



The elephant in the room: Patient safety and Integrated Care Systems

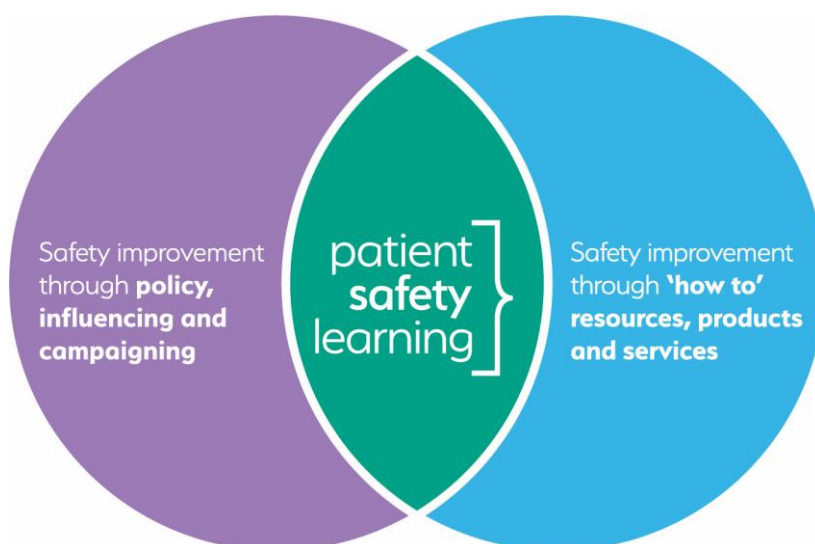
11 July 2023

Patient Safety Learning

[Patient Safety Learning](#) is a charity and independent voice for improving patient safety.

We believe that the persistence of avoidable harm is the result of our failure to address the complex systemic causes that underpin it. As outlined in our report, [A Blueprint for Action](#), to tackle this we believe that there needs to be a fundamental transformation in our approach, with patient safety treated as core to the purpose of health and social care, not simply as one of several competing strategic priorities to be traded off against each other.

Through our work, we seek to harness the knowledge, enthusiasm and commitment of healthcare organisations, professionals and patients for system-wide change and the reduction of harm. We support safety improvement through policy, influencing and campaigning, and the development of 'how to' resources such as [the hub](#), our free award-winning platform to share learning for patient safety, and our unique [Patient Safety Standards and support tools](#).



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Executive Summary

This report by Patient Safety Learning considers the roles and responsibilities of Integrated Care Systems (ICSs) in relation to patient safety, and how this fits in with the wider patient safety landscape in England.

Persistence of avoidable harm in healthcare

Avoidable harm during health care and treatment is a global challenge, with millions of patients suffering injuries or dying as a result of this. The World Health Organization (WHO) estimates that one in every ten patients is harmed while receiving hospital care. In this report, we set out what we mean by avoidable harm in healthcare, outlining the scale of this problem and the need for a transformation in approach to improving patient safety.

We go on to detail the landscape of different coordinating groups and organisations in England that have roles and responsibilities to improve patient safety and reduce avoidable harm. What is revealed is a complex and fragmented environment, lacking strong measures for cross-organisational thinking and coordination to address complex systemic threats to patient safety.

Patient safety and Integrated Care Systems

Having provided this context, the report looks at how ICSs have been created and initially developed with little mention of their role in, or impact on, patient safety. We set out why we believe that patient safety is clearly linked to the main aims of ICSs and how they operate, and that they clearly have a role in reducing avoidable harm in the National Health Service (NHS).

Recommendations

Considering the steps that could be taken to address the current gap that exists between patient safety and ICSs, and the wider fragmentation of the patient safety landscape in which they operate within, the report concludes making the following recommendations:

- 1. The Department of Health and Social Care and NHS England should consider introducing a fifth aim for ICSs making explicit their role in helping to improve patient safety and reduce avoidable harm.**
- 2. NHS England should update the NHS Patient Safety Strategy to account for ICSs being placed on a statutory footing in July 2022 and set out their roles and responsibilities in relation to this.**
- 3. The Department of Health and Social Care and NHS England should consider revising the remit of the National Patient Safety Committee to take on a greater role in coordinating and joining-up the existing patient safety landscape in England.**
- 4. The National Patient Safety Committee should regularly publish agendas, papers and the minutes of its meetings to help inform all bodies that may be impacted by this, such as ICSs and individual healthcare providers, and also patients and the wider public.**

Introduction

ICSs have recently passed their first anniversary of being formally placed on a statutory footing on the 1 July 2022. These partnerships bring together NHS organisations, Local Authorities, voluntary sector organisations and others to plan and deliver healthcare services, to improve the lives of people who work and live in a specific geographical area.

In their creation and initial development, conversations about the roles and responsibilities of ICSs have often been a 'patient safety free zone'. Given the persistence and scale of avoidable harm in healthcare, at Patient Safety Learning, we believe this is a serious oversight that needs to be urgently addressed.

In this report, we will first explain what we mean by avoidable harm in healthcare, outlining the scale of this problem and the need for a transformation in approach to improving patient safety. We will then map out the complex landscape of existing patient safety roles and responsibilities in England, before considering how ICSs have been initially developed and their relationship with patient safety.

We will then seek to set out why we believe that patient safety is clearly linked to the main aims of ICSs and how they operate, before considering the potential role that ICSs can potentially play in helping to embed and improve patient safety. Finally, we will put forward recommendations aimed at closing the gap that exists between ICSs and patient safety, and concerning the wider fragmented patient safety landscape which they operate within.

Avoidable harm and patient safety

Before discussing the role of ICSs and patient safety, it is first important to explain what we mean by avoidable harm in healthcare, outline the scale of this problem and the need for a transformation in approach to tackling this.

Modern healthcare is increasingly complex and there are a range of different ways in which avoidable harm can occur during care and treatment. This is a global challenge, with millions of patients suffering injuries or dying as a result of this. The WHO estimates that one in every ten patients is harmed while receiving hospital care.¹ This harm can be caused by a range of patient safety incidents, with more than 40% of them being preventable.²

Patient safety is concerned with avoiding unintended harm to people during their care and treatment. It is defined by the NHS as "the avoidance of unintended or unexpected harm to people during the provision of health care".³ WHO provides a slightly broader definition of this:

"Patient safety is a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur."⁴

Types and causes of avoidable harm

Some examples of ways in which avoidable harm can occur in healthcare include:

Diagnostic errors – all aspects of the diagnostic process are potentially vulnerable to error and this can occur in all healthcare settings and services. They can broadly be divided into three categories can result in harm:

- Delayed diagnosis.
- Incorrect diagnosis.
- Missed diagnosis.

Medication errors – unsafe medication practices and medication-related harm is one of the leading causes of injury and avoidable harm in healthcare across the world. They can broadly be divided into four categories and can occur in all healthcare settings and services:

- Prescription – where medication may be under or over prescribed.
- Dosage – where harm results from patients either missing or receiving incorrect doses of medicine.
- Route of administration – where medication is administered in the incorrect way resulting in harm.
- Omission – where patients fail to receive the correct medication for their condition.

Healthcare associated infections – these can develop either as a direct result of healthcare interventions, such as medical or surgical treatment, or from being in contact with a healthcare setting. Common types of healthcare association infections include:

- Central line-associated bloodstream infections.
- Catheter-associated urinary tract infections.
- Surgical site infections.

Unsafe surgery – this is concerned with errors occurring during an operation that can result in serious harm. Common types of surgical error can include:

- Wrong site surgery.
- Retained foreign objects.
- Anaesthesia errors.
- Identification errors resulting in surgery on the wrong patient.
- Surgical fires.
- Avoidable damage to tissue, internal organs, or nerves.

Causal factors of patient safety incidents – healthcare is a complex adaptive system with high levels of interdependence and connectivity, competing and changing demands, unpredictability, uncertainty with myriads of relationships often with insufficient resources (people, money, infrastructure etc). Healthcare system performance and behaviour changes over time and cannot be completely understood by simply knowing about the individual components.⁵ Examples of potential causes of avoidable harm relating to this include:

- Communication errors – these can occur both between healthcare professionals, and between healthcare professionals and patients.
- Staff workload and workforce related issues – this can relate to unsafe staffing levels and high levels of fatigue and burnout among healthcare professionals.
- Failure to listen to concerns – raised by patients, carers and families.

- Organisational cultures and leadership – failing to support staff in raising concerns.
- Failure to learn from incidents of unsafe care and good practice – whether in their own organisations or others.
- Consent – failure to obtain appropriate informed consent before and/or during care and treatment.

Scale of avoidable harm in the NHS

NHS England estimated, pre-Covid, that there were around 11,000 avoidable deaths annually due to safety concerns.⁶ A separate academic study has suggested that there are likely to be between 19,800 and 32,000 cases of ‘probably avoidable’ significant harm to patients in primary care in England each year.⁷ Both these figures are likely to be a serious underestimate given the current post-Covid pressures on primary care, social care and hospital care. In January this year, the Royal College of Emergency Medicine estimated that there were at least 300–500 excess deaths occurring across the UK associated with crowding and extremely long waiting times.⁸

Every avoidable death and disability is an unnecessary tragedy for patients, families and healthcare professionals. Beyond the cost in human lives, unsafe care also extracts other significant tolls, such as:

- Physical and psychological discomfort of patients who experience a long hospital stay or permanent disability because of errors.
- Loss of trust in the healthcare system by patients.
- Diminished satisfaction by both patients and health professionals.
- Loss of morale and frustration of health professionals at not being able to provide the best care possible.

Avoidable harm is also accompanied by a huge financial cost to the healthcare system, patients and families. The Organisation for Economic Co-operation and Development (OECD) estimates that in high-income countries the direct cost of treating patients who have been harmed during their care approaches 13% of health spending.⁹ Excluding safety lapses that may not be preventable, this figure is 8.7% of health expenditure.

In 2023/24, £160.4bn (85%) of the total Department of Health and Social Care budget is being passed on directly to NHS England.¹⁰ Based on the OECD figures, even saving 5% of this expenditure by reducing preventable harm would release an eye watering £8bn of funds to reinvest in service improvements and additional capacity.¹¹

The costs for NHS litigation alone are a clear indication of the financial impact of this. The cost of settling claims in 2021/22 came to £2.5bn, with a further £13.3bn spent on compensation claims settled in previous years.¹²

Patient safety as a core purpose of health and social care

The impact of avoidable harm and the need to make significant improvements is well-established. There was a growing recognition of the need to improve patient safety in the 1980s and 1990s and over the last 20 years there have been a variety of international and national initiatives aimed at reducing avoidable harm. However, despite this knowledge, and the hard work of many people involved in the sector, avoidable harm continues to persist at an alarming rate.

Avoidable harm in healthcare is driven by our failure to address the complex systemic causes that underpin this. These include:

- Safety being simply one priority of many.
- A failure to design safe systems; too often healthcare focuses on responding to incidents of unsafe care, less on designing systems and processes for safety.
- Persistence of blame culture that undermines incident reporting and staff's ability to speak up about safety concerns.
- Organisational and system leaders not focusing on patient safety.
- Failures to engage with patients around the safety of their care.
- Gaps between learning and implementation.

At Patient Safety Learning we believe that the persistence of avoidable harm is the result of our failure to address the complex systemic causes that underpin it. In our report, *A Blueprint for Action*, we set out the need for a transformation in approach to patient safety.¹³ This sets out how too often patient safety is typically seen as a strategic priority, which in practice will be weighed (and inevitably traded-off) against other priorities. To transform our approach to this it is important patient safety is not just seen as another priority, but as a core purpose of health and care.

Underpinned by systemic analysis and evidence, the report identifies six foundations of safe care of patients and practice actions to address them, detailed in figure 1 below.

Figure 1. The six foundations of safe care for patients

1. **Shared learning** – organisations should set and deliver goals for learning, report on progress and share their insights widely for action. It is not enough to say, 'we've learned from incidents of unsafe care', we need to see action for improvement and impact.
2. **Leadership** – the importance of overarching leadership and governance for patient safety is emphasised. This is not just about governance; it is about behaviours and commitment too.
3. **Professionalising patient safety** – recognising that organisations need to set and delivery high standards and accreditation for patient safety. These need to be developed and implemented and used by regulators to inform their assessment of whether organisations are doing enough to prevent avoidable harm and assess whether they are safe.
4. **Patient engagement** – to ensure patients are valued and engaged in patient safety, at the point of care, if things go wrong and for redesigning healthcare for safety.
5. **Data and insight** – better measurement and reporting of patient safety performance, both quantitative as well as qualitative.
6. **Just Culture** – all organisations should publish goals and deliver programmes to eliminate blame and fear, introduce or deepen a Just Culture, and measure and report progress.

Patient Safety Standards

As noted above, in stating that the need to professionalise patient safety as one of the six foundations of safe care for patients, standards are a central part of this. We consider one of the primary reasons for the persistence of avoidable harm is that healthcare does not have or apply standards for patient safety in the way that it does for other safety issues. The standards it does have are insufficient and inconsistent.

We believe that by adopting and implementing comprehensive patient safety standards, organisations will be able to deliver safe care and embed a commitment to patient safety throughout their work. This would also enable patients, leaders, clinicians, the wider public and regulators to assess their progress and performance in improving patient safety.

Patient Safety Learning has developed a set of unique Patient Safety Standards, based on *A Blueprint for Action*, and centred around seven key foundations of patient safety.¹⁴ The seven foundations are supported by 26 specific patient safety aims. In total, there are 144 identified standards, based on 20 years of research, as well as learning from inquiries, policy and good practice from healthcare. We have begun working with several organisations to implement these standards as part of their organisational safety improvement strategies.

Current patient safety landscape

Patient safety responsibilities in England

Formally placed on a statutory footing on the 1 July 2022, ICSs have become part of a complex and fragmented patient safety landscape. In this report we focus specifically on healthcare in England, where patient safety roles and responsibilities are divided between a range of different coordinating groups and organisations. Although not exhaustive, below is a summary of these different bodies, with a more detailed list included as an Appendix at the end of this report.

Government and Parliament

At the summit of the patient safety landscape in England is the Secretary of State for Health and Social Care who is responsible for the overall oversight of NHS delivery and performance. Patient safety is also assigned as part of the portfolio for a specific minister, with this currently sitting with the Minister for Mental Health and Women's Health Strategy, Maria Caulfield MP.

In Parliament, the cross-party House of Commons Health and Social Care Select Committee is responsible for scrutinising the work of the Department of Health and Social Care and associated government policy. While many areas of health and social care include significant patient safety issues, they will at times also look at specific patient safety topics, such as following up earlier this year on the implementation of the recommendations of the Independent Medicines and Medical Devices Safety Review.¹⁵

National coordinating groups

Below the government level, and cutting across a range of different organisations, is the National Patient Safety Committee. Established in 2021, its membership is composed of different public bodies which hold patient safety responsibilities, with its purpose stated as follows:

“The National Patient Safety Committee will play a strategic role in considering the existing landscape of national patient safety planning, response and improvement within the healthcare system and consistently share insight and thinking about how as a system we can improve the effectiveness of these patient safety functions.”¹⁶

It is possible that this group in future could emerge as the central coordinating body for patient safety activity across the system. However, in its current guise it is not clear to what extent it may have the ability to do so, with its Terms of Reference not reflecting an ambition to be a broader safety system oversight board. Its role has not been particularly promoted to date and there is little transparency around its activities, with seemingly no agendas, reports or minutes from its meetings currently published in the public domain. This group is accountable to the National Quality Board.

National NHS bodies

There are two national NHS bodies with clear patient safety responsibilities:

1. NHS England – they are responsible for the national NHS Patient Safety Strategy, which describes how the NHS aims to improve patient safety over the next five to ten years.¹⁷ Within NHS England sits the National Patient Safety Team, whose role is stated as “supporting the NHS to achieve the strategy’s aims through a series of programmes and areas of work”.¹⁸
2. NHS Resolution – they are responsible for providing expertise to the NHS on resolving concerns and disputes fairly, sharing learning for improvement and preserving resources for patient safety.

National improvement agencies and programmes

There are also a number of different NHS improvement bodies and improvement programmes that can have a direct or indirect patient safety focus, as outlined in the Appendix. One example of this is Getting It Right First Time (GIRFT), a national programme designed to improve the treatment and care of patients through in-depth review of services, benchmarking and presenting a data-driven evidence base to support change.¹⁹

System and professional regulators

At the regulatory level, the Care Quality Commission (CQC) as the independent regulator of health and social care in England, tasked with ensuring these services provide safe, effective, compassionate and high-quality care. The Medicines and Healthcare products Regulatory Agency (MHRA) meanwhile regulates medicines, medical devices and blood components for transfusion in the UK. It has a specific responsibility to ensure these products meet applicable standards for safety, quality, and efficacy.²⁰

In addition to the CQC and MHRA, there are a number of other regulators who have a significant patient safety aspect to their role, such as bodies governing the conduct of different healthcare professionals and regulators from outside of healthcare such as the Health and Safety Executive.

Ombudsman

The Parliamentary and Health Service Ombudsman (PHSO) provides the independent complaint handling service for complaints that have not been resolved by the NHS in England and UK government departments.²¹ Though it does not have a direct responsibility for patient safety, through its casework and investigations into the NHS it can play an important role in highlighting patient safety failings, sharing learning and making recommendations for change.

Patient safety bodies

There are three patient safety specific bodies that we identify as forming part of the governance landscape in England:

1. Healthcare Safety Investigation Branch (HSIB) – this first came into operation in April 2017 and has the aim of improving patient safety through independent investigations into NHS-funded care in England. It is currently undergoing an organisational transformation, due to completed in October this year, where its functions will be transferred to a new non-department public body, the Healthcare Services Safety Investigations Body, and its maternity investigations programme moved to the CQC.²²
2. The National Guardian's Office – they are responsible for leading, training and supporting a network of Freedom to Speak Up Guardians in England, and conducts speaking up reviews to identify learning and support improvement of the speaking up culture of the healthcare sector.
3. Patient Safety Commissioner for England – their role is to act as a champion for patients and lead a drive to improve the safety of medicines and medical devices.

Standard-setting bodies

In addition to the regulators, organisations that set standards for healthcare providers and professionals also have a significant influence and impact on patient safety. We include a list of these the Appendix, including the National Institute for Health and Care Excellence (NICE) and the various Medical Royal Colleges.

Regional and local area bodies

There are also a range of bodies that work at a regional or local level that have aspects of patient safety responsibilities, including NHS England Regional Teams, Academic Health and Science Networks, and Coroners.

Providers

All individual NHS organisations have a responsibility to deliver safe care to their patients. In its broadest sense, as set out in the NHS Constitution, patients can expect from health and care services:

“... the right to be treated with a professional standard of care, by appropriately qualified and experienced staff, in a properly approved or registered organisation that meets required levels of safety and quality.”²³

Individuals

Individual healthcare professionals have specific responsibilities as registrants with the healthcare regulators that govern their work. There are also specific roles with set patient safety responsibilities. We include a list of these in the Appendix, including Medical Examiners, Board members and Patient Safety Specialists.

Figure 2 on the following page illustrates the current patient safety environment in England.

Figure 2. Patient safety environment in England

Government and Parliament <ul style="list-style-type: none"> • Department of Health and Social Care • Health and Social Care Select Committee 	Standard setting bodies <ul style="list-style-type: none"> • Medical Royal Colleges • National Institute for Health and Care Excellence • Professional Record Standards Body
National coordinating groups <ul style="list-style-type: none"> • National Quality Board • National Patient Safety Committee 	Regional and local area bodies <ul style="list-style-type: none"> • NHS England Regional Teams • Integrated Care Systems • AHSNs and patient safety collaboratives • Healthwatch • Coroners
National NHS bodies <ul style="list-style-type: none"> • NHS England National Patient Safety Team • NHS Resolution 	
National improvement agencies and programmes <ul style="list-style-type: none"> • NHS Horizons • AQUA • Getting it Right First Time (GIRFT) • NHS Impact 	Providers <ul style="list-style-type: none"> • Acute Trusts • Ambulance Trusts • Mental Health Trusts • Community Health Trusts • Primary care organisations • Primary care networks
Ombudsman <ul style="list-style-type: none"> • Parliamentary and Health Service Ombudsman 	System and professional regulators <ul style="list-style-type: none"> • Care Quality Commission • Medicines and Healthcare products Regulatory Agency • Individual regulators of healthcare professionals • Health and Safety Executive
Patient safety bodies <ul style="list-style-type: none"> • Healthcare Safety Investigation Branch • Patient Safety Commissioner for England • National Guardian's Office 	
Individuals <ul style="list-style-type: none"> • Healthcare professionals • Board members and non-executive directors • Governors • Medical Examiners • Patient Safety Specialists • Patient Safety Partners • Freedom to Speak Up Guardians 	

A fragmented landscape

Even before looking at where ICSs fit into the picture, it is clear that the patient safety landscape they have entered is a complex one. Roles and responsibilities are spread across many different organisations, both within and outside the NHS.

Is this a concern? Undoubtedly there are reasons for this historical division in roles and responsibilities; however persistent and new threats to patient safety are rarely contained within a single domain or organisational remit. Putting in place measures that reduce avoidable harm often requires cross-organisational thinking and coordination.

Although the recently established National Patient Safety Committee is a step in the right direction, it seems unlikely that in its current form this will evolve into a more comprehensive overarching coordination body.

Currently its remit is limited to only looking at system-wide issues “for which there is no other mechanism for delivery and monitoring already in place”.²⁴ A concern with this approach is that on some systemic issues, one body may be charged with responsibility and, therefore, this falls outside of the Committees purview. Furthermore, if the lead body is failing to improve safety and reduce harm, there is no mechanism to highlight this problem or trigger action to change approach, except perhaps through patients and families raising concerns in the next major patient safety incident or scandal. Effective change will not happen without multi-organisational cooperation, accountability, and action.

Concerns about the fragmented nature of this landscape, and its consequences for patient safety, have been highlighted several times in recent years.

The CQC noted this, prior to the introduction of ICSs, in a 2018 report, *Opening the door to change*, which considered the underlying issues that contribute to the occurrence of Never Events in the NHS.²⁵ Never Events are defined as Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.²⁶

In their report, the CQC highlighted the difficulties that healthcare organisations encountered in implementing different guidance and messages from multiple bodies from across the system, stating that:

“The current patient safety landscape is confused and complex, with no clear understanding of how it is organised and who is responsible for what tasks. This makes it difficult for trusts to prioritise what needs to be done and when.”

Since this report, arguably this complexity has only increased further, with the introduction of new bodies such as the Patient Safety Commissioner for England, the forthcoming division of the responsibilities of HSIB and the emergence of ICSs.

The Independent Medicines and Medical Devices Safety Review also raised this issue. Chaired by Baroness Julia Cumberlege, this looked at the harmful side effects of medicines and medical devices and how to respond to them more quickly and effectively in the future. The review focused on the use of three medical interventions in England: hormone pregnancy tests, sodium valproate and pelvic mesh implants.

Considering the shocking degree of avoidable harm to patients associated with these interventions, it found evidence of a wider system that was unable to spot and act on

emerging safety concerns quickly enough and one that was not responsive to patient concerns. It stated that:

“We have found that the healthcare system – in which I include the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers, and policymakers – is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its *raison d’être*. It has failed to listen to their concerns and when, belatedly, it has decided to act it has too often moved glacially.”²⁷

This was highlighted again in September last year by the Professional Standards Authority for Health and Social Care. Setting out their views on the biggest challenges affecting the quality and safety of health and social care in the coming years, they said:

“For too long, individual organisations with different and specific remits have been expected to work together to address workforce and patient and service user safety issues. This approach is structurally flawed as there is generally no accountability for joint working and collaboration; bystander apathy and differing organisational priorities also present significant barriers. Everyone understandably looks at the problem through the lens of their own remit, but no one has the overview.”²⁸

As recently as last month, the PHSO highlighted this issue again. In a report analysing findings from healthcare complaint investigations in cases of avoidable harm, it summarises that:

“... political leaders have created a confusing landscape of organisations, often in knee-jerk reaction to patient safety crisis points. HSIB, the Patient Safety Commissioner, PHSO, NHS England, NHS Resolution and more than a dozen different health and care regulators all play important roles in patient safety. But there are significant overlaps in functions, which create uncertainty about who is responsible for what. This means patient safety voice and leadership are fractured. This is not due to a lack of dedication and professionalism from those tasked with championing patient safety. The problem is structural.”²⁹

The PHSO suggests that the Government needs to consider streamlining some of these functions to create a system that is more coherent and easier to navigate for people who use the NHS.

Safety Management System

There is also a growing debate in patient safety circles about the possible benefits that healthcare may gain from moving towards a Safety Management System approach. This is used in many other high-risk industries and can be described as follows:

“The basics of any safety management system is to have safety objectives, so you set out what you want to achieve. This requires assessment of the hazards and risks and the mitigation to those risks and these need to be transparent. You need an assurance process that constantly monitors the safety performance of the organisation and investigates incidents when they occur. This in turn will drive learning which will further improve safety and crucially embed a safety culture amongst all staff. All this needs to be recognised at Board level, continually stretching the organisation’s safety objectives.”³⁰

This is currently the subject of a HSIB national learning report, which is exploring the requirements for effective safety management systems, how they could apply to healthcare, potentially barriers to implementation and how this may support better everyday work within the NHS.³¹

Integrated Care Systems

Having set out the current patient safety landscape, how do ICSs fit into this picture?

The role of ICSs

ICSs are partnerships that bring together NHS organisations, local authorities and others to plan and deliver healthcare services in a geographical area. There are currently 42 ICSs across England, which were formalised as legal entities with statutory powers and responsibilities following the passing of the Health and Care Act 2022.^{32 33 34} Each ICS is made up of an Integrated Care Board (ICB) and an Integrated Care Partnership (ICP), as detailed in Figure 3.

Figure 3. Integrated Care Boards and Integrated Care Partnerships

Each statutory ICS includes two key components: an ICB and ICP, which are described by *The Hewitt Review* as:

The ICP is a statutory committee jointly formed between the ICB and the relevant local authorities within the ICS area. The ICP brings together the broad alliance of partners and is responsible for producing an integrated care strategy on how to meet the health and wellbeing needs of the population in the ICS area.

The ICB is the statutory NHS organisation responsible for bringing NHS and other partners together to plan and deliver integrated health and care services and accountable for the finances and performance of the local NHS as a whole.³⁵

Other important elements of ICSs include:

- Local Authorities – those which are within the ICS area who are responsible for social care and public health functions.
- Place-based partnerships – these will lead on the detailed design and delivery of integrated services across their localities and neighbourhoods. These will involve a range of different groups, including the NHS, local councils, community, voluntary organisations and service users.
- Provider collaboratives – these groups bring together providers to achieve the benefits of working at scale across multiple places and one or more ICSs. They are composed of two or more NHS Trusts that provide hospital, mental health and community services.
- Primary care networks – led by clinical directors, their purpose is to have an impact and achieve economies of scale through collaboration between GP practices and others in the local health and social care system.

Working through their ICB and ICP, ICSs have four key aims:

1. Improve outcomes in population health and healthcare.
2. Tackle inequalities in outcomes, experience, and access.
3. Enhance productivity and value for money.
4. Help the NHS support broader social and economic development.

ICSs and patient safety

In the initial plans to develop and formulate the role of ICSs in the healthcare system very little was said explicitly about their role in, or impact on, patient safety. In 2020, NHS England in their consultation document, *Integrating care – next steps to building strong and effective integrated care systems across England*, set out their initial thoughts on how ICSs could operate but, there was not a single reference to safety.³⁶ The four key aims of ICSs do not include an explicit reference to patient safety.

Since ICSs have been placed on a statutory footing on 1 July 2022 there has not been an obvious development in thinking on this from the Department of Health and Social Care or NHS England. The oversight and governance of ICSs was subject to assessment recently as part of *The Hewitt Review*, published on the 4 April 2023. However again this paid little attention to patient safety, with ‘safety’ only given a passing mention six times in the document.³⁷ Where this was mentioned, these are only passing references with no clear indication of any responsibilities that ICSs may have in relation to this.

The NHS Patient Safety Strategy does refer to the future role of ICSs briefly. It highlights their potential to plan and oversee the provision of safe care and tackle problems that cut across care settings, and states that NHS England integrated regional teams will help ICSs by:

- Supporting Sustainability and Transformation Partnerships (STPs)/ICSs and healthcare providers to implement features of the NHS Patient Safety Strategy.
- Acting as the conduit for change to help STPs/ICSs and healthcare providers transform their local system to the new ethos and working arrangements embodied in the strategy.³⁸

There has been no substantial update to the NHS Patient Safety Strategy since it was published in 2019; therefore, these references to ICSs and their role in patient safety have not been developed subsequently. There also currently appears to be no public guidance on the role of ICSs in relation to the NHS Patient Safety Strategy or patient safety more broadly from NHS England. This is a significant omission.

Case study: Rapid review into data on mental health inpatient settings

Despite the current absence of guidance around the roles of ICSs in patient safety, simply by their very inclusion in the health system, these considerations are beginning to come to the fore. An example of this can be seen in the findings and recommendations of the Department of Health and Social Care’s recent rapid review into data on mental health inpatient settings.³⁹

This review was commissioned by the Minister for Mental Health and Women’s Health Strategy, Maria Caulfield MP, on the 23 January 2023, with its Chair Dr Geraldine Strathee, and was asked to consider how improvements could be made to the way that data and information is used in relation to patient safety in mental health inpatient care settings and pathways, including for people with a learning disability and people with autism.⁴⁰

It is noticeable how, despite their lack of a formally identified patient safety role, ICSs have an integral role to many of the recommendations made by the review aimed at improving patient safety. ICSs are included in six of the 13 recommendations, and in three of these ICSs are identified as one of the principle actors in their implementation, tasked with:

- Bringing together trusts, independent sector providers and all relevant stakeholders to facilitate cross-sector sharing of good practice in data collection, reporting and use.
- Working with provider collaboratives to map out a pathway for all their mental health service lines to establish which parties need access to relevant data at all points on the pathway and take steps to ensure that data is available to those who need it. To facilitate this, the review suggests they should also be responsible for making sure that their members have access to data literacy training relevant to mental health, including in relation to quality improvement and safety.
- Through their system-wide infrastructure strategies, to review the mental health estate to inform these and future strategies, recognising there are evidence-based therapeutic design features that can contribute to reducing risk and improving safety.

The Government has yet to formally respond to this review, so it may be that some or all of these recommendations are not implemented. However, it provides a useful and timely illustration of how, when thinking about solutions to tackle wider patient safety concerns, ICSs are quickly becoming part of the conversation, even without a specific patient safety role being set out in their initial formulation and development.

Placing patient safety at the heart of ICSs

Safety at a system level

In December 2022, the Advancing Quality Alliance (AQUA), an NHS health and care quality improvement organisation, convened a selection of expert panellist to discuss a wide range of topics covering safety within ICSs and the factors affecting it.⁴¹ An outcome of this discussion was the report, *What should safety look like at a system level?*, which was shaped around considering two key questions:⁴²

- Why should ICSs prioritise safety?
- How will ICBs deliver effective system safety?

Making the case for why ICSs should prioritise patient safety, the report identifies a key reason for this as being that safety should be “a property of the whole system; it’s never just a matter for a single service or provider”. It makes the case for the ICSs leading on safety at a system level, arguing that this must be central to both their governance and oversight. The report also touches on some of the points we have discussed earlier in this paper for why ICSs should prioritise safety. Namely, that the sheer scale of avoidable harm makes a strong moral case for this to be a priority, coupled with the need to reduce the significant ongoing financial burden resulting from its persistence.

Considering the role ICSs and their ICBs have in delivering patient safety, the report goes on to highlighted seven key safety themes to consider when thinking about this, which are detailed below in Figure 4.

Figure 4. How can ICBs deliver effective system safety

Summarised from the AQUA report *What should safety look like at a system level?*:

Culture

- Enabling a culture shift in health and care across primary, ambulatory, secondary and social care with new ways of working.
- Developing a system-safety culture that is collaborative, crafted, nurtured, and created and sustained so all can flourish.
- An improved culture supported by new ways of working within services, within organisations and across the whole system.

Leadership

- Leaders at all levels demonstrating the correct behaviours to lead a safety culture across their system.
- ICB leaders asking searching questions and being open to hearing the truth.

Systematic management

- Safety can be proactively managed in a consistent way across the whole system.
- Strategic goals for system safety can be set, linked to data and health inequalities.
- Opportunities to explore a framework and principles for how we manage safety at a system level.

Model of care

- Developing relationships across whole pathways of care.
- Listening to patients and people in local communities and learning from their experiences will ensure that new models of care provide safe care.

Lived experience

- Hearing and acting on the voice of patients, which is crucial in setting the right safety priorities and establishing the right culture, in decision making, if there is harm, in improvement and for accountability.

Health inequalities

- ICBs can play a significant role looking at the systems in place to reduce inequalities related to patient (and staff) safety.
- System leaders can take a wider view of inequalities using NHSE Core20PLUS5 approach.
- Learning from safety events for people in those groups who are more likely to experience unsafe care can be used to drive improved safety for all.
- Safety can be considered as a cross-cutting theme when policy and pathways are developed.

Innovation

- Collaboration, innovation and improvement within systems, between different services, with patients and the local community, and with other systems is vital to learn from others and to identify areas of best practice.

ICS priorities and patient safety

At Patient Safety Learning we believe that the introduction of ICSs represents a significant opportunity to help to embed patient safety at a system-level in the NHS. We believe that patient safety is already clearly linked to the four main aims set for ICSs as detailed below.

Aim – Improve outcomes in population health and healthcare

As highlighted earlier in this report, at least 11,000 patients die every year as a result of avoidable harm in the NHS (these figures are likely to be a serious underestimate given the current post-Covid pressures on primary care, social care and hospital care), with thousands more seriously injured as a result of this. Improving patient safety and reducing avoidable harm is key to improving healthcare outcomes.

Aim – Tackle inequalities in outcomes, experience and access

Equality is a patient safety issue. One area where we see health inequalities intersect with patient safety is racial bias, such as the significant disparities that exist for Black, Asian and mixed ethnicity women in maternal outcomes.^{43 44} Another areas where there is a growing body of evidence in this regard is how sex and gender bias in health and social care can have a negative impact on patient safety, such as the impact of women being historically underrepresented in medical research and in failures of informed consent.^{45 46 47}

Aim – Enhance productivity and value for money

As highlighted earlier in this report, the costs associated with both treating patients who have been harmed during their healthcare and the NHS litigation bill demonstrate a clear financial imperative for ICSs to make improving patient safety a key priority.⁴⁸

Aim – Help the NHS support broader social and economic development

Gauging the wider socio-economic costs of the persistence of avoidable harm is complex. While there is not any UK-specific research to draw on in this area, in 2012 a study in the United States explored this issue in some detail.⁴⁹ Looking at data from 2008, they put the cost of medical errors in the United States at around \$19.5 billion, with 87% of this directly associated with additional medical costs. However, when taking into account the wider economic impact, applying quality-adjusted life years, they estimated that the total cost was perhaps \$1.1 trillion annually. There is likely to be a wider socio-economic benefit to improving patient safety, however a separate piece of research is needed to explore this further.

How ICSs can help to embed and improve patient safety

Although patient safety was not set out as an explicit priority for ICSs in their creation and initial development, the delivery of safe care runs implicitly through each of their intended aims. So how can ICSs potentially help to embed and improve patient safety? Further to the points highlighted in Figure 4, we would identify the following areas as a starting point for this:

- a) **Commissioning** – patient safety should be prioritised and at the heart of decisions in commissioning and funding new services.
- b) **System-wide learning** – providing a central point for safety surveillance and insights, pooling findings from incident reporting, patient safety initiatives and quality improvement activities in their area. ICSs could potentially be a key means by which to share and learn from these insights nationally.

- c) **Care pathways** – helping to design patient safety into cross-organisational care pathways and between acute and community provision, in areas such as elective care, access to mental health services etc. In designing new models of care that work around patients needs, ICSs can help ensure safety considerations are built into this process.
- d) **Engagement and collaboration** – fostering cross-organisational working, connecting those working in roles in patient safety and public involvement across their areas, such as Patient Safety Specialists, Patient Safety Partners, etc.
- e) **Creating a performance framework** – enabling comparative analysis of patient safety performance and impact in their areas, reducing variation and helping to promote best practice.
- f) **Culture** – supporting the development of a safety culture, modelling positive behaviours, and sharing and promoting examples of good practice within organisations across the whole system.
- g) **Engaging and involving patients** – supporting and sharing good practice across their local areas to help ensure that patients are engaged for safety at the point of care, if things go wrong, in improving services, advocating for changes and in holding the system to account.

We would also envisage that ICSs over time develop a greater oversight role of patient safety activities within their areas, which may involve assessment and monitoring of organisations patient safety strategies and delivery plans. Further to this, ICSs may choose to develop their own overarching patient safety strategies, in line with plans to deliver on local priorities.

Implementing the Patient Safety Incident Response Framework

In addition to the areas listed above, we believe going forward that ICSs can potentially play an important role in helping to implement and embed the new Patient Safety Incident Response Framework (PSIRF).

PSIRF is the NHS's new approach to developing and maintaining effective systems and processes for responding to patient safety incidents, replacing the existing Serious Incident Framework.⁵⁰ This new approach, focused on learning, places a greater emphasis on engaging patients and families as part of the investigation process and seeking to adopt a range of system-based approaches to learning from patient safety incidents. NHS organisations are currently in the process of implementing this, with significant progress expected by September 2023.

This represents a major change in approach to patient safety investigations, the success of which will depend on having the right organisational leadership and resources to support this transition and renewed focus on healthcare becoming a learning system; insights from errors, harm and good practice being used to improve safety and reduce avoidable harm.

PSIRF also allows organisations more flexibility in how they focus investigations or reviews, which has raised some concerns that this could be problematic in Trusts with poor cultures who do not carry out investigations as they should.⁵¹ The PHSO in their recent report, *Broken trust: making patient safety more than just a promise*, has suggested a specific ICS role in relation to this, namely that:

“Integrated care boards, with oversight from NHS England, should closely monitor the impact of the PSIRF to identify any negative consequences of the new flexibility it offers, which gives Trusts more autonomy to decide when a patient safety investigation is needed. This should include paying special attention to the balance of patient safety investigations versus other learning responses in Trusts (or service areas of a Trust) where there are poor CQC ratings for safety and leadership, or where other national bodies have raised concerns.”⁵²

We would concur with this recommendation, and further to this believe that PSIRF is an area where ICS involvement could be particularly beneficial. Although Trusts taking different approaches to how they implement PSIRF may lead to helpful innovations and learning, we believe that there also needs to be appropriate forums and transparent insights, both to share outcomes and compare and contrast approaches. With several different providers within their remit, ICSs are particularly well-placed to facilitate this, helping to share good practice and potentially identify any emerging concerns about implementation at specific organisations.

Recommendations

In this paper we have detailed the scale of the challenge to reduce avoidable harm in the NHS and the complex landscape that ICSs find themselves facing in relation to patient safety. We have also shown how, despite not having a formal patient safety role in their creation and initial development, patient safety is clearly linked to the main aims of ICS; in how they operate and in reducing avoidable harm in the NHS. We believe implementing the following recommendations would help to reduce avoidable harm and should be implemented as a priority.

Clarifying the role of ICSs and patient safety

For ICSs to effectively embrace their patient safety role, there needs to be clarity around how they fit within the existing landscape and where their responsibilities lie. We believe this would be helped by the following actions.

Recommendation 1: The Department of Health and Social Care and NHS England should consider introducing a fifth aim for ICSs making explicit their role in helping to improve patient safety and reduce avoidable harm.

Recommendation 2: NHS England should update the NHS Patient Safety Strategy to account for ICSs being placed on a statutory footing in July 2022 and set out their roles and responsibilities in relation to this.

Joining-up a fragmented system

As noted earlier in the paper, in a new report published just last month, the PHSO highlighted the specific challenges because of the complexity and fragmentation of patient safety in the healthcare system. They recommended the Department of Health and Social Care should commission an independent review of what an effective set of patient safety oversight bodies would look like.

We are supportive of this recommendation and would not seek to duplicate it here. However, in seeking to support ICSs finding their way in the current patient safety environment, in the absence of such a review we would suggest that the National Patient Safety Committee might play a helpful role in increasing coordination in the system. However, as noted, its current form has significant limits. We would therefore recommend that:

Recommendation 3: The Department of Health and Social Care and NHS England should consider revising the remit of the National Patient Safety Committee to take on a greater role in coordinating and joining-up the existing patient safety landscape in England.

We also would note that with any expanded role, the current limited level of transparency around the activities and work of this Committee would not be appropriate. We would recommend there that:

Recommendation 4: The National Patient Safety Committee should regularly publish agendas, papers and the minutes of its meetings to help inform all bodies that may be impacted by this, such as ICSs and individual healthcare providers, and also patients and the wider public.

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Appendix – Patient safety roles and responsibilities in England

Government and Parliament

Department of Health and Social Care

The Secretary of State for Health and Social Care is responsible for the overall oversight of NHS delivery and performance.

Patient safety, while being an issue that cuts across many different aspects of health and social care, has in recent years been assigned as a specific portfolio responsibility for a junior minister. This currently sits with Maria Caulfield MP, Minister for Mental Health and Women's Health Strategy, who is listed as being responsible for patient safety and the following aspects of this:

- Clinical negligence.
- Historic inquiries.
- Quality regulation.
- Death certification.
- Indemnity.
- Patient Safety Commissioner.

House of Commons Health and Social Care Select Committee

The cross-party Health and Social Care Select Committee is responsible for scrutinising the work of the Department of Health and Social Care and associated government policy.

National coordinating groups

National Patient Safety Committee

Established in 2021, this body membership is composed of different public bodies which hold patient safety responsibilities. Its purpose is to play a strategic role in considering the existing landscape of national patient safety planning, response and improvement within the healthcare system and consistently share insight and thinking about how as a system we can improve the effectiveness of these patient safety functions. This group is accountable to the National Quality Board.

National Quality Board

Jointly chaired by Professor Stephen Powis, National Medical Director at NHS, and Dr Sean O'Kelly, Chief Inspector of Health at the Care Quality Commission, this provides advice, recommendations and endorsement on matters relating to quality.

National NHS bodies

NHS England

An executive non-department public body, NHS England is responsible for leading the health service in England. It published the national NHS Patient Safety Strategy in July 2019 which describes how the NHS aims to improve patient safety over the next five to ten years. Within NHS England sits the National Patient Safety Team whose role is to support the NHS to achieve the NHS Patient Safety Strategy's aims through a series of programmes and areas

of work. The National Patient Safety Team also provides coordination and secretariat to the National Patient Safety Committee referred to above.

NHS Resolution

This is an arm's-length body of the Department of Health and Social Care, responsible for providing expertise to the NHS on resolving concerns and disputes fairly, sharing learning for improvement and preserving resources for patient safety. Its key functions are:

- Claims management.
- Practitioner performance advice.
- Primary care appeals.
- Safety and learning.

As part of its fourth function, NHS Resolution publishes guidance on learning from clinical negligence claims and thematic reviews on specific areas of work.

National improvement agencies and programmes

NHS Horizons

A specialist team within NHS England focused on helping to deliver transformation and large-scale improvement.

AQUA

A membership organisation within the NHS which provides quality improvement expertise, specialist learning and development, and consultancy.

NHS Impact

A single, shared NHS improvement approach.

GIRFT

A national programme designed to improve the treatment and care of patients through in-depth review of services, benchmarking, and presenting a data-driven evidence base to support change.

System and professional regulators

CQC

The CQC is the independent regulator of health and social care in England, tasked with ensuring these services provide safe, effective, compassionate and high-quality care. As part of upholding this role, its Regulation 12 places a patient safety obligation on health and social care organisations. Breaking down this regulation into its component parts, the CQC outlines that meeting this involves:

- Care and treatment being provided in a safe way for service users.
- Assessments being made of the risks to health and safety of service users receiving treatment.
- Organisations doing all that is reasonably practicable to mitigate such risks.

MHRA

The MHRA regulates medicines, medical devices and blood components for transfusion in the UK. It has a specific responsibility to ensure these products meet applicable standards for safety, quality, and efficacy. It also oversees the Yellow Card Scheme, the formal

process for reporting side effects, safety concerns and adverse incidents concerning medicines and medical devices.

Other regulators

There are a number of other regulators who have a significant patient safety aspect to their role, including the bodies that govern the conduct of different healthcare professionals, such as:

- General Medical Council.
- General Pharmaceutical Council.
- General Optical Council.
- General Dental Council.
- Nursing and Midwifery Council.
- General Osteopathic Council.
- Health and Care Professionals Council.
- General Chiropractic Council.
- Professional Standards Authority for Health and Social Care.
- Health and Safety Executive.

Ombudsman

PHSO

The PHSO provides an independent complaint handling service for complaints that have not been resolved by the NHS in England and UK government departments. Though it does not have a direct responsibility for patient safety, through its casework and investigations in the NHS it can play an important role in highlighted patient safety failings, sharing learning and making recommendations for change.

Patient safety bodies

HSIB

HSIB first came into operation in April 2017 and has the aim of improving patient safety through independent investigations into NHS-funded care in England. It is currently undergoing an organisational transformation, due to completed in October this year, where its functions will be divided into two:

1. Healthcare Services Safety Investigations Body (HSSIB)

HSSIB, established with powers set out in the Health and Social Care Act 2022, will be a non-department public body with responsibility for the current HSIB national investigation programme, designed to improve patient safety at a national level and promote learning across the NHS.

2. Maternity investigations

The current HSIB maternity investigations programme will move to be hosted by the CQC, while retaining its independence as a programme within this organisation.

National Guardian's Office

This is an independent, non-statutory body which was created in response to recommendations made in Sir Robert Francis QC's report *The Freedom to Speak Up*. This

report found that NHS culture did not always encourage or support workers to speak up, and that patients and workers suffered as a result.

The National Guardian's Office is responsible for leading, training and supporting a network of Freedom to Speak Up Guardians in England and conducts speaking up reviews to identify learning and support improvement of the speaking up culture of the healthcare sector. There are over 900 guardians in the NHS and independent sector organisations.

Patient Safety Commissioner for England

The post of Patient Safety Commissioner was created by the UK Government following a recommendation from the Independent Medicines and Medical Devices Safety Review, led by Baroness Julia Cumberlege. The first Commissioner, Dr Henrietta Hughes, took up the post in September 2022.

The Commissioner's role is to act as a champion for patients and lead a drive to improve the safety of medicines and medical devices. The Commissioner is funded by the Department of Health and Social Care and accountable to Parliament through the Health and Social Care Select Committee.

Standard setting bodies

In addition to the regulators, organisations that set standards for healthcare providers and professionals also have a significant influence and impact on patient safety. This includes, but is not limited to:

- National Institute for Health and Care Excellence.
- Professional Record and Standards Body.
- Royal College of Anaesthetists.
- Royal College of Emergency Medicine.
- Royal College of General Practitioners.
- Royal College of Obstetricians and Gynaecologists.
- Royal College of Ophthalmologists.
- Royal College of Paediatrics and Child Health.
- Royal College of Pathologists.
- Royal College of Physicians.
- Royal College of Physicians and Surgeons of Glasgow.
- Royal College of Physicians of Edinburgh.
- Royal College of Physicians of Ireland.
- Royal College of Psychiatrists.
- Royal College of Radiologists.
- Royal College of Surgeons in Ireland.
- Royal College of Surgeons of Edinburgh.
- Royal College of Surgeons of England.

Regional and area bodies

There are also a range of bodies that work at a regional or local level which have aspects of patient safety responsibility, including:

NHS England Regional Teams

These teams support the implementation of the NHS Patient Safety Strategy.

Academic Health and Science Networks and patient safety collaborative

These groups that bring together the NHS, industry, academic, third sector and local organisations to collaborate on innovations, improvements and promote good practice.

Coroners

There is a statutory duty for coroners to issue a Prevention of Future Deaths report to any person or organisation where, in the coroner's opinion, action should be taken to prevent future deaths.

The report must state the coroner's concerns and that in the coroner's opinion action should be taken to prevent future deaths. The report need not be restricted to matters causative (or potentially causative) of the death in question. The report must be sent to a person or organisation who the coroner believes has power to take such action. These reports are made publicly available on the Coroners Tribunals and Judiciary website with the organisations involved having a duty to respond within 56 days.

These reports when relating to healthcare can highlight existing and emerging patient safety concerns and are often accompanied by recommendations aimed at addressing these issues.

Providers

All individual NHS organisations have a responsibility to deliver safe care to their patients. In its broadest sense, this is set out in the NHS Constitution, which states what patients can expect from health and care services, saying that they have the right to be treated with a professional standard of care, by appropriately qualified and experienced staff, in a properly approved or registered organisation that meets required levels of safety and quality. These organisations can include:

- Acute Trusts.
- Ambulance Trusts.
- Mental Health Trusts.
- Community Health Trusts.
- Primary care organisations.
- Primary care networks.

Individuals

Individual healthcare professionals have specific responsibilities as registrants with the healthcare regulators that govern their work. There are also individual roles with specific patient safety responsibilities, including but not limited to:

Board members, Non-executive directors and Governors

Have a responsibility for patient safety stemming from their governance and oversight roles in their respective organisations.

Medical Examiners

Medical examiners are senior medical doctors who are contracted for a number of sessions a week to provide independent scrutiny of the causes of death, outside their usual clinical duties. As with Coroners, their reviews can potentially highlight existing and emerging patient safety concerns.

Patient Safety Specialists

These are individuals in healthcare who have been designated to provide dynamic senior patient safety leadership. Each Patient Safety Specialist is intended to help provide expert support to their organisation and is expected to have direct access to their executive team, which facilitates the escalation of patient safety issues or concerns.

Patient Safety Partners

These are roles for patients, carers and other lay people who support and contribute to a healthcare organisation's governance and management processes for patient safety. Their roles can include:

- Membership of safety and quality committees whose responsibilities include the review and analysis of safety data.
- Involvement in patient safety improvement projects.
- Working with organisation boards to consider how to improve safety.
- Involvement in staff patient safety training.
- Participation in investigation oversight groups.

Freedom to Speak Up Guardians

Freedom to Speak Up Guardians are intended to support workers to speak up when they feel that they are unable to do so by other routes. They aim to ensure that:

- Workers are supported in speaking up.
- Barriers to speaking up are addressed.
- The organisation encourages a positive culture of speaking.
- Matters raised are used as opportunities for learning and improvement.

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