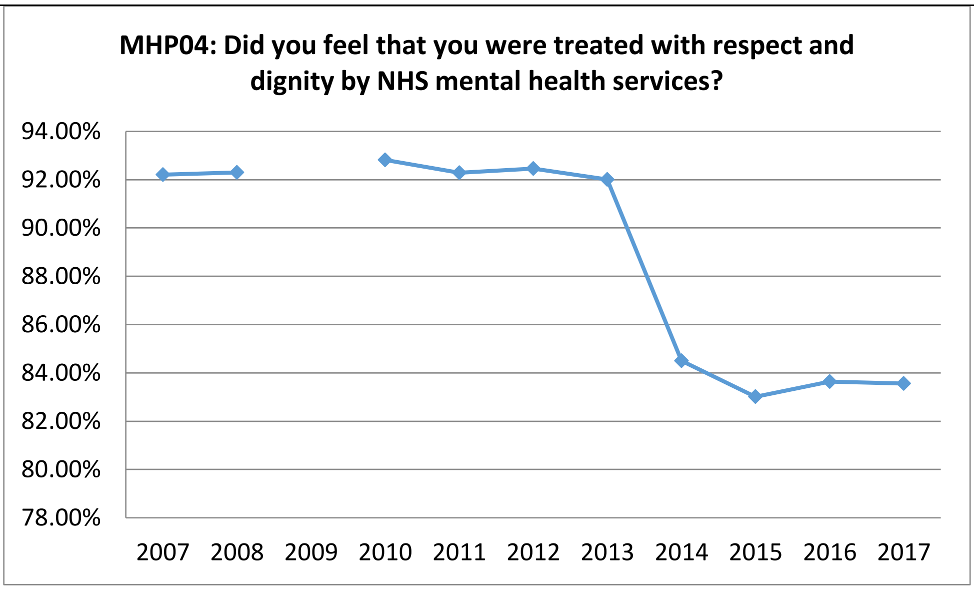

IPP03: Did you find someone on the hospital staff to talk to about your worries and fears?
62.00%
61.00%
60.00%
59.00%
58.00%
57.00%
56.00%
55.00%
54.00%
2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016

Primary variables: NHS Community Mental Health Service User Survey

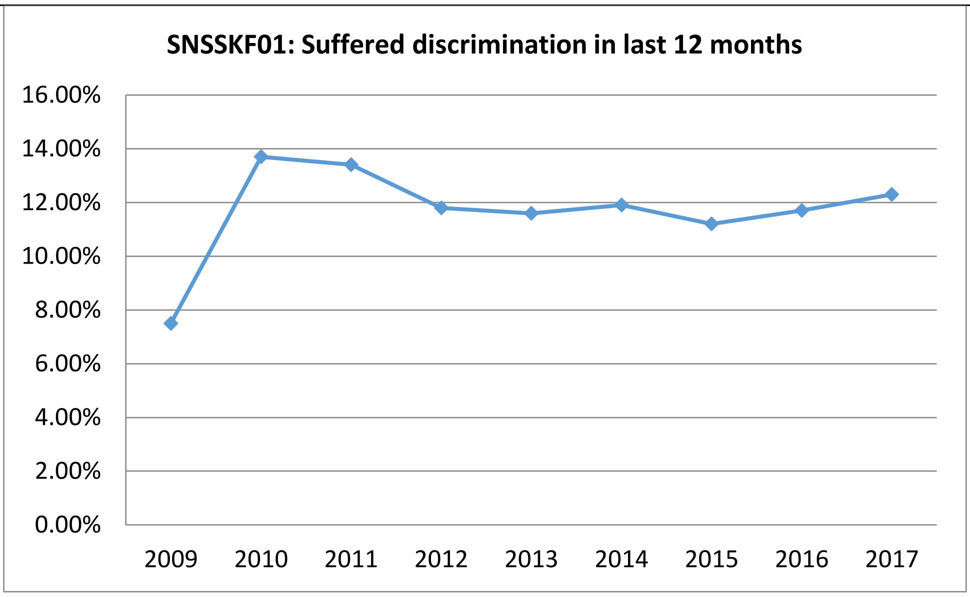


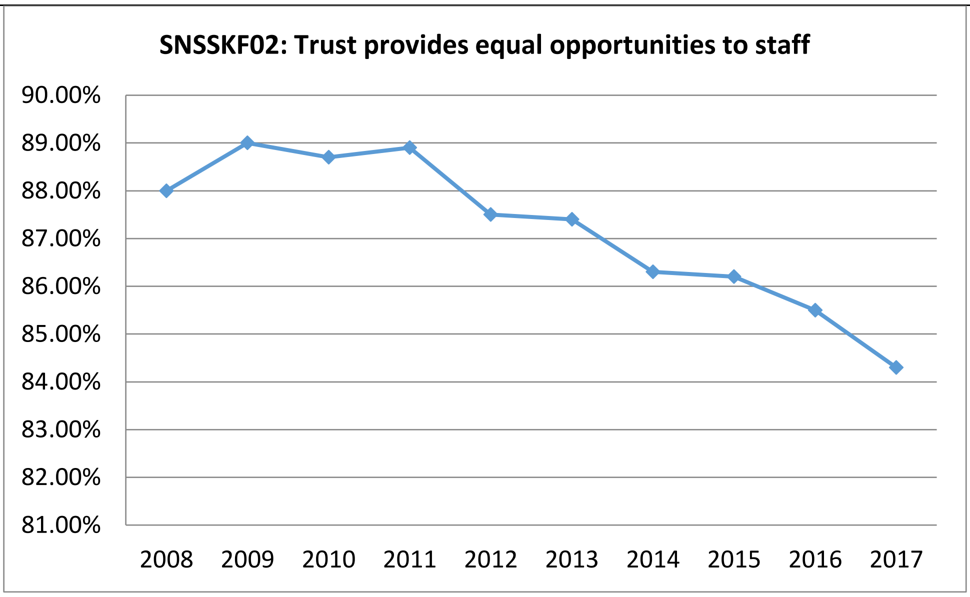


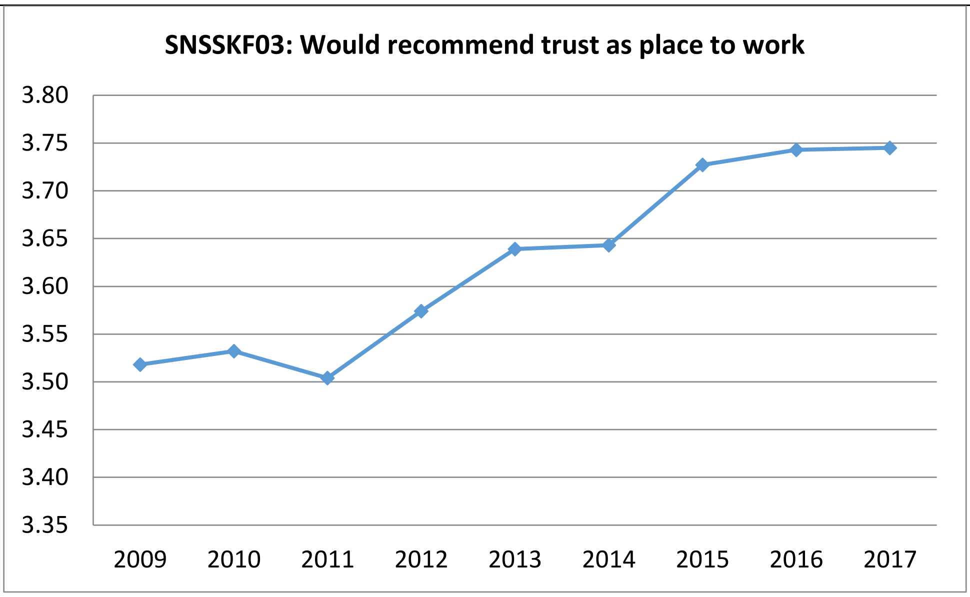

MHP03: In the last 12 months have you had a formal meeting with someone from NHS mental health services to discuss how your care is working?


MHP04: Did you feel that you were treated with respect and dignity by NHS mental health services?

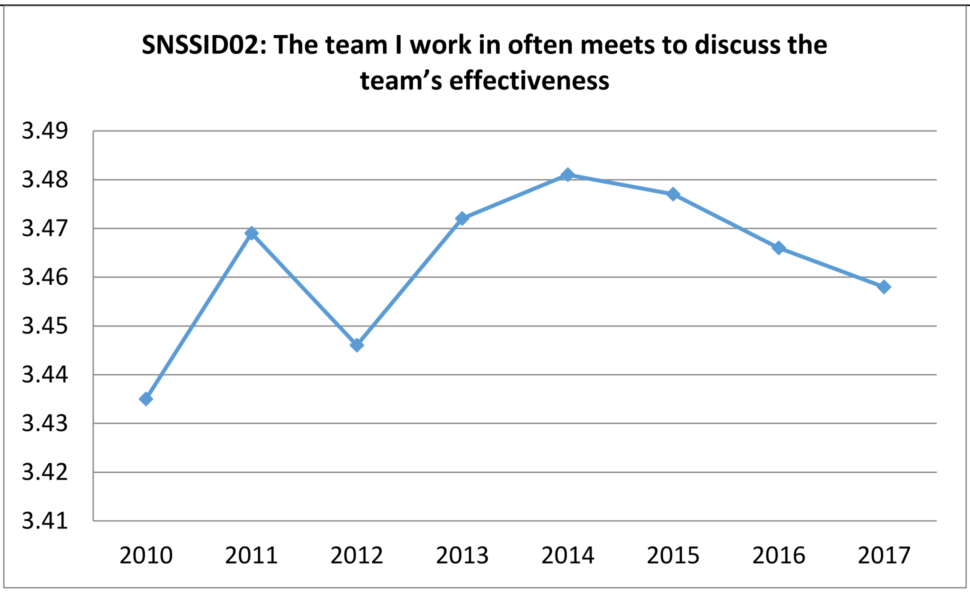
Secondary variables: NHS National Staff Survey (key findings)



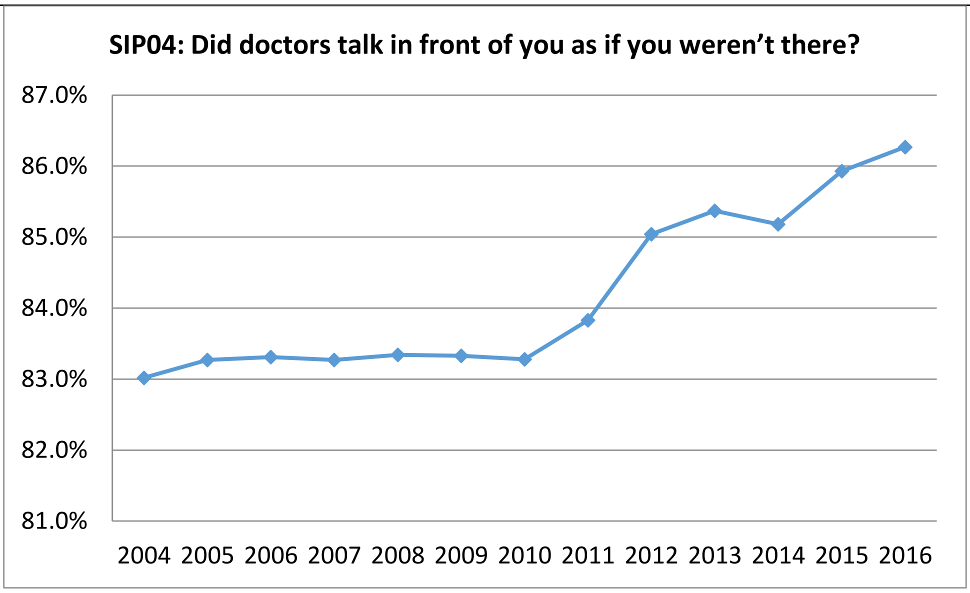


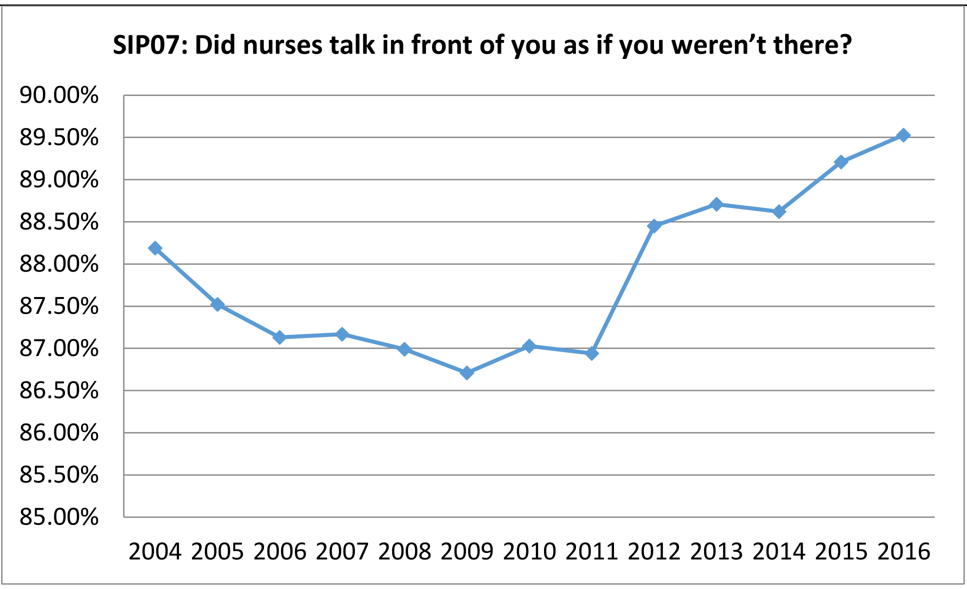


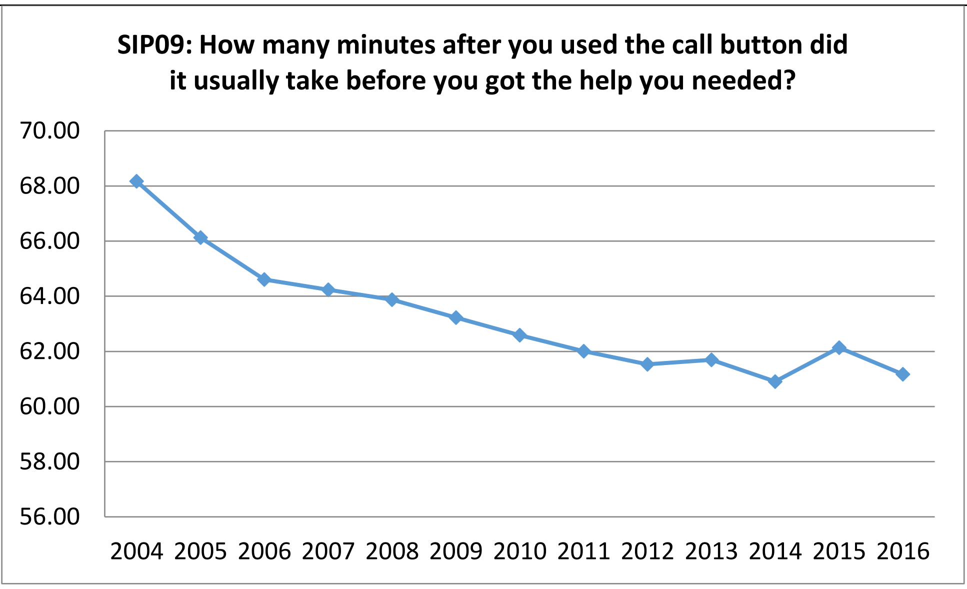
Secondary variables: NHS National Staff Survey (individual items)

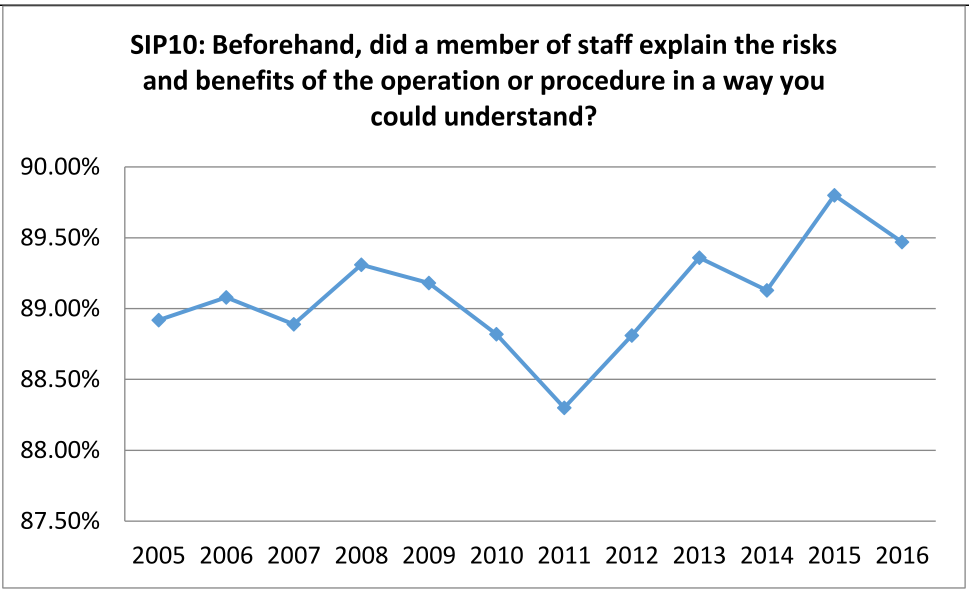


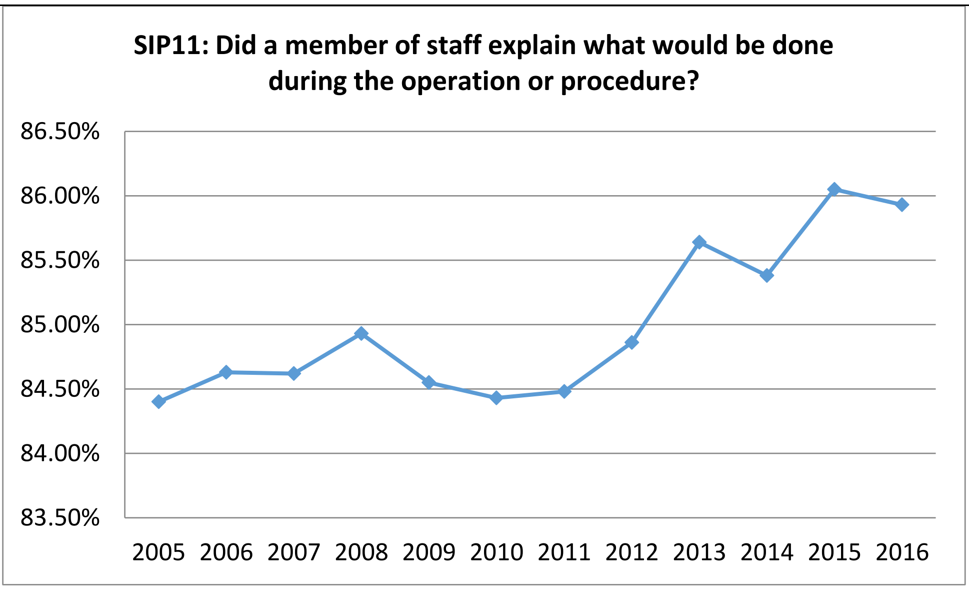
Secondary variables: NHS Acute Inpatient Survey

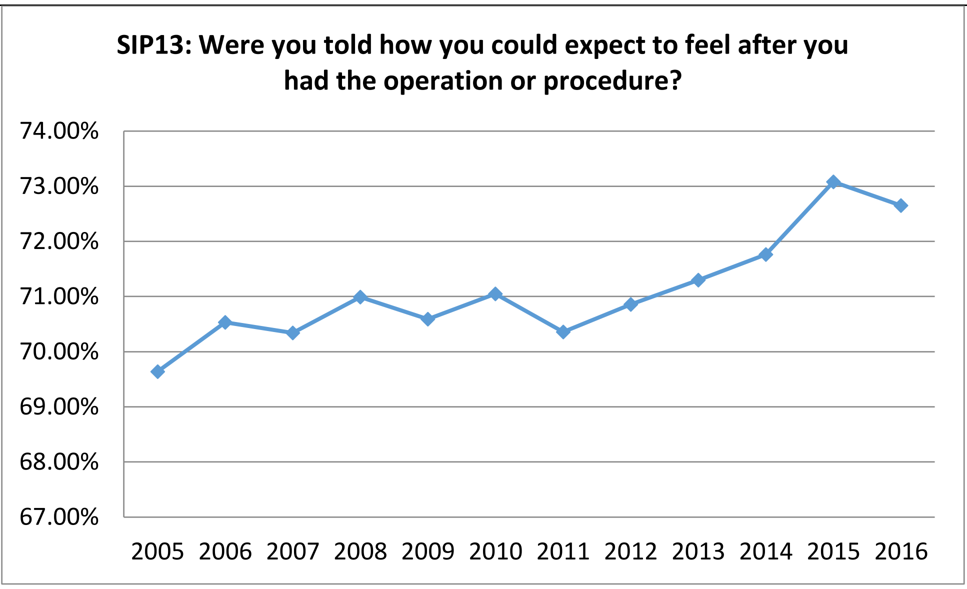


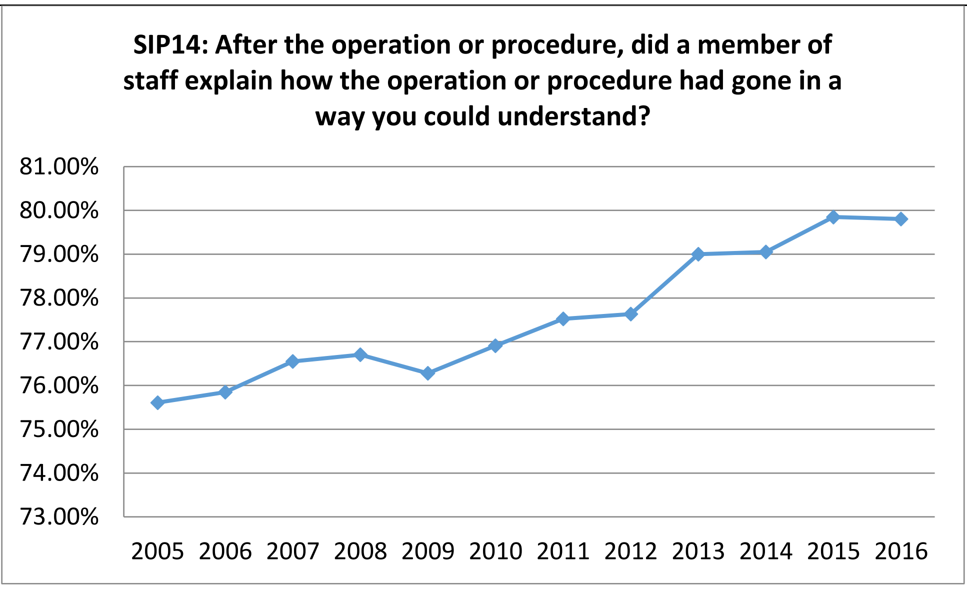

SIP07: Did nurses talk in front of you as if you weren't there?
90.00%
89.50%
89.00%
88.50%
88.00%
87.50%
87.00%
86.50%
86.00%
85.50%
85.00%
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016

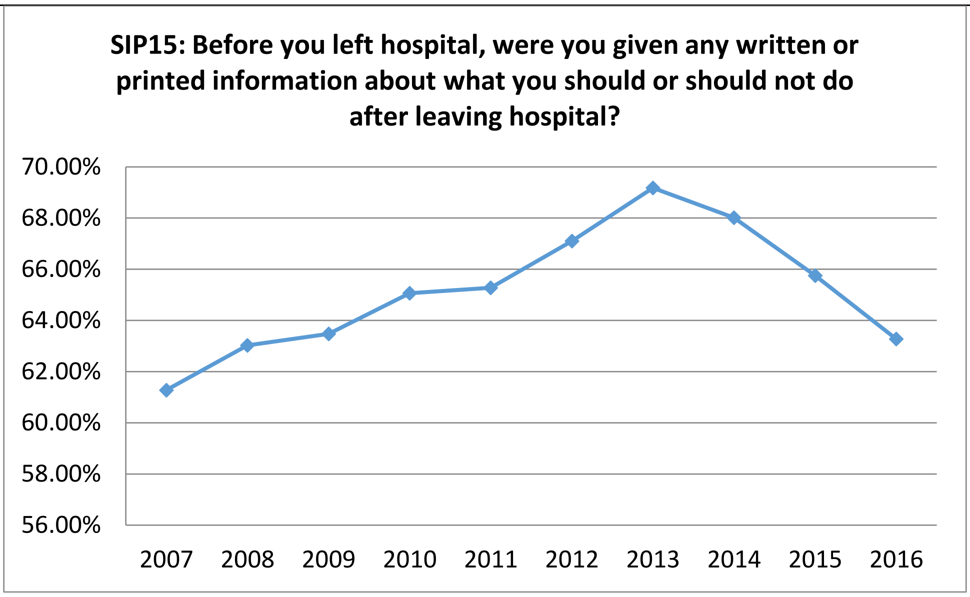

SIP09: How many minutes after you used the call button did it usually take before you got the help you needed?
70.00
68.00
66.00
64.00
62.00
60.00
58.00
56.00
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016

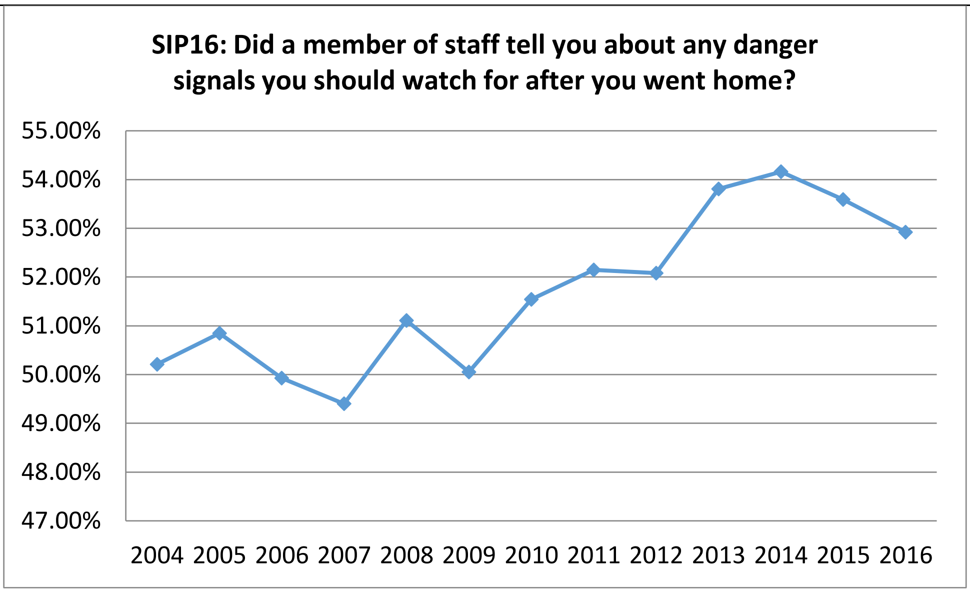

SIP10: Beforehand, did a member of staff explain the risks and benefits of the operation or procedure in a way you could understand?
90.00%
89.50%
89.00%
88.50%
88.00%
87.50%
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016


SIP11: Did a member of staff explain what would be done during the operation or procedure?
86.50%
86.00%
85.50%
85.00%
84.50%
84.00%
83.50%
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016

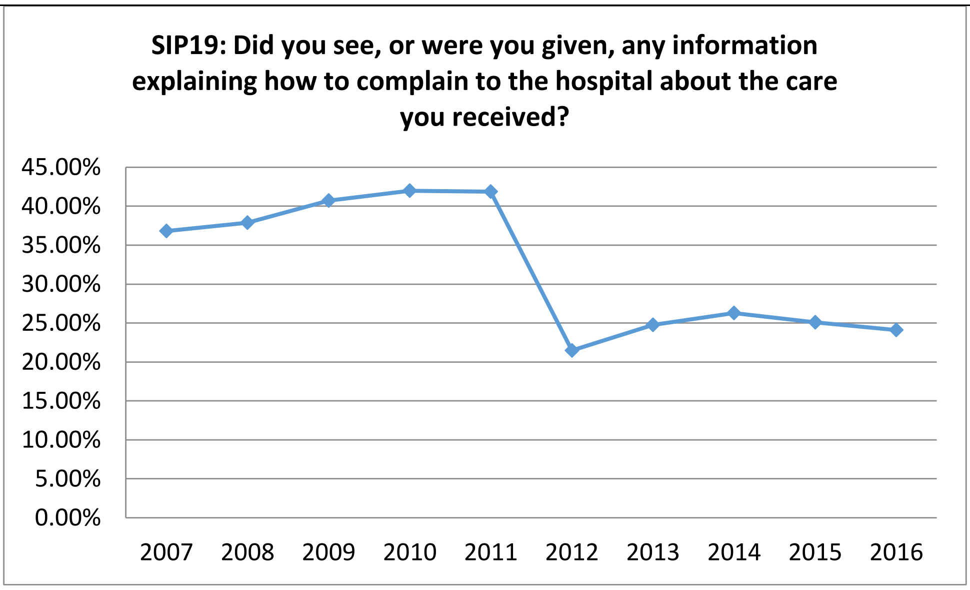

SIP13: Were you told how you could expect to feel after you had the operation or procedure?
74.00%
73.00%
72.00%
71.00%
70.00%
69.00%
68.00%
67.00%
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016


SIP14: After the operation or procedure, did a member of staff explain how the operation or procedure had gone in a way you could understand?
81.00%
80.00%
79.00%
78.00%
77.00%
76.00%
75.00%
74.00%
73.00%
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016

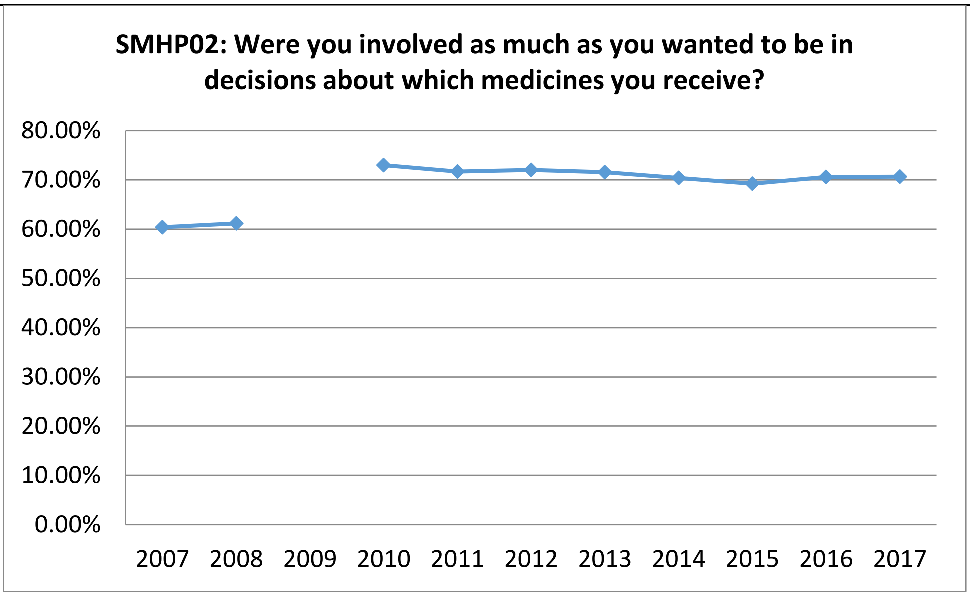

SIP15: Before you left hospital, were you given any written or printed information about what you should or should not do after leaving hospital?

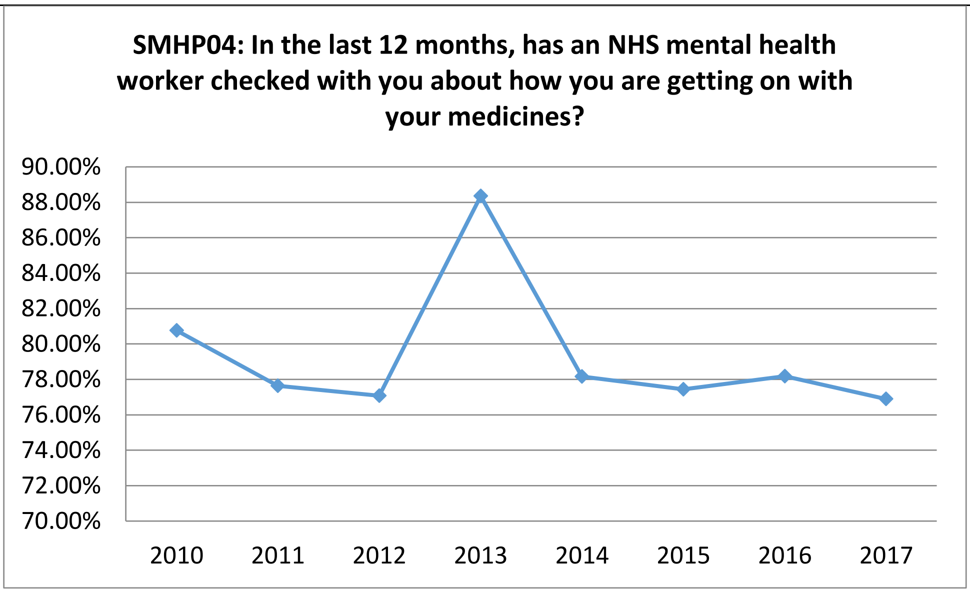

SIP16: Did a member of staff tell you about any danger signals you should watch for after you went home?


SIP18: During your hospital stay, were you ever asked to give your views on the quality of your care?


SIP19: Did you see, or were you given, any information explaining how to complain to the hospital about the care you received?

Secondary variables: NHS Community Mental Health Service User Survey





Items excluded due to question format changes

The items below were excluded from the analysis due question format changes which meant the statistical models did not converge.

Primary variables

- NHS National Staff Survey
    - Key finding: Last error seen reported (2009-2017): This is the percentage of staff that had, in the last month, seen errors, near misses, or incidents that could have hurt staff or patients and said that they or a colleague had reported it. This key finding cannot be included in the analysis because the format of the question changed between 2009 and 2017. Prior to 2012 one of the questions that formed this key finding altered. Reference to

errors that impact on ‘patients’ and ‘staff’ were initially measured as two separate questions. From 2012 onward the questions merged.

Secondary variables

- NHS National Staff Survey
    - Key finding: Experienced harassment, bullying or abuse from colleagues (2006 - 2017): This is the percentage of staff that, in the previous 12 months, had experienced harassment, bullying or abuse from colleagues or managers. This key finding was excluded from the analysis because up until 2011 the response options were binary (yes/no), but from 2012 onward the response options changed to categorical (I have experienced harassment, bullying or abuse: never, 1-2 times, 3-5 times, 6-10 times, more than 10 times).
    - Key finding: Experienced violence from colleagues (2006 - 2017): This is the percentage of staff that, in the previous 12 months, had experienced physical violence from colleagues or managers. This key finding was excluded from the analysis because up until 2011 the response options were binary (yes/no), but from 2012 onward the response options changed to categorical (I have experienced violence: never, 1-2 times, 3-5 times, 6-10 times, more than 10 times).

Items excluded due to non-model fit

The items below were excluded from the analysis due to the models used (PGCM and ITS) not fitting the data well enough to attribute any change to the publication of the Francis report. The items that follow showed an increase over time but not a significant increase that could be attributed to the study period (2012/2013).

Primary Variables

- NHS Acute Inpatient Survey
    - Did you feel you were treated with respect and dignity while you were in the hospital? (2004-2016) Contemplating their overall experience of inpatient care, participants were asked to consider whether they felt they were treated with respect and dignity whilst in hospital. This item was measured as a percentage ranging from zero (no) to 100% (yes, always). [IPP04]

Secondary variables

- NHS National Staff Survey
    - Key finding: Support from supervisor (2006-2017): Support from immediate managers assesses the extent to which employees feel their manager or supervisor provides them with support, guidance and feedback on their work and takes into account their opinions before making decisions that affect them. This item is measured on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). [SNSSKF04]
    - I am involved in deciding on changes introduced that affect my work area / team / department. (2006-2017): This question is about employee involvement, the extent to which staff can take part in decisions and have influence in matters that affect their work area, team or department. This item is measured on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). [SNSSID01]
    - I am satisfied with the recognition I get for good work. (2006-2017): This question considered whether employees were satisfied with the recognition they received after a job well done. The question is scored on a five-point Likert scale ranging from 1 (very dissatisfied) to 5 (very satisfied). [SNSSID04]
- NHS Acute Inpatient Survey

  - How much information about your condition or treatment was given to you? (2004-2016): Patients were asked to consider whether they felt the amount of information they were given in A&E department about their condition or treatment was sufficient. This item is measured on a percentage ranging from zero (not enough or too much) to 100% (the right amount). [SIP01]
  - Did you have confidence and trust in the doctors treating you? (2004-2016): This question explored whether patients felt confidence and trust in the doctors treating them. This item is measured a percentage ranging from zero (no) to 100% (yes, always). [SIP03]
  - Did you have confidence and trust in the nurses treating you? (2004-2016): This question investigated whether patients felt a sense of confidence and trust in the nurses treating them. This item is measured on a percentage ranging from zero (no) to 100% (yes, always). [SIP06]
  - Did hospital staff tell you who to contact if you were worried about your condition or treatment after you left hospital? (2004-2016): This item assessed whether patients knew who to contact if they had concerns about their condition or treatment following discharge from hospital. This item is measured on a percentage ranging from zero (no) to 100% (yes). [SIP17]
  - Did a member of staff answer your questions about the operation or procedure in a way you could understand? (2005-2016): This item explored whether patients received information about their care in a way that was comprehendible. This item is measured on a percentage ranging from zero (no) to 100% (yes). [SIP12]
  - Sometimes in a hospital, a member of staff will say one thing and another will say something quite different. Did this happen to you? (2006-2016): This item explored the extent to which patients received conflicting messages and is measured a percentage ranging from zero (yes) to 100% (no). [SIP08]
  - When you had important questions to ask a doctor, did you get answers that you could understand? (2004-2016): This item assessed whether patients received comprehendible answers from doctors and is measured a percentage ranging from zero (no) to 100% (yes). [SIP02]
  - When you had important questions to ask a nurse, did you get answers that you could understand? (2004-2016): This item assessed whether patients received comprehendible answers from nurses and is measured a percentage ranging from zero (no) to 100% (yes). [SIP05]
- Community Mental Health Service User Survey
  - Do you know who to contact out of office hours if you have a crisis? (2007-2017): This item assessed service users' awareness of crisis care protocols and whether patients know who to contact out of hours if they have a crisis. This item is measured as a percentage ranging from zero (no) to 100% (yes). [SMHP01]
  - The last time you had a new medicine prescribed for your mental health needs, were you given information about it in a way that you were able to understand? (2010-2017): Measured as a percentage ranging from zero (no) to 100% (yes, definitely) this question assesses whether patients, have access to and/or fully comprehend information relating to new medications. [SMHP03]

I. Output: ‘Openness in the NHS: a secondary longitudinal analysis of National Staff and Patient Surveys’

This paper is currently under review with *BMC Health Services Research* (authors: McCarthy, I., Dawson, J. and Martin, G.P.).

Abstract

Objective: Using data from NHS annual surveys of staff and patients this study aims to explore perceptions of openness before and after the publication of the Francis report (2013) by examining whether staff and patients’ views on openness, and experiences of giving voice to concerns, have changed over time for better or worse.

Methods: Organisational-level data was collated for all trusts from the NHS National Staff Survey (2007-2017), NHS Acute Inpatient Survey (2004-2016) and NHS Community Mental Health Service User Survey (2007-2017). Survey items related to openness were identified and longitudinal statistical analysis conducted (piecewise growth curve and interrupted latent growth curve analysis) to determine whether there was evidence of a shift in the rate or direction of change following publication of the Francis report.

Results**:** For some indicators of openness, there was a discernible change in trajectory when comparing trends over time before and after the publication of the Francis report. For most openness questions in the NHS National Staff Survey, there was a positive increase in the rate of change after 2013. For the NHS Acute Inpatient and NHS Community Mental Health Service User Surveys, there was a more mixed picture: while the general trend in the measures from the NHS Acute Inpatient Survey was positive, for the measures from the NHS Community Mental Health Service User Survey it was negative.

Conclusions**:** Data suggest that the Francis inquiry may have led to a positive impact on staff and acute inpatients’ perceptions and experiences of openness in the NHS. However such improvements have not yet transpired in mental health. How best to create an environment in which patients can discuss their care and raise concerns openly in mental health settings may require further consideration.

Introduction

Calls have been made for greater openness within the NHS, with the intention of creating of a culture ‘*where mistakes are acknowledged and learned from’*,[27] thus attempting to counteract the effects of past failings that have come to public attention in recent years.[5,15] The most notable of these is the case of Stafford Hospital where concerns about poor care and high patient mortality rates came to light in the late 2000s. Sir Robert Francis chaired two inquiries[4,5] which cited a lack of vigilance on the part of hospital administrators and system regulators as contributing factors to the tragedies that occurred. Disconcertingly, it was recognised that many employees were aware of the problems before they became public but were either reluctant to speak up[223] or had their concerns disregarded by those in power.[215]

The events at Stafford Hospital were tragic and extreme but may not have been unique. Accordingly the Francis inquiry[5] called for cultural change across the whole NHS, in terms of greater openness cascading from the top to the bottom of all trusts, to prevent mistakes and promote learning. The Department of Health acted on these recommendations by introducing the Duty of Candour,[12] changes to the reporting of Care Quality Commission (CQC) inspections,[15] and introducing Freedom to Speak up Guardians in all NHS trusts, among other measures.[13] Such changes were intended to create an NHS culture of openness and honesty—two factors key to organisational trust.[231] Research suggests that trust has a beneficial impact on working life, including increased job satisfaction and organisational effectiveness.[232] Trust is also important to patients and has been associated with positive perceptions of the quality of care they receive.[232]

The impact these initiatives remains unclear; accordingly a longitudinal research design was applied using data from NHS annual surveys of staff and patients to explore perceptions of openness since the publication of the Francis report (2013) to answer the research question: Are staff and patients' views on openness and experiences of giving voice to concerns changing through time, for better or worse?

Methods

Full details for all surveys and years can be found in Table 1. Data were analysed from the NHS National Staff Survey (hereafter 'Staff Survey') years 2007-2017. The Staff Survey collects staff views about working in their NHS trust.[233]

The NHS Acute Inpatient Survey ('Inpatient Survey') is conducted each year within acute care. The survey collects patients' views about their stay in hospital.[234]

Data from the NHS Community Mental Health Service User Survey ('Mental Health Survey') was sourced for years for 2007-2017 (excluding 2009 as no survey was conducted that year). The survey collects patients' views about the care they received whilst using mental health services.[235]

Questions relating to opportunities to contribute to decisions/make improvements, respond to errors/incidents and act on concerns of patients were extracted from the Staff Survey. Items concerning receiving understandable answers, quality of information about care/treatment and opportunities for feedback were extracted from the Inpatient and Mental Health Surveys.

The number of years' data varied by question due to new questions being introduced or existing questions being modified. A list of items was generated using the selection criteria and reviewed by the authors. Analysis included trusts that had remained single organisations over the period.

Longitudinal statistical analysis was conducted in Mplus Version 8. This modelled staff and patient survey outcomes over time to determine any change in responses to questions relating to openness. To search for the optimal growth trajectory, piecewise growth curve analysis was conducted to compare the intercept (the starting level) and the slope (rate of change over the period of interest) either side of 2013 for each survey outcome. For illustration, a Piecewise Growth Curve Model (PGCM), with a breakpoint at 2013, for Staff Survey data available from 2007 to 2017, would have two linear trajectories, the initial piece representing data 2007-2013 and the latter piece representing data 2013-2017. The Wald test is then used to test whether the initial trajectory differs significantly from the latter trajectory.

PGCM analysis assumes continuous change following a turning point - however this is not always the case. Change may be temporary before a trajectory returns to its original path, or takes a different direction. Accordingly we tested for the possibility of an interrupted time series using Interrupted Latent Growth Curve Model (ILGM) analysis. Building upon the illustration above, an ILGM with an interrupt 2013-2014, would allow an immediate, separate change between 2013 and 2014, and would test (using the Wald test) for a significant difference between the mean of the initial and latter piece of the growth curve at the point of interruption.

Results

The results presented here assume a general pattern of growth in the direction of the trajectory stated, unless specified otherwise (see Table 2 and Graphs 1-4).

Staff Survey

Good communication between managers and staff increased from 2008-2017 (national averages ranging from 26.0% to a maximum of 33.5%). Between 2008 and 2013 this increase represented growth of 0.2% per annum. There was a slight decrease between 2013 and 2014 (significant at $p < 0.01$) of -0.1%. Rates of growth returned to a positive trajectory of 0.8% per annum between 2013 and 2017: a non-significant ($p > 0.1$) increase compared to previous years.

Opportunities for staff to contribute towards improvements at work increased between 2008 and 2017 (ranging from 61.6% to 70.2%). An initial increase of 1.0% per annum between 2008 and 2013 was followed at slower rate between 2013 and 2017 of 0.7% per year, although this difference was not significant ($p > 0.1$). However there was a period of stagnation between 2013 and 2014 ($p < 0.05$).

There was an overall increase in perceptions of the fairness and effectiveness of incident reporting procedures between 2007 and 2017 (ranging from 3.36 to maximum of 3.73 on a 1-5 Likert scale). Between 2007 and 2013 this increase averaged 0.02 scale points per year and continued at a faster rate between 2013 and 2017 with an average annual increase of 0.06 scale points. The difference between rate of change pre- and post-2013 was significant ($p < 0.001$).

Inpatient Survey

Between 2005 and 2016 there was an improvement in patients' views about the amount of information provided by A&E staff (ranging from 80.8% to 83.6%). Between 2005 and 2013 this increase averaged 0.3% per year. Between 2013 and 2014 there was a slight decrease of -0.1% ($p < 0.01$), before returning to a positive trajectory between 2013 and 2016 of 0.8% per year—a significant increase ($p < 0.01$) compared with the pre-2013 trajectory.

From 2004 to 2016 positive responses to the question 'Were you involved as much as you wanted to be in decisions about your care and treatment?' ranged from 70.3% to 75.1%. Between 2004 and 2013 these increased by an average of 0.4% per year. This continued at a slightly faster rate between 2013 and 2016, at an average of 0.8% per year. The difference in rates of change pre and post 2013 was significant at $p < 0.01$.

Overall between 2004 and 2016 scores for the question about whether patients had access to someone on the hospital staff whom they could talk to about their worries and fears ranged from 56.6% to 61.5%. Between 2004 and 2013 scores decreased by an average of 0.04% per year; however between 2013 and 2016, this trend changed to one of annual fluctuations in either direction, and on average over this period a slight increase ($p < 0.05$) of 0.2% per year.

Mental Health Survey

For the question, 'Did the person or people you saw listen carefully to you?' scores ranged from 81.5% to 88.3%. From 2007 to 2013 this increased by an average of 0.3% per year; after this (until 2017) there was a significant decrease ($p < 0.001$) at an average of -1.9% per year, suggesting patients may not feel as listened to as they once did. It must be noted that the wording of this question has altered slightly: before 2010, participants were asked specifically about their psychiatrist, but in latter years, the question referred to their experience of the service generally.

Scores for the question 'Were you given enough time to discuss your needs and treatment?' ranged from 75.5% to 83.1%. There was an increase from 2007 to 2013 by an average of 0.3% per year; after this (and up until 2017) there was a significant decrease ($p < 0.01$) at an average of -1.8% per year, indicating patients are becoming less satisfied with the amount of consultation time available to them. Again, there is a change in the phrasing of this question from 2010 as above.

When asked, 'In the last 12 months have you had a formal meeting with someone from NHS mental health services to discuss how your care is working?' positive responses ranged from 55.1% to 73.9%. Positive responses to this question increased between 2007 and 2013 by an average of 1.8% per year. There was a significant increase ($p < 0.01$) at a rapid rate from 2013-2014 by 3.2%. From 2013-2017 there was still an increase but at a slower rate on average of 0.5% per year—a significant deceleration ($p < 0.001$) compared to previous years.

Scores for the question, 'In the last 12 months, did you feel that you were treated with respect and dignity by NHS mental health services?' ranged from 83.0% to 92.8%. Between 2007 and 2013 this decreased by an average of -0.1% per year; this continued but at a faster rate of -6.6% ($p < 0.001$) between 2013 and 2014. Between 2013 and 2017 there was still a decrease but at a slower rate of -0.4% per year—a slight but non-significant ($p > 0.1$) worsening compared to the 2007 to 2013 timeframe.

Discussion

A discernible change was observed amongst Staff, Inpatient and Mental Health Survey data in the rate and sometimes the direction of change after the publication of the Francis report (2013).

For Staff Survey variables relating to openness there were some significant improvements after the publication of the Francis report. This included an increased upwards trajectory in the fairness and effectiveness of incident reporting procedures (which was already improving before the Francis report). For communication between managers and staff, and opportunities for staff to contribute towards improvements at work, the increases continued after publication of the Francis report, although not at a higher rate than before.

For Inpatient and Mental Health Survey measures the picture was more mixed. The general trend for the Inpatient Survey was generally positive, with increases at a faster rate during the second period. Specifically, from 2013 satisfaction with the amount of information given to patients in A&E about their condition or treatment increased at a faster rate, and patients' satisfaction with their involvement in decisions about their care and treatment also increased more sharply.

For the Mental Health Survey the pattern of change was rather different. Patients continued to report better access (as indicated by whether they had attended a meeting to discuss their care in the last year), though at a slower rate after 2014. However, levels of satisfaction indicated in other questions relating to openness deteriorated: patients felt less listened to, believed they were not given enough time to discuss their care, and felt treated with less respect and dignity compared to previous years. Such findings are perhaps noteworthy in view of recent commentary on the disparity between physical and mental health, which includes an imbalance between perceptions, services, resources and funding in favour of physical health.[111]

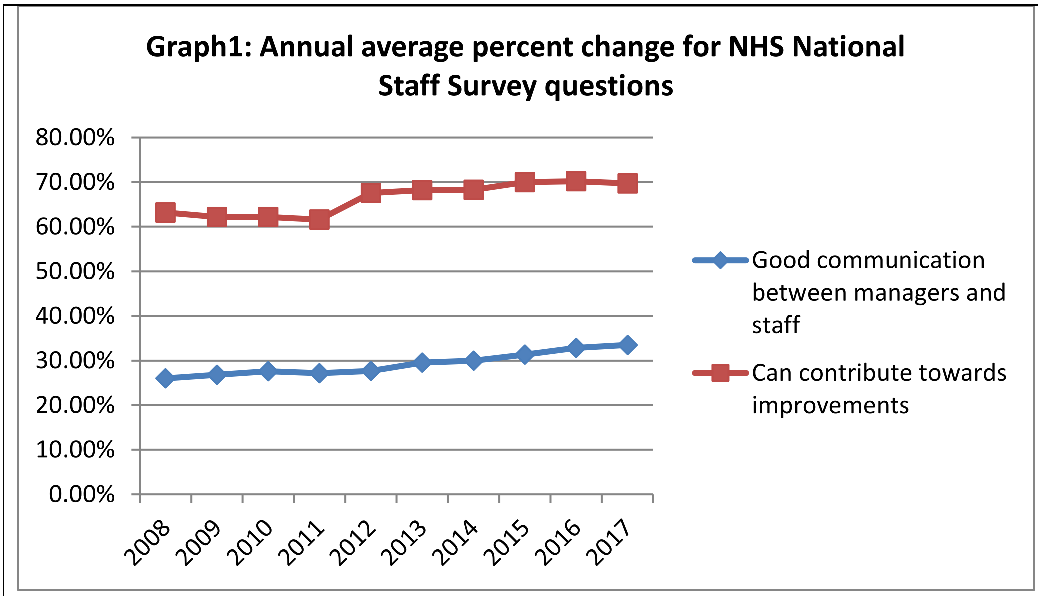
Mental health has long been considered the poor relation of the NHS.[236] Only a properly resourced mental health service can assure decent and humane outcomes for patients and their families.[237] When services are not properly resourced change is often slow or limited.[238] Our findings here suggest that increased policy attention to the importance of mental health has not yet translated into improved patient experiences, at least in relation to matters relating to openness; indeed, over the period since the publication of the Francis report, the disparity has increased.

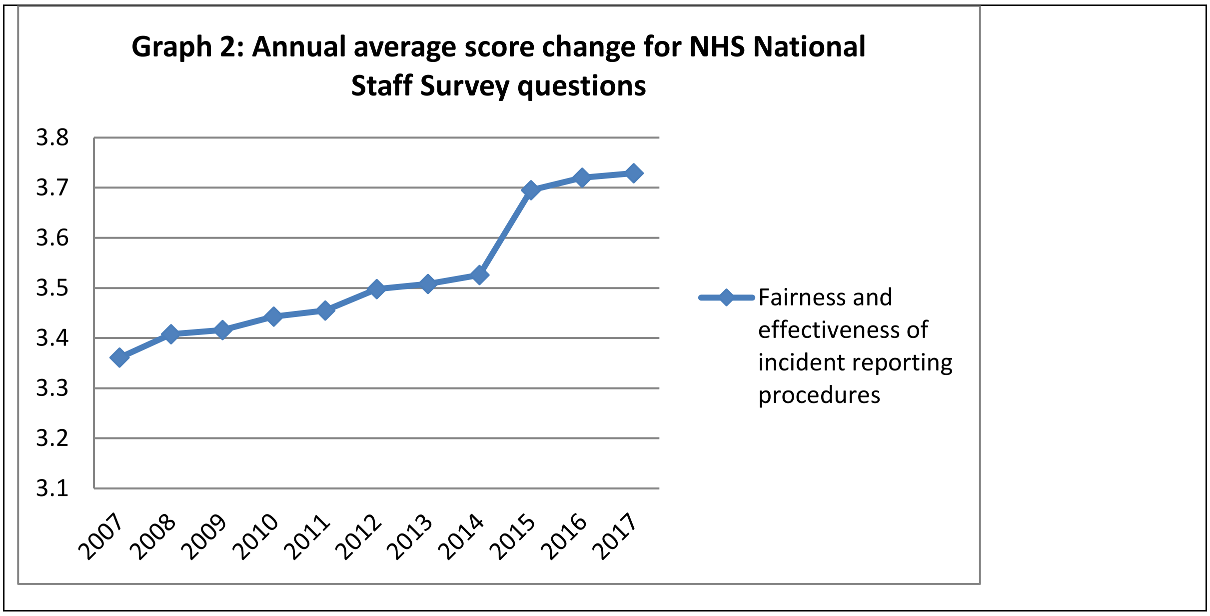
Limitations

The paper is not able to explore causal effects between the Francis inquiry and openness because there was no control group. The breakpoint chosen was the year of the publication of the second Francis inquiry, suggesting the inquiry may have had an impact. However, we cannot evidence a causal relationship, since other major changes in the NHS were also taking place at the time—most notably the Health and Social Care Act[113] that came into effect on the 1 April 2013—which may have had an equal or greater impact.

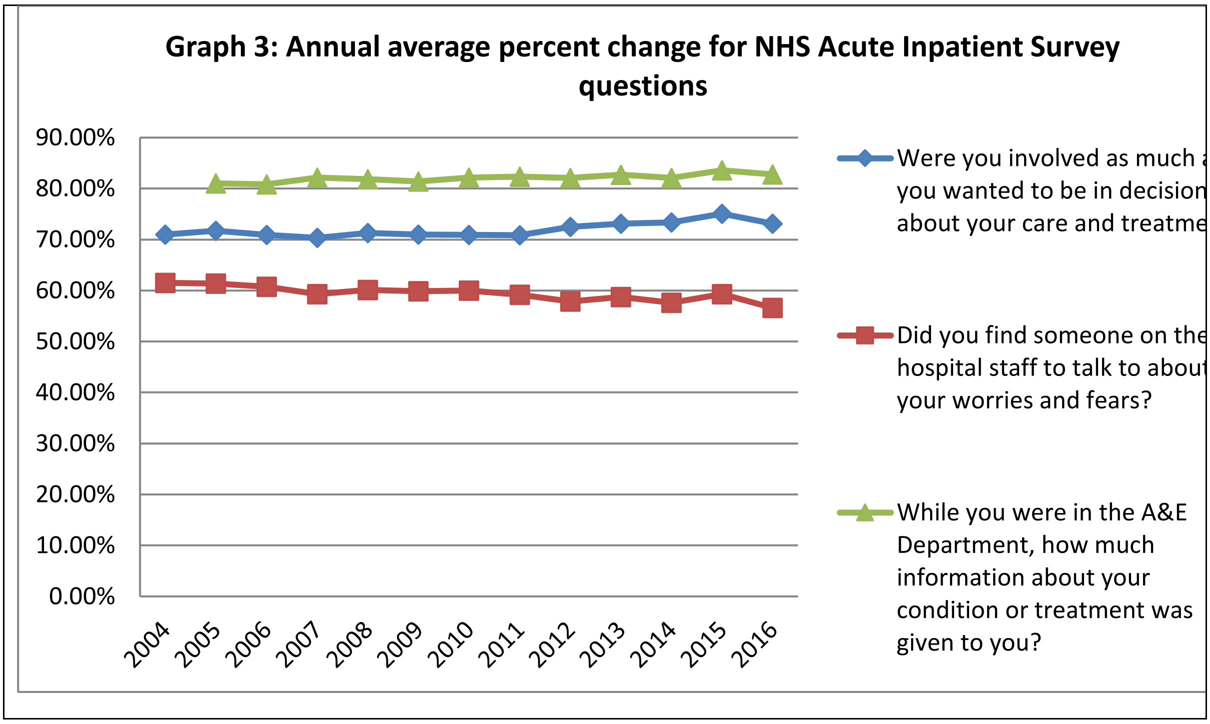
Implications

The UK Government has pledged £2.3bn in funding to improve mental health services as part of a ten-year plan focused on prevention and early detection.[112] This effort reflects a longstanding policy commitment to 'parity of esteem' between physical and mental health services in the NHS. Ensuring that patients feel able to discuss their conditions and raise concerns about care is an important component of ensuring high-quality care, but our findings suggest a worrying and sustained trend for several indicators as assessed by mental health service users. Our findings point towards the scale of the challenge facing ambitions to improve quality of care in mental health, as many indicators of an open culture, as perceived by mental health patients, deteriorate or stagnate, while their counterparts in the acute inpatient survey improve over the same period. Policymakers might consider how they can support a culture of openness in the mental health sector of the NHS, noting that many of the interventions introduced after the publication of the Francis inquiry were modelled on the acute hospital setting, and do not translate so easily into settings where care may be dispersed across sites or provided primarily in the community.[64] Alternative approaches, designed around the particularities of mental healthcare provision and the needs of mental health service users, may be required to optimise opportunities for voice in this setting.

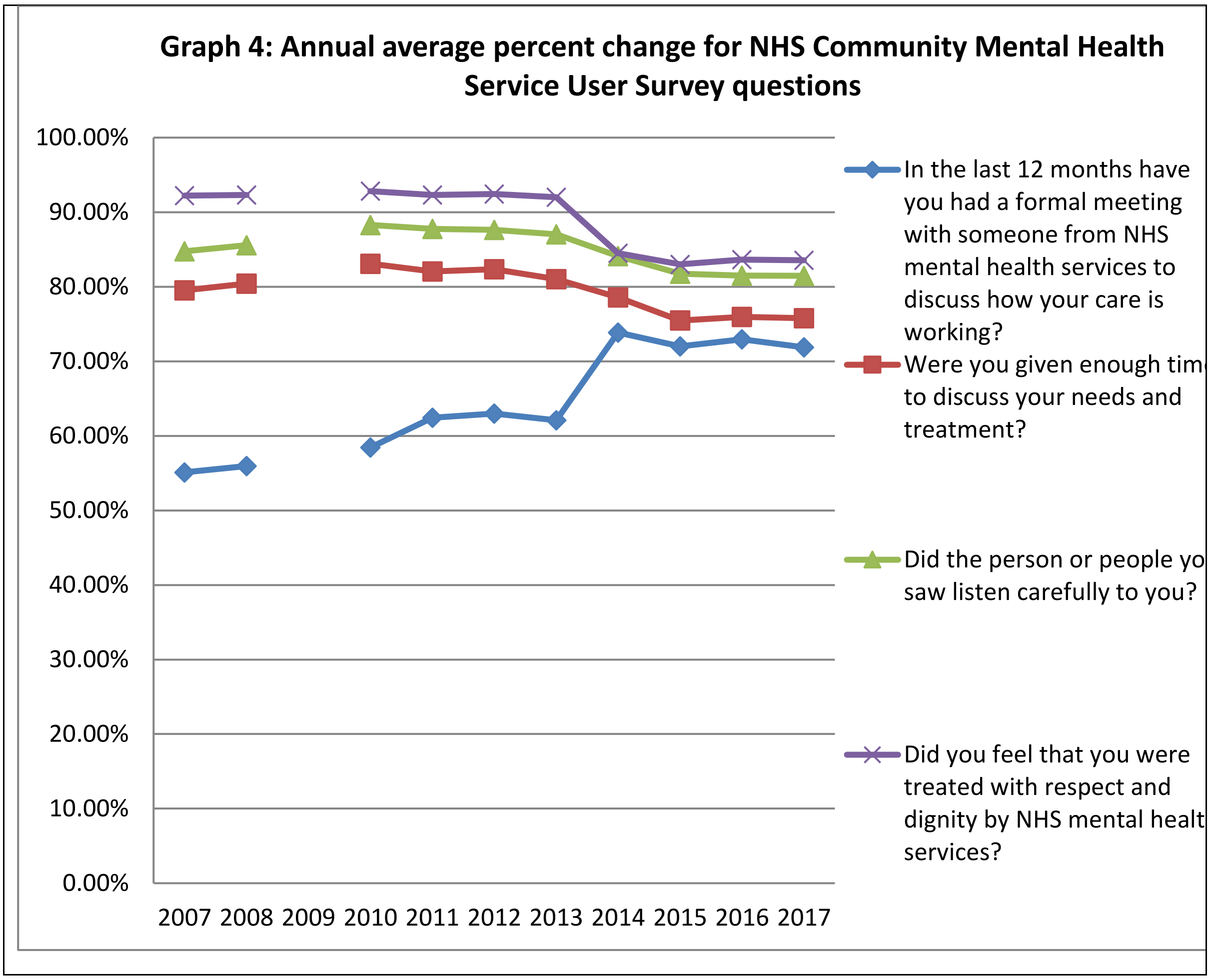




Graph 2: Annual average score change for NHS National Staff Survey questions



Graph 3: Annual average percent change for NHS Acute Inpatient Survey questions



Graph 4: Annual average percent change for NHS Community Mental Health Service User Survey questions

Table 1: Response rates for NHS Staff and Patient Surveys

Survey	Year	Number of questionnaires sent out*	Number of questionnaires returned	Response rate	Number of Trusts
NHS National Staff Survey	2007	291,843	157,667	54%	392
	2008	289,919	159,691	55%	360
	2009	289,277	157,450	54%	387
	2010	311,098	167,736	54%	390
	2011	250,000	134,967	54%	365
	2012	203,188	101,169	50%	259
	2013	416,313	203,028	49%	264
	2014	603,937	255,150	42%	289
	2015	722,811	298,817	41%	296
	2016	948,640	414,330	44%	316
	2017	1,067,266	478,872	45%	309
NHS Acute Inpatient Survey	2004	142,432	88,308	62%	169
	2005	136,937	80,793	59%	164
	2006	136,769	80,694	59%	166
	2007	135,623	75,949	56%	165

	2008	134,415	72,584	54%	165
	2009	133,362	69,348	52%	161
	2010	132,696	66,348	50%	161
	2011	133,704	70,863	53%	161
	2012	126,480	64,505	51%	156
	2013	127,435	62,443	49%	156
	2014	125,709	59,083	47%	154
	2015	176,843	83,116	47%	149
	2016	176,932	77,850	44%	149
NHS Community Mental Health Service User Survey	2007	41,842	15,900	38%	69
	2008	41,014	14,355	35%	68
	2009				
	2010	53,746	17,199	32%	66
	2011	52,852	17,441	33%	65
	2012	49,619	15,878	32%	61
	2013	46,552	13,655	29%	57
	2014	46,552	13,500	29%	57
	2015	41,650	11,695	29%	52
	2016	49,300	13,254	28%	58
	2017	47,600	12,139	26%	58