Report to the Thirlwall Inquiry: addressing Part C of the Terms of Reference

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Contents

Relevant extracts from the Terms of Reference

"The effectiveness of NHS management and governance structures and processes, external scrutiny and professional regulation in keeping babies in hospital safe and well looked after, whether changes are necessary and, if so, what they should be, including how accountability of senior managers should be strengthened. This section will include a consideration of NHS culture".

Questions 28 and 29:

28. Whether recommendations to address culture and governance issues made by previous inquiries into the NHS have been implemented into wider NHS practice? To what effect?

29. What concerns are there about the effectiveness of the current culture, governance management structures and processes, regulation and other external scrutiny in keeping babies in hospital safe and ensuring the quality of their care? What further changes, if any, should be made to the current structures, culture or professional regulation to improve the quality of care and safety of babies? How should accountability of senior managers be strengthened?

Questions posed by the Inquiry's Solicitors:

a. How would you define a healthy culture within (a) the NHS and (b) to the extent you are aware of work in that area any NHS neo-natal unit?

b. Have definitions of a healthy culture changed over time? If so, why and it what way? Please focus in particular on the periods before the Mid-Staffordshire Inquiry, 2013 onwards and the present day.

c. How would you identify an unhealthy culture in the NHS and what source(s) of information would you use?

d. Are there accepted practices for improving culture in the NHS?

1 Introduction

I have been asked by the Thirlwall Inquiry team to address a number of questions in relation to Part C of the Terms of Reference. The views expressed here are based on my experience and knowledge of the relevant research evidence. By way of background, I have been studying quality and safety in healthcare for around 30 years, and was for 20 years involved in editing one of the major journals in the field. I currently direct a major research centre - The Healthcare Improvement Studies (THIS) Institute in the Department of Public Health and Primary Care at the University of Cambridge. THIS Institute is funded by the Health Foundation (an independent charitable organisation) with a mission to improve the evidence base for improving quality and safety.

I have offered a personal interpretation of a very large and wide-ranging body of research evidence using multiple sources. Given that the research literature on most of the topics covered is vast, I do not claim to have undertaken a comprehensive assessment of all relevant material. I present my discussion in a number of sections that have been organised to maximise coherence and minimise repetition while responding to the questions and offering sufficient explanatory background. I have more depth of expertise in some areas than others, but, in areas where I have less familiarity, I have offered high-level overviews where likely to be helpful to the work of the Inquiry.

References to the research literature that support my views are given using superscripted numbers that correspond to entries in the bibliography. For example,[1] refers to reference 1 in bibliography, and this source is always referred to as [1] even if it appears again much later in the text. Some material, particularly when it is from my own research (including that conducted with others) closely reproduces wording used in the original.

The views expressed in this report are mine alone, and not necessarily those of any funder or any of my collaborators.

2 Selected key concepts

In this section, I present a small number of key concepts that the Inquiry team asked me to explain. These are mostly based on my own research and publications (usually in collaboration with others), supplemented with other literature.

2.1 A systems approach to patient safety and the bad apple problem

This explanation draws on, but is not limited to "Bad apples: time to redefine as a type of systems problem" (Shojania and Dixon-Woods, 2013) [1]

The modern patient safety movement can be dated back to around a quarter of a century ago, with the publication of a number of key reports in the USA[2] and the UK.[3] The approach to improving safety that emerged around this time was founded on the principle that many risks to patient safety arose from *errors* – understood as unintentional accidents, mistakes, slips and lapses. Errors were themselves seen to result from inadequately designed and/or poorly functioning systems. A crucial distinction was made between "active failures" (the immediate causes of safety incidents, such as surgery on the wrong body part) and "latent conditions" (weaknesses in systems that allow the failure to occur, such as absence of a well-designed method for ensuring that the surgical site is marked correctly).

System weaknesses may be multiple, and are often represented through the "Swiss cheese"[4] model, which shows how patient safety incidents can occur when successive layers of defences are breached. For example, the particular action that led to surgery on the wrong body part might be the immediate cause of harm, but it may follow a whole series of other events and be rooted in a wide range of vulnerabilities. A systems approach proposes that many patient safety failures can be prevented through careful system design, including re-engineering systems to modify error-creating conditions and thereby avert or mitigate error.

A classic example is administration of a drug through the wrong route. Sometimes, as in the case of vinca alkaloid chemotherapies, wrong-route administration may be fatal.[5] [6] A series of tragic incidents involved patients (many of them children) being administered the drug vincristine through the spine rather than, as it should have been, intravenously. [6] [7] All of these errors were unintentional, and arose because of multiple vulnerabilities in how the drugs were handled. Repeatedly blaming the individuals who administered the drug (in some cases, criminalising them) was clearly an ineffective solution, and one that obscured the nature of the faults that predisposed to error. A systems solution, such as using mini-bags instead of syringes when dispensing the drug, can more effectively help reduce the risk by designing it out.[8]

A "no-blame" approach was seen as important to encouraging openness and learning to prevent future error. [9] [10] This is based on the principle that blaming individual clinicians – who are inherently prone to error because of human fallibility – is a flawed strategy for improving patient safety, since it may encourage concealment of mistakes and inhibit improvement. The no-blame principle is also based on the assumption that most professionals are "good apples" (not wilfully or recklessly engaged in harming patients). The US Institute of Medicine report that helped launch the patient safety movement accordingly declared that: "The problem is not bad people; the problem is that the system needs to be

made safer."[2] The "no-blame" approach continues to be widely encouraged as a feature of a systems-based approach to improving patient safety. It is, for example, promoted for hospital-based perinatal mortality review,[11] with the World Health Organization guidance on audit and review of stillbirths and neonatal deaths strongly recommending a "no blame" approach, noting that: "Mortality audits for stillbirths and neonatal deaths should not be used to blame or punish individuals, groups or institutions."[12]

Much progress in improving safety has been made by using a systems approach, particularly one underpinned by the discipline of human factors/ergonomics – which takes an integrated approach to organisational design, individual skills, roles, tasks and teamwork, equipment and technology, and environment and workspace design.[13] A key recognition of recent years is that safety in healthcare is characterised by an especially large dependency on the skills and actions of individuals and teams, so people represent both a strength and vulnerability. Among other things, people contribute to the prevailing conditions and environments for safety through the norms they produce and reproduce and through their behaviours and demonstration of professional values.[14]

It is absolutely correct that disciplining individuals who make errors in contexts of weak systems may occlude organisational pathologies and obstruct improvement by frustrating learning. However, searching for defects in systems when individuals are at fault may be an equally fruitless effort. An especially important challenge for the no-blame approach is that, while the vast majority harm that comes to patients is the result of unintentional accidents (errors), a distinctive form of patient safety risk arises from "bad apples." [1] These are individuals who display grossly incompetent, unprofessional behaviour or conduct (what might be termed "transgressive behaviours"), as reported in multiple investigations and inquiries discussed throughout this report. Though they often have overlapping features, different types of bad apple can be distinguished, including the following:

- Those who demonstrate grossly incompetent or substandard clinical practice, but nonetheless persist
- Those who demonstrate unacceptable behaviours, including abuse, bullying, racism, and disrespectful or negligent care
- Those whose behaviour is so transgressive that it reaches the threshold for criminality, and may include murder, assault, rape, and other violations.

The 2011 analysis that I co-led of a series of scandals involving doctors identified the dangers of assuming that bad apples do not exist.[15] That mistaken assumption can mean that the alertness needed to identify miscreants may be deficient, that systems for monitoring the conduct, behaviours and actions of people may be underdeveloped, and that the necessary mechanisms for taking action may be inadequate. Similarly, Baker and Hurwitz's analysis shows that, in the case of the GP Harold Shipman, the active failure (the murders) was not the result of the holes in the Swiss cheese model accidentally lining up.[16] Instead, using the metaphor of a snake, they show how Shipman was able to slip through the holes that then existed.

These dangers were also vividly highlighted by the 1994 Inquiry into the state-enrolled nurse Beverly Allitt.[17] While it rejected the possibility that Allitt could have been detected and stopped easily, the report concluded that: "No measures can afford complete protection against a determined miscreant. The main lesson is that the Grantham disaster should serve to heighten awareness in all those caring for children of the possibility of a malevolent intervention as a cause of unexplained clinical events." [17]

It is crucial to avoid blaming individuals for errors that arise from weaknesses in systems. Maintaining a focus on avoidable error must remain a cornerstone of patient safety improvement. However, in my opinion, a systems approach should also recognise that not

all harms in healthcare result from errors in the classical sense of accidents, mistakes, slips and lapses. An approach to patient safety that focuses solely on error can risk missing a rare but important contributor to harm – that of transgressive behaviour. I propose that transgressive behaviour should also be regarded as a system risk in its own right, and managed accordingly.[1]

2.2 A voiceable concern

The explanation below is based on: "What counts as a voiceable concern in decisions about speaking out in hospitals: A qualitative study" (Dixon-Woods et al, 2022)[18]

It is often not straightforward to classify issues in healthcare as concerns, especially when it comes to the messy and subjective situations often characteristic of healthcare. A recent study I co-led with an international team of authors [18] suggests that classifying a situation, incident or pattern as a *voiceable concern* has two components: first, it must be recognised as a concern, and second, it must also be recognised as one that could or should be voiced.

Our analysis shows that how people come to recognise concerns as concerns, and their judgements about whether those concerns should give rise to voice, may not be straightforward matters involving objective criteria. Decisions about what counts as a concern that should and/or could be voiced are contextually embedded, and distinctions between the nature of a concern and the entitlement or opportunity to speak are not always easily made. Accordingly, what counts as a voiceable concern is not simply a function of the concern itself, but is also powerfully determined by whether the person who notices it feels it could and should be voiced by them, in a given situation.

What comes to be classified as an occasion for voice is powerfully affected by wider organisational and cultural influences, including expectations, standards and norms[19 20] and, more broadly, the fit of an episode into wider patterns of organisational or individual behaviour. Our study identified four specific influences on people's judgements about what counted as a voiceable concern: certainty about whether something is wrong and is an occasion for voice by a candidate speaker, system versus conduct issues, forgivability, and normalisation.

2.2.1 The certainty that something is wrong and is an occasion for voice

Some situations are easily and straightforwardly recognised as sources of concern, for example where there is unequivocal risk or harm or when an egregious injury or violation has already taken place. But many others are fraught with ambiguity. Possible opportunities to speak are more complicated when they relate to an emerging or established pattern rather than to a specific, easily defined incident. Such patterns may lead to a generalised sense that things are 'not right', even though each individual incident or signal may be minor.

Identifying something as a voiceable concern is intimately linked to the quality of the evidence underlying the concern, and to whether people who notice it feel qualified to make a well-informed judgement and feel they can justify the reasons for their concern. People can feel discomfort about a situation but insufficient certainty to determine whether the concern was legitimately a matter of concern requiring voice. In such instances, people might feel they lack the clinical, technical or procedural knowledge to make a call. When describing such situations, people may be uncertain about who has the authority to define what should be an occasion for concern.

2.2.2 System versus conduct issues

A key influence on identifying something as a voiceable concern relates to whether it is a system issue, a conduct issue, or a hybrid of both. People generally, though not universally, find it easier to identify systems issues, such as IT problems, test ordering, or medication processes, as voiceable concerns. These issues are seen to be factual in character and capable of remediation, but also, critically, they are not seen as being blameworthy. Concerns related to behaviour or conduct are often seen as potentially harder to judge and more discomfiting to evidence and to articulate.

2.2.3 Forgivability

Sociologists have often distinguished between errors or mistakes that might be seen as "normal" and might be deemed forgivable, and "deviant" errors or mistakes, which may be seen as arising from "negligence, ignorance, or ineptitude."[21] People may find it especially hard to determine what is a voiceable concern when they have to assess whether behaviour is unacceptable or unprofessional as opposed to 'just' unpleasant, or excusable given the circumstances. One-off lapses may be seen as more forgivable than a pattern.

2.2.4 Normalisation

People may be uncertain about whether something counts as a voiceable concern when the issue they are seeing is highly normalised in the environment where it is occurring. For example, poor standards in systems in processes may be accepted on a particular ward, as may poor conduct, including disrespectful, aggressive behaviour towards colleagues.

What Vaughan describes as the "normalisation of deviance"[22] (discussed in more detail below) may be enabled by cultural reluctance to tackle difficult problems head-on, especially if such problems are already entrenched. In some cases, the situations may be so discomfiting, and the consequences of raising them so fearful, that people may choose not to confront them at all. Normalisation may also contribute to misplaced trust, by reducing scepticism and alertness to the possibility that poor conduct or practice might be occurring.[15]

2.3 Patient safety and the problem of many hands

The explanation below is based on "Patient safety and the problem of many hands" (Dixon-Woods and Pronovost, 2016)[23] and on other literature.

The *problem of many hands* arises in contexts where multiple actors – organisations, individuals, groups – contribute to the performance seen at the system level, but no single actor can be held responsible for the overall outcome. [24] Described by the political philosopher Dennis Thompson, it applies to situations where many people contribute in many different ways to particular outcomes, to the extent that the "profusion of agents obscures the location of agency."[25]

Healthcare in England is characterised by an exceptional level of institutional complexity. There is no single statute governing healthcare, so services are subject to multiple statutory requirements and sanctions of both a civil and criminal nature. For example, common law and professional guidance and codes of practice may impact on care, as may a range of possible criminal offences (e.g. under the Offences against The Person Act, the Data Protection Act and the Human Tissue Act amongst others). A key element of the complexity is the number and range of bodies and agencies that have a role in providing some kind of direction to healthcare organisations.

When responsibility and authority are diffused, confused or absent,[26] one risk is that troubling patterns and warning signs may go unnoticed, and clarity about who is responsible for addressing them may be lacking. [27] At the time of the Mid Staffordshire disaster, for example, agencies and bodies found it difficult to share intelligence and coordinate their interactions with one another and with the organisations they were overseeing. The complex network of bodies and agencies at the time had multiple, overlapping, and sometimes conflicting responsibilities, resulting in "regulatory gaps," with regulators operating in a siloed and sometimes territorial way.[28] Some of these gaps have been closed since the Mid Staffordshire Inquiry, but significant complexity remains.

A review published in 2019[29] sought to map the complete ecosystem of all organisations with patient safety regulatory effect on NHS providers. Including all organisations exerting regulatory influence, not just those designated as statutory regulators, it identified over 126 organisations, of which 104 had regulatory effect or regulatory influence. Only a small number (e.g., the Care Quality Commission (CQC), NHS England, and the Human Fertility and Embryology Authority) have the authority to impose sanctions and enforcement measures, but others can take actions with some similar effects.

The number of agencies has reduced since this mapping was done, but it remains the case that NHS organisations continue to be overseen by many agencies and bodies who can set standards, visit, undertake formal inspections, and request or require information, operate financial and reputational incentives and sanctions, and otherwise control or direct the behaviours of organisations. The result is that services may become answerable to a number of different regulatory agencies whose rules, principles, and procedures conflict or fail to cohere, and who demand different information – or the same information in different forms – and impose varying requirements.

When organisations are answerable to too a wide variety of accountability forums, conflicting signals about what is important may be issued. Too many organisations with a say in providers' activities may also impose significant costs and inefficiencies. The number of agencies can easily ratchet up to create a multiplicity of regulators, each with its own organisational dynamic and administrative requirements to be satisfied. The heterogeneity of regulatory forms, regulatory actors and objects of regulation means that there are multiple points at which variations in regulatory practice are possible, while the multiple tiers of regulation can interact in ways that are difficult to anticipate or control.

3 Culture in the NHS

In this section, I identify the challenges of defining and assessing culture, while strongly emphasising that systems and culture are intimately inter-related and mutually reinforcing. I offer some insights into what constitutes a "healthy" culture by summarising what good might look like at unit level in an NHS organisation. I am not a specialist on NHS neonatal units, but comment using relevant research literature where possible. In the section that follows this one, I comment on specific themes relevant to inquiries and investigations before and after the Mid Staffordshire Inquiry.

3.1 Understanding culture

A uniting feature across the many (over 100) investigation and inquiry reports into major NHS failings over several decades is the significance of *culture,* sometimes as directly implicated in egregious conduct (e.g. abusive, reckless or criminal or otherwise transgressive behaviours) and sometimes as enabling poor quality and safety, misconduct, and unacceptable behaviour to go undetected, tolerated, or unaddressed for too long. However, defining culture is not straightforward, nor is assessing it.

3.1.1 Difficulties in defining culture

Problems in organisational culture are frequently blamed for failings and disasters across sectors as diverse as mining, oil extraction, space exploration, and healthcare itself. [22 28 30-33] Despite its prominence, and its significance across so many sectors and industries, no single standard definition of "culture" exists, nor is there a single consensually agreed way of measuring or assessing it.[34 35] In part, this is because culture is a multi-faceted concept that is used in everyday colloquial discourse, in popular paperback guides to management, and in the academic literature.[35] Academic definitions derive from many different disciplines, and accordingly may not overlap at all or may emphasise different features. However, an authoritative and useful overview of culture in healthcare is provided by Russell Mannion, who proposes that:

> *Given the plethora and diversity of perspectives, a universally accepted definition of culture is unlikely ever to be achieved. But at the heart of many definitions is the view that culture comprises that which is shared and taken for granted between members of an organisation. That might include, for example, the beliefs, values, attitudes, habits, codes of practice, and social norms that guide working behaviour, as well as the routines, traditions, symbols, ceremonies, and rewards that underpin organisational life. These shared ways of thinking and behaving help define what is legitimate and acceptable in a group setting. They act as the social and normative glue that binds people in collective enterprise.* [35]

This analysis makes clear that aspects of culture can be appreciated as specific dimensions of organisations, including the behaviours, attitudes, practices, and basic assumptions that people share about their work and the values that guide them. It covers the routine, taken-for-granted aspects of organisational life: the things that come so naturally, it may be hard to conceive of any other way of doing them, including values, beliefs and expectations.[36] The intricate webs of behaviours, norms, understandings, interpretations, expectations that make up cultures are influenced in multiple ways, including, for example, how comprehensively newcomers are socialised into the prevailing culture, individual personalities, the specifics of local groups and leadership, and often complex socio-political and professional dynamics.[37]

Also crucial in influencing cultures are, as emphasised throughout this report, features of systems and structures – including the "outer contexts" in which organisations operate.[38]

Cultures depend on being continually reproduced (e.g. people doing and thinking what other people are doing and thinking). They do this in multiple ways – for example through repeated interactions that in turn structure everyday life, through the socialisation of newcomers, through the design and functioning and systems and processes.[42] However, features of culture are highly dynamic and interdependent – they are both enduring and prone to change, but are typically very hard to shift deliberately.[39]

A further complexity is that culture is very rarely, if ever, uniform across organisations. Healthcare organisations are often exceptionally large and complex, and their cultures may be patterned along specialty, occupational groupings, professional hierarchies, service lines, departments and wards. Different professional groups and different units may have different subcultures: different sets of assumptions, different ways of relating to each other, different ways of carrying out their work and even different ways of talking.[40-42] Some subcultures may operate at the level of professions or occupations (and groupings within them) and transcend any individual unit or organisation – for example, orthopaedic surgeons might have quite a different culture from occupational therapists. The norms, behaviours and values of these groups may be a distinct subculture of the occupation rather than the organisation in which individuals work.

Though the concept of a "healthy" culture is even less well defined than that of culture itself, cultures and subcultures may have features that could be seen more or less "healthy," in the sense of demonstrating appropriate values, behaviours, norms and practice. A large multi-method study of culture in the NHS that I co-led with collaborators, conducted 2010-2012 and published in 2013, [38] found that both "bright spots" and "dark spots" of culture and systems may co-exist across a single NHS trust. Further, sometimes dramatic gulfs appear between the culture espoused by the executive and board level of an organisation (the "senior management") and the cultures in different parts of the same organisation. As a result, organisations are best understood as "cultural mosaics"[20] rather than a single, homogeneous culture.

As well as different subcultures in different parts of organisations, cultures may also vary in terms of their orientation towards particular issues. This can be highly consequential when one set of cultural norms dominates over another. For instance, one cultural orientation might be to seek to preserve harmony and consensus among colleagues. These behaviours might be evident in many positive ways, but also in a reluctance to challenge or raise questions. Such an orientation might, for example, be at odds with an orientation towards effective risk management, which would require people to be able to notice, identify, and escalate problems. Similarly, an orientation towards efficiency might support rapid throughput, which might be positive in ensuring that people are seen quickly, but might compromise other aspects of care, such as dignity. This is not to say that harmony and consensus or efficiency are bad in their own right (clearly not) – only to recognise that cultures are full of paradoxes and that features of cultures that have bright sides may also have dark sides.

3.1.2 Relationships between systems and culture

As I shall emphasise throughout the discussion that follows, cultures are powerfully influenced by structural issues, by features of organisational and institutional systems,[43 44] and by their broader environments (including the budgetary and policy environment, broadly conceived). For example, at unit level, technologies, teams, tasks, processes, individuals' technical competence, and aspects of work systems (e.g., staffing, resourcing, equipment, training, guidance, workspaces, administrative processes, IT) all interact to powerfully affect

behaviours, norms, decisions, actions and performance,[45] but they also "act back" on culture and behaviour in a highly recursive, mutually reinforcing cycle that is often highly sensitised to wider contexts and influences.

As an example, civility towards colleagues clearly has a cultural character – it is inherently about behaviours and values. But the influences on incivilities are multiple. Specific situational triggers such as high workload and heavy responsibilities, issues with coordination, communication and teamwork, competence, team composition, and under-resourcing and inefficient processes [46] may result in frustration and fatigue that impact on civility. Similarly, normalisation of unsafe conditions may occur when system weaknesses, including poorly designed systems, equipment defects, and production pressures appear to indicate to staff that safety is not truly a priority. These weaknesses may impose cognitive loads, create frustration, distract attention from risk anticipation, strain collective competence, and increase wear-and-tear, [45] and accordingly reduce staff capacity to demonstrate civility. Many of these issues may have their origin outside the immediate work system. For example, structural issues such as staffing shortages can also reduce teams' ability to notice and react to small signs of safety deterioration, and can affect their capacity for debriefing, mentoring, and informal knowledge-sharing, which are all important to maintaining a culture of learning, teamwork, and cooperation.[47]

3.1.3 Inner and outer contexts

It is useful to distinguish between the "blunt end" of provider organisations, where senior management (members of executive and board teams) operates, and the "sharp end" (or "front line") where care is delivered.[38] The blunt end, by shaping the environment where care is delivered, may create the latent conditions that increase the risks of failure at the sharp end, but may equally generate organisational contexts that are conducive to providing high-quality care. These inner contexts of organisations are powerfully influenced by their outer contexts, which include a very wide range of bodies and agencies, including NHS England (formerly NHS England and Improvement) and the Department of Health and Social Care (formerly the Department of Health), as well as those involved in commissioning care (Integrated Care Boards, formerly Clinical Commissioning Groups, as well as national level commissioning) and a range of other bodies and agencies, including regulators.

As a general principle, "the broader environment within which organisations operate emits powerful injunctions about what they should look like and what they should be doing." [48] This is especially true in the NHS, where the wider institutional contexts have major influence on culture in provider organisations through budget-setting, directions and guidance, priority setting and regulation, and, in a more diffuse way, powerful cues about what constitutes legitimate forms of organisation and practice. The behaviours of those in external organisations towards those in provider organisations are also relevant here.

One major feature of the outer context is, of course, budgetary control, which flows from the Treasury through the Department of Health and Social Care and on to commissioners (who, in broad terms, decide what services to provide and pay organisations to provide them) and then provider organisations. NHS provider organisations typically operate in conditions of scarce resources, which they have to allocate across many competing priorities. For example, in a single organisation, there may be competing demands to resource different departments or cross-departmental infrastructure. Constraints on what organisations can spend necessarily affect how they can respond to safety issues, including those arising from issues such as staffing levels, estates and facilities, and IT and equipment.

Provider organisations also have to address multiple priorities, targets, standards, requirements, guidance documents, programmes, incentives and measures that are set externally. As discussed above, NHS organisations face great institutional complexity,

answerable to many different bodies with overlapping and potentially conflicting requirements.[49] The proliferation of externally-set priorities may create what my work with others has termed "*priority thickets"* [38] – dense patches of overlapping or disjointed goals that consume substantial attention and resources, but do not necessarily provide coherent direction at organisational level. In particular, priority thickets risk saturating organisations with external demands to the extent that the clarity of their own goals becomes obscured. By consuming most or all available attention and resource, priority thickets can also make it more difficult for organisations to respond to locally-arising issues (including those that arise ad hoc) compared with externally imposed expectations.

Other challenges arise from efforts at "blame engineering," a concept developed by the political scientist Christopher Hood to describe various forms of blame avoidance. Hood defines blame as the act of attributing something bad or wrong to some person or entity.[50] Blame, he suggests, involves some (actual or perceived) harm or loss, as well as, crucially, an attribution of agency. Though Hood emphasises that blame is not always bad, he explains that, faced with external demands for accountability, blame avoidance may become a dominant preoccupation for organisations and institutions. This means that some techniques, strategies and courses of action may be chosen and implemented with the (albeit often undeclared) intention of deflecting or evading blame.

What Hood calls "blame games" can involve multiple elements of the whole system, not just individual organisations – and may indeed involve transfer of blame to organisations providing care from other parts of the system. The outer context more broadly, from ministerial level down, is highly impactful for culture and behaviour in NHS organisations. Pressures and behaviours (including bullying or aggressive behaviour) from those at the centre may be implicated in poor cultures at the level of NHS provider organisations: as well as being unpleasant experiences for those on the receiving end, they will tend to indicate that these are legitimate ways to behave that can be reproduced within organisations themselves. The 2022 Messenger review of leadership in the NHS, for example, identified that how performance is managed in the NHS (from the centre, through NHS England and other bodies as well as the Department of Health and Social Care) is a major factor in organisational culture. It identified, for example, how this context creates pressures in the workplace that prioritise tasks over people, and commented that the major contributors to "reactive rather than constructive behaviours" are:

> *[…]those pressures from above that force upward-looking rather than outward-looking responses. Some staff, for example, are presented with the responsibility to meet an external metric while lacking the ability or resource to meet it, while others operate freely without oversight in isolated areas. We saw accountability without authority, and vice versa.*[51]

3.2 Institutional secrecy: a product of both culture and systems

An important feature of culture concerns behaviours, systems, practices and attitudes towards potentially discomfiting information. Discounting of warning signs of deterioration or other problems has been a prominent feature of organisational behaviour reported in many investigations and inquiries in healthcare, [52] as discussed later in this report. A common theme is opacity: there may be some awareness (of different kinds) of problems in some part of the organisation, but it may take a long time for the intelligence to surface, and for action to be taken either to avert tragedy or to prevent further harm.[53]

In the failure to identify and address problems in a timely way, healthcare disasters often demonstrate striking similarities with catastrophic events in sectors outside healthcare,[54]

especially in the organisational and social preconditions that tend to nurture disaster. Pioneering work by the sociologist Barry Turner[55] characterised common factors in major accidents and disasters in the period 1965-1975 (including the Aberfan pit disaster), showing that faulty or inaccurate information is frequently a feature of what he calls the "incubation period." [56]

During this time, "failures of foresight" can mean that accumulating latent conditions, [57] a history of discrepant events, and warning signs are not noticed, are misinterpreted, or are ignored. Some potentially concerning issues may not come to notice in the right part of the organisation, may not be recognised as a problem, or may not be attributed significance. Sometimes problems appear to be "ill-structured" at the time but, once an adverse event has occurred, they may subsequently appear (e.g. in investigations) as obvious. Turner also identifies what he calls patterns of "administrative behaviour" that result in challenges in diagnosing a hazard accurately and determining a response. [55] These problems include (though are not limited to) the following:

(i) *Information warning of the hazard potential of particular events may be misunderstood because of erroneous assumptions.* Turner notes that warning signs may be disregarded because people are preoccupied with other matters, because they do not recognise the significance, or because those who do perceive the issues are low status. He suggests that in the most extreme cases, the institution not only fails to recognise the danger, but also becomes convinced that the problems have been dealt with.

(ii) *Hazard signs may be overlooked or not responded to because of information handling difficulties.* Turner notes that information handling difficulties (including the basic limitations of cognitive capacity) make a major contribution to the ability to recognise warning signs. Particular issues arise when confusing and excessive amounts of information are generated.

(iii) *Hazard signs are overlooked because of a feeling of invulnerability.* This observation of Turner's is less intuitively obvious, but describes how people may not feel that something will happen to them, and accordingly are unprepared when a disaster does break. They may then have to cope with the surprise of the event, the stress of taking action in a crisis, and "the rigidity of response which may stem from reluctance to abandon established procedures or abandon inappropriate fixed responses." [55] Further, different parts of the organisation may not share understanding of the nature of the crisis or the needs of the larger situation, or may use a crisis to advance their own sectional interests or organisational politics.

These behaviours and responses have a profoundly cultural character. As Carl Macrae puts it, writing in the context of NHS disasters: "Critically, it is the shared beliefs, collective assumptions, cultural norms and patterns of communication across organisations that shape what information is attended to and how it is interpreted and communicated—and most importantly, what is overlooked, discounted and ignored."[58]

While inherently cultural and behavioural, issues relating to detection of troubling patterns and warning signals are also product of systems. In her account of the NASA Challenger disaster, the sociologist Diane Vaughan uses the term "structural secrecy" [22] to explain how information can become hidden through the way systems are organised. She defines structural secrecy as "the way that patterns of information, organisational structure, processes, transactions, and the structure of regulatory relations systematically undermine the attempt to know and interpret situations." [22]

I prefer to use the term *"institutional secrecy*" to describe how information and intelligence relevant to quality and safety may become obscured in the NHS. I believe this term helpfully frames how features of structure, systems, human sense-making and culture, as well as properties of information, can combine and interact to hamper problem recognition and action. Institutional secrecy means that warning signs may go unnoticed or neglected both because of how information is organised and because of behaviours in relation to warning signs, and in ways that are not always fully predictable.

Institutional secrecy is not (at all) unique to healthcare. It is a feature of most complex socio-technical systems (e.g. banking).[59] It arises for many reasons, linked to how information is organised and processed, but is especially inclined to flourish where there are multiple forms and layers of communication and complex organisational structures and processes.[60] In complex socio-technical systems such as healthcare, institutional secrecy arises in part because the relevant information may be located in different places, is technically difficult (capable of being understood only by experts), is variably accessible, and may be difficult to collate meaningfully. It may also take multiple forms, ranging from "hard data" about system performance through to "soft intelligence," which describes information known to (or suspected by) particular individuals, particularly at the sharp end of care, that escapes easy measurement or capture but may be a signal of potential problems. [61] [62]

Some causes of institutional secrecy have highly practical origins in systems and structures. In the NHS, administrative, technical and legal infrastructures may inhibit making information available, known in the right places, and actionable. Multiple sources of information are designed and operate separately from each other (see section 5.4), with differing goals, professional and institutional norms, confidentiality, data protection, and information governance requirements, methods for processing, and reporting lines. How information is handled through various systems, subject to varying requirements and legal restrictions on sharing, may frustrate the ability for any single view to be formed. For instance, problems with a particular individual's conduct or practice might be investigated through more than one process, entirely separate from patient safety incident investigations, and confidentiality may inhibit sharing of the information beyond a very small number of people. Other practical problems involve the highly resource-intensive nature of data collection endeavours to monitor and investigate quality and safety. The time taken to quality assurance and validate data can mean that valuable information may be received too late. Teams and organisations may struggle with the range of capabilities and skills required for data analysis, perhaps assuming that all is within the acceptable range, when in fact disturbing issues and patterns are evident on further investigation.

Some level of institutional secrecy is probably unavoidable because risks abound in healthcare organisations, but attending to all of them at once is not feasible. As the anthropologist Mary Douglas remarks, "risks clamour for attention; probable dangers crowd in from all sides, in every mouthful and every step. The rational agent who attended to all of them would be paralysed." [63] Information must be filtered through various parts and hierarchies in organisations to render it manageable. But one consequence is, as Vaughan shows in her analysis of the Challenger disaster, [22] is that information that reaches the higher levels of organisations may be filtered, with those in senior positions left unaware of details or of how technical issues are being handled in terms of risk at the sharp end.

Institutional secrecy can arise without any conspiratorial intent or effort to conceal or deflect. But, while filtering of intelligence is perhaps an inevitable feature of organisational life, the risks associated with institutional secrecy – in particular failure to detect warning signs – are very substantially increased where defensiveness and an instinct for concealment are culturally institutionalised, and where external contexts – from ministerial level down – increase anxieties at organisational level, and serious blind spots can arise when organisations are preoccupied with demonstrating compliance with external expectations.

One example (among many) can be seen in the unintended consequences of data collected and used as part of performance management systems.[64] [65] [66] Even when launched with an explicit emphasis on improvement, such programmes may become regarded by staff at the sharp end more as blame allocation devices than supports for practice.[67] For organisations with a tendency towards comfort-seeking, measurement aimed at performance management may too easily incentivise behaviours such as gaming. In this context, compiling a full picture of possible signs of trouble may not be easy.

3.3 The influence of human sense-making processes on detection of problems and warning signs

Normal human sense-making processes can help to explain why problems can go detected and unchecked, even when there is no organisational attempt to actively try to conceal, deny or evade problems. The psychology behind cognitive biases and heuristics (rules of thumb) is increasingly well understood, though the science is also diverse, with many different definitions and approaches and much debate and dispute. Briefly, however, one way of understanding heuristics is to see it as a cognitive strategy for dealing with uncertain situations that "ignores part of the information, with the goal of making decisions more quickly, frugally and/or more accurately than more complex methods." [68]

Humans use heuristics on a daily basis, for example to judge the size of a parking space by looking at it (rather than measuring), or to assess whether the milk is off by smelling it rather than obtaining a laboratory analysis. In an organisational setting, use of heuristics is pervasive as a way of dealing with the huge volume and variety of information, often through unconscious processes. Heuristics may be highly functional for teams and organisations, allowing decision-making to be efficient and to benefit from expertise and experience,[69] but can have a dark side – sometimes leading to the wrong judgements, decisions and actions.

The literature on cognitive biases is also vast, covering everything from "hindsight bias" (tendency to see past events as predictable at the time the events occurred), "availability bias" (tendency to over-estimate the chance of an event occurring because it happened recently, "anchoring" (tendency to rely too much on one piece of information acquired early on when making decisions) through to "optimism bias" (the tendency to be over-optimistic about the outcome of planned actions and underestimation of negative events).[70]

While heuristics and biases are inherent to human functioning, their effects may be to distort perceptions and judgements: "they lead us to overlook subtle, but sometimes important distinctions between similar objects; to mistake the salience or memorability of an event with its frequency of occurrence; to draw deep associations based on superficial similarities; to cling to old beliefs despite new, contradictory evidence; to impose a biased interpretation on ambiguous events; and to exaggerate the sameness of people or objects in one category and their difference from objects in other categories."[71]

The effects of cognitive biases and heuristics help to explain why not all failures or delays in recognising warning signs arise from denial, defensiveness, or active rejection of concerning evidence. Instead they may arise through normal processes of human sense-making in complex organisations and through how attention (which is scarce resource) and information (which is often overwhelming) are organised and directed. Vaughan's analysis of the NASA Challenger disaster, for example, identified that many judgements about risk were influenced by production pressures (the need to get things done), which, "originating in the environment, become institutionalised in organisations, having nuanced, unacknowledged, pervasive effects on decision making." [22] Further, blindspots and ambiguities arise because of necessary processing information through various layers of organisations. One of Vaughan's key conclusions is that "no extraordinary actions explain what happened: no

intentional managerial wrong-doing, no rule violations, no conspiracy. The cause of the disaster was a mistake embedded in the banality of organizational life and facilitated by an environment of scarcity and competition, elite bargaining, uncertain technology, incrementalism, patterns of information, routinization, organizational and interorganizational structures, and a complex culture." [22]

Some of what Vaughan calls the "banality of organizational life" involves drift in customary practices over time. At the sharp end of healthcare, staff are typically engaged in continuous trade-offs, tensions and conflicts over priorities – for example, deferring clinical observations until patients have had their breakfasts on grounds that this is humane practice. [72] These judgements about risk and how they can be balanced are a routine part of providing care, and indeed are often essential to keeping patients safe and respecting their dignity. However, over time, work practices and systems may decline so that behaviours that do not promote safety become normalised. [22] This may happen when no incidents have occurred (the Fukushima nuclear disaster) or there is a shared assumption that the system is robust to failure (the sinking of the Titanic, for example), or both.

Some of these behaviours are the result of normal human cognitive biases and heuristics or sensemaking, as discussed above, but also arise when there are multiple and sometimes competing conceptions of what constitutes safe practice, or when production pressures and scarce resources mean it is impossible to do everything required by guidance. Standards may be multiple, while at the same time resources remain limited and there may be other constraints on what can be delivered (e.g. availability of suitably qualified staff, equipment, and facilities).[73] For instance, several studies have shown that it is often impossible for clinicians to meet all guideline recommendations during routine care; up to 27 hours per working day would be required for primary care physicians to implement all applicable guidelines in the US.[73] In these circumstances, staff are forced into inescapable trade-offs and judgements, and adaptations to processes or prioritisation of tasks in ways that adjust for risk but may also create risk, possibly in ways that are occluded.

Over time, these challenges can mean that a phenomenon known as "*normalisation of deviance*", described by Diane Vaughan in the context of NASA disasters, emerges. [22] Normalisation of deviance occurs when people within an organisation become desensitised to a deviant practice or behaviour that it is no longer recognised as deviant. It can, in Vaughan's words, "neutralize signals of danger, enabling people to conform to institutional and organizational mandates even when personally objecting to a line of action."[74]

A further challenge in detecting warning signs is that normal human and organisational sensemaking tends to favour plausibility and coherence, [75] particularly when a pattern is complex, rare, difficult to discern, or lacking in strong signals. These processes may mean that people reach (sometimes prematurely) for the most credible or easiest explanation, rather than the most discomfiting one. [75] Some events, particularly initially, may be easily "explained away" as attributable to issues of staffing levels, acuity of patients, process defects, or ambiguities about whether an error or other incident really occurred and how it should be understood (see above comments on voiceable concerns). None of this is to say that deliberate concealment, refusal to listen, denial, and defensiveness do not occur, and, as the discussion throughout this report shows, these behaviours are deeply implicated in healthcare disasters – but it is to recognise that minimising institutional secrecy also demands understanding these normal human patterns and requires alertness to their significance.

3.4 Voice, psychological safety, and systems

"Speaking up" about concerns, often known as employee voice, is recognised as an important source of organisational intelligence about risks across a wide range of industries and sectors.[76] Voice may be especially important in offering insights about problems not readily detected through formal measures and risk management systems, [61] so is a crucially important source of soft intelligence in addition to harder forms of data (many of them discussed in section 5). Failures of voice are a powerful contributor to institutional secrecy, and have been identified in healthcare failings worldwide.[77] [78]

A considerable body of research has investigated why voice failure occurs. [79] [80] [81] [82] [83] It suggests that influences on voice include perceptions of hierarchical or unsupportive organisational climates, fears of damage to relationships (including with peers), anxieties about being viewed negatively, and having insufficient authority or security of employment. This work shows that, in any given situation, individuals draw heuristically on a range of considerations, such as their perceptions of whether speaking up will be deemed appropriate by a range of audiences, including managers and colleagues. Much of the time, "decisions" about whether to speak up (and how) may not be made rationally or even consciously, but informed by an implicit sense of whether voice is appropriate.[84] These "implicit voice theories" [84] are often informed not by explicit cues, but by a deeply rooted sense that speaking up may be "wrong or out of place."

People may be especially prone to consider voice "out of place" when the issue involved is discomfiting, when it involves potential blaming or criticism of others, when it involves challenge to the authority or competence of others, when it threatens relationships and harmony, when it lacks inherent plausibility or is based on uncertain, imperfect information, when it disturbs professional or peer loyalty or identity, or when it risks the person raising the concern looking ignorant, incompetent, negative or critical.[85] All of these issues can make speaking up in uncomfortable or distressing. Further, how concerns are expressed, and the (perceived) credibility of the speaker, has a crucial bearing on what is or is not done with them.[86] Characteristics including ethnicity, gender and social status interact with interprofessional dynamics, cultural norms and hierarchies to influence who gets to say what and what is acted upon.[87]

3.4.1 Psychological safety: a necessary but not sufficient condition

The importance of psychological safety in supporting voice is well established through a significant body of work over almost two decades. [88] The concept of psychological safety – defined as "a belief that one will not be punished or humiliated for speaking up with ideas, questions, concerns or mistakes" [88-90] – was originally developed in part based on research by Ingrid Nembhard and Amy Edmondson in 23 US neonatal units.[91] This research set out to investigate engagement in quality improvement work when status differences are present in teams, based on the premise that: "Speaking up freely occurs when people are not constrained by the possibility of others' disapproval and/or the negative personal consequences that might accrue to them as a result—a state of psychological safety." The authors note that, in many organisations, high status people may assume their voice is valued, whereas those with low status may experience interpersonal risk in giving voice, for example fearing embarrassment or rejection. Nembhard and Edmondson identify psychological safety and leadership inclusiveness as important to managing these risks.

When staff feel able to speak up without fear of retaliation or embarrassment, share ideas and ask questions, it can help to foster a culture of openness, improve team performance, and, in turn, help to improve performance and the safety of the service. [92] [93] [94] Psychological safety can enable people to raise concerns about their patients,[95] report adverse events,[96]

and communicate across professional boundaries. [97] Psychological safety is also important in developing a supportive diversity and inclusion climate. [98]

Psychological safety, while necessary, is not sufficient for understanding what may appear to be failures of voice. Also important is the nature of concerns themselves and the need for organisations to have legitimate ways of handling them through organisational systems in ways that are fair, non-discriminatory, lawful, and justifiable. However, as I note above and discuss in more detail later, systems for processing concerns are not always well equipped to collate and act on the many different forms that concerns may take and how they are expressed. [99-101]

As discussed in the analysis of voiceable concerns above, issues in healthcare are not always readily characterised as discrete activities that are evidently problematic, readily identifiable or deliberate.[100] Concerns do not always present themselves clearly as vivid "problems" that warrant disclosure or voice, but may be more diffuse, ambiguous and subject to interpretation. They may cover a broad range of issues. Some can be hard to judge, and a proportion may be more rooted in interpersonal difficulties than safety concerns.[102] Some warning signs may take the form of hints, speculations, rumours or gossip that may be signals of a problem, but are hard to handle through organisational systems because of their abject, ill-formed and potentially libellous (or otherwise litigable) status.[103]

Other failures of voice arise because of challenges in how well organisations listen.[104] Some organisations are culturally indisposed to hearing about problems, demonstrating "comfort-seeking" behaviour[105] or lack of hearer courage,[106] so engage in denial, defensiveness, and suppression. Other issues are more practical: organisations may struggle with the sheer volume of issues raised and the forms in which they come to attention through multiple sources of data as well as soft intelligence. Further, not all concerns are well founded; systems for raising concerns, designed with the best of intentions, and mostly used in good faith, may sometimes become weaponised or used strategically to advance local or personal interests.[107]

Once an organisation has been made aware of a concern, it may (potentially inadvertently) induce "voice futility," [107] where people feel that there is no point in giving voice because nothing appears to change in response. What appears to be a failure of action can arise when the process involved in handling the concerns is confidential (e.g. when information about a human resources (HR) process to deal with bad behaviour cannot be shared). More generally, as discussed below, organisations often struggle to address concerns and problems effectively for a variety of reasons.

3.5 Challenges of addressing quality and safety concerns

Learning about problems is just one key step in securing patient safety. Understanding the nature of the problem and risk and taking the right action in response is even more important, but is often exceptionally difficult. One useful way of thinking about this is in terms of the cybernetic model proposed by the political scientist Christopher Hood and colleagues.[108] This model identifies a generic trio of three elements – standard-setting, monitoring, and mechanisms for modification – inherent in any system of control. [108] As Hood and colleagues point out, absence of (or defects in) any of the three elements means that the system is not in cybernetic control. In addition, the three elements must be linked effectively. Yet ensuring this integration is "often the Achilles heel of control systems in human organisations, with their frequent underlaps, conflicts, and communication failures".[108] Put more simply, the link between finding a problem and taking action to address it may be weak.

One major challenge is linked to how organisations can prioritise risks among the many they face since management time, attention and resource is inherently limited, as is capability and capacity for improvement. Faced with internally-arising intelligence and information about possible risks or problems as well as the externally imposed "priority thickets" mentioned earlier, organisations can become overwhelmed by the number of demands for action. Over-saturated with recommendations and requirements, they may struggle with focus, energy, and capacity. In this context, organisations have to make judgements about what counts as a "warrant for action." [109] Given the outer context in which NHS organisations operate (discussed above), they may choose to prioritise those risks where there is an external imperative to do so – for example because it is a specific target or because it is incentivised, rather than because it has been raised as a concern or a complaint through a soft intelligence mechanism.

Once a risk has been identified, organisations are not always able to address it effectively. Organisational leaders at the blunt end, while they have responsibility for ensuring quality, safety, and risk control, often experience major challenges in making improvement: they are working within budgetary limits and multiple other constraints, as well as having to balance many potentially competing demands and risks from within their organisation and externally. A current example where concerns and risks are clearly evident is in relation to the issue of "corridor care," where people are looked after in inappropriate places in hospitals where care is neither safe nor dignified. No-one doubts the importance of this problem. Concerns are expressed frequently. Yet without significant additional bed capacity and improvements in social care, these concerns remain extraordinarily hard for organisational leadership to address.

At the sharp end, well-trained clinical teams with improvement capability and capacity may be able to make effective changes within their own scope of control – for example, they may be able to improve adherence to audit standards such as having every stroke patient weighed, because this can be organised within their department. [110] But such teams may not have sufficient power and access to resources to address risks that are institutional or structural in character, even though these may be most impactful. For example, they may not be able to get adequate timely access to scanning facilities or specialist nursing time, in part because they have to compete with other parts of their own organisation or the wider system for these resources. [111]

An example of how difficult it may be to secure improvement even when risks have been clearly identified and demonstrated can be seen in NHS organisations' responses to a feasibility study of a technique known as a "safety case." [109] A safety case is "a structured argument, supported by a body of evidence, that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given environment" [112] requiring organisations to proactively describe what procedures and actions are in place to minimise risk, as opposed to purely prescriptive approaches where organisations enforce externally imposed safety standards. [113] In the UK, safety cases became used as a regulatory technique in some high-risk industries following the 1990 Cullen report on the 1988 accident on the Piper Alpha offshore oil platform. [114] A key principle of the safety case approach is that organisations must rigorously assess risks in their systems and "make the case" that adequate measures to reduce risks to a level "as low as reasonably practicable" (often abbreviated as *ALARP*) are in place. [115]

A study I co-led of a test of the safety case approach in NHS settings [109] found that clinical teams at the sharp end appreciated the value of the approach in offering a proactive, prospective, and rigorous approach to identifying safety risks and identifying how well risks were controlled. The safety cases produced by these teams showed that risks in clinical pathways on which they focused had not been reduced as far as reasonably possible. Since clinical teams lacked the power and access to resources to address those risks that were

institutional or structural in character (e.g. IT, facilities), they often fell back on weaker administrative measures, like training or procedures, but this left many unaddressed residual risks. When these risks were brought to the attention of leaders through the safety case, leaders had to make decisions about what to do about these risks versus the multiple other risks they had to consider. Leaders were uncertain whether areas that did have safety cases should be considered to have a stronger warrant for action than those that did not – for example, risks that had been identified because an incident had already occurred, or problems occurring in one department compared with organisation-wide issues. More broadly, leaders were challenged to make the necessary improvements given their limited capacity and resources for radical systems redesign, improved staffing, IT infrastructure, buildings, or other major re-engineering or influencing of activities outside the organisation itself.

Further problems arise because each organisation may come up with its own solutions to safety issues, but may lack the necessary skill or resource to do so – and may potentially introduce new risks through de-standardisation of processes across the system. [116] For example, a study led by Farhad Peerally on which I was a collaborator identified that when safety risks are identified following an organisation's investigations into serious incidents, the risk controls recommended in action plans to address them may be lacking altogether, may not adequately focus on the contributory factors identified in the investigation report, and/or may be poorly matched to the nature of the risk. [117] Many risk controls proposed could be classified as weak, and some were directed at the wrong level – e.g., changes in clinical policies, audits and training were recommended, even when even the contributory factors were systemic in character.

Poor risk controls mean that the risk of recurrence remains, as well as creating waste and misdirected energy. Highly localised (and potentially sub-optimal) solutions to problems that are ubiquitous across a healthcare system can pose challenges in their own right, for example when clinicians move between organisations and have to re-learn protocols and techniques. The NHS still lacks a strong infrastructure for developing, evaluating, and testing risk controls at scale, so it remains the case that organisations often come up with their own solutions to problems that affect many, and those solutions may be sub-optimal.

3.5.1 Variability in improvement capability and capacity

While the problem of making effective improvement is a general one, capability and capacity for improvement is highly variable across NHS organisations, with some much more high-performing and some much more challenged. Even when organisations have been the subject of a poor Care Quality Commission (CQC) rating or enforcement action (so are highly incentivised to make change), they may struggle to make the improvements needed.

CQC does not provide improvement support directly – other parts of the system take on this role, rather than CQC itself. In maternity care, for example, services are formally entered into the NHS England Maternity Safety Support (MSS) Programme if they are rated "requires improvement" or "inadequate" in the *well-led* or *safe* domains by the CQC. The available evidence appears equivocal about the effectiveness of current efforts to secure improvement following a poor outcome of an inspection.[118] For example, of the 40 NHS hospitals that were under the Special Measures and Challenged Providers regime [119] between 2013-2018, only six were rated as 'good' subsequently, with the same number re-entering the regime.[120] Similarly, some trusts have been on the maternity safety support programme for several years, and some trusts that exited the programme have been placed back in it.[121] East Kent has been part of the programme since December 2019, yet has continued to be identified as a challenged trust by CQC. A recent observational study using routine data suggested little evidence of improvement in poorer-rated maternity units following inspection and rating.[122]

Organised improvement efforts have been a long-standing feature of the NHS, but their impacts are typically variable. [111] [123-127] The reasons for their often very mixed success relate to how they are designed and implemented, [128] [129] [124] [130] Local improvement efforts may lack the momentum, access to expertise, time and large-scale coordination necessary to find the best solutions and evaluate them rigorously.[131] A key problem is that teams are not always provided with enough training or support to enable the level of change needed,[132] and the evidence base for many quality improvement methods has remained somewhat mixed. [133] [134] [135-139] [140] [141] What is clear, however, is that organisations need to have the capability and capacity for noticing problems, prioritising them, and using structured methods to make improvements. High-performing units typically demonstrate exactly these capabilities.[92] It also likely that organisations that are struggling overall are likely to need different forms of support from those that are performing moderately or well.[142]

While improving clinical processes (the target of most improvement programmes) is often challenging, addressing concerns relating to culture (and people issues generally), may be even more difficult. Some of the most intractable problems are those involving transgressive behaviour, but these are also, as discussed in section 4.5, the areas where improvement programmes are rarely targeted, where organisations have to operate in a complex wider institutional framework, and where those who seek to address unacceptable behaviours and misconduct are most exposed to risk to themselves.

3.6 What good looks like for culture in healthcare organisations

Partly because of the difficulties in defining culture, the many different dimensions of culture that need to be considered, and the multiple levels at which cultures and subcultures may operate, the question of what makes for a "healthy" culture escapes consensus. Nor are all aspects of culture easy to see or apprehend, perhaps especially by those who are part of the culture. As summarised by Mannion,[35] based on work by Edgar Schein, these aspects may be multi-layered and variably visible, involving:

- Things that are immediately visible, heard or felt, such as the physical environment, induction and training programmes, and "ceremonies and rites" including meetings, ward rounds, dashboards used for displaying data, and policies and procedures. These things are known as *artefacts.*
- *Beliefs and values* comprise the largely unwritten rules governing behaviour, including what is considered appropriate and acceptable, what is deemed a priority, and what is rewarded socially (e.g. through being praised or criticised). The beliefs and values of a culture may be formally described in the artefacts of an organisation, for example in mission statements or brochures, but may be quite different in reality – for example, the organisation's website may declare that kindness is an important value, but in practice it might be the case that people are routinely rude to their colleagues. These incongruities are sometimes known as the difference between espoused values and values in practice, or as the difference between "work as done" and "work as imagined".[143]
- *Basic assumptions* describe the pre-conscious expectations and perceptions that may guide people in their work. They are deeply implicit and often incorporate some element of groups operating as though some things are the natural order. These assumptions, which may concern, for example, whose job it is to do something or what priorities should be given to certain tasks. These basic assumptions may be especially challenging to elicit.

Despite these complexities, much can be gained by clarity about what needs to be achieved in terms of culture in the NHS.[144] A helpful approach lies in identifying the features of "what

good looks like" for a culture for safety in healthcare settings (which might be taken as indicating a healthy culture), and also identifies what happens when these features are absent (which might be taken as indicating an "unhealthy") culture. Such an approach builds on the concept of a "safety culture" that has become increasingly popular in some sectors. The term "safety culture" entered into the lexicon almost 40 years ago, following the Chernobyl disaster, and has since been adopted by multiple high-risk industries and sectors. The nuclear industry more recently has sought a move towards what it sees as a practical concept of a "culture for safety," involving five high-level cultural characteristics, each with its own set of attributes: safety is a clearly recognised value; leadership for safety is clear; accountability for safety is clear; safety is integrated into all activities; safety is learning-driven.[145]

In the discussion that follows, I identify selected features of what, based on my knowledge of the relevant literature, good looks like in culture in healthcare, particularly (though not only) in relation to culture at the level of an individual unit. Where possible, I cite some evidence relevant to neonatal care in England, while noting that it has not been a specialist area of study of mine. Neonatal care is for babies needing specialist care after birth (for example because of premature birth or illness). It is a nationally commissioned specialised service (meaning that the contracts for provision of the service are coordinated nationally rather than by individual Integrated Care Boards) and is delivered through networks of hospitals, organised into three types of units: neonatal intensive care units, local neonatal units, and special care of baby units.

Research specifically on healthy cultures in neonatal care has been relatively limited, to the extent that a recent US study identified that creating a culture of safety was identified as the second highest priority for patient safety research topics in paediatrics,[146] after high reliability. A major challenge in conducting research on culture is that some of the methods best suited to studying culture (e.g. ethnography, which typically combines observations and interviews) may be ethically and practically challenging in the neonatal setting. However, there is a small body of work in neonatology, much of it (though not all) USA-based. For example, research by Jochen Profit and others in 44 neonatal intensive care units (NICUs) in the USA found significant variations across units in measures of clinical quality and ratings of safety and teamwork climate (assessed using validated questionnaires), but also found that on only one clinical metric (healthcare associated infection) was there an association between safety and teamwork climate as measured. [147] Dhurjati Ravi and colleagues have also published a review article on changing safety culture in neonatology, proposing that:

> *Changing the safety culture of the NICU is a long-term process that requires attention, time, and resources. The initial efforts of measurement, identifying strengths and opportunities, and implementing specific interventions, should lead to institutionalized structures that enable ongoing measurement, help reflect on progress and set the framework for continuous improvement. Key to the sustaining change, is getting buy-in and commitment from all the key stakeholders, including the staff, leadership, and hospital management to commit to the long-term process of change. Sustaining change also requires celebrating achievements, and carefully setting the stage for the next improvement cycle through a nuanced understanding of the strengths and challenges of the NICU, and building on current capabilities. The trajectory, and process of change might be different for different NICUs, but common elements of a sustainable process of change are buy-in from staff, leadership behaviors that reinforce priority placed on safety, including providing appropriate incentives for change, and a clear demonstrated institutional commitment to change through provision of resources.*[148]

The discussion below is largely consistent with Ravi et al's conclusions, though it differs on some of the detail (e.g. the importance of measuring culture and use of some specific techniques recommended in the article).

3.6.1 Clarity about vision, purpose, goals, values and priorities, including inclusive, respectful and safe care

An important feature of a healthy culture is that it demonstrates clarity about purpose, goals, values and priorities, including a clearly articulated vision and shared understanding of what teams are trying to achieve.[38] The priority given to safety and quality in particular should be clear and explicit at every level, from board to ward. Goals should also be clear at every level, since shared goals are a key feature of well-functioning teams. [38] A US study using surveys, benchmark visits and literature reviews in neonataology[149] affirmed the importance of these principles in neonatal context, noting that clear, shared purpose, goals, and values were critical to good practice in neonatal intensive care units.

Also critical are the values that inform care. In a neonatal setting, these will include inclusive, patient/family centred care, which is one of the defining features of a healthy culture. A US Institute of Medicine report defines such as care as being "respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions".[150] In a healthy culture, patients and families are treated with dignity and respect, their needs are comprehensively assessed and discussed in accessible ways using a range of techniques and in a timely way, and shared decision-making is the norm.[151]

One challenge is that misalignments can appear between the declarations of the blunt end of organisations (e.g. at board and senior management level) and the perceptions of those at the sharp end. In a large study of culture and behaviour in the NHS in many diverse clinical settings,[38] my co-authors and I found that sharp-end staff tended to identify threats to safety and quality in weaknesses in systems, failures of reliability, suboptimal staffing, inadequate resources and poor leadership. Lack of support, appreciation and respect, and not being consulted and listened to were seen as endemic problems by staff in some organisations. In contrast, some senior staff located the causes of quality and safety problems in the behaviours and cultures of frontline staff. These misalignments are likely to be indicators of a less healthy culture, and may indicate weaknesses in value congruity throughout the organisation.

3.6.2 Clarity about standards of service and practice

In a healthy culture, the standards of service and practice are clear and evidence-based, with shared understanding from board to ward about the expectations, and with the right support in place to ensure they can be achieved. Standards of service and practice for neonatal care are published by a range of bodies, and are regularly updated. As examples, they include but are not limited to the following:

- NHS England sets standards through publishing guidance aimed at improving care and by developing delivery plans.
- Service specifications set out standards of service through the commissioning process (whereby NHS trusts are contracted to deliver specific services). Neonatology is a nationally commissioned service, not one commissioned by local bodies. In England, neonatology commissioning is coordinated through NHS England, led by a Clinical Reference Group.
- The National Institute for Health and Care Excellence (NICE) publishes guidelines on specific clinical topics (e.g. on managing neonatal infection)

- Regulators set standards for organisations and inspect, monitor, and report against them. The Care Quality Commission is the primary regulator for health and social care in England, though a large number of other bodies and regulators with different functions are also involved.
- Professional regulators, such as the Nursing and Midwifery Council and the General Medical Council) publish standards relating to education and training, conduct and performance, maintain registers of professionals, and can investigate allegations relating to fitness to practice.
- Arm's length bodies may set standards through schemes that incentivise or require particular actions by NHS organisations. For example, review of neonatal deaths using the Perinatal Mortality Review Tool is incentivised by NHS Resolution (the litigation authority).
- The royal colleges (such as the Royal College of Paediatrics and Child Health, the Royal College of Obstetricians and Gynaecologists, and so on) set standards for education and training (e.g. to determine admission of doctors to specialist registers in medicine, such as in paediatrics) and may issue clinical guidance and standards relevant to specialist areas.
- National clinical audits are large-scale exercises that collect data against specific standards of care, so those standards of care typically become priorities for organisations. Some of those relevant to neonatology are discussed later in this report.

In neonatology, professional associations and charities are another important further source of standards, guidance, expectations. For example, the British Association of Perinatal Medicine (BAPM) has provided significant leadership in relation to standards of service for neonatal care, e.g., through its publication of standards for hospitals providing neonatal care in 2010.[152] Its more recent National Service Quality Indicators, published in 2017, which define the features of a high quality neonatal service, was endorsed by the Bliss charity (which is for babies born prematurely or unwell.) The BAPM indicators relate to structure and delivery of services, rather than care of individual patients. Each Quality Indicator is accompanied by specific Quality Measures. In a healthy culture, neonatal units would, as recommended by BAPM, engage in regularly reviewing themselves against these standards and would publish information about their current status and future plans in an Annual Report.

Clarity and consistency about standards of practice is important at all levels, not least so that everyone has shared understanding of the expectations and it is possible to detect deviations. Technical proficiency is a key feature of safety, and has a strong impact on culture. [92] In a healthy culture, staff can perform their tasks to a very high standard of competence. The importance of keeping skills and knowledge up-to-date is consistently reinforced and is supported by high quality training and protected time for attendance. Such training is likely to be well structured, multidisciplinary, to include teaching, skill drills, and simulations, t to strengthen team members' understanding of their work environment and mutual roles as well as their technical skills. [92]

A sign of a healthy culture is low dissonance between the standards as articulated and standards in practice. However, gaps can appear between standards "as imagined" or espoused, and what happens in practice. One issue is that the "informal curriculum"[153] (what people learn by seeing how others behave and practice) may mean that standards of good and safe practice are unclear, resulting in individual confusion and collective unwarranted variation. Other reasons include, as discussed above, drift and normalisation of deviance, which can arise because of multiple influences, including an excess of expectations over what can actually be delivered.

In a healthy culture, the leadership of organisations and the teams providing care demonstrate skill in navigating the “priority thickets” problem, but this is not always straightforward. A particular concern is to recognise the risks associated with “fantasy documents” [74] that appear to suggest all is well when the reality is very different.

3.6.3 Clarity and consistently reinforced standards of conduct and behaviour

Standards of conduct and behaviour are critically important to safety culture and to delivering high-quality, safe healthcare.[154] [155] Standards of conduct and behaviour are articulated by a range of bodies, including professional regulators and bodies, guidance to the NHS, employment law, organisations’ own policies, and other sources. Taken together, they make clear the requirement for inclusive, respectful and ethical behaviours towards all colleagues and all those using services (patients, carers, and families).

In healthy cultures, staff consistently demonstrate behaviours characterised by civility, inclusivity, trust, respect and professional courtesy. They have sound understanding of the behaviours and conditions that promote safety, including civility. Team members understand and value each other's roles, skills and competencies.[156] Communication is respectful, honest, two-way and inclusive across disciplines and professional groups, and is devoid of racist language and discriminatory attitudes or behaviours towards anyone. Colleagues value respectful curiosity and seek to understand the perspectives of others.[156]

The Francis Freedom to Speak Up review, [157] which reported in 2015, was clear that oppressive behaviour, bullying, and dysfunctional team relationships are patient safety issues in their own right. Disruptive, disrespectful, and uncivil behaviours have far-reaching consequences, for example by undermining teamwork, communication, decision-making, and clinical performance. [158] Unhealthy cultures are characterised by tolerance of unacceptable behaviour, including rudeness, bullying and harassment, disrespectful behaviour towards patients, families and colleagues, and conflicts between staff groups. Specific challenges arise in relation to discriminatory and racist behaviours, which are, by definition, disrespectful, unethical and unacceptable. [159] Unacceptable behaviour by healthcare professionals may not only reduce the clinical performance of teams [160] [161] [162] but can also have important collateral effects, including impacts of simply witnessing such behaviour. [163] [164] Tolerance of poor behaviours can generate a contagion-based spiral of unacceptable conduct. [165] [166] In neonatology, a US study using a simulation of a case of a pre-term infant whose condition had deteriorated owing to necrotising entercolitis found that those who were exposed to rudeness had poorer diagnostic and procedural performance. [161]

3.6.4 Optimised teamwork, team communication and coordination

Looking after very ill neonates involves multidisciplinary teams who have to provide highly complex routine care for very vulnerable patients, manage unexpected emergencies, and coordinate care effectively across a range of disciplines and departments. The importance of good teamwork and team communication for quality and safety care cannot be over-estimated. [149] [167]

Effective teamwork of the kind that can be found in a healthy culture can be defined as the ability of team members to work together, communicate effectively, meet each other’s needs, inspire confidence, and achieve coordinated collective action.[168] Teamwork is characterised by clear shared goals, team leadership, mutual performance monitoring, backup behaviour, adaptability, and team orientation, and is supported by coordinating mechanisms including shared mental models, effective communication, and mutual trust. [169] Team members together meet each other’s needs, inspire confidence, and achieve coordinated collective action.[168] They share knowledge and expertise effectively, and demonstrate mutual respect. [170] [171] [172] [173] They feel motivated and empowered to put forward

ideas. [156] They describe a feeling of belongingness, identify with their unit's and organisation's values, and experience pride in what they achieve.

Good teamwork depends on and contributes to effective coordination and integration of care. This requires that operational systems are effective and that roles and responsibilities are clearly defined and allocated.[174 175 176 177] In a healthy culture, professional divisions of labour and task allocations are clear, with the boundaries between differing professional groups managed clearly and explicitly. Staff cohere around common ground, and are actively socialised to a cultural frame that allows them to link their own interests and identities to a collective purpose [178] while retaining a strong sense of professional identity and pride. Staff from different disciplines, professions and roles can clarify mutual expectations, experiment with different leadership and followership styles, pick up on each other's social cues, and appreciate the roles of all colleagues.[47]

When teamwork, communication, interprofessional working and coordination are not optimised, there may be higher levels of conflict and distrust between professional groups and dysfunctional relationships, [179] especially when allegiance to a particular "tribe" (e.g. a professional or work group) comes to dominate behaviours, a problem sometimes known as "myside" bias. Poor team functioning can lead to staff feeling deterred from escalating issues due to negative emotions, fear of reprimand, fear of being wrong, intimidation and retribution.[177 180] Poorly functioning information and coordination systems are a significant threat to safety. Inadequate handover,[180-183] differing role expectations [180 184] and lack of shared decision-making [180 184] which can all contribute to poor collective understanding, increase risk, and cause delays and failures in care.[156] Patient safety risks and poor outcomes may result.[185] One US study identified an association between quality of teamwork and rates of healthcare-acquired infections in neonatal ICUs,[186] for example.

3.6.5 Orientations towards problem-sensing and voice and nurturing of conditions for psychological safety

A feature of healthy culture is one that actively seeks out weaknesses in systems and behaviours relating to quality and safety, typically using multiple techniques and sources of organisational intelligence, and that is attentive to staff and patient voice – a group of behaviours characterised by "problem-sensing". [105] These behaviours include actively seeking out information and views that offer challenge, disrupting any incipient risk of complacency.[187] For example, when a particular area is identified as an outlier – e.g., it appears to be performing especially poorly compared with others, or demonstrates deterioration over time – healthy cultures have awareness at the different levels of the organisation, curiosity is demonstrated, appropriate methods are used to determine whether there is cause for concern, the factors contributing to the situation are explored, and, where needed, the appropriate actions are taken to improve. Problem-sensing behaviours also involve caution about being self-congratulatory.[38]

In a healthy culture, staff are alert and sensitive to cues and signs of deterioration of performance that may be difficult to articulate or report formally. [61 62] This is critical, because staff are an invaluable source of information about safety concerns, poor care, faulty systems or inappropriate conduct. [47 61] Culturally, problem-sensing encourages staff voice, including active noticing of where there might be issues, speaking up about them, and ensuring that systems are in place to make improvements.[92] Noticing may take place both in real-time and during more reflective periods. Staff are encouraged to notice problems and operational failures [188] rather than tolerating or working around them. [189]

Problem-sensing behaviours therefore often involve going beyond mandated measures, and using multiple techniques for gaining access to "softer" forms of intelligence [61] through active and participatory forms of listening to patients and staff. In a healthy culture, staff and

patients/carers are respected as an important source of intelligence about safety concerns: their “ground knowledge” is seen as an invaluable resource. Multiple opportunities and different methods are provided for staff and patients to provide feedback (including both positive and negative feedback), raise concerns, and be heard. The methods address the varying preferences and capacities of diverse groups.

In a healthy safety culture, psychological safety, discussed above, and defined as the ability of members of a group to feel free to speak up, ask questions, report errors, raise concerns and ask for feedback without fearing the consequences and being judged [156] – means staff feel comfortable in challenging inappropriate decisions or actions. They can make suggestions, give and take criticism, and assess their rights and responsibilities.[190] When errors do happen, they are seen as an opportunity for collective learning, and discussed openly and honestly. Leadership support for speaking out and speaking up is clear, consistent, and demonstrated through action. [191]

In contrast, behaviour at the other end of the spectrum, known as comfort-seeking, [105] is a less healthy feature of culture. It is characterised by seeking reassurance, by taking undue confidence from the data available, and by the inability or unwillingness to seek out information that might challenge the sense that all is well. Comfort-seeking behaviours may result in organisations neglecting or being highly selective in how they access and use soft intelligence.

3.6.6 Effective systems of clinical governance, capabilities to monitor quality and safety of care, and risk management

A key responsibility of NHS organisations is for clinical governance, a term introduced around the time of the Bristol Inquiry to describe how organisations are accountable for the quality and safety of the care they provide. Clinical governance encompasses risk management, quality assurance, incident reporting and management, and continuous improvement. Where it is not sound, or where engagement is poor, risks are less likely to be detected or managed appropriately.[192]

In a healthy culture, systems of governance and risk management are designed and function well, participation is authentic and comprehensive, and systems are regarded as supportive and trustworthy by staff and are used as the basis of learning. In such a culture, formal risk management systems based on sound methods are used both in proactively identifying risks and putting plans in place to mitigate them, and in responding to hazards, which may be identified through one of many intelligence-gathering modalities.[47] There is an emphasis on learning and improving the management of risks, and risk management and mitigation designed collaboratively and using best practices (e.g. from the human factors/ergonomics discipline). Staff and patients are encouraged to make suggestions for innovation and improvement.

To discharge their responsibilities in relation to clinical governance, organisations need the organisational, and institutional capacity to use the data and soft intelligence available to them as the basis of monitoring safety and quality of systems, and the corresponding ability to use that information as the basis of action.[193] [194] [195-202] Data and other forms of intelligence are used effectively in identifying unwarranted variation across settings and over time, establishing targets for improvement, learning from positive deviance, building feedback loops with healthcare units about their performance, and informing the design, development and testing of improvement efforts.[197-199] [202] [203]

Examples of effective participation in systems of governance and risk management in a neonatal setting include high quality and complete data reporting to national clinical audits e.g., Mothers and Babies Reducing Risk through Audits and Confidential Enquiries

(MBRRACE) and the National Neonatal Audit Programme (NNAP), as discussed in section 5.3 below) and use of that data as a source of learning for improvement. There are some suggestions in the literature that high engagement with data completion to allow accurate monitoring may reflect an organisational culture of striving for ongoing quality improvement. [204] As an example, the NNAP Online tool (available since 2014) allows units to see an overall annual summary report for a specific neonatal unit or network, to compare the results for specific NNAP audit measures for different units, unit designations or networks, and to see whether a result for a unit or network is outside the expected range. A unit with a healthy culture is likely to engage with audit findings such as these guided by a spirit of learning, seeking, for example, to identify areas where improvement is required, sharing best practice, responding to NNAP recommendations on how to improve, and taking action.

Another important marker of a healthy culture, particularly one that values learning, centres on high quality incident reporting, investigation, and continuous improvement. In neonatal care settings, one marker of a healthy culture would be consistent and high-quality use of the Perinatal Mortality Review Tool (PMRT), as discussed in section 5.9. The tool was launched in early 2018 as part of the MBRRACE programme with the aim of providing a nationally standardised approach to high quality and systematic local evaluation of every perinatal death – for neonates, this includes babies who die in the first four weeks after birth. Among other things, the PMRT recommends the engagement of parents in the review process. Other markers would include taking part in morbidity and mortality review at both network and trust level and using the findings from incident investigations conducted locally and nationally as the basis of learning and improvement.

3.6.7 Highly effective operational and clinical systems, with capability for continuous improvement

As noted above, systems issues and structural conditions – including staffing levels, quality of facilities and estates, design, availability and maintenance of equipment, and so on are all crucially implicated in safety cultures. Providing an orderly, supportive environment not only facilitates good practice, it also serves important moral and social functions, serving to demonstrate respect for staff. [205] Accordingly, a healthy culture is one in which there is a commitment to sound operational and clinical systems and continuous improvement. Systems of this kind do not arise by accident, but instead take purposeful priority-setting, sustained attention and investment, capability and capacity.

Staff frequently identify gaps between what they were supposed to do and the available resources for achieving it, including poorly designed and poorly functioning micro-systems.[14] When staff at the sharp end are not provided with supportive, orderly environments, and have to balance too many competing priorities, the emphasis may shift to ‘getting on with things’. [205] They get used to compensating, making do, and taking short-cuts, and cooperative norms may be undermined, contributing to a less healthy culture, including normalisation of deviance.

3.6.8 Leadership and management

The importance of hospital leadership in organisational culture [206] is clear in the research literature, in major investigations and inquiries, and in guidance documents. In a healthy culture, leadership demonstrates unwavering clarity on its values, including respect and dignity for patients and safety and quality, and ensures that these values govern what is done. Leadership recognises the importance of optimising structures, including staffing, skill mix, environment and equipment, in so far as resources allow. Where it is not possible to address challenges relating to staffing and facilities, the reasons are made clear, as are the mitigations put in place.

In a healthy culture, good management practices, including in relation to people, operations and planning, are highly valued and performed to a high standard. Staff know what is expected of them. People management is strong. Individuals notice transgressive or disruptive behaviours and poor practice and intervene so that they do not become normalised. High quality management systems, including HR practices and procedures, support action to escalate concerns about conduct and behaviour. [207] These HR systems are effective, and the processes are clear, transparent, equitable, and work well.

In a healthy culture, leadership and management support for speaking out and speaking up is clear, consistent, and demonstrated through action. [191] Individuals in management roles are visible and accessible. They listen carefully to frontline staff and families, seeking to respond promptly to concerns or suggestions reported to them. Patients and families are recognised as partners, and are enabled to influence and improve the delivery, governance, and leadership of safety in services. Leadership behaviour is consistently implicated in promoting psychological safety.[208] [85] A key feature of such behaviour is leadership inclusiveness:[91] the extent to which leaders are perceived as accessible, invite input, and acknowledge their own fallibility.

4 Concepts of culture over time

Culture is very frequently invoked in reports of investigations and inquiries into failings in the NHS. Even when the transgressions of particular individuals have been the focus, reports have often identified culture as facilitating or complicit in failures of detection or action. Much can be learned from them that is relevant to an understanding of the role of culture in NHS failings. However, the term "culture" and underlying concepts are not defined in a consistent way in reports, and reference to the academic literature tends to be rare. This means that it is not easy to formally assess changes in concepts of culture over time through the various investigations and inquiries. Many of the insights of earlier reports hold true in later reports, and indeed the findings themselves tend to have a repetitive character, with similar themes emerging time and again, [209] often shared with disasters in other sectors.

In the discussion that follows, I identify a selection of major or recurrent issues relevant to culture from recent investigations and inquiries (mostly from 2000 onwards) with which I am familiar, seeking where possible to distinguish between the epoch pre-2013 (when the Mid Staffordshire public inquiry was published) and the epoch post-2013. I expand on the general discussion of culture above to highlight themes that are especially relevant to institutional failures, and I use some literature from disasters in areas other than healthcare to show their general relevance. Most, if not all, of the themes remain of enduring relevance regardless of epoch, so can be understood as contributing to understanding of how failings can develop, how they may go undetected, and how deficits in action to address problems may occur.

I continue to emphasise that it is rarely possible to separate out culture entirely from issues of systems and structure. I stress that institutional secrecy (discussed above) is in part a product of how information is organised and in part a product of behaviours in relation to information. Normal human sense-making processes in organisations mean that it is not always easy to recognise a potentially troubling situation and in particular to address situations where a "credibility gap" arises. These problems are compounded, and especially prone to disaster, when there are defects in systems, when cultural entrapment occurs, and when denial and defensiveness are cultural features. Because of the significance of organisations having the ability to detect and respond to problems noted by the Mid Staffordshire Inquiry, a full section on this topic follows, together with a subsequent section that describes handling of concerns and complaints from patients and staff over time.

4.1 Investigations and inquiries relevant to culture, up to the Mid Staffordshire Inquiry

One of the first major NHS scandals, involving abuse of patients at Ely Hospital in Cardiff, reported in 1969. Since then, there have been over 100 formal inquiries and investigations into health and care services.[210] Some involve sub-standard care resulting in harm to patients, some involve abuse and neglect of patients, and some involve criminal acts or other seriously transgressive behaviours by particular individuals – and sometimes all three.

A recurrent theme across reports of investigations and inquiries is the role of culture. The Bristol Inquiry, published in 2001, for example, mentioned "culture" 195 times. [30] The Mid Staffordshire Inquiry, published 12 years later in 2013, mentioned "culture" over 500 times across its three volumes. It identified, among other things, an "insidious negative culture involving a tolerance of poor standards and a disengagement from managerial and leadership responsibilities," and concluded that "extent of the failure of the system shown in this Inquiry's report suggests that a fundamental culture change is needed." Culture has

continued to be identified as a major contributor to risk and harm in more recent reports, with the investigation into failings in maternity services at East Kent [192] mentioning culture almost 100 times.

As noted above, I have sought to distinguish between reports before 2013 (when the Mid Staffordshire Inquiry was published) and those following, but the line cannot be clearly drawn (e.g., some post-2013 reports refer to events occurring several years before), and, as also mentioned above, many of the themes are common between the two epochs. The issues I note should therefore be considered as challenges that more generally need to be addressed in any future efforts to prevent or address failings in NHS organisations.

4.1.1 Systemic and cultural issues in enabling persistently substandard clinical care and allowing serious misconduct to go undetected and unchecked

A repeated finding of NHS investigations and inquiries is that failures in care are not identified in a timely way and addressed. Whether they focus on poor clinical practice resulting in serious harm that was allowed to persist, or on serious misconduct, or both, these reports have consistently identified both systemic and cultural issues in contributing to the failings.

A key example is the 2001 Bristol Inquiry, led by Sir Ian Kennedy,[30] into paediatric cardiac surgery at Bristol Royal Infirmary over the period 1984-1995. Kennedy did identify the proximal (immediate) causes of the disaster in the inadequate quality of surgical practice of two individuals, but did not suggest that the doctors involved did not care, nor that they wilfully harmed patients. Instead, the Inquiry reported, they lacked insight, and their poor performance was not addressed. Defining culture as “those attitudes, assumptions, and values which condition the way in which individuals and the organisation work,” Kennedy was particularly critical of what he saw as an insular “us and them” feature of what was identified as a “club culture,” with too much control in the hands of few individuals. He noted that “staff were not encouraged to share their problems or speak openly. Those who tried to raise concerns found it hard to have their voices heard.” He also identified problems with teamwork, where it was difficult for anyone to “stand out, to press for change, or to raise questions and concerns”. There was resistance on the part of surgeons to understand or accept the implications of mortality data when presented.

As well as characterising these cultural problems, Kennedy also, notably, located blame in the wider organisational and institutional context, which he saw as making a powerful contribution to the disaster. The surgeons at Bristol were operating in environments where failings ranged from structural issues (inadequate resources, equipment, facilities, building and staffing) through to poor leadership and management, weak governance and supervision. Also important were systems defects, including lack of systematic mechanisms for monitoring and accountability for clinical quality, defects in proper systematic monitoring of surgical outcomes, and inadequate complaints and concerns handling systems.

Multiple other investigations and inquiries have also repeatedly reported combinations of structural, institutional, systems, and cultural factors in healthcare disasters where very serious misconduct has gone undetected or unchecked, sometimes over long periods. For example, two of the most notorious examples of criminality concerned the GP Harold Shipman, who murdered over 200 of his patients in Greater Manchester,[211] and Beverley Allitt, a state-enrolled nurse, who injured or murdered 13 children on a paediatric ward in Grantham in Lincolnshire. In both cases, the behaviour was recognised by the respective inquiries as the responsibility of the individuals themselves, but features of both culture and systems were seen to have enabled them, especially in evading detection – in Shipman’s case, extending over many years.

Defects of both a cultural and institutional nature were also evident in a series of investigations and inquiries into transgressions by doctors during the 1990s and 2000s.[15] Systems for raising concerns about problematic individuals were weak and lacking in clarity. Managers felt unable to act unless they received a complaint from a patient, found it difficult to take effective action in the face of senior doctors with intimidating personalities in powerful positions, and recognised that any disciplinary efforts would be arduous, time-consuming, uncomfortable, and prone to failure. [15] It was also exceptionally difficult for doctors themselves to raise concerns about a colleague; the managerial process by which concerns might be raised and addressed was often unclear or actively obstructive.[15] These deficits in systems for handling complaints and concerns were, for example, implicated in the case of Clifford Ayling, a GP and gynaecologist, who was convicted in 2000 of 13 counts of indecent assault on female patients. [212] The Ayling Inquiry identified concerns about his behaviour dating back to 1971, and repeated complaints about his inappropriate sexualised behaviour, incompetence and brutality. But serious deficiencies in complaint handling systems, that for example required patients to present their complaints in person and to provide a case for disciplinary action, inhibited action over a period of decades.

Similarly, in the Jimmy Savile case, no evidence was found that rumours and talk about his inappropriate behaviour were ever escalated or came to the attention of senior managers, in part because the hospitals involved were hierarchical institutions operating in silos, and in part because the systems and processes in place at the time were not robust.[103]

4.1.2 Institutional secrecy and the relevance of organisational sensemaking

Across reports of investigations and inquiries is evidence of institutional secrecy, where, as discussed above, combinations of systems and culture suppress intelligence about problems and action to address them. Institutional secrecy is a pervasive risk, but it especially likely to occur when there are defects in how information is organised for safety purposes and cultural issues inhibit the surfacing of troubling information. Defective systems have an especially important role in institutional secrecy, for example when they are poorly designed and function badly.

Particular challenges arise when especially unusual features of a case or a pattern of events provide clues to a possible problem. These clues may be sensed intuitively (e.g., by those with clinical knowledge or by family members) and may be expressed as a form of soft intelligence, which then requires those to whom the concern is expressed to recognise its non-routine nature and to be well placed to undertake the relevant investigation and action. This may not happen because of organisational sense-making processes (as discussed above) and, as discussed below, credibility gaps and weaknesses in institutional systems.

As an example, the Shipman case demonstrated how an amalgam of culture and systems inhibited detection of a sustained pattern of murder. Culturally, norms at the time inhibited questioning of doctors' practice and tended to treat colleagues who raised concerns as disruptive or badly motivated.[15] But systems were also deficient – the death certification system did not work well, procedures for monitoring the prescribing and administration of controlled drugs were inadequate, Shipman was not supervised even after he was convicted of drug offences in 1976, and a series of complaints made against Shipman were not systematically investigated.[213] The processes for investigating concerns were defective, and soft intelligence was not actioned.

The Shipman Inquiry, [213] chaired by Dame Janet Smith, reported that when Dr Linda Reynolds, a neighbouring GP, contacted the coroner with her concerns, she not only reported the apparent excess of deaths at Shipman's practice, but also identified what she saw as unusual features of the deaths. They were disproportionately among older women who died at home – when more usually deaths are equally distributed between men and

women, and people who die at home have usually had a period of illness and typically die in bed with family present. Further, it is unusual for a GP to be present at a death or to find a patient dead. Though initially dismissed by a police-led investigation, Dr Reynolds' suspicions were later confirmed by a detailed notes review undertaken by Richard Baker, [211] and by the Inquiry itself, which reported distinctive patterns in the time of day the murders were committed (often in the afternoon).

Another example is the Allitt case, which saw 26 incidents involving 13 children over 61 days at Grantham hospital. Locally, the unusual pattern of these incidents was noticed by some, but was initially attributed to unusual run of bad luck and poor facilities and staffing. The night services manager wrote to the nurse manager pointing out that there had been seven "cardiac arrests" in the last three months, compared with none in the previous three years, but focused on concerns about staffing and equipment as the likely causes of the issues. Clinical investigations that might have provided earlier insights into what was happening were either not undertaken or were misinterpreted, and a paediatric consultant at Grantham was unsuccessful in persuading the coroner to order a specialist post-mortem examination on one of the early victims. The clinicians were extremely busy in a high-complexity, under-staffed, intense work environment, where it was possible to attend to only a small number of cues in each case and, indeed, the sheer volume of incidents became overwhelming. [75] Accordingly, for a sustained period, the prevailing view was that the series of incidents at Grantham was an unfortunate cluster.

The Allit case can be understood as a classic instance of organisational sensemaking, and in particular a form of sensemaking known as "satisficing", where the least disruptive conclusion is reached too early. Satisficing is often highly functional, given the huge costs (of many kinds) that might be involved in searching for non-standard explanations, but it is also sometimes (particularly in healthcare failings) disastrously wrong.

> *In this instance [Allit], however, the standard explanations drew on the culture (Schein, 1985) or ideology (Trice and Beyer, 1993, p. 33) of the medical profession, and this incorporated implicit premise controls (Perrow, 1986) which caused individuals to downplay 'deliberate harm' as an explanatory category, resulting in a 'professional blindspot'(Weick, 1995, p. 113)…. Short of actually witnessing Allitt in the act of harming a child, it seems, the social sanctions which prohibited individual or social reference to the possibility of murder meant that almost any other explanatory category was more available for making sense of events.*[75]

Once an organisation has become blinded to an issue or have understood it in a particular way, it may become vulnerable to what is called "cultural entrapment," a term used by the sociologists Karl Weick and Kathleen Sutcliffe to describe events in the paediatric cardiac surgery programme at Bristol Royal Infirmary (BRI).

> *The example of BRI represents a sustained period of blindness associated with organizational culture. Culture can entrap hospitals into actions from which they cannot disengage and which subsequently lead to repeated cycles of poor performance. …entrapment means the process by which people get locked into lines of action, subsequently justify those lines of action, and search for confirmation that they are doing what they should be doing. When people are caught up in this sequence, they overlook important cues that things are not as they think they are.*[214]

Inquiries and investigations have repeatedly shown that varying degrees of denial, concealment and deliberate evasiveness at senior level greatly compound the challenges of normal sense-making as an element of institutional secrecy. These patterns are particularly likely to occur when comfort-seeking behaviours neglect negative information, focus on reputational management, and use a dismissive approach to criticism and concerns raised

by staff and patients.[38 62 215] Cultural issues may powerfully aggravate poor intelligence about incipient problems[216] or suppress it altogether, for example when leaders and managers dismiss warning signs and expressions of concern and anxiety, instead "normalising" them.[216] Habit and routine, false assumptions, poor communication, and misplaced optimism[217] and poorly designed and coordinated improvement efforts may mean that remedial action is misdirected.

4.1.3 The credibility gap and transgressive behaviours

A recurrent finding of inquiries and investigations is that, in the absence of formally available data showing a problem, suspicions nonetheless form among clinical colleagues, patients and relatives, or others, in advance of official signals but based on soft intelligence. The "credibility gap", a term used in the Shipman Inquiry, describes how these individuals may encounter scepticism or active resistance when they first raise concerns. Those who raise the concerns may be seen as unreliable, lacking in credibility, hysterical or over-imaginative, or badly motivated. Benign explanations may be offered for the issues at hand (as above, as a result of organisational sensemaking and satisficing), and, initially at least, appear much more plausible.

Perhaps ironically, disbelief is particularly likely when the events reported are so exceptionally transgressive and unusual that they defy credulity. One consequence is that any investigations conducted in response to such concerns may be misdirected or inadequate, and may not, for example, be designed to or be capable of investigating the possibility of extraordinary explanations, including a malign, and potentially criminal, actor.

As noted above, Dr Linda Reynolds, a GP at a practice close to Shipman's, developed concerns about the number of cremation certificates her practice was being asked to countersign for Shipman, but she was not alone in her sense that something was amiss. Her concerns were shared by a local undertaker. As Dr Reynolds had died by the time the Inquiry took place, her husband described how she agonised over whether to escalate her concerns formally. Some of her colleagues at her own practice, demonstrating sensemaking behaviour (and without being part of a culture of denial) felt that there were rational explanations for the large number of female patients of Shipman's who died in their own homes. Dr Reynolds nonetheless contacted the coroner, reporting the large excess in cremation forms at the single-handed Shipman practice she had noticed compared with her own practice, which had a patient list three times larger, and, as noted above, some unusual features of the patterns of deaths.

The coroner contacted the police. Dame Janet Smith, who chaired the Inquiry, was very critical of the conduct of the subsequent police investigation, which was not undertaken competently or, apparently, with the possibility that criminal behaviour might be involved. The police investigation concluded that there was no cause for concern, largely because both the police and linked Health Authority investigations were insufficiently alert to the possibility that Shipman might be killing patients. The Inquiry suggested that the medical investigator "found the suggestion so incredible that it is doubtful that he contemplated it as a real possibility….if he did notice anything which was odd, he immediately found an innocent explanation for it." It was not until the death of Kathleen Grundy three months after this initial investigation concluded, and the raising of the alarm by her daughter, that the reality of the situation became more clear.

In the case of Allitt, one paediatric consultant (Dr Porter) at Grantham came to the view that someone might be deliberately harming the patients. However, he encountered incredulity – the "credibility gap" when he tried to raise his suspicions, to the extent that he was discredited and described as having "fanciful ideas". The second paediatric consultant at Grantham remained unconvinced of the possibility of malign behaviour, and other staff

appeared to believe that the problems were arising because of staff shortages, equipment issues, and other structural problems.

It was a group of doctors at Queens Medical Centre (QMC) in Nottingham who raised the alarm about the exceptional number of children admitted for specialist care from Grantham over a short period.[218] The doctors communicated their concerns to David Hull, QMC Professor of Paediatrics, who urged Dr Porter at Grantham to call the police. A second important intervention was that of Vincent Marks, a well-known pathologist and clinical biochemist, who, convinced that one of the babies had been intentionally injected with huge doses of insulin, [218] was able to persuade those attending a meeting convened by the police of evidence of possible criminal behaviour.

Inquiries involving sexual assault of patients demonstrate similar patterns, where the unusually extreme nature of the transgressions may mean that allegations are met with incredulity. In the Ayling case (involving sexual abuse and assault), patients were making their reasons for wishing transfer out of his practice known to neighbouring practice throughout the 1980s and early 1990s. These issues were noticed to the extent that a log of these complaints was kept at the neighbouring practice over many years. But a combination of cultural reticence, failure to recognise the seriousness, a history of being accused of "poaching" patients by Ayling's practice, system defects, and inadequate responses when attempts were made to raise the issue with authorities combined to suppress action.[212]

Similarly, William Kerr and Michael Haslam were two psychiatrists who, working in North Yorkshire, sexually abused female patients over a period of more than 20 years. [219] Both were convicted of indecent assault (Kerr in 2000; Haslam in 2003). The Inquiry led by Nigel Pleming, published in 2005, noted that, even by the 1970s, a pattern had begun to emerge where women who complained were automatically disbelieved, no action was taken, and no attempt was made to join up accounts of different patients with similar stories. It identified "cultural, systemic, and moral issues" that allowed repetition of the abuses over a prolonged period. Few patients submitted formal complaints, and all declined to take part in formal disciplinary proceedings (in some cases because they were intimidated). Investigations were drawn to an early conclusion owing to lack of evidence. The Inquiry was clear that issues of systems and process were clearly implicated in the unchecked persistence of appalling conduct, identifying poorly developed and poorly understood processes, particularly for dealing with concerns, rumours and withdrawn allegations, poor record-keeping, and failure to share concerns (whether proven or unproven) across organisations,

The credibility gap was also a key feature of the Savile case. A "themes and lessons learnt" report led by Kate Lampard, published in 2015,[103] noted that: "Much of the story of Savile and his associations with NHS hospitals is unusual to the point of being scarcely credible." The investigations were extensive, including 28 reports published in June 2014 and 16 published in February 2015. The Kirkup and Marshall report into Savile's behaviour at Broadmoor (2014) found a culture at ward level that tolerated "boundary violations, including those of a sexual nature, and discouraged reporting." Crucially, while cultural in character, these transgressions were facilitated by systems defects: written policies and procedures were lacking.

4.2 The Mid Staffordshire Inquiry 2013: a landmark report

The Mid Staffordshire Public Inquiry (2013), led by Sir Robert Francis and published more than a decade after Kennedy's 2001 Bristol Inquiry, identified the causes of organisational degradation at the trust as systemic: though Francis criticised (often trenchantly) many people, no single agency or individual was identified as blameworthy on its own. The faults,

Francis concluded, were institutional in character. While he attributed the catastrophic failings primarily to management at the Trust, he also emphasised weaknesses in the wider systems designed to oversee quality of care, ensure accountability, and drive improvements.[28] Francis was emphatic about the role of culture, reporting an "insidious negative culture involving tolerance of poor standards and disengagement from managerial responsibilities."

> *Aspects of a negative culture have emerged at all levels of the NHS system. These include: a lack of consideration of risks to patients, defensiveness, looking inwards not outwards, secrecy, misplaced assumptions of trust, acceptance of poor standards, and, above all, a failure to put the patient first in everything done.*

The Inquiry identified that a key contributor to the disaster at Mid Staffordshire was that clarity of purpose in relation to patient safety and quality of care tended to be displaced by issues of finance and performance (narrowly defined). Cultural issues were deeply implicated in failure to notice or address how bad things were. For example, the report found that the trust board "did not listen sufficiently to its patients and staff or ensure the correction of deficiencies brought to the Trust's attention." However, the report also identified multiple systems problems, including what we might now term institutional secrecy: information that might have alerted external bodies to the situation was fragmented, poorly structured, or not actioned.

Comfort-seeking behaviours were a key feature of institutional secrecy at Mid Staffordshire. Those in senior positions appear to have developed "blindsight" – a way of not seeing or denying what was going wrong, and then repeating a pattern of downplaying them. The public Inquiry found that signals of concern from both staff and patients were routinely ignored by the board at the trust. Over 900 messages went from staff to the National Patient Safety Agency giving feedback on under-staffing, yet they were ignored by the trust itself. Patients received formulaic responses to complaints, and the Board never looked at complaints.

This was a problem compounded by the institutional and regulatory complexity that characterised the NHS during this period. As George Boyne[27] (and many others) have pointed out, a proliferation of regulators can be harmful, because multiple competing pressures, expectations and priorities may be created, resulting in confusion and demotivation. Francis identified that the number of different agencies and bodies with a say in the NHS contributed to fragmentation, ambiguity and diffusion of responsibility: accountability for patient safety and quality of care was dispersed and poorly coordinated. Though many bodies were charged with some degree of responsibility for patient safety and quality of care, their duties were not clearly defined, nor was the remit of their authority and powers. Illustrating the "problem of many hands" [26] discussed earlier, accountability and authority were not clearly demarcated, coherent or authoritative.

In consequence, trusts, including Mid Staffordshire, received confusing signals about where they should direct their attention and effort. This permeated all levels from the "blunt end" (the board and executive) to the "sharp end" where care was delivered. The Inquiry made clear that regulatory complexity also had a number of serious impacts on intelligence-gathering, including both gaps and substantial duplication in some areas. Despite the large volumes of data being collected, information was not shared effectively between agencies. This obstructed the compilation of a profile of any individual trust, including Mid Staffordshire. It also meant that many warning signs went unnoticed because patterns were not recognised. Further, there was evidence of considerable rigidity in the way each agency/body operated, such that they lacked (or perceived that they lacked) useful discretion in how to interpret, share or act on information.

External demands for accountability in fact had perverse effects, as the senior level of the trust became focused on defending what it saw as its own organisational interests, managing external impressions, secrecy, and the reinterpretation of failure as success. Senior leadership at the trust demonstrated behaviours that appeared to be rooted in hubris, including the belief that it was compliant with quality and service standards despite numerous indications that it was not.

Those at the sharp end who recognised how bad things were seemed helpless and disempowered; those at the blunt end who did have more power seemed to be too distant from the realities of the wards. As in the Challenger disaster[22] and other failures in high risk industries,[220] staff at the trust with specialised technical expertise – including doctors and nurses – were marginalised from the trust's decision-making structures. Even when evidence of poor practices and performance came to light, diffusion of responsibility and confusion of remit across the multiple actors in the regulatory environment meant an absence of clarity about what actions could be taken and who should take them with what expectations of securing improvement.

4.3 After the 2013 Mid Staffordshire Inquiry

The Mid Staffordshire Inquiry was in many ways a sentinel event for the NHS, leading to a wide range of policy responses and statutory and regulatory changes mentioned throughout my report. Significant service re-design and changes in arrangements for quality and monitoring have also taken place in the period since 2013, not all of them directly linked to the Inquiry itself. I briefly summarise a small selection of these here (others are described elsewhere, e.g., in the sections on complaints and concerns, duty of candour, and so on.).

4.3.1 Regulatory changes

Much of the response to Mid Staffordshire involved regulatory changes in light of Francis's criticism of the failure to detect or act on signs of organisational degradation at Mid Staffordshire. The Care Quality Commission's 2013-2016 strategy[221] saw the launch of three separate inspection directorates, each headed by a Chief Inspector; quality ratings modelled on the Ofsted approach; risk-based inspections; and use of five key questions to be asked in every inspection. Fundamental standards of care were also introduced, as was a duty of candour and a "fit and proper person" test for NHS directors.

CQC gained wide-ranging powers of enforcement under civil or criminal law. The model of enforcement built into the CQC is that of a government agency that is empowered to take enforcement action. Some of the actions the CQC can take include issuing warning notices that highlight areas of concern, requiring organisations to take action, imposition of conditions, requiring an improvement plan, issuing fines or civil penalties, taking action to prosecute, and cancellation of registration. It can also impose conditions on registration. Where people are at immediate risk of significant harm, the CQC can use its 'urgent' powers, which means that in some cases it can take immediate action such as suspending or restricting the service. Being denied the right to undertake an activity is a powerful deterrent against breach of standards, but it is currently relatively rarely used in the NHS. More commonly, a package of NHS England support and monitoring may be activated under the NHS System Oversight Framework.[222]

4.3.2 Changes in organisation and delivery of services

Though not always linked directly to the Mid Staffordshire Inquiry, much has changed in the organisation and delivery of services since the report was published, in some cases continuing efforts that began before the Inquiry. Neonatal care in particular has undergone substantial reform over the last two decades, dating to a National Audit Office report in 2007[223] that identified significant variation in the delivery of neonatal services.[224] A Department of Health Toolkit for high quality neonatal services was published in 2009. The February 2016 *Better Births* report, [225] which set out the Five Year Forward View for NHS Maternity Services in England, identified a range of challenges in neonatal services, including medical and nurse staffing, nursing training, and cot capacity.

In response, NHS England published the 2019 Neonatal Critical Care (NCCR) Transformation Review, [226] which set out a range of priorities including putting the baby and family first, improving family experience, transforming workforce, strengthening networks and transport services, improving patient pathways, reducing medication errors, and ensuring best outcomes for pre-term infants. There are now 10 Neonatal Operational Delivery Networks (ODNs), organised by geographical footprint. These networks are mandated by NHS England to work with neonatal units and other key stakeholders on an operational, strategic and transformational level to support and enhance quality and equity of neonatal care.

4.3.3 Priority given to culture

A prominent feature of the government's response to the Mid Staffordshire Inquiry was to give priority to culture, including a culture of learning and improvement that could recognise safety issues quickly and take appropriate action. The 2013 Berwick report on the safety of patients in England commissioned by the Government [10] in the wake of Mid Staffordshire, for example, sought a positive culture characterised by learning and improvement that would eschew blame and engage in patient partnership. The 2015 Department of Health publication on "Culture change in the NHS: applying the lessons of the Francis Inquiries" [227] laid out a framework for improvement organised around four themes: preventing problems, detecting problems quickly, taking action quickly and ensuring robust accountability, and ensuring staff are trained and motivated.

4.3.4 Patient safety strategy and other initiatives

The Care Quality Commission published a report in 2018 known as *Opening the Door to Change: NHS safety culture and the need for transformation*, [228] making seven recommendations. Several of these have been implemented, including, as mentioned above, a new patient safety strategy and a revised framework for serious events. Others are only partially implemented or have more progress to make, including standardisation of healthcare processes where appropriate.

NHS England published its Patient Safety Strategy in 2019, [229] with its sub-title explicitly including an emphasis on "safer culture, safer systems, safer patients." Based explicitly on developments in safety science, the Strategy sought to promote systems thinking, human factors (including the SEIPS framework mentioned above), and "just culture" principles.

Some of the innovations since the publication of the Strategy, which was updated in 2021, include The Patient Safety Incident Response Framework (discussed in more detail in section 5.6), national clinical review and response to patient safety incidents, including an NHS Patient Safety Alert system for issues that require national action, and the medical examiner system (discussed in section 5.10). Many of these initiatives are supported by a novel role in NHS organisations – the *patient safety specialist* role in NHS organisations,

which was introduced with the intention that that patient safety specialists would coordinate action across their organisations and work to embed evidence-based, scientifically informed approaches. These specialists are intended to be “key leaders within the safety system” who will promote “systems thinking, human factors and just culture principles.” [229] All NHS organisations were asked to identify one or more patient safety specialists by late 2020, and were asked to prioritise local implementation of the Strategy relating in the following areas:

- Support transition from National Reporting and Learning System (NRLS) and Strategic Executive Information System (StEIS) to the new Learn from Patient Safety Events (LFPSE) service
- Involvement in implementing the new Patient Safety Incident Response Framework (PSIRF)
- Improving safety culture
- Responding to National Patient Safety Alerts
- Implementation of the Framework for Involving Patients in Patient Safety
- Improving patient safety education and training
- Addressing patient safety improvement
- Implementing the medical examiner system

Other initiatives since Mid Staffordshire have included the creation of regional patient safety collaboratives to deliver a range of objectives around quality and safety, defined nationally and locally.[230]

4.4 Selected themes since the Mid Staffordshire Inquiry

Despite policy and organisational efforts subsequent to the Mid Staffordshire Inquiry, the period since 2015 has seen further investigations and inquiries into organisational catastrophes around the NHS, again involving criminal behaviour, issues of neglect and abuse, and seriously substandard performance and practice, and again with sometimes substantial overlaps between them. Many themes have sadly continued to recur, though some of the reports largely refer to events before 2013. What the various reports have in common is that they have increasingly and insistently emphasised the role of culture. In the discussion below, I identify some recurring themes, particularly those that are relevant to understanding the role of culture. As well as mentioning selected inquiries with which I am familiar, I cite other relevant evidence.

The discussion below is not meant to suggest that no improvement has occurred – but it is to indicate that the factors that contribute to failures of care tend to have features in common, in particular in enabling an adverse situation to develop, in failing to detect it in time, and in failing to address it effectively. This section is followed by a section on problems in human resources management (HR) systems in the NHS and the influence of the wider institutional and legal environment, which I believe make a significant and under-appreciated contribution to dealing with issues involving transgressive behaviour.

4.4.1 Institutional secrecy

Bill Kirkup’s 2015 investigation into failings at the maternity unit in Morecambe Bay NHS Foundation Trust, [179] examining 20 significant incidents including three maternal deaths and 16 infant deaths over 11 years (2004-2013), was published two years after the Francis public inquiry. Illustrating the challenges of institutional secrecy discussed earlier, the Morecambe Bay report found that information about quality and safety of clinical care was poorly structured and fragmented, that clinical governance systems were weak and that responses to adverse events were grossly inadequate – the combination of systems and culture that predisposes to disaster noted by other inquiries.

The quality of investigations into adverse events at Morecambe Bay was poor, conducted by the same senior midwife (on their own), adopted a protective approach towards midwives, did not identify failings of care, relied on poor quality health records and did not give weight to the accounts of patients and relatives. Complaints from families were treated cursorily. The reactions of maternity unit staff to concerns about quality and safety of care were characterised by denial and rejection of criticism. A letter from a consultant obstetrician set out concerns to the clinical director and medical director, but did not receive a documented response. The board at Morecambe Bay failed to acknowledge and address problems effectively; it was instead focused, as the Board at Mid Staffordshire had been, on gaining foundation trust status.

Though there was knowledge of the dysfunctional nature of the unit at Trust level by 2009, the action in response was flawed, partly because of poor flow of information through professional and managerial reporting lines and partly because incidents were treated as unconnected events – a classic example of institutional secrecy. A 2010 review (the Fielding Report) with significant criticisms of the maternity unit was given limited circulation, and the Strategic Health Authority accepted assurances that there were no systemic problems and that action plans were in place. A Care Quality Commission investigation team declined a referral to investigate partly on the basis that the five incidents up to that point appeared unconnected, based on superficial information provided on cause of death. Failed communications between CQC and the Parliamentary and Health Service Ombudsman then followed. The Trust was registered with the CQC without conditions in April 2010. It was also approved for foundation trust status by Monitor in September 2010. The position only began to change in 2011 following receipt of the Fielding report by CQC and Monitor, a highly critical coroner's report into the death of baby Joshua Titcombe, the commencement of a police investigation, and further families coming forward in response to the police investigation.

Sadly, many of these findings were repeated seven years later in Kirkup's 2022 investigation into the failures in maternity and neonatal services in East Kent. Again, institutional secrecy was evident, and a pattern of comfort-seeking was a clear feature: the report found that "the Trust wrongly took comfort from the fact that the great majority of births in East Kent ended with no damage to either mother or baby."[192] Multiple instances of concerns raised by a range of parties (junior and senior; staff and service user) were given inadequate attention by trust leadership.

In another case with some similar features, involving abuse and poor care of those using the Edenfield Centre, a mental health service for people with complex needs, Oliver Shanley [231] found that "insufficient curiosity" blighted the response of the board to the wealth of information presented to it. The board focused more on issues such as expansion, reputation and meeting operational targets than on quality of care, operated insufficient oversight of the quality, and relied disproportionately on the periodic opinions of external regulators rather than strong clinical governance.

4.4.2 Cultural contributions to poor care

Culture at Morecambe Bay was a major factor in the analysis Kirkup presented of a dysfunctional unit, the leadership and management of the organisation in which it was located, and the wider system of monitoring and regulation.[179] The report identified that clinical competence, skills and knowledge were deficient. Risk assessment and planning was poor. Pursuit of "normal birth" was allowed to dominate practice and behaviour. Working relationships between and within professional groups of midwives, obstetricians and

paediatricians were exceptionally bad, grimly echoing Kennedy's language of "them and us" in the Bristol Inquiry.

The Ockenden reports into maternity care at Shrewsbury and Telford Hospital NHS Trust similarly revealed poor quality care linked to tensions and rivalries between different clinical groups, failure to listen to and respect families, and inadequate handling of concerns and complaints at all levels. [232] [233]

4.4.3 Failures relating to voice and response

Voice covers a wide range of behaviours, as discussed above. A repeated theme in investigations into organisational degradations in the NHS is failure of voice, such that staff do not raise concerns or, when they do, they receive inappropriate or inadequate responses. Investigations frequently identify dissonance between formally espoused values of openness and listening, and the realities of raising concerns as they are experienced by those at the sharp end. [234]

Reports repeatedly find that staff unwillingness or inability to raise concerns is strongly linked to perceptions that, whatever the official organisational position, exercising voice is likely to be risky and ineffectual. [38] [235] At East Kent, for example, concerns raised by families were sidelined. Staff experienced *voice futility* (discussed above)*:* they had largely given up reporting concerns because little happened to improve and because made them vulnerable to do so. It was particularly difficult to raise concerns when it was senior people who were bullying and HR processes were so poor.

Recent inquiries and investigations have also shown that patient concerns have not always been heeded as they should have been. In several cases, concerns have only been heard when patients mobilised as a group and took advocacy action – as in the Morecambe Bay, East Kent, Shrewsbury and Telford maternity services, and the case of the surgeon Ian Paterson, who was convicted in 2017 of intentional wounding.

4.4.4 Leadership and management, and cultural entrapment

Inquiries and investigations into recent major organisational failings point to significant shortcomings on the part of senior managers. At East Kent, for example, the report found that leadership demonstrated false assurance and defensiveness. The denial of problems "ran right through the Trust, from clinical staff to Trust Board level." The report documents clear examples of brushing things under the carpet, including eight missed opportunities for change. A critical 2016 Royal College of Obstetricians and Gynaecologists report was said by the trust to be based on "hearsay and uncorroborated comments". Legitimate challenge by the Care Quality Commission and the Health Service Investigation Branch was "always met with anger and defensiveness."

A recurrent theme (though the term is not used explicitly) across the reports is that of cultural entrapment – the phenomenon described by Weick and Sutcliffe in their analysis of the Bristol Inquiry.[214] As above, it means that people get locked into lines of action, justify those lines of action, and look for confirmation that they are doing the right thing: "when people are caught up in this sequence, they overlook important cues that things are not as they think they are."

4.4.5 Workplace behaviours and conditions

Behaviours in the workplace were identified in the Mid Staffordshire Inquiry and Sir Robert Francis's subsequent reports as a key patient safety issue. Workplace conditions and

behaviours remain a major concern since then. Some workplace cultures in the NHS are highly adverse, leading to poor experiences of work, mental health difficulties, and consequent negative impacts on patient safety and quality, including those that erupt into organisational crises and disasters.[236]

Workplace conditions have an important role in staff behaviours towards each other and towards patients. The East Kent report, for example, found that it was not an organisation that made its staff feel valued or safe. Some of the contributors to poor conditions were structural. The estate was poor: there was only one staff toilet for the whole unit at William Harvey Hospital, and staff on one ward had to notify colleagues that they were going to use it. Midwifery staffing levels were too low, routinely creating a very difficult working environment with colleagues stretched across too many duties.

Some staff groups, especially those that are minoritised, are particularly at risk of poor behaviours and culture, to the extent that the NHS has been described as diverse but not inclusive. [237] Lack of effective and safe processes to escalate concerns for those who experience overt racism has been reported. [238] Although around a quarter of NHS staff are from ethnic minority backgrounds, they are less likely to progress to senior and leadership roles. [237] Reports of bullying and disrespect, harassment, sexual abuse, and racism and discrimination, are alarmingly high. The UK REACH study found that around a fifth (21.2%) of staff surveyed October- December 2021 reported they had experienced discrimination in the previous six months, either from patients, colleagues, or both, but only half the staff who had experienced harassment, bullying or abuse said that they or a colleague had reported it. [239]

The NHS People Plan is clear that everyone should benefit from effective management,[240] but the realities are often very far from this aspiration. Line managers are often under-resourced and poorly trained and supported for the roles they are asked to take on, frequently on top of other duties, [241] and are often “accidental managers.”

4.4.6 Teamworking

Teamwork remains a key challenge in the NHS, despite being identified repeatedly as a contributor to organisational disasters. The East Kent report recommended that relevant bodies be charged with reporting on how teamworking in maternity and neonatal care can be improved, with particular reference to establishing common purpose, objectives and training. However, in the most recent NHS staff survey (2023),[242] only 54% of respondents believed that teams within their organisation work well together. Only 57% of respondents reported that their team disagreements were dealt with constructively. Fewer than three-quarters (74%) said the team they work in had a set of shared objectives, even though shared goals are one of the hallmarks of a good team.

4.5 Problems in HR systems in the NHS and the influence of the wider institutional and legal environment

Organisational and institutional failure to address transgressive behaviours and unacceptable practice over a very lengthy period has continued to be reported in investigations and inquiries both before and after Mid Staffordshire, and more widely. A major challenge, and one that receives inadequate attention, is that NHS HR (human resources) functions are not always fit for the challenges they have to address. HR departments demonstrate wide variation in the quality and practice of local procedures for grievances, disciplinary processes, and whistleblowing, [159] though this remains an under-

studied area. Increasing concern is expressed that the institutional and legal environment surrounding employment law may not be well suited to promoting positive workplace relationships and equity, nor the specifics of healthcare environments. [243]

A key challenge for the NHS is that HR processes and procedures are focused specifically on employment rights rather than, necessarily, patient safety, quality of care, or protection of patients. Employment rights are governed by a complex set of legal rights and obligations arising from Acts of Parliament, regulations, contract law, case law and Employment Tribunal judgments. ACAS (the national Advisory, Conciliation and Arbitration Service) provides guidance on how many employment rights should operate in practice. For example, employment rights in relation to unfair dismissal are specified in the Employment Rights Act 1996, with ACAS providing a Code of Practice which requires that employers should have a disciplinary procedure in place. The ACAS code of conduct covers both disciplinary issues (where the organisation identifies as possible disciplinary concern, for example relating to performance or conduct) and grievances (where the employee raises a concern about the employer).

The various penalties that may be given for disciplinary breaches may also pose difficulties for those seeking to deal with issues of conduct and behaviour, (and culture generally) in a healthcare setting. The sanctions identified by ACAS guidance usually take the form of warnings that escalate from informal to final, or, under specific circumstances, dismissal. The warnings are intended to be “disregarded” for disciplinary purposes after a specified period. If an employee receives a final written warning, further misconduct or unsatisfactory performance may warrant dismissal. Depending on the employee’s contract, another disciplinary penalty may also be used (e.g. disciplinary suspension without pay, demotion, loss of seniority, or loss of increment). These sanctions can only be applied if they are allowed for in the employee’s contract or with the employee’s agreement.

Suspensions can be used only in certain circumstances when an investigation is being carried out, and it is expected under ACAS guidance that most disciplinary situations will not require suspension. Suspension can only be considered exceptionally if there is an allegation of serious misconduct and other conditions apply (one of which is the person being the subject of criminal proceedings). Unless there is a clear contractual right for an employer to suspend without pay or benefits, employees must receive their full pay and benefits during a period of suspension – something that may be a significant challenge when trying to run a cash-constrained clinical service.

The threshold for “gross misconduct” (which can lead to dismissal) is high. If an employer wishes to end the employment of an individual, they must do so in a legally compliant way. In particular, organisations are required to have both a good reason for dismissal and to have followed a fair procedure. People who have worked for the same employer for more than two years can make a claim for unfair dismissal. Those making a claim must go through an Early Conciliation process. This process can result in a Settlement Agreement being drafted, often with ACAS involvement, which is binding on all parties. The correspondence about reaching the Settlement Agreement is usually considered legally privileged, so cannot be disclosed.

If a claim for unfair dismissal reaches an Employment Tribunal, the tribunal will typically scrutinise the process of dismissing the person, and will consider whether the employer has acted within the range of reasonable responses to the disciplinary issue. The burden of proof is on the employer to show that they had good reason to dismiss the person and acted fairly by following a fair procedure consistent with the ACAS code of practice.[244] It has been suggested that around 50% of cases are lost at employment tribunals on grounds of procedural unfairness,[245] yet many staff in the NHS are given very little induction, training or guidance on how to investigate concerns about colleagues’ conduct, behaviour, or practice;

they may rise to management level without clear understanding of how to handle such situations. [246]

The risks associated with unfair dismissal are a major focus of concern for organisations seeking to deal with unacceptable conduct or performance. Involvement in an employment tribunal will typically result in significant costs for the employer, for example in legal costs, time and energy, and distraction from business and clinical activities, as well as potentially causing reputational damage. For the most part, many of the costs (e.g., legal costs) are not recoverable, so the organisation incurs costs regardless of the outcome. If the employee succeeds with their claim, the tribunal may make an unfair dismissal award which can be of two types: (i) basic, and calculated similar to redundancy pay or (ii) compensatory, which is capped unless the dismissal is deemed "automatically unfair." The employer will be liable for these awards on top of the costs associated with being involved in tribunal.

A claim for unfair dismissal may consume a huge amount of senior management time (possibly extending over several years) and potentially hundreds of thousands of costs in litigation costs, payments to those who are suspended, and payouts for awards made by tribunals. In one recent case in an NHS trust, an individual whose behaviour was considered bullying and abusive over a 15-year period went through multiple HR investigations and disciplinary processes before being dismissed because of a breakdown in relationships between her and colleagues. The case went to a tribunal, which found in favour of the trust, but not before very large costs and burdens would have been incurred.

NHS organisations often experience a high level of HR issues. Given costs, risks, burdens and uncertainties associated with the employment tribunal system, and the nature of the legal advice they receive, their approach to handling these issues may be adversarial in character, focused on organisational risk mitigation and procedural compliance.[159] Concern to avoid expensive litigation with uncertain outcomes means that most claims are settled before proceeding to a final hearing, since organisations may see this as a way of containing risks and costs. Settlement agreements may involve a payment (e.g. equivalent to a number of months' salary) and often involve confidentiality clauses, which can mean the circumstances of the departure are not disclosable, even when people move from one NHS employment to another. Employers are not obliged by law to give a work reference for any individual, and they are exposed to claims for damages if any references they do give are perceived to be unfair or misleading. The effect is that new employers may be unaware of issues in a previous employment.

Concerns about those who are registered health professionals may more easily be shared under certain circumstances, particularly when a professional regulator has been involved or when an issue has been recorded on an individual's training record. For example, NHS Resolution operates a system known as Health Professional Alert Notices to inform NHS bodies and others about health professionals who may pose a significant risk of harm to patients, staff or the public. HPANs are usually used whilst the regulator is considering concerns and is intended to provide an additional safeguard during the pre-employment checking process. The request for a HPAN must be made by an Executive Board member or their authorised deputy, and must relate to a healthcare professional (or someone holding themselves out to be a healthcare professional) who poses a significant risk of harm to patients, staff or the public and who might continue to work or seek additional or other work in the NHS as a healthcare professional. No such system operates for those who are not registered health professionals.

Overall, how employment law operates in practice (whatever the good intentions of the system and the critical importance of ensuring fairness) may impact on ensuring that problems with the conduct of an individual are effectively addressed or made known to a subsequent employer. The absence of a standard HR framework for the NHS and lack of

supporting infrastructure (including but not only the quality and capacity of HR departments in trusts) is a key problem in this regard.

4.5.1 Impact on managing transgressive behaviour in NHS workplaces

Multiple challenges arise in managing transgressive and other unacceptable conduct in NHS workplaces in part because of the difficulties of making such concerns known, in part because of the concern of organisations to avoid Employment Tribunals, and in part because of how employment practice is operationalised in NHS organisations. For example, there is encouragement in ACAS national guidance to use an "informal" approach to possible workplace issues in the first instance. Some NHS organisations interpret this as meaning that those raising concerns must speak to the person they are complaining about in the first instance, before any further action is taken. A different challenge is that whose who are the subject of concerns may take advantage of organisational processes, [247] perhaps using HR procedures strategically, for example by introducing delays and deflections, making counter-grievances or claims of discrimination, perhaps supported by their trade union (which is typically focused on the protecting the interests of the individual).

Both of these challenges were illustrated in the East Kent report. The Trust was had endemic problems with bullying and harassment, and was rated as one of the worst in the country for workplace diversity and attitudes towards cultural difference. One midwife with a minority ethnic background went to HR three times, but each time the complaint was seen as an "over-reaction," linked in part to absence of a structured way of dealing with allegations. People were deterred from raising concerns about colleagues partly because bullying and harassment policies required that an opportunity be provided for people to speak to each other in an informal way first, yet the prospect of an effective informal conversation was remote given negative relationships on the unit and fearfulness about speaking to those who were the subject of the concern. HR processes did not work well even when concerns were raised directly, so serious behaviour problems amounting to a "daunting and frightening work environment" were not handled effectively. The report concluded that:

> *The problems among the midwifery staff and the obstetric staff were known but not successfully addressed. The failure to confront these issues further damaged efforts to improve maternity services and exposed critical weaknesses in the Human Resources (HR) function. When bullying and divisive behaviours among midwives were challenged, the staff involved began a grievance procedure, following which, it appears to us, the Head of Midwifery was obliged to leave and not speak out. The bullying and divisive behaviours were not addressed.* [45]

A newly appointed Head of Midwifery did seek, around 2014/15, to tackle the issues, working with HR to undertake a review. This identified numerous reports of bullying, harassment and racism, abrupt and sarcastic behaviour by senior staff, intimidation and undermining in front of patients, and other problems. The Head of Midwifery was sufficiently concerned to recommend that one of the services should be shut down because of the risk to women. A group of senior midwives were identified as central to the issues and the decision was made that they should be suspended or relocated. However, a collective letter of grievance was submitted via the Royal College of Midwives (which, like the Royal College of Nursing, and unlike the medical royal colleges, is both a trade union and a professional body). The Trust then withdrew support from the review process and from the Head of Midwifery, who resigned her post following advice to her from the Royal College of Midwives that she should move on to protect herself and that whistleblowing was not in the public interest.

These problems at East Kent provide important insights into the challenges of taking action in relation to transgressive behaviour. The illustrate the particular challenges of culture –

which by definition involves more than one person – since HR processes are generally set up to deal with cases individual by individual. Attempts to deal with groups may greatly increased the organisational risks associated with investigation and action. The East Kent case further illustrates how those who seek to take action faced with an adverse culture may themselves be exposed to risk. It also shows that, while bullying is often assumed to involve poor behaviour from those more senior in the hierarchy, it can occur laterally (between peers) and also involve "bullying up."

Even when a disciplinary process is ongoing or concluded, the information that can be shared with colleagues is extremely restricted under ACAS guidance: such processes are treated as confidential. The confidentiality of the processes mean those who raise concerns about poor conduct may be left feeling that nothing has been done in response, even when it has. At East Kent, this was described to the Panel as*: "a cloud of secrecy as staff members were involved in the disciplinary processes. It wasn't openly discussed. They had to deal with individuals confidentially and professionally."*

Further problems arise because the seam with professional regulators (covering most though not all health professionals, and not currently covering managers or most other NHS employees) is not always neatly stitched. Confusion may then arise about which problems should be dealt with by employers and which by regulators.[236] These problems were, again, vividly illustrated by the East Kent investigation, which found that unprofessional behaviours by some consultant obstetricians went unaddressed. Some did not attend labour ward rounds, review those in labour, draw up care plans, or attend the hospital on request when they were on call. Though identified by the Royal College of Obstetricians and Gynaecologists in its 2016 report on the Trust as a major problem, it appears that these practices and their consequences may have contributed to the death of a baby in 2017. The trust seemed paralysed in taking appropriate action, believing that it would likely lose at an employment tribunal if it took disciplinary action against consultants, while the General Medical Council declined to initiate fitness-to-practise proceedings in 2020 on grounds that its role did not extend to "lower-level behavioural issues, or cultural issues, or attitudinal issues."

5 A persistent challenge: detecting and investigating possible problems

Detecting and investigating possible problems is a key element of safety, but remains a persistent challenge, contributing to the challenges of institutional secrecy discussed above. In the discussion that follows, I summarise a selection of the ways that an organisation might become aware of a potential issue and might explore it. Given that it does not make sense to parse out culture and systems as distinct entities, the discussion below presents some evidence on how potential problems might be detected in healthcare, commenting where possible in neonatal units and, again, where possible, tracing developments over time, particularly since around 2015. I briefly mention aspects of a healthy culture where relevant. A separate section on patients and staff, including concerns and complaints, follows this section.

5.1 Challenges in measuring safety

A healthy culture with a problem-sensing approach would foster active monitoring of safety issues, would ensure that any concerning evidence of deviance from expected standards or deterioration is identified early and understood, and would take steps to address issues. However, the ability of teams and organisations to monitor patient safety and quality of care is variable and often difficult. Despite recent efforts to improve monitoring and measurement, [248] data on quality and safety remains a challenge for the NHS. Safety in particular has remained difficult to measure in part because of the absence of a unifying construct and associated valid indicators,[249] and because methods of effective and reliable surveillance have been slow to develop.[250] More generally, collecting data is expensive and difficult, and data analytics expertise is much rarer than it should be. These challenges frustrate the routine measurement and monitoring of safety at unit level, within organisations, and at system level. These are problems in neonatology as elsewhere. Though multiple forms of data on perinatal care are collected in the UK,[195 196 200 201 251 252] its reliability and integration across different sources,[201 253 254] inclusion and presentation of data most relevant to families,[203 255] and deployment in data-driven improvement efforts[202] are all still evolving.

5.2 Variations in care

One important way that possible concerns may come to the attention of teams, senior management in trusts, and external bodies is through detection of variations in care – for example, in rates of infection, mortality after surgery, compliance with national standards for timeliness of care, and so on, across different organisations. Variations may also surface as inequities affecting different groups – for example, excess of perinatal mortality in Black women. Variations can occur not only across organisations and population groups, but also within the same organisation or clinical area over time – for example, infection rates or inpatient death rates might go up over a particular period in a specific unit. Sometimes variations have a benign explanation – for example, in differences in the types of populations served by a particular hospital or patient preference. However, the issue of "unwarranted variation" in health services has been recognised for many decades, going back to the 1930s [256] and is seen as a signal that something might be amiss and requires further investigation and possible action.

Variations may be picked up in a number of different ways, including, as I explain below, through national clinical audits and other large-scale data collection exercises and through organisations' local systems, which might include local clinical audit, quality improvement projects, or other sources. Specific techniques (including, for example, statistical process control) can be used to understand whether the variation being observed appears to be within normal limits or represents "special cause variation" that should be investigated further,[257] though the limitations of this type of statistical analysis should also be recognised.

5.3 National clinical audits

National clinical audits are an important source of information on quality of care in specific clinical areas, allowing, among other things, organisations to benchmark their own care and to see where they lie in comparison with others. National clinical audits are large-scale exercises that seek to assess care against defined standards (e.g. from national guidance). They require participating clinical centres to prepare information on specific measures (usually by reviewing clinical records or prospectively establishing data collection systems) using standardised definitions, and then submit the data to a central register using a standardised template.[258] There around 70 national clinical audits in England, many of them operated by professional groupings (such as the royal colleges or professional societies). Over 30 audits are run as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP), [198] which is supported by NHS England funding.

Participation in NCAPOP audits, which are commissioned and managed on behalf of NHS England by the Healthcare Quality Improvement Partnership (HQIP), is mandatory for NHS organisations, following the introduction of a contractual requirement in 2012. Audit data are published regularly on a cycle specific to each audit, but generally report both national and organisation-specific results so that they can be used to identify trends over time and to support both large-scale and local improvement efforts. In a healthy culture with a problem-sensing approach, trust boards and the units/services use the data to monitor the quality of the care they are providing, compare their performance with other units, and identify targets for improvement.

One challenge with national clinical audit reports is that their publication can take some time, since, under current arrangements, the data have to be verified and go through an approvals process. This means that the published national data is often lagging behind the present day – sometimes by a year or more. However, in a healthy culture, organisations are aware of the data they are reporting and are able to detect changes over time within their own units, and undertake investigation appropriately if they identify any unusual changes.

Two national clinical audits are especially relevant to neonatal care: the National Neonatal Audit Programme (NNAP) and the Maternal, Newborn and Infant Clinical Outcome Review Programme, usually known as MBRRACE (Mothers and babies: reducing risk through audits and confidential enquiries across the UK).

The National Neonatal Audit Programme, which was established in 2006, is commissioned by HQIP and run by the Royal College of Paediatrics and Child Health to assess whether babies admitted to neonatal units receive consistently high quality care and to stimulate improvement in care delivery and outcomes. Data for NNAP, which covers a mix of outcome data (e.g. bloodstream infections, mortality) and evidence-based standards aimed at improving care, is entered onto the BadgerNet summary care record daily for all babies on a unit. The measures used by the NNAP to guide its assessments are aligned to a set of professionally agreed evidence-based guidelines and standards. The measures include

outcomes such as mortality (in the 2022 report 6.5% of babies born at less than 32 weeks died before being discharged home,[259]), forms of brain injury, and bloodstream infection. Other measures relate to perinatal care, parental partnership in care, and care processes and nurse staffing (in the 2022 report, 71% of nursing shifts were staffed according to recommended levels). A key feature of NNAP is that it identifies variation in the provision of neonatal care at local unit and regional network levels as well as nationally. It can help to identify outliers, including "alarm" outliers (three standard deviations below the set standard). Local units identified as alarm outliers will be expected to produce an action plan and to communicate their status to the Care Quality Commission.

The Maternal, Newborn and Infant Clinical Outcome Review Programme is commissioned by HQIP and delivered by MBRRACE-UK **(**Mothers and Babies: Reducing Risk through Audits and Confidential Inquiries across the UK)**,** and is led by National Perinatal Epidemiology Unit at the University of Oxford and its collaborators. The Programme conducts surveillance and investigation of the causes of maternal deaths, stillbirths, and infant deaths. Since 1 January 2013, all neonatal deaths – defined as a liveborn baby (born at 20 completed weeks' gestational age or later) who died before 28 completed days after birth – have had to be reported to MBRRACE by trusts using a secure online form.

MBRRACE reports hospital-based mortality rates "stabilised" to account for fluctuations due to chance, which can happen more often in smaller hospitals, and "adjusted" to account for centres that act as referral units for high-risk pregnancies and for maternal and neonatal risk factors. The mortality rates reported are not intended to be definitive indicators of quality of care provided, since some variation may arise due to differences in the proportion of high-risk pregnancies that cannot easily be detected. However, they do highlight organisations where extra investigations should be targeted with the aim of improving quality.

In a healthy culture, it would be expected that units are reliably reporting data to the national clinical audits, that data quality is consistently good, that both units and trust boards use the findings to understand the quality of their care (especially when compared with others), that any unwarranted variation is investigated, and that effective action is taken to improve quality where needed.

5.4 Local clinical audits

Not all care is audited at national level, so trusts often conduct local audits on specific topics themselves. The audit cycle remains the same whether national or local – it involves specifying a standard of care, undertaking a review of practice against those standards, typically by examining patient records, and then seeking to make improvements where needed. Audits are usually aimed at assessing care in relation to a highly focused topic at service level, not at undertaking a detailed investigation of what happened to a particular individual patient. Such audits may seek to compare care given in the unit or service setting with national guidelines and best practice to identify possible areas of improvement and examples of good care, In a healthy culture, local audit would be conducted routinely and well, perhaps as part of quality improvement efforts. Local audit may also be done in response to a concern being raised or something being noticed, or may be driven by the interests and enthusiasm of particular clinicians.

5.5 Risk management

NHS trusts are required to operate risk management systems, with the work typically being coordinated through dedicated committees and supported by clinical risk managers, data analysts and others. Risk management systems and the associated committees are expected to generate information on patient safety incidents (including those reaching the

threshold for external reporting and investigation – see below), patient complaints, local audits, and clinical negligence claims, all of which can be scrutinised by the trust board. Trusts are also expected to maintain risk registers, which comprise a catalogue of issues that have been identified by the organisation together with an assessment of the likelihood the event may occur, the outcome if it did occur, and the mitigations in place to try to prevent it – an example might be failure of a hospital's electricity supply. Risks are assigned to a lead person who has responsibility for managing and reporting on the risk. Risk registers may operate at different levels of the organisation (e.g. the one reviewed by the Board of a trust generally operates at a high level of organisational risk, whereas a risk register at a unit level might focus more on immediate clinical risks).

Risk assessment can be done in a range of ways. In the NHS, Incident reporting and investigation (see further details in section 5.6) is a dominant method in most organisations. However, other techniques (some of them adapted from industry) can be used, sometimes as part of quality improvement projects. Examples include Failure Modes and Effects Analysis, Hierarchical Task Analysis, process mapping, and use of the Systems Engineering Initiative for Patient Safety (SEIPS). The SEIPS framework is based on principles on human factors/ergonomics, [260] [261] which is an important discipline characterised by a focus on the components of work systems and their interactions, [262] and human-centred systems engineering.

SEIPS takes a whole-system view that identifies the elements of socio-technical systems using a structured framework and examines how they interact[263] to influence processes and, ultimately, outcomes. It can be used to understand or design socio-technical systems and to support planning, evaluation and research. A key commitment of SEIPS is to understanding how tasks are conducted in practice (work "as done"), rather than how they are documented or prescribed (work "as imagined").[264-267] Recently, a SEIPS toolkit has been published, which offers seven tools to support practical application of the approach.[268]

An important feature of SEIPS is its ability to recognise interdependencies and interactions across systems, including how risks, events and inefficiencies can occur and propagate through system-level properties. For example, a recent application of the SEIPS toolkit to understanding surgical instrument reprocessing (where instruments used in surgery are sterilised, prepared and delivered for specific procedures) revealed a highly complex set of interactions between people, tasks and tools, where breakdowns in interdepartmental or leadership awareness, mistrust, role-switching, scheduling issues, production pressures, and workload pressures were all important.[269] Similarly, a study that I co-led of electronic fetal monitoring in NHS maternity units combining SEIPS and social science analysis found that fetal monitoring is a profoundly collective process, involving multiple interactions between people, tasks, tools and technology, organisation, culture, and behaviour.[45] It also found that the work systems appeared to be poorly optimised for safety, yet their diverse elements are intimately interrelated and interdependent. Structural challenges were pervasive, for example in relation to staffing, equipment design and supply, and buildings and facilities. Further complexity is introduced by the contested nature of the evidence underpinning some practices. This work showed how fetal monitoring is best understood as a sociotechnical system involving multiple interdependent elements that may interact in complex ways, but the same is likely to be true of most clinical practices in the NHS.

Human factors-based approaches have, until recently, had slow uptake in the NHS. They are now being implemented much more widely, in part because of their promotion through NHS England's new Patient Safety Incident Response Framework (see section 5.6). A healthy culture is likely to embrace human factors/systems engineering approaches to risk management, and to avoid a "box-ticking" approach (e.g. to risk registers).

5.6 Incident reporting and investigation

NHS trusts have long been required to operate incident reporting and investigation systems. Incidents are reviewed (typically by risk managers) and those meeting certain thresholds must undergo a formal structured investigation. In a healthy culture, investigations are treated as opportunities for learning and are undertaken competently using a systematic and structured methodology. If done well, these investigations may help to explain why a particular event or instance of harm has occurred. Incident reporting and investigation systems have evolved significantly over time. I describe some of the changes below.

Staff members at NHS trusts can report any patient safety concerns or near misses in their local incident reporting system or local risk management system, irrespective of the level of harm associated with the event. This is often informally known as "submitting a Datix" after the proprietary name of the software used by many trusts (though some are now replacing their software). In addition to using the incident reports for their own purposes and conducting investigations where required, NHS organisations in England and Wales must also submit incident reports to a central database. Until August 2022, this was the National Reporting and Learning System (NRLS), but a transition is now taking place to a new Learn from Patient Safety Events (LPSE) service. My comments below focus primarily on the system as it operated 2012-2022, but I also briefly describe newly introduced systems.

5.6.1.1 *2013 Serious Incident Framework*

Following the 2012 Health and Social Care Act, NHS England published a revised Serious Incident Framework in 2013. Serious incident management was identified in this guidance as a critical component of corporate and clinical governance. The framework emphasised that care providers are responsible for arranging and resourcing investigations and must ensure robust systems are in place for recognising, reporting, investigating and responding to serious incidents, and that the principles and processes associated with robust serious incident management must be endorsed within an organisation's Incident Reporting and Management Policy. The guidance required that Serious Incidents must be declared internally as soon as possible and that immediate action taken to establish the facts, ensure the safety of the patient(s), other services users and staff, and to secure all relevant evidence to support further investigation. The guidance also stated that such incidents be disclosed as soon as possible to the patient, their or carers. The commissioning body was required to be involved within two working days of a serious incident being discovered, and other regulatory and advisory bodies were intended to be informed without delay.

Further guidance was published in March 2015.[270] It set out the circumstances under which a serious incident must be declared, which included unexpected or avoidable death, unexpected or avoidable injury that resulted in serious harm, actual or alleged abuse (including but not limited to sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse), all incidents defined as "never events," incidents or series of incidents that threatened to prevent an organisation's ability to deliver an acceptable level of care, and major loss of confidence in the service.

All incidents meeting the criteria for serious incidents were required to be declared and investigated. The guidance recommended using a technique known as Root Cause Analysis, and identified three levels of investigation: concise, comprehensive, and independent. Concise and comprehensive investigations were expected to be completed within 60 days and independent investigations within 6 months of being commissioned. The guidance was clear that investigations carried out under the Framework were to be conducted for learning to prevent future recurrence, and were not suitable for investigating how a person died or to hold any individual or organisation to account. Trusts were required

to submit their final report and action plan to the commissioning body, which had responsibility to review and feedback to the trust. Under Standard condition 35 of the NHS Commissioning Board 2013/2014 contract, the outcome was to be sent to patients or families within 10 days of conclusion of the investigation.

5.6.1.2 *Operation of the serious incident system up to 2022*

The incident reporting system under the 2013 guidance (and its updates) worked variably well. While a large number of incidents were submitted to local systems (and thence to the NRLS), assessments of seriousness and the quality of investigations has often been problematic. One problem was the apparent "downgrading" of incidents to less serious categories. For example, a number of high-profile cases have involved incidents that were initially classified by trusts as not meeting the criteria for a serious incident, including some of those identified in the East Kent Inquiry. If events were not correctly classified, they did not trigger the appropriate declarations and investigation.

Quality of local investigation, including quality of root cause investigation reports[116 271] was often highly variable. A government-commissioned review into 14 trusts with persistently high mortality rates by Sir Bruce Keogh found, in 2013, evidence of poor quality investigations and limited dissemination of lessons learnt from failures across organisations. As noted above, the 2015 Morecambe Bay report was highly critical of the serious incident investigation processes at the trust.

Two Care and Quality Commission (CQC) reviews into how NHS trusts were identifying, investigating and learning from patient deaths in 2016 [272 273] identified highly variable quality, including variable involvement of families and carers during investigations, inconsistent thresholds to report and investigate deaths, poor quality investigations focusing on individuals rather than systems, variable strengths of recommendations, a lack of systems to ensure recommendations were acted upon and learning shared across organisations. The Health Service Investigation Branch similarly identified problems with local investigations, including failure to involve patients and families, lack of robust methods, and a tendency to focus on individual actions and ineffective solutions.[274] A further challenge was that of treating incidents as single episodes, rather than identifying patterns. [62 275]

Disturbing evidence has also emerged of families' experiences of incident investigations during this period. The East Kent Inquiry, for example, found, as noted above, that not only were some incidents misclassified as not meeting the threshold for a serious event, but also that incident handling processes were exceptionally poor. Families were, for example, not told what had happened, were not offered clarity on what the response would be, were left waiting on next steps, and were sometimes themselves blamed for poor outcomes, and their distress was not acknowledged. For families, the effect was to compound the initial harm they had suffered.

5.6.1.3 *Reform of incident reporting and investigation*

A healthy culture is likely to be one that engages authentically and in a learning-oriented way with patient safety incident reporting. The incident reporting system has undergone recent reform, following NHS England's 2019 patient safety strategy. A new Patient Safety Incident Response Framework (PSIRF)[276] was launched by NHS England in 2022 following considerable development and piloting. A contractual requirement under the NHS Standard Contract, the PSIRF is mandatory for all providers of NHS care.

The PSIRF advocates "a co-ordinated and data-driven approach to patient safety incident response" and seeks to embed "patient safety incident response within a wider system of improvement and prompt[s] a significant cultural shift towards systematic patient safety management.". It is built on four key principles: (i) compassionate engagement and

involvement of those affected by patient safety incidents; (ii) application of a range of systems-based approaches to learning from patient safety incidents; (iii) considered and proportionate responses to patient safety incidents, and (iv) supportive oversight focusing on improvement. A critically important feature of the new approach is that it is based on human factors principles, replacing the root cause analysis tools proposed in the previous framework. The national tools promoted by the framework include the SEIPS framework discussed earlier. A range of resources to support use of SEIPS and other systems-based approaches to patient safety is published by NHS England, including a safety action development guide.

The PSIRF also recommends that the event investigation teams should include people with human factors training and use tools based on systems engineering. Various education programmes to improve investigation have been introduced,[274] and the Academy of Medical Royal Colleges published a national patient safety syllabus in 2020 that included a learning outcome of "understanding the systems-based approach to investigating patient safety incidents."[277]

The PSIRF is explicitly focused on learning for patient safety improvement, but recognises that some incidents may require a separate response. It identifies, for example, that some deaths may be subject to investigation by a coroner, that the police may need to be involved if there is suspicion of criminal activity, or that the individuals' fitness to practice or ability to do their job might need to be considered by their employer or a professional regulator.

Incidents are now expected to be reported to the Learn from Patient Safety Events service (previously the National Reporting and Learning system). The new system seeks to improve data quality and support organisations in drawing meaningful conclusions from the themes identified from reported incidents, including learning more individualised to particular organisations and learning resources that are specific to risks in their area of work. Patients and carers will be able to use the system alongside staff. It is also proposed that machine learning will be able to identify learning more clearly. Organisations are still in the process of transitioning to the new system. The original deadline was set for August 2023, but only 70% of trusts had implemented the LFPSE by February 2024.

The new system is currently being rolled out and NHS England updates on patient safety incidents have paused while the LPSE system is being adopted at scale. The most recently available data suggests that between April and June 2022, a total of 652,246 incidents were reported to the NRLS from England. 72% of these occurred in an acute hospital setting. Most incidents reported (70.6% or 1,656,070) were said to have caused no harm, with a quarter 26% (608,959) said to have caused low harm. 2.9% were reported as causing moderate harm, 0.3% as causing severe harm, and 0.2% as causing death. This would equate to around 3,260 incidents involving severe harm or death in a three-month period (averaged out over the year, around 13,000 such incidents).

5.6.1.4 *Health Service Investigation Branch/Health Services Safety Investigation Body and the Maternity and Newborn Safety Investigation Programme*

Most investigations into adverse events are conducted locally, but those meeting defined criteria may (now) be undertaken by the Health Services Safety Investigations Body (HSSIB) or the CQC's Maternity and Newborn Safety Investigation Programme (MNSIP).

The precursor to HSSIB was the Health Service Investigation Branch (HSIB), which was established in 2017 following a recommendation from the 2015 Public Administration Select Committee report into incident investigations in the NHS. This report had concluded that there was a need to create an independent national patient safety investigation body similar to the Air Accident Investigation Branch in aviation. HSIB's maternity investigations

programme commenced in 2018 with the aim of providing independent investigation of stillbirths, early neonatal deaths and potential severe brain injury, in babies born at term, and sharing findings, recommendations and general themes from its reviews.

The Health Services Safety Investigations Body (HSSIB), replacing HSIB, was established in 2023 as a non-departmental body under the Health and Social Care Act 2022. The Act made statutory provision for 'safe space' protections for evidence gathered during HSSIB investigations, formally described as 'prohibition on disclosure,' as well as increased powers to require people and organisations to cooperate with patient safety investigations. The Act sets out a statutory duty not to assess blame or liability and to protect the identity of individuals. [274] HSSIB has a remit to investigate patient safety concerns that meet its criteria, which largely concern seriousness and impact.

Investigations relating to maternal deaths, early neonatal deaths, intrapartum stillbirths and severe brain injury in babies born at term had been conducted by HSIB, but are not conducted by HSSIB. Instead, under a written ministerial statement, the arrangement is that a specialist unit in the Care Quality Commission – the Maternity and Newborn Safety Investigation Programme – has this responsibility for incidents meeting its criteria.

Only incidents meeting the threshold for referral to HSSIB and CQC Maternity and Newborn Safety Investigations are investigated by those bodies. Investigation of incidents remains largely local. An Emerging Concerns protocol, which includes signatories such as HSSIB, CQC, the GMC, and the NMC and others, provides a framework for sharing concerns quickly with other organisations.

Evaluations of the new PSIRF and the HSSIB/MNSIP processes are not yet available, but thus far it appears that their design represents improvement on previous processes.

5.7 Medical record reviews

Medical record reviews have a valuable role in improving quality and safety in many areas, including in maternal and newborn care.[278] Such reviews involve obtaining care records, which are usually anonymised, and then having them reviewed by experienced clinical assessors (e.g. obstetricians, pathologists, paediatric nurses). Broadly speaking, when it comes to patient safety, records reviews may be done for two purposes – first, to provide information on pattern, frequency and preventability of adverse events (essentially, to describe the epidemiology of harm), and second, to review individual cases. In both situations, much depends on the quality of the records.

When seeking to establish data on frequency and type of adverse events, a range of techniques can be used. One of these (sometimes known as the Harvard method), which was used in a widely-cited study conducted in the USA in the 1980s,[279] involves screening records for presence of criteria meeting the study's definition of an adverse event. Studies using this method typically suggest that around 9% of adult hospital admissions are associated with an adverse event, but it has been much less used in neonatology or paediatric settings.

Another technique, known as the Global Trigger Tool, typically detects higher rates of harm and identifies many adverse events that are not reported in incident systems. A USA study published in 2006 using the Global Trigger Tool to describe adverse events in neonatal intensive care units found that, in the 749 records reviewed, 554 unique adverse events occurred, giving an average of 0.74 adverse events per patient. [280] Low birth-weight, early gestational age infants were most susceptible to adverse events. The most common events were healthcare-associated infections, catheter infiltrates, abnormal cranial imaging, and

accidental extubations requiring re-intubation. More than half (56%) of the adverse events were classified as preventable. However, the Global Trigger Tool is known to suffer from issues of reliability linked to diversity of reviewer interpretation, documentation quality, and review procedures, and training.[281] [282]

Medical record reviews to establish frequency and preventability of adverse events (using any method) are usually conducted as part of research studies rather than as a risk-management process undertaken by individual organisations, in part because they are very resource-intensive. When seeking to review individual cases, a different approach may be needed from the epidemiological approach. When the purpose is to seek to explain an outcome of a particular case, reviews need to be done in a highly structured way and with the involvement of a multidisciplinary team. Such reviews are crucially dependent on what is available for review in the notes, and may be influenced by poor quality entries, missing information and investigations, and so on.

Where there is a cluster of cases, additional methods and investigations and oversight of all the cases may be needed. In the Allitt case, now three decades ago, and before many of the methods now used were in place, the police asked a senior paediatrician to review 14 suspicious events, but in only one of these cases did he think there was enough definite evidence to raise the possibility of foul play.[283] The finding that one child was killed by injection of air was not made following initial x-ray, but only later, when police asked for all victims' x-rays to be examined.

Following significant reforms of recent years, a case involving the death of a child will enter the Child Death Review Process (see below). Depending on features of the case, incidents (including serious adverse events) not resulting in death are likely to be investigated through incident investigation methods, as discussed above, and is likely to involve review of the medical records.

5.8 Child death review process

Review of deaths of those under 18 has evolved significantly in the last couple of decades, partly as a result of high-profile NHS failings. A review of the role and functions of Local Safeguarding Children's Boards in 2016 identified that most children die in hospital, predominantly in neonatal and paediatric units, and was critical of the existing arrangements for child death review.[284] It recommended that government oversight should move from the Department of Education to the Department of Health.

In October 2018, the government published statutory and operational guidance on the Child Death Review (CDR) Process. [285] Seeking to place bereaved families at the heart of the review process, it outlines what should happen from the moment of a child's death, covering the immediate actions after the death of a child, the investigations that should follow some deaths, local review by those who cared for the child, review by a multi-agency Child Death Overview Panel (CDOP), and actions professionals should take in certain situations. CDOPs comprise a multi-agency group of professionals who review information about each child death, covering all those who die under 18 years of age and the death of any live-born baby (though not stillbirths). CDOP membership is drawn from a range of organisations (e.g. police, education, health services and others) and typically have public health and lay representation.

Around this time (2017), a National Child Mortality Database was also established, with the aim of enabling analysis of data collected through the child death review process to inform policy and healthcare decisions.[286] CDOPs provide standardised data to the database using an online platform.

5.9 Review and investigation of neonatal deaths

Investigation of neonatal deaths has evolved significantly since the mid-2010s in response to growing concern about the quality of local review of perinatal deaths. As noted above, poor quality review was noted in the Morecambe Bay Inquiry, which reported in 2015. [92] Around this time, the MBRRACE-UK Perinatal Confidential Enquiry into Term, Singleton, Intrapartum Stillbirth and Intrapartum-related Neonatal Death [287] concluded that 43% of the reviews it examined were poor, with very little involvement of parents or the neonatal team.

A further development was the Each Baby Counts programme, commissioned by the Department of Health and run by the Royal College of Obstetricians and Gynaecologists between 2015 and 2020. It sought to bring together the results of local investigations into stillbirth, brain injury, and early neonatal death (up to 7 days after birth) meeting certain criteria, with the aim of ensuring UK-wide surveillance of term intrapartum stillbirth, early neonatal death, or severe brain injury in normally formed infants and ongoing analysis of local governance/risk management of these babies, with the aim of encouraging improvement of maternity services.[288]

NHS England issued an Action on Neonatal Mortality to Local Maternity Systems/Local Maternity and Neonatal Systems (LMSs/LMNSs) in August 2017, aimed at ensuring that all neonatal deaths were investigated at a local level using a standardised framework, that all deaths in the delivery room and neonatal unit from 23 weeks' gestation were investigated, and that lessons learned from reviews be implemented and shared through regional maternity boards. National guidance on child death review published in 2018 [285] required a standard set of notifications for all child deaths, including, for perinatal deaths, to the lead MBRRACE reporter at the hospital where the baby was born.

The national Perinatal Mortality Review Tool (PMRT) was launched in 2018, following earlier work by the SANDS charity and a Department of Health Working group. It provides a standardised web-based approach to local review of babies who die. All neonatal deaths are required to be reviewed using the national PMRT. Neonatal deaths notified to the MBRRACE/PMRT system are immediately referred to the relevant CDOP, and are also recorded in the National Child Mortality Database. For neonatal deaths in hospitals, the report from the local PMRT review is expected to be used by CDOPs as the basis of their discussions. Many reviews identify areas for improvement, and where they do should be accompanied by an action plan.

The PMRT system has the capacity to produce summary reports of the findings of all reviews carried out over a period of time. Teams in trusts can use this report as the basis of their reporting to their Executive Board and demonstration of compliance with the NHS Resolution Maternity Incentive Scheme (see below).

Investigation of perinatal deaths using the PMRT took some time to implement. A survey of trusts undertaken by the Getting it Right First Time[289] programme in late 2019 showed variability in implementation and use of morbidity and mortality review processes. Only six of the 10 operational delivery networks were reviewing all deaths at that time. 20-30% of networks had oversight of trust Perinatal Mortality Review Tools (PMRT) and local mortality processes, 30% of Operational Delivery Networks were involved with Child Death Overview Panels process. At trust level, 57% of neonatal units were reviewing all neonatal deaths at the time of the GIRFT survey in 2019, with a further 35% reviewing deaths occurring on-site but excluding those moved to another location. Half were using the Perinatal Mortality Review Tool for all deaths.

Use of the PMRT is now incentivised by NHS Resolution's Maternity Incentive Scheme, and the most recent (2023) PMRT report indicates considerable improvement over time. The report found that the vast majority of eligible babies' deaths are now assessed using the PMRT, but also reported that challenges remain in quality of reviews, resourcing the process and ensuring that effective actions are taken in response to the findings. In England, the proportion of neonatal deaths where a review was started increased from 74% in 2018 (the first year of use) to 95% in 2022. A somewhat smaller proportion of reviews was completed and printed. Variability in the quality of the reviews was reported, for example in the extent to which reviews are conducted by a multidisciplinary team of the right size, involvement of neonatologists, involvement of an external reviewer, and involvement of a member of the risk/governance team. In a significant proportion (30% of cases reviewed) there were issues with documentation, meaning that it was very difficult to assess the quality of care and, so the quality of the review process itself could be compromised.

The 2023 PMRT report found that the proportion of reviews where care was graded as A (no issues with care identified) was 32% in 2022, compared with 46% in 2018-19. The proportion graded as B (issues with care that would have made no difference to the baby) was 47%, while the proportion graded as C and D (issues with care that might or were likely to have made a difference to the outcome) was 18% in 2022-23, compared with 9% in 2018-2019.

5.10 Medical examiner system

The medical examiner system was introduced in 2019 following recommendations from the Shipman Inquiry, the Mid Staffordshire Inquiry and the Morecambe Bay Investigation and a number of initiatives and a decade of various pilots. Its purpose is to scrutinise all deaths that are not subject to a coroner's review (which is reserved for the investigation of sudden, violent, or unnatural death, and is conducted by an independent judicial officer with a legal background). The system seeks to address identified gaps in the medico-legal investigation of death, including concerns of families about the care of the deceased and the potential for concealed homicide, and to improve patient safety.[290]

As explained by Lishman and Payne-James, [291] medical examiners must be registered medical professionals (from any specialty background) who have been specifically trained to undertake the tasks. They are employed by NHS trusts. Their lines of accountability are to the medical director of the employing organisation and to the Regional and National Medical Examiner. The medical examiner's role is to engage with the clinical team to ensure that the cause of death is determined as accurately as possible, to advise on which deaths need to be referred to the coroner, to speak with families and explain cause of death, to answer questions and identify any concerns with care, and to escalate any clinical governance concerns identified during the review process. Escalation routes are established locally by medical examiners, and may involve a range of processes from feedback to the ward manager through to review as a serious incident. Medical examiners can signpost the family to other resources (e.g. Patient Liaison and Advice Services), arrange a conversation with the relevant consultant, or refer the case to the coroner. They do not undertake post-mortem examinations or investigate possible crimes.

Hospital trusts have, since 2019, been expected to operate a medical examiner service to scrutinise deaths occurring in their organisation. The majority of in-hospital deaths are now reviewed through the medical examiners system, and roll-out to include deaths in the community is now taking place.[291] Once the scheme has been fully implemented, it will not be possible to register a death without either coroner or medical examiner scrutiny.

Medical examiners provide independent scrutiny of neonatal and child deaths not taken for investigation by a coroner in the same way as they do adult deaths. Medical examiners are

expected to make contact with families who have experienced the death of a child to offer the opportunity of discussion. They are also expected to work closely with paediatric colleagues to establish processes to capture learning that can support improvements in care. Lishman and Payne-James emphasise that medical examiners should be especially attentive to proposed causes of neonatal death to ensure the broad clinical background, including peripartum issues and antenatal care, is accurate. Since detailed review of the circumstances of death are conducted by Child Death Overview Panels, medical examiners are expected to liaise closely with CDOP clinicians to agree on the approach (not least because the numbers of agencies involved in reviewing the deaths of children and babies may become overwhelming for families). Liaison may include participating in meetings or discussions or joining panels if invited to do so. [291] Where a medical examiner is not satisfied that appropriate action is being taken to address concerns relating to the care of babies and children, they are expected to escalate concerns, including to regional-level quality oversight committees where appropriate.

The medical examiner service shows considerable promise, though it has not yet been subject to much evaluation given its newness and introduction just before the Covid-19 pandemic.

5.11 Invited external service reviews

External service reviews may be triggered when concerns arise about a particular service. They are often commissioned by the executive team in an organisation, often from royal colleges or specialist consultancies, and are usually led by clinical specialists and/or those with other specialist expertise (e.g. in leadership). A framework to guide such reviews was published by the Academy of Medical Royal Colleges in 2016 [292] and updated in 2022. [293] The framework was a response to the criticism by Bill Kirkup of “the ad hoc nature and variable quality of the numerous external reviews of services that were carried out at the University Hospitals of Morecambe Bay NHS Foundation Trust.”

External service reviews operate according to terms of reference that agreed in advance with the commissioning organisation. They are conducted by a team with the relevant specialist knowledge, typically involve interviews with key staff (which are generally in confidence and non-attributable), review of documentation, a visit to the site(s) involved, and production of a report (which may be quality assured) with findings and recommendations[294] to the person or group that has commissioned the review.

The Royal College of Physicians (the largest of the medical royal colleges) has operated an invited service review scheme since 2000. Such reviews are usually commissioned to help with issues that have proven difficult to understand or address locally, for example relating to clinical practice and outcomes, dysfunctional clinical teams, and patient safety.[294] The Royal College of Paediatrics and Child Health (RCPCH) launched an invited review service in 2012, and similarly is intended to address problems that might not be picked up or tackled through other processes (e.g. inspection, clinical audit), including, for example, team dynamics, outdated practices, poor leadership, under-resourcing, governance or individual practice concerns. An overview of 70 RCPCH reviews conducted up to end of 2017 (approx.), including 9 in neonatal services, noted that the trigger issues were often long-standing difficulties relating to issues such as leadership, teamwork, and safety and quality concerns, and that typically the review is invited when efforts at local resolution have failed.[295]

Invited reviews have no formal or statutory role, and participation in such reviews by staff is voluntary.

5.12 Care Quality Commission monitoring

Regulatory monitoring by the Care Quality Commission (CQC) can offer insights into culture at NHS organisations, with CQC ratings and reports providing important evidence of quality and safety of care for boards, individual services, and patients and the public.

Established by the Health and Social Care Act 2008, CQC is responsible for the registration, inspection, and monitoring of providers of health and social care, and those who are carrying out a regulated activity. Its system of registration designates those who may lawfully engage in activities regulated by the CQC. Once registered, services are obliged to continue to demonstrate compliance with the registration requirements.[296]

In 2015, CQC assessed the quality of providers through a system of peer-led inspections and accompanying reports and ratings led by the Chief Inspector of Hospitals. CQC can: inspect services both on a regular basis and in response to concerns; carry out investigations into why care fails to improve; and monitor multiple sources of information (national and local, and from the public, local groups, care workers and whistleblowers). The onus of proof is on the provider to demonstrate compliance. The CQC may take a range of actions where it finds that services are not meeting the required standards.

The most recent CQC strategy,[297] published in 2021, is organised around the four themes of people and communities, smarter regulation, safety through learning, and accelerating improvement. Two core ambitions run through each of these themes: (1) assessing local systems to provide independent assurance to the public of the quality of care in their area, and (2) tackling inequalities in health and care. As part of its strategy in relation to smarter regulation, the CQC now seeks to regulate in a more dynamic and flexible way, for example by making better use of data to target resources on risk and where care is poor. On-site inspections remain part of the agency's performance assessments, and are regarded as essential to observing the care people receive. However, ratings are intended to be more dynamic, updated in response to changes in quality.

The Single Assessment Framework[298] is a key element of the new approach. Applying to providers, local authorities and integrated care systems, it replaces the previous sector-specific frameworks and aims to streamline and simplify the assessment process, replacing the previous "key lines of enquiry" approach. At the top of the Single Assessment Framework pyramid sit 5 key questions, asking whether services are safe, effective, caring, responsive and well-led). This is followed by quality statements and then evidence. Six categories are used for the evidence to be collected, including: people's experiences; feedback from staff and leaders; feedback from partners; observations of care; processes; and outcomes of care.

To make their judgments, the CQC reviews evidence types within the required evidence categories for each quality statement, applies a score to each of these evidence categories, combines these required evidence category scores to give a score for the related quality statement, and combines the quality statement scores to give a total score for the relevant key question. This score generates a rating for each key question. Aggregation of the key question ratings gives the overall rating:

4 = Evidence shows an exceptional standard of care (Outstanding)

3 = Evidence shows a good standard of care (Good)

2 = Evidence shows shortfalls in the standard of care (Requires Improvement)

1 = Evidence shows significant shortfalls in the standard of care (Inadequate)

CQC intends in the future that ratings will be updated more frequently by considering diverse forms of intelligence, without relying solely on inspections. Scores for different quality statements will be updated at different times, leading to a more current and up-to-date view of quality. In addition, there will be a move away from long inspections reports to shorter, simpler and more accessible ones.

5.13 Concerns about individuals' practice or conduct

Concerns about individuals' practice or conduct may come to light in a number of ways, including issues raised by patients or by colleagues. Such concerns are highly varied, ranging from issues about professional competence (e.g. ability to carry out procedures safety) through to health (including impairments arising from addiction), conduct (e.g. bullying), and communication and relationships both with patients and colleagues. Some concerns are serious, others much less so. Concerns that focus on especially transgressive behaviour are particular challenge. In my view, the processes, systems, wider legal and institutional environment are currently poorly optimised for dealing with concerns about transgressive behaviour in the NHS, and both compound and significantly contribute to the cultural issues frequently identified in inquiries and investigations.

As noted in the discussion above of voiceable concerns, colleagues' ability and willingness to raise concerns about people (versus systems) is strongly influenced by psychological safety, by their perceptions of whether the concern warrants raising, and by whether they are the right person to do so, as well as by their perceptions of voice futility.[18] Voice about individuals' practice and conduct is also influenced by multiple uncertainties about whether the concern is a voiceable one, including whether others will share the same view of the issue:

> *It is extraordinarily challenging to devise reliable ways of investigating the incidence of, and circumstances surrounding, bad behaviour at work. There is no single definition capable of distinguishing acceptable from unacceptable conduct for all workplaces, all working people, and across all times. What is regarded as unacceptable differs with context, sometimes widely; individuals have different reactions and ways of being; attitudes and perceptions change, both generally as to acceptable workplace behaviour and specifically about particular interactions.*[299]

As well as the qualms that people may experience in judging whether behaviour they have witnessed or heard about constitutes a warrant for speaking up, weaknesses in systems (including HR processes, as discussed above) and the wider ecosystem and discourses around patient safety may also have the unintended consequence of making it more difficult to raise concerns, persist with them, or take action.

One aspect of this wider ecosystem is that how patient safety is talked about in policy documents and other guidance tends to discourage recognition of the possibility of transgressive behaviour. How patient safety governance and management is organised tends to mean that risks arising from transgressive behaviour are handled through different processes from other risks, with consequences for detecting and recognising those risks and taking appropriate action. The overall effect, while not intended, may be to obscure the possibility that, on occasion, harm can occur through transgressive behaviour, can make it difficult for people to even suggest that this is a possibility, and can "hand off" the problem to other systems that, in reality, often function poorly.

For example, NHS England guidance on "*Just Culture*," (notably, not "no blame"), which outlines the steps to be taken when the investigation of an incident begins to suggest a concern about an individual action,[300] proposes that action singling out an individual is rarely

appropriate. Where deliberate harm is suspected, “organisational guidance for appropriate management action” should be taken including contact with regulatory bodies, referral to police and disciplinary processes. However, local processes may not always be well designed or function well in such circumstances. Further, the Just Culture guidance focuses on specific incidents, when the warning signs about transgressive behaviour may be difficult to classify in this way, and it also focuses on individuals, when sometimes groups may be involved. Perhaps most powerfully, this guidance can act, as noted above as a “powerful injunction” [48] about how organisations should behave faced with a possible safety issue.

The recently introduced Patient Safety Incident Response Framework, discussed above, explicitly excludes activities that apportion blame or determine culpability, determine preventability, or identify cause of death, instead emphasising that some patient safety incidents may require a separate response not focused on learning for patient safety improvement. It recommends that referrals be made to ensure such a response is conducted entirely separately. While this approach is consistent with a learning-focused approach, systems for addressing and managing transgressive behaviour as a patient safety risk remain under-developed and under-specified, as discussed below.

5.13.1 Investigations and disciplinary processes

Once a concern about an individual has been raised, how it is handled is often messy and complex, depending, among other things, on whether the individual is a registered professional and which regulator governs that role, the nature of the concern at hand, and how and by whom the concern is raised and to whom.

As a general principle, conduct issues (for clinical and non-clinical staff) are handled through local HR systems rather than being classified and managed through the safety management and governance systems for NHS trusts. Two effects of this are notable. First, once it enters an HR process, issues regarding individuals are generally treated as confidential, and may become occluded from the risk management systems of organisations and indeed from the board. Studies conducted for the Openness project [99] that I co-led found that responses led by HR departments tend to focus solely on employees’ accountability and disciplinary responses, to the exclusion of other considerations. Second, as noted above, features of the wider institutional environment may mean that the interests of HR processes are not always fully aligned with those of ensuring safety. Instead, HR processes in practice may, for example, prioritise reducing organisational exposure to risks of legal claims related to employment (e.g. for unfair dismissal), encouraged by their legal advisers.

Current institutional arrangements also demonstrate weaknesses in dealing with poor conduct in the environments external to organisations – for example, it may be difficult for someone in a provider organisation to take forward a concern or complaint about behaviours in a national body, even when those behaviours are adverse to patient safety. Within organisations themselves, HR departments are typically aligned administratively with leadership functions in organisations, potentially making it more challenging (or appear more challenging) for someone within the organisation to raise an issue regarding senior management.

Concerns involving non-clinical staff are, in the main, handled through local HR processes. The majority of concerns regarding professionals are also handled locally, particularly in the first instance. If the issue concerns a doctor’s professional practice, it might be reported to the Medical Director’s Office, where the Medical Director is the “responsible officer” for regulatory purposes. Similarly, a concern about a nurse might be reported to the Director of Nursing. Depending on the nature of the concern, organisations may notify a professional regulator. Patients are also entitled to contact professional regulators with concerns.

5.13.2 Involvement of professional regulators

In the UK, 10 statutory regulators currently register and regulate health and care professionals, including the General Medical Council (GMC), which maintains the register of around 350,000 medical practitioners, and the Nursing and Midwifery Council, which maintains the register of around 758,000 nurses, midwives, public health nurses, and nursing associates. Both have a council structure including both “lay” and “registrant” members. Both regulators publish professional standards for registrants and can investigate allegations of impaired fitness to practice (where there is concern that the standards are not met). Both have power to impose restrictions on practice or to remove individuals from their registers following fitness to practice procedures. As discussed below, however, only a very small minority of concerns raised with professional regulators progress to formal fitness to practice procedures, leaving the vast majority of concerns to be handled locally.

The work of the regulators is overseen by the Professional Standards Authority, which reviews the performance of the regulators, scrutinises their decisions about fitness to practice, and can appeal those decisions.

5.13.2.1 *Nursing and Midwifery Council*

The Nursing and Midwifery Council (NMC) has legal powers to investigate two kinds of concerns: fraudulent or incorrect entry onto the register, and fitness to practise of a nurse, midwife or nursing associate. Concerns about fitness to practise can be based on the following: misconduct; lack of competence; criminal convictions and cautions; health; not having the necessary English language skills; or a decision from another regulator. Patients and families are encouraged to raise concerns initially with person’s employer in the first instance. Employers can then refer to the NMC once they have investigated the concern themselves. All concerns received at the NMC are screened to determine whether the concern is sufficiently serious and there is clear evidence to show the person is currently fit to practice. A decision is then made about whether an investigation is needed.

According to their most recent Annual Report,[301] the NMC reported receiving 5,063 new concerns in the period 2022-23 and reached decisions on 6,131. Concerns are reviewed to determine what action may be needed. Investigations are commissioned for around a fifth of concerns. On conclusion of an investigation, case examiners decide whether any further steps are needed to protect the public, or whether no further action is needed. Of the 1,210 investigations completed 2022-23, no further action was taken in 411 cases; advice, a warning, or undertakings were agreed in 133 cases; and 666 were referred for adjudication. In 2022-23, Fitness to Practice panels made 533 decisions, resulting in 191 people being removed from the register, 155 suspensions, imposition of conditions in 65 cases, cautions in 31 cases, and no further action in 108 cases.

5.13.2.2 *General Medical Council*

Concerns about a doctor can be raised by any person or organisation. Trusts typically have a committee for doctors in difficulty, which reviews the facts and the data using a pre-determined process. Some concerns, particularly those of a more serious nature, might be addressed under the Maintaining High Professional Standards in the Modern NHS procedure, [302] which covers conduct and discipline, capability, and health. This procedure outlines the points at which an issue might be discussed with the General Medical Council (GMC). However, not all issues involving doctors are addressed through the Maintaining High Professional Standards procedure – for example, a recent Employment Tribunal established that a Trust and Confidence process can be followed where there is a breakdown in working relationships.

When a concern is raised with the GMC, it is assessed to determine whether it meets the statutory threshold for investigation, which specifies that the GMC can only take action where it is concerned there is a risk to patient safety or to public confidence in the medical profession. Most cases are closed at the screening stage because they do not meet this threshold. If it is determined that a investigation should be undertaken, the GMC can refer the case to the Interim Orders Tribunals to decide whether the doctor's practice should be restricted while the investigation is ongoing. Once a GMC investigation is completed, a decision is made on the action needed. Like the NMC, this can include taking no action, issuing advice or a warning, restricting the doctor's practice, or agreeing with them and their employer that they will retrain or work under supervision. Cases can also be referred to Medical Practitioners Tribunal Service (MPTS), which runs hearings to make decisions about whether doctors are fit to practise medicine. The MPTS is accountable to the GMC Council and to the UK Parliament, but operates separately from the investigatory role of the GMC. An MPT hearing follows three stages: facts, impairment, and sanction. MPTS tribunal hearings are independent in their decision-making.

The GMC's most recent annual report (2022)[303] shows that, In 2022, it received 8,893 concerns, with most of these (75%) raised by patients or members of the public. Of these, only a small fraction (9%) met the statutory threshold for an investigation, and 22% of these related to concerns raised by the public. Almost half (48%) of investigations concluded with no action, and under a third (30%) were referred to the MPTS. When referring for an MPTS hearing, the GMC may allege that a doctor's fitness to practice is impaired on one or more of the following grounds: misconduct; deficient professional performance; a conviction, or caution, for a criminal offence; adverse physical or mental health; not having the necessary knowledge of English; determination made by another regulatory body. The MPTS annual report indicates that 403 hearings took place in 2022 and decisions were made in 273 cases. Of the cases where decisions were made, 68 resulted in erasure, 101 in suspension, 18 in conditions, no action in 4, and a variety of other outcomes. Some of these cases (especially some of those resulting in erasure) involved extremely transgressive behaviour.

5.13.3 Confidence in fairness and transparency of professional regulators

Some loss of confidence in the transparency, consistency and fairness of professional regulatory practices and decisions is evident, not least because of the risk of suicide associated with a regulatory referral. There is particular disquiet about disproportionate rates of referral by employers to regulatory authorities of professionals of minority ethnicity and those trained outside the UK.[304]

The Professional Standards Authority has also identified a number of concerns with professional regulation. In its 2022 report *Safer care for All*,[305] it highlighted four key issues it saw as important to patient safety: the impact of inequalities in regulation and health and care on patients, service users and professionals, and on public confidence more widely; the challenges facing regulators in adapting to new disruptive factors in how health and care professionals deliver care, the workforce crisis and how professional regulation may need to evolve to better support the workforce needs across the UK; and how to make learning cultures and individual accountability work for both patient and service user safety.

6 Concerns and complaints from patients/parents/families and from staff

In the discussion below, I first discuss staff and patient surveys, which offer a general picture of staff and patient experience at national and organisational level, and then explain the background to the handling of specific complaints and concerns by patients/parents/families. I then describe the complexities of what happens in response to the raising of concerns, whether from patients or staff, distinguishing where possible between pre-and post-2015, though this is not always straightforward. I emphasise the importance of soft intelligence and the difficulties of making it actionable.

6.1 Staff and patient surveys

A range of tools and survey instruments – over 70 in total – for measuring culture in organisations has emerged in recent years.[35] They include, for example, the Safety Attitudes Questionnaire, which is a reworking of a tool using the aviation industry; the Manchester Patient Safety Framework, which is intended to assess different levels of maturity in relation to patient safety, ranging from "pathological" (why do we waste our time on patient safety issues?) to "generative" (managing patient safety is an integral part of everything we do)'; and the Culture of Care Barometer, which explores four broad dimensions related to supporting the delivery of high quality of care: i) the resources to deliver quality care; ii) the support needed to do a good job; iii) a worthwhile job that offers the chance to develop; iv) the opportunity to improve team working. However, much controversy surrounds whether it is in fact possible to measure culture, and many of the tools are used in an ad hoc way or mostly in the context of research.

Notwithstanding these challenges with specific tools, various large-scale surveys of staff and patients are regularly undertaken and do provide important information on culture. A key source is the NHS staff survey, which is conducted annually, and typically gets a relatively strong response (around 700,000 respondents in 2023). It provides valuable indications at both local and national level so that trusts can understand where they lie in relation to others.

Indicators of culture on the NHS staff survey include whether staff feel secure in raising concerns about clinical safety (71% in 2023).[306] In response to another question, only 57% were confident that the organisation would address their concern. Less than two-thirds (62%) would feel safe to speak up about anything that concerns them, and only half (50%) were confident that their organisation would address their concern. Around 70% of staff believe that their organisation acts on concerns raised by patients. Only 61% would recommend their organisation as a place to work, and only 65% would recommend it as a place for their friends or family to receive care. Though harassment and bullying are frequently identified as patient safety issues (including in the Mid Staffordshire report) they continue to be a problematic feature of working in the NHS: less than three-quarters (72%) reported that colleagues are polite and treat each other with respect, and at least one incident of harassment, bullying or abuse in the last 12 months is reported to have been experienced by 10% (behaviour from managers) and by 18% (from other colleagues). However, only 51% of those who had experienced harassment, bullying or abuse reported it.

Several national patient surveys are also conducted. All eligible trusts participate in the NHS Patient Survey programme, which includes five surveys that ask patients their views on their

recent healthcare experiences. The surveys are used by CQC to measure and monitor performance and are also used by stakeholders including NHS England, the Department of Health and Social Care, and NHS trusts and commissioners. The surveys include the Children and Young People's Survey, which was most recently run in 2020 (and is being run again in 2024). This survey asked parents and carers of children aged 0 to 7 to answer a questionnaire to feedback on their child's experiences. It reported mainly positive experiences about many important aspects of care and treatment: children and young people overall felt well treated, staff were friendly, and they were given privacy treatment. Most children reported staff always answered their questions and listened to what they had to say. However, children were less positive about feeling involved in decisions about their care and knowing what was going to happen next with after leaving hospital. Some children and young people also reported poorer experiences about having enough to do in hospital or being played with.

6.2 Patient/parent/family complaints and concerns

6.2.1 Concerns and complaint handling in the NHS

Until the 1985 Hospital Complaints Procedure Act, which came into force in 1989,[210] hospitals were not required to have a complaints procedure in place. The Act obliged health authorities in England and Wales (and Health Boards in Scotland) to establish a complaints procedure and to draw such a procedure to the attention of patients, but, although it had been in gestation since the 1970s, the legislation provided little more in terms of specificity. Pressure from patients' groups in the 1990s led to the Wilson Committee, which reported that the arrangements in place at the time were complex, lengthy and confrontational. 1996 guidance from the Department of Health required that NHS organisations establish a 3-stage complaints procedure, starting with a stage of local resolution and ending with enabling the complainant to ask the Health Service Ombudsman to investigate. This guidance did not have statutory force, however.

The NHS Constitution, first published in 2009, specifies that the NHS should actively encourage feedback from the public, patients and staff. It requires that complaints are investigated and the patient informed of the outcome. Typically, this involves a hospital's complaints team in gathering information from the complainant and from the clinical setting where the issue occurred, with a view to achieving a resolution (e.g. an apology, rescheduling of an appointment etc). Incidents that appear to have resulted in harm may be more complex and may trigger an investigation.

The current NHS complaints procedure, which all NHS organisations are required to operate, is governed by the Local Authority Social Services and NHS Complaints Regulations 2009. The Regulations apply to "responsible bodies," which includes all NHS providers. These Regulations were the underpinning statutory mechanism for dealing with complaints about NHS care and treatment in 2015 and still apply now.

The Regulations specify that a complaint may be made by "a person who receives or has received services" or "a person who is affected, or likely to be affected, by the action, omission or decision…..which is the subject of the complaint". The scope of a complaint that can be made under the NHS complaints procedure, while wide, is not unlimited. For example, it cannot be used to ask for care or treatment for the first time, to ask for a second opinion, to get compensation, or to complain about an issue where legal action is already being taken.

Under the Regulations, a complaint must be made within 12 months of the incident or from when the complainant first knew about it, but the responsible body should consider a complaint outside this time period if the complainant has good reason for delay or if it is still

possible to investigate the complaint fairly and effectively despite the delay. The regulations do not set timescales for the procedure, but do specify that if a response is not given within six months the complaints manager must explain the delay in writing to the complainant.

Where the patient is a child (as would be the case for a baby on a neonatal unit), the "responsible body" must be satisfied that the representative is acting in the patient's best interests. If the responsible body is not satisfied, it should not consider the complaint and must give appropriate reasons in writing.

Alongside operating the NHS complaints procedure, every NHS trust in England is required to have a Patient Advice and Liaison Service (PALS). First established following the NHS Act 2002, PALS have responsibilities to listen to concerns, comments and questions from patients and their representatives, to provide helpful support and accurate information and advice to resolve concerns as quickly as possible, to assist staff who are raising a concern on behalf of patients, and to provide information about the NHS complaints procedure and how to get independent help if a further complaint is being considered

If a satisfactory resolution is not provided within 6 months, the complainant has the right to escalate the issue to the Parliamentary and Health Service Ombudsman (PHSO). The purpose of the Ombudsman is to provide a service to the public by undertaking independent investigations into complaints where the NHS has 'not acted properly or fairly or have provided a poor service.'

6.2.2 Reforms of complaints systems

The report of the 2013 Mid Staffordshire Public Inquiry emphasised the importance of patient complaints, noting that:

Complaints, their source, their handling and their outcome provide an insight into the effectiveness of an organisation's ability to uphold both the fundamental standards and the culture of caring. They are a source of information that has hitherto been undervalued as a source of accountability and a basis for improvement.

The Mid Staffordshire Inquiry recommended that NHS organisations have a more open and transparent complaints process and that complaints information is provided to inform patient choice. However, by 2019, significant problems were still being identified. The NHS complaints system has recently gone through reform, with new NHS Complaint Standards published in 2021 following a consultation in 2020. The Standards were piloted with 11 NHS organisations and around 70 early adopters. Aiming to set out a single vision of what should happen when someone raises a complaint, the standards are intended to address the absence of a single set of guidelines for managing complaints. The Standards, which are published on the PHSO's website, apply to all NHS providers and are supported by a model complaint handling procedure and guidance on using the standards in practice, with the intention that NHS organisations will follow similar processes across the country and a better, more consistent approach to complaint handling.

The standards relate to: welcoming complaints in a positive way; being thorough and fair when looking into complaints; giving fair and accountable responses; and promoting a just and learning culture. They have a strong focus on: early resolution by empowered and well-trained people; all staff, particularly senior staff, regularly reviewing what learning can be taken from complaints; how all staff, particularly senior staff, should use this learning to improve services.

This guidance is non-binding and, given how recently it was introduced, its impact is not yet clear.

6.2.3 Volume of complaints under the NHS complaints procedure

The volume of patient complaints in the NHS is significant, and has been steadily increasing over the last two decades. In 2012-13, 162,019 written complaints were received. In 2022-2023, nearly 229,500 written complaints were reported across NHS hospital and community services and primary care, covering multiple subject areas.[307] For that year (the latest for which data is available at time of writing), in hospitals: clinical treatment accounted for around a quarter (26%) of all complaints, with paediatrics (which covers neonatal care) accounting for 1.2% of the total number of complaints. Around 17% of complaints concerned communications, 12% patient care including nutrition/hydration and 10% staff values and behaviour (10%). The proportion of patient complaints about hospitals fully upheld was 27.6%, while 39.7% were partially upheld. Around a third (32.7%) were not upheld. The PHSO is able to review complaints that have not been resolved through the NHS complaints procedure.

The volume of complaints has more than doubled in 20 years (in 2005/6, there were 95,047 complaints),[308] and is indicative of people increasingly using the routes available for expressing dissatisfaction with NHS services. The sheer volume presents a challenge in its own right, potentially increasing the risk that important signals might be lost by overwhelming the ability for organisations to identify concerning patterns or other indications. [309]. At the same time, however, it is likely that many people who were unhappy with care (or were harmed) do not complain.

6.2.4 Other ways for patients and families to raise concerns

As noted above, the scope of the NHS complaints procedure is not exhaustive, and there are other ways patients or families can raise concerns. One of these is by making a complaint about *professional misconduct* in relation to a particular individual to the relevant professional regulator, including, as discussed above, the General Medical Council and the Nursing and Midwifery Council, overseen by the Professional Standards Authority.

People can make complaints both to a professional regulator and under the NHS complaints procedure, but the regulator may decide to wait until the organisational investigation has concluded before initiating its own processes. As noted above, though a large number of complaints to professional regulators are made each year by patients and families, only a minority are heard by a professional misconduct committee. Many are screened out at an early stage.

Patients and families may also raise concerns by making a claim for *clinical negligence*, under tort law, though they can only do this when harm appears to have occurred arising from a breach of duty of care that directly results in an injury or loss. Claimants must prove on the balance of probabilities that the care provided has caused the damage because it was delivered in a negligent way. Responsibility for managing clinical negligence claims against the NHS lies with NHS Resolution (a special health authority formerly known as the NHS Litigation Authority), which operates the Clinical Negligence Scheme for Trusts (a risk-pooling scheme funded through members' contributions). Many potential claims, however, are filtered out by personal injury lawyers the basis that they are not actionable – perhaps as many as 85-97% of claims do not make it past this initial stage.[309] At the same time, a very high proportion of adverse events do not result in a claim for clinical negligence.

Finally, and increasingly, patients and families may raise concerns by using social media and mobilise through campaigning and advocacy. Recent years have seen multiple examples of this, including the major maternity scandals, deaths among those with learning disabilities, and abuse and neglect of older people, among others.

6.3 Systems for staff to raise concerns

Staff can raise concerns through a variety of mechanisms, which vary in formality and in how they are handled, and also vary between different organisations. Many are discussed throughout this report (e.g. incident reporting, participation in invited reviews etc), so are only briefly discussed here. To support staff voice, as discussed in some detail below in section 7, all NHS trusts are now required to have a Freedom to Speak Up Guardian, who can help to support people with concerns – though Guardians typically cannot generally resolve the concerns by themselves.

Some trusts go further than the policy requirements to support speaking up. They may, for example, operate a staff reporting line, where people can report concerns anonymously but not confidentially. Staff can also use various other ways of raising a concern, for example by discussing it with colleagues or the relevant head of service. This can often mean that the issue is explored further and potentially resolved, particularly if the culture and systems are supportive. But it can also be a risky strategy for the person or group who raises the issue. The head of service might not welcome the notification, may trust or be friendly with the target of the concern, may distrust the credibility of the person raising the concern, may not regard it as a significant issue, or may not see it as a priority among the thicket of other priorities. Another option is to bring the issue to the attention of a Non-Executive Director. This is likely to be something only those in relatively senior positions would know how to do and would do. A further challenge is that longstanding patterns of voice behaviour (including who is encouraged to speak and how seriously concerns are taken), related for example to ethnicity, national origin and seniority, have proved difficult to shift.[310] [311]

A further option open to staff is to "whistleblow." The term "whistleblowing" is widely used colloquially to refer to voice and speaking up, but has quite a specific meaning in terms of the Public Interest Disclosure Act 1998. This protects employees from detriment (e.g. dismissal, redundancy, victimisation) if they make a "protected disclosure," which must satisfy the following criteria:

- A disclosure of information, not opinion
- The person making the disclosure must reasonably believe it is in the public interest
- It must be a "qualifying disclosure," so refer to one or more types of wrongdoing, such as failure to comply with legal obligations and health and safety breaches, or deliberate concealment of these failures
- It must be made in a protected manner (e.g. disclosed to the employer, a relevant regulatory body, or other suitable person or organisation)

Whistleblowing claims can result in uncapped unfair dismissal awards at Employment Tribunals.

Finally, another strategy sometimes used by staff is to take their concern (often anonymously) outside the organisation, for example to a national body or to the press/mass media.

6.4 Issues in systems for handling complaints and concerns from staff and patients

Much of the discussion below is based on a number of studies that I co-led in the area of voice, [312] including an NIHR (National Institute of Health Research)-funded project to study implementation of openness policies led by Graham Martin of THIS Institute (discussed in more detail in section 7, on the duty of candour). In this report, I refer to it as the Openness

project. Overall, the findings indicated that the inadequacies and fragmentation of systems for handling complaints and concerns – whether from patients or staff – remained problematic at the time the project was conducted (2017-2019). Some of the material below is largely verbatim (word for word) from the original publications.

6.4.1 Findings from the Openness project

Concerns and complaints systems in the NHS continue to be characterised by complexity, and may be poorly suited to dealing with issues that are not straightforward. [99] Some systems can also add insult to injury for complainants, [99 313] resulting in compounded harm. Complaints and concerns systems are often fragmented, confusing, and highly variable in design and operation across different organisations. Issues may be raised by different people in different ways, and may be routed through different pathways that may be highly variable across and even within organisations.

Each pathway has its own procedures, policies and personnel, as well as timelines and terms of reference. This means, for example, that the parsing of issues into different categories can mean they are handled through very different governance and management systems, with very different processes, timeliness, reporting requirements, and confidentiality standards. Thus, concerns regarding an individual's performance might be handled through a HR process, for example, while specific safety incidents might be handled through the risk management system. One consequence of this is that data from different sources of insight are often held separately, reducing their potential aggregate value in identifying problems in a timely fashion. [101] The capacity and skill of those processing complaints and concerns is often limited, particularly in their ability to collate and analyse concerns and complaints to identify patterns that merit further investigation. [314] Taken in the round, the various systems may contribute to the challenges of institutional secrecy discussed above.

One study undertaken as part of the Openness project involved 88 interviews conducted in 2018-2019 with people involved in raising and responding to concerns in the NHS. [99] Many participants in this study, both staff and patients, felt that the systems they encountered were poorly designed and poorly realised. Participants described obscure procedures for raising concerns and complaints, long delays in responding to concerns, and attempts to resolve cases that they found unsatisfactory. They reported processes seemed poorly thought through and under-resourced, moved along achingly slowly, and that left the onus on them to keep things moving. The general impression of an ill-coordinated system together with a sense that much of the activity was more concerned with addressing formal requirements than with either resolving people's concerns or improving quality of care. Several participants characterised processes for responding to concerns raised by staff or complaints raised by patients or carers as a matter of "box-ticking." Some went further, suggesting that organisations tended towards deflection and defensiveness when faced with complaints or concerns. There was a perception among some that administrative expediency, the need to serve administrative requirements, or fear of disciplinary or legal consequences trumped efforts to address the concerns they raised.

One challenge was that the web of pathways for handling concerns was often tangled, involving multiple different processes for speaking up, reporting issues, raising grievances, commenting on care and complaining, as well as other more and less formal channels that varied by organisation and for staff and non-staff. Each pathway had its own procedures, policies and personnel, as well as timelines and terms of reference, all oriented towards its own objectives.

The various pathways could work well when the concern was relatively simple, the process for handling it was well-suited to resolving it, and the system objective was easy to serve.

However, other concerns and complaints were much more problematic: often, the issues people raised were not easily allocated to a pathway without significant contortion. Sometimes participants perceived their concerns were stripped of meaning as the issues became packaged into a form that could be processed. For example, systems were often best suited to dealing with a specific incident, but staff and patients might be concerned about behaviour repeated over time, or with specific episodes that typified broader patterns, an intuitive sense of a hostile or unsupportive culture, or experiences over time, rather than discrete, identifiable incidents or acts.

Concerns were sometimes allotted to pathways that were not equipped to handle unwieldy concerns, instead rendering them manageable by imposing simpler terms of reference. These pathways might reconstruct disparate concerns and timeframes as manageable episodes and fail to give people the opportunity to explain things on their own terms. For example, some things might be ruled within scope and others out-of-scope by a particular process or pathway, yet they were all part of the concern or complaint from the perspective of the person who raised it. Features such as terms of reference and strict timelines for conclusion and reporting could mean that the process could proceed and conclude in a way that was formally complaint, but did not always address what mattered to the complainant. This was not a matter of simple ill-intent on the part of organisations, but was reflective of the inability of these systems to process, cope with, or even understand the kinds of concerns that some participants may seek to raise.

Some pathways were particularly prone to misaligned expectations and objectives. Families, patients and staff members described the negative consequences of systems and processes that appeared bound by their own internal order, timescale and rationality. “Coldly efficient” systems that ground away inflexibly might give little quarter to the needs or wishes of the individuals involved. These processes might serve the purpose of learning and improvement, but they did so in ways that sometimes left those affected with the sense that they had been used, or even harmed further.

Sometimes, the same concern, issue or complaint might be investigated or addressed through several different processes, which might be overlapping or consecutive, and governed by different degrees of confidentiality and different methodologies. The potential for patients and carers to be bounced between different systems has been identified as a broader issue.[309] For instance, people might go to the PHSO, only to be told that their complaint needs to be handled locally first, or go to the GMC, only to be redirected back to the employer.

6.5 Soft intelligence

In addition to being able to gather, analyse and act on metrics and use formal systems, detection of warning signs and troubling signals requires attention to things that are not measured: forms of soft intelligence.[61] Those working at the sharp end of care and those who use services often become aware of possible problems through their everyday work, [62] but, for these issues to be made known and actionable, voice needs to be given to these concerns. However, soft intelligence is often highly fugitive in character. Concerns may be nascent, partial and only partially formed. [62] They may be known about at some level and in some place, but surface in ways that are especially difficult for organisations to process – e.g. as rumours, suspicions, hearsay, and so on, or that, initially at least, might appear to be more rooted in interpersonal conflict (colleagues not getting along) more than in genuine patient safety risks. As discussed above, current processes, systems, and procedures may be ill-suited to handling these types of concerns or compiling them into an overall picture.

Also important are behaviours in relation to self-censorship, including, as discussed above, “implicit voice theories”[84] that may have deep roots. [315] People may experience significant uncertainties about what counts as a concern (“a voiceable concern”). They may consider any personal and interpersonal risks involved in giving voice, and may be influenced by the nature of the information available to them (which may be imperfect); perhaps only rarely will a single act or event be recognised as an unambiguous imperative to speak up.[100]

Faced with deficits in systems and the very nature of voiceable concerns, people may use varied tactics. They may, for example, talk to peers and other colleagues [312] [316] if they notice that something might be wrong. They may seek to see if there is shared understanding of a problem and to get a sense of how serious it is, bearing in mind, as noted above in the discussion of voiceable concerns, that there is often considerable uncertainty about whether there is something wrong and that raising conduct/behaviour issues may be significantly more difficult that raising systems issues. Hybrid problems (involving systems and individual behaviour or practice) may also be challenging, particularly when there is ambiguity about how much of the apparent issue arises from a systems defect (e.g. staffing, equipment) or arises because of the competence, conduct or character of an individual or team.

While the willingness and ability of those at the sharp end to speak and the willingness and ability of those at the “blunt end” of senior leadership to listen tends to exist in a somewhat reciprocal relationship,[317] the ability to access and make use of intelligence, soft or hard, is not dependent solely on the attitudes and behaviours of leaders and board members. Rather, it is also crucially reliant on the broader culture and systems of the organisation, requiring alignment of values, norms, behaviours and institutional capacities.[318] In particular, it requires leadership inclusiveness.

7 Expected standards in the NHS for openness, transparency and candour, comparing 2015 and now

7.1 Openness, transparency, and candour

Openness, transparency and candour are three interlinked concepts relating to disclosure, honesty, and accuracy in the aftermath of an incident involving harm, or possible harm, to a patient. In the discussion below, I explain that these concepts had long been discussed in the NHS, but were only finally given legal standing (in the form of the duty of candour) following the Mid Staffordshire Public Inquiry.

7.1.1 Openness, transparency and candour before the 2013 Mid Staffordshire Public Inquiry

The value of openness, as a broad concept involving communicating effectively and honestly with patients, families and carers in relation to safety incidents, has long been recognised. However, until 2014, there was no legal duty on care providers to share information with people who had been harmed or their families. The case of Robbie Powell, a child who died tragically following failure to diagnose his illness, highlighted the absence of a legal (as opposed to professional) duty of candour in 1996 at the High Court in Cardiff. A case by Robbie's parents went to the Court of Appeal, the House of Lords, and finally the European Court of Human Rights, which concluded that:

> *As the law stands now… doctors have no duty to give parents of a child who died as a result of their negligence a truthful account of the circumstances of the death, or even refrain from deliberately falsifying records.* [319]

Subsequent to Robbie's case, several calls were made for a duty of candour, for example following the 2001 Bristol Inquiry, [319] but were not implemented into law. Though there was no statutory duty of candour, various measures to encourage openness were in place. One of these took the form of professional guidance. For example, the General Medical Council's 2001 version *Good Medical Practice* offered the following guidance, which could only be enforced through professional disciplinary procedures against particular individuals:

> *If a patient under your care has suffered serious harm, through misadventure, or for any other reason, you should act immediately to put matters right, if that is possible. You should explain fully to the patient what has happened and the likely long and short-term effects. When appropriate, you should offer an apology.*

The Chief Medical Officer's "Making Amends" report (2003)[320] proposed introduction of a duty of candour that would apply to the health system as a whole (including health professionals and managers) with exemption from disciplinary action when reporting incidents with a view to improving patient safety, thus potentially giving statutory force to the GMC's professional guidance noted above. [319] Despite support from a range of organisations, it was opposed by others, including the GMC, and ultimately the proposal was not taken forward.

The now-disbanded National Patient Safety Agency published guidance on openness ("*Being open*")[321] in 2005. Setting out 10 principles of openness, it sought to provide best

practice guidance on how to create an open and honest environment where patients, their families and carers would receive the information they needed to understand what went wrong in a safety incident and reassurance about minimising the risk of recurrence. It also aimed to ensure that all involved—patients, families and healthcare professionals—would feel supported. It was re-released with supporting documentation in 2009, [322] apparently in response to concerns about lack of impact.[323]

The 2012 Constitution, which all those supplying NHS services were required by law to take account in their decisions and actions, affirmed a commitment to openness, stating that:

The NHS also commits when mistakes happen to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively.

Finally, the National Health Service and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 required the NHS Commissioning Board (now NHS England) to include a duty of candour in the NHS standard contract for 2013/14.

These measures to encourage openness were highly variable in their effectiveness. A 2012 survey found that progress in relation to openness after safety incidents was slow, and that some NHS trusts had failed to recognise the importance of the issue.[323] A study including 86 interviews with stakeholders (policy-makers, professional organisations, NHS managers and health professionals, and patients and patient organisations), published in 2014, found the principle of truthfulness was widely supported but variably upheld, with many difficulties in turning the principle into practice. While culture was identified as a major influence on the slow pace of change, participants also identified lack of clarity about the legal status of disclosures, lack of training and skill, and absence of incentives. [324] How the duty of candour might be monitored and enforced was also unclear.

7.2 Policy actions to improve openness following the Mid Staffordshire Public Inquiry

The 2013 Mid Staffordshire Inquiry was deeply troubled by lack of openness and candour at the trust under investigation, but identified that a tendency towards secrecy and suppression of unwelcome insights into quality of care was not confined to that organisation alone. Sir Robert Francis was critical of what he saw as an “institutional instinct” towards opacity and defensiveness. Since then, a wide range of interventions relevant to openness has been implemented, including the statutory duty of candour, a professional duty of candour, and freedom to speak up policies.

7.2.1 Statutory duty of candour for organisations, from late 2014 onwards

The statutory duty of candour for organisations called for in the Mid Staffordshire Inquiry report was implemented into law through Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and applied to NHS organisations from November 2014. Since April 2015, the Regulation has required all health and social care providers registered with the Care Quality Commission (CQC) to be open and transparent with people using services, and their families, in relation to their treatment and care.

The effect of Regulation 20 is to impose a positive requirement on organisations to be fully truthful and to share material information. It also identifies the specific actions that providers must take when a “notifiable safety incident” occurs. Regulation 20(2) is very specific about exactly how the duty of candour must be carried out in relation to:

- the definition of notifiable safety incidents (defined, for NHS organisations, as "'any unintended or unexpected incident that … in the reasonable opinion of a healthcare professional could result in, or appears to have resulted in a) the death of the service user or b) severe harm, moderate harm or prolonged psychological harm to the service user.")
- the various process steps, meetings and records that must take place
- what those meetings and records should cover
- that the process should be carried out in a timely manner
- that appropriate support should be provided to the person harmed or their representative

CQC issued guidance on Regulation 20 in March 2015. It indicated that notifiable safety incidents were those that met the harm threshold, even when the harm arises from a recognised complication of procedure and not from any failing in care. Updated guidance in 2022 indicated that providers should identify whether something is a notifiable incident with reference to whether the harm experienced by a patient was "unexpected or unintended", leaving some ambiguity about whether and when the duty of candour applies in situations where complications or side effects of treatments are known.

The duty of candour is written into the NHS Standard Contract, which is published annually by NHS England for use by NHS Commissioners to contract for all healthcare services other than primary care services.

7.2.2 Professional duty of candour, from 2015 onwards

The General Medical Council (GMC) and the Nursing and Midwifery Council (NMC) published joint guidance in 2015 on the professional duty of candour for those registered with them. The guidance has two parts:

- duty to be open and honest with patients, people who use services, and those close to them. This includes apologising if something goes wrong
- a duty to be open and honest with your organisation(s) and encourage a learning culture by reporting adverse incidents that lead to harm or near misses.

The guidance strongly stresses the responsibility of health professionals to be open and honest when things go wrong. They must tell the person affected when something has gone wrong, apologise, offer and appropriate remedy or support, and explain fully the long and short-term consequences. Within organisations, they are required to open and honest with their colleagues, employers and relevant organisations, and take part in reviews and investigations. They must also be open and honest with regulators, raising concerns where appropriate. They must support and encourage each other to be open and honest, and not stop someone from raising concerns.

The joint guidance specifies that professionals in management roles must make sure that "individuals who raise concerns are protected from unfair criticism or action, including any detriment or dismissal." It emphasises that senior clinicians have a responsibility to set an example and encourage openness and honesty in reporting adverse events and near misses, and must make sure that systems are in place to give early warning of any failure, noting that "you must make sure that any concerns about the performance of an individual or team are investigated and, if appropriate, addressed quickly and effectively."

The GMC/NMC joint guidance was refreshed in 2022, primarily to update links and references – no additional duties were created.

7.2.3 Differences between clinical and non-clinical staff

The standards for candour are different between clinical and non-clinical in that, as noted above, there are two types of duty of candour – statutory (applying to organisations) and professional. Only registered healthcare professionals (e.g. doctors, nurses, midwives) are subject to the professional duty. The regulatory bodies for the healthcare professions are clear, as noted above, about professional expectations in relation to openness, transparency and candour. Non-clinical staff, by contrast, are not typically registered with a statutory body, so are not subject to the same professional guidance.

The statutory organisational duty of candour does not apply to individuals. However, organisations registered with the CQC are expected to implement the duty throughout their organisation by making sure that staff understand the duty and are appropriately trained. CQC guidance is clear that if something qualifies as a notifiable safety incident, carrying out the professional duty alone is not sufficient to meet the requirements of the statutory duty.

The standards do not differ on a neonatal unit compared with the rest of an NHS organisation.

7.2.4 Freedom to speak up policies, 2015 onwards

Following the Mid Staffordshire Inquiry (2013) and a subsequent linked review of *Freedom to Speak up* 2015,[157] voice has been recognised as a major element of patient safety. The review noted a widespread reluctance to speak up among healthcare staff, linked to a sense of futility and concerns about detriment. Setting out 20 principles aimed at promoting a consistent approach to raising concerns while leaving some flexibility for organisations for local adaptation, the review is clear that every NHS organisation should, as a single overarching principle, "foster a culture of safety and learning in which all staff feel safe to raise concerns."

Policy steps to foster openness – defined in the Mid Staffordshire Inquiry as "enabling concerns to be raised and disclosed freely without fear, and for questions to be answered" have taken several forms. A distinctive emphasis of the policy response was on *culture,* including the extent to which it "actively promotes the benefits of openness and transparency" and the expectation that senior leaders, including trust boards, would promote a culture of openness by translating regulatory requirements into cultural change.[325]

One novel policy initiative was a new role – the Freedom to Speak Up Guardian. It was introduced in 2016 in every healthcare provider in England across the acute, mental health, community health and ambulance sectors. Every organisation providing healthcare was mandated to appoint one or more Guardian to act as a point of contact for anyone with a "concern about risk, malpractice or wrongdoing" that they think might be causing harm.

A National Guardian's Office was established in 2016 on a non-statutory basis, funded by the Care Quality Commission (CQC) and NHS England. It provides training, advice and guidance to FTSU guardians, conducts case reviews, and reports annually to the boards of CQC and NHS England.

7.3 Monitoring of expected standards for openness, transparency and candour in 2015 and now

7.3.1 Monitoring compliance with the duty of candour

The duty of candour is included in the NHS Standard Contract. The Care Quality Commission (CQC) is responsible for monitoring compliance with the duty of candour as part

of their monitoring, assessment and inspection processes. Relevant CQC guidance explains, among other things, the background to the duty of candour, defines “notifiable safety incidents”, and identifies what providers must do if they discover a notifiable incident. CQC monitors the duty of candour “through the lens of the service being well-led, having an open and safe culture, and meeting the regulatory requirements for the duty of candour.”[326] CQC notes in its guidance that it is possible for the provider to be open and transparent but still fail to meet some specific aspects of the duty of candour, for example in relation to specific notifiable incidents.

CQC assesses compliance with the duty of candour using a range of methods, including: checking incidents marked as triggering the duty of candour to ensure the process was followed correctly; following incidents that might appear, based on descriptions and levels of harm, to have warranted triggering the duty but were not marked as such; asking providers to tell the regulator about recent incidents; following up on reports of incidents from the public or people using services to ensure the requirements were met; asking people who experienced a notifiable safety incident how the provider responded; asking frontline staff about their understanding of the duty of candour and notifiable incidents; questioning the registered person at the provider about their policies and processes for recording and carrying out the duty and how they train staff; and investigating senior staff and board members’ level of understanding of the duty and how they ensure staff feel supported to speak up and be open and honest about incidents.

CQC has powers to take enforcement action for breaches of the duty of candour. Regulation 20 allows it to move directly to criminal enforcement action; specifically, CQC can prosecute for a breach of parts 20(2)a and 20(3) of the regulation. It may also use warning, requirement notices, or imposition of conditions. Examples of where CQC has taken enforcement action are now appearing. It used its criminal enforcement powers for the first time in 2019, issuing a Fixed Penalty Notice to Bradford Teaching Hospitals NHS Trust for failing to apologise to the family of a baby boy who died following delays in diagnosis and missed opportunities for hospital admission. The first reported prosecution resulted in a fine being imposed on University Hospitals of Plymouth for a breach of Regulation 20 in September 2020.

7.3.2 Non-regulatory monitoring

In addition to these regulatory mechanisms, implementation of policies on openness, transparency and candour is monitored in other ways. The National Guardian’s Office guidance explains that Freedom to Speak Up Guardians must report non-identifiable information to the Office regarding the cases brought to them. The data submitted to the National Guardian’s Office is collated quarterly and published in its annual report, which is an important source of information on speaking up.

Until 2022, the National Guardian’s Office also used the data reported through the annual NHS Staff Survey to construct a Freedom to Speak Up Index to characterise the performance of organisations. This showed improvement over time, but also increasing disparity between the highest and lowest performing trusts, with the Index positively correlated with CQC ratings. Following changes to the NHS Staff Survey, the Index is no longer calculated.

7.4 Evidence of implementation and effectiveness of openness policies since 2015

Concerns expressed around the time the new policies and duties of candour were being designed and implemented included the risk of defensive, compliance-focused “box-ticking”

approaches, e.g. in relation to apologies,[327] or for organisations or healthcare staff, deliberately or subconsciously, to "downgrade" their assessments of the level of harm sustained in the course of their care.[328]

7.4.1 Implementation of openness policies in the period immediately following implementation of Regulation 20 in 2014/15

Some insights into the very early impact of Regulation 20 in 2015, in the first year after its introduction, can be found in a study carried out by the charity Action against Medical Accidents (AvMA), reporting in August 2016.[329] It involved an analysis of 90 CQC reports of inspections that took place between 1 January and 31 December 2015 and had been published by CQC. It found significant variation in how organisations had implemented the duty of candour, with hospitals generally consistent in complying in cases of severe harm or death but showing more variability in cases of moderate or psychological harm. The study also identified that only 9% of reports contained a detailed analysis of duty of candour, while 19% offered only superficial accounts of the duty of candour, and six did not mention it at all. It found 34 examples of criticisms or comments suggestive of poor implementation or non-compliance with the duty of candour in inspection reports, but also noted that in 20 of these the reports did not follow up with a recommendation for improvement. One trust, for example, was complying with the duty of candour in only 40% of cases of moderate harm, but no recommendation to improve was made. All inspection reports were heavily reliant on what the trusts themselves told inspectors about their implementation of the duty of candour.

Some concerns were also expressed by NHS Resolution in its 2019 report on the Early Notification Scheme about compliance with the Duty of Candour, for example in maternity care.[330]

7.4.2 National Guardian's Office annual report

The National Guardian's Office annual report for 2022-23 shows that, by March 2023, 642 organisations were supported by one or more Guardian. However, 157 organisations registered on the National Guardian's Office directory did not submit any data. Four of these were NHS trusts.

Over 25,380 cases were raised by NHS staff with FTSU Guardians in 2022-23, with 9.3% of these raised anonymously. Nurses and midwives accounted for the largest proportion (29%) of those raising concerns. Over a fifth (22%) of cases included an element of bullying and harassment and 30% involved an element of inappropriate behaviours and attitudes, while 19.3% of cases included an element of patient safety/quality. Disturbingly, detriment for speaking up was indicated in 3.9% of cases.

7.4.3 NHS staff survey

Efforts to improve employee voice (speaking up and speaking out) remain highly variable in implementation and effectiveness,[318] to the extent that lack of psychological safety remains a persistent problem in the NHS. As noted earlier, in the most recent (2023) NHS staff survey, 71% of staff reported that they would feel secure about raising concerns about unsafe clinical practice, and only 57% were confident their organisation would address them. Less than two-thirds (62%) would feel safe to speak up about anything that concerns them, and only 50% were confident that their organisation would address their concern. These disappointing indicators of openness in the NHS have coincided with wider challenges for the NHS, including resourcing, industrial relations, and post-pandemic elective backlogs, as well as very significant operational pressures, [331] likely indicating the relevance of the external context for experiences at the sharp end.

7.4.4 Research and evaluation studies: the Openness project and selected relevant literature

Another source of information about the implementation of openness policies and duty of candour is research and evaluation studies. The academic literature broadly has explored issues of voice in some depth, both in healthcare settings and elsewhere. This work is clear that cultural issues play a major role in voice and silence, [76 79 82 332 333] for example by identifying the importance of psychological safety (discussed above) in reducing fear about speaking up and by characterising how self-censorship can be driven by "implicit voice theories" about when it is appropriate to speak.[84] Accordingly, voice behaviours may have their roots an organisation's cultural cues, and in entrenched assumptions about appropriate behaviour. Gaps may appear between a formal policy "work as imagined" and what happens in practice "work as done", and variability may be evident across and within organisations.

As mentioned above, an evaluation led by Graham Martin of THIS Institute, on which I was a co-investigator along with others, provided insights into implementation of openness policies across the NHS during the period 2017-2019. The project was initially commissioned by the Department of Health's Policy Research Programme. This programme transferred to the National Institute of Health Research (NIHR) and was subsequently managed through NIHR, so is most easily described as an NIHR project.

I summarise below some of its key findings, which involved a number of sub-studies. Overall, the project found mixed evidence of progress towards a culture of safety and learning at the time it was conducted, with variability in how well supported staff felt they would be if they raised concerns. It identified that evidence of innovation and of leadership commitment to improving culture in some organisations was matched by evidence of passivity in others. [318] Much of the account below is closely based (sometimes verbatim/word for word extracts) on the report of the Openness Project.[334] I also note some other relevant findings from the wider research and evaluation literature.

7.4.4.1 *Senior stakeholders' views on implementing the duty of candour*

The Openness Project included interviews with 51 senior stakeholders in a variety of middle and senior management roles across the NHS, conducted 2017-2018. [335] This work indicated broad welcome at senior level for joined-up systems of oversight, intelligence and regulation relevant to candour, and that the need to normalise openness was widely held to be an important aspiration. At the level of senior management, the statutory duty of candour was seen as setting out a reasonably clear framework for responding to incidents, and was viewed by 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.

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 participants that such concerns were diminishing. This was attributed partly 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. Some felt that the statutory 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 discussed below, however, it would be premature to suggest that such a shift constituted a cultural change, at least at the time the Openness project was undertaken.

By and large, participants indicated that awareness of the duty of candour 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 CQC's regulatory regime. But there was much variation between, and sometimes within, organisations in the way that they had interpreted and acted upon the duty beyond awareness-raising.

It was clear that implementing the duty of candour was operationally challenging. Systems for tracking and monitoring disclosures were required, as was coordination with wider processes, including incident investigation. Organisations varied in how well advanced in meeting these needs they were. 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 organisations, a sophisticated socio-technical infrastructure (e.g. making the duty of candour a mandated field in incident reporting) was in place to ensure identification, actioning and documenting of disclosures, with roles and teams dedicated to the process. Others had made much less progress.

Practical difficulties in determining when the duty of candour applied were reported. Deciding whether moderate (or worse) harm had occurred was not straightforward, for example because different clinicians would make different judgements around the thresholds. Assessing psychological harm could be particularly challenging. Determining how long-lasting the impact of harm might be was also not straightforward. And sometimes, harm would manifest long after the events that precipitated it had taken place, making it hard to link the event and the outcome. Also relevant was that making a disclosure under the duty was often both time-consuming and often emotionally difficult for staff, so there were sometimes debates and tensions about who would do it.

While sound operational systems were clearly needed to deliver the duty, one risk was that it could become a mechanistic exercise, linked to the legal imperatives around the duty of candour and driven by requirements of compliance and reporting (for example, to provide evidence of activity for CQC monitoring) rather than by a (cultural) will to openness. One challenge for organisations was balancing accountability requirements with patient-centredness, particularly where patients' needs and preferences might not automatically be best served by the default approach to disclosure. For example, participants noted tensions 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, for example, when patients or family members expressly declared their wish to be treated differently, or where following the statutory timescale might risk adding insult to injury.

7.4.4.2 *Encouraging voice*

Broader efforts to encourage voice (beyond the legally mandated responsibilities for candour) were also seen as a daunting challenge by senior stakeholders in the Openness project. Participants described fear of speaking up as having multiple, complex origins, with issues occurring long in the past leaving long legacies. Participants expressed concerns that the wider system was still replete with conflicting signals about the risks and benefits of openness, so local efforts to reassure could founder. Accordingly, there were worries that preoccupation with the letter of the law could undermine its spirit, turning behaviours into ritualised displays of compliance rather than genuinely delivering on aspirations for openness. In some instances, normalised incuriosity was a challenge – staff might not notice what was going on, particularly when poor practice was normalised and when the prevailing

culture was not to question. When something was noticed, implicit voice theories (as discussed above) were seen as highly influential in taking action to speak up. Staff might possibly associate speaking up with significant detriment (such as being forced out of their job), but equally if not more significant were fears such as difficult interactions with colleagues, being seen as the cause of trouble, or causing extra work. The behaviours of managers and leaders was also reported as a powerful influence on voice, particularly when they discouraged voice through indifference or aggressive response.

In nurturing a culture of voice, participants identified the need for clarity and consistency about the mutual obligations and expectations of the employee–management relationship and to reassure staff about a non-punitive response to concerns being raised. Consistent with insight that organisations are "cultural mosaics," as discussed earlier, participants reported that no one strategy for improving openness was consistently effective, and that the different parts of organisations and different teams were very heterogenous. They stressed the need to ensure alignment between espoused and enacted values by senior leaders – the value congruity mentioned earlier. They suggested that senior leaders needed to role-model openness and embrace vulnerability, where leaders and managers accepted that being uncomfortable about what they were hearing was a good thing. Further, they felt it important to position voice as an element of collaborative improvement rather than a hierarchical accountability, and that problem-solving and closing feedback loops was a key responsibility in nurturing a culture of voice.

Overall, this study of senior stakeholders concluded that: "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 organisational environment about the propriety of giving voice to concerns. Visible efforts to reframe the relationship between blunt and sharp ends of organisations 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 organisational action."[335]

7.4.4.3 *Implementing Openness policies at organisational level*

The Openness project included six case studies of NHS organisations, looking in particular at implementation of the statutory duty of candour, the Freedom to Speak Up programme, and investigation of incidents.

Organisations diverged in their cultures around openness, particularly in the extent to which they treated requirements in relation to openness as exercises in compliance or as tools to engender culture change. Some had managed to raise consciousness around the need for openness, learning and improvement to a much greater extent than others, reflecting efforts they had been engaged in before 2013. Maturity of culture of openness seemed to be due in part to the history, geography and function of the organisation. Places that were less dispersed and fragmented seemed better able to maintain and communicate a coherent sense of organisational identity and unified mission. More "openness-mature" organisations also had more success in positioning openness as an organisational priority. A particularly effective strategy was for organisations to commit to openness as part of the mainstream of its business, avoiding the impression that it was a separate or optional bolt-on, and making appropriate investments.

As had also been identified in the study of senior stakeholders discussed above, important to ensuring timely and effective delivery of openness obligations was a sophisticated socio-technical infrastructure. 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 those involved, were crucial. Some places had done well in establishing such systems, often pre-dating the formal requirements. In other sites, however, such systems did not exist or were less well developed. In some instances, pre-existing systems that operated on a directorate-by-directorate basis were difficult to coordinate into a whole-organisation, single-approach and were prone to lack of reliability.

These differences in part arose from variation in the priority, attention and resource given to implementation, including system design and staff training. 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. Participants in the senior-stakeholder interviews also described how asserting the evidence base for the association between various forms of openness and patient safety could help to persuade sceptical colleagues of the value of this kind of activity.

Across all organisations, there was some level of cultural misalignment with the openness policies. Two distinct sets of concerns were raised. First, there was some evidence, albeit very limited, that both the statutory and professional duties of candour were seen by a small number as a challenge to professional authority, probably reflecting a more traditional, paternalistic view of the relationships between clinicians and patients. Much more common was apprehension that the openness agenda was more about blame than about learning. Often, these suspicions were grounded in personal experience, for example in relation to incident investigation.

Even when senior individuals in organisations acknowledged the need to move away from punitive processes, this commitment was not always seen in how the processes worked in practice. Anxieties were expressed not just about the immediate organisation but also the wider medico-legal environment. 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.

The external context was also highly influential. Participants in the case studies 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. However, some commissioners used their influence less wisely, and could risk reinforcing the sense of fear and lack of transparency that staff felt.

7.4.4.4 *Duty of candour and incident investigations*

The Openness project case studies and senior stakeholder interviews together suggested that implementing the statutory duty of candour involved considerable complexity. Deeming an incident as an occurrence of harm, and its severity, was often not a clear-cut or simple matter involving application of unambiguous criteria.[336] Also challenging were cases where it was not clear that candour was the right approach – for example when potential abuse was suspected as contributing to an incident, and the person to whom the disclosure might be made was the suspected abuser.

Reflecting underlying variability in culture and systems, the obligations relating to duty of candour were undertaken variably well. How organisations engaged with families was variable, for example in having processes that accounted for families' and patients' preferences, and in the support provided for those affected by an incident. Sometimes organisations were said to default to oppositional approaches, with legal teams always on

standby. More generally, weak administrative systems and insensitive behaviour were implicated in poor handling of openness from the perspective of those harmed.

In some cases, “coldly efficient” implementation of the initiatives could be found, where adequate administrative systems for the duty of candour and incident investigations were in place, but they were not consistently operationalised with sensitivity or flexibility. Approaches to disclosure, investigation and learning that were beholden to inflexible pathways, timescales and forms of interaction had potential to add insult to injury, especially when people were still raw from injury. Partial, insincere or poorly coordinated approaches to investigation, disclosure and involvement could, for example, 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 did not care.

One issue was that, 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.[337] Written apologies drafted under Regulation 20 varied markedly in style and standard. Some participants spoke of their hesitancy about writing letters with such profound significance for the recipients. Others described how their efforts to apologise in writing to patients and families had been influenced by their organisations’ legal departments.

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 one case study site, 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. There were suggestions that this had reduced complaint and litigation—but crucially it did so *because* it prioritised the emotional needs of families.

Many patients and family members suggested that, done badly, the impression could be given that the duty was being treated simply a duty: discharged reluctantly, compliantly, even officiously. Participants described processes that felt like ongoing exercises in box-ticking, leaving patients and families with the sense that disclosure and apology were no more than events that needed to take place to populate a form. At worst, poorly managed disclosure processes and shortcomings in communication leaving patients, families and sometimes members of staff feeling as though they were adversaries in an oppositional process. 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 that was quickly sucked away when organisations defaulted to positions of defensiveness. This is not to say that organisations did not see serious incidents as opportunities for learning. But in prioritising improvement and learning, they might risk appearing indifferent to the needs of patients and families.

The Openness project highlighted the importance of building systems for surveillance and improvement into strategic objectives and managerial infrastructures.[334] Where systems for encouraging openness, collating insights and improving quality were seen as optional ‘bolt-ons’ or time-limited projects, their engagement and impact were at risk of being stifled. [338] More generally, it showed that the work of disclosure, investigation and speaking up is much more than what can be contained within formal documents, pathways and processes. Doing openness is laborious, messy and infused with emotion. Doing it right requires judgement, flexibility, discretion and the occasional workaround.

7.4.4.5 *Implementation of the Freedom to Speak Up Guardian role*

The Openness project also found that implementation of the Freedom to Speak Up Guardian role was highly variable. All organisations were required to nominate a Guardian, but the role came without associated funding or a clear specification, and in practice their access to senior decision-makers varied, as did their role in seeking to inculcate culture change. [100 102 334]

Some Guardians received significant support and protected time from their organisations; others were expected to absorb this work on top of existing responsibilities. Typically, those Guardians with protected time found that they enjoyed the support of their organisations in other ways, too. 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," but an integral part of their work.

On the other hand, lack of organisational commitment to the policy agenda was clear when, for example, a Freedom to Speak Up Guardian was a remote figure or when the Freedom to Speak Up was grafted onto existing roles without protected time. 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 time and effort, face-to-face presence, and administrative support. 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. These inconsistencies are also reflected in the levels and kinds of activity reported by Guardians to the National Guardian's Office. [339]

Participants in the Openness project, including Guardians themselves, described a wide range of functions for the role. The most prominent largely reflected three of the functions imagined in the *Freedom to Speak Up* review and other documents. 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, describing how the Guardian could detect "weak signals" that might be the precursors to serious trouble, or that indicated something perhaps already wrong. This kind of soft intelligence passed to Guardians could be synthesised with other data to provide early warnings of where all might not be well. This required considerable effort—and thus funded time and capacity—from Guardians. It also required a well-integrated, functional infrastructure for collating and coordinating the intelligence provided, including high quality information systems and administrative support. In reality, these were variably available to Guardians.

One important role for Guardians was in mediating and explaining systems for handling and processing complaints and concerns. People who approached Guardians did not always understand how these systems worked and were confused by their opacity. Sometimes, Guardians could provide reassurance that concerns were being treated seriously rather than

falling into a vacuum. But, for those involved (either raising or the subjects of concerns) delay and lack of information (for example linked to confidentiality) was often difficult to distinguish from defensiveness, obfuscation and duplicity.

Those who approached Guardians sometimes also demonstrated some misunderstanding of the nature and scope of the Guardian role, for example believing that the Guardian themselves could initiate an investigation or produce a resolution to an issue (e.g. new facilities). Several Guardians described the very wide range of issues—from the serious to the seemingly very trivial, or even the vexatious—that were brought to them. Some issues involved qualms, discontentment and distractions. In such instances, Guardians could offer emotional support, but the concerns might turn out not to warrant further escalation.

Other issues concerned various troubles with colleagues, with a proportion of these concerning bullying and harassment. As noted above, this is consistent with the identification of workplace bullying and harassment as a patient safety risk in the Mid Staffordshire report, and it has been a repeated focus in the National Guardian's Office's annual reports. A separate study of the introduction of the Freedom to Speak Up Guardian role led by Aled Jones and colleagues[340] was conducted in 2018/2019. Involving interviews with 87 Guardians, it concluded that the majority of the concerns raised with Guardians relate to often time-consuming, contentious and antagonistic cases of staff bullying and harassment. However, Guardians also reported that dealing with these issues was typically not part of their role descriptions or training, and that there was ambiguity about what counted as bullying and harassment. Guardians were often surprised at the volume of such concerns, noting, for example, that people seemed reluctant to handle them through HR processes and thus they went unaddressed. Some participants expressed concern about role creep, and inadvertently becoming a "staff rep" or intervening in processes that needed to be handled by HR departments. The study suggested that some of the challenges arose from the limited guidance on role implementation in Francis's *Freedom to Speak Up* review, which instead left executive boards at liberty to "decide what is appropriate for their organisation."

7.4.4.6 *Subcultures hostile to voice*

One concern across case-study sites in the Openness study was the phenomenon of "fiefdoms", involving subcultures within organisations that seemed to be immune to external influence. [318] Some fiefdoms comprised groups of individuals who had come to wield significant power over their colleagues 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. For those working in fiefdoms, stress, misery and distraction from their roles were common experiences. Examples were described in all six cases; recent literature similarly highlights the untoward impact of "untouchables" [207]and "divas",[341] and they have been, in one form or another, a feature of several recent inquiries and investigations.

Sometimes these fiefdoms were a function of hierarchy. More often, they were based on or supplemented by the informal power of certain groups: their longevity, the people they knew, the favours they felt they were owed. Deep-rooted friendships, or shared secrets, could create bonds between individuals in different units, or friends in high places, that were invisible to others until they stumbled across them – and sometimes appeared when someone tried to raise a concern. Over time, normalisation of deviance [22] could create a vicious circle, as those subjected to inappropriate behaviours came to perceive that organisations were indifferent or unwilling to act.

Sometimes, 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. When Guardians had been appointed through opaque processes or were seen as distant individuals, participants could not be certain that they too were not bound up in hidden social networks.

The informal nature of fiefdoms and how their influence was yielded 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.

7.4.4.7 *Staff experiences and perceptions of openness over the period 2007-2017*

The Openness Project included an analysis of responses to the NHS staff surveys for periods from 2004 to 2017.[342] Responses to Staff Survey variables relating to openness suggested some significant improvements after the publication of the Mid Staffordshire report in 2013. These included an increased upwards trajectory in the fairness and effectiveness of incident reporting procedures (which was already improving before the 2103 report, but which continued to improve at a faster rate after 2013) (Fig 1).

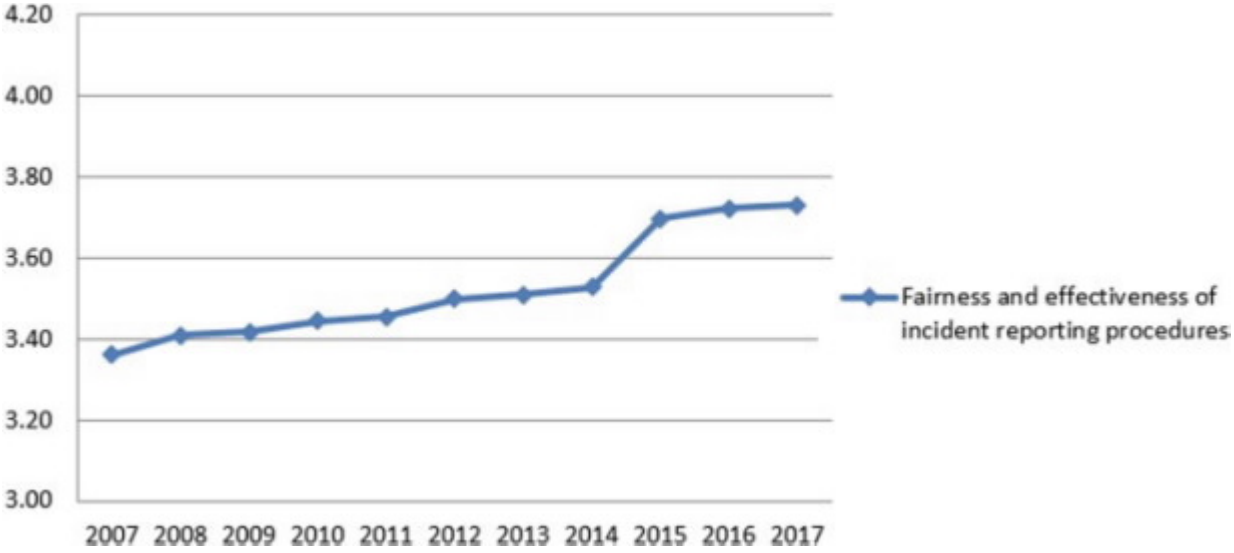

Fig 1: Annual average scores for NHS Staff Survey question on fairness and effectiveness of incident reporting procedures based on McCarthy, Dawson, and Martin [342]

7.4.4.8 *Overall conclusions of the Openness project*

The Openness project concluded that, for openness to work, it needs to be a priority integrated into the organisation's core mission. Declared priorities, however, mean little if the infrastructure is not in place. Sound operational systems, processes and routines, proper investment and protection for key roles, and the right administrative support are essential to openness – but they are not on their own sufficient. Attending to culture, including different subcultures (including dysfunctional fiefdoms), is vital too. Delivering on the goals of openness also requires recognising the scale of the effort, the enduring nature of the work involved, and the need for sensitivity, tact, and discretion to serve the spirit of the policies rather than formal compliance. Support for the emotional labour of openness work is needed too. Finally, it was disappointing to find continued marginality of patients and their families in the implementation of openness policies.

8 Improving culture

While structural and systems issues are readily recognised as difficult to address (e.g., a hospital with a crumbling estate or inadequate IT system may not be able to find funds to make improvements), cultural issues may appear, in principle, potentially tractable. Nor is there any shortage of guides and resources seeking to support improvement in culture in healthcare organisations. As just one example, NHS England has, through a partnership with the King's Fund and the Centre for Creative Leadership, developed a Culture and Leadership programme [343] that aims to provide practical support and resources to help organisations improve their culture. These resources were first published in 2016 and have been used by over 80 organisations.

However, changing culture is often exceptionally challenging. Simply recommending cultural change does not always lead to impact,[20] to the extent that it remains unclear whether culture can be deliberately engineered or "managed" to improve. As Russell Mannion notes, culture is so often rediscovered as both the culprit and solution to failings in patient care that culture change recommendations have something of a "Groundhog Day" character. [35] Mannion notes that staff may be resistant to "top-down" efforts to change organisational values, assumptions, and beliefs which underpin ways of working, such that even modest changes to a working culture may stall. As an example, despite the many exhortations for culture change following a number of catastrophes in maternity care (many of them discussed in this report), a recent report by the Care Quality Commission on maternity services found, in some units, poor working relationships, poor teamworking, and staff feeling unsupported or not feeling confident to seek support from senior colleagues, escalate concerns or challenge.[144]

One problem is that the evidence base for culture improvement interventions, particularly at organisational level, has remained weak. A 2011 systematic review identified only two studies meeting its criteria for study design, and, while both reported positive results, both were at high risk of bias because of methodological issues. [344] The review authors concluded that the available evidence did not identify any effective, generalisable strategies to change organisational culture. This is not to say that nothing is known about how to change culture, but most of the evidence relates to culture change in relation to specific clinical practices – for example, in relation to infection prevention and control. [345] Generally, this evidence suggests that improving clinical practices requires that both social and technical aspects of change are brought together and treated as interdependent parts of a complex system. It also suggests that the supporting infrastructure for improvement is crucial.

More generally, design, delivery and evaluation of improvement programmes remains a major problem for the NHS, posing threats to learning and accountability and frustrating the search for effective interventions. A recent review led by James McGowan, on which I was a collaborator, found that there had been over 50 large-scale maternity improvement programmes in the English NHS in the period 2010-2023. [346] However, only 15 had been evaluated. Those that had been evaluated often demonstrated evident flaws in transparency and quality of programme specification, use of evidence-based interventions, implementation support, patient and public involvement, use of formal published theories, models, and frameworks, and evaluation design. Those that had not been evaluated include NHS England's Maternity and Neonatal Safety Improvement Programme, which has been running (albeit initially under a different name) since 2017. The programme aims to improve the safety and outcomes of maternal and neonatal care by reducing unwarranted variation and

provide a high quality healthcare experience for all women, babies and families across maternity and neonatal care settings in England, but a formal evaluation has not yet been published.

Below, I present selected examples what appear to be the more promising approaches (based on current evidence) for improving aspects of culture, but I stress that there is no single solution, and that these are illustrations only. Safety is an emergent property of complex socio-technical systems – it comes out of multiple interacting factors that need to be optimised in highly challenging settings involving trade-offs and the balancing of competing risks. Creating the conditions for safety therefore requires fostering favourable systems and culture. Neither systems nor culture will be "solved" with any single intervention, and free-standing efforts to target "culture" alone are likely to founder. Instead, many individually small actions as well as a larger strategy are required.

Multi-faceted, multi-component, and long-term approaches are therefore needed, involving multiple different strategies and continuous commitment. Some of this may involve specific interventions – for example, training courses, policies and procedures – but many changes also require efforts that are harder to codify, measure or evaluate, such as consistent values-driven behaviours, role-modelling, ability to have difficult conversations and offer challenge, value congruity, and consistent and repeated demonstrations of respect for all colleagues and patients. Further, it requires attention to the broader contexts of working conditions, systems for handling unacceptable conduct, methods for understanding and improving operational and clinical systems, and attention to what cues are given by the outer contexts of healthcare organisations about values, acceptable behaviours, and what is important.

8.1.1 Teamwork training

Too often, teamwork is seen as a fluffy thing that people know how do naturally, but research has suggested that it needs to be taught, learned and constantly reinforced. There is now a good evidence base for a range of teamwork interventions – including simulation-based multidisciplinary training with high quality debriefing, use of structured communication tools, promotion of psychological safety, and role modelling, good clinical leadership, defined roles and responsibilities, and effective communication, team coordination, escalation and clear routes of accountability. [174-177]

The benefits of teamwork training in particular are reasonably well evidenced, [347] with some research demonstrating the effectiveness of specific types of teamwork training in neonatal care specifically. For example, one US study found that taking part in an evidence-based team training programme (TeamSTEPPS) improved teamwork skills, including situation monitoring, communication, mutual support, and team structure in neonatal intensive care units, which in turn led to improvements in patient safety. [348] A trial of team training and human error reduction for neonatal resuscitation found that those randomised to the intervention programme demonstrated more team behaviours during simulated resuscitation than those on the standard course.[349]

8.1.2 Simulation

Simulation is now increasingly widely used not just as an education method, but as an improvement technique. [350] It is particularly helpful in supporting clinicians in the development of both technical and non-technical skills, where the latter refer to issues such as leadership, communication and teamwork. It has a good evidence base in maternity care, where it has been associated with significant reductions in poor clinical outcomes.[351-355] Simulation has been widely used and recommended in training for neonatal resuscitation, where teams need to be prepared for optimal performance in highly pressurised and unanticipated situations.[356]

8.1.3 Dealing with unprofessional and transgressive behaviours

A body of evidence on interventions to address unprofessional behaviours is now appearing. A recent review of interventions to reduce, mitigate and prevent such behaviours identified 42 reports of interventions, but concluded that most were small in scope, and are at an early stage of development and evaluation with uncertain evidence of effectiveness. [357]

One example was a study I co-led at a US hospital that sought to improve employee voice in relation to transgressive or disruptive behaviours by colleagues. [207] It used a two-phase approach of diagnosis and intervention involving confidential interviews with senior leaders and frontline workers. The diagnostic interviews identified a “culture of fear” which pervaded the organisation, with powerful individuals known as “untouchables” engaged with apparent impunity in transgressive or disruptive behaviour. Widely-held perceptions about the likely response to concerns discouraged staff from speaking up.

The study involved development and implementation of a structured intervention programme, based on four actions: sharing the interview findings, coordinating and formalising mechanisms for identifying and dealing with disruptive behaviour, training leaders in encouraging voice among employees, and building capacity to facilitate difficult conversations. Although the study was limited in its ability to detect long-term effects, the actions appeared to have had impact in developing a culture in which employees felt more psychologically safe in voicing concerns, not least because of the visibility of removal of several problematic individuals from positions of power.

This programme has not been formally evaluated in an NHS context, but the findings are important in identifying that leaders need to be able to take the necessary action without themselves and the organisations being exposed to unwarranted risk. It also showed that ensuring that organisations that are more supportive and fairer towards those who speak up about quality of care and patient safety is likely to require both innovation in systems (e.g., to review how employment practices operate in safety-critical areas, and how HR processes interact with the work of ensuring patient safety) and cultural change.

8.1.4 The value of collaboration-based approaches

Much of the available evidence in in the area of improvement studies points to the value of collaboration in enabling improvement to be achieved more efficiently, inclusively and effectively.[129] [358] Collaborative or participatory approaches, including those using co-design methods with staff and patients, seek to focus on practical problems, enable shared learning and understanding, support stakeholder agency, tackle imbalances in power, and use learning-focused approaches to evaluation. [359] Approaches of this kind have the potential to overcome the disadvantages associated with both bottom-up and top-down approaches to improvement; build on existing large-scale data infrastructures to ensure appropriate measurement; identify and learn from examples of positive deviance; secure engagement from those at the sharp end (including patients and staff); and accelerate the identification of successful interventions and their dissemination on a large scale.[360] [361] A particular strength of large-scale collaboration and co-design is their potential to facilitate the development of solutions that can be used at scale across systems. This is important in addressing the problems of multiple local “solutions” discussed above, and in avoiding improvement waste.

Collaboration-based approaches have had variable uptake and impact over time in the NHS.[362] [363] What is clear is that these kinds of large-scale collaborations require a strong coordinating and data infrastructure[364] and leadership that provides direction, facilitation, and participation of all parties. A key task of leadership, for example, involves patients in an inclusive, respectful way, along with managing the challenges associated to bringing together of multi-professional groups across diverse locations (e.g., risks of hierarchy or rivalry). [365] [366]

8.2 Improvement programmes in neonatology

Quality improvement efforts based on collaboration at scale are among those that have most consistently demonstrated success,[360] [361] including in neonatal care. The Vermont Oxford Network in the US, now over 30 years in existence, is an important example in neonatology. As well as supporting quality improvement, it uses its platform to conduct observational studies, intervention studies, and research on the role of differences in the structure and organisation of units in explaining patient outcomes. [367] By so doing, it has made a substantial contribution to the evidence-base for neonatal care.

In the NHS, a national programme known as Getting it Right First Time (GIRFT) has been running since 2012 (initially in a limited number of clinical areas) in an effort to reduce unwarranted variation between NHS trusts. The programme collates available data from multiple sources (e.g., Hospital Episode Statistics, registries, data from professional bodies, litigation rates) and also collects information through questionnaire to each trust. A bespoke data pack is given to the trust detailing where variations exist and recommendations that might be addressed. A GRIFT clinical lead then visits the trust to present the data pack and discuss it with clinicians and senior managers. GIRFT clinical leads compile a national report for their specialty and develop recommendations that may be addressed to a range of stakeholders, including commissioners of care and national bodies as well as clinicians and organisations.

One of the specialty-specific GRIFT workstreams is neonatology, but it is quite recent. The first review commenced in 2020, with its national report appearing in April 2022. [289] The report noted, among other things, that half of all neonatal deaths occur in babies aged less than 28 weeks, but there is variation across units, with mortality ranging from 9.5% to 21% for babies admitted at less than 28 weeks. The report also found variations in clinical practices, for example relating to respiratory care, adherence to haematology guidelines, and access to breast milk. Though half of units were using universal pulse oximetry screening for all infants, there was marked regional inequity. The report emphasised the

need putting family experience at the heart of neonatal care, and for governance and mortality review processes at local and network level to conform to national structures and include clear structures for escalation of risk.

8.3 Example of an effective response to a concern in neonatology

Neonatology is a relatively young specialty that has become increasingly formalised and distinct since the mid-1970s. Studies suggest that neonates experience a relatively high rate of adverse events, including medication errors, healthcare-associated infections, air leaks, and complications relating to the catheters (lines inserted into the body) used to support their care. [368] [369] A study of medication safety incidents reported in neonatal and paediatric intensive care units to the NHS's National Reporting and Learning System over the period 2010-2018[370] identified 25,578 medication-related incidents, with neonates involved in 12,235 of these. Incidents that were reported to have caused patient harm accounted for 12.2% (n = 3129) of all incidents, and often involved neonates (n = 1570/3129 [50.2%]). Important contributory factors associated with these incidents identified by the authors included working conditions, such as staff shortages, heavy workload and fatigue; problems in systems, such as inadequate guidelines and systems that were not standardised across interfaces of care; poor continuity of care between intensive care units and other hospital departments; and the challenging physiology of neonates.

Most studies of attempts to improve care in neonatology are in response to specific clinical issues, including, for example, variations in implementation of standard practices. Some examples of quality improvement efforts that have reduced adverse event rates in neonatology have been published. This body of work generally illustrates the principle that improvement can most easily be demonstrated by focusing on specific clinical practices. For example, a French trial based on 3454 patients suggested that a multifaceted, multi-professional safety education programme may help to reduce adverse event rates. Though mortality was unchanged, adverse events reduced from 33·9 per 1000 patient-days to 22·6 per 1000 patient-days from the control to the intervention period, and severe adverse events also reduced significantly from 11·5 per 1000 patient-days to 6·9 per 1000 patient-days.

While some evidence is accumulating of how to address clinical practice variations in neonatology, published evidence on responding to a recognised specific concern is currently less established. However, features of a best practice response are likely to include steps to understand the nature of the concern, to explore and where necessary investigate, to draw on evidence-based approaches to design, test, and implement an effective solution, and to work collaboratively in so doing.

9 Defining an effective senior manager, including leadership qualities and behaviours

9.1 Senior managers in the NHS

Those in management positions of seniority may be found at many different levels in the NHS (e.g., ward manager, divisional director and so on), but the term "senior manager" is often (though not always) used to refer to members of the board of directors of a trust.

Broadly, there are two types of trust: NHS trusts and NHS foundation trusts. They vary in their constitutions, but they are all bound by the same Code of Governance for provider trusts.

The board comprises both executive and non-executive directors, who have specific responsibilities under law. Among other things, boards are expected to work closely with Integrated Care Systems (regional partnerships of NHS organisations, local authorities and patients in geographical footprints). Integrated Care Systems had, by 2021, replaced the commissioning bodies and other structures that were previously in place.

Non-executive directors (NEDs) are appointed through defined selection processes (depending on whether the trust is an NHS trust or an NHS foundation trust), and may come from a range of backgrounds (e.g., broadcasting, industry, finance). They may receive financial compensation for their service. Executive directors are employed directly by the organisation.

The executive team at a trust (which may be broader than the executive members of the board, but will often be referred to as senior managers) comprises those involved in the day-to-day running of the organisation, and include the Chief Executive Officer (CEO), the Chief Finance Officer, the Chief Nursing Officer (CNO), the Chief Medical Officer (CMO), and so on. Each of these individuals holds a portfolio for a specific set of responsibilities, and usually (depending on size) a set of other senior individuals who report to them. Those holding some types of positions (e.g., CNO and CMO) are required to be clinically qualified. There is no requirement for the CEO to be clinically qualified, but it is not uncommon to find those who qualified as nurses in the CEO role. Medically qualified CEOs are rarer in the NHS, though not unknown.

The board is expected to act in a unitary way, so that non-executive and executive directors make decisions as a single group and share the same responsibility and liability. Below the board, trusts usually have a set of structures and committees with responsibility for clinical governance. These may include, for example, heads of clinical quality, patient safety, and risk management. Most organisations also have a clinical audit structure for monitoring quality of care, and a service or quality improvement function.

9.1.1 Changes over time

Many aspects of the roles, responsibilities and accountabilities of senior managers have become more codified over time, it is also clear that many have remained the same between 2015 and the present day. For instance, a well-evidenced review of guidance and research published in 2010 [371] identified that boards have a dual responsibility for formulating strategy and ensuring accountability. It noted that boards should be assured that a formal and transparent system is in place to hold the organisation to account in its efficient and effective achievement of strategic objectives, while not having to engage in operational micro-management. This system should support identification and management of risks (including those relating to performance delivery, financial and clinical quality and safety), ensure suitable external and internal reporting, and ensure compliance with relevant legal and regulatory requirements. Risk was identified as central to boards' decision-making roles. Culture was also recognised as a key factor in the functioning of healthcare organisations, with boards having a role in setting its values. Much of this remains as relevant now as it was in 2015, though guidance has continued to evolve.

Changes in the responsibilities and roles of senior leaders over time are reflected in codes of governance, for example from the NHS Foundation Trust Code of Governance in 2006

(during a period when there was an emphasis on enabling trusts to gain more “freedoms” by attaining foundation trust status and operating new ways), through to a code of governance for NHS provider trusts published in 2014, and an updated code of governance published in October 2022. [372]

In addition, there has been considerable policy focus on leadership and management, resulting in the emergence of new frameworks and guidance specifically aimed at leaders. The Messenger review (2022) [51] identified institutional inadequacy in how leadership and management was trained, developed and valued in the NHS, and made recommendations relating to: collaborative leadership and organisational values; promoting action on equality, diversity and inclusion; a consistent set of management standards delivered through accredited training; a simplified, standardised appraisal system; a new career and talent management function for managers; more effective recruitment and development of non-executive directors; and encouraging talent into challenged parts of the system. These recommendations, if implemented authentically and in full, could be highly impactful.

9.2 Qualities of an effective senior manager

The qualities of an effective senior manager are widely discussed across the academic literature, textbook and popular books, podcasts and other media on management, as well as in formal guidance. An NHS Leadership Competency Framework for Board Members [373] has been recently published (2024), setting out six domains including: driving high quality and sustainable outcomes, setting strategy and delivering long-term transformation, providing robust governance and assurance, creating a compassionate, just and positive culture, and building a trusted relationship with partners and communities. Each of these domains has a set of competencies.

My personal summary of the qualities of an effective senior manager relevant to the interests of the Inquiry, based on my research and experience, are as follows:

- Clear about the values that drive them, and demonstrate value congruence – what they say is aligned with what they do
- Articulates and reinforces the expected behaviours and standards of conduct on a daily basis through role modelling and through leading by example
- Works effectively as part of a senior team, with clear goals that are shared with others and aligned with the mission and vision of the organisation
- Effective in shaping an environment where colleagues feel valued, supported, and satisfied in their work
- Consistently demonstrates a commitment to equality, diversity and inclusion
- Demonstrates leadership inclusiveness, defined as “words and deeds exhibited by leaders that invite and appreciate others’ contributions”
- Demonstrates and values good management practices, including in relation to people, operations and planning
- Manages conflict effectively, using skill in having difficult conversations
- Demonstrates “problem-sensing” rather than “comfort-seeking” behaviours
- Exercises good judgement in selecting priorities for attention and action
- Accepts and offers challenge constructively
- While demonstrating civility and respect, capable of being firm and persistent when faced with problematic conduct and transgressive behaviour
- Commits to optimising structures, including staffing, skill mix, environment and equipment, in so far as resources allow. Where it is not possible to address them, the reasons are made clear to staff and patients, as are the mitigations put in place.

9.3 Effective direction on acceptable standards of conduct and practice

Organisations are expected to set standards of clinical care as part of their responsibilities for clinical governance. Very often, these standards are based on national guidance (e.g., from the National Institute for Health and Care Excellence or from the relevant royal colleges), as discussed above. Effective direction on these standards includes ensuring that staff are aware of them and fully supported to implement them. In practice, implementation of standards of care tends to be highly variable across and within organisations. Effective direction therefore requires evidence-based improvement approaches to diagnose problems in implementation, identify appropriate solutions, and evaluate them.

Acceptable standards of conduct should be grounded in the values of organisation and, where appropriate, professional standards for particular groups. How standards will be enforced should be clear and explicit, using a graduated approach. This might start with minor problems are dealt with through talking to offending colleagues, perhaps using humour or other social sanctions to show what is required to maintain the "regard" of peers, for example. [316] If this is not enough, a private word and an offer of support may be made, but there must be a willingness to resort to more formal intervention (e.g., reporting or escalating concerns) if needed, and colleagues must be supported to do so. As discussed above, it is crucial that the HR systems in organisations are capable of providing effective support in these circumstances, that the legal advice given to organisations is appropriate, and that the wider institutional framework and legal framework for managing suspected transgressive behaviour in healthcare settings is optimised.

9.4 Support for NHS staff to voice concerns about the quality and safety of care

I have discussed issues relating to voice extensively above, but, in brief, leadership support for speaking out and speaking up needs to clear, consistent, and demonstrated through action,[191] but this requires both cultural and systems-level alignment. Culturally, enabling NHS staff to give voice about concerns involves embrace of activities that seek normalise speaking up and make it a routine part of organisational life, rather than an occasional activity fraught with risk. [374] At the same time, organisations must take steps to ensure that those who speak up are protected, especially in situations where confidentiality is difficult to maintain, or where retaliation from colleagues (including peers) might be expected. [207] The efforts of boards and other senior leaders to foster openness, and the extent to which they model good behaviour and listen and act on voice and soft intelligence, are crucial in setting the organisational tone, for better or worse. But the extent to which "transformational leadership" can influence behaviour across complex, disparate and dispersed organisations and their many sub-cultures should not be over-estimated, particular when, as discussed earlier, some of the institutional support and systems for handling concerns such as transgressive behaviours remain under-developed and when outer contexts may be highly influential.

9.5 Accountability of senior managers

Senior managers (those operating at executive and board level) are accountable through the governance structures of the NHS. The refreshed *Code of Governance for NHS Provider Trusts*, published in October 2022, sets out the overarching framework for the corporate governance of trusts,[372] which is defined as the means by which boards lead and direct their organisations so that decision-making is effective, risk is managed, and the right outcomes

are delivered. Trust boards are expected to report on their compliance in an annual report to the Department of Health and Social Care. Under the “comply or explain” principle, trusts are expected to explain any deviations from the code to NHS England. The Care Quality Commission reviews organisations’ governance arrangements when assessing it for ratings purposes.

Regulation 5 of the Health and Social Care Act 2008 seeks to ensure that people who have director-level responsibility for the quality and safety of care, and for meeting the fundamental standards, are “fit and proper” to carry out their roles. This requires, among other things, that individuals at this level are of good character; have the qualifications, competence, skills and experience which are necessary; are able by reason of their health, after reasonable adjustments are made, of properly performing their work; have not been involved in or facilitated, any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or equivalent; should not be undischarged bankrupts or under bankruptcy or other credit restrictions; and should not be on the disclosure and barring services list for vulnerable adults and children. CQC cannot prosecute for a breach of this regulation or any of its parts, but can take regulatory action.

The Kark review of the Fit and Proper Persons test, [375] published in 2019, was critical of frailties in the test itself and in its implementation, but also pointed to how these failures signalled deeper faults, relating to clarity and training on the function of boards, how a good board operates, what a good board “looks like”, how to be an effective board, how to ensure there is independent analysis and assessment of the board function and how to provide support and training where required.

The Kark review also identified cases where senior managers committed serious acts of misconduct or mismanagement, yet were able to move into other parts of the NHS or were given settlement agreements and a “bland agreed reference” together with a confidentiality clause. The latter arises largely because, as discussed earlier, of the wider institutional contexts for employment practice and the ways that HR functions in trusts operate. For trusts, a settlement agreement may seem a practical way of handling a situation where there are substantial risks associated with entering into an employment dispute, including costs, reputational damage, and uncertain outcomes. Poor documentation practices, inadequate HR procedures and failure to follow procedures all increase the risks.

The *Leadership Competency Framework for Board Members* [373] (discussed briefly above) was published in February 2024 (partly in response to the Kark review) so it is too early to assess its impact. It is expected that the competency domains will be incorporated into all NHS board members’ job/role descriptions and recruitment processes, and that they should be a core part of board member appraisals and the ongoing development of individuals and the board as a whole. A new Board Member Appraisal Framework incorporating the competencies will be published to support this. Employment references for senior leaders are expected to be taken up using a standard reference template published by NHS England.

Senior leaders who are members of regulated professions are additionally subject to the requirements of their regulatory body (e.g., General Medical Council, General Nursing and Midwifery Council). These bodies can accept referrals, conduct investigations, and impose sanctions up to and including removal from the register.

9.6 Proposals to regulate managers

It has been proposed that health service managers should be regulated similar to healthcare professionals. While many reviews of the NHS give prominence to senior leadership, the

importance of management at all levels gets undeservedly less attention, as identified by the Messenger review. In my opinion, therefore, any proposal to regulate managers should extend well beyond those deemed to be in a senior leadership position and should be inclusive of all those who occupy positions in management and leadership throughout the NHS. This is potentially a very large group, and one that does not get sufficient consideration in the tendency to focus on senior managers only. In the discussion that follows, I therefore consider regulation for managers broadly, not just for those at director level. A separate discussion could be had about how to regulate the management and leadership responsibilities of those in registered health professions, but I do not cover that here.

In brief, regulating managers would involve creating a register, to which access is controlled (e.g. through requirements for particular credentials, such as qualifications); definition of a set of competencies; issuing of a licence or chartered status to those on the register; codified standards of conduct to which members are bound; the ability to monitor and/or investigate compliance with the standards and/or take note of any alleged breaches or deviations; and a system of enforcement (e.g. sanctions for breaches of the standards, up to and including removal from the register).

A system of formal accreditation and registration could offer several advantages in regulation of health service managers. Some of these benefits concern the generic benefits of professionalisation, including accepted standards of education and training, an occupational identity, codes of ethics, erasure from the register of those no longer considered suitable, and so on. These features might also potentially help in making management and leadership in the NHS more attractive by enhancing its status as a profession, as recommended by the Messenger review. It might be also, crucially, be useful in helping managers in dealing with pressures they experience from the external environment, particularly those that arise at policy level – since they would be able to point to how what is being sought is against their professional standards. Put more bluntly, regulation might offer managers and leaders protections that are currently lacking, for example when they are being directed externally.

Practical advantages can also be identified. Registration would maintain a single list of those licensed to practice, would make explicit the standards against which their conduct can be judged, and would provide for any sanctions to be recorded against individuals and made known to current and future employers. Again, put more bluntly, a system of regulation might help in tackling bullying, harassment, or other transgressive behaviour on the part of managers and leaders, since it would offer an independent means of investigating and recording concerns, and sharing them with future employers where appropriate.

A system of professional regulation of managers in the NHS is, however, likely to pose some challenges in design and operation in practice. A unifying concern across the regulatory studies literature is how to regulate in the most effective, efficient, and legitimate way, while avoiding unintended consequences. [108] *Effectiveness* describes how well a regulatory regime delivers on its aims. This requires designing the system appropriately, for example by selecting the right goals, setting the correct standards, and ensuring it operates well. None of this is straightforward. Management and leadership especially vulnerable to being asked to pursue a multiplicity of objectives, some of which are likely to come into conflict – for example, being required to respond to competing directions on finance, patient safety, and staff wellbeing. Setting standards and judging the conduct of an individual in balancing these is likely to be challenging.

A second consideration is that of *efficiency or regulatory economy*. The balance between regulatory effectiveness and regulatory economy may not be easy to achieve; [376 377] the system might be expensive relative to benefits in ways that are not all possible to predict. Also important are considerations of *legitimacy,* which is a key feature of any regulatory regime, including how far its actions and values perceived to be desirable, acceptable and

appropriate. [378]Views of legitimacy may vary between different stakeholders – for example between patients who have been harmed and occupational groups.

Overall, while some advantages and disadvantages for a system of regulation for managers can be identified based on current evidence and theory, on balance regulation appears a promising approach. A major programme of design, consultation, piloting and evaluation would be required to take the idea further.

10 Recommendations from previous inquiries to improve culture and governance in the NHS

The NHS has, as discussed throughout this report, experienced multiple scandals throughout its 76 years. Each failing is distinctive, and each involves terrible human suffering and grief. However, they typically demonstrate many shared features – including many similarities in problems described, the causes identified, and the recommendations made. The health services researcher Kieran Walshe, writing in 2003, [209] noted that typical themes of NHS inquiries include: organisational or geographic isolation; Inadequate leadership, lacking vision and willingness to tackle known problems; systems and process failures, in which organisational systems and processes are either not present or do not work properly; poor communication within the organisation and with patients, meaning that problems are not picked up; and disempowerment of staff and patients, so those who might raise concerns are discouraged or prevented from doing so.

It appears that little has changed in more than 20 years since this was written. The growing catalogue of investigations and inquiries into disasters in maternity care, for example, displays repetitively characteristic features, typically involving a complex tangle of behaviours and systems, dysfunctional organisations lacking good management systems, degraded cultures involving disrespect both to families and colleagues, inadequacies in clinical and professional conduct and practice, and problems that are known about at some level but somehow evade detection and effective action over a long period. [52 379-381 92 232 382] Recent inquiries have been especially critical of discounting of warning signs, failure to listen or act on patient and staff concerns, fragmentation of knowledge about problems and vacuums of responsibility for addressing them, and norms of secrecy and protectionism.

There has been no shortage of recommendations arising from inquiries and investigations, but they have had variable impact. Some good progress has been made in some areas since Mid Staffordshire, especially when policy and practice has been advancing in a coherent way at the same time. In the area of patient safety and neonatology, for example, positive developments since 2015 include the new patient safety incident reporting framework and the embrace of human factors principles as part of this; the introduction of the medical examiner system; widespread implementation of the perinatal mortality review tool; strengthening of the child death review process; the introduction of the patient safety specialist role in NHS organisations; continued participation in national clinical audits; and increased recognition of the importance of openness, albeit mixed evidence (as discussed above) of successful implementation of openness policies. All of these are likely to contribute to reducing the risk of a problem going undetected in neonatal care, though none is likely to eliminate it. Monitoring and evaluation will be needed to assess the impact, particularly since the cultural shifts and systems improvements needed to deliver on these initiatives are likely to be variable across organisations.

Not all recommendations have resulted in positive impacts. One legacy of inquiries and investigations is the “tombstone effect,” described by Christopher Hood as involving the construction of procedural rituals or regulatory requirements in response to high profile scandal or failure. [383] These organisational and institutional symbols of mourning and reparation are erected to signal the seriousness of the events, the respect due to victims, and the determination to prevent a repeat of suffering. They help complete a narrative arc of wrongdoing or failure, punishment or retribution, and restoration. But they may also get caught up in the blame game, helping to organise responsibilities and arrange what Hood calls “procedural armour” against the next catastrophe while also providing a way of distributing blame if a repeat does occur. In such circumstances, compliance may easily become institutionalised as a means of self-preservation: filling in that form, or taking that procedural precaution, or documenting that process may all provide a defence against anxiety while failing to fully contain the risk it was intended to address.

Some recommendations arising from inquiries and investigations have not translated into action at all or only in a limited way. One key problem, of course, is the sheer volume of recommendations: the Bristol Inquiry made 198 recommendations; the Mid Staffordshire Inquiry made 290, and hundreds of others have been made. The recommendations are often added to the already dense priority thickets confronting NHS organisations emanating from multiple sources (e.g. over 1200 for maternity alone in one year). The institutional complexity arising from the array of regulatory and oversight bodies that give direction to NHS organisations means that recommendations may compete, conflict, and fail to cohere. The number of recommendations can cause confusion about which are most important, and can quickly overwhelm the ability of organisations to take action in response, particularly in the absence of the right kinds of infrastructure and support. Too often, organisations are left to come up with their own ways of responding to a recommendation without additional resource, and may come up with a sub-optimal approach. This is a problem that may be especially consequential for the more vulnerable organisations that already struggle to improve.

Other reasons for failures of implementation include: the non-binding nature of recommendations and absence of oversight; the extent to which the recommendations are given priority by policy-makers; failures of resourcing; the complexities of coordinating actions and responsibilities across multiple bodies and agencies; and duplicative or contradictory recommendations. A key problem is that though many recommendations are made, not all are of equal value, capable of being operationalised, or equally likely to be effective in targeting the issue they are designed to solve. In my view, the scale of design expertise, intervention development and testing, engagement with patients, families and staff, and implementation capacity needed to deliver on many recommendations are often very significantly under-estimated. These problems are compounded by lack of rigorous evaluation.

Finally, while inquiries and investigations frequently identify cultural problems, their recommendations for addressing culture may (too) often take the form of exhortation to behave better. The firmer recommendations tend instead focused to be on regulation and structure, which are unlikely on their own to solve the problems of culture. The extent to which culture is influenced by aspects of systems and wider institutional contexts (including those at policy level and the legal environment) tends to be under-recognised, particularly when it comes to dealing with transgressive behaviour.

10.1 What recommendations do you think this Inquiry should make in the light of its terms of reference under C?

10.1.1 Recognise transgressive behaviour as a distinct class of patient safety risk, and design and implement systems for managing it

Transgressive behaviour is a rare but distinct class of patient safety risk that needs to be addressed with appropriate strategies, policies, and processes that are standardised and properly supported throughout the NHS. A review and consultation on the wider institutional environment relating to employment law and practices and professional regulation should be undertaken to inform an NHS-wide framework for managing this risk. It should include specific standards and processes for addressing concerns about transgressive behaviour involving either individuals or groups in any part of the NHS or its outer contexts, and a strong supporting infrastructure (which might include a new body) to enable the framework to be implemented effectively and equitably.

10.1.2 Recognise the risks of institutional secrecy

The risks of institutional secrecy should be recognised as an inevitable feature of complex organisations, linked both to how information is organised and behaviours in relation to information, some of which are rooted in normal human sense-making. This means that, in any organisation, managers and leaders should be alert to how heuristics and cognitive biases may influence their interpretation of situations, and should appreciate the significance of unusual patterns, soft intelligence and the role of psychological safety. Achieving this kind of alertness is likely to require awareness-raising and other interventions. The risks of institutional secrecy are significantly increased when there are comfort-seeking behaviours or instincts towards denial and concealment, so those bodies involved in direction and oversight of NHS provider organisations should be accountable for the possible impacts of their own behaviours, policies and practices and their role in blame games.

10.1.3 Reduce institutional complexity and priority thickets

Reducing institutional complexity and priority thickets would support NHS organisations in having a clear and coherent set of imperatives, reduce confusion and waste, and improve focus and ability to deliver. A consultation on how this can best be achieved would be helpful.

10.1.4 Address the need for evidence-based improvement efforts

Since culture is strongly linked to systems, significant investment is needed in improving operational and clinical processes in the NHS. However, improvement efforts need to be based on evidence and to generate evidence. This is likely to be best achieved through an infrastructure that operates collaboratively and at scale to understand problems, co-design and test solutions with patients and staff, and evaluate them, and through supporting implementation.

10.1.5 Improve workplace conditions and behaviours

Improving workplace conditions and behaviours is a priority for improving culture, and will require: making workforce stewardship a key priority; collaboratively designing a framework of workforce standards which can be monitored; creating capabilities for work system design based on human factors principles throughout the NHS; improving workforce planning; and improving training and education.

10.1.6 Improve and value management at all levels and undertake a consultation on the regulation of managers

Management at all levels (not just senior leadership) needs to be strengthened at all levels of the NHS. This will require, at a minimum, fuller implementation of the findings of the Messenger review, but will also require that management is recognised as a key priority for the NHS, is resourced and trained for appropriately, and is valued by political leadership.

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